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SPECIAL ACTION OFFICE FOR DRUG
ABUSE PREVENTION

DOCUMENTS

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HEARINGS

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BEFORE THE

SUBCOMMITTEE ON

PUBLIC HEALTH AND ENVIRONMENT

OF THE

COMMITTEE ON

INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

NINETY-SECOND CONGRESS

FIRST SESSION

ON

H.R. 9264

A BILL TO ESTABLISH A SPECIAL ACTION OFFICE FOR
DRUG ABUSE PREVENTION TO CONCENTRATE THE RE-
SOURCES OF THE NATION IN A CRUSADE AGAINST
DRUG ABUSE

H.R. 9059

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CENTERS AND HOSPITALS AND OTHER MEDICAL FACILI-
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NEEDED TREATMENT AND REHABILITATION PROGRAMS
FOR DRUG ADDICTS AND OTHER PERSONS WITH DRUG
ABUSE AND OTHER DRUG DEPENDENCE PROBLEMS, AND
FOR OTHER PURPOSES

(and all other identical or similar bills)

JUNE 28, 29, 30; JULY 9, 10, 13, 14, 15, 23, 27, 28, 29, 30;
AUGUST 2, 5; SEPTEMBER 9; OCTOBER 22, 26, 27; AND
NOVEMBER 8, 1971

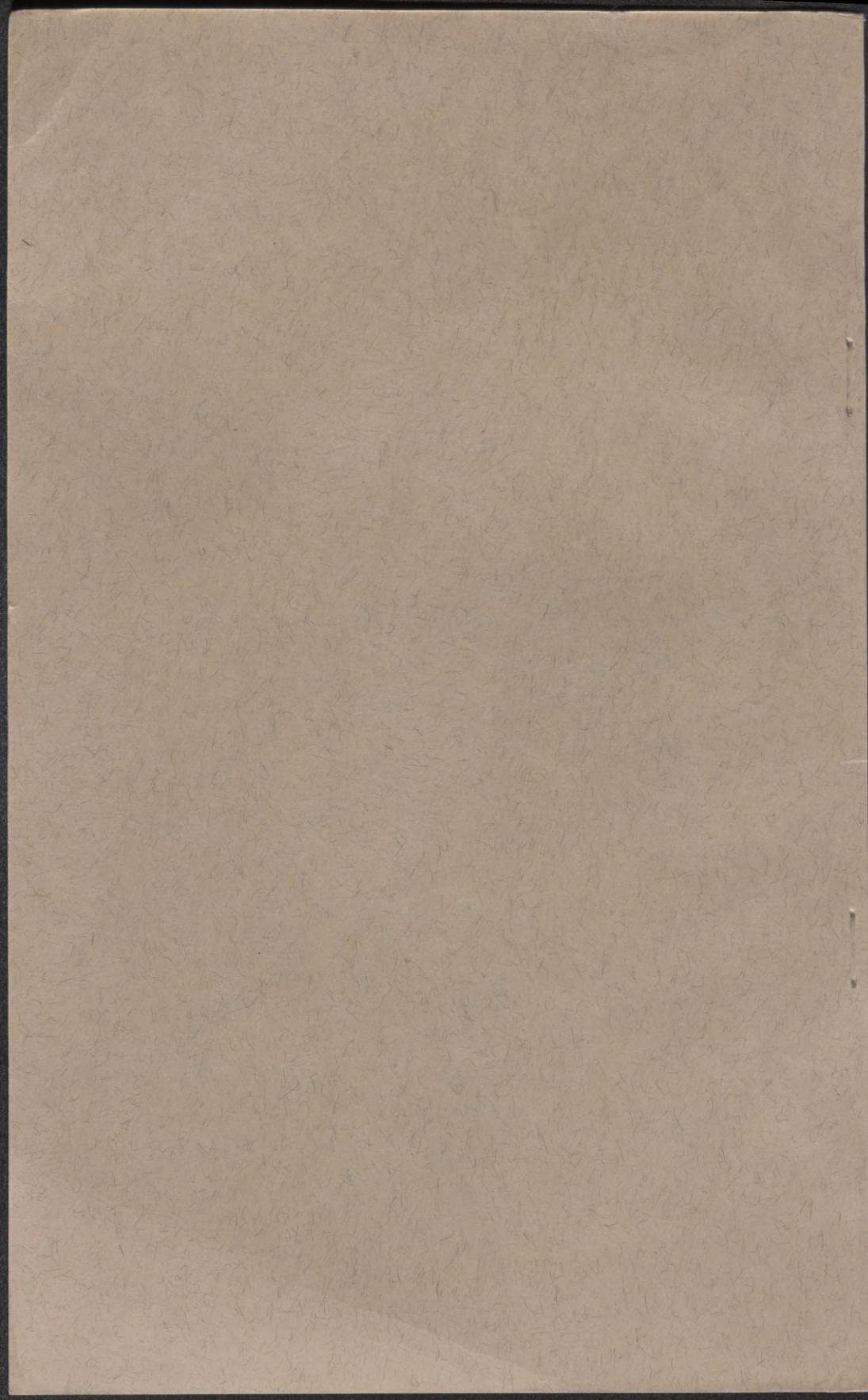
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Addicts Rehabilitation Center, New York City, Rev. James Allen, director.

American Legion:

Lyngh, Robert E., deputy director, Veterans' Affairs and Rehabilitation Commission.

Wertz, Terrell M., assistant director, legislative division.

American Medical Association:

Palmer, Dr. Richard E., member, board of directors.

Peterson, Harry N., director, legislative department.

SeEVERS, Dr. Maurice H., member, committee on alcoholism and drug dependence.

Committee for Effective Drug Abuse Legislation, Neil L. Chayet, counsel.

Defense Department:

Carney, Brig. Gen. Robert B., Jr., Deputy Assistant Chief of Staff G-1, Headquarters, USMC.

Hayes, Brig. Gen. George J., Principal Deputy Assistant Secretary of Defense for Health and Environment.

Kester, John G., Deputy Assistant Secretary of the Army, Manpower and Reserve Affairs.

Rauch, Rear Adm. Charles F., Jr., Executive Director, Drug Abuse Advisory Council, Department of the Navy.

Roberts, Brig. Gen. John W., Deputy Director, Personnel Planning, DSC/Personnel Headquarters, USAF.

Taber, Lt. Gen. Robert C., Principal Deputy Assistant Secretary of Defense for Manpower and Reserve Affairs, Office of the Secretary.

Williams, Maj. Cecil W., USAF, legislative attorney, Office of Legislative Liaison.

Executive Office of the President:

Carlucci, Hon. Frank, Director, Office of Economic Opportunity.

Cooper, Dr. Leon, Director, Comprehensive Health Program, Office of Economic Opportunity.

Jaffe, Dr. Jerome H., Special Consultant to the President for Narcotics and Dangerous Drugs.

ORGANIZATIONS REPRESENTED AT THE HEARINGS—Continued

Executive Office of the President—Continued

Konopka, Arthur F., Acting General Counsel to the Special Consultant to the President for Narcotics and Dangerous Drugs.

Perito, Paul L., General Counsel and Assistant Director, Special Action Office for Drug Abuse Prevention, Office of Special Consultant to the President for Narcotics and Dangerous Drugs.

Smith, Dr. Carl, Acting Director, Office of Health Affairs, Office of Economic Opportunity.

Weber, Arnold R., Associate Director, Office of Management and Budget.

Health, Education, and Welfare Department:

Besteman, Karst J., Deputy Director, Division of Narcotic Addiction and Drug Abuse, National Institute of Mental Health, National Institutes of Health.

Brown, Dr. Bertram S., Director, National Institute of Mental Health.

Duncan, Dr. Tommy, Clinical Research Center, Fort Worth, Tex., U.S. Public Health Service.

Edwards, Dr. Charles C., Administrator, Food and Drug Administration.

Gardner, Dr. Elmer H., Division of Neuropharmacological Drugs, Food and Drug Administration.

Hutt, Peter, General Counsel, Food and Drug Administration.

Kurzman, Stephen, Assistant Secretary for Legislation.

Lacovara, Dr. Dominick, Director, Clinical Research Center, Fort Worth, Tex., U.S. Public Health Service.

Lawrence, James, Executive Officer, National Institute of Mental Health, National Institutes of Health, Public Health Service.

Richardson, Hon. Elliot L., Secretary.

Wilson, Dr. Vernon E., Administrator, Health Services and Mental Health Administration.

Zapp, Dr. John S., Deputy Assistant Secretary for Legislation (Health).

Justice Department:

Burrows, Carl, Assistant Commissioner for Investigation, Immigration and Naturalization Service.

Carlson, Norman A., Director, Bureau of Prisons.

Coppock, Donald R., Deputy Associate Commissioner for Domestic Control, Immigration and Naturalization Service.

Farkas, Gerald M., Executive Assistant to Director, Bureau of Prisons.

Garfield, Frederick, Assistant Director for Scientific Support, Bureau of Narcotics and Dangerous Drugs.

Greene, James F., Associate Commissioner for Operations, Immigration and Naturalization Service.

Heaney, Richard, Deputy Director, Bureau of Prisons.

Ingersoll, John E., Director, Bureau of Narcotics and Dangerous Drugs.

Levinson, Dr. Robert B., Mental Health Coordinator, Bureau of Prisons.

Maloney, Andrew J., Chief, Narcotics and Racketeering Unit, Southern District of New York.

Miller, Donald, Chief Counsel, Bureau of Narcotics and Dangerous Drugs.

Seymour, Whitney North, Jr., U.S. Attorney, Southern District of New York.

Kemper Insurance Group, Lewis F. Presnall, director of rehabilitation; and manager, Corporate Alcoholism and Other Behavioral Problems Department, National Loss Control Service Corp. (NATLSCO).

Louisiana Narcotics Rehabilitation Commission:

Alderette, Edward, executive director.

Srignar, Dr. Chester, chairman.

Swanson, Dr. William C., member.

Malcolm Bliss Community Mental Health Center:

Buis, Jon, NARA aftercare counselor.

Davis, Mike.

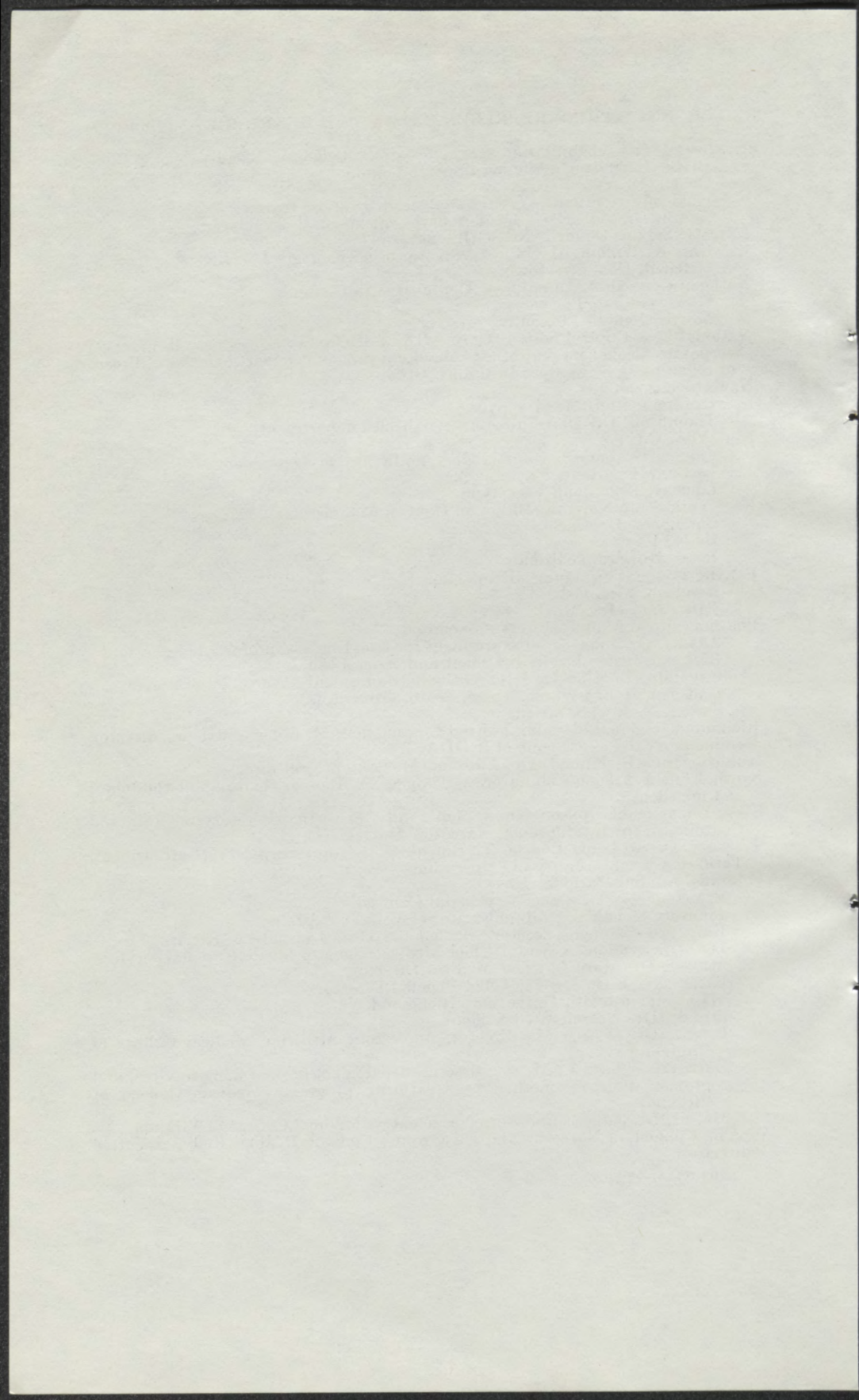
Missouri Division of Mental Health:

Knowles, Dr. Raymond R., program director, narcotic addiction treatment program, and chief, alcoholic and drug abuse program.

Muse, Alvin.

ORGANIZATIONS REPRESENTED AT THE HEARINGS—Continued

- Narcotic addict rehabilitation agency program, Tulane University:
 Clark, June, drug addiction research team.
 Cohen, Dr. Gary, head.
 Goldsmith, Bernard, systems analyst, drug abuse team.
 Heath, Dr. Robert G., head, department of social psychiatry.
- Narcotic Service Council (NASCO)—St. Louis:
 Harvey, William M., Ph. D., director of psychological services.
 Mitchell, Don, director.
- National Council of Community Mental Health Centers:
 Levin, Gilbert, Ph. D.
 Morris, Jonas V., executive director.
- National Loss Control Service Corp. (NATLSCO), Lewis F. Presnall, manager,
 corporate alcoholism and other behavioral problems department; and director
 of rehabilitation, Kemper Insurance Group.
- New Orleans, La.:
 Landrieu, Hon. Moon, mayor.
 Thompson, Dr. Doris, director, city health department.
- New York City:
 Finney, Graham S., commissioner, addiction services agency.
 Lacey, Miss Diane, mayor's office.
 Lindsay, Hon. John V., mayor.
- New York State Narcotic Addiction Control Commission:
 Chambers, Dr. Carl.
 Hesse, Ray.
 Jones, Howard, chairman.
- Parents Foundation Against Drug Abuse:
 Rembish, Mrs. Helen.
 Tarantino, Mrs. Mary.
- Pharmaceutical Manufacturers Association:
 Adams, Dr. John G., vice president for scientific and professional relations.
 Brennan, Bruce J., vice president and general counsel.
 Cavallito, Dr. Chester J., executive vice president, Ayerst Laboratories.
 Gadsden, Henry W., chairman, board of directors.
 Stetler, C. Joseph, president.
- Richmond Regional Planning District Commission, M. Miles Matthews, director,
 council on drug abuse control (CODAC).
- Rubicon, Inc., Richmond, Va., Edmund Menken, project director.
- Smith Kline & French Laboratories, Thomas M. Rauch, chairman of the board
 and president.
- State Department, Nelson Gross, Senior Adviser to the Secretary of State and
 Coordinator for International Narcotics Matters.
- Treasury Department, Eugene T. Rossides, Assistant Secretary (Enforcement,
 Tariff and Trade Affairs, and Operations).
- Veterans' Administration:
 Bronaugh, A. T., Associate General Counsel.
 Johnson, Donald E., Administrator of Veterans' Affairs.
 Kaim, Dr. Samuel, Director, Alcohol and Drug Dependence Service.
 Lee, Dr. Lyndon, Assistant Chief Medical Director for Professional Services.
 Musser, Dr. Marc J., Chief Medical Director.
 Peckarsky, J. C., Deputy Chief Benefits Director.
- Virginia Commonwealth University, Richmond, Va.:
 Brandt, Dr. Warren W., president.
 Bright, Dr. George M., director, Adolescent Medicine Medical College of
 Virginia.
 Harrison, Willard I., M. Sc., director, department of pharmacy services, and
 project director, methadone treatment program, Medical College of
 Virginia.
 Mathis, Dr. James, professor of psychiatry, Medical College of Virginia.
- Virginia Council on Narcotics and Drug Abuse Control, F. John Kelly, executive
 director.



SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION

TUESDAY, OCTOBER 26, 1971

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND ENVIRONMENT,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to notice, in room 2322, Rayburn House Office Building, Hon. Paul G. Rogers (chairman) presiding.

Mr. ROGERS. The subcommittee will come to order, please.

We are continuing hearings on legislation to establish a Special Action Office of Drug Abuse Prevention and also looking at public health hospitals.

Our first witness this morning is one of our distinguished colleagues, Hon. Jim Wright, a Member of Congress from Texas. Congressman Wright has followed the situation at Fort Worth very closely and we are very anxious to hear from him and the recent report that he is ready to present to the committee.

We welcome you to the committee and will be glad to receive your report at this time. If you have anyone you would like to join you at the table we would be glad to have him.

STATEMENT OF HON. JIM WRIGHT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS; ACCOMPANIED BY ROBERT G. LAWRENCE, SHERMAN S. WILLSE, SALVATORE J. D'AMICO, AND WILLIAM O. NOLEN, INVESTIGATORS FOR THE PUBLIC WORKS COMMITTEE, SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

Mr. WRIGHT. Thank you very much, Mr. Chairman.

There are present in the committee room four members of the professional investigative staff of the Subcommittee on Public Works Investigations and oversight who, at my direction and upon your request, Mr. Chairman, did conduct a study and an investigation in the field following the closing of the Fort Worth facility by the Department of Health, Education, and Welfare on October 8. Those investigators who did extensive traveling and interviewing are Mr. Robert Lawrence, Mr. Sherman Willse, Mr. Sal D'Amico and Mr. William Nolen, all four of whom are here in case the committee should want to inquire of them. I think it is possible for me to summarize their findings in that they made the report directly to me and I then transferred it over to you.

Actually, Mr. Chairman, I should say first of all that I am very grateful for the opportunity to come and make this report to this subcommittee. Beyond that I am deeply appreciative of the continuing interest of this subcommittee as has been manifest throughout the year in the future of the Fort Worth facility.

Earlier this year I believe it was six members of the subcommittee who visited Fort Worth and held hearings there in the clinical research center. That group included not only the chairman but Mr. Satterfield, Mr. Kyros, Mr. Preyer, and Mr. Symington, and I believe it was the clear consensus of the group who held those hearings that the facility should stay open.

Mr. HASTINGS. Excuse me, if the gentleman will yield?

In addition to that list, the only Republican, last but not least, I was there, too.

Mr. WRIGHT. Mr. Hastings, I was trying to mention those not present in the room today who were there and certainly do recall your being in our city and with great appreciation acknowledge your attentiveness to the importance of this problem. I believe Mr. Roy was also present.

Actually it may be a fait accompli that that facility has been transferred to the Bureau of Prisons. I have nothing against the Bureau of Prisons, most certainly. If the facility is no longer to be used by the National Institute of Mental Health or by the Public Health Service, then surely it ought to be used for the most beneficial possible purpose. If it is not to be used as it has been used in the past, then it is far preferable that the Bureau of Prisons should make use of it than that it be dropped from the facilities available to drug patients.

But I would like to address myself to the action of the Department of Health, Education, and Welfare in so summarily closing this facility on October 8 at the very time when a House-Senate conference had its future under active consideration. To me that abrupt termination of the facility and the abrupt release of the 94 patients then in the facility constituted an act of almost incredible bad faith with the Congress. That is the first thing I want to say.

It was obvious to the Department that the Congress has been interested in this facility. I think it should have been obvious to the Department that the Congress wanted it to remain open.

Two years ago a Senate committee conducted similar investigations when the center's closure was being contemplated, and the Department decided in deference to the wishes of the Senate that it be kept open. This year, under the direction and leadership of the distinguished chairman, Mr. Rogers, the House acted on two occasions in overwhelming fashion to express its desire that the facility be continued as a treatment facility for patients committed under the Narcotics Addict Rehabilitation Act of 1966. We did this in an amendment to an appropriation bill—an unusual procedure on the floor of the House. We did it again in the passage by an overwhelming vote of, I think, 370 to four, in passing the resolution which called upon the Department of Health, Education, and Welfare to keep open all Public Health Service hospitals, expressly including those at Fort Worth, Tex., and Lexington, Ky. While this discussion was proceeding in the conference with the Senate on that resolution, on the morning of Friday, October 8, officials in the Department of Health, Education, and Welfare suddenly, abruptly and summarily terminated the facility and

instructed those in charge to release all the patients and send them home by nightfall.

Now, these were patients committed under the NARA Act; some of them were committed in lieu of prosecution. None of these patients had completed his course of treatment. None of them, according to the doctors treating them, was ready to be released. None of them had been under treatment for more than 4 months, and it has been a general rule of thumb that a 6 month inpatient treatment was the minimum.

Notwithstanding this, they were released in what I regarded to be an act of bad faith with the Congress. I made the statement last week that it seemed to me that these victims of narcotics were being used as pawns in a power play to present the Congress with a fait accompli on a subject that we had under consideration at the time. That may have been unwarranted language. What I really meant to say and what I would like to say today is that I think the Department of Health, Education, and Welfare has been blind and deaf to the wishes of Congress, that it has not given weight to the wishes of Congress, and that it has actually been misled in some of the factual situations surrounding this center. For example, a letter written on October 5 to Hon. Harley Staggers, chairman of the full Committee of Interstate and Foreign Commerce, and signed jointly by Secretary Richardson and Attorney General Mitchell, contains numerous inaccuracies. I shall not labor this in detail, but on page 2 of that letter, in which an appeal is being made to Chairman Staggers to drop the insistence of the House that the facility be kept open, it refers to the facility as having "an inpatient capacity of 200."

Now, if the rest of the matter contained in this letter signed by two Cabinet Officers is as inaccurate as that, the letter itself should stand as only a partial statement of fact. The truth is that the center doesn't have an inpatient capacity of 200. It has a comfortable capacity for 750, and on occasion in periods of stress during World War II has treated as many as 1,100 patients at one time. The staff of my investigating subcommittee has prepared a memorandum commenting upon various statements contained in this letter and I should like, with the committee's permission, to submit a copy of the letter and a copy of the memorandum of comments for the record.

Mr. ROGERS. Without objection the material will appear in the record following your statement (see pp. 1373-1382).

Mr. WRIGHT. The second thing I should like to say with respect to that abrupt termination is that not only was it an act of bad faith with the Congress; it was, I think, an act of disregard for the welfare of those patients.

On Friday morning, October 22, Miss Candy Leinweber of the Fort Worth Star Telegram wrote a story which is the result of an interview she had with Michael White, a spokesman for NIMH drug abuse programs. Mr. White took issue with some of my conclusions, or the conclusions rather of the investigators who had gone down and made these inquiries. I shall not labor the record with each of the points but, essentially what I want to say is that according to this news account, the NIMH spokesman said that the closing of the Fort Worth center—and here it is referred to as a 500-bed hospital—meant the discharged patients are now in the "aftercare" phase of drug addiction treatment and, therefore, they will not be treated as inpatients. This was in response to my pointing out as a result of the inquiry that

there exist only 15 beds in the Tulane Community Center in New Orleans for drug victims. Twelve of these beds were occupied and 13 patients were returned to New Orleans without adequate treatment. I discovered, as a result of our investigations, that one of those patients from Fort Worth was reported to be back on the streets pushing hard drugs. He had been a drug pusher before.

Now, the reply of the NIMH spokesman was that they "did not know anything about the so-called nefarious traffic the Congressman referred to."

It seems to me if they had gone down there and been sufficiently concerned to interview the patients themselves, they could have discovered the very things that the investigating staff discovered. Those three patients sent back, for instance to Anchorage, Alaska, have no inpatient treatment facility that they can report to, any closer than Portland, Oreg.

It seems to me that is quite a difficult burden to place upon them. I have copies of letters that were written at an undisclosed date, presumably prior to or about the first of August, to certain judges who have been in the practice of committing patients to the Fort Worth facility, in which the Department is advising them to commit no more patients to Fort Worth in that it will be closed.

One written to Hon. Richard E. Robinson, the chief judge at Omaha, Nebr., says that the development of NARA community contract agencies to provide inpatient treatment will enable us at a later date—at a later date—"to designate an inpatient treatment facility either in or closer to Nebraska."

This indicates to me that as of that date, presumably around the first of August, there were no inpatient treatment facilities anywhere in Nebraska.

I have only a few of these carbon copies of letters that were sent out. I believe that similar letters were sent to all courts west of the Mississippi River which had been regularly committing patients under the NARA provisions and I should like to offer these for the record similarly.

Mr. ROGERS. Without objection they will be made a part of the record following your statement (see pp. 1373-1382).

Mr. WRIGHT. Only one other thing, Mr. Chairman, that I do think ought to be said. Regardless of the future of the Fort Worth facility, whatever happens there, I do believe that is something the committee seriously wants to consider, as to whether the people who are charged with the drug abuse program for the administration are on the right track in their conclusion that there is no place for a big hospital which treats a person in a setting far removed from his home. Obviously they have developed a theory in which unquestionably they must believe to the effect that the best form of treatment is going to be treatment in small community-based facilities, principally on an outpatient basis.

Now, I am not a penologist and I don't make any claims to know a great deal about drug treatment. I am certainly not a professional in that regard. However, I have been exposed to a great deal of it simply by reason of the fact that I represent the Fort Worth district and have been close to the operations of the Fort Worth Clinical Research Center, formerly the Public Health Service Hospital, and have met and talked with a great many patients and a great many others who

were involved in the program. I just don't believe that it is a valid theory that in all cases, or necessarily in most cases, a person is going to stand a better chance of being cured if he is treated on an outpatient basis. Drugs certainly are far more impelling in their ensalvement of their victim than alcohol and yet, I think, it is well-accepted that an alcoholic in some cases might better be treated if he is removed from the environment which reminds him of his old desires and his old acquaintances. I am one of those who frequently has quit smoking and I am on one of those kicks right now. I know doggone well that at least for the first little while I do a great deal better if I am not around people who are smoking and certainly drugs are something far worse than that.

It seems to me logical that there ought to be some places, whether they be at Lexington, Fort Worth, or wherever, not fewer but more places where people could be removed from the temptations environment of the street where old associations and old habits and old temptations are constantly brought to their minds, where old pushers who knew them and will see them again may expose them to this devilish entrapment.

Now, that is about all I had to say, Mr. Chairman. I appreciate the indulgence of the subcommittee in hearing me out this far. There are, as I mentioned earlier, in the committee room these four investigators who conducted this investigation. I have absolute confidence in whatever they would report to the committee if the committee sought to ask them for their answers. These investigations have been with the subcommittee which I have had the privilege to Chair for a great many years. Mr. Willse, prior to coming with the subcommittee, was involved in New York in investigations relating directly to narcotics abuse. Others prior to coming with the subcommittee were with the Federal Bureau of Investigation and other investigating activities. So I would just say to you that I have total confidence in anything that they would report to you.

(The attachments referred to follow:)

[Memorandum]

OCTOBER 21, 1971.

To: Chairman Jim Wright.

From: Robert G. Lawrence and Sherman S. Willse.

Subject: Letter from Secretary Richardson and Attorney General Mitchell to Representative Harley O. Staggers, October 5, 1971.

The above-captioned letter, explaining Administration policy and reasons for closing the Fort Worth Clinical Research Center, contains certain questionable assertions.

P. 1, para. 2, states that "This process" (i.e., adequate and effective community-based drug abuse treatment and rehabilitation services) "has now reached the point where we can continue to expand our national capacity for voluntary and civilly-committed addicts without utilizing the Fort Worth Clinical Research Center...".

Staff Comment:

From the survey conducted last May and particularly from what we saw and learned in San Diego and New Orleans just this past week, no such point has in fact been reached. From the entire State of California, only one addict is being afforded in-patient treatment at San Diego, which is the only NARA in-patient facility under contract and functioning at this time in that State.

We were told there are several thousand addicts in the immediate San Diego area alone, with untold thousands more throughout the State.

P. 1, para. 3 makes reference to "addicts not charged with crimes who voluntarily petition for civil commitment".

Staff Comment:

While Title III of the statute is, indeed, captioned "Civil Commitment of Persons Not Charged With Any Criminal Offense", the characterization is misleading and untrue.

The fact appears to be that the overwhelming majority of Title III patients are referrals from State courts where they *are* charged with crimes, some of which are crimes of violence including armed robbery and strongarm robbery.

While some of the subjects are first offenders, others were reported to have lengthy criminal records. One 37-year-old had a criminal record over the past 20 years, including a five-year stretch in Sing Sing prison among other incarcerations, and had recently committed a strongarm robbery in Phoenix.

It is not unreasonable to suggest that some among such referrals "voluntarily petition" as the alternative to a long stretch in a State penitentiary.

P. 2, para. 1, states, "Based on our experience, we now believe that the other phases of the program . . . should also be carried out in the community. It is often counterproductive for patients to leave their families, friends, and community resources and difficult to adjust to centralized institutional care with other patients from widely divergent sections of the country . . .".

Staff Comment:

This is exactly the opposite to what we were told at the Fort Worth Center and elsewhere during our inspection trip.

We were told that, on the contrary, if there is anything an addict needs it is to break completely from his scene of addiction and its associations, which of course include fellow addicts and their pushers.

Those persons out in the field, in actual contact with the problem, vigorously and uniformly advised us of their disagreement with the concept set forth in the letter.

P. 2, para. 2. This paragraph claims that in addition to aftercare facilities, "... we have been successful in creating capabilities in a number of localities to replace the services now available at Fort Worth, which has an inpatient capacity of 200."

Staff Comment:

We were told that Fort Worth has a normal capacity of 750, and has on occasion accommodated as many as 1,100 at one time. The "capacity of 200" is incorrect. Attachment 1 lists 15 agencies, not the 18 ascribed to it in this paragraph.

Listed among the inpatient agencies "we have been successful in creating" is San Diego, where the staff found only one patient (who was "out" at the time of our visit) in residence after four months of operation, no "contraband-free environment" as called for under the \$133,650 one-year contract with NIMH, etc. This single inpatient is the only one they have had, although the contract provides for 15 during the current period. He is not from San Diego, and was admitted only after his Congressman acted in his behalf.

In the New Orleans facility, 12 of the 15 beds available for addicts at Tulane Hospital were filled. There was already a waiting list of eligible addicts when the 13 from Fort Worth arrived; had any of the latter needed inpatient care, they would have had to "get in line" or some current patient would have had to leave to make room.

The same paragraph adds that "By the end of FY 1972 it is expected that the cumulative capacity of these agencies will exceed the level of patient care provided at Fort Worth during 1971." This, in view of inquiries thus far, appears to be very optimistic and possibly accepts as fact the patient volume estimated in advance . . . i.e., 15 inpatients for San Diego where the fact is they have but one.

P. 2, para. 3 states that "Three treatment centers in Houston, Harlingen and San Antonio, which are already in operation will provide inpatient care to 175 civilly-committed narcotic addicts."

Staff Comment:

Staff was advised that this figure is extremely high, and that the number of beds available at these three facilities would be nearer 15 for Houston, 3 for Harlingen and possibly 50 for San Antonio, for a total of 68.

If the actual facilities proposed for another 250 addicts in the remainder of the paragraph are *equally* over-optimistic, the total number of beds for all Texas facilities, operating and proposed, will be much smaller than suggested in the letter.

Page 4, para. 2 states "The 105 NARA patients now remaining in the facility have received sufficient inpatient treatment to permit their immediate transfer to an appropriate community facility for aftercare and follow-up."

Staff Comment:

The evaluations of each patient by the medical staff, together with what we found happened to the patients within five days of their exodus, testify to the inaccuracy of this statement.

It was stressed to us at the hospital that this decision was an administrative one, *not* a medical one. We were told, further, that few if any of these patients would have been recommended for release to aftercare at the current stage of their treatment, most of them having been there less than four months.

P. 4, para. 4 states "Any further delay in the execution of this plan will seriously hinder our efforts to broaden and strengthen the capacity of State and local authorities to deal effectively and realistically with this serious problem."

Staff Comment:

It is difficult to understand in what respect the continued operation of Fort Worth would so obstruct.

On the contrary, its continuation would provide an on-going, staffed, well-equipped center for badly needed research and training.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY,
Washington, D.C., October 5, 1971.

HON. HARLEY O. STAGGERS,
Chairman, Interstate and Foreign Commerce Committee, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: I understand that the Conference Committee will begin work shortly on S. Con. Res. 6 and H. Con. Res. 370 relating to the Public Health Service Hospitals. The major difference between the two resolutions is the House addition of language to include the Fort Worth and Lexington Clinical Research Centers. The Administration strongly opposes the reference to the Fort Worth Center. As you know, we have since January 26, 1971, planned to transfer the Fort Worth Center from the National Institute of Mental Health of the Department of Health, Education, and Welfare to the Bureau of Prisons within the Department of Justice.

The express policy of the Department of Health, Education, and Welfare has for several years been to work toward the development of adequate and effective community-based drug abuse programs under State and local auspices rather than in Federally-operated facilities. The implementation of this policy has resulted in Federal support, through contracts and grants, for drug abuse treatment and rehabilitation services in many communities. This process has now reached the point where we can continue to expand our national capacity for voluntary and civilly-committed addicts without utilizing the Fort Worth Clinical Research Center and at the same time strengthen the drug abuse programs within our Federal prison system by making the Fort Worth facility available to the Bureau of Prisons.

In the past the Fort Worth Clinical Research Center (CRC) has provided examination, evaluation and treatment services under the Narcotic Addict Rehabilitation Act (NARA) of 1966 for addicts charged with certain Federal crimes who elect civil commitment in lieu of prosecution and for addicts not charged with crimes who voluntarily petition for civil commitment. After treatment, addicts are returned to their communities for supervised aftercare provided by local agencies, under contract with the National Institute of Mental Health. Aftercare in the community has increased the likelihood of the addict's return to a productive life.

Based on our experience, we now believe that the other phases of the program—examination, evaluation, and inpatient treatment—should also be carried out in the community. It is often counterproductive for patients to leave their families, friends, and community resources and difficult to adjust to centralized institutional care with other patients from widely divergent sections of the country. Many decide that institutionalization for four to six months is too high a price to pay for help and convince themselves and others that they are not suitable for treatment.

Through contracts with community agencies for the provision of examination, evaluation and inpatient treatment services in addition to aftercare, we have been successful in creating capabilities in a number of localities to replace the services now available at Fort Worth, which has an inpatient capacity of 200. There are currently eighteen such agencies throughout the United States, as shown in Attachment 1. By the end of FY 1972 it is expected that the cumulative capacity of these agencies will exceed the level of patient care provided at Fort Worth during 1971.

In this process special attention has been given to Texas, which except for Michigan, has had the greatest number of narcotic addicts petitioning for civil commitment. Attachment II describes the existing, planned, and potential community agency capacity in Texas. Three treatment centers in Houston, Harlingen, and San Antonio, which are already in operation, will provide inpatient care to 175 civilly-committed narcotic addicts. Contract negotiations are being conducted, and should be completed by November 1, with treatment centers in Austin, Dallas, and El Paso, which will provide care and rehabilitation for an additional 110 narcotic addicts. In addition, contracts are being proposed in Amarillo and Corpus Christi and a second one in San Antonio, which could provide inpatient services for another 140 addicts. These treatment programs will provide Texas with the potential for considerably greater participation in the NARA program than has been possible in the past.

The Federal Bureau of Prisons plans to utilize the Clinical Research Center as a 500-bed medical-correctional facility whose primary mission will be focused on the treatment of offenders who have histories of drug abuse. During the past year, 30 per cent of all offenders committed to Federal custody had a history of drug abuse, representing a significant increase over previous years. Because of the rapidly-growing need for drug abuse treatment for Federal offenders, the present capacity of the Bureau of Prisons facilities is exceeded by 1700 inmates.

The Fort Worth facility would become a specialized treatment center with emphasis on offenders having serious drug problems. Since enactment of the Narcotic Addict Rehabilitation Act, the Bureau of Prisons has been responsible for providing specialized institutional treatment and aftercare services to those offenders who meet the statutory criteria for commitment. It is now obvious that efforts must be expanded to include the large population of offenders with drug addiction problems who do not qualify for inclusion under the NARA statute but who have an equal need for intensive treatment.

NARA units are presently operating at five institutions with a total capacity of 600. At a minimum, an additional 250 would be accommodated in the expanded program. Acquisition of the Fort Worth facility will enable the Bureau of Prisons to increase the total capacity of its drug treatment program of 1200. The Fort Worth facility will also be utilized for treatment programs for men and women who pose other medical-correctional problems, including various chronic medical and surgical cases, psychiatric cases and alcoholics. These offenders present unique difficulties because their medical problems are not serious enough to require hospitalization at the Medical Center for Federal Prisoners in Springfield, Missouri, and the institutions in which they are confined lack proper facilities to meet their treatment needs.

Comprehensive correctional treatment activities, a total health services program, and extensive research and training will also be conducted at Fort Worth. The correctional program activities will consist of education, vocational training, work programs, religious, recreational and social work services, and community-based programs. The Bureau's research efforts will include an evaluation program to assess program effectiveness in each of the special treatment categories and close collaboration with local universities, colleges and medical centers.

As a medical-correctional facility the center will provide treatment for persons who are within eighteen months of their release dates. The inmate population will, appropriately, consist of offenders who will be released to destinations in the southwest and south central sections of the country.

The Fort Worth facility is especially suitable for these needs. The physical plant is in generally good condition, and apart from the addition of appropriate security measures, will require only minor renovations. Since the Bureau of Prisons does not plan to utilize this facility for inmates posing serious escape risks, the principal security addition will be a perimeter fence.

A total of 206 Clinical Research Center employees will remain at the Fort Worth facility as employees of the Bureau of Prisons. Of the 40 employees now remaining at the Center who will not transfer to the Bureau of Prisons, 26 are eligible for retirement. Continuing efforts will be made to assist all employees to

obtain suitable employment. In this connection, local 1298 of the American Federation of Government Employees forwarded a plea to the Department of HEW that there be no further delay in the transfer of the Center in view of the adverse effect this period of uncertainty has had on the staff and patients.

The 105 NARA patients now remaining in the facility have received sufficient inpatient treatment to permit their immediate transfer to an appropriate community facility for aftercare and follow-up.

As you know, this Administration has proposed broad new initiatives to combat drug abuse, including the establishment of a Special Action Office on Drug Abuse Prevention under the leadership of Dr. Jerome Jaffe, who is now serving as a Special Consultant to the President. Dr. Jaffe has carefully reviewed and fully endorsed our proposal to transfer the Center. He is now actively engaged in planning efforts, involving the National Institute of Mental Health, which will result in considerable expansion of community treatment and rehabilitation capabilities throughout the Nation. The NIMH budget request for treatment services was amended to provide a total of \$91.3 million for this purpose in FY 1972. The NIMH budget for 1972 also includes funds to strengthen and expand the Addiction Research Center located within the NIMH Clinical Research Center in Lexington, Kentucky. As this action indicates, there are presently no plans for closing or transferring the Lexington facility, which will maintain the level of resident narcotic addict patients required for Federal research purposes.

In conclusion, the proposed transfer of the Fort Worth CRC is not a capricious or isolated issue. It is an integral part of a broad, inter-departmental strategy which strengthens our national capacity to combat narcotic addiction and drug abuse. Any further delay in the execution of this plan will seriously hinder our efforts to broaden and strengthen the capacity of State and local authorities to deal effectively and realistically with this serious problem.

We strongly urge your deletion of the reference to Fort Worth in the final version of this resolution.

Sincerely,

JOHN N. MITCHELL,
U.S. Attorney General.

ELLIOT L. RICHARDSON,
Secretary, Department of Health,
Education, and Welfare.

ATTACHMENT I

NARA COMMUNITY CONTRACT AGENCIES

States/area :	Agency
Florida-----	Christian Community Service Agency, 10 Southeast Ninth Street, Miami, Florida 33131, Telephone: (305) 358-5400, Reverend Fred Harrison, Director.
New Jersey-----	New Jersey Regional Drug Abuse Center, P.O. Box 4099, Bergen Station, Burma Road, Liberty Park, Jersey City, New Jersey 07205, Telephone: (201) 451-2275, Mr. Raymond Cubino, NARA Coordinator.
Rhode Island-----	Marathon House, 148 Waterman Street, Providence, Rhode Island 02906, Telephone: (401) 331-4250, Mr. Vito Russo.
Puerto Rico-----	CISLA, Department of Health, Psychiatric Hospital, Building J, Commonwealth of Puerto Rico, Rio Piedras, Puerto Rico 00928, Telephone: (809) 765-0575, Mrs. Antonio Pagan-Marrero, NARA Coordinator.
Tennessee, western district-----	Alcoholism and Drug Abuse Clinic, Tennessee Psychiatric Hospital and Institution, P.O. Box 4966, 865 Poplar Street, Memphis, Tennessee 38105, Telephone (901) 534-6640, Mr. Robert Wood, NARA Coordinator.

Virginia, northern area-----	Second Genesis, 1013 King Street, Alexandria, Virginia 22315, Telephone: (703) 836-2202, Sidney Shankman, M.D., Executive Director.
Arizona and Nevada-----	Arizona Family Inc., 48 East Foothill Drive, Phoenix, Arizona 85020, Telephone: (602) 944-2413, Mr. Jack Baker, Director.
California-----	Catholic Family Service, 349 Cedar Street, San Diego, California 92101, Telephone: (714) 235-6481, Dr. James Kleckner, Coordinators.
Louisiana-----	Tulane University, Department of Psychiatry and Neurology, 1430 Tulane Avenue, New Orleans, Louisiana 70112.
Minnesota-----	Hazelden Foundation, Inc., Box 11, Center City, Minnesota 55112, Telephone: (612) 257-7184, Mr. Dan Anderson, Director.
Missouri, western district ; Kansas-----	Greater Kansas City Mental Health, Foundation, 600 East 22nd Street, Kansas City, Missouri 64108, Telephone: (816) 513-8363, Charles B. Wilkinson, M.D., Executive Director.
Missouri, eastern district-----	Missouri Division of Mental Health Alcoholism and Drug Abuse Program, 5400 Arsenal Street, St. Louis, Missouri 63139, Telephone: (314) 644-2400, Raymond R. Knowles, M.D., Director.
New Mexico-----	Bernalillo County Mental Health-Mental Retardation Center, 2600 Marble Avenue, N.E., Albuquerque, New Mexico 87106, Telephone: (505) 265-3511, Walter M. Winslow, M.D., Director.
Oregon, Alaska, Idaho, Montana, Wyoming-----	Oregon State Division of Mental Health, Alcohol and Drug Section, 309 S.W. Fourth Avenue, Portland, Oregon 97204, Telephone: (503) 229-5525, Mr. Robert R. Wippel, Director.
Washington-----	Community Psychiatric Clinic, Inc., 5324 Talman Avenue, N.W., Seattle, Washington 98106, Telephone: (206) 789-2263, Mr. Larry Gilbert, Coordinator.

* * *

ATTACHMENT II

NARA COMMUNITY CONTRACT AGENCIES IN TEXAS

IN OPERATION

State/area :

Texas :

U.S. District Court, Southern District, Galveston Division, Houston Division, Eastern District, Northern District; all divisions.

Texas :

U.S. District Court, Western District, all divisions, Southern District, Victoria Division, Corpus Christi Division.

Texas :

U.S. District Court, Southern District, Laredo Division, Brownsville Division.

Agency

Vocational Guidance Service, 2525 San Jacinto Street, Houston, Texas 77004, Mr. John Hargraves, program director.

The Patrician Movement, 410 South Main Street, Room 300, San Antonio, Texas 78204, Father Dermot Brosnan, executive director.

Rio Grande State Mental Health-Retardation Center, 2115 North 28th Street, Harlingen, Texas 78550, Mr. Tom Laws, administrator; Mr. Max Smith, counselor.

UNDER NEGOTIATION

State/area :

Texas-----

Agency
Alivane, Inc., 1003 East San Antonio Street, El Paso, Texas 79901, Mr. Ramo Adame, director.

Texas-----

Austin-Travis County Mental, Health-Mental Retardation Center, 1516 Red River Street, Austin, Texas 78701, James Ferrero, M.D., director.

Texas-----

Dallas Rehabilitation Institute, 7850 Brook Hollow Road, Dallas, Texas 75235, William H. Henderson, director.

PROPOSED

State/area :

Texas-----

Agency
Nueces County Mental Health-Mental Retardation Community Center, 1611 5th Street, Corpus Christi, Texas, Mr. N. J. Huestis, executive director.

Texas-----

Amarillo Mental Health-Mental Retardation Regional Board of Trustees, 7201 Evan Street, Amarillo, Texas, Louise Evans, coordinator.

Texas-----

Bexar County Mental Health-Mental Retardation Board of Trustees, Robert B. Green Hospital, 527 N. Leona Street, San Antonio, Texas, Mr. James R. Bailey, executive director.

NATIONAL INSTITUTE OF MENTAL HEALTH,
Washington, D.C.

HON. OLIVER J. CARTER,
Chief Judge,
San Francisco, Calif.

DEAR MR. CARTER: This is to advise you of changes in the manner in which inpatient treatment services will be provided by the National Institute of Mental Health under Public Law 89-793, the Narcotic Addict Rehabilitation Act of 1966 (NARA), and to request your cooperation in the Implementation of these changes.

In January the Department of Health, Education, and Welfare and the Department of Justice announced jointly that the Fort Worth Clinical Research Center facility will be transferred to the Bureau of Prisons during the summer of 1971. The transfer is the result of coordinated plans of the two Departments to fulfill the Bureau's need for an additional medical facility and to further the National Institute of Mental Health's objective to provide the NARA civil commitment services in community facilities.

As you may know, our experience has indicated that community-based treatment can be more effective than treating addicts in centralized Federal institutions. By carrying out all phases of the NARA program in the communities, a continuum of care can be achieved with a minimum of disruption in the total treatment process. Additional advantages are fewer "dropouts," immediate attention while the addicts are highly motivated, greater opportunity for addicts to adjust to the stresses and strain located in their communities which caused them to turn to drugs, creation of trained manpower in the communities, and the opportunity to maximize family and community interest in addiction programs.

Consistent with this experience, the National Institute of Mental Health has expanded its NARA contract program with community agencies. Among those agencies to whom we have awarded contracts is Catholic Family Service, 349 Cedar Street, San Diego, California 92101; telephone (714) 235-6481 or (714) 272-3335, Dr. James Kleckner.

This agency has been designated a treatment facility of the United States Public Health Service as authorized under Public Law 89-793, the Narcotic Addict Rehabilitation Act of 1966 (28 USC, Sec. 2905 and 42 USC, Sec. 3414) for the inpatient treatment of narcotic addicts civilly committed under Titles I and III of the Act.

Effective August 1, 1971, all narcotic addicts, both male and female, from the State of California who have been examined and evaluated, and found suitable for treatment will be sent to Catholic Family Service for inpatient treatment. Starting on the same date patients recommitted for additional treatment will also be sent to this facility.

Effective August 1 the National Institute of Mental Health Clinical Research Center, Fort Worth, Texas will no longer accept patients from California. The Clinical Research Center, Lexington, Kentucky will be available for only special cases from California.

We believe that having all phases of the treatment of narcotic addicts civilly committed under the Act by community-based treatment and rehabilitation programs will provide better and more effective treatment.

We appreciate the cooperation the U.S. Attorneys and Courts have given in the past and hope these changes will not cause too great an inconvenience. If you have any questions feel free to call Mr. Glen Smutz, Project Officer, Federal Building, 11000 Wilshire Boulevard, Room 13120, Los Angeles, California 90024; telephone (213) 824-7456.

Sincerely yours,

KARST J. BESTEMAN,
Acting Director,
Division of Narcotic Addiction and Drug Abuse.

cc: Santa Barbara County Medical Health Services, Family Service Center, Narcotics Prevention Project, Kings View Homes, Inc., DBA, Catholic Social Service, Sacramento County Mental Health Services, Catholic Family Service, Westside Community Mental Health Center, Inc., Santa Clara County Medical Health Department, Family Service Agency of Santa Barbara, Family Service of Long Beach, Family Services Association of Riverside, Monterey County Department of Public Health, Mr. Cecil F. Poole, U.S. Attorney; Mr. George E. Tobin, U.S. Marshal; Mr. Pickerstein, Mr. Glen Smutz, NARB R&E Section AO Contract File, CRC—Lexington, CRC—Fort Worth, CMS—Mr. Robert Gradwell.

Identical letter to all chief judges state of California.

NATIONAL INSTITUTE OF MENTAL HEALTH,
Washington, D.C.

HON. RICHARD E. ROBINSON,
Chief Judge
Omaha, Nebr.

DEAR MR. ROBINSON: This is to advise you of changes in the manner in which inpatient treatment services will be provided by the National Institute of Mental Health under Public Law 89-793, the Narcotic Addict Rehabilitation Act of 1966 (NARA), and to request your cooperation in the implementation of these changes.

In January the Department of Health, Education, and Welfare and the Department of Justice announced jointly that the Fort Worth Clinical Research Center facility will be transferred to the Bureau of Prisons during the summer of 1971. The transfer is the result of coordinated plans of the two Departments to fulfill the Bureau's need for additional medical resources and to further the National Institute's objective to provide NARA civil commitment treatment in community facilities where justified.

Our experience has indicated that community-based treatment can be more effective than treating addicts in centralized Federal institutions. Consistent with this experience, the National Institute of Mental Health is expanding its NARA contract program in localities in which the prevalence of NARA commitments justify community inpatient treatment programs.

The development of NARA community contract agencies to provide inpatient treatment will enable us at a later date to designate an inpatient treatment facility either in or closer to Nebraska.

Until that time, and effective August 1, 1971, narcotic addicts, both male and female, from the State of Nebraska committed for examination and evaluation, or who were committed for examination and evaluation to a NARA community contract agency and found suitable for treatment will be sent to the National Institute of Mental Health Clinical Research Center, Leestown Pike, Lexington, Kentucky 40507, Harold T. Conrad, M.D., Chief, telephone FTS (606) 252-2581, Commercial (606) 255-6812. Starting on the same date patients recommitted for additional treatment will also be sent to this facility.

If you have any questions or if we can be of any assistance, feel free to call Mr. Ronald White, Project Officer, Parklawn Building, Room 13C-05, 5600 Fishers Lane, Rockville, Maryland 20852; telephone (301) 443-4174.

Sincerely yours,

KARST J. BESTEMAN,
Acting Director,

Division of Narcotic Addiction and Drug Abuse.

cc: Mr. Lloyd H. Grimm, U.S. Marshal, Mr. Pickerstein, Mr. Ronald White, NARS R&E Section, AO Contract File, CRC—Lexington, Kentucky, CRC—Fort Worth, Texas, CMS—Mr. Robert Gradwell.

NATIONAL INSTITUTE OF MENTAL HEALTH,
Washington, D.C.

HON. JOE EWING ESTES,
Chief Judge, Dallas Tex.

DEAR MR. ESTES: This is to advise you of changes in the manner in which inpatient treatment services will be provided by the National Institute of Mental Health under Public Law 89-793, the Narcotic Addict Rehabilitation Act of 1966 (NARA), and to request your cooperation in the implementation of these changes.

In January the Department of Health, Education, and Welfare and the Department of Justice announced jointly that the Fort Worth Clinical Research Center facility will be transferred to the Bureau of Prisons during the summer of 1971. The transfer is the result of coordinated plans of the two Departments to fulfill the Bureau's need for an additional medical facility and to further the National Institute of Mental Health's objective to provide the NARA civil commitment service in community facilities.

As you may know, our experience has indicated that community-based treatment can be more effective than treating addicts in centralized Federal institutions. By carrying out all phases of the NARA program in the communities, a continuance of care can be achieved with a minimum of disruption in the total treatment process. Additional advantages are fewer "dropouts," immediate attention while the addicts are highly motivated, greater opportunity for addicts to adjust to the stresses and strains located in their communities which caused them to turn to drugs, creation of trained manpower in the communities, and the opportunity to maximize family and community interest in addiction programs.

Consistent with this experience, the National Institute of Mental Health has expanded its NARA contract program with community agencies in Harlingen, Houston, and San Antonio to provide the inpatient treatment phase.

These agencies have been designated "treatment facilities of the United States Public Health Service" as authorized under Public Law 89-793, the Narcotic Addict Rehabilitation Act of 1966 (28 U.S.C. Sec. 2905 and 42 U.S.C. Sec. 3414) for the inpatient treatment of narcotic addicts civilly committed under Titles I and III of the Act.

The enclosed list designates the NARA contract facility to which the U.S. District Courts will commit individuals for inpatient treatment. Effective August 1, 1971, all narcotic addicts, male and female, from the State of Texas committed for examination and evaluation, or who were committed for examination and evaluation to a NARA community contract agency and found suitable for treatment will be sent to these agencies.

Effective August 1, 1971, the National Institute of Mental Health Clinical Research Center, Fort Worth, Texas will no longer accept patients from Texas. The Clinical Research Center, Lexington, Kentucky will be available for special cases from the State of Texas.

NARA community contract agencies are being developed in Austin, Amarillo, Dallas, Fort Worth, and El Paso. When these community agencies are operational they will provide an effective network of community-based treatment and rehabilitation programs for addicts civilly committed in the State of Texas.

We appreciate the cooperation the U.S. Attorneys and courts have given in the past and hope these changes will not cause too great an inconvenience. If you have any questions feel free to call Mr. Howard Huchlbarger, Project Officer, New Moore Building, Room 515, 106 Broadway, San Antonio, Texas 78205; telephone (512) 225-4105.

Sincerely yours,

KARST J. BESTEMAN,
Acting Director,

Division of Domestic Addiction and Drug Abuse,

All agencies in Texas, Mr. Elden B. Mahon, U.S. Attorney, Mr. William C. Black, U.S. Marshal, Mr. Fischerstate, Mr. Edward Mechlerberger, NARA R & E Section, AO Contract File, CRC—Lanieron, CRG—Fort Worth, CMS—Mr. Robert Cradwell.

Identical letter to all Chief Judges, Texas.

NARA COMMUNITY TREATMENT FACILITIES, DESIGNATED TO ACCEPT NARCOTIC ADDICTS, CIVILLY COMMITTED FOR INPATIENT TREATMENT, UNDER THE NARCOTIC ADDICT REHABILITATION ACT OF 1968—EFFECTIVE, AUGUST 1, 1971

U.S. DISTRICT COURT—DISTRICT DIVISION COMMIT TO NARA AGENCY

Southern District, Galveston Division, Houston Division, Western District, all divisions, Northern District, all divisions: Vocational Guidance Service, 1525 San Jacinto Street, Houston, Texas 77004, Mr. John Hargraves, Program Director, Telephone (713) 225-3688.

Western District, all divisions, Southern District, Victoria Division, Corpus Christi Division: The Patrician Movement, 410 South Main Street, Room 300, San Antonio, Texas 78204, Father Bernot Brennan, Executive Director, Telephone (513) 224-4841.

Southern District, Laredo Division, Brownsville Division: Rio Grande State Rental, Health-Mental Detection Center, 1115 North 25th Street, Mr. Tom Laws, Administrator, Mr. Max Smith, Counselor, Telephone (512) 423-5077.

Mr. ROGERS. Thank you very much, Mr. Wright, for a statement that is really shocking, I think, in the carrying out of this whole closing of Fort Worth.

Mr. Preyer?

Mr. PREYER. I am sorry I missed the earlier part of your statement, Mr. Wright, but I certainly agree with your conclusions that the closing of Fort Worth was bad; we do need central hospitals, it seems to me, for drug treatment.

As you pointed out, first, there are not enough community facilities yet. Second, it seems to me we need to train people to man the com-

munity hospitals. Where are these people coming from that are going to man them? Third, your controlled environment point is certainly a good one. Everything we have seen about drugs indicates that you often need a fence around a treatment place.

The drive for drugs is so strong you must at time, control these people as if they are almost in a prison to keep them away from drugs. I regret, like you, seeing this close.

Thank you very much for your testimony.

Mr. ROGERS. Mr. Hastings?

Mr. HASTINGS. I would like to commend my colleague from Texas who is interested not only in a facility in his district but in a problem of nationwide impact. I hope my smoking doesn't contribute to your withdrawal symptoms.

I would like to know, have you complete followup documentation of all 94 patients that were released?

Mr. WRIGHT. No; Mr. Hastings, I do not have that. I made a statement on October 20, last week, in the House listing the results of the partial inquiry that has been made. It just wasn't possible on that short a notice to track down every one of them and I thought by releasing the energies of four of these investigators for approximately 5 days we could get enough information at least to indicate that some of these fellows haven't been cured, and we did discover that.

I don't know what percentage of them are back on drugs now. I had noted as a result of this that half of them reporting to San Antonio's facility were back on drugs when they checked in. San Antonio people told our investigators this. I also reported that I had the impression that five had been returned to Phoenix and that all five of them by the time the weekend had passed and they reported back in on Monday showed as a result of urinalysis tests that they had had hard drugs. Now, that is in dispute because Mr. White of the NIMH apparently talked with the community center in Phoenix following my report and got word from them that six of the eight patients assigned were accounted for and clean. Now, that is a discrepancy that I don't know how to resolve. I am not certainly going to say that Mr. White misrepresented the facts. I simply say that my investigators were told that all five of them had shown positive results of the test.

Now whatever the percentage of those who had gone back on drugs, whatever the number of those who are back out pushing drugs, whatever the number of those who are back in crime in an effort to get the money to sustain this horrible habit, I think is somewhat moot. If it is 10 percent who are back in crime, that is bad. That is too many. If it is 50 percent who are back on drugs so soon after their release, that is bad. The point of it to me is that the abrupt termination and the sending back out onto the streets of these 94 people was unwarranted because they had not completed their treatment. Maybe some of them upon the completion of their treatment would have followed the same course. I must say in all candor that I do not believe even after the best of inpatient treatment and the best of facilities that you can expect an unusually high percentage of permanent cures. I do not think history would show that.

Mr. HASTINGS. I not only agree with you, I think we cannot use the terminology "cure" as it relates to a drug addict. I think we had 90 percent according to our figures. The fact that they do come back is one we are well acquainted with.

Consistent with this experience, the National Institute of Mental Health has expanded its NARA contract program with community agencies in Harlingen, Houston, and San Antonio to provide the inpatient treatment phase.

These agencies have been designated "treatment facilities of the United States Public Health Service" as authorized under Public Law 89-793, the Narcotic Addict Rehabilitation Act of 1966 (28 U.S.C. Sec. 2905 and 42 U.S.C. Sec. 3414) for the inpatient treatment of narcotic addicts civilly committed under Titles I and III of the Act.

The enclosed list designates the NARA contract facility to which the U.S. District Courts will commit individuals for inpatient treatment. Effective August 1, 1971, all narcotic addicts, male and female, from the State of Texas committed for examination and evaluation, or who were committed for examination and evaluation to a NARA community contract agency and found suitable for treatment will be sent to these agencies.

Effective August 1, 1971, the National Institute of Mental Health Clinical Research Center, Fort Worth, Texas will no longer accept patients from Texas. The Clinical Research Center, Lexington, Kentucky will be available for special cases from the State of Texas.

NARA community contract agencies are being developed in Austin, Amarillo, Dallas, Fort Worth, and El Paso. When these community agencies are operational they will provide an effective network of community-based treatment and rehabilitation programs for addicts civilly committed in the State of Texas.

We appreciate the cooperation the U.S. Attorneys and courts have given in the past and hope these changes will not cause too great an inconvenience. If you have any questions feel free to call Mr. Howard Huchlbarger, Project Officer, New Moore Building, Room 515, 106 Broadway, San Antonio, Texas 78205; telephone (512) 225-4105.

Sincerely yours,

KARST J. BESTEMAN,
Acting Director,

Division of Domestic Addiction and Drug Abuse,

All agencies in Texas, Mr. Elden B. Mahon, U.S. Attorney, Mr. William C. Black, U.S. Marshal, Mr. Fischerstate, Mr. Edward Mechlberger, NARA R & E Section, AO Contract File, CRC—Lanier, CRG—Fort Worth, CMS—Mr. Robert Cradwell.

Identical letter to all Chief Judges, Texas.

NARA COMMUNITY TREATMENT FACILITIES, DESIGNATED TO ACCEPT NARCOTIC ADDICTS, CIVILLY COMMITTED FOR INPATIENT TREATMENT, UNDER THE NARCOTIC ADDICT REHABILITATION ACT OF 1968—EFFECTIVE, AUGUST 1, 1971

U.S. DISTRICT COURT—DISTRICT DIVISION COMMIT TO NARA AGENCY

Southern District, Galveston Division, Houston Division, Western District, all divisions, Northern District, all divisions: Vocational Guidance Service, 1525 San Jacinto Street, Houston, Texas 77004, Mr. John Hargraves, Program Director, Telephone (713) 225-3688.

Western District, all divisions, Southern District, Victoria Division, Corpus Christi Division: The Patrician Movement, 410 South Main Street, Room 300, San Antonio, Texas 78204, Father Bermot Brennan, Executive Director, Telephone (512) 224-4841.

Southern District, Laredo Division, Brownsville Division: Rio Grande State Rental, Health-Mental Detection Center, 1115 North 25th Street, Mr. Tom Laws, Administrator, Mr. Max Smith, Counselor, Telephone (512) 423-5077.

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I make one additional comment. I am in agreement that although the outpatient treatment facilities certainly have a definite place in drug addiction, I am personally convinced that we must have facilities like Fort Worth. I am one who favors going further because I think we must use the disciplinary approach to the problem of drug addiction. I think it goes across every type of program that we have available to us including the one where there must be incarceration with the right type of rehabilitation offered at the same time.

I appreciate very much your testimony.

Mr. ROGERS. Mr. Symington?

Mr. SYMINGTON. Thank you, Mr. Chairman.

Mr. Wright, you put a general question to this committee which I think is an important one for the committee and for the country. That is, whether now even before the establishment of a special action office which was intended to identify the nature of these problems, we should come down firmly with the conclusion that centers, such as Fort Worth, have outlived their usefulness and that somehow people are to get along with aftercare or community based centers or some other form of treatment or nontreatment. Like you, I and most members of this committee are not medical men but it does seem to me if we have 200,000 addicts, just to state a figure, on hard drugs, that there ought to be enough beds and enough centers to take care of a certain percent of them. I think it behooves this committee to find out, after Fort Worth is removed from the scene, what does that leave? And what is the scientific justification for this approach? This legislation which we have been asked to pass out of this subcommittee gives the special action office the authority to promote major drug abuse programs, centrally developed, funded, and managed and evaluated to achieve maximum effectiveness.

They already made an evaluation before they have the law. It may be a correct one but I think we should examine it. He also has power to construct, improve, repair facilities, and use anybody's budget to that extent. That is the testimony we have received.

Any department's budget which has programs relevant to the fight on drugs can be used, so I think that it is very useful for us to have you come this morning and to flag this particular development. We do not know if it is one of a kind or whether it is a beginning of a trend. I do hope that we will learn enough from the subsequent witnesses about the overall Federal evaluation of drugs to help us decide in our own minds whether the decisionmaking faculties of the Government are sufficient today without this law or whether some changes ought to be made.

I thank you for your testimony.

Mr. WRIGHT. I thank you, sir, for your comments.

This committee knows there are people who have been, if not cured, arrested for long periods of time from drugs. One witness whom I recall testifying before this subcommittee when it was in Fort Worth was a man who has been off drugs now for 15 years and who is working with the police department in San Antonio, I believe, in the pro-

gram. So there are modes of treatment that can be effective and, of course, we all ought to work to achieve the maximization of those modes of treatment and I really, very, very, seriously question the theory that you do not need some big places rather far removed from the home base of those who are the patients.

Mr. SYMINGTON. One other thing, we know some addicts are returning from Indochina. The estimates vary from 2 percent to maybe 15 percent, depending on the degree of addiction that people are willing to accept as equivalent to being hooked, and I suspect that this decision is based on an assumption that none of them really should return to a facility of this kind for any length of time. I think that is a rather interesting assumption.

Mr. ROGERS. As I understand you to say, your investigators had found three had been sent back to Alaska?

Mr. WRIGHT. Yes, sir; that is correct.

Mr. ROGERS. There are no facilities in Alaska to carry out this treatment.

Mr. WRIGHT. That is correct, sir. Mr. Lawrence and Mr. Willse checked with the Alaska patients. Is that correct?

Mr. LAWRENCE. There was outpatient care available in Anchorage at a psychiatric clinic. There was no inpatient facility anywhere in Alaska, we were told.

Mr. ROGERS. I believe in New Orleans—what did we find as far as the numbers of people returned to New Orleans?

Mr. WRIGHT. Mr. D'Amico and Mr. Nolen went to New Orleans. They can correct me if I am in error. Thirteen patients of the 94 were returned to New Orleans. There exists in New Orleans, at the Tulane Clinic an inpatient capacity of 15. Twelve of those beds were occupied, leaving only three unoccupied beds for inpatient treatment.

The investigators talked with some of those people who had been returned and developed the information that one, a former drug pusher was back out on the streets peddling drugs again.

Mr. ROGERS. Thank you very much. We appreciate your bringing this information to the committee because I think it does point up concern in the positive action taken by the House. In spite of the feeling of the House, this action should not be closed. This action was taken, as you pointed out, in complete disregard of the patients care. Also what concerns me is the fact that the authorities in HEW have assured us that these patients have been taken care of. This obviously has not been the case.

Thank you for letting us have this information.

Mr. WRIGHT. Thank you, Mr. Chairman. Thank you and each of my colleagues on the committee.

Mr. ROGERS. Our next witnesses are from the Department of Health, Education, and Welfare, Dr. John S. Zapp, Deputy Assistant Secretary for Legislation, Dr. Vernon Wilson, Administrator, Health Services and Mental Health Administration, and Dr. Bertram S. Brown, Director of National Institute of Mental Health.

The committee welcomes you.

STATEMENT OF DR. JOHN S. ZAPP, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH), DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY DR. VERNON E. WILSON, ADMINISTRATOR, HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION; DR. BERTRAM S. BROWN, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH; AND KARST J. BESTEMAN, DEPUTY DIRECTOR, DIVISION OF NARCOTIC ADDICTION AND DRUG ABUSE, NATIONAL INSTITUTE OF MENTAL HEALTH

Dr. ZAPP. We also have with us and I would like to have permission to have accompany us to the table, the Deputy Director, National Institute of Mental Health, Division of Narcotics Addiction and Drug Abuse, Mr. Besteman.

Mr. ROGERS. The committee welcomes you.

Dr. ZAPP. We appreciate very much, Mr. Chairman and members of the committee, the opportunity to appear before you this morning to discuss the administration of our drug abuse program, particularly the circumstances which made it possible for the Department of Justice to expand its treatment capability as we expanded and refocused ours.

I would like to add here, I think it is appropriate for the controversy that has developed around the transfer of the Fort Worth facility that we have the opportunity to appear right after Mr. Wright, who is from the district and very concerned about this.

Because of the intense interest and concerns which this action has provoked within Congress, we would like to place our actions in the context of contacts and considerations raised by the Congress in passing similar resolutions in both the House and Senate that certain DHEW facilities remain under our direct administration.

These resolutions, while similar in general coverage and intent, had one area of significant difference, namely, the House version included the clinical research centers at Fort Worth, Tex. and Lexington, Ky.

Originally the planning for the transfer of the facility at Fort Worth had August 1, 1971, as the date on which the Department of Justice would assume the responsibility for the facility. In the light of congressional concerns expressed, the Secretary of Health, Education, and Welfare voluntarily extended this date until October 1, 1971.

Because alternate resources were available and in developing an orderly sequence to assure the proper care of patients, new admissions to the facility from the U.S. courts were suspended on August 1, 1971. Each U.S. court which referred patients to the Fort Worth Clinical Research Center was sent a letter notifying the court of this decision and designating an alternative resource.

When Congress reconvened after the Labor Day holiday the disparate resolutions were scheduled for discussion and negotiation by the House-Senate conference.

Because of the heavy schedule of important legislative issues the conferees with the agreement by the Secretary, DHEW, deferred consideration of the issue until early October.

On Tuesday, October 5 and Wednesday, October 6 the conference committee met. At that time all conferees received a joint letter from

the Attorney General and the Secretary of Health, Education, and Welfare, describing our desire because of the need that the facility be placed with the Department of Justice as a resource to the Bureau of Prisons.

I might at this point state, when the letter was inserted in the record by Congressman Wright, he picked up an obvious typographical error which was corrected on the bottom of this page, when it discussed it as a 500-bed facility. The last paragraph on the page.

On October 6, 1971 the conferees deadlocked on this issue and tabled this matter after indicating no agreement could be reached. With the Congress no longer considering this matter, the Secretary of Health, Education, and Welfare, and Attorney General moved to accomplish the much delayed transfer.

The Narcotic Rehabilitation Act of 1966 authorized a civil commitment system that has basically three phases. The first is examination and evaluation not to exceed 30 days, which is followed by an inpatient phase not to exceed 6 months. Subsequently the patient is discharged to aftercare which consists of a community-based outpatient rehabilitation process not to exceed 3 years.

The patients at the Fort Worth Clinical Research Center, during October of 1971, were, with two exceptions, being treated in the inpatient phase and being prepared for aftercare treatment.

The arrangements to refer these patients were adequate and proper. Contact by the professional staff at Fort Worth with the various agencies outlined the patient's situation to the receiving agency. Because we had anticipated this activity approximately 1 week earlier, the transition to aftercare, while creating minor travel difficulties, did not present any difficulties beyond the usual concerns in referral of a patient to outpatient status.

It should be emphasized that the men involved were being returned to their home communities to family situations and agencies where there was previous contact and the capability to provide necessary care.

If we may we would like to summarize briefly the results of a single survey which was completed over the weekend. The subjects are the 89 patients discharged from the Fort Worth Clinical Research Center on October 8 and 9, 1971.

All 89 patients who were discharged on October 8 and 9, 1971, returned to their home communities for treatment and rehabilitation under the care and direction of personnel of agencies who are under contract to the National Institute of Mental Health.

Of the 89, 86 reported as scheduled to the aftercare agency; there were no special escorts for these men as a group and this is rarely, if ever, provided.

Of the 89, we have evidence that 29 abused a drug since returning to the community. Three have been arrested on various traffic charges. One of the three has spent a total of 11 days in jail as a result of a previous warrant issued prior to commitment to Fort Worth.

Of the 89, 31 already are gainfully employed, 86 continue on active status in the program. One of the 89 has been rehospitalized at a local community contract facility.

It is our opinion that this behavior does not vary greatly from any other 89 male patients who would be released back to the community from an isolated treatment center. Narcotic addiction is frequently a

chronic relapsing process. Evidence clearly points to the fact that the first 3 months in aftercare are critical ones. We believe that these men will, as they are treated and progress through the program, demonstrate the same pattern of improvement previously experienced by patients in this program.

Mr. Chairman, we appreciate the opportunity to appear before you today to clarify the situation with regard to the transfer of the Fort Worth Hospital from the Department of Health, Education, and Welfare to the Bureau of Prisons, Department of Justice. We would be pleased to answer any questions you or the other members of the committee may have.

Mr. ROGERS. Thank you very much, Dr. Zapp.

Mr. Nelsen?

Mr. NELSEN. Mr. Chairman, I missed some of the testimony so I would like to reserve a little time to see how things go. Frankly, I supported the transfer and my reason for so doing was that all of the evidence that I could see showed that this area was blessed with drug abuse and facilities, that there were more facilities for treatment in this area than any other area that I know of.

In the law enforcement, for example, here in the District of Columbia, most of the crimes on the streets are committed by drug addicts that have been arrested and then released. Ninety percent of the inmates in the Women's Detention Center are users of narcotics. If there is any area where the public suffers the most, it is from the release of addicts by penal institutions. This has provided a greater problem to the public than any other area that I know of.

I did not support a transfer of any of the Public Health Service hospitals until a good alternative use was provided and in my judgment this area was an area that needs attention. Therefore, in the conference I supported the view that the Senate took. I think it can honestly be said that in this area there has been a tinge of politics. In conference, the Senate stood fairly firm on the transfer and some of us on the Republican side supported the Senate's view. I will be asking for more time later.

Mr. ROGERS. Mr. Preyer?

Mr. PREYER. Thank you, Mr. Chairman.

Perhaps this has been covered earlier when I was not here, but is there some explanation of the discrepancy between the 94 patients and 89 patients in your testimony?

Dr. ZAPP. I will refer that question to Mr. Besteman.

Mr. BESTEMAN. I can account for the discrepancy up to 92 but I cannot account for 92 to 94. We are talking about 89 patients who were in the NARA program and going to aftercare. There were three other patients in the facility who were not in that status. So then I get a total of 92. I cannot account for the 94, sir.

Mr. PREYER. Which status were the other three in?

Mr. BESTEMAN. There was, in fact, still one prisoner there who would remain on site. There was one person there awaiting escort because of status to be returned to a U.S. marshal and there was one other patient there who was not scheduled to go to aftercare.

Mr. PREYER. The standard treatment at Fort Worth, I gather, involved a 30-day period of examination and then a period of up to 6 months of treatment. Did most of your patients stay the entire 6 months as a part of your usual treatment?

Dr. BROWN. The patients ranged in their inpatient phase 2, after the initial 30-day evaluation, anywhere from 1 month to 6 months with perhaps an average of $4\frac{1}{2}$ to 5 months as a whole.

Mr. PREYER. So the average was closer to the 6 months period?

Dr. BROWN. Yes, sir.

Mr. PREYER. These patients which have been discharged on an average—how long had they been in phase 2?

Dr. BROWN. Approximately a month less. Approximately $3\frac{1}{2}$ to 4 months.

Mr. PREYER. What would be the extremes?

Dr. BROWN. I think the shortest would have been at least $2\frac{1}{2}$ months.

Mr. BESTEMAN. As was indicated in the testimony, we asked the courts to cease sending patients on August 1 and, since discharge occurred on—this is commitment to inpatient treatment—since discharge occurred on October 8 or 9, this would be the least amount of time available to any one person.

Mr. PREYER. So there were discharges earlier than there would have been ordinarily under the standard treatment?

Dr. BROWN. As an average I would say that is so. No individual, however, was discharged before it was felt it was proper.

Mr. PREYER. You contend that they were all returned to care that was under the direction of personnel from agencies under contract to the National Institute of Mental Health? Is that true, in the Alaska situation, for example?

Dr. BROWN. Yes, sir; when Congressman Wright asked his investigators about being sent back to Alaska with no care, supplementary information was provided that it was for an outpatient psychiatric clinic, so that the three people in Alaska were returned to one of our contract aftercare agencies at a psychiatric clinic in Anchorage.

It is true there is no inpatient facilities. We have to clarify this very basic point—I think it is an important one—that some of the patients were, indeed, returned to aftercare outpatient clinics in communities that did not yet have inpatient facilities. This is accurate. None were returned to places that had no treatment. All were returned specifically to an aftercare person, agency, clinic, or professional.

Mr. PREYER. How many were in Anchorage—all three of them?

Dr. BROWN. I think so. I cannot say that specifically. Whether it was Anchorage per se. I can only say it was Alaska.

Mr. ROGERS. If the gentleman would permit. That is fairly important. Anchorage is almost the same distance as Fort Worth from town to town, to get there—I would think that would be fairly important to know.

Dr. BROWN. We will track that down specifically.

Mr. ROGERS. Don't we have where they came from, their homes?

Mr. BESTEMAN. Yes, but here I only have where they were discharged to. Three went to Anchorage. I know from personal experience that that has been the source in Alaska which is the reason for choosing that one aftercare agency.

I would be almost certain it would be but we will get their exact home addresses to you.

Mr. ROGERS. I think that would be interesting to have before we conclude the hearing. Could we get that? Is there any way?

Dr. BROWN. Surely.

(The following information was received for the record:)

Two of the men were from Anchorage and one from Spenard.

Mr. PREYER. Of the three who vanished between Fort Worth and their homes—you have no idea where they are?

Dr. BROWN. One has called in so our figures are 87 to 89, so again this is not dissimilar from the usual experience.

The great bulk will phone in or call or visit their after-care clinic or doctor, or agency within 24 hours of arriving.

There are a goodly number, as you brought out, who do not show up for 3 days, or 5 days, or 7 days and disappear, vanish, drop out, though almost all do call in by the end of the week. I would presume the two missing ones will show up at the end of the week. I cannot be sure. But this is not dissimilar from our other experiences.

Mr. PREYER. And they are released without any escort. That is your usual experience?

Dr. BROWN. That is correct.

Mr. PREYER. Was any effort made here, where some came up well-short of the usual period—was any consideration given to escorting those who may have been there for a month or 2 instead of their 6 months?

Mr. BESTEMAN. Our experience has been that we have not provided escorts through the entire history of the program unless requested by the court to do so. Or unless the psychiatric or medical condition is such that they are considered unable to travel alone. Even when we have a person only for examination and evaluation and returning to his home community, he returns unescorted. The experience over the last 3½, going on 4 years, has been excellent. We have not had untoward incidents.

Mr. PREYER. Thank you. I have no more questions at this time.

I will yield to my associates here.

Mr. HASTINGS. I would like to reemphasize, particularly of the 89 that you talk about, there did not appear to be a great deal of difference to what happened to them in the after-care than would normally happen to any other 89 patients; is that correct?

Dr. ZAPP. That is correct.

Mr. HASTINGS. The report uses language as “summarily closing of facility.” Your testimony indicates that is not true.

Dr. ZAPP. The proposed transfer of the clinical research facility in Fort Worth is something that has been under active consideration during the course of the calendar year and was mentioned in the budget justification of the Department of Justice, Bureau of Prisons, as well as our own, and there has been frequent correspondence between the committee chairman, the subcommittee chairman of this committee and the Secretary of HEW on this issue. It was scheduled to be transferred on the 1st of August. Then it was the first of October and because of the Conference and the heavy workload, it was delayed 1 week to allow for completion of consideration before the Conference. It was only at that time, after two delays, that the transfer was made.

Mr. HASTINGS. Then another statement in the report, “sudden and abrupt termination and release of 94 patients.” You would not agree with that either?

Dr. ZAPP. It is something that again has been planned. The staff there were aware of it. The people in the communities, the aftercare treatment centers were aware of it. I would hardly term that sudden and abrupt. When the time comes, they walk out of the facility. That is an abrupt detachment from the facility, regardless of what the forewarning may be.

Mr. HASTINGS. And also, "HEW instructed patients to be released by nightfall and none had concluded treatment."

Dr. ZAPP. Again I would return to my earlier answer. This is something, the transfer of these people back to their communities has been postponed twice. It was only at such time as the Conference had this under consideration that the transfer of the patients back to the community was made. I have a difficult time correlating that with "sudden and abrupt" when it had been planned for months and obviously the day has to come and whenever that day is, it is abrupt.

I certainly would not relate to that the amount of forewarning or planning that took place.

Mr. HASTINGS. With reference to Louisiana, Tulane facility, only 15 beds with 13 already occupied.

Dr. ZAPP. I would refer that to Dr. Brown, as to the status of those patients.

Dr. BROWN. This gets at the problem of the inpatient and the outpatient. These men were transferred to outpatient. The fact there were two or three backup beds available I would think makes sense. We were not transferring to inpatient at Fort Worth, to inpatient in Louisiana. If that were the case, it would have indeed been irresponsible.

Mr. HASTINGS. Do you have any statistics as to the success of the rehabilitation?

Dr. WILSON. We have previously testified on this point. I would, however, be glad to summarize again. Evaluation of our program is one of the most important things we have to do particularly for our own edification. How much success have we had? How well is the patient doing? Well, we will have our first studies completed on the 36 months plus the inpatient phase. We do have an active research program.

It is a great deal more successful than in the old days of just inpatient. It is clear from the Lexington experience, that we are still dealing with a very difficult problem of recidivism. However, we can give you facts and figures on the 3-month period, the 8-month period, et cetera.

Mr. HASTINGS. How about a year or 2 years?

Dr. BROWN. At the point we have—and this has been testified to before the full committee—we point out that as many as 70 percent of those in aftercare will be gainfully employed at the end of 2 years; 50 percent will have stayed clean for 6 months or more.

We have these different parameters, employment, being clean from drugs, arrest records, it is overall. If you ask me to summarize that in a commonsense way and say, "How successful are you?" I would say that we are having a success rate in the 50 or 60 percent level as opposed to failure rate of 90 percent level in the old days.

Mr. HASTINGS. Over how long a period of time?

Dr. BROWN. Two to three years.

Mr. HASTINGS. Fifty to sixty percent would not come up with positive—

Dr. BROWN. The 50 or 60 percent would have been gainfully employed, not been arrested, and had clean urine tests, or a portion of those again might be on methadone maintenance. This another very important issue.

Mr. HASTINGS. We won't get into that at the moment. I would like to another time, though.

By and large then, you again—and this is reiteration of your position—say that these patients were not too substantially different than were any others, other than the fact you were closing your facility and you moved the date up a little bit?

Dr. BROWN. That is a clear summary; yes, sir.

Mr. HASTINGS. I am not asking for a policy statement from HEW on the possibilities of the future of continuing such, not specifically Fort Worth, but such facilities under either existing commitment or proposed commitment. In the field, is there a place for this type of a facility other than strictly on an outpatient basis?

Dr. BROWN. Yes. I feel definitely there is a place for an inpatient facility, an inpatient facility with good security.

Mr. HASTINGS. For example, California's "See Our City" program, which I think is a model in the country. California seems to be working substantially well. I always attach to that question, with full rehabilitation facilities involved. Not just incarceration. You do feel—and I don't want to put you on a spot—but along the line that we should actively consider that even further than we have under the existing statute?

Dr. BROWN. There would be a place, though it would not be the most important modality, but the question, the issue of whether or not it should be Federal or State Government or other local jurisdictions who support it is inherent in the issue.

Mr. HASTINGS. If there is a place for it, I would suggest perhaps the Federal Government must take a look at it.

I have no further questions.

Mr. ROGERS. Mr. Symington?

Mr. SYMINGTON. Thank you, Mr. Chairman.

I think we are interested in these 89 people, if they are just a statistic we want to know what that means. I would point out that these men were released on the 8th of October; is that correct?

Dr. BROWN. Eighth and ninth. It was over a 2-day period.

Mr. SYMINGTON. And within 16 days you have evidence that more than 30 percent of them have used drugs?

Dr. BROWN. That is correct.

Mr. SYMINGTON. Were any of these men in a shorter time, say, than 2 months? Were they all in at least that long?

Dr. ZAPP. They would have had to be in in excess of 2 months.

Mr. SYMINGTON. You were prepared to release them on the 1st of August originally? The planning for the transfer was August 1?

Dr. ZAPP. Yes, sir; but that date was set back in May. And had that date been carried out then the termination time, as far as commitments, would have probably be set up some time, I assume, into even June, or May.

Mr. SYMINGTON. The need to make this change was in part or, I guess, in its entirety the need to make room for prisoners, is that true?

Dr. ZAPP. Well, yes; it was essentially a matter of the Department of Justice having a great need. Also, because of their increasing numbers of their Federal inmates who are in need of this type of treatment.

Mr. SYMINGTON. These are men over whom the Justice Department has some control probably for the foreseeable future. Do you have any indication what kinds of people they will put in there, people who are in for 6 months, a year, 2 years?

Dr. ZAPP. I personally don't. I would have to defer to the Department of Justice who will testify after us or perhaps Dr. Brown or Mr. Besteman may have an idea. I would think they would have people of all different terms and individuals who have had repeated incidents, not only with drugs but also with the relationship to crime.

Mr. SYMINGTON. It would be interesting to know the rationale that will be used in determining who gets into this facility and who does not. Of the 89, is it certain that none of them were charged with crimes before entering that facility?

Dr. BROWN. We know that one was arrested on a traffic offense and was then jailed because of a prior warrant.

It is likely out of 90 men, many, if not most, have been involved in some kind of antisocial or criminal or court behavior. I think that is the very nature of the issue.

At the time they were accepted through the court process, it was hoped they were "clean" of warrants that had not been served, but at no point could one be absolutely certain of that fact.

Mr. SYMINGTON. What is confusing to me is that it might have been better off for them to have gone to prison so they could enjoy this facility for a greater length of time. If, indeed, the facility serves a useful purpose for anyone who has a drug problem, it would appear that there has been a discrimination against the civilly committed, voluntarily committed addicts in favor of the prisoner.

Would you respond to that?

Dr. BROWN. Following on the logic of your presentation and I think there is merit in the logic, from my point of view I would like to say I do not think the Department of Justice and the Bureau of Prisons plans to use this facility primarily for drug addicts. Specifications as to their plans will be available in a moment.

Dr. WILSON. It is our contention that the treatment provided to the people who are discharged from Fort Worth was, indeed, the optimal treatment. The Bureau of Prisons does not have the option to provide ambulatory treatment so they must deal with incarceration because that is a part of their charge in handling people who have offended against society.

Mr. SYMINGTON. But it has been stated that most of the 89 probably committed an offense against society.

Dr. WILSON. At the moment we are not in violation of the law so far as we know.

Mr. SYMINGTON. But whatever the law had done in dealing with them, their problem exceeded that of mere drug addiction, if indeed they had probably committed an offense against society, regardless if they were caught, or caught and released, or caught and not released, tried, acquitted, any of those things could have happened to this 89.

And it seems to me out of a strange, perhaps misplaced sense of expediency, that they are being taken out from under this form of treatment, not because they could well afford to be but because the Bureau of Prisons so badly needed a place to put some of their people.

Doesn't that appear to be so to you? Do you think that all those people need when they go home is a little aftercare for drugs?

Dr. WILSON. We believe the success rate is higher if you treat the individual in an ambulatory and voluntary setting than if you treat them in full seclusion. We do not have the privilege with prisoners to treat them in other than seclusion. They are incarcerated for other reasons but they do need treatment.

I think some of the newspapers have been making it very clear to us within recent weeks that we do need to be concerned about those people who are incarcerated, about their health problems and their other problems. We feel this is a logical development which is evolving under the leadership of the Department of Justice. They treat people who are going to be incarcerated for a period of time, they give them the benefit of treatment. They do not have the option of treating them outside of incarceration.

Mr. SYMINGTON. I think it would be helpful to the committee to have a memorandum submitted which would detail as much as is known about each of the 89 so we could follow this, inasmuch as you deem it to be typical. We want to know what that signifies. The 29 who have returned to drugs. It would be helpful to know how long each one of them had the benefits of the service of that facility. Naturally it could be they were in for the 2-week period. It could be that one would argue that is irrelevant but didn't you say, sir, in response to Mr. Hastings—I forget the precise words you used—but that after a year's treatment, didn't you indicate that ability to hold a job was somewhat increased? That would be civilly committed people who may or may not have had a criminal record.

Dr. BROWN. Yes, sir.

Mr. SYMINGTON. I think it is somewhat discouraging to society to be told that the best you can do is 30 percent recidivism.

Dr. BROWN. We would be glad to provide a very detailed report at 3 months for the group as a whole as to how they have done in comparison with all the rest of the patients we have had, and again at 6 months and a year. We would be pleased to do that.

This would be a natural point because then we can say whether this group of 89 did better than, worse than, as good as, or average, to follow out our contention that they are no different.

As to any individual, we would have to be very careful to protect the name and the person because of the matter of confidentiality.

As to the latter point I think it is a case of either a glass of water two-thirds empty or one-third full. I think it is discouraging, depending on how you look at it. If you look upon the issue that it is a 90- or 100-percent-failure rate and you have two-thirds gainfully employed within a few days, it is encouraging. If you look at it as one-third within the first week that use drugs, that is discouraging. And we have to deal with this reality.

To some of us it is rather encouraging because our experiences with some were so different when we had no aftercare at all and we can see improvement of that one-third in general who used drugs within the first week. To put it in plain English, they get high as soon as they can.

Many of them settle down. They have a worker with them, an ex-addict and they have a family. They are gainfully employed.

The real issue is how well they have done at the end of 6 months or a year. So we do not get discouraged by this relapsing kind of behavior.

We have the answer to the chairman's earlier question. They are all three from the Anchorage area.

Mr. SYMINGTON. We are telling society, aren't we, that some people whose names we will not release are being returned to their communities and that 30 percent of them are back on drugs, raising the entire spectre of what that implies, especially if they do not have money to pay for them. And we have to justify this in our respective constituencies. I am not sure that anything has been said, at least this morning, that beefs up my ability to justify this. It seems a pragmatic move perhaps at the expense of the public in order to accommodate an even more necessitous situation, that of the prisons.

That is all I have at the moment, Mr. Chairman.

Mr. ROGERS. Let me ask you this, I am concerned about the way this whole matter is being handled, what responsibility do you have to a court that assigns someone to a facility? All of a sudden there is a decision made after the people have been assigned by a court to an in-patient facility that they are all cured and well enough to go out. Who made this decision?

Dr. BROWN. I am not aware of a decision that was made that they were all cured, Mr. Chairman.

Mr. ROGERS. That they are ready to be released. Isn't it strange that the decision is made that they are all immediately able to be released on the night of the 8th? I am somewhat surprised that they were all suddenly cured to that degree. Was that a medical or administrative decision?

Dr. BROWN. It was a medical decision.

Mr. ROGERS. By whom?

Dr. BROWN. By the staff at the hospital.

Mr. ROGERS. Had you verified that?

Dr. BROWN. Yes. Perhaps Mr. Besteman can clarify the mechanics.

Mr. ROGERS. I think that would be interesting.

Mr. BESTEMAN. Knowing October 1 was the target date for the facility to be transferred, we sent staff from our headquarters unit to the facility to survey every patient who was in residence there. They got lists by name, identifying the matter, and they asked the physicians to identify those patients who would not be able to leave in the time schedule now of the October 1 transfer. They asked specifically whether any of those patients would need to be transferred to Lexington because of their need for continued in-patient care.

The staff at the Fort Worth facility, the physicians, psychologists, social workers, did not identify any patients that needed this type of continued care at the time of the transfer. One week later they did not change their decision when the time came for the transfer.

Mr. ROGERS. In other words, no patient left had to have in-patient treatment? This was the medical decision?

Mr. BESTEMAN. None of the 89 that went to aftercare had to have in-patient treatment by the decision of the physicians that were treating them.

Mr. SYMINGTON. What was the date at which the Secretary of HEW extended the date until October 1? When did he make the decision and announce that it would be October 1 and not August 1?

Dr. ZAPP. I would have to supply the exact date for the record. It was some time in May, Mr. Symington.

(The following information was received for the record:)

The exact date was during this hearing on July 30, 1971.

Mr. ROGERS. Now, let me ask you this, when did they make these medical judgments?

Mr. BESTEMAN. They were asked to make these medical judgments during the months of August and September, but mainly in September because we knew, at least from what our planning was, that October 1 was the deadline and you have to be talking to community agencies, you have to be talking to make the referral and making specific plans for each patient. This was a concern of ours, would any of them need to continue in in-patient, one, and two, would any of them need transferring to our Lexington facility which is also administered in our Division. We got a negative reply.

Mr. ROGERS. Why weren't they immediately discharged as soon as that medical decision was made? Why did you hold them?

Mr. BESTEMAN. The decision was made in terms of an October 1 transfer date.

Mr. ROGERS. Now, that hardly gives with the letter you sent to the U.S. attorney in New Orleans. Have you seen that letter?

Mr. BESTEMAN. I suspect so.

Mr. ROGERS. Do you know when that was sent out?

Mr. BESTEMAN. Are you speaking of the letter indicating that Fort Worth would no longer accept inpatients?

Mr. ROGERS. I am talking about a discharge of a patient. You said a medical judgment was made in September and you went about getting him all set up for community treatment.

Mr. BESTEMAN. That is right.

Mr. ROGERS. Do you know when you sent the letter to the U.S. attorney in New Orleans?

Mr. BESTEMAN. I don't know.

Mr. ROGERS. I will tell you and I will submit this for the record without objection.

(The document referred to follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE.
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION,
NATIONAL INSTITUTE OF MENTAL HEALTH CLINICAL RESEARCH CENTER.
Fort Worth Tex., October 8, 1971.

Mr. GERALD J. GALLINGHOUSE,
U.S. Attorney,
New Orleans, La.

DEAR Mr. GALLINGHOUSE: The above named patient was committed to the care and custody of the Surgeon General for treatment in a hospital of the Service by order of your Court. This patient is in the process of completing his hospital treatment and we plan to release him on October 8, 1971.

We respectfully recommend that the patient be committed to care and custody of the Surgeon General for posthospitalization treatment pursuant to Section 307 (a) of the Narcotic Addict Rehabilitation Act (42 USC 3417(a)).

Posthospitalization treatment will be provided by the aftercare agency listed below. We have instructed the patient to report to that agency and will provide transportation for him.

The patient has signed a waiver of his right to a personal hearing for his commitment to posthospitalization care. This waiver is enclosed, and it is requested

that you file it with the Court. Therefore, we respectfully request that the patient be committed in absentia to posthospitalization treatment.

Unless we receive contrary instructions from the Court we will release the patient to posthospital care on the above date.

Sincerely yours,

DOMINICK J. LACOVARA, M.D.,
Chief, NIMH Clinical Research Center.
(For the Surgeon General).

Enclosure

UNITED STATES DISTRICT COURT, EASTERN DISTRICT OF LOUISIANA
In re Civil No. [deleted].

[Deleted]

WAIVER OF HEARING ON COMMITMENT TO POSTHOSPITALIZATION CARE

Explanation of rights

Pursuant to Title III, Section 307, of the Narcotic Addict Rehabilitation Act, 42 U.S.C., 3417, the Surgeon General will recommend to the United States District Court that you be committed to the care and custody of the Surgeon General for posthospitalization treatment.

You are now entitled to be returned to the court which committed you. Upon your return, the court will conduct a hearing with respect to the recommendations of the Surgeon General concerning your commitment to posthospitalization treatment. As a result of this hearing, the court may commit you to the care and custody of the Surgeon General for posthospitalization treatment and supervision for a period not to exceed three years.

You may waive your right to be returned for a personal appearance before the court. You may instead request immediate commitment to posthospitalization care. If you elect to waive a personal appearance before the court, the Public Health Service will provide you with common carrier transportation to the aftercare agency appointed by the Surgeon General.

Whether you execute the waiver or request a personal appearance before the court is entirely your own decision.

Waiver

I, the undersigned patient in the above cause, hereby state that I understand and agree that the Surgeon General will recommend to the court that I be committed to the custody of the Surgeon General for posthospitalization treatment.

I hereby voluntarily waive any right to be returned to court for a hearing. I respectfully request the court to commit me to the custody of the Surgeon General for posthospitalization treatment and supervision for a period not to exceed three years.

I do all of this voluntarily and with the understanding that the Surgeon General will provide common carrier transportation to the aftercare agency and a reasonable amount, if necessary, to cover incidental travel expenses.

[Deleted].

October 8, 1971.

Subscribed and sworn to before me this 8th day of October, 1971.

ESTHER W. CARLTON,
Notary Public and for Tarrant County, Tex.

My commission expires June 1, 1973.

I, the undersigned physician, have examined the patient executing this waiver. In my judgment, the patient was mentally competent to understand the nature and consequences of the waiver. The patient was advised of the voluntary nature of this waiver and was given an opportunity to ask questions regarding the available procedures.

JANUARY 8, 1971.

ERNEST BRAASCH, M.D.

Mr. ROGERS. You sent it October 8. The U.S. attorney received it on the 12th. But you had already discharged the man on the eighth. We have here a saying that "posthospitalization treatment will be provided by the after-care agency listed below. Tulane University Hospital."

Well, you sent 13 of them down there, but they only had three beds open.

Now, further, you have them all sign a waiver of hearing before the court. Now, did you check to see if this man had committed a crime and that this confinement was given in lieu of a prison sentence? Did you check that?

Mr. BESTEMAN. Do you want a factual answer?

Mr. ROGERS. I hope so.

Mr. BESTEMAN. The legal responsibility for whether or not this man is under prosecution is at the time of commitment into the program and is the responsibility of the U.S. attorney in New Orleans.

Mr. ROGERS. You let him go before you contacted the U.S. attorney?

Mr. BESTEMAN. I said a commitment into the program. In other words, the people that come to us are to have all local and other charges fully determined before petition is entered on his behalf upon entering the program. So we can assume anybody a court sends to us is without legal encumbrances.

Mr. ROGERS. I am not sure you can assume that. You know how the NARA program operates. Many of these people have been convicted of crimes before. They have a criminal record, and many of them are put in, in lieu of crimes. I do not think you are naive enough to presume that is not true, having dealt with the program.

What concerns me is, you let all of these people go without checking with the court or the district attorney and just release them and then he gets the letter 4 days after you release them. Now, if that is protecting the public or even protecting the man, then this is a new way to do it.

Mr. SYMINGTON. Mr. Chairman, I would at least suggest that any man so released who is arrested, charged, and sentenced should have first preference to go back to the facility.

Mr. ROGERS. I would think so. I don't see that they were given any alternative there. They were only given the right of waiver of a hearing on commitment to posthospitalization care, which they had to sign and I have it here. And the doctor says he knew what he was doing when he signed that.

This causes me concern, the U.S. district attorney does not have much choice after the patient has already been released. He may have wanted him committed. He may have rather, picked up the criminal record and said, "We would rather keep this man in jail." Now, I think it is shocking that none of this work was done in all of these cases before you just let them loose into the communities.

Now, let me ask you about another situation, what about here in northern Virginia, where do you send them all? Where are all the judges sending these NARA patients now? Have you told the judges where to send them?

Mr. BESTEMAN. In northern Virginia the court has up until recently been using the Lexington facility.

Mr. ROGERS. But you have stopped that, now, haven't you?

Mr. BESTEMAN. Yes, and in notifying the court, we indicated to the judge that in exceptional cases that he desires them to go to Lexington he can contact our project officer and make those arrangements.

Mr. ROGERS. So where does he send them in northern Virginia for inpatient care?

Mr. BESTEMAN. In Virginia we have a contract with the Alexandria Community Mental Health Center at 720 South Asaph Street, Alexandria, Va.

Mr. ROGERS. Is that called Second Genesis?

Mr. BESTEMAN. One of their subunits is called Second Genesis.

Mr. ROGERS. In fact that is where you say he should be sent, to Second Genesis?

Mr. BESTEMAN. That physically is where they are entered.

Mr. ROGERS. How many beds do they have there?

Mr. BESTEMAN. I do not know the exact capacity of their beds. I do know the capacity of the contract service they have agreed to provide.

Mr. ROGERS. But do you not know whether they are in being or not?

Mr. BESTEMAN. I know they are in being because at the time the contract is negotiated, the contract officers go to the site and check this out.

Mr. ROGERS. Where is Second Genesis located?

Mr. BESTEMAN. I do not have that address.

Mr. ROGERS. What area does this cover, you say northern Virginia?

Mr. BESTEMAN. It would be the patients who come from the geography covered by the northern district of the U.S. court.

Mr. ROGERS. You are going to take them out of one community and put them way over here in the Genesis facility?

Mr. BESTEMAN. The northern district, yes, sir, of the northern district of Virginia.

Mr. ROGERS. So you are doing the same thing here that you did in Fort Worth, yank them out of their local community and send them to Alexandria.

Mr. BESTEMAN. I think you will find that the commitment of northern Virginia are heavily concentrated in the Alexandria and other suburban communities.

Mr. ROGERS. Now, I think that is a supposition that neither you or I are in a position to make. In other words, you are saying all of the addicts are from Alexandria?

Mr. BESTEMAN. I did not say that.

Mr. ROGERS. That would be the impression. And I doubt if that is true and we are checking that out. I would think that probably is not true.

So it looks to me like you are setting up a few of these where you are going to yank them out of their community, and that terrible way of treatment that you say must not be done in Fort Worth. It looks like you are going to do it in Alexandria for anyone who is not from Alexandria.

Now, the Commonwealth attorney has written the President about the lack of treatment facilities in northern Virginia. Were you aware of that?

Mr. BESTEMAN. Are you talking about Mr. Hogan?

Mr. ROGERS. Mr. Hogan, August 30, 1971, in a letter to the President. I am aware of other letters he has written.

Mr. BESTEMAN. I am not aware of his letter to the President.

Mr. ROGERS. Well, he says he is very much concerned that they are no longer taking them at Lexington. They won't be able to take care of them. Also that only 25 percent of the bedspace would be filled at Lexington. Is that about right?

Mr. BESTEMAN. Not to my knowledge.

Mr. ROGERS. What is the situation at Lexington? Are you using only 25 percent of its bed capacity?

Dr. ZAPP. I am not personally familiar with the facility at Lexington.

Mr. ROGERS. Does anybody know?

Dr. WILSON. We can get the census for you but it is not operational at 25 percent of capacity.

(The following information was received for the record:)

Totally 498 beds with an average use of 407 or 80 percent. Strictly drug addicts 340 beds with an average use of 249 or 73.2 percent.

Dr. BROWN. The issue is not again what one could hold physically in beds. The issue is the amount of staff and the programing. One can say a facility such as Fort Worth has held as many as 1,000 or it could hold 500 or 250. It gets down not to the physical capacity of the building but the size of the staff and the program designed.

In that sense, Lexington is closer to 80 or 90 percent of its capacity by the staff facility and funding we have available. Physically it is closer to perhaps half of what it could contain physically. That is correct.

Mr. ROGERS. I think that is kind of around the bush. You are cutting programs where you have the facility and yet you want to build up facilities somewhere else. Maybe it helps to move them over only 100 miles instead of 200 miles. I don't know. Maybe it makes them feel better.

Dr. BROWN. I think it does in northern Virginia. It is more of a home community in terms of family visiting, vocational facilities.

Mr. ROGERS. I would think where you are getting drug treatment, I would think you would want a secure area where people are not bringing them drugs all the time. That is the normal treatment we have seen over the country. If they have to have inpatient care, you do want it fairly secure, don't you?

Dr. BROWN. Yes, sir.

Mr. SYMINGTON. In that connection, of the 29 who have abused, are they receiving now inpatient care or any of them?

Dr. BROWN. I am glad you asked that. As far as I know, they are not receiving inpatient care but the implication of your remarks, Mr. Symington, about these 29 or 30, or 30 percent who abused, this is not what we mean, back on drugs. For many of them it is that first time experiment. They go back and shoot up or take pills but, after one or two, they stop and go to work and visit the clinic. It is not as if 30 percent are instantly back in addiction. That is not the nature of the process.

In fact, those who do go back will build up, over a few weeks they experiment and they find they need it and the next hard knock, they start to take it regularly. We found within the first week or two in this group as in other groups about a third have used drugs. It does not mean they have all gone back to fulltime intensive and criminal addiction.

Mr. SYMINGTON. You do not know what they have gone back to, do you?

Dr. BROWN. Well, we will report to you in 3 months on that specific group, as I said.

Mr. ROGERS. Are you familiar with the San Diego Center for drug treatment that you have arranged for?

Mr. BESTEMAN. Not personally.

Mr. ROGERS. Do you know their only patient is from Philadelphia? That is a pretty good way from home.

Dr. BROWN. I would say so.

Mr. ROGERS. So, I am not so sure about the theory of your treatment. As a matter of fact, the Fort Worth facility was to treat west of the Mississippi, was it not? It was designed for that.

Mr. BESTEMAN. Yes, sir.

Mr. ROGERS. Now, that, of course, is closed. It is my understanding, too, according to Mr. Horan that Cross Roads and Second Genesis are both overcommitted and yet we want to close or reduce the treatment at the Federal facilities.

Let me ask you this, are you doing only research work at Lexington now?

Dr. BROWN. No. The plan, or the hope is for Lexington to be occupied primarily fulltime with research endeavors in the treatment and understanding of drug abuse. Right now its dominant activity is still treatment of NARA patients.

Mr. ROGERS. But you are reducing the inpatient load at Lexington.

Dr. BROWN. I think the inpatient program has been relatively stable over the last 2 years in terms of size.

Mr. ROGERS. How many are there?

Dr. BROWN. We will be glad to provide the exact figures.

Mr. ROGERS. About how many; do you recall?

Mr. BESTEMAN. I would say somewhere around 300.

Mr. ROGERS. About 300; and the capacity is what? Not by staffing; by physical capacity?

Mr. BESTEMAN. 625 set-up beds.

Mr. ROGERS. Is there any reason not to use that facility?

Mr. BESTEMAN. No staff.

Mr. ROGERS. Can't you get staff?

Mr. BESTEMAN. From a professional judgment standpoint, we think that the most effective treatment can be handled at a different point.

Mr. ROGERS. Closer to home; I understand that.

Mr. BESTEMAN. And during the entire history of NARA we have persistently tried to move the program to the community and we have had some success with this, and it is encouraging. We started on a very small pilot basis a couple of years ago.

Mr. ROGERS. Isn't it true, no matter what you do with Lexington, you need aftercare in the community? This is to be expected. This is part of NARA, as I understand it. So that is not changing that situation anywhere. This is talking about inpatient treatment to get them away from the drug situation, trying to get them off drugs, then give them the aftercare in their own community when they go back.

Don't you do that?

Mr. BESTEMAN. We can also have inpatient care occur in local areas.

Mr. ROGERS. You cannot have it occur in every community in the country. You and I know that.

Mr. BESTEMAN. Hopefully, someday this kind of resource will be available in every community.

Mr. ROGERS. Hopefully, but it will be a long time.

Not to use existing facilities that you now have does not make sense, when you have a 620-bed capacity for inpatient care and not to use it.

This makes one look at the whole setup of how treatment is being given in this country, and when we have facilities and have put money into it and built these facilities and then do not use them or make a prison out of them and turn out people who may not be prisoners, actual criminals—maybe they are and maybe they are not, some of them—it makes you wonder about the values we set in HEW.

Mr. SYMINGTON. Mr. Chairman, this pilot program that you started 2 years ago, what was that exactly?

Mr. BESTEMAN. We chose first one community and then subsequently another one to start with the whole process of examination and evaluation of inpatient and aftercare taking place in a territory so that the person never left their home community and they did not enter "our facilities" in terms of Lexington or Fort Worth at any time during their treatment in the entire program. We watched how that worked and what were the advantages and what were the disadvantages and what was the response of, (1) the community which is being served, (2) the Federal court to the kind of communication and relationship they could have with the agency and this sort of thing.

As a result of, I would say, encouraging kinds of experience, we slowly started to move some examination and evaluation to the community level and generally tried to move our whole program to that level.

Mr. SYMINGTON. How many addicts were involved in the pilot program?

Mr. BESTEMAN. I think the first year was about 20.

Mr. SYMINGTON. Twenty?

Mr. BESTEMAN. The very first piece.

Mr. SYMINGTON. Were these 20 people civilly committed?

Mr. BESTEMAN. Yes, sir.

Mr. SYMINGTON. Without criminal backgrounds as far as you know?

Mr. BESTEMAN. Under the same legal requirements for all commitments to the program. That is, the U.S. attorney was satisfied that all charges were fully determined.

Mr. SYMINGTON. I find it surprising that on the basis of a pilot program involving 20 addicts, that is than 2 years old, that a conclusion would be reached that we no longer need one of two major inpatient treatment facilities.

Mr. BESTEMAN. I think you have to remember that at the same time the community grant program was developing and while the patients who are treated within the community grant program are not civilly committed, the kind of experience that we had there was confirmation of our community-based contract program.

Mr. SYMINGTON. Community grant program?

Mr. BESTEMAN. Yes, sir. We have the authority to give grants to nonprofit organizations where the community can propose to treat their own drug addicts and drug abusers in a locally funded and administered treatment organization.

Mr. SYMINGTON. How many addicts has that taken care of?

Mr. BESTEMAN. The last census figures had approximately 10,000 drug abusers. I don't know how many were addicts and how many were drug abusers but about 10,000 in that system.

Mr. SYMINGTON. And your experience is you can decide from the type of treatment given and the success that Fort Worth was no longer necessary?

Mr. BESTEMAN. You had to arrive at this decision somehow.

Mr. SYMINGTON. This is a very fundamental decision that you are making. We are talking about the life hopes of hundreds of thousands of people of different backgrounds, experience and many more coming back from Vietnam and from Europe. In a general time of social unrest you have adopted a philosophy to the point where you are willing to do away with a facility like Fort Worth which only handles a few hundred—I think 750 beds it may handle—but according to you, you say 200 and there is a dispute on that. But in any event, if it is as little as 200 beds, one would think it would be even more necessary to handle at least 200 of these 200,000 or 300,000 people.

Mr. ROGERS. New Orleans has a population of 6,000 addicts. Twenty-five people come into the court and say, "I want in-patient care." What happens to them?

Mr. BESTEMAN. If for some reason the number is overwhelming, the contractor has the relationship with us which would enable him either if he has a capacity to expend or to come to us and say, "I need help," and help could come in one or two different forms. The quickest help would simply be to allow that court to use our Lexington facility.

Mr. ROGERS. But you do not have the staff there, you said.

Mr. BESTEMAN. Within its capacity.

Mr. ROGERS. This is over capacity. What do you do with them?

Mr. BESTEMAN. All I can say is up until now, in this program this has not occurred.

Mr. ROGERS. It has not occurred because you have turned away about 3,000 from Lexington and Fort Worth, 3,000 to 4,000. You simply said, "We won't take you" haven't you?

Dr. BROWN. I don't think that is an accurate statement. There have been people gone through reevaluation.

Mr. ROGERS. This can be a very convenient way of simply turning people away. Who is to make that judgment before treatment is given or tried on him. A man turns himself in to get off drugs and we are here to try to treat them. Suppose it is a veteran and you say, "We don't think you are treatable, we are not even going to let you in." This is not what the Congress was thinking about or intending in drug treatment programs. It may be the way you are administering it, it may be an administrative judgment but this is not the intent of the Congress, I am sure.

Now, do you know how all of these facilities are operating? Are they really doing a good job? What about San Diego? Are you familiar with that one? Does anybody check it?

Mr. BESTEMAN. We have a man who is the project officer who checks it regularly.

Mr. ROGERS. He has to do more checking than he has done in the past because I have the copy of the contract. It is for \$133,650 and is supposed to provide in- and out-patient care. Well, they have had one in-patient earlier this month. He was not in at the time for the check. One in-patient and you are paying them \$133,000.

The director said he had 18 or 19 outpatients but he was not sure just where they were. There is one man kind of running his own program because he turns up at the city hospital for methadone treatment and he lectures to elementary and junior and senior high school groups at a \$4-an-hour rate as a consultant, and the conditions of the NARA

contract, I understand, call for a drug-free atmosphere. I would doubt that this is possible at the San Diego Clinic with all 17 outpatients roaming around as well as the inpatient.

Dr. BROWN. We will be glad to provide a report on the San Diego facilities. We will look into it this afternoon.

Mr. ROGERS. I would be most interested and I am sure the committee will.

(The following information was received for the record:)

SUMMARY OF NARA CONTRACT NO. HSM-42-69-21 WITH CATHOLIC FAMILY SERVICE, 349 CEDAR STREET, SAN DIEGO, CALIFORNIA 92101

1. The Narcotic Addict Rehabilitation staff in developing a contract for aftercare services for narcotic addicts from San Diego made a total of four field trips to San Diego during February, October, and September, 1968. The Community Welfare Planning Council, the Director of San Diego County Department of Medical Institutions responsible for Community Mental Health Services, Directors of four hospitals, one private community mental, and three family service agencies were contacted and informed of the services needed. With the exception of two family service agencies all agencies and hospitals contacted stated they were not interested in contracting to provide aftercare services for addicts civilly committed under NARA.

2. Contractor's proposals were received from Jewish Family Service and Catholic Family Service. The review committee recommended that a contract be negotiated with Catholic Family Service.

3. The cost reimbursement contract was awarded for \$14,000 with an effective date of April 2, 1969. Prior to that time the agency provided services for three patients through a purchase order.

4. The contract period of performance was extended to June 1, 1970, with an additional \$2,000. The contract was renewed June 1, 1970, with \$20,240 additional funds making the total contract amount \$36,500 for the period of performance of April 2, 1969, to March 31, 1971.

5. The development of community examination and evaluation and community inpatient treatment in California was started in January, 1971. Two contractor's proposals were considered, one from San Francisco and Catholic Family Services. The review committee recommended the negotiation of the proposal from Catholic Family Service because of their past performance and the fact that the greatest number of civil commitments had been and were expected from Southern California.

6. The contract with Family Catholic Service was renewed with an effective date of June 26, 1971. The services for period of performance of June 26, 1971 to June 26, 1972 were increased to provide examination and evaluation of 15 patients, inpatient treatment of 30 patients, and aftercare for 20 patients.

Additional funds of \$97,400 were provided to make the total contract amount \$133,650 for the period of performance starting April 2, 1969 through June 26, 1972. The cost reimbursement contract allows payment for only those services that have been provided.

7. The agency has provided aftercare for a total of 17 patients during the period of December, 1968 through October, 1971. The primary NARA counselor has a doctors degree. He has been with the program since the beginning. The services provided have always been satisfactory. The Narcotic Addict Rehabilitation Branch project officer is stationed in Los Angeles and has monitored the contract on an average of once every three months.

In keeping with the policy on methadone maintenance the NARA patients who have shown that they are unable to remain drug free and continued treatment would require serial recommitment may be referred to an acceptable methadone maintenance program. NARA patients in San Diego have been referred for methadone maintenance. The plan developed must allow for detoxification and approximately 12 months drug free time before completion of their civil commitment.

One patient, previously employed by the San Diego City Board of Education is being treated by methadone maintenance. The methadone maintenance program is administered by the University of California at San Diego, School of Medicine.

8. The community inpatient treatment service was available on August 1, 1971. As of November 16, 1971, one patient has been committed to inpatient treatment. Four patients have been committed for examination and evaluation. Of these one has been found suitable for treatment and is to be committed to treatment November 19. Three are still being examined. Five additional individuals have petitioned the U.S. Attorney for treatment and are waiting for a court hearing for commitment for examination and evaluation.

9. An evaluation of the effectiveness of the inpatient treatment is not possible at this time. However, the treatment plan is sound. Phase I which will be detoxification and medical restoration, will take place at Vista Hill Hospital. This phase will be for a period of 7 to 14 days. Phase II will take place at a 10 bed treatment facility. Here social rehabilitation will take place through individual and group counseling, remedial education and vocational planning. The after-care counselor will work with the patient in planning housing, job placement and vocational training during the period of inpatient treatment.

Mr. ROGERS. How many facilities do you have in the United States for NARA contracts?

Mr. BESTEMAN. I would say about 140.

Mr. ROGERS. 140. How many in-patient beds are represented in the 140?

Mr. BESTEMAN. Can I make a definition here a second? We talk about treatment slots not about beds because one bed may be used more than once during the year. So, when you say beds, I do not have the answer. We have over 1,000 persons that can be treated in community contracts, in-patient, nationwide. Of those the vast majority of those resources are west of the Mississippi in anticipation, as was pointed out, of the proposed transfer for many months.

Mr. ROGERS. I think it would be helpful to the committee to have a list of the 140. How many beds in each.

Mr. BESTEMAN. How many people they can treat in the course of a 12-month period, or do you want beds?

Mr. ROGERS. I think just physical beds.

Dr. BROWN. He will provide that.

(The following information was received for the record:)

NARB PATIENT CARE CONTRACT AGENCIES, AS OF JUNE 30, 1971

	Contract capacity		
	Examination and evaluation	Inpatient	Aftercare
ALABAMA			
Jefferson Blount-St. Clair Mental Health Authority, 1210 South 20th St., Birmingham.....	24		20
Madison County Mental Health Center, Post Office Box 425, Huntsville.....			1
ALASKA			
Langdon Psychiatric Clinic, 207 East Northern Lights Blvd., Anchorage....	5		10
ARIZONA			
St. Joseph's Hospital and Medical Center, 350 West Thomas Rd., Phoenix....	100		100
Family Service Agency of Tucson, Inc., 650 North 6th Ave., Tucson.....			20
Arizona Family, Inc., Post office Box 628, Phoenix.....		100	
ARKANSAS			
Family Service-Travelers Aid Agency, 220 Greenwood Ave., Fort Smith.....			3
Family Service Agency of Pulaski County, Post Office Box 500, North Little Rock.....			3

NARB PATIENT CARE CONTRACT AGENCIES, AS OF JUNE 30, 1971—Continued

	Contract capacity		
	Examination and evaluation	Inpatient	Aftercare
CALIFORNIA			
Santa Barbara County Mental Health Services, 4440 Calle Reale, Santa Barbara.....			1
Family Service Center, 442 North Fulton St., Fresno.....			2
Economic and Youth Opportunities, Los Angeles.....			40
Kings View Homes, Inc., DBA, Merced County MH Service, Post Office Box 2108, Merced.....			2
Catholic Social Service, 433 Jefferson St., Oakland.....			10
Sacramento County Mental Health Services 2315 Stockton Blvd., Sacramento.....			1
Catholic Family Service, 349 Cedar St., San Diego.....	15	30	20
Westside Community Mental Health Center, Inc., 2201 Sutter St., San Francisco.....	15		20
Santa Clara County Health Department, 2220 Moorpark Ave., San Jose.....			10
Family Service Agency of Santa Barbara, 800 Santa Barbara Ave., Santa Barbara.....			2
Family Service of Long Beach, 1041 Pine Ave., Long Beach.....			5
Family Services Association of Riverside, 3833 Jurupa St., Riverside.....			3
Monterey County Department of Public Health, 1270 Natividad Rd., Salinas.....			1
COLORADO			
Southern Colorado Comprehensive MH Center, 1600 West 24th St., Pueblo.....			5
Bethesda Mental Health Center, 4400 East Iliff Ave., Denver.....	20		20
CONNECTICUT			
City of Stamford, Department of Health, 229 North St., Stamford.....	48		30
State of Connecticut Department of Mental Health, Alcohol and Drug Dependence Division, 51 Coventry St., Hartford.....			20
Greater Bridgeport Mental Health Council, Inc., 1067 Park Ave., Bridgeport.....			20
DELAWARE			
Alcoholism Services, Department of Mental Health, 3000 Newport Gap Pike, Wilmington.....			2
DISTRICT OF COLUMBIA			
Bureau of Rehabilitation of the National Capitol Area, 666-11th St., NW., Suite 520.....			20
FLORIDA			
Henderson Clinic, 330 South Riverland Rd., Fort Lauderdale.....	20		20
Mental Health Clinic of Jacksonville, Inc., 2627 Riverside Ave., Jacksonville.....			1
Christian Community Service Agency, 10 Southeast 9th St., Miami.....	60	40	80
Mental Health Association of Palm Beach County, Inc., 909 Fern St., West Palm Beach.....			1
Dr. Theodore Machler, Jr., 3545-5th Avenue North, St. Petersburg.....			1
Brevard County Mental Health Center, Inc., 1770 Cedar St., Rockledge.....			1
Orange Memorial Hospital Mental Health Center, 1416 South Orange Ave., Orlando.....			1
Jackson Memorial Hospital, 1700 Northwest 10th St., Miami.....			1
Guidance Center of Hillsboro County, 5707 North 22d St., Tampa.....	20		20
GEORGIA			
Georgian Clinic Division, Georgian Mental Health Institute, 1256 Briarcliff Road, NE., Atlanta.....			30
Northwest Georgia Mental Health Center, Hutcheson Memorial Tri-County Hospital, Fort Oglethorpe.....			1
Floyd County Health Department, 315 West 10th St., Rome.....			1
Bibb County Health Department, 770 Hemlock, Macon.....			1
Family Counseling Service of Savannah, Inc., 428 Bull St., Savannah.....			2
Peach County Health Department, Post Office Box 467, Macon Rd., Fort Valley.....			1
HAWAII			
Child and Family Service, 200 N. Vineyard Blvd., Honolulu.....			5

NARB PATIENT CARE CONTRACT AGENCIES, AS OF JUNE 30, 1971—Continued

	Contract capacity		
	Examination and evaluation	Inpatient	Aftercare
ILLINOIS			
Near North Family Guidance, 12 East Walton St., Chicago.....			40
St. Leonard's House, 2100 West Warren Ave., Chicago.....			60
Family Services Association of Oak Park and River Forest, 124 South Mation St., Oak Park.....			30
INDIANA			
Mental Health Center of Fort Wayne, Ind., 227 East Washington Ave., Fort Wayne.....			1
North Side Psychiatric Center, 3716 North Sherman, suite 5, Indianapolis.....			1
Family & Children Service of Mishawaka, 1411 Lincolnway West, Mishawaka.....			1
David Crane, M.D., 409 East 4th St., Bloomington.....			1
IOWA			
Mid-Iowa Drug Abuse Council, 265 Jewett Bldg., Des Moines.....	36		30
KANSAS			
Sedgwick County Mental Health Center, 1045 North Minneapolis St., Wichita.....			1
KENTUCKY			
University of Kentucky Research Foundation, University of Kentucky Medical Center, Outpatient Psychiatric Clinic, Lexington.....			20
Louisville Region 8 Mental Health and Mental Retardation Board, Post Office Box 388, Louisville.....	10		20
Green River Comprehensive Care Center, 403 West 3d St., Owensboro.....			1
LOUISIANA			
Family Counseling Service of East Baton Rouge Parish, Inc., 4438 North Blvd., Baton Rouge.....			8
Tulane University School of Medicine, Department of Psychiatry and Neurology, 143 Tulane Ave., New Orleans.....	120	150	120
MARYLAND			
Echo House Foundation, 1705 West Fayette St., Baltimore.....	24		30
Family Services of Prince Georges County, 4318 Hamilton St., Hyattsville.....	20	12	20
Johns Hopkins Drug Abuse Clinic, 709 Rutland Ave., Baltimore.....			20
Alleghany County Mental Health Center, 111 Union St., Cumberland.....			1
MASSACHUSETTS			
East Boston Social Centers, 68 Central Sq., East Boston.....	100		20
Lawrence General Hospital Rehabilitation Center, Andover St., Lawrence.....			1
MICHIGAN			
Ingham County Mental Health Board, 401 West Greenlawn Ave., Lansing.....			1
Oakland County Community Mental Health Service Board, 1880 South Woodward Ave., Birmingham.....			1
Wayne County Health Department, 2334 Clifford St., Detroit.....	100	100	100
Snead's Psychiatric Clinic, 3717 Van Slyke Rd., Flint.....			1
Riverwood Mental Health Center, 2611 Morton Ave., St. Joseph.....			1
Family Service and Children's Aid of Midland, 116 Harold St., Midland.....			1
Family Service and Children's Aid of Jackson, 729 W. Michigan Ave., Jackson.....			1
Project Rehab, 722 Eastern SE., Grand Rapids.....			1
MINNESOTA			
Catholic Social Service of St. Paul, 355 Washington St., St. Paul.....			20
Catholic Welfare Service of Minneapolis, 404 South 8th St., room 222, Minneapolis.....	60		30
Division of Vocational Rehabilitation, 1821 University Ave., 180 Griggs Midway Bldg., St. Paul.....			30
Hazelden Foundation, Inc., Box 11, Center City.....		45	
MISSISSIPPI			
Mr. James P. Lee, Box 245, Ackerman.....			1
Dr. Jan Kloek Mental Health Clinic, Post Office Box 1046, Clarksdale.....			1

NARB PATIENT CARE CONTRACT AGENCIES, AS OF JUNE 30, 1971—Continued

	Contract capacity		
	Examination and evaluation	Inpatient	Aftercare
MISSOURI			
Greater Kansas City Mental Health Foundation, 600 East 22d St., Kansas City.....	60	30	50
Malcolm Bliss Mental Health Center, 1420 Grattan Ave., St. Louis.....			30
Narcotic Services Council Nasco, 2305 St. Louis Ave., St. Louis.....			30
Missouri Division of Mental Health, Alcoholism, and Drug Abuse Program, 5400 Arsenal St., St. Louis.....	30	20	
MONTANA			
Wesley Community Center, Box 841, Great Falls.....			1
Mr. Helmuth "Bud" Fichtler, 606 North Ave., West, Missoula.....			1
NEVADA			
Family Counseling Service of Clark County, 214 Maryland Pkwy., Las Vegas.....	12		40
Marriage and Family Counseling Service, Inc., 108 Roff Way, Reno.....			3
NEW JERSEY			
New Jersey Regional Drug Abuse Center, Post Office Box 4099, Bergen Station, Burma Road, Liberty Park, Jersey City.....	100	60	60
Drug Addiction Aftercare Clinic, Roosevelt Hospital Box 151, Metuchen.....			15
Morris County Narcotic Aftercare Clinic for Drug Abuse, Thebaud Building 95 Mt. Kemble Ave., Morristown.....			1
Passaic County Narcotic Aftercare Clinic, 323 Main St., Paterson.....			1
Mercer County Narcotic Addiction and Drug Abuse Program, Court House, Market and Broad Sts., Trenton.....			1
Community Child Guidance Center of Camden County, 322 White Horse Pike, West Collingswood.....			1
New Jersey State Department of Health, Division of Narcotic and Drug Abuse Control, Box 1540, Trenton.....			1
NEW MEXICO			
Bernalillo County Mental Health-Mental Retardation Center, 2600 Marble Ave., N.E., Albuquerque.....	24	20	40
Southwest Mental Health Center, 1501 North Solano, Las Cruces.....			1
NEW YORK			
Albert Einstein College of Medicine, Yeshiva University, drug-abuse service program, 333 Southern Blvd., Bronx.....			20
Kinsman Hall, Box K, Hillsdale.....			1
Cage Teen Center, Inc., Cage Prevention Center, 203 Main St., White Plains.....			1
NORTH CAROLINA			
North Carolina Division of Vocational Rehabilitation, 305½ West Martin St., Raleigh.....			20
OHIO			
Ohio Valley Goodwill Industries Rehabilitation Center, 10600 Springfield Pike, Cincinnati.....			30
Talbert Halfway House, 1062 Wesley Ave., Cincinnati.....			30
Vocational Guidance & Rehabilitation Service, 2239 East 55th St., Cleveland.....			40
City of Cincinnati Department of Health, Cincinnati.....			
Candlelight Rehabilitation Center, Post Office Box 3555, station D, 3125 Cherry St., Toledo.....			30
Health & Welfare Planning Council, NARA of Dayton, 404 Salem Ave., Dayton.....			20
Alvis House, 971 Bryden Rd., Columbus.....			1
OKLAHOMA			
Sunbeam Home & Family Service, 616 Northwest 21st St., Oklahoma City.....	12		20
Tulsa Psychiatric Foundation, Inc., 1620 East 12th St., Tulsa.....	10		5
OREGON			
Alcohol and Drug Section, Mental Health Division, 309 Southwest Fourth Ave., Portland.....	36	50	80

NARB PATIENT CARE CONTRACT AGENCIES, AS OF JUNE 30, 1971—Continued

	Contract capacity		
	Examination and evaluation	Inpatient	Aftercare
PENNSYLVANIA			
Jewish Employment Vocational Service, 1913 Walnut St., Philadelphia . . .	120	50	60
Alpha House (Harmarsville Rehabilitation Center), 238 Shady Ave., Pittsburgh			20
PUERTO RICO			
CISLA, Department of Health, Psychiatric Hospital, Building J, Common- wealth of Puerto Rico, Rio Piedras	48	20	50
RHODE ISLAND			
Marathon House, 148 Waterman St., Providence	20	20	30
SOUTH CAROLINA			
Mrs. Dorothy P. Harmon, 1523 Clarkson Ave., Newberry			1
Counseling Center, 114 Kuger St., Florence			1
TENNESSEE			
Alcoholism and Drug Abuse Clinic, Tennessee Psychiatric Hospital and Institute, Post Office Box 4936, 865 Poplar, Memphis	48	22	40
Helen Ross McNabb Center, 1520 Cherokee Trail, Knoxville			10
Department of Psychiatry, Hubbard Hospital, Meharry School of Medi- cine, 1005 18th Ave., North, Nashville			10
TEXAS			
Amarillo MH-MR Regional Board of Trustees, Post Office Box 1110, Amarillo			1
Austin-Travis County MH-MR Center, 1516 Red River St., Austin			40
Mr. James Hicks, 2408 Avenue E, Bay City			1
Family & Children's Service, 650 South Main St., Beaumont			1
Dallas Rehabilitation Institute, 7850 Brook Hollow Rd., Dallas			40
Family Service of El Paso, 2930 North Kansas St., El Paso			1
Aliviana, Inc., El Paso			1
Mrs. Connie Walker, R.N., 406 Varisco Bldg., Bryan			15
Family Service Association, 212 Burnet St., Fort Worth			20
Rio Grande State MH-MR Center, 2115 North 28th St., Harlingen	15	15	80
Vocational Guidance Service, 2525 San Jacinto St., Houston	60	60	20
South Plains Guidance Center, 1717 Avenue K, Room 205, Lubbock	6		5
Gregg-Harrison MH-MR Center, Family Guidance and Consultation Service, Post Office Box 1224, Marshall			10
Nueces County MH-MR Center, 1611-5th St., Corpus Christi			40
Inman Christian Center, 1014 South San Jacinto, San Antonio			150
The Patrician Movement, 410 South Main, Room 300, San Antonio	150	100	140
Mental Health-Mental Retardation for Greater West Texas, 244 North Magdalen St., San Angelo			1
Gulf Bend MH-MR Center, 2005 North Navarro, Victoria			1
Waco-McClellan County MH-MR Center, 110 South 12th St., Waco			20
Family Service of Galveston, 401 Texas Bldg., 413-22d St., Galveston			1
UTAH			
University of Utah, Alcohol and Drug Abuse Clinic, 50 North Medical Drive, Salt Lake City			20
VIRGIN ISLANDS			
Department of Health, Division of Mental Health, Box 520, Christeneds, St. Croix, United States			1
VIRGINIA			
The Alexandria Community Mental Health Center, 720 South St. Asaph St., Alexandria	60	40	50
Peninsula Family Service and Traveler's Aid, Inc., 3015 West Ave., New- port News			5
Mental Health Center of Norfolk & Chesapeake, 401 Colley Ave., Norfolk	40		20
Richmond City District Health Department, 500 North 10th St., Richmond	44		20
Roanoke City Health Department, 515 8th St. SW, Roanoke	24		10
Fairfax County Department of Health Services, 4100 Chain Bridge Rd., Fairfax			10

NARB PATIENT CARE CONTRACT AGENCIES, AS OF JUNE 30, 1971—Continued

	Contract capacity		
	Examination and evaluation	Inpatient	Aftercare
WASHINGTON			
Community Psychiatric Clinic, Inc., 5324 Talman Ave., NW., Seattle	60	100	120
Narcotic Center of Tacoma-Pierce County, Post Office Box 165, 2510 South Fawcett, Tacoma			30
Benton-Franklin Mental Health and Family Counseling Program, 1329 George Washington Way, Richland			1
Metropolitan Development Council, Tacoma			
WEST VIRGINIA			
Charlestown Guidance Clinic, 56th and Noyes Ave., S.E., Charleston			5
WISCONSIN			
Wisconsin Correctional Service, 436 West Wisconsin Ave., Milwaukee	24		30

NARA COMMUNITY INPATIENT TREATMENT CONTRACTS

	E. & E. ¹	Inpatient treatment, number of pat ents ²	Inpatient facility, bed capacity ³	Aftercare ⁴
Arizona Family, Inc., Post Office Box 628, Phoenix, Ariz		100	60	
Catholic Family Service, 349 Cedar St., San Diego, Calif	15	30	10	20
Christian Community Service Agency, 10 Southeast 9th St., Miami, Fla	69	40	40	80
Georgian Clinic Division, Georgian Mental Health Institute, 1256 Briarcliff Rd. NE., Atlanta, Ga	40	22	5	40
Tulane University School of Medicine, Department of Psychiatry and Neurology, 1430 Tulane Ave., New Orleans, La	120	150	15	120
Family Services of Prince Georges County, 4318 Hamilton St., Hyattsville, Md	20	12	10	20
Wayne County Health Department, 2334 Clifford St., Detroit, Mich	100	100	100	100
Hazelden Foundation, Inc., Box 11, Center City		45	5	
Greater Kansas City Mental Health Foundation, 600 East 22d St., Kansas City, Mo	60	30	15	50
Missouri Division of Mental Health, Alcoholism, and Drug Abuse Programs, 5400 Arsenal St., St. Louis, Mo	30	20	20	
New Jersey Regional Drug Abuse Center, Post Office Box 4099, Bergen Station, Burma Rd., Liberty Park, Jersey City, N.J.	100	60	30	60
Bernalillo County Mental Health-Mental Retardation Center, 2600 Marble Ave., NE., Albuquerque, N. Mex	24	20	40	40
Alcohol and Drug Section, Mental Health Division, 309 Southwest 4th Ave., Portland, Oreg	50	50	25	120
CISLA, Department of Health, Psychiatric Hospital, Building J, Commonwealth of Puerto Rico, Rio Piedras, P.R.	48	20	20	50
Marathon House, 148 Waterman St., Providence, R.I.	40	35	40	40
Alcoholism and Drug Abuse Clinic, Tennessee Psychiatric Hospi- tal and Institute, Post Office Box 4966, 865 Poplar, Memphis, Tenn	48	22	10	40
Aliviane, Inc., El Paso, Tex	20	20	20	30
Rio Grande State MH-MR Center, 2115 North 28th St., Harlingen, Tex	40	30	10	40
Vocational Guidance Service, 2525 San Jacinto St., Houston, Tex	60	60	30	80
The Patrician Movement, 410 South Main, Room 300, San Antonio, Tex	150	100	46	140
Second Genesis, Inc., 1013 King St., Alexandria, Va	60	40	25	50
Community Psychiatric Clinic, Inc., 5324 Talman Ave. NW., Seattle, Wash	60	100	57	120

¹ Number of addicts that may be examined under the contract.² Number of addicts that may be provided inpatient treatment under the contract.³ Number of inpatient bed available to NARA patients at the inpatient treatment facility.⁴ Number of patients that may be provided aftercare under the contract.

Mr. ROGERS. I would think that would be the easiest way. You do not know how many people they can treat. They may keep one for months, or the doctors may decide they are all cured on one day and send them all out, like at Fort Worth, and whether they are secured areas or not. I think this would be well to know, how many of those have facilities to make them a secured facility?

I know my good friend Mr. Nelsen wants to do some questioning. I apologize to him for questioning this long. I think these are facts that need to be brought out and we have more we want to develop later.

Mr. NELSEN. Thank you, Mr. Chairman.

Observing the trend of the hearings, I think it is obvious that the hearings are triggered by the fact that this transfer was made after a hearing which indicated opposition in some quarters to the transfer. So that my thinking on the entire project might be a matter of record I want to say, I personally visited the Galveston Public Health Service hospital and I think they are doing a fine community service. The medical school there needs the facility. The interns are doing a fine job. It was an opportunity there for them and is a valuable asset to the medical school.

The transfer of the Fort Worth facility has been in the picture in years past and it has been kicked around in, I think, a political fashion for a long time. I did not support a transfer of any of the Public Health facilities prior to the time that it became obvious that the Bureau of Prisons needed a facility for what they were trying to do. On examination of all of the facts it would seem to me that I, as a Minnesotan, ought to be shouting long and hard about the fact that we do not have comparable facilities to the ones that are presently provided in the State of Texas. I have no quarrel, however with giving them the facilities they need. Also, may I ask this question, of those that were released, had there been no transfer involved, would they have been released anyway?

Dr. BROWN. Yes; they would have been released pretty much as they had been. That is a fact.

Mr. NELSEN. Now, on the transfer, I notice in your letter of October 5 that Dr. Jaffe was mentioned. There have been some statements to the effect that he really did not have a chance to examine this transfer. That this order was rammed through and that he did not have an opportunity to make a thorough examination. Has Dr. Jaffe really gone into this transfer as thoroughly as you feel he should have?

Dr. BROWN. Definitely, yes. I know personally of two occasions where he reviewed it in depth.

Mr. NELSEN. And he supports the program?

Dr. ZAPP. That is correct.

Mr. NELSEN. Reference has been made to the letter to the President regarding the number of patients and that adequate facilities are not available.

In order to get facilities you have to have money and we, in some cases, supply the money. Would it appear that we have not appropriated enough money to build adequate facilities nationwide, and that staffing is impossible to get? Health manpower is one of the real problems. Do you find that to be a problem?

Dr. BROWN. When the question is asked have adequate funds been provided, my intuitive answer is always, of course not. We could have used more. Of course, funds are provided in a general context of other competing demands of priorities. In that sense it is our responsibility

to do the most we can with funds we have. I think it is true we could have used more funds.

Mr. NELSEN. I don't want to leave the impression there should be no congressional overview, but I also have the feeling that sometimes we sort of go overboard from our level and I sometimes wonder why anybody wants an administrative job. I have had one. So I try to be fair in our hearings at all times. Paul sort of kids me about it.

May I ask this question, too, you have three treatment centers, in Houston, Harlingen, and San Antonio, is that right?

Mr. BESTEMAN. In Texas?

Mr. NELSEN. Yes, sir. You have plans for facilities that will be completed by November 1 for Austin, for Dallas, and for El Paso, is that right?

Mr. BESTEMAN. That is correct.

Mr. NELSEN. In addition contracts are being proposed for Amarillo, Corpus Christi, and a second facility in San Antonio, is that correct?

Mr. BESTEMAN. That is correct.

Mr. NELSEN. How does this compare in number with similar facilities in Minnesota, with other States?

Mr. BESTEMAN. I think you will find by number of treatment slots we are contracting for many more from Texas because I believe the letter also points out Texas supplied the greatest number of civil committees.

Mr. NELSEN. I would go along with that and endorse what you are doing but at the same time I would expect them to be fair to other areas where problems exist.

Now then, getting back to the Bureau of Prisons. I spent a good deal of time with one of the gentlemen from the Bureau of Prisons. I was impressed by the pleading for a facility for the treatment of persons in the prison system. As a citizen I think if you release a prisoner that is an addict, not properly cared for and turned loose in society, you really have a problem. So I do not separate one group from another. I think all human beings should be given the best possible service in this field.

I have the feeling that some of the momentum of years ago still continues as far as the Fort Worth facility is concerned. I have the feeling that the purpose that you seek to gain by this transfer is in the public interest and will serve a great purpose. I also agree with the idea that we have to get back home with treatment centers.

I think you stepped these treatment centers up to what is a figure of more than 700 facilities that have been set up nationwide in recent years. I know in our community health center back home we move in the direction of not only psychiatric treatment but also drug treatment and the progress that we made has been tremendous. So in defense of your department, I want to say that while certainly we want to be sure you are doing the best possible job, I do feel that the thing that triggered this controversy results more from the facility transfer than the personnel involved. So I hope we can resolve it and our good chairman here has done a very fine job. He and I work closely together.

I would like to submit this letter for the record, your letter of October 5.

Mr. ROGERS. Without objection it is received.

(The letter referred to follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY,
Washington, D.C., October 5, 1971.

HON. HARLEY O. STAGGERS,
Chairman, Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: I understand that the Conference Committee will begin work shortly on S. Con. Res. 6 and H. Con. Res. 370 relating to the *Public Health Service Hospitals*. The major difference between the two resolutions is the House addition of language to include the *Fort Worth* and *Lexington Clinical Research Centers*. The Administration strongly opposes the reference to the Fort Worth Center. As you know, we have since January 26, 1971, planned to transfer the Fort Worth Center from the National Institute of Mental Health of the Department of Health, Education, and Welfare to the Bureau of Prisons within the Department of Justice.

The express policy of the Department of Health, Education, and Welfare has for several years been to work toward the development of adequate and effective community-based drug abuse programs under State and local auspices rather than in Federally-operated facilities. The implementation of this policy has resulted in Federal support, through contracts and grants, for drug abuse treatment and rehabilitation services in many communities. This process has now reached the point where we can continue to expand our national capacity for voluntary and civilly-committed addicts without utilizing the Fort Worth Clinical Research Center and at the same time strengthen the drug abuse programs within our Federal prison system by making the Fort Worth facility available to the Bureau of Prisons.

In the past the Fort Worth Clinical Research Center (CRC) has provided examination, evaluation and treatment services under the Narcotic Addict Rehabilitation Act (NARA) of 1966 for addicts charged with certain Federal crimes who elect civil commitment in lieu of prosecution and for addicts not charged with crimes who voluntarily petition for civil commitment. After treatment, addicts are returned to their communities for supervised aftercare provided by local agencies, under contract with the National Institute of Mental Health. Aftercare in the community has increased the likelihood of the addict's return to a productive life.

Based on our experience, we now believe that the other phases of the program—examination, evaluation, and inpatient treatment—should also be carried out in the community. It is often counterproductive for patients to leave their families, friends, and community resources and difficult to adjust to centralized institutional care with other patients from widely divergent sections of the country. Many decide that institutionalization for four to six months is too high a price to pay for help and convince themselves and others that they are not suitable for treatment.

Through contracts with community agencies for the provision of examination, evaluation and inpatient treatment services in addition to aftercare, we have been successful in creating capabilities in a number of localities to replace the services now available at Fort Worth, which has an inpatient capacity of 200. There are currently eighteen such agencies throughout the United States, as shown in Attachment 1. By the end of FY 1972 it is expected that the cumulative capacity of these agencies will exceed the level of patient care provided at Fort Worth during 1971.

In this process special attention has been given to Texas, which except for Michigan, has had the greatest number of narcotic addicts petitioning for civil commitment. Attachment II describes the existing, planned, and potential community agency capacity in Texas. Three treatment centers in Houston, Harlingen, and San Antonio, which are already in operation, will provide inpatient care to 175 civilly-committed narcotic addicts. Contract negotiations are being conducted, and should be completed by November 1, with treatment centers in Austin, Dallas, and El Paso, which will provide care and rehabilitation for an additional 110 narcotic addicts. In addition, contracts are being proposed in Amarillo and Corpus Christi and a second one in San Antonio, which could provide inpatient services for another 140 addicts. These treatment programs will provide Texas with the potential for considerably greater participation in the NARA program than has been possible in the past.

The Federal Bureau of Prisons plans to utilize the Clinical Research Center as a 500-bed medical-correctional facility whose primary mission will be focused on the treatment of offenders who have histories of drug abuse. During the past year, 30 percent of all offenders committed to Federal custody had a history of

drug abuse, representing a significant increase over previous years. Because of the rapidly-growing need for drug abuse treatment for Federal offenders, the present capacity of the Bureau of Prisons facilities is exceeded by 1700 inmates.

The Fort Worth facility would become a specialized treatment center with emphasis on offenders having serious drug problems. Since enactment of the Narcotic Addict Rehabilitation Act, the Bureau of Prisons has been responsible for providing specialized institutional treatment and aftercare services to those offenders who meet the statutory criteria for commitment. It is now obvious that efforts must be expanded to include the large population of offenders with drug addiction problems who do not qualify for inclusion under the NARA statute but who have an equal need for intensive treatment.

NARA units are presently operating at five institutions with a total capacity of 600. At a minimum, an additional 250 would be accommodated in the expanded program. Acquisition of the Fort Worth facility will enable the Bureau of Prisons to increase the total capacity of its drug treatment program of 1200. The Fort Worth facility will also be utilized for treatment programs for men and women who pose other medical-correctional problems, including various chronic medical and surgical cases, psychiatric cases and alcoholics. These offenders present unique difficulties because their medical problems are not serious enough to require hospitalization at the Medical Center for Federal Prisoners in Springfield, Missouri, and the institutions in which they are confined lack proper facilities to meet their treatment needs.

Comprehensive correctional treatment activities, a total health services program, and extensive research and training will also be conducted at Fort Worth. The correctional program activities will consist of education, vocational training, work programs, religious, recreational and social work services, and community-based programs. The Bureau's research efforts will include an evaluation program to assess program effectiveness in each of the special treatment categories and close collaboration with local universities, colleges and medical centers.

As a medical-correctional facility the center will provide treatment for persons who are within eighteen months of their release dates. The inmate population will, appropriately, consist of offenders who will be released to destinations in the southwest and south central sections of the country.

The Fort Worth facility is especially suitable for these needs. The physical plant is in generally good condition, and apart from the addition of appropriate security measures, will require only minor renovations. Since the Bureau of Prisons does not plan to utilize this facility for inmates posing serious escape risks, the principal security addition will be a perimeter fence.

A total of 206 Clinical Research Center employees will remain at the Fort Worth facility as employees of the Bureau of Prisons. Of the 40 employees now remaining at the Center who will not transfer to the Bureau of Prisons, 26 are eligible for retirement. Continuing efforts will be made to assist all employees to obtain suitable employment. In this connection, Local 1298 of the American Federation of Government Employees forwarded a plea to the Department of HEW that there be no further delay in the transfer of the Center in view of the adverse effect this period of uncertainty has had on the staff and patients.

The 105 NARA patients now remaining in the facility have received sufficient inpatient treatment to permit their immediate transfer to an appropriate community facility for aftercare and follow-up.

As you know, this Administration has proposed broad new initiatives to combat drug abuse, including the establishment of a Special Action Office on Drug Abuse Prevention under the leadership of Dr. Jerome Jaffe, who is now serving as a Special Consultant to the President. Dr. Jaffe has carefully reviewed and fully endorsed our proposal to transfer the Center. He is now actively engaged in planning efforts, involving the National Institute of Mental Health, which will result in considerable expansion of community treatment and rehabilitation capabilities throughout the Nation. The NIMH budget request for treatment services was amended to provide a total of \$91.3 million for this purpose in FY 1972. The NIMH budget for 1972 also includes funds to strengthen and expand the Addiction Research Center located within the NIMH Clinical Research Center in Lexington, Kentucky. As this action indicates, there are presently no plans for closing or transferring the Lexington facility, which will maintain the level of resident narcotic addict patients required for Federal research purposes.

In conclusion, the proposed transfer of the Fort Worth CRC is not a capricious or isolated issue. It is an integral part of a broad, inter-departmental strategy which strengthens our national capacity to combat narcotic addiction and drug

abuse. Any further delay in the execution of this plan will seriously hinder our efforts to broaden and strengthen the capacity of State and local authorities to deal effectively and realistically with this serious problem.

We strongly urge your deletion of the reference to Fort Worth in the final version of this resolution.

Sincerely,

JOHN N. MITCHELL,
U.S. Attorney General.

ELLIOT L. RICHARDSON,
Secretary, Department of Health,
Education, and Welfare.

Dr. BROWN. Mr. Nelsen, I would like to say, speaking as a professional and a public health psychiatrist, that much of the inspiration and leadership in community treatment came from the very distinguished medical health leader in your State, Dr. David Vale. Dr. Vale in your State has been a leader in the community approach.

Mr. NELSEN. Dr. Shepard out there worked with Dr. Vale.

Mr. ROGERS. I will be very anxious to receive the report on the number of facilities, the number of beds, the number of inpatients and where the courts and the judges have been told to send these people for treatment. I think this is needed.

Also we are still awaiting the reports from the FDA. Do you think we will ever get it?

Dr. ZAPP. This week, Mr. Chairman.

Mr. ROGERS. Also you were going to let us know when the advisory council emergency health personnel agent would be a reality. Letters went out some months ago. Has this yet been appointed?

Dr. WILSON. Yes, sir, they have been appointed. We have their acceptances back and I think a date has been set for a meeting.

Mr. ROGERS. Let us have specifics on that.

Thank you so much. We appreciate your presence here today.

Our last witness and we will try to do this very rapidly, Mr. Richard Heaney, Deputy Director, Bureau of Prisons, Department of Justice. The committee welcomes you.

STATEMENT OF RICHARD HEANEY, DEPUTY DIRECTOR, BUREAU OF PRISONS, DEPARTMENT OF JUSTICE

Mr. HEANEY. Mr. Chairman, I have just a brief statement here.

Mr. ROGERS. That will be fine.

Mr. HEANEY. Then I will be glad to answer any questions you might have.

I am pleased to have this opportunity to discuss with you plans the Bureau of Prisons has for utilizing the Federal Correctional Institutions at Fort Worth, Tex.

Transfer of the Clinical Research Center at Fort Worth to the Federal Bureau of Prisons will enable us to increase the total capacity of our drug treatment programs to 1,200 Federal offenders.

With the enactment of the Narcotic Addict Rehabilitation Act in 1966, the Bureau of Prisons was given the responsibility for providing specialized institutional treatment and aftercare services to offenders meeting the criteria outlined in title II of the act. NARA treatment units are in operation at five institutions with a capacity for 600 inmates.

Over and above the addict offenders who meet the criteria for commitment under title II of the Narcotic Addict Rehabilitation Act, each year we receive a very substantial number of offenders from the courts,

under regular sentencing procedures, who have serious problems involving the use of drugs. Last year alone, about 30 percent of all those committed to our institutions had a history of drug abuse, and there is no doubt that this drug usage played a significant role in the offender's criminal career.

Based on our experience in our NARA programs, we now have five additional units providing treatment to non-NARA drug abusers. These units, at our institutions at Lewisburg, Pa., Petersburg, Va., Terre Haute, Ind., El Reno, Okla., and Lompoc, Calif., have a total capacity of 250. We are hopeful that these programs, when supplemented by appropriate aftercare services, as proposed in H.R. 11352, will be helpful in reducing the number of men and women who return to lives of crime following release from a correctional institution.

The Fort Worth facility is exceptionally well suited to provide additional capacity for offenders with drug related problems. It is presently planned to utilize from 300 to 350 beds of this 500-550-bed capacity facility for offenders with drug abuse problems. The first 25 to 30 drug offenders will be received at Fort Worth during the week of November 14. The program for them will be modeled after our NARA programs, and will include intensive counseling, vocational training and education, and a variety of other supportive programs.

More than 200 former Clinical Research Center staff members have been transferred to the Bureau of Prisons rolls. These individuals have had considerable training and experience in treating addicts and drug users, and their skills will be invaluable in getting the new program underway. Only a small number of career Bureau of Prisons employees will be moved to Fort Worth.

While major emphasis will be placed on treatment programs for drug users, the balance of the facility's capacity, between 200 and 250 beds, will be used for offenders with other medical-correctional problems. There will be a demonstration unit for about 50 offenders who are chronic alcoholics. There will be another unit for geriatric cases, who are not ill enough to require full-time hospitalization, but who will benefit from treatment in a facility having well-developed medical services and a staff trained in working with such patients. Another unit will be developed to provide treatment to offenders with psychiatric problems.

Generally, offenders committed to Fort Worth will be persons who will eventually be released to the southwest and south central States. For the most part, prisoners at Fort Worth will be within 18 to 24 months of being released to the community.

In addition to providing much needed specialized programs for about 550 persons, the transfer of Fort Worth to Bureau of Prisons will allow us to reduce the population levels at some of our more seriously overcrowded institutions. On September 1, our present facilities held more than 1,300 offenders above the maximum rated capacities of these institutions.

The Dallas-Fort Worth community provides an excellent opportunity for us to develop collaborative programs with colleges and universities, and with community groups anxious to work with us in developing a wide range of community and volunteer programs. A research protocol to evaluate the effectiveness of the Fort Worth program is being designed. This gives us a unique opportunity to evaluate an institutional program from the very beginning of the activity.

We believe the programs proposed for Fort Worth will contribute significantly to our Nation's correctional progress in the treatment of drug abusers and other special types of offenders.

Thank you, Mr. Chairman, and I will be happy to answer any questions you gentlemen may have.

Mr. ROGERS. Mr. Nelsen?

Mr. NELSEN. I have no questions. It's a very fine, interesting report and I want to thank the witness. I am interested in your background. You have been serving in this capacity for many years; have you not?

Mr. HEANEY. Yes, sir; I am a Minnesotan, also. I started at our correctional facility in Sandstone, Minn., 25 years ago.

Mr. NELSEN. Are you any relative of Gerald?

Mr. HEANEY. That is my older brother.

Mr. NELSEN. You are just as handsome as he is.

Mr. HEANEY. Thank you, sir.

Mr. ROGERS. Let me ask you two or three questions. We appreciate your statement.

You are keeping the staff there pretty much as it was.

Mr. HEANEY. Yes, sir; almost all of the staff. There are some few that have chosen to retire or have accepted positions with Public Health or NIMH and other places.

Mr. ROGERS. I think it is interesting that they cannot find staff at Lexington but they are willing to turn over staff to the prison system. That is an interesting point to me.

Now, let me ask you this, suppose you have a man that has been in prison 5 years. He was a drug user and he was sentenced for drugs. What happens to him during that time? Hasn't he gone cold turkey within that time?

Mr. HEANEY. He obviously has. For the most part the real physiological addiction is over by the time he is committed to the institution.

Mr. ROGERS. What do you have to do to him in an inpatient hospital?

Mr. HEANEY. I think you need to provide a whole variety of services to that man.

Mr. ROGERS. I can see you may want to get him trained for a job or something like that, but is actually having specialists in treatment of drug withdrawal and addiction—I am not sure that you really need those people there.

Mr. HEANEY. I think there is a concensus among the people that are most involved that our drug abusers have some problems that are peculiar to that group and that these drug abusers do need some kinds of group and individual counseling and therapy that most of the others perhaps do not need, at least in the same intensity.

Mr. ROGERS. I can understand that but I question whether an expert staff is necessary. I would think most of that has already been done by the time they get to Fort Worth.

Mr. HEANEY. The withdrawal will already have been accomplished. But if you are going to work with them, you need to have the——

Mr. ROGERS. I understand but I question whether you need the expertise and the learning that we had there developed to turn it over when most of them have withdrawn or hopefully are withdrawn. This is not always the case, I understand. Is that true?

Mr. HEANEY. The withdrawal is almost always accomplished in a medical situation. The emotional needs of the patients need people who really know how to relate to patients.

Mr. ROGERS. What is the plan of the prison system to build a new hospital facility?

Mr. HEANEY. We are presently underway with a new facility, a behavior research center in Hutner, N.C., for which money has already been appropriated. That will be underway soon. The final plans are being drawn now and hopeful ground will be broken down there within the next 60 to 90 days.

Mr. ROGERS. How many beds will there be there?

Mr. HEANEY. About 350 to 400 beds.

Mr. ROGERS. Will you treat any drug patients there or not?

Mr. HEANEY. This is going to be largely an experimental demonstration kind of program. We may set aside 50 beds for the treatment of certain kinds of behavior disorders of one kind or another. Those specific kinds of treatment have not yet been fully decided but it is entirely possible that there may be a unit for addicts with certain kinds of problems.

Mr. ROGERS. After the North Carolina facility is built, will you utilize all of Fort Worth?

Mr. HEANEY. I would assume that at least for the next several years that the facility will be used to its capacity.

Mr. ROGERS. Otherwise you might shift some of them to North Carolina?

Mr. HEANEY. That would be possible.

Mr. ROGERS. Thank you so much. We appreciate your presence here today.

The subcommittee on Public Health and Environment conducted an official visit to the Kingdom of Thailand, the Republic of South Vietnam, Hong Kong, and Japan during the period August 6, 1971, through August 22, 1971. A report on that visit has been transmitted to Hon. Harley O. Staggers, chairman, Committee on Interstate and Foreign Commerce, a copy of which, without objection, will be placed at this point in the record of these hearings.

(The report entitled "Production and Abuse of Opiates in the Far East," follows:)

[COMMITTEE PRINT]

PRODUCTION AND ABUSE OF OPIATES
IN THE FAR EAST

A REPORT OF MEMBERS OF THE SUBCOMMITTEE
ON PUBLIC HEALTH AND ENVIRONMENT,
COMMITTEE ON INTERSTATE AND FOREIGN
COMMERCE



OCTOBER 1971

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(II)

LETTER OF TRANSMITTAL

SUBCOMMITTEE ON PUBLIC
HEALTH AND ENVIRONMENT,
HOUSE OF REPRESENTATIVES,
Washington, D.C.

HON. HARLEY O. STAGGERS,
*Chairman, Committee on Interstate and Foreign Commerce, House of
Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: Transmitted herewith is the report of findings of the undersigned members of the Subcommittee on Public Health and Environment during our recent official visit to Thailand, South Vietnam, Hong Kong, and Japan in order to investigate the extent of production and abuse of opiates in that area of the world.

We found much to be praised and much to be criticized. Nevertheless, we agree with the admonition of a noted sociologist, Alfred R. Lindesmith, author of "The Addict and the Law," who cautions:

International discussions of the Far Eastern opium and drug problems have often been highly charged with emotion and filled with political crosscurrents, mutual recriminations, charges and countercharges. * * * Countries in which there is an illicit drug traffic with supplies originating outside the country invariably blame the country of origin for their problems; no blame appears to attach to those countries which provide the markets for illicit supplies.

It is our hope that the criticisms in the report will stimulate constructive responses and that our recommendations will be seriously considered. We also earnestly hope that the drug abuse legislation which this committee will report in the next few weeks will have a positive effect on the problems detailed herein.

Respectfully submitted.

PAUL G. ROGERS,
DAVID E. SATTERFIELD III,
PETER N. KYROS,
RICHARDSON PREYER,
Members of Congress.

(III)

PRODUCTION AND ABUSE OF OPIATES IN THE FAR EAST

INTRODUCTION

Members of the Subcommittee on Public Health and Environment conducted an official visit to the Kingdom of Thailand, the Republic of South Vietnam, Hong Kong, and Japan during the period August 6, 1971 through August 22, 1971.

The subcommittee presently is conducting hearings on drug abuse, and is considering H.R. 9264, the Administration's "Drug Abuse Prevention Act"; H.R. 9059, introduced by certain members of the subcommittee; and approximately 60 related bills.

The principal purpose of the visit was to investigate the sources of and traffic in illicit drugs and to determine the extent of drug abuse among U.S. servicemen stationed in Southeast Asia. A secondary purpose was to become acquainted with environmental problems and anti-pollution measures in Japan.

The visiting team included Representative Paul G. Rogers, Chairman of the Subcommittee on Public Health and Environment, Representative David E. Satterfield, III, Representative Peter N. Kyros, Representative Richardson Preyer, Adrian Swain of the Bureau of Narcotics and Dangerous Drugs, and Stephan E. Lawton, Subcommittee Counsel.

SUMMARY OF FINDINGS

Sources, production and distribution of opium and its derivatives

Turkey's decision to ban opium production probably will promote the tri-border area of Thailand, Burma and Laos into the principal source of heroin and other opiates which ultimately reach the blood-streams of America's hundreds of thousands of addicts, both at home and in the armed services abroad. In an effort to determine the extent of opium production in the tri-border area and to gain information on which to base recommendations and legislation to curtail the accessibility of opiates, members of the subcommittee went straight to the source—the tri-border area.

The subcommittee members found that present efforts of the United States and Thai governments to eliminate poppy growth in the tri-border area are futile. The poppy which flourishes at the three to seven thousand foot level in the tri-border area's rugged, mountainous terrain, is the only cash crop which affords the area's hill tribesmen an existence beyond subsistence level. U.S. estimates of the amount of opium that will be produced in the tri-border area this year run as high as 1000 tons.

Although a considerable amount of the raw opium is refined in Thailand itself, both Hong Kong and Tachilek, Burma, serve as major refining points. The principal convoy route is from Mae Sai

near the Burma-Thai border south along an all-weather highway to Bangkok. Various methods are used to redistribute opiates to South Vietnam, Okinawa, Japan, the U.S. and other countries. Most of the opiates shipped from Bangkok are transported to Hong Kong for redistribution; some shipments are flown directly from Bangkok, Huai Sai, Laos and Tachilek to South Vietnam. Because of inadequate inspection procedures servicemen stationed in Thailand apparently have little difficulty shipping heroin by army post office into South Vietnam. Other groups, mainly ex-servicemen, are flying opiates into the United States via body pack. In Hong Kong, a major R&R area for South Vietnam, bargirls have acted as couriers.

Prevention

Representatives of the Bureau of Narcotics and Dangerous Drugs are attached to embassies in Bangkok, Chiang Mai, Saigon, Hong Kong and Tokyo and seem on the whole to enjoy good relationships with the local officials. Unfortunately, these BNDD officials are somewhat hampered by their responsibility to the embassies because they often seem to be at cross purposes with the State Department officials. A lack of funds and manpower also deters prompt and efficient action. Probably the greatest obstacles to fruitful results are indigenous ones. Northern Thailand is a remote unstable area and stern measures to control the production of opium at its source are dependent in great measure on maintaining control of the northern provinces by the Bangkok government. The Border Patrol Police, the only law enforcement agency in the area, is simply not equipped with either the men or the arms required to deal with the smuggling and production of opium. Control of opium is only a secondary function of the police. The majority of their efforts include combating communist insurgents and protection of border integrity.

The further opiates are transported from their source, the more difficult prevention becomes. In Vietnam, real attempts are being made by South Vietnamese authorities to suppress heroin traffic within Vietnam. In 1970, the South Vietnamese police made 3,880 drug-related arrests and seized 1,054 pounds of opium, an obvious step-up in activity over the 1,050 arrests and eleven pounds of heroin seized in 1968. Nevertheless, there is little indication of difficulty in obtaining vials of heroin in major population centers in Vietnam.

Given the lack of adequate manpower, the proliferation of "junks" in Hong Kong harbor makes inspection an impossible task. Apparently, most of the opium traffic in Hong Kong is controlled by a few impenetrable Chinese families, very much like our Mafia.

Another serious obstacle to enforcement is the attitude on the part of some of the "donor" governments that opium shipments are the problem of the recipient.

Japan is the sole exception to the rule that heroin addiction appears to be spreading throughout the world. The country has experienced a remarkable reduction in addiction during the past few years. Although the principal reasons appear to be cultural in nature as well as the lack of criminal procedural guarantees, Japan's success rate with compulsory hospitalization indicates that civil commitment of addicts in this country should be carefully considered.

The U.S. Military

One of the main missions of the subcommittee visit was to determine the extent of drug abuse by United States servicemen. The subcommittee met with great difficulties in obtaining hard data regarding involvement with drugs by military personnel stationed in the Far East. Both in Thailand and in Vietnam, military personnel had been instructed not to reveal statistics obtained by urinalysis screening beyond those which had already been publicized. Figures based solely on the urinalysis statistics do not appear to be a reliable indicator of involvement in any case, particularly in light of the fact that with few exceptions urinalysis is done only on those men leaving the area. Figures based on indicators other than urinalysis indicate that drug abuse among enlisted servicemen in Vietnam greatly exceeds the much-publicized figure of five percent and ranges as high as forty percent in some units.

Spurred by White House and Congressional action, the military has begun to develop new methods for dealing with the widespread problem of drug abuse among our servicemen stationed in the Far East. Until a few months ago, drug involvement was, like alcohol abuse, considered to be a behavioral problem requiring disciplinary action only. The military has now recognized a greater responsibility, not only to men exposed to drugs but also to society in general, and is responding with treatment and rehabilitation programs despite a lack of trained personnel and the necessity to work within the confines of the military mission.

According to several surveys and descriptions by medical personnel, the typical service addict is indistinguishable from his fellow enlisted men. A high school graduate, he turns to drugs because of boredom. He probably is not a draftee. Usually, he has not received punitive action prior to treatment. The military estimates his chances of rehabilitation at 80 percent.

Despite an increased awareness of the reasons for drug addiction and recent strenuous efforts to provide adequate treatment, rehabilitation measures in Vietnam are not successful. At Bien Hoa Army Base, home of the First Cavalry Division, military officials estimate the cure rate at the base treatment center to be as low as 10 percent. The subcommittee members doubt whether drug treatment programs will ever be successful in Vietnam, given the lack of trained personnel, the pressure of military affairs and the short period of treatment afforded in Vietnam.

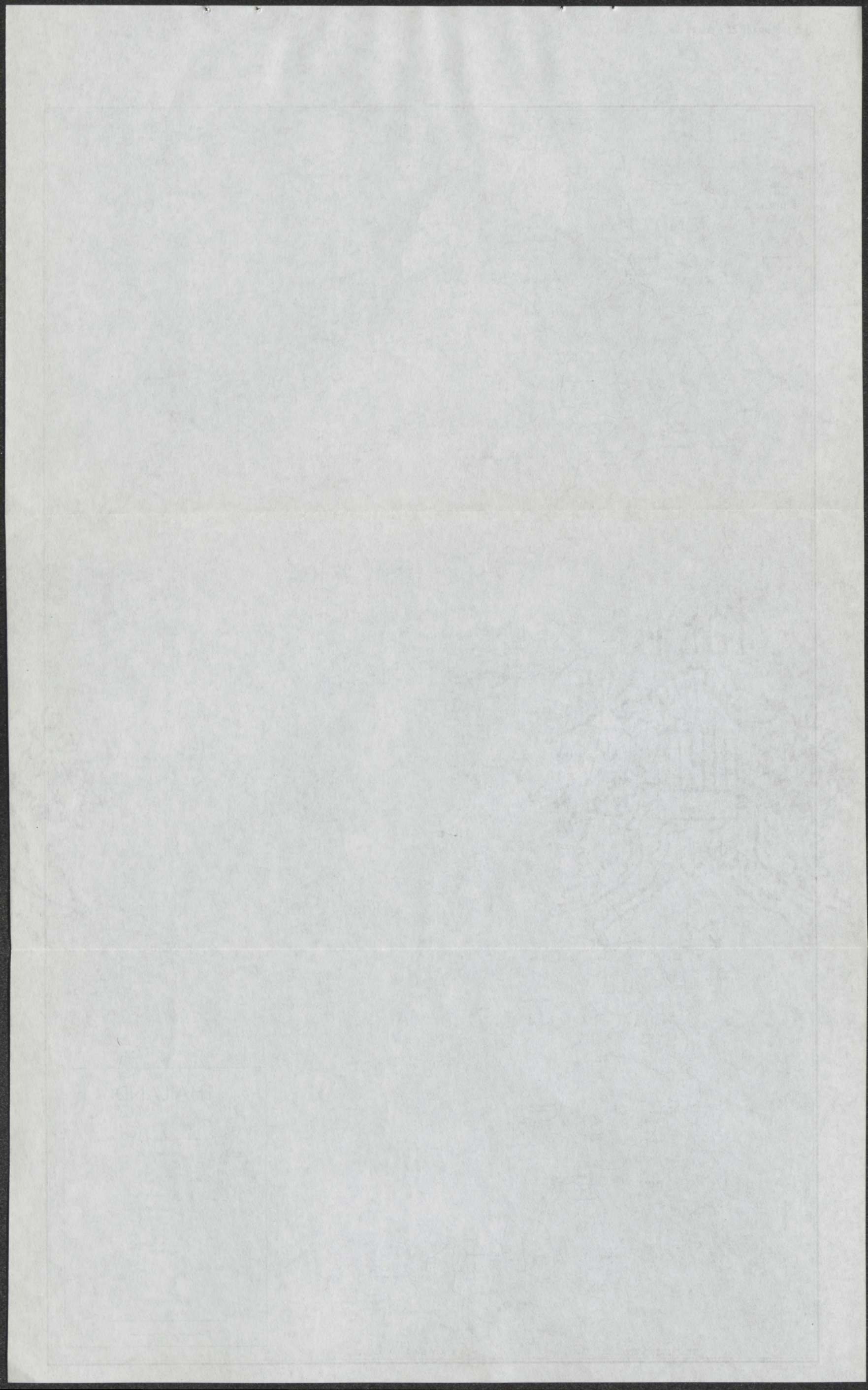
FINDINGS

THAILAND

Background

Production and trafficking of opium have been widespread in the tri-border area of northern Thailand and the bordering countries of Laos and Burma as well as Yunnan Province, China, for decades. The recent agreement by the Turkish government to cease the production of opium and the probability of similar action by Iran and Afghanistan undoubtedly will convert this area, sometimes known as the Golden Triangle, into the world's largest source of heroin ultimately imported into the United States. Indeed, the area has the potential to supply the entire world market.





Growth and abuse of opium and its derivatives is traditional with many of the 275,000 hill tribesmen living in northern Thailand. Fighting in Burma and China forced hill tribes into the area. These tribes include the Miao and the Yao; both are culturally close to the Chinese. They brought with them the practice of growing and smoking opium and are considered the primary growers of opium in northern Thailand today. They have been permitted to settle in the country without disturbance to their tribal integrity.

Some of the ethnic Chinese groups in the tri-border area are frequently referred to as Chinese Irregular Forces or as the KMT irregulars. Many of these groups are led by, and include within their ranks, the Chinese Nationalist troops who fled China in 1949 to escape the Communist takeover. A larger portion of the approximately 4,000 "troops" of the Chinese Irregular Forces are natives of the area and second-generation offspring of the many inter-marriages with natives of the area. In the 1950's a vigorous effort by local governments resulted in the removal to Taiwan of several thousand of the China-mainland escapees and their dependents. The remnants have, since their arrival, maintained a paramilitary status as a matter of necessity, to survive against various hostile governments in whose areas they have settled. Many of these groups hire out as mercenary military units to local merchants and traders and occasionally to local governments. They have involved themselves in various commercial enterprises, including opium traffic. They have become involved with opium as have a number of other ethnic groups in the area, primarily as a means of profiting from the area's only cash-crop—currently the sole available means of exceeding a subsistence-level existence.

During the trip, a law was passed in Laos making possession of opium illegal. It is too early to evaluate the effects of the law on the production of opium in the area.

Production and transportation of opium and its derivatives

The tri-border area is rugged, mountainous and dense. Opium is grown on mountainsides at the three to seven thousand foot level. It is relatively easy to identify potential poppy fields from the air; however, positive identification is not possible without the use of special equipment.

During the harvest, which usually occurs during January and February, the poppy bulb is sliced. From this incision oozes a gum which dries and turns dark brown. This is raw opium. Merchants transport raw opium to assembling and distribution localities, forming so-called "opium caravans."

Much opium is converted in a "refinery" to smoking opium by cooking it in water, screening out twigs and other foreign matters, pouring off the water and allowing the substance to harden. At times, various substances are added before smoking. In various parts of the Malay Peninsula, smoking opium contains a pigskin additive, which is reputed to make the smoke more aromatic. In South Vietnam, opium with vegetable additives is not unusual. This opium, although generally used for smoking, can also be soaked in water and hypodermically injected.

Before drying, opium can undergo a laboratory process and be converted to morphine. The morphine-based opiate, termed 999 (the designation of a World War II, Burma-based Nationalist Chinese army

outfit), is marketable in most Asian countries, especially Singapore. It can be chipped into a powder, liquified, and injected. "Red rock" or "number 3" heroin is a by-product of the morphine process. Red rock heroin contains a low percentage of heroin and is almost exclusively smoked. Most of the drug abuse by the tribesmen of northern Thailand consists of smoking opium or red rock heroin. Few Asians "mainline" heroin.

Morphine can undergo a second laboratory process and be converted into heroin hydrochloride, which is "white" or "number 4" heroin.

Annual production of opium in the tri-border area is estimated by the Department of State to be in the volume of 650 to 800 metric tons: 400 tons from the northern insurgent-controlled hills of Burma, 150 to 200 tons in the northern hills of Thailand and from 50 to 100 tons in Laos. The Department of Defense and the Bureau of Narcotics and Dangerous Drugs estimate that 1,000 tons of opium will be produced in the tri-border area this year. During 1970 only 400 tons were produced in Turkey.

The fantastic profit involved in the production and sale of opium and its derivatives is shown by the following table:

TABLE A.—JUNE, 1971 AVERAGE SELLING PRICE OF OPIATES BY AREA

	<i>U.S. Dollars per kilogram</i>
Raw opium:	
Hill tribe remote areas in the tri-border area of Thailand, Burma and Laos-----	30-40
Bangkok-----	75-90
Singapore-----	125-175
Hong Kong-----	165-200
Prepared opium:	
Vientiane (Laos)-----	70-75
Bangkok-----	100-125
Singapore-----	175-250
Saigon-----	600
Hong Kong-----	200-300
Morphine:	
Chiang Mai (999 morphine)-----	350-400
Bangkok (999 morphine)-----	450-500
Singapore-----	above 700
Hong Kong-----	990
Heroin No. 3 (colored):	
Bangkok (3-4% heroin)-----	90-100
Hong Kong (30% heroin)-----	300-400
Heroin No. 4 (white):	
Bangkok-----	2, 000-2, 500
Hong Kong-----	2, 100
Saigon-----	10, 000
New York (wholesale)-----	18, 000-25, 000

During 1970, sixteen refineries producing opium, morphine or heroin were identified in the tri-border area. Only three were producing heroin. As of August 1 of this year, of the 24 refineries which had been identified, 16 were producing heroin.

According to a representative of Thailand's Central Bureau of Narcotics based in Chiang Mai, most refineries are located approximately ten kilometers from the Thai border near Tachilek, Burma, the only sizable town near the tri-border area. He believes that most factories are approximately ten kilometers from the Thai border although probably only a few are located in Thailand. The most likely area is near Fang, where many KMT live. Refineries occasionally are discovered in Bangkok.

A considerable amount of opium is grown for local consumption. It is generally assumed that no ethnic Thais are involved in the growing or transportation of the product from its source. Virtually all traders have been identified as ethnic Chinese although some have taken Thai names. The principal convoy route is from Mae Sai, located near the Burma-Thailand border north of Chiang Rai, south along an all-weather highway to Bangkok.

Thai military sources state that opium presently is being transported by air into South Vietnam from Huai Sai, Laos and Tachilek, Burma.

It is also reported that many shipments of opiates to Vietnam are by civilian couriers on commercial airlines from Vientiane, Laos.

Shipments from Thailand

Most opiates shipped from Bangkok are transported to Hong Kong, where they are redistributed to South Vietnam, Okinawa, Japan, the United States and other countries. Some shipments go directly from Bangkok to South Vietnam.

Four operative "systems" transporting heroin directly to the United States have been identified. One group of ex-servicemen is shipping heroin via army post offices to U.S. military installations. Shipments from this source have been seized at Walter Reed Army Hospital and at Fort Monmouth, New Jersey. Two groups, both consisting of ex-servicemen and contract employees, are located in Okinawa. One has a source in Bangkok, the other in Hong Kong. From Okinawa both groups engage in transportation of heroin by body packs into the United States. A fourth target is Philippine citizens who fly to Geneva via the United States transferring body packs of heroin to sources in this country. In the past, little attention has been given to these persons because of their transient status.

Because military officials lack the authority to inspect first class mail at the mailing points, little can be done to retard shipments by mail from U.S. servicemen. U.S. officials are extremely concerned over the implications of the scheduled opening of a new military post office 60 miles east of Chiang Mai at Lampang, the future site of a space tracking station. Approximately 250 Air Force personnel will man the station.

The drug abuse problem among U.S. military forces stationed in Thailand

On June 24, 1971, the Air Force implemented a comprehensive plan to screen and detoxify military personnel departing Thailand. On July 23rd the rest of the military services followed suit. Like their counterparts in Vietnam, military personnel stationed in Thailand have been instructed not to reveal statistics stemming from the screening of returning service-members. Results of a recent military survey of enlisted men reveal that 4.5 percent admitted heroin use. Approximately 8 percent of first-termers responding to the survey admitted to heroin abuse. Twenty-three percent of all surveyed admitted to the use of some drugs while in Southeast Asia.

On July 26, 1971, the Fifth Field Hospital began receiving military drug abusers for detoxification. Between that date and August 10th, 23 patients were admitted to the hospital's detoxification unit. Because the program was initiated only recently, it is not possible to assess its efficacy.

U.S. Government activities against drug traffic

Representatives of the Bureau of Narcotics and Dangerous Drugs have been stationed in Thailand for several years and enjoy a good

relationship with Thai officials. BNDD officials, who are attached to the United States embassy, are based in Bangkok and Chiang Mai. Embassy officials have been instrumental in forming an Illicit Drug Control Committee under the chairmanship of the Deputy Chief of Mission. It includes representatives from the Bureau of Narcotics and Dangerous Drugs, the U.S. military, the United States Information Service, the U.S. Overseas Mission and the Regional Economic Development Agency. The committee has submitted to the Department of State for approval a \$1,193,000 program designed to pose economic alternatives to the opium producer, assist in law enforcement activities, provide medical care and rehabilitation of addicts and initiate an educational program directed against drug abuse. To date, no money has been programmed to implement the committee's recommendations.

Thai law enforcement attempts

Despite the King's clear support of attempts to eradicate opiates and the Thai government's official position of cooperation with United States officials, positive actions have been minimal. Most Thai officials discount their government's responsibilities and place the blame on the countries to which drug traffic flows. The 1966 pamphlet, "Thailand's Hill Tribes", by General Prapas Charusathira, Minister of the Interior and Chairman of the Hill Tribes Welfare Committee, reflects this attitude:

Several of the larger tribes derive their income from opium cultivation. The real culprits in the Thailand opium trade are the consumers in London, Sydney and New York.

Thai attempts to eradicate the growth and distribution of opium and its derivatives are failing. Despite an apparently cooperative police effort and a sincere desire by the King to develop crop substitution programs, the poppy fields in northern Thailand are flourishing, the number of refineries is increasing and shipments from tri-border countries travel the Mae Sai-Bangkok highway virtually unimpeded.

The number of men and amount of modern equipment devoted to the effort are minimal. The only law enforcement agency in the area, the Border Patrol Police, consists of approximately 1,000 men responsible for 1,079 kilometers of border—about one man per mile.

Although the BPP evidences concern about its obligation to interdict the incoming flow of opium across these borders, insurgency by Chinese communists and thirteen Burma based rebel groups has forced the BPP to accept pressing military concerns as its primary mission. Leaders of the BPP reason that unless and until border security against communist insurgency is established, it cannot establish effective border integrity against the illicit importation of opiates.

The commander of one of the Border Patrol Police units, whose troops were engaged in a counterinsurgency operation at the time he briefed subcommittee members in Chiang Khan, clearly accepted as one of his responsibilities the support of programs such as crop substitution designed to discourage the hill people from cultivating the poppy. However, it appeared that practically of his troops were involved in combat operations at the time.

Despite the fact that the communist insurgents are equipped with AK-47's, a Russian-made automatic weapon similar to the U.S. M-16, weapons used by the police and their supporters predate

World War II. The subcommittee members observed a team of Miao hill tribe volunteers equipped with Springfield '03 rifles prepared to commence a combat operation. They are unable to secure U.S.-made M-16s due to the apparent belief of officials within the Public Safety Division of USAID that, because the unit is referred to as "police", it does not conduct military operations.



Miao Hill Tribe Volunteers

The four man Central Bureau of Narcotics in Chiang Mai, whose responsibility includes the four northernmost provinces, is equipped with one vehicle and three carbines. Obviously, theirs is an impossible task.

Another obstacle to meaningful control is the remoteness, both geographic and political, of northern Thailand from the Bangkok government. As a result, stern measures against the Thai government, such as threats to cut off aid, would have little effect on the hill tribesmen. One embassy official believes that if the Thai government were to mount a strenuous campaign against opiates, an action which would pose an economic threat to the tribesmen, the government would lose the northern provinces to the communists.

VIETNAM

Background

Four months ago, a report drafted by the participants in a conference and workshop on drug rehabilitation, composed of 182 officers and enlisted men, was withheld from the Commanding General, United States Army, Vietnam, to whom it was intended to be directed. The report described in shocking detail the seriousness of the drug abuse problem in Vietnam. It recommended that a task force directly responsible to the Commanding General be established in order to alleviate "the demand for immediate information to combat this nemesis". The report stated:

A disparity presently exists between the reports shown on the level of drug abuse in Vietnam and the consensus held by the conferees. The conference established that the "gut-feeling", undocumented reports from people who live with the problem, placed heroin addiction among lower ranking EM in the US Army at 25%. A USARV Task Force would provide the Commanding General with a more realistic base, from which to judge the accuracy of this "gut-feeling". Hard statistical data, based on surveys presented to the conference, showed a range of heroin use between 10% and 44%. Time is essential! This Task Force should be established as soon as possible in order to present the accurate status of the drug problem to the Commanding General. Most conferees were openly skeptical of the accuracy of the information thus far presented to the Commanding General on drug abuse. The Task Force will be an action agency. It must focus all of its attention on this problem.

The report which ultimately was placed on the General's desk contained none of this information. Nor did it recommend the establishment of the sorely-needed task force. To the best of the subcommittee's knowledge, the Commanding General still has not seen the original report.

Spurred by an increasing awareness of the magnitude of the problem, as well as pressure from Congress and the White House, the various armed services in Vietnam have developed educational and treatment programs. Although the educational programs appear to be having a positive effect, treatment programs suffer from a lack of trained personnel and facilities.

The extent of drug addiction in Vietnam

The subcommittee members believe that it is insignificant whether the rate of drug abuse by our troops in Vietnam is five percent or forty percent. Whatever the rate, military commanders and the United States Government must marshal all possible efforts against the availability and use of heroin and other crippling drugs. Nevertheless, in order to enact meaningful legislation, the subcommittee must receive information concerning the nature and extent of the problem. Despite repeated requests, members of the subcommittee were not given statistical information which would indicate the extent of the use of heroin in Vietnam by U.S. servicemen. This refusal results in further difficulties for those charged with the responsibility for finding solutions to the drug abuse problem and undermines confidence in statistics which have been released to the public. Officials at the Military Assistance Command, Vietnam, stated that the instructions to withhold information came from the White House.

The only statistical information afforded the subcommittee members in Vietnam was that previously provided by Dr. Jerome Jaffee, Special Consultant to the President for Narcotics and Dangerous Drugs during testimony in Washington. Dr. Jaffee's figures indicated that between 5.33 percent and 5.46 percent of all servicemen who had undergone urinalysis prior to leaving Vietnam had been determined to have abused hard drugs during the previous forty-eight hour period. While the subcommittee has no basis on which to contest the urinalysis statistics, they are not an accurate indication of the extent of the drug addiction problem in Vietnam. These percentages probably are not even indicative of the number of Army personnel who fail the urinalysis tests at the centers located at Cam Ranh Bay and Long Binh, because the figures are based on total military population in Vietnam: generals, as well as admirals, and sailors stationed aboard ship are included in the percentages released to the public.

At Long Binh, from 1000 to 1200 samples are taken per day. On August 13, 1971, the day before the subcommittee visited the Long Binh testing facility, 87 positive urines were found, indicating a percentage of from 7.25 to 8.7.

Moreover, the much-publicized five percent figure does not include servicemen who have been arrested for drug-related crimes, participants in amnesty programs, deaths as a result of overdoses or hospital discharges for drug related illnesses. The percentage of servicemembers identified through these means is higher than the percentage identified through urinalysis. Table B is a United States Army listing of cases involving possession or use of narcotic drugs identified by these means during the period January through May 1971, prior to implementation of the urinalysis program. The figures rose from a percentage of 9.23 in January-February to 11.6 during April-May, despite the absence of the testing procedures being employed today. Figures for subsequent months have been suppressed.

Subcommittee members were advised by one knowledgeable Army medical officer that the heroin use in his brigade approximated 30 percent. One serviceman undergoing detoxification under an amnesty program stated that 95 percent of his unit smoked or snorted heroin. Another stated that "everyone but the First Sergeant" in his unit abused drugs. Both statements may be exaggerations, but they do point out the extent of the problem in the mind of those involved—the addicts.

The subcommittee members conclude that the extent of drug abuse among servicemen in Vietnam far exceeds the recently publicized figure of five percent. While figures obviously vary considerably between units and branch of service, the members do not quarrel with estimates that drug addiction by enlisted men in many units ranges from 15 to 40 percent and believe the estimates that 10 percent of enlisted men stationed in Vietnam are addicted to heroin to be cautious.

Present military programs

During the past four months, the military has responded to the drug abuse crisis in Vietnam with social and medical programs. At Long Binh Post, home of the Third Regional Army Command, the Army's Pioneer House is capable of assisting up to 65 volunteers at a time by means of its "cold-turkey", therapeutic community approach to the problem. Although the Pioneer House has in the past suffered from the recidivism of "ex-addict" counsellors, the program appears to be stabilizing. The remaining brigade of the Army's First Cavalry Division, headquartered at Bien Hoa, conducts an amnesty program. The "cure" rate is reported to be as low as ten percent, however.

The security features built into the urinalysis testing procedures at the centers in Cam Ranh Bay and Long Binh appear to be adequate. However, it might prove possible for servicemen to cease using drugs for three or four days prior to departure and thus, to "beat the tests." The Army treatment centers retain a serviceman only until the results of the urinalysis tests are known to be negative, and a serviceman may be discharged for home within 18 hours of his tests. The desire to return home to family and/or to civilian life is a strong motivation and could lead some to curtail their habits temporarily with no efforts or even desire for total rehabilitation.

When the results of the tests are positive, there is no "treatment" afforded the serviceman, but merely a "drying out" process. He is retested until the results are negative and then released for home. Therefore, it is critical that treatment centers in the United States be strengthened to provide the necessary rehabilitative measures for the serviceman.

The Air Force Treatment Center at Cam Ranh Bay retains its men for seven to ten days after testing confirms heroin use. The Air Force emphasizes the psychological factors in the determination of a man's readiness to return to the United States and submit himself for further treatment. Because of the relatively small number of Air Force personnel who become addicted to heroin, the Air Force provides a more comprehensive approach.

The Air Force centers, however, are without recreation facilities, and patients are retained in beds in Quonset huts. The Army, on the other hand, does allow patients to move in a confined area outdoors and to have swimming periods at Cam Ranh Bay.

Several counter-offensive measures have been effected by the Navy in Vietnam in an effort to discourage the use of and traffic in narcotics. Most of these measures parallel the Army's drug program, at least in a broad sense. Teams of six petty officers who have attended a drug education course in San Diego brief all incoming naval personnel on the facts about drugs and drug abuse. The Navy has used former addicts as counselors and advisors to those participating in the exemption program. The Navy's experience with former addicts working in these programs has not been good, though two ex-users are still being used. All personnel departing the area, whether for rotation, separation or temporary leave, as well as those who request an extension in Vietnam are screened by urinalysis. Exemption, the Navy's designation for amnesty, is extended to those detected by the screening if they voluntarily surrender for rehabilitation within 24 hours of the test. Many drug users, realizing that they will eventually be caught by the urinalysis screening, voluntarily apply for detoxification. Exemption is available only once.

Unless an individual is found to be only an experimenter, in which case he may be returned to his command, anyone "volunteering" for the rehabilitation program is delivered to one of six detoxification sites and then forwarded to the rehabilitation center in Nha Be for 30 days of evaluation and ultimate disposition.

The Navy maintains two barrack ships at Nha Be which serve as facilities for the rehabilitation center. The program is designed to make the environment more like a ship than a hospital or a prison. If an individual progresses satisfactorily, he is given an opportunity to leave the confines of the ship and roam at liberty on the base. After the 30 day period at Nha Be, however, most are evacuated to Miramar, California for further rehabilitation. After October 1st, the rehabilitation center at Nha Be will be closed, and all personnel who have gone through detoxification units will be evacuated directly to Miramar.

Education programs—especially those broadcast over Armed Forces Vietnam radio and television—are already showing a positive effect, the committee believes. The serviceman who originally estimated that 95 percent of his unit was involved with heroin stated that the number is now probably only 65 percent, due to the concentrated education program directed toward new arrivals in Vietnam.

The subcommittee members conclude that military treatment programs are not successful, due to lack of trained personnel, the pressure of military affairs and the environment of Vietnam itself. The members doubt whether successful drug treatment programs will ever be possible in Vietnam.

Who is the Vietnam drug addict?

He is, according to a recent survey of 250 patients passing through Pioneer House (Table C) a clerk, or perhaps a vehicle maintenance man, stationed in a rear area where heroin is readily available. He is a high school graduate. Little or no disciplinary action has been taken against him during his tenure with the Armed Forces in Vietnam. He comes from a stable home. He is between 19 and 21 years old.

He did not begin the use of drugs out of fear of the war. The principal reason was boredom. Contributing factors included the accessibility to drugs and a belief that he was being harassed by his superiors.

He probably smokes or "snorts" (sniffs) heroin—generally, only if he used heroin in the states will he "mainline". He may have believed that smoking heroin was non-addictive, or he may have believed he was smoking cocaine, which is non-addictive. Perhaps he acquired the habit through smoking marijuana which, without his knowledge, was laced with white heroin. He can purchase a quarter gram of white heroin of from 94 to 97 percent purity for \$2.50. Depending on the proximity to payday, a vial can be purchased for from \$3.00 to \$10.00.

Although over 30 percent of servicemen undergoing treatment admitted to use of hard drugs prior to entry into the Army, the chances of rehabilitation are estimated at 80 percent by Army medical personnel.

The typical addict in the Navy mirrors his Army counterpart according to a psychiatric consultant at Nha Be. He is a 20 year old, white, high school graduate who joined the Navy to avoid the draft. He is single, professes to be religious and admits to using marijuana prior to entering the service. He is generally healthy, not a disciplinary problem, but he is bored. Faced with boredom and the vague threat of physical injury, he finds few avenues of escape except through the use of drugs. Because he prefers solitude and small groups to the noise and

crowds of the enlisted men's clubs, and also because he associates alcohol with senior petty officers and officers, he turns to drugs, which he identifies with the younger set.

TABLE C.—PIONEER HOUSE QUESTIONNAIRE

[Groups 1 to 10=250 patients]

	Number	Percent
1. Your age range:		
17 to 20.....	139	56
21 to 23.....	99	40
24 to 26.....	11	4
Over.....	1	
2. Marital status:		
Single.....	194	77
Married.....	55	22
No reply.....	3	1
3. Are both your parents still alive?:		
Yes.....	218	87
No.....	30	12
No reply.....	2	1
Are they separated or divorced?		
Yes.....		120
No.....		180
4. Are you working in your primary MOS?:		
Yes.....		165
No.....		135
5. Service contract:		
Enlisted.....	185	74
Drafted.....	62	25
No reply.....	3	1
6. Length of time in Vietnam?:		
Less than 3 months.....	12	5
3 to 6 months.....	58	23
More than 6 months.....	179	72
No reply.....	1	1
7. Educational level:		
6th grade.....	2	1
7th grade.....	1	1
8th grade.....	3	1
9th grade.....	17	7
10th grade.....	28	11
11th grade.....	52	21
12th grade.....	103	41
1st year college.....	27	11
2d year college.....	6	2
3d year college.....	2	1
4th year college.....	5	2
No reply.....	4	2
Acquired GED.....	37	15
8. Number of articles 15's:		
0.....	147	59
1.....	55	22
2.....	24	10
3.....	2	1
4.....	10	4
5 or more.....	3	2
Number of courts-martial:		
0.....	232	93
1.....	18	7
9. Primary reasons for the drug problem in Vietnam:		
Don't think there is a problem.....	4	2
Drugs are so easy to get.....	46	18
Boredom.....	52	21
Anger toward the war.....	5	2
Fear of the war.....	0	0
Drugs are popular in the States.....	3	1
Personal problems.....	14	6
Encouragement from friends or other users.....	12	5
Harassment from NCO's or officers.....	30	12
Because of experimentation.....	7	3
No particular reason.....	6	2
Multiple responses.....	57	22
No reply.....	14	6
10. Experience with marihuana:		
Never tried it.....	4	2
Tried it once or twice.....	11	4
Use it a couple of time a month.....	10	4
Use it several times a week.....	162	64
No reply.....	67	26
11. Should marihuana be legalized?		
Yes.....	232	93
No.....	11	4
No reply.....	7	3

¹ Approximately.

TABLE C—PIONEER HOUSE QUESTIONNAIRE—Continued

[Groups 1 to 10=250 patients]

	Number	Percent
12. Did you use:		
Marihuana before entering the Army:		
Yes.....	173	74
No.....	60	26
Marihuana before coming to Vietnam:		
Yes.....	198	87
No.....	29	13
Marihuana after coming to Vietnam:		
Yes.....	197	90
No.....	13	10
Hard drugs before entering the Army:		
Yes.....	78	34
No.....	150	66
Hard drugs before coming to Vietnam:		
Yes.....	93	42
No.....	129	58
Hard drugs after coming to Vietnam:		
Yes.....	225	94
No.....	13	6
13. Percentage of personnel in your unit on heroin:		
Less than 25 percent.....	79	32
25 to 50 percent.....	82	33
50 to 75 percent.....	63	25
75 to 100 percent.....	13	5
No reply.....	13	5
14. Why do you think you got on hard drugs?:		
Through your own fault.....	114	46
Through no fault of your own.....	3	1
Because of an unhappy childhood.....	4	2
Talked into it by your friends.....	20	8
Because you are emotionally weak.....	12	5
Because you used alcohol.....	1	
Don't know why.....	45	18
Because you used marihuana.....	4	2
Multiple reply.....	29	11
No reply.....	12	5
Other reply.....	6	2
15. Do you consider:		
Aspirin:		
Safe.....	225	98
Hard.....	7	2
Smack:		
Safe.....	2	1
Hard.....	235	99
Speed:		
Safe.....	21	9
Hard.....	214	91
Downers:		
Safe.....	42	22
Hard.....	192	78
Marihuana:		
Safe.....	225	95
Hard.....	13	5
Barbiturates:		
Safe.....	30	13
Hard.....	200	87
Uppers:		
Safe.....	53	23
Hard.....	181	77
Heroin:		
Safe.....	2	1
Hard.....	234	99
Cocaine:		
Safe.....	28	12
Hard.....	206	88
Alcohol:		
Safe.....	91	41
Hard.....	127	59
BT's (a French barbiturate):		
Safe.....	39	17
Hard.....	193	83
16. Why do you think people are afraid of the amnesty program?		
Afraid of losing job.....	9	2
Afraid of losing rank.....	15	9
Afraid of being identified as a user.....	58	33
Afraid of unreasonable harassment from unit.....	81	47
No reply.....	14	9
17. Downers, barbiturates, BT's:		
Concordant replies.....	181	79
Discordant replies.....	45	21
Speed, uppers, amphetamines:		
Concordant replies.....	190	79
Discordant replies.....	46	21

HONG KONG

Background

The expansion of British commercial interests in the first half of the nineteenth century was directly related to the increase in the opium trade. The profitability of this trade gave impetus to British demands for territorial and commercial concessions in China. In 1839 these demands led to the outbreak of the First Opium War. As a result of the opium war, the island of Hong Kong was ceded in perpetuity to Britain in 1842 by the Treaty of Nanking.

Due to its proximity to the opium trading center of Canton, Hong Kong's fine harbor has long been used to shelter opium-carrying vessels. After Britain's acquisition of Hong Kong, the island assumed an important role in the opium trade in Asia. Hong Kong's involvement in illicit traffic of opiates has continued to the present.

In 1914, a government monopoly system was established under which government opium was sold to smokers, who were permitted to smoke legally except that the operation of opium dens was outlawed. Government opium was sold by vendors who were paid a monthly wage and who made no profit of their own from it. The main weakness of the system was the high price charged for the superior quality opium sold by the government. Inevitably the low income level population patronized the illicit market, where opium was available at one quarter of the government price. By the beginning of World War II, fewer than 1000 smokers in Hong Kong purchased government opium in contrast to tens of thousands who relied on the smuggled product. These failures led to opium smoking being prohibited in 1949.

The prohibition of opium smoking has, in a relatively few years, transformed Hong Kong's problem with opium smoking into a problem with heroin which is much easier to smuggle and conceal. Most addicts use heroin by one of three methods of inhalation: the "ack ack," "chasing the dragon" and "playing the mouth organ." The first of these involves smoking a cigarette held vertically with heroin on its tip; the second consists of inhaling heroin fumes from tinfoil on which the drug is heated; the third involves inhaling with the aid of a matchbox held to the mouth.

Imports

Hong Kong serves both as a final market and a transshipment point for opium produced in the Far East. Large quantities of opium, estimated at over 100 tons annually, are smuggled into the crown colony. The large addict population, estimated at 150,000, consumes most of the opium although some is available for further refinement and eventual export.

There is substantial evidence that the traffic into and through Hong Kong is increasing. In the first three months of 1971 alone, over four tons of opium were seized in Hong Kong Harbor. Officials believe that most if not all of these seizures were shipped from Thailand, although certainly not all were manufactured in that country. Curiously, the price of opium declined after the large seizures, indicating stockpiling.

Large amounts of morphine are also being transported into Hong Kong. Most morphine blocks are refined into Number 4 heroin in

one of the estimated 50 factories and exported. Unlike opium, most morphine comes into Hong Kong via airplane through the use of body packs. A single courier can carry as much as eight kilograms on his person. Today, Number 4 heroin sells for \$117 per ounce and \$4,000 per kilogram in Hong Kong, compared with \$2,100 per kilo only a few months ago.

The most frequent means of importing heroin is by trawlers originating in Vietnam and Thailand. Opiates usually are transferred from these trawlers to junks outside Hong Kong harbor before British officials are able to inspect the ships themselves. This compounds the already tedious task of inspection: from 10,000 to 12,000 junks are located in the harbor. The junk will transport its opium to the Kowloon beach where the cargo is given to Chinese couriers who easily disappear into the dense Chinese population. Subcommittee members were advised that more than twelve trawlers made such trips during July, 1971.

British narcotics officials in Hong Kong feel strongly that the Government of Thailand does very little to stop the flow of opiate traffic in that country. Despite their efforts (including the search of 90,000 pieces of cargo last year), the British feel that their labors are wasted unless the Thai government becomes more cooperative.

Hong Kong refineries

Recent evidence indicates that over 50 refineries are presently in operation in Hong Kong. It is estimated that only 15 refineries are necessary to support the habits of the local populace. The British have located two refineries within the past two months.

Although the understaffed Hong Kong police are able to catch couriers on occasion, their efforts to develop evidence against processors have thus far been fruitless. There is strong evidence that processors are members of Mafia-like Chinese families whose operations are impregnable by non-family members. Reportedly, they never come into contact with heroin themselves but use agents, most of whom do not know their identity.

There is some indication that Hong Kong bargirls were providing heroin to American servicemen on leave from Vietnam while it was a sanctioned R & R center.

Exports from Hong Kong

Opiates are transported from Hong Kong principally to the United States, South Vietnam, Australia, Taiwan and the Philippines. Most shipments are by body packs.

The British are scarcely interested in shipments from Hong Kong—they consider such shipments the problem of the recipients.

BNDD activity

As in Thailand, the BNDD is attached to the American Embassy. Although Hong Kong ranks as the world's busiest "middleman" in heroin traffic, U.S. support of BNDD efforts to arrest the flow lags. A recent request for five additional agents and two clerks has not been granted, despite the fact that our Hong Kong agent had been doing his own typing as late as January of this year.

JAPAN

Background

Prior to World War II Japan was perhaps the only country in the Far East without a drug problem. Following the war, however, Japan was found to have an illicit drug traffic equal to other victim countries. Interestingly, the United States established in occupied Japan a system of narcotics control closely modeled after the American version. Japanese narcotics squads were organized and trained in American techniques of enforcement and new legislation was enacted which was based on United States laws. Shortly after the war, Japan's addict population, which consisted primarily of young urban males, soared.

Present programs

Japan has won a decisive victory over drug abuse. The number of heroin addicts—estimated at 40,000 in 1961—has declined to only one-fourth of that number, according to Japanese authorities.

Several programs of the Japanese government provide a partial explanation of the phenomenon. Japanese narcotics officials credit strict enforcement of importation restrictions, severe laws for use of opiates (including capital punishment for trafficking) and an excellent educational program as reasons for their success. While these factors undoubtedly have contributed to the decline in hard drug abuse, three other reasons appear to have affected the Japanese addict population more directly. One is Japan's program of compulsory hospitalization of narcotic offenders, which combines medical, sociological and psychiatric treatment. Methadone is not used during treatment. The maximum required treatment period is six months; the average length of stay is 50 days. Japanese narcotics officials report the recidivism rate to be extremely low, but follow-up studies do not include urinalysis testing.

A second reason is the relative lack of procedural legal guarantees afforded suspected criminals in Japan, when compared to the United States practice. A criminal suspect in Japan is not released from custody until indicted; an indictment is not required until the 23d day following arrest. During this period many criminal addicts are forced to undergo withdrawal without medical treatment.

Perhaps the principal reason for Japan's apparent success in combating narcotic drug abuse is cultural in nature. When the Japanese government mounted a campaign against drug abuse in the early 1960's, its use became distasteful to the country's homogeneous, disciplined people. An opium abuser became a social outcast.

A BNDD agent alternates between Tokyo, which is a transshipment point and refining location for opiates, and Okinawa, where the United States Marine Corps is reported to be experiencing a major drug addiction crisis. As in other Far East countries, BNDD officials in Tokyo are dependent upon the American Embassy for support. Embassy personnel in Tokyo apparently view drug abuse as a secondary concern and relations between BNDD and Embassy officials appear strained.

SUBCOMMITTEE RECOMMENDATIONS

The following recommendations are based on personal impressions of subcommittee members as a result of the Far East visit. They are not intended to be inclusive, nor do they necessarily constitute legislative judgments to be included in the drug abuse bill scheduled to be reported by the subcommittee within the next few weeks. They do, however, represent recommendations by members who have become convinced that the drug abuse problem in this country and among our servicemen stationed overseas has reached a critical stage, and that actions such as those outlined below must be taken immediately.

1. That our government urge the United Nations to take firm action requesting the governments of Thailand, Laos and Burma to take more positive steps to combat the growth of the poppy in those countries. Specific requests to Secretary General U Thant of Burma are recommended.

2. That highly trained BNDD and customs officials familiar with the language of the country to which they are assigned be stationed in every major city in the Far East through which drug traffic passes as soon as possible and that these agents have only one major city within their assigned area. Several additional BNDD agents should immediately be assigned to Thailand, Hong Kong and the Republic of Vietnam.

3. That Department of State should immediately review and take appropriate action with respect to the \$1.193 million request of the Illicit Drug Control Committee submitted through the United States Embassy in Thailand.

4. That a massive air photo detection program be immediately initiated in coordination with the parent nations over Burma, Laos and Thailand, and in any event prior to the 1972 harvest. The detection program should be directed at locating both refineries and poppy fields. Specific locations should be immediately reported to appropriate BNDD officials. Reports of the extent of poppy growth in this area should be made public.

5. That in cooperation with Thai narcotics officials, flexible checkpoints should be established along the Mae Sai-Bangkok highway to deter the shipment of opiates.

6. That military postal officials in the Far East be given authority for on the spot inspection of first class mail.

7. That the Public Safety Division of USAID make modern weapons, such as the M-16 rifle, ammunition, mortars and transportation equipment available to the Thai Border Patrol.

8. That BNDD officials no longer be attached to our Embassies except for logistical support and that, to insure that every U.S. government official stationed in the Far East supports our efforts to eradicate drug traffic in these countries, one government official be given total responsibility for all efforts of BNDD, USAID, other State Department agencies, the Bureau of Customs and other agencies responsible for the drug control effort in all Far East countries. This official should be a member of the Special Action Office on Narcotics and Drug Abuse.

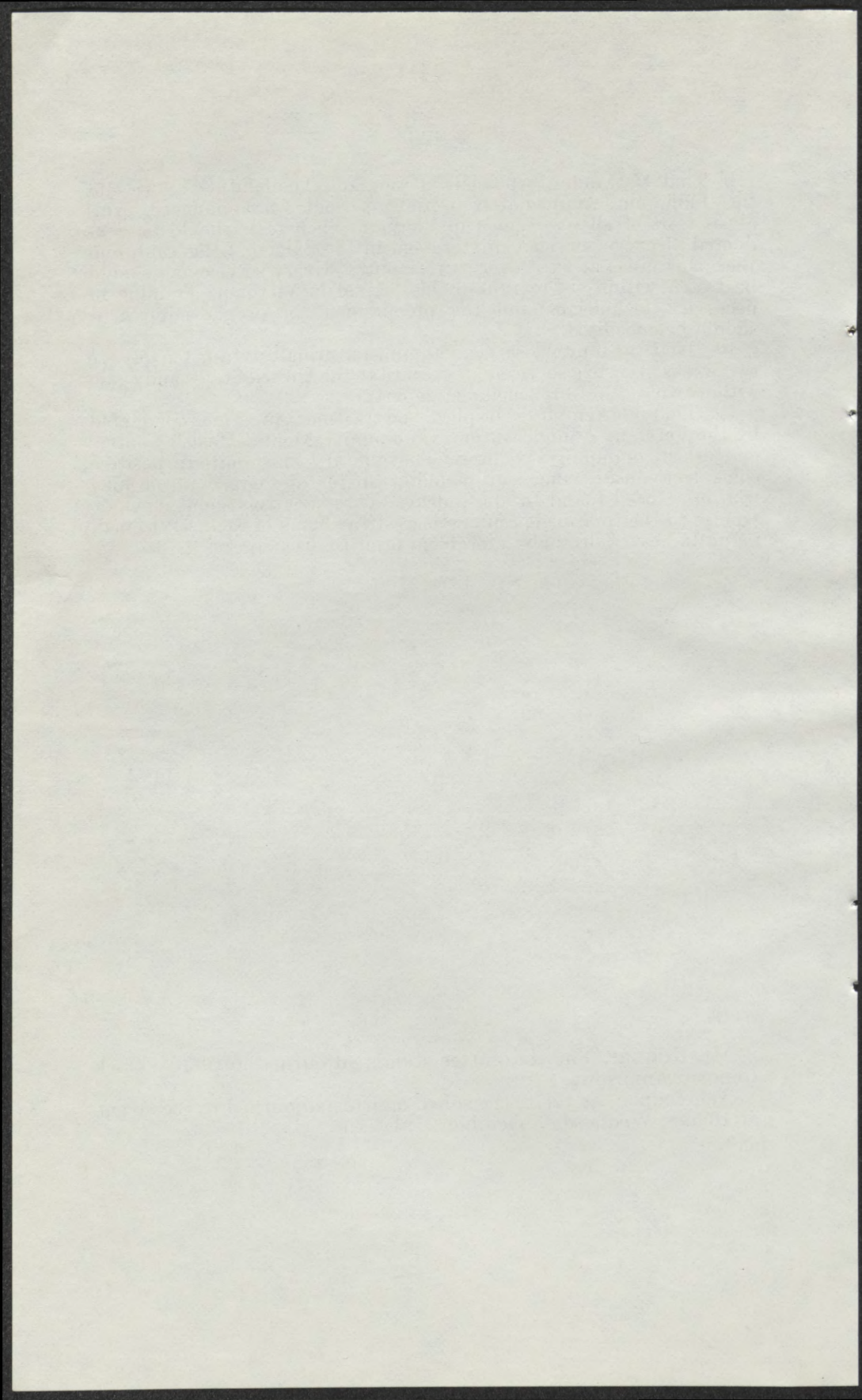
9. That U.S. military officials in Vietnam, Thailand, Okinawa and the Philippines immediately initiate periodic, unannounced urinalysis tests of all servicemen in Vietnam. Such tests should be conducted of every serviceman stationed in the Saigon, Long Binh and Bien Hoa areas at least every two months. Every serviceman should be tested within six months of his arrival in Vietnam. Training of necessary technicians and the procurement of proper equipment should be expedited.

10. That the military services administer urinalysis tests ten days to two weeks prior to a serviceman's return to the United States and again within two days of his scheduled departure.

11. That more emphasis be placed on treatment programs conducted by the Veterans Administration, Community Mental Health Centers and other community facilities. The military must initiate positive controls to insure an accurate follow-up for discharged servicemen who have been found to abuse drugs. These controls should include reports to the treatment centers nearest the home of each serviceman found to have a drug abuse problem prior to discharge.

Mr. ROGERS. The committee stands adjourned until 10 o'clock tomorrow morning.

(Whereupon, at 12:15, the subcommittee adjourned to reconvene at 10 a.m. Wednesday, October 27, 1971.)



SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION

WEDNESDAY, OCTOBER 27, 1971

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND ENVIRONMENT,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to notice in room 2322, Rayburn House Office Building, Hon. Paul G. Rogers (chairman) presiding.

Mr. ROGERS. The subcommittee will come to order. We are continuing hearings on legislation to establish a Special Action Office for Drug Abuse Prevention, and we are also looking into the closing of the Fort Worth Clinical Center.

We have as our first witness today Dr. Jerome Jaffe, Special Consultant to the President for Narcotics and Dangerous Drugs.

We welcome you again to the committee, Dr. Jaffe.

As I understand it you are not going to make a statement but simply be available for questioning.

**STATEMENT OF DR. JEROME H. JAFFE, SPECIAL CONSULTANT TO
THE PRESIDENT FOR NARCOTICS AND DANGEROUS DRUGS, EX-
ECUTIVE OFFICE OF THE PRESIDENT; ACCOMPANIED BY PAUL L.
PERITO, GENERAL COUNSEL AND ASSISTANT DIRECTOR**

Dr. JAFFE. I can make a brief comment.

As I understand it, Mr. Chairman, the primary focus of this hearing is to discuss the Fort Worth Clinical Center and the decision to transfer that to operate as a center under the Bureau of Prisons for the rehabilitation of individuals who are Federal prisoners who are also drug addicts.

That decision was made prior to my becoming a member of the Federal Government but I think, in all candor, I should tell you that I chaired a committee of nongovernmental experts who were familiar with the field of drug addiction sometime last November. One of the issues we took up was the role of Lexington and Fort Worth. It was the unanimous feeling of that committee that, given the progress made in the field of rehabilitation of drug addiction, the continued operation of a large center such as Fort Worth, where people were away from their communities for prolonged periods and then sent back with no linkage, was no longer justifiable but that kind of rehabilitation is best accomplished in the community for people who have not otherwise been convicted of crimes.

So, I can say, although I did not participate in the decision to transfer Fort Worth, had I been in the Federal Government, I would probably have participated heartily and endorsed it if not initiated it.

Mr. ROGERS. Thank you.

According to the letter signed by the Attorney General and Secretary of HEW, you approved the closing of Fort Worth.

Dr. JAFFE. I never approved any closing. We approved a transfer of that facility which will continue to operate in the same physical plant, and which will have a major focus on working with prisoner addicts. If it is being closed, that is news to me. It is my understanding it continues to operate.

Mr. ROGERS. But closed to clinical research as had previously been done and to take care of the public, NARA people.

Dr. JAFFE. As I understood it, the demand for space for civil commitment had fallen off appreciably. There was sufficient capacity at Lexington and, furthermore, the facility had been closed to the public in terms of voluntary patients since 1966. It had been available only as a civil commitment facility and, with respect to clinical research, that was largely a euphemism. In fact, no research I know of has ever emanated from that facility.

One cannot conduct research on people who are civilly committed unless one spends years building up that kind of imminent staff to make the research worthwhile.

Mr. ROGERS. That is not the testimony we received at Fort Worth when we visited there. Have you ever visited the facility?

Dr. JAFFE. I have seen the facility. I have never been within it, per se. I am familiar with Lexington and the layout is similar.

Mr. ROGERS. But you have never been in the Fort Worth facility?

Dr. JAFFE. That is correct.

Mr. ROGERS. Because the testimony was that they have done research there. Particularly the psychiatrist, I believe, who was from Fort Worth or Dallas went into that in some detail.

Dr. JAFFE. As I said, I have looked for the reports of their research and the literature. They have not appeared. I have not seen any evidence of that research.

Mr. ROGERS. What is the inpatient capacity presently of our facilities that are federally run for the NARA program?

Dr. JAFFE. If you ask for the NARA program, I cannot give you a specific figure. It is continuously changing as people write new contracts. I can say that we do not know, in all honesty, the total Federal capacity for inpatients in the entire United States, let alone NARA. Our first step, when we were created, was to modify a contract which was designed to conduct a survey of the 6,000 known treatment programs in the United States so that it would at least give us some estimate of the capacity for inpatients, for residential care and for outpatients. This had not been part of the original contract. That contract was finally signed several weeks ago in its modified form and, hopefully, within several months we can report to you on what our inpatient capacity in this country is.

Mr. ROGERS. HEW testified yesterday that they had 100 slots where they could treat people. In other words, they could treat 1,000 people with inpatient care.

Dr. JAFFE. 1,000 slots?

Mr. ROGERS. 1,000; not beds but that they could take care of that many people during the year.

Dr. JAFFE. That sounds a little bit on the low side.

Mr. Chairman, I have no specific figures but in my travels I am aware that our residential capacity in this country is really that of many thousands of available slots. How many people you can treat in a year is a function of how long you elect to keep them in residential status. If you keep them 1 month you can turn over 12 times and treat 12,000 people. If you elect to keep them 6 months you can treat 2,000. These are somewhat arbitrary figures.

Mr. ROGERS. This is what they provided for, as I understand it, 1,000.

Take New Orleans, we want to be specific. They have 15 beds for inpatient treatment. They have an addict population estimated to be 6,000. Now, is that a sufficient inpatient treatment?

Dr. JAFFE. Are you referring specifically to civilly committed people or voluntary patients?

Mr. ROGERS. Both.

Dr. JAFFE. It is important to make a distinction.

Mr. ROGERS. Why? Don't they both have to have inpatient treatment?

Dr. JAFFE. No; not necessarily. I do not know where the 15 figure comes from.

Mr. ROGERS. It comes from the Tulane Hospital facility.

Dr. JAFFE. This is the same for both voluntary and civil commitment?

Mr. ROGERS. It is the only inpatient treatment center.

Dr. JAFFE. If we had had those figures, we would have suggested to the various funding agencies that residential capacity be expanded in that area.

I think, as you know, we have been working on a reasonable formula. Speaking with people around the country we have tried to determine what ratio of residential beds one needs to handle a particular subgroup of patients. In general, it is between 10 and 18 percent residential capacity at any given time, which would mean if they had several thousand people in treatment at a given time, they may need more than 100 or 200 beds.

Mr. ROGERS. This is my concern.

Dr. JAFFE. It is my concern, too, sir.

Mr. ROGERS. That you close Fort Worth when there are no beds available in New Orleans.

Dr. JAFFE. There is no waiting list for Fort Worth. The waiting list is in New Orleans.

Mr. ROGERS. Do you know why there is no waiting list in Fort Worth?

Dr. JAFFE. Because it is obliged to take people only under civil commitment.

Mr. ROGERS. More than that. Do you know why?

This is a letter written by HEW telling the judges not to send people to Fort Worth. Surely you are aware of that?

Dr. JAFFE. That was not the case in 1967 and 1968.

Mr. ROGERS. They did it in 1967, too, when they were trying to close it out. Now they sent them out again. They released those who were civilly committed at Fort Worth on the 8th of October and they sent

a letter to the district attorney in New Orleans that day and he gets the letter on the 12th without any opportunity for him to make any judgment or decision.

All of them were released on the 8th. I presume you did not necessarily approve that procedure?

Dr. JAFFE. No, sir; I was not aware of the decision or the details or how they had planned to make the transfer from HEW to the Bureau of Prisons.

Mr. ROGERS. That was pretty amazing that all of a sudden they decided they can all be released at once.

Dr. JAFFE. Not amazing but——

Mr. ROGERS. Unusual.

Did your office do any checking as to those people as to their——

Dr. JAFFE. My office does not have sufficient authority to check on anything. As you know, we have no legislative authority and it is extremely difficult for us to recruit the staff we originally projected. Now we can participate in making policy. We have no way of finding out if that policy is being adhered to or even whether the details are followed up. We have to rely on whatever information comes back to us.

Mr. ROGERS. How large an office do you anticipate having if the legislation is passed?

Dr. JAFFE. Sixty professionals and 60 support people.

Mr. ROGERS. 120 people.

Dr. JAFFE. That was the original projection.

Mr. ROGERS. You presently have what?

Dr. JAFFE. Somewhere around 60 but many of those are detailees who, in fact, are not fully trained. They are there to help us answer inquiries and letters. The professionals we have that can be considered sufficiently trained and experienced to participate in these policy decisions in a meaningful way number only about 30 people. So we really cannot accept responsibility for appropriate implementation of any rational policy that we have been able to make.

Mr. ROGERS. Even though you are the Special Assistant to the President?

Dr. JAFFE. A Special Assistant to the President can only participate in policymaking.

Mr. ROGERS. You can give some pretty strong directives, can't you?

Dr. JAFFE. In general. I don't think one should give a directive that you cannot back up or follow up.

Mr. ROGERS. You are speaking for the President. Are you saying now you would not have sufficient authority, being in the White House?

Dr. JAFFE. I think policymaking is always something that is a gray area between policy and operations. We have preferred in some instances to wait to see the intent of Congress, to see where they will draw the lines between policy and operations and what that authority is.

Mr. ROGERS. What did the President give you as your charge when he made you Special Assistant? It was an office it was not necessary to have legislation for.

Dr. JAFFE. He specifically gave us the responsibility of formulating and developing policy which, as I understand, is as far as we can go.

Mr. ROGERS. I presume that policy once made is enforced by the Office of Management and Budget; isn't it?

Dr. JAFFE. I was not aware that the Office of Management and Budget was an enforcement agency.

Mr. ROGERS. Then you have a lot to learn. I would say it is the most effective enforcement agency the President has.

Dr. JAFFE. It can do certain things.

Mr. ROGERS. You even have to clear statements with the Office of Management and Budget before you come to Congress.

Dr. JAFFE. That is one of the policies.

Mr. ROGERS. That is the way they enforce it. Surely you know that.

Dr. JAFFE. I was aware of that, sir.

The fact is there is not sufficient staff to monitor the details of the transfer of a facility from one agency to another. Those operational kinds of activities and that particular operation proceeded between HEW and the Bureau of Prisons. Many of the things that you are telling me perhaps would have found their way to me in due course, but are now being brought to my attention for the first time.

Mr. ROGERS. Well, I realize that and hope you can check into this. For instance, we had information that these people that have been released just automatically on that night, when the Senate and House did not agree, they went ahead with the transfer, not taking proper steps to let people know in the communities. Coming back, New Orleans is a good example. As a result these people were just thrown out. The evidence is that about one-third have already turned back to drugs immediately and one guy is even pushing in New Orleans.

Dr. JAFFE. I would like to comment on that in general. This kind of general behavior indicates the difficulty in bridging the gap between a man's home community and a hospital that may be several hundred miles away. It has been a problem which has been recognized by people in the field for many years. Even if an individual received letters, phone calls, personal visits, it does not necessarily guarantee that you can take him from Fort Worth and have him feel part of another organization back in his hometown.

This was part of the consideration that caused them to say this model could not work with efficacy. These relapses can be expected under optimal conditions. There is the tendency of people with this particular problem, when they return to the community, not to seek help, not to feel part of it.

We can use the military analogy in the sense that at one time Fort Worth and Lexington were the battleships of our attack on this problem but, like battleships in general, they have served their time. There are better approaches, more effective, more modern, perhaps with more impact, and I do not think that it is any more reasonable to expect HEW to keep operating a battleship than to ask the Navy. There are perhaps some that would like to continue operating battleships. Most people feel they in fact belong in mothballs. I think in this particular situation, most people who worked in the field felt this large hospital based on civil commitment, hundreds of miles from most people's homes with no real linkage does not tend to produce the kinds of results that we could expect from facilities in the community where people have a feeling, where they have already a job, hopefully, that they have been helped to get by the people working with them while they are still in residential care.

This linkage back at home makes it easier for them to succeed or, being very realistic about it, when they fail—because we are talking about a chronic relapsing disorder—when they fail you can get them back into treatment rather quickly. Nobody wants to get back to Fort Worth rather quickly because it represented to them a period of months—and you used the term—“they viewed themselves as prisoners too.” They were civilly committed. They are called patients but from their point of view, they felt like prisoners.

They were taken away from their homes into a facility that had bars. They were not permitted the kind of privileges and family interactions that are most typical of a general hospital and, consequently, nobody says, “I am not doing so well, please send me back to Fort Worth.”

These are the things that went into the decision to say, “This is a facility better suited to prisoners than people who have committed no crime.”

Mr. ROGERS. Do you know where they go in northern Virginia now?

Dr. JAFFE. Not as yet, sir.

Mr. ROGERS. I will tell you, They go to Alexandria from all northern Virginia. They are taken out of their communities and sent there. Do you realize that?

Dr. JAFFE. Well—

Mr. ROGERS. And there are certain places in California—they are not established in every community, so this idea of saying that everybody is going to be in their own little community is just not realistic.

Dr. JAFFE. Their own little community is not what I am saying. They should be sufficiently close so that one can maintain contacts with one's family and get back and forth. I can only say to you that California has also had some problems with its large facility at Corona.

The same problem of continuity has developed, these kinds of problems have evolved, and I think they are also moving toward community facilities.

Mr. ROGERS. Let me ask you this, are you saying then that when you have a hard addict, you do not have to have any secured area, that there must be an interplay between all of the people, all of the people he was associated with?

Dr. JAFFE. I am not saying that.

Mr. ROGERS. Of course, you have to have a secured area if you are going to get him off drugs or he is going to have someone passing him drugs, or that is the experience.

Dr. JAFFE. Drug free and secured are two different terms. I think if you visited facilities, community mental health centers, general hospitals, places like Synanon, Daytop Village, these are not secured areas. They have no bars. Generally the level of drug use within those facilities is as low—I am not saying they are always entirely drug free but it is as low as in any local jail.

Mr. ROGERS. But not in a secured treatment center. Surely you are not telling us that. We just visited them, where they say they do keep a secured area because otherwise they do not make progress in getting him off his drugs.

Dr. JAFFE. The issue, you see, is they feel they make a great deal of progress getting him off his drugs but, if he returns within a week

or two, or a month, the man is back on his drug, then perhaps they have invested poorly in terms of—

Mr. ROGERS. Of course, you have to give him followup treatment, which is what you are saying, in the community. But at some point you have to get him away from the drugs to get him off of it, I think; don't you? This is the experience we have seen.

Dr. JAFFE. The issue is whether or not one has to develop highly secured, lockup-type facilities to get people away from their drugs.

Mr. ROGERS. I don't know how you want to typify them but the fact is you have to have some secured areas. Whether you want to call them drug free or not, you do not allow drugs in there and there must be some way to prevent those drugs from getting in. Isn't this true?

Dr. JAFFE. Generally that can be accomplished in smaller units.

Mr. ROGERS. I understand that but it also can be accomplished in large units such as Arthur Kill, in New York.

Dr. JAFFE. Yes; it can.

Mr. ROGERS. Such as Lexington. Do you now propose to close Lexington?

Dr. JAFFE. No, sir.

Mr. ROGERS. Why not?

Dr. JAFFE. Lexington can accomplish some useful clinical research.

Mr. ROGERS. So could Fort Worth if you put the staff there. But when you tear down the staff it can't.

Dr. JAFFE. I understand the staff was there for a number of years, several decades, and I really think we should look at the total research output of that facility over the last decade.

Mr. ROGERS. That is simply because they did not demand it then.

Dr. JAFFE. Research is not something you demand. Research is something that evolves.

Mr. ROGERS. There is no point in arguing that. You either give them something to do or you don't. There is no point in that.

I will come back.

Mr. CARTER?

Mr. CARTER. If I might say, we might well be, some of us—not particularly me, because I don't feel that way—might be fighting for really a lost cause, a cause that has already gone by the board.

What is the capacity of Fort Worth Hospital at the present time? What was it?

Dr. JAFFE. Well, in 1961 its capacity was approaching 800.

Mr. CARTER. I believe it is about 600 at the present time. How many patients were in that hospital, do you remember?

Dr. JAFFE. I was told there were roughly 200 about 6 months ago.

Mr. CARTER. I would say 2 weeks ago from 200 to 300. How many addicts are there in the United States at the present time?

Dr. JAFFE. The estimates range to 250,000.

Mr. CARTER. From 250,000 to 365,000. So that as a place for treatment, it really does not amount to much considering the entire addict population throughout the country; does it?

Dr. JAFFE. I don't think it is significant.

Mr. CARTER. Actually at capacity it would provide only 12 beds for each of our States; is that not correct?

Dr. JAFFE. That calculation has been made.

Mr. CARTER. Really, it is just minuscule; it would present just a

minuscule effort in comparison to what we have throughout our country. Over the years the theory of treating the addict in his community has been developed, has it not, and in our mental health centers which have been funded throughout our country, isn't that true, that in almost every community a certain number of beds are allocated for treatment of these patients? Is that correct?

Dr. JAFFE. I think the tendency is to have communities get involved.

Mr. CARTER. Years ago we had committed beds even back in the mountains of Kentucky for patients for this. And that is the theory on which you wish to work; is it not?

Dr. JAFFE. In general; yes, sir.

Mr. CARTER. You will have a small mental health facility to which these people go. You have psychiatrists who visit there and who treat them in their local neighborhoods; is that not correct?

Dr. JAFFE. Yes, sir.

Mr. CARTER. Otherwise if we had to incarcerate every addict in the country, we would have to build institutions like Fort Worth in every State, not just one institution in Texas and one in Kentucky, but we would have to have them everywhere; wouldn't we? Why have we gotten away from this idea of treating addicts in Fort Worth?

Dr. JAFFE. Because, looking at the end of the year, at the end of the period of treatment, the results have not been overwhelmingly gratifying.

Mr. CARTER. What has been the rate of recidivism at Fort Worth and at Lexington?

Dr. JAFFE. I cannot tell you the Fort Worth figures. I assume the figures at Lexington are comparable.

Mr. CARTER. It approaches 90-percent recidivism; doesn't it?

Dr. JAFFE. Yes, sir.

Mr. CARTER. I hope they have done a better job at Fort Worth.

Since they turned these people out only a third of them have returned to addiction; is that correct? According to statements we heard here today that is correct.

Dr. JAFFE. The question is over what period of time. If a third have relapsed in a matter of 3 months, you can be certain that the other two-thirds may relapse in the next year and one-half.

Mr. CARTER. Really it has not amounted to too much, has it? I think that without doubt the right action has been taken. We on this committee should attempt to be part of the solution and not part of the problem. As far as I am concerned I mean to support you in every way I can to try to help to get authorization for your funds because we know we need coordination in the various areas for treatment of addiction.

There is no doubt but what you are well qualified, as is shown by your record. I feel that as a committee, this is a great problem we are facing and we should all get with it and get your authorization and try to help you.

Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Symington?

Mr. SYMINGTON. Thank you, Mr. Chairman.

Dr. Jaffe, there is a conflict in opinion, apparently, between you and Dr. Brown who testified yesterday concerning these 29 newly re-

addicted patients from Fort Worth because in response to our questions, Dr. Brown said that that was a rather high figure, one-third, because they quickly take a drug when they get home but after they have had a chance to find themselves again, the figure will drop. They will get a job and so forth, whereas you have said the figure will increase, be likely to increase.

How do you explain this difference?

Dr. JAFFE. It is a matter of semantics and knowing the precise terminology we are using. If one really understands the terminology, there really is no conflict whatsoever. If your definition of unsuccessful treatment is that within a period of time people try drugs once or twice, then I would guess that the number who will try over the next year, the percentage of the group released will increase.

On the other hand, to try a drug is not to become totally addicted or to relapse totally to the life-style that resulted in the civil commitment. In fact these people who have tried may not all do poorly. They may get linked up to a treatment program. They may change their life style and they may stop using the drug altogether long before they move from experiment taking back to total relapse.

If that seems complicated, it is because the field is complicated. But without question the people who have been designated here as failures would not necessarily be viewed as failures. They have not in fact returned to the status they achieved prior to going into Fort Worth.

To the extent some of them are working, their health is better, experimenting once may be risky for them but they still have many of the gains they have achieved. Some of them may do well. Some of them inevitably will relapse and, hopefully, they will be worked into a full-fledged, widespread community program so they can get treatment when this happens.

But the number who will have experimented before the year is out in the group that left will increase unless they have some secret formula at Fort Worth that has not come to our attention.

Mr. SYMINGTON. Let me try to get it straight in my own mind.

Dr. Brown said that of the 90 who were released on October 8, evidence showed that 29 had experimented, had abused drugs. I said I thought that figure was rather high. It indicated perhaps they should have stayed in a little longer. He said, "Not at all. Although it seems high, it will drop. Of those 29 people, some or most or perhaps all of them will in due course, or may well in due course be off drugs."

You have said that it is more likely that the number will increase.

Dr. JAFFE. Of the 89 a larger percentage over time will at some point experiment. In other words, at some point 2 years from now it may be that 90 percent of the 89 will have experimented. So that percentage will increase.

If you are asking what happens to the 29 who thus far within a matter of weeks after their discharge have abused drugs, that does not mean they are readdicted. What will happen with time, there are a number of possibilities. Some in fact will become readdicted, others will in fact stop experimenting and develop a reasonable life style.

Mr. ROGERS. Would the gentleman yield?

Dr. JAFFE. I don't think Dr. Brown and I have any fundamental disagreement on that.

Mr. ROGERS. That is pretty much the pattern of the Nation, I guess; isn't it, this type of thing? Isn't that what you are saying?

Dr. JAFFE. No; duration of sojourn in a facility such as Fort Worth does not guarantee that an individual will not experiment with drugs after release and even an infinitely prolonged sojourn does not offer that guarantee.

Mr. ROGERS. That is true with any treatment center; isn't it?

Dr. JAFFE. Yes.

Mr. ROGERS. Well, of course.

Dr. JAFFE. Yes, it is.

Mr. ROGERS. So community treatment does not improve that situation?

Dr. JAFFE. Community treatment would never make that claim.

Mr. ROGERS. We are not at the state of the art where we can do that.

I thank the gentleman for yielding.

Mr. SYMINGTON. Dr. Brown also testified that after a year's treatment in a facility such as Fort Worth and Lexington, the probabilities were much stronger that the released patient would hold down a job and resume normal life style. Do you concur with that?

Dr. JAFFE. I have not seen that data.

Mr. SYMINGTON. You are not prepared to accept that?

Dr. JAFFE. I would be willing to examine his data in its context and then to comment on it but I am not aware that any controlled comparisons have been carried out with respect to duration of hospitalization so that one could talk about the relationship between duration of inpatient treatment and later adjustment.

Mr. ROGERS. If there is no study, then how can you make judgments that hospitalization is not a proper approach?

Dr. JAFFE. I did not say hospitalization is not a proper approach. We plan to have residential facilities all over the country.

Mr. ROGERS. What did you say, you said long hospitalization?

Dr. JAFFE. I said our data based on prisons, based on every general consensus is that it is difficult to demonstrate that whether somebody stays a month, 2 months, 3 months or 4 months, the prolongation, per se, if it were carried out in a reasonable way, would in fact affect the outcome.

Thus far most data is derived from people who have elected to stay 1, 2, 3, and 4 months. That is not a controlled study because obviously you are dealing with someone who is motivated to stay longer.

Mr. ROGERS. So you are saying we really do not know?

Dr. JAFFE. I am saying after 30 years nobody did those studies. They had ample opportunity.

Mr. ROGERS. So we do not know?

Dr. JAFFE. But our general impression is, if you kept people 3 years, chances are it would not be much better than if we kept them one.

Mr. ROGERS. We do not know that.

Dr. JAFFE. There are lots of things we don't know. That is among them.

Mr. SYMINGTON. You say the information is derived from people who elect to stay 2, 3, or 4 months?

Dr. JAFFE. Or from prisoners.

Mr. SYMINGTON. I would have thought that—let's stick with the people who elect to stay because you have described Fort Worth's

environment as one which people would like to leave. On the other hand, if you are deriving your information from those who elect to stay, it is clear they prefer to stay for that period of time rather than leave, so that would appear to contradict your suggestion that the first thing they want to do when they arrive is to get out. They want to get cured, don't they, as much as possible?

Dr. JAFFE. I think that it is important that we do not make inappropriate generalizations. Lexington used to admit 8,000 people a year. A certain number of them were attempting to avoid being arrested back in New York or Chicago. They may have elected to stay 6 weeks because they thought their situation would cool a little better. It is not that they loved Lexington more, but they loved Chicago less.

Now the example, therefore, is not that the place was particularly attractive for them. Many did want to leave at first. On the other hand, there were a number who were sincerely interested in helping themselves and felt they would take the advice of the doctors there and stay a few months. There were others—there were physicians who were told to go and stay until the doctor said, "you are now fully cured," which is usually 4 months and 15 days, or they could not get their license back. They elected to stay because they knew somebody back home said if they left 1 day before, they would not be able to practice. There were all kinds of situations which make it almost impossible to make adequate inferences from different durations of stay. What happened later, what they do is they look at durations of stay. There does not seem to be any correlation in general with how people stayed and what happened later because they had multiple reasons for staying as long as they did.

Many came resolved to stay several months. They got a call from home that some business thing was not going well and they left after 2 weeks.

There were those who left after 2 days who originally came fully resolved to stay several months.

Mr. SYMINGTON. What makes me curious is these broad areas of doubts that are unresolved, nevertheless, you were able to come down firmly on one conclusion, that is, that Fort Worth is no longer necessary.

Dr. JAFFE. We were able to decide that to take someone several hundred miles from home and hope to see him fully integrated into another program later was not the best way to proceed.

Mr. SYMINGTON. And you were able to make that decision for roughly a potential figure of 250 or more thousand addicts, following Dr. Carter's line of questioning. You don't even need a few hundred beds for certain special cases, for certain kinds of clinical research in an environment such as Fort Worth. That you do not need at all, you are sure of that?

Dr. JAFFE. We are certain that in that particular environment the kind of research that needs to be done will probably not evolve.

If you are asking if we need beds for civilly committed patients, the answer is probably. It depends on to what extent local prosecutors use civil commitment.

NIMH has been evolving the capacity to handle the civil commitment. The residential phase of it is carried out closer to a person's home. The idea being when somebody has a problem after the resi-

dential phase, if the alternative is to go back to some place miles from home and be isolated from all the people he knows in a rather strange and hostile environment, as he perceives it, or evade the detection of his problem, he will evade the detection in which case treatment is not realistically available.

Mr. SYMINGTON. I am not sure that we are thinking of Fort Worth as a place to send the recurring addict because perhaps he is a one-time visitor and then, if he cannot manage it when he gets home, as hoped, then he can be sent to a nearer place. But that is not a justification for not taking one swing at it in a more isolated environment where treatment will be intensified without any emanations from the neighborhood.

I am surprised to think that you are that sure that even a one-time visit is useless for everyone of the 250,000 addicts.

Dr. JAFFE. I am not really sure of the direction of your comment. Are you saying that based on the results that they have achieved over the last 30 years, we should perpetuate it indefinitely?

What does a unit have to do to convince reputable people that it is not the most efficacious way to proceed? I am concerned, as a physician, if we continue to stay there—can we be certain, for example, that leeches are not the best approach to rheumatoid arthritis?

Maybe it is good for some one of 100,000 people. At some point we have to say, "we looked at it. It does not seem to be the best way."

There were many treatments we thought were good in the beginning. Maybe they are good for some rare individual. Perhaps magic boxes with blinking lights will cure cancer in some rare cases, but since we cannot tell for how many it will work because it does not seem to work for many people, we should put that talent and resources into places that will make it more probable that people with a relapsing disease will get back into treatment.

We have no guarantee there is not a selected group that will benefit from it. We are just trying to make the best judgments without any consideration of other ramifications.

What is good for the patients? We think it is better to have residential facilities close to home.

Mr. SYMINGTON. What is the distinguishing rationale for closing Fort Worth and not closing Lexington, another "battleship"?

Dr. JAFFE. To be entirely candid, some of the best research that has ever been done has come out of Lexington in some of these areas. There is the Addiction Research Center, which is a distinguished group of people within the same building that had influenced—

Mr. SYMINGTON. Does that continue to be useful?

Dr. JAFFE. The history of this is interesting. As you know, at one point only the Addiction Research Center was a division of NIMH but the Lexington Center was a division of the Public Health Service. Two different staffs administratively reported in two different ways, although they were both within HEW.

Gradually both were absorbed within NIMH. I think the relationship might be more useful now. When I was there Lexington trained most of the people that are still in the field. I think there is still the potential that given the eminent scientists who are at the Addiction Research Center, given the kind of experience it has, that good clinical research may evolve.

But if we were to talk about the question of, is it there purely for treatment, the answer would have to be, if we can make those same beds—let us say 500 of them—if we can have 50 available in every State which brings us to 2,500 beds, then I guess it would be difficult to justify Lexington as a hospital on the basis of its treatment capacity except as it pertains to the immediate vicinity. On the other hand, because of its contiguity with a fine group of researchers, and I know some of them, and the history of that group is known to the world, some of the most eminent people in the world studied and did their work there, there is still some hope that good clinical research will come out of Lexington. They have an opportunity to make themselves a track record over the next few years.

Mr. SYMINGTON. A track record?

Dr. JAFFE. Yes, sir.

Mr. SYMINGTON. You mean in suggesting forms of cure or treatment? What kind of track record?

Dr. JAFFE. There is a wide range of things, in looking at things such as what is the relationship, arbitrarily, between length of hospitalization and later follow up. These are obvious kinds of things that a clinician might elect to study so we could have some answers a year from now.

Mr. SYMINGTON. Then you are not defending Lexington on the ground that it has patients there?

I won't argue that with you. You are defending it on the ground that it is a valuable source of clinical research.

Dr. JAFFE. For the time being, as I understand it, under the 1966 act people can still be committed to the Federal Government, and so we must have a clinical resource.

As I recall, Lexington has a flexible capacity which could go up, as it did at one time when I was there, to 1,200 people. Sometimes it shrinks down but the fact is as long as that law is on the books and as long as there are not community resources where people can get residential care, there has to be a unit somewhere that can receive people that are civilly committed. Lexington fills that role.

Whether or not in several years, with increasing residential capacity throughout the country, we will still require a Federal facility to do that is not clear at this time.

Mr. SYMINGTON. Just looking at the facility from the point of view of their contributions to clinical research, we have been told in fields such as cancer that there is a benefit to be derived from a multiplicity of clinical centers where competing ideas can be tested and where they are not all under the philosophy of one particular group or individual.

Here we are only talking about two in a drug world and the drug scene seems as complicated to me as any other health problem. So, from a clinical point of view, I would have thought one more would have made a valuable contribution to your clinical findings, properly staffed and equipped.

Dr. JAFFE. The judgment was made by groups of people who had only the best interests of the country and the patient population before them. The decision was made that much more would come out if you took those 200 beds—if you had 30 of them at five or six different medical centers and, in fact, achieve even greater diversity.

Mr. SYMINGTON. Without the intensity of treatment and of experience that you would receive in one facility.

Dr. JAFFE. I don't think filling 300 beds in one place necessarily makes for intense treatment or intense care.

Mr. SYMINGTON. I am talking about the intensity of the experience, that is the interaction between the staff, the learning experience of the institution.

Dr. JAFFE. Are you postulating that to have 500 patients and a large staff in one place guarantees a greater intensity than having a group of 30?

Mr. SYMINGTON. I am only taking your own argument in favor of Lexington—I am only saying if Lexington is good, how about one more?

Dr. JAFFE. Lexington is good because Lexington has been good. What you are really saying is that no matter how poorly something performs, we are to maintain it forever. If we were to work on this idea with respect to the work of research grants, somebody would get a grant once in his life, never produce any particular research of value but we would always give it to him on the idea that some day something will come out of it.

Mr. SYMINGTON. That is a new objection that has not been put with such force before. The reason we are closing Fort Worth is that it has done a bad job.

Dr. JAFFE. If it was doing a fine job, we would not be discussing it. It has not produced clinical research that merits the size of the investment, nor is it suited, 30 or 40 years after it was built, as the best treatment operation.

Mr. SYMINGTON. But the question remains, is there a job to do? By stating it has done a bad job, you imply a good job might have been done. I think what the committee is interested in is why shouldn't we try to get a good job done?

Dr. JAFFE. We are trying to get a good job done across the entire United States and you are saying, if we have to get a good job done, it should be done in Fort Worth.

Mr. ROGERS. Dr. Jaffe, as a matter of fact, recidivism from Lexington has been the same as at Fort Worth.

Dr. JAFFE. Are you suggesting we should close Lexington?

Mr. ROGERS. With your argument, yes. They have not done such a great job. You know the record. So you know the same argument prevails. That is what the Congressmen are saying.

To say it has been so glorious in their record—

Dr. JAFFE. I did not say their treatment record was glorious.

Mr. CARTER. On that very thing you are stating that actually Lexington has excelled in research; is that not correct?

Dr. JAFFE. That is correct.

Mr. CARTER. That Fort Worth has not?

Dr. JAFFE. To the best of my knowledge—

Mr. CARTER. And, therefore, Lexington should be continued for that reason and with that I would agree.

Thank you, Mr. Chairman.

Mr. ROGERS. They are not putting into practice all this great research, if you have 90-percent recidivism.

Mr. Hastings?

Mr. HASTINGS. Thank you, Mr. Chairman.

Doctor, I would like to continue my questions on the same non-partisan basis as this committee is noted for and redirect the questioning perhaps to Fort Worth. I don't know; I am not sure we are not beating a dead horse.

As I understand, the facility is closed as of today. There has been a suggestion that perhaps there could have been contracts from your office or HEW to continue some rehabilitative efforts at Fort Worth. Were you ever part of any discussions along those lines?

Dr. JAFFE. No; I was not.

Mr. HASTINGS. Would you have any recommendation to make that perhaps the facility could be used as a treatment center, outpatient perhaps, even at this time?

Dr. JAFFE. The placement of treatment facilities for a given community has been largely determined and carried out by the various agencies that have been trying to develop facilities. There are at least six or seven of them.

I would think that would be the decision of HEW. I know they have looked into Fort Worth-Dallas area to develop treatment facilities for the local community. But I do not know what their negotiations have been with the Bureau of Prisons which now is operating the Fort Worth facility.

Mr. HASTINGS. Will your office, once it is fully established, statutorily given authority, be able to make those decisions as to where contracts may be made? Will you have some influence?

Dr. JAFFE. I think, ultimately, we would have considerable influence but that depends on the statutory authority which is put into the bill.

Mr. HASTINGS. In other words, you might be saying, too, that if the Congress got on with it and passed this legislation that gave you that necessary authority you could consider that question.

Dr. JAFFE. I think you would be in a better position to hang the albatross around our neck than you are now. Now we make policy and we cannot accept the responsibility for the actual decisions made. We have neither the staff nor the statutory authority to do it.

At the same time, depending on what has been put in the bill, you could say what is done there is our responsibility.

Mr. HASTINGS. As the bill is presently constituted, would you have that authority at some time?

Dr. JAFFE. Yes.

Mr. HASTINGS. So, if Congress does, in fact, pass the bill, you could have made a decision in relation to a contract at Fort Worth?

Dr. JAFFE. Yes.

Mr. HASTINGS. One other question on a different approach.

I am very interested in methadone, as I know you are. Could you tell me what the current status of methadone is in the NDA and NFDA?

Dr. JAFFE. It would take a long time but I can try to summarize it.

It is clear, as Mr. Symington points out, that even those things that seem least valuable to some may be valuable to some select group. In fact, methadone is neither a panacea nor a cruel and dangerous hoax, it is a useful medication for some groups of drug users. It will take us time to know which group will benefit most.

Mr. HASTINGS. I am interested in what is the current status of NDA and FDA.

Dr. JAFFE. We are trying to evolve regulations to move it from IND to NDA. The process we want to prevent is abuse, which could happen if we turn it loose as a prescription drug available to every physician regardless of his background and training.

Mr. HASTINGS. Will that take a statutory change?

Dr. JAFFE. It may ultimately take a statutory change to have the full range of options to prevent abuses.

On the other hand, within the NDA there may be mechanisms that we can get moving rather quickly that will permit us to make the treatment available and do so in a controlled way.

Mr. HASTINGS. This is precisely my concern. I have some reason to believe that this NDA will be approved before the end of this year and I am absolutely sure there will be no time for change in statute to give us the necessary controls and I certainly would hope that there are the administrative capabilities.

Dr. JAFFE. Our office is working with FDA and BNDD as well as the AMA and other groups trying to come up with the best transition from a research to a treatment approach while providing in this transition, within the NDA itself, those safeguards that we feel are necessary. We are looking toward a way of determining what additional legislation may be required to prevent the abuses that have emerged over the last few years in the course of using this drug.

Mr. HASTINGS. At the time of approval, can we be sure every doctor in this country will not have the capability of prescribing methadone at will?

Dr. JAFFE. Yes, sir, without question.

Mr. HASTINGS. I did not mean to divert my questions but this is an extremely important one.

Thank you very much.

Mr. ROGERS. Mr. Roy?

Mr. ROY. I am just curious about one thing. You say there are long lists of names of distinguished and eminent scientists that have trained at Lexington?

Dr. JAFFE. Yes, sir.

Mr. ROY. When we were at Fort Worth they told us the same thing about their facility. Is it true at Fort Worth?

I cannot recall the names.

Dr. JAFFE. It may well be. I am not familiar with the names of the Fort Worth people but I do know the names of the Lexington people. It may well be that the Lexington facility was once used as a residency training program for the Public Health Service and that many of the people who came there are now the people who are most active in the field and are most likely to dedicate their professional activities to moving things along.

Mr. ROY. This, as I recall, was the statement that was made to us. Do the VA hospitals have the same problem of isolation and distance that you speak about in regard to Lexington and Fort Worth?

Dr. JAFFE. Some do. There are a lot of them. Obviously the ones that are directly in a community do not have that problem. Those that are located at great distances from where people live certainly will have that problem.

I am not sure that the argument that I applied here will not apply to distant VA hospitals. The point is, this is not an argument that is directed merely to Fort Worth.

If you look at California, you will find that California has closed down major mental hospitals that are located at great distances from where people live, moving these services to the community. This has been done in almost every State so this is not an isolated instance. The entire thrust of mental health is to move it from distant far off hospitals closer to the community. This is only a special instance of what is a general trend and there are many throughout this country, many large buildings, that are no longer used, not because somebody does not feel that more buildings are needed but just because in an earlier era they put them in the wrong places and made them too big. They could not anticipate the technological and attitudinal changes that would come about 40 years later.

These hospitals were built in 1930 and many things have changed.

Mr. Roy. Where are the addicts for Fort Worth-Dallas area being treated?

Dr. JAFFE. There is a community mental health center in Dallas. Contracts have been let in the Dallas area.

In the Fort Worth area negotiations have been going on for several months. We have a series of correspondence for that particular area.

HEW has made it a high priority to develop adequate resources for that community, and the means for that purpose have been sequestered.

Mr. Roy. You probably put your finger on what has puzzled me about the thing; that we are pulling the rug out from under one institution when we have not yet developed institutions to replace it in any sense of the word; have we?

Dr. JAFFE. I cannot tell you whether as of this moment in time many institutions are functioning precisely there. But to talk about a 400- or 500-bed facility when the number of residential beds needed to serve Fort Worth may be 15 or 20, or 30—Dallas has a very different problem and they do have some facilities going. I think that we can provide those materials for you if Dr. Brown does not have them, but I am sure he has the same materials I do.

(The following information was received for the record:)

AGENCIES WORKING AT PRESENT IN NARCOTIC ADDICTION AND DRUG
ABUSE IN THE DALLAS, TEX. AREA

The following agencies are working in narcotic addiction and drug abuse in Dallas, Texas.

A. A NARA contract with the Dallas Rehabilitation Agency to handle 30 evaluations for suitability of treatment, 50 in-patients and 40 aftercare patients.

B. The South Dallas YMCA has a prevention and education program.

C. The Shindo House of the American Services Foundation has an intake and short term counseling with room and board for seeing about 30 persons per day.

D. The Dallas Mental Health Retardation Agency has a methadone maintenance program which is predominantly a drinking station. Currently 45 patients are on methadone in this program. The Agency wants methadone maintenance but does not wish to give ancillary services.

All agencies have been contacted to determine their interests in working with addicts. Five groups have expressed some interest. These are predominantly ministerial groups. None have come forward to submit applications. The Shindo House of the American Services Foundation did submit an application which is under review. It would appear that as long as the CRC is open, few agencies in the Dallas area are interested in undertaking the treatment of drug abusers.

We do not believe that there is any OEO money or LEAA money in Dallas related to drugs.

Staff will continue to work in the area to see if a competent agency can put together a reasonable treatment protocol for funding our auspices.

Fort Worth, located 30 miles from Dallas, the Mental Health and Mental Retardation Center at Fort Worth is interested in coming in under P. L. 91-513 for funding. LEAA money has been involved in the prevention and education program. The latter is up for refunding but it is doubtful that it will be refunded.

NIMH staff has met with all agencies through the Drug Council in Fort Worth and we have had no "takers" apart from a recent expression of interest by the Mental Health and Mental Retardation Board. This is being actively pursued.

NARA has a NARA contract with the Family Services. They handle 30 E & E and 40 aftercare patients under this program. Fort Worth in-patient care under NARA is handled in Dallas.

Mr. ROY. I want to ask one question. Is anything happening as far as the military getting their addicts into VA hospitals? I visited a veteran's hospital, as many of us did, and I find relatively large facilities in a VA hospital. With nine patients, two of them were heroin addicts. I said to the director, "Has anybody said anything to you about addicts that have been located in bases close by"? He said, "We had a couple of calls. We had had no communication."

Dr. JAFFE. As you know the directive we put out that this would be done has been in effect for about a month. I cannot tell you what has been done. We do not have the staff to follow-up. We will wait until things filter up to us. We cannot, without the necessary personnel and authority, go and find out what happens.

We did recognize this. We talked about it before and we have taken whatever steps are within our purview to see that people do have the option either of staying in the military or being transferred to VA hospitals, but those are the only options available now.

Mr. ROY. Nothing has happened as far as 20 beds in Topeka?

Dr. JAFFE. That leaves only 31 facilities I do not know about.

Mr. ROY. Thank you.

Dr. JAFFE. I have some major appointments that have been on my calendar for months with your fellow Congressmen that I should try to keep. If there are some other questions—

Mr. ROGERS. I knew you did have to leave at 11 and it is a little past 11. There are other questions I would like to go into. I will try to do it in writing or else by telephone.

I am anxious to know about what you feel on enforcing, what authorities your office should have on enforcement, on the international scene, on the military.

Dr. JAFFE. We can answer that in writing or on the telephone, sir.

Mr. ROGERS. I think that would be helpful.

There are other questions, too, but I won't pursue them at this time.

Thank you for being here, Dr. Jaffe, and Mr. Perito. It has been a pleasure to have you.

Our next witness is Mr. Eugene Rossides, Assistant Secretary of the Treasury for Enforcement and Operations.

STATEMENT OF EUGENE T. ROSSIDES, ASSISTANT SECRETARY (ENFORCEMENT, TARIFF AND TRADE AFFAIRS, AND OPERATIONS), DEPARTMENT OF THE TREASURY

Mr. ROSSIDES. Mr. Chairman and members of the committee, I welcome the opportunity to appear before you during your consideration of the President's proposal for the creation of a Special Action Office for Drug Abuse Prevention to recommend urgently the passage

of the legislation and to discuss Treasury's role in the President's overall antidrug abuse program.

The problem of drug abuse and particularly heroin abuse was not created overnight, and it will not be cured overnight. The drug problem of the 1950's became the drug crisis of the 1960's. It will take hard work and cooperative effort in the 1970's by many groups on the Federal, State, and local levels to win this battle.

The program which the President announced June 17, which includes the legislation to establish the Special Action Office for Drug Abuse Prevention, was another major step in an overall program.

Early in his administration the President moved on several fronts with a multidimensional action program:

First, he elevated the drug problem to the foreign policy level and has taken personal initiatives in soliciting the cooperation of other governments.

Second, he placed particular emphasis on the crucial role of education, research, and rehabilitation and provided increased funds and emphasis in these essential areas even before the recommendations in his June 17 message.

Third, he recommended differentiation in the criminal penalty structure between heroin and marihuana; and flexible provisions for handling first offenders.

Fourth, he provided a substantial increase in budgetary support for Federal law enforcement in this area.

Fifth, he recognized the central role of the States and the need for close Federal-State cooperation in a unified drive against drug abuse; and

Sixth, he stressed total community involvement—the private sector as well as governmental agencies—in this antidrug abuse drive.

In that program we saw for the first time not only the total involvement of the institution of the Presidency in the battle against drug abuse, but also the personal involvement of the President. The legislation now before you to create the Special Action Office as a part of the Office of the President again demonstrates that intense personal interest.

In my judgment this program has arrested the United States incredible downward slide into drug abuse. But, as we all realize, we have a long steep climb ahead of us to return to the level from which we fell.

Another major result of action under the President's program is that it has alerted the international community to the global problem of drug abuse. More has been done by the international community to attack drug abuse in the last 2½ years than in the previous 25.

The President has been as innovative in his attack on the drug problem as in his recent new economic policy.

FOREIGN POLICY AND PRESIDENTIAL INITIATIVE

One of the serious errors of the past was the failure to appreciate drug abuse as a worldwide problem calling for an international response. Prior to this administration, international activity by the United States was principally on the enforcement level.

President Nixon raised drug abuse to the foreign policy level at the beginning of his administration and took personal initiatives to elicit the cooperation of other governments.

The result of this major change in the approach of the executive branch was to make the Department of State, as the primary representative to foreign governments, responsible for doing everything necessary to advance our anti-drug-abuse policy through diplomacy.

Secretary of State William P. Rogers has given the highest priority and personal leadership to the Department of State's efforts in this area.

Last month the President announced creation of a Cabinet Committee on International Narcotics Control under the chairmanship of Secretary Rogers. The committee is responsible for the formulation and coordination of all policies of the Federal Government relating to the goal of curtailing and eventually eliminating the flow of illegal narcotics and dangerous drugs into the United States from abroad.

The role of the State Department in the administration's war on drugs has had a unique and important impact. Through the use of diplomacy we have achieved a substantial advance in our objectives.

The most important and dramatic diplomatic news was the joint announcement on June 30, 1971, by Prime Minister Erim of Turkey and President Nixon that Turkey has decreed that within 1 year, in accordance with the law of Turkey, the opium poppy will no longer be planted in Turkey.

We have sought to stimulate multilateral action through the United Nations. The creation of the special fund in the United Nations for action on drug abuse is an example. The United States has contributed \$1 million to this fund and has pledged a second million. We regret that the contributions from other nations have not been as great as we had hoped.

We also seek multinational support for amendments to strengthen the 1961 Single Convention on Narcotics.

The administration's diplomatic efforts have been worldwide. It is working through every available channel to find new approaches to this problem and to explore possibilities for more effective action. The President's words, in his address to the United Nations on its 25th anniversary in October 1970, sum up the problem:

It is in the world interest that the narcotics traffic be curbed. Drugs pollute the minds and bodies of our young, bring misery, violence, and human and economic waste. This scourge of drugs can be eliminated through international cooperation.

As examples of such cooperation, the United States has bilateral mutual assistance and cooperation arrangements with Canada and Mexico, because of our common borders, and with France and Turkey to control drug trafficking and smuggling.

As existing sources of supply in the Middle East are reduced or disrupted, illegal traffickers will turn increasingly to other areas of supply, such as Southeast Asia, where there is substantial illegal production of opium. The so-called golden triangle where Burma, Laos, and Thailand converge, is probably the most extensive area of illegal production, producing approximately half of the world's illicit output of opium. For years this area has been virtually beyond the control of any government.

Until fairly recently, this production was consumed entirely by East Asian addicts. However, the appearance of white, 96- to 98-percent pure heroin is a recent phenomenon aimed almost entirely at

U.S. servicemen in Vietnam. The U.S. Government, with the full cooperation of the Government of South Vietnam, is devoting major attention to bringing this problem under control.

Recently, the United States and Thailand signed a memorandum of understanding, which provides a framework for major efforts in suppressing illegal traffic in dangerous drugs. Thailand, recognizing there is a serious problem, will do what it can, and the United States will assist them in combating drug abuse, drug trafficking within and smuggling across their borders.

We are also examining, with other governments in Southeast Asia, what can be done to stop the growing traffic in heroin. To this end, an interagency antinarcotic working group chaired by the State Department, meets regularly to formulate country programs based on recommendations from embassies in the countries concerned. Similar working groups are covering geographic areas in other parts of the world.

Mr. Chairman, I know your next witness is Mr. Nelson Gross and he will give you a fuller analysis of the State Department's efforts. I would say I think we are fortunate in having the services of Mr. Gross, which recently have become available to the Department of State. He is a senior adviser on a Presidential appointee level with Secretary Rogers. In the few months he has been onboard, he has made a difference.

EDUCATION, RESEARCH, AND REHABILITATION

The proposal for the creation of the Special Action Office for Drug Abuse Prevention which you are now considering is, of course, an important development concerning effort in the fields of education, research, and rehabilitation. It is a major intensification of effort in an area which previously has received substantial attention.

The drug abuse problem has long been recognized as one of both supply and demand, and President Nixon's response has been guided accordingly. While we are working to eliminate the supply at the sources, to stop the smuggling of illicit drugs into the United States, and to stop the distribution of illicit drugs internally, eliminating the demand for drugs among our young is also central to success.

The key to eliminating the demand for drugs lies in education. The vast majority of youth, when given access to the facts, will reject drug abuse as against their own self-interest as well as against the interest of their Nation.

President Nixon is convinced that much of our problem is attributable to the mass of misinformation and street corner mythology which has filled the vacuum left by our failure in the past to deal with the young on a mature, reasoned and factual basis. In the past, our Government took the easy but ineffective route of "do as I say because I say so" rather than the more difficult route of clearly presenting the facts necessary for informed decision.

In his June 17, 1971, message, which included the recommendation for the creation of the Special Action Office, President Nixon stressed "reclamation of the drug user himself," and requested congressional approval of a total of \$105 million in addition to funds already contained in the fiscal year 1972 budget to be used solely for the treatment

and rehabilitation of drug-addicted individuals. He asked the Congress to provide an additional \$10 million in funds to increase and improve education and training in the field of dangerous drugs. This will increase the money available for education and training to more than \$24 million. This will be the muscle that the Special Action Office will bring to bear on the problem.

DIFFERENTIATION IN PENALTY STRUCTURE AND FLEXIBLE PROVISIONS FOR HANDLING FIRST OFFENDERS

President Nixon realized that the provisions concerning penalties in the laws in effect before the passage of the Controlled Dangerous Substances Act of 1970 had created substantial problems of credibility in dealing with the youth of our country. Treating marihuana as though it were the same as heroin created serious problems in convincing young people who were conditioned to be skeptical of all established programs that there was any logic or reason in the attack on drug abuse. The minimum mandatory penalties created serious problems for prosecutor and judges dealing with first offenders.

The President proposed, and the Congress adopted changes in the penalty structure which for the first time provided a reasonable distinction between narcotic drugs and marihuana and provided the courts needed flexibility in dealing with the first offender. The courts were granted authority to clean the slate on the first offender by striking from the record mention of the first offense without adjudication of guilt.

LAW ENFORCEMENT

Drug law enforcement is a difficult and dangerous business. It demands the highest standards of professional competence of enforcement agents. President Nixon has increased substantially the budgets of the two Federal agencies primarily concerned with drug law enforcement—the Bureau of Narcotics and Dangerous Drugs of the Department of Justice and the Treasury's Bureau of Customs—and has initiated a major new Treasury enforcement program of tax investigations by the Internal Revenue Service of middle and upper echelon narcotics traffickers. I will discuss the Treasury programs later.

CENTRAL ROLE OF THE STATES AND FEDERAL-STATE COOPERATION

Federal-State cooperation is one of the essential elements for success in the struggle against drug abuse. This administration is working closely with the States to bring this about. Except for certain areas of special Federal interest, law enforcement and our educational system have been and must continue as essentially State and local responsibilities.

The States must continue to be responsible for and must increase their activities in the areas of enforcement of State and local laws, education and rehabilitation. The Federal Government has worked with the States to help them carry out their responsibilities in these areas. Substantial funds for these purposes have been made available through the Law Enforcement Assistance Administration. Some States, not-

ably New York and California, have done excellent work in these fields, but in most States only the very beginnings of the attack that will be necessary have been made.

President Nixon emphasized Federal-State cooperation in his message to Congress of July 14, 1969, on control of narcotics and dangerous drugs, again at the Governors' conference on drugs at the White House held in December 1969, and again in his message to the Congress of June 17, 1971.

ACTION WITHIN THE PRIVATE SECTOR

The President has stressed that the private sector must provide community leadership in organizing drug abuse education and other action programs. Religious organizations and community and civic groups such as Rotary, Kiwanis, Chamber of Commerce, and Jaycees are best equipped to get directly into the home where they can assist parents in handling the problem of drug abuse with intelligence and credibility. Effects of the President's program to get private persons and groups involved in the attack on the drug problem are being seen and felt. I personally experienced it several times recently in meetings with community groups.

TREASURY'S ROLE IN THE PRESIDENT'S ANTIHEROIN ACTION PROGRAM

On the Federal level, several departments of government have made excellent strides in narcotics enforcement. I would like to highlight to you Treasury's part in the President's program.

Treasury is playing a major role in the President's antiheroin action program. The President appointed Secretary Connally to the Cabinet Committee for International Narcotic Control, with its broad mandate for action.

In the enforcement area, Treasury's Bureau of Customs, the Nation's first line of defense against heroin smuggling, has achieved spectacular success. The Internal Revenue Service is embarked on a major Presidential program designed to take the profit out of dealings in narcotics and thus further disrupt the traffic.

BUREAU OF CUSTOMS

In his September 16, 1968, Anaheim, Calif., speech the President stated:

Let us recognize that the frontiers of the United States are the primary responsibility of the United States Bureau of Customs. I recommend that we triple the number of customs agents in this country from 331 to 1,000.

The President followed through on that pledge and more. In his July 14, 1969, message to the Congress on the control of narcotics and dangerous drugs, he stated:

The Department of the Treasury, through the Bureau of Customs, is charged with enforcing the nation's smuggling laws. I have directed the Secretary of Treasury to initiate a major new effort to guard the nation's borders and ports against the growing volume of narcotics from abroad. There is a recognized need for more men and facilities in the Bureau of Customs to carry out this directive.

This directive was backed up with a substantial antinarcotic supplemental budget request. The Congress responded with full bipartisan support in December of 1969 by passing an appropriation for \$8.75 million for 915 additional men and for equipment for Customs.

The hiring of these people, begun in January 1970, and completed in June of that year, has produced remarkable results.

CUSTOMS SEIZURES

In a 2-year period the quantities and the number of narcotic and drug seizures by customs has more than doubled. Most dramatic is the increase in seizures of hard drugs which in fiscal year 1971 totaled over 1,200 pounds, far in excess of the amount seized in the preceding 7-year period.

Customs seizures of marihuana increased substantially and seizures of hashish in fiscal year 1971 totaled more than 3,000 pounds, nearly twice the amount seized the preceding year.

Over 6 million 5-grain units of dangerous drugs such as amphetamines and barbiturates were seized during fiscal year 1971. This is about one-half the number of units seized last fiscal year, although the number of seizures increased to 1,553 from 1,080. A chart setting forth customs drug seizure for the past 3 fiscal years is attached. (Attachment 1, see p. 1471.)

The new personnel hired by customs in the last half of fiscal year 1970 completed their training in the first part of fiscal year 1971. The effects of these additional customs employees began to appear in the second quarter of fiscal year 1971. The effect is most dramatically evident in the statistics for customs' seizures during the first three quarters of this calendar year.

Preliminary figures for heroin seized in the first 9 months of 1971 show more than 1,000 pounds compared to 26 pounds seized in the comparable period in calendar 1970, an increase of almost 4,000 percent. During the last year seizures of pure heroin by customs have included:

Ninety-eight pounds (October 1970—Miami); 210 pounds (December 1970—Miami); 58 pounds (January 1971—San Juan, Puerto Rico); 98 pounds (April 1971—Newark); 155 pounds (May 1971—Miami); 246 pounds (May 1971—San Juan); 156 pounds (July 1971—New York) 24 pounds (August 1971—Laredo); 186 pounds (September 1971—New York), and 69 pounds (September 1971—Miami).

We in Treasury feel that these seizures directly support the education and rehabilitation work that will be coordinated by the Special Action Office.

We feel that these huge seizures of heroin in addition to causing appreciable financial losses to the traffickers who owned the seized contraband, has had some effect on the supply. Obviously, it is impossible to obtain completely reliable statistics on any part of this illegal traffic. However, there are some indications that the supply has been affected.

The men and women of the Bureau of Customs, under the dynamic leadership of Commissioner Myles J. Ambrose, deserve enormous credit for these outstanding accomplishments.

These results took dedication, imagination, and total commitment of forces. Let me mention some of the things customs has done with the resources provided by Congress for this drive:

In 6 months after the first supplemental appropriation became available customs added 915 trained personnel to its staff. These included an increment of inspectors who were able for the first time to give priority attention to checking for narcotics enforcement purposes persons, vehicles, cargo, and mail entering the country. A substantial addition to our force of special agents enabled us to run down intelligence leads, investigate violations of the smuggling laws and gather evidence for the convictions of those apprehended.

CADPIN, from the initial letters of Customs Automated Data Processing of Intelligence, has been installed across the country. One hundred and sixty terminals, located at every important port of entry along the Mexican-United States border, at major international airports, and at various intelligence centers now have access to Cadpin's huge data bank. Merely by punching the keys of this terminal, the inspector on duty at a border crossing or an airport can obtain an almost instantaneous reply if a car or person is suspected of smuggling, the car is stolen, or the person is the subject of an outstanding warrant.

Customs' communications system has been expanded and modernized, with better radios, repeater stations, and sector communications centers. Physical equipment, particularly cars, boats, and planes, both fixed-wing and helicopters, have been increased, giving customs agents the tools with which to deal rapidly and responsively with smugglers and their syndicates.

Additional customs stations have been opened. Two of these are in the remote Big Bend area of Texas, a favorite section of the border for smugglers.

New laboratories, to provide rapid identification of narcotic and dangerous substances, now speed the judicial processing of violators.

The use of dogs specially trained to locate marihuana in cars or in mail packages entering the country has been greatly increased, and they are now making substantial contributions in intercepting that substance as it enters the country.

Early this spring, U.S. Customs instituted a 100 percent examination of all APO mail, parcel post, and household effects of military personnel from South Vietnam and Thailand. A joint Customs-military group is in place in Vietnam and is examining all personnel being rotated back to the United States.

A joint Customs-DOD program for examining all APO mail, parcel post, and household effects shipped from South Vietnam is being developed. We are working toward extending it to the entire Far East.

EXPANDED CUSTOMS PROGRAM—1971

The President, in his program announced on June 17, 1971, recognized these accomplishments of Customs and proposed a budget amendment of \$18 million to maximize Customs' demonstrated capabilities in interdicting the flow of drugs into the United States. This amendment funded major additions to equipment and 1,000 additional personnel.

The Congress, with bipartisan support, authorized \$15 million and the Appropriations Subcommittees stated they would entertain a supplemental request after use of the \$15 million. The Congress acted swiftly, passing the appropriation bill on June 30.

The effects of these additional resources will be felt from the New York docks to the Florida airports, from the marinas of southern California to sod airfields in the State of Washington, and along the lengths of the Mexican and Canadian borders. They will yield better enforcement at border crossings without increased delays.

The additional funds also provide for major equipment additions, principally aircraft and boats, with appropriate detection systems for both new craft and those in current inventory. The current intelligence indications of extensive smuggling by unscheduled planes and boats create this substantial need for detection, communication, and interception resource. These will have particular impact along the Mexican border and against small craft making end runs into southern California, Florida, and Texas.

A substantial amount of the equipment to be acquired from this increase in the fiscal year 1972 appropriation has already been delivered. It is being adapted for operations at this time.

Preliminary experimentation has indicated that it will be of substantial value. In fact some minor cases have already been made. I wish I could go into details, because the methods used are fascinating. But a large part of their success will depend on keeping the smugglers from knowing how the equipment will function.

CUSTOMS-TO-CUSTOMS COOPERATION

As one part of the anti-drug-smuggling program, designed to disrupt the traffic in drugs between countries, Treasury early in this administration established the policy of fostering and strengthening cooperation between and among the customs services of the various countries. The Bureau of Customs was directed to put the policy into effect.

The first Customs-to-Customs contacts, and the ones that have resulted in the most cooperation, have been with our neighbors to the north and south. In discussions with the Governments of Mexico and Canada we have improved cooperation in the attack on the drug traffic through Customs-to-Customs cooperation.

Applying the policy of increased Customs-to-Customs cooperation to a wider area, the Treasury Department obtained authorization and appropriations for U.S. Customs to become a full member of the Customs Cooperation Council. This is an organization of the Customs Services of more than 60 nations. Its purpose is to foster close working relationships between and among these services.

At its annual meeting in Vienna in June of this year this Council adopted a resolution calling for its member countries to exchange information on illicit traffic in narcotic drugs and psychotropic substances. A copy of that resolution is attached (attachment 2, see p. 1471). Previously, the customs services of many countries had paid little attention to the drug traffic.

The Bureau of Customs has an ongoing program, sponsored through AID, with the Vietnamese customs service. This has been helpful to the Government of Vietnam in its efforts to stem smuggling of heroin into the country as well as to combat black marketing. The Bureau is also preparing plans for technical assistance to the customs services of other countries in Southeast Asia. Specific proposals are being submitted to the Governments of Thailand and Laos to improve the capabilities of indigenous customs antismuggling operations along the borders of those countries.

As part of this ongoing program of full cooperation among the customs services, the Commissioner of Customs recently made an on-spot survey and talked with his counterparts in Yugoslavia, Bulgaria, Czechoslovakia, and Hungary. In these contacts, the resolution adopted at Vienna for the exchange of information on the drug traffic was the stepping stone for talks on increased action against drug traffic by the customs services of each of these countries against the flow of opium and morphine base from Turkey to Western Europe. Recently, within the last few weeks, customs representatives from Eastern Europe and the U.S.S.R. met to discuss problems of transit trafficking in narcotics in that area.

PROGRAM FOR TAX INVESTIGATIONS OF MAJOR NARCOTICS TRAFFICKERS

Included in the June 17, 1971, Presidential message, which announced the administration's expanded effort to combat the menace of drug abuse, is a high priority program to conduct systematic tax investigations of middle- and upper-echelon narcotics traffickers, smugglers and financiers. These are the people who are generally insulated from the daily operations of the drug traffic through a chain of intermediaries. This program will mount a nationally coordinated effort to disrupt the narcotics distribution system by intensive tax investigations of these key figures. By utilizing the civil and criminal tax laws, our objective is to prosecute violators and to drastically reduce the profits of this criminal activity by attacking the illegal revenues of the narcotics trade.

Reflecting the high priority given this program by the President, Congress has provided financial support for the program amounting to \$7.5 million in fiscal 1972 and authorization for 541 additional positions—200 special agents, 200 revenue agents, and 141 support personnel.

Certain major features of this program should be noted:

(1) Treasury will not only coordinate its efforts with all other interested Federal agencies, but will actively seek the maximum cooperation of State and local enforcement agencies as well. This is a vital feature of this program;

(2) With the manpower provided, our goal is to have at least 400 full-scale ongoing IRS investigations;

(3) In line with the high priority given this program by the President, the Internal Revenue Service has already assigned more than 100 experienced special agents and more than 100 experienced revenue agents, full time to this program. Additional experienced agents are presently being phased into the program.

We believe that this program will make a major additional contribution to the President's offensive against drug abuse.

INTERPOL

The International Criminal Police Organization (INTERPOL) plays an important role in providing the mechanism for cooperation and the exchange of information among the law enforcement agencies of all member nations. Earlier this year, the United Nations recognized Interpol as an intergovernmental organization enabling the two bodies to share and exchange information on narcotic production, trafficking, and consumption as well as providing funds from the Special Fund for Interpol to initiate a narcotic training program for police throughout the world.

As chairman of the U.S. Delegation to the last three annual Interpol general assemblies, and as vice president on the executive committee of the organization, I have urged Interpol vigorously to continue its initiative in sharpening the world enforcement agencies' focus on the international narcotic problem at these forums. At the last general assembly held in Ottawa this past September the organization approved resolutions urging severe prison sentences on traffickers; recommended the strengthening of measures designed to eliminate the illegal cultivation of cannabis; urged that licit opium poppy crops be progressively limited and subsequently eliminated; and urged that the young be educated to the direct and indirect dangers of consumption of cannabis and its derivatives.

In closing, I would like to express Treasury's appreciation of the bipartisan support that the Congress has given the Treasury programs. We realize that this is only a part of the tremendous contribution of the Congress to the attack on the drug abuse problem. The hearings that this committee and others have held have been of great value in gathering the information on drug abuse and organizing it in an understandable manner. Of equal and perhaps greater value has been the effort of those hearings in making the citizens of the country aware of the extent and the nature of the problem, and in enlisting their support for the attempts to solve it.

I want to express our personal thanks for the support and swift action of the Appropriations Subcommittees of the House and Senate in approving the amendment to the Treasury appropriation bill for fiscal year 1972 which made the funds for the new increased programs promptly available to us. This was made possible under the leadership of Chairman Tom Steed and Congressman Howard W. Robison in the House and of Chairman Joseph M. Montoya and Senator J. Caleb Boggs in the Senate.

I assure you that all the personnel in Treasury will do their utmost to express that appreciation in the way I know that each Member of the Congress wants it to be expressed—in the most effective possible attack on the illicit heroin traffic.

Thank you, Mr. Chairman.

(The attachments referred to follow:)

ATTACHMENT 1

DRUG SEIZURES BY FISCAL YEAR—TREASURY DEPARTMENT, BUREAU OF CUSTOMS

	1969		1970		1971	
	Seizures	Pounds	Seizures	Pounds	Seizures	Pounds
Heroin.....	240	311	203	45.5	503	937.11
Cocaine.....	42	(1)	88	109.0	176	360.42
Opium.....	186	34	42	21.0	141	38.19
Hashish.....	2,673	623	646	3,122.0	1,335	3,162.76
Marijuana.....	630	57,164	4,113	2,522.0	5,953	2,882.2
Dangerous drugs.....	253	4,763,361	1,080	12,271,000.0	1,553	6,309,922.0
Other.....	253	199	335	255	255	47.82
Total (seizures).....	4,024		6,507		9,916	

¹ Cocaine figures for 1969 included in the "other" column.

² Tons.

³ 5 grain units.

ATTACHMENT 2

BRUSSELS, June 29, 1971.

RECOMMENDATIONS OF THE CUSTOMS CO-OPERATION COUNCIL ON THE SPONTANEOUS EXCHANGE OF INFORMATION CONCERNING ILLICIT TRAFFIC IN NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES, JUNE 8, 1971

The Customs Co-operation Council, considering that abuse of narcotic drugs and psychotropic substances constitutes a danger to public health and is prejudicial to Members' economic and social interests;

Considering that the illicit international traffic in narcotic drugs and psychotropic substances is a major contribution to the illegal supply of such substances in many countries;

Taking note of the Single Convention on Narcotic Drugs (New York, 30th March 1961) and of the Convention on Psychotropic Substances (Vienna, 21st February 1971), both drawn up under the auspices of the United Nations;

Having regard to the Recommendation of 5th December 1953 of the Customs Co-operation Council on Mutual Administrative Assistance;

Having regard to the Resolution of 7th June 1967 of the Customs Co-operation Council concerning the prevention of illicit traffic in narcotics, stimulants and similar substances;

Considering that action to combat illicit international traffic in narcotic drugs and psychotropic substances can be rendered even more effective by the spontaneous exchange of information between Customs Administrations;

Recommends to Members that their Customs Administration should spontaneously and without delay communicate to other Customs Administrations which may be directly or indirectly concerned any available information concerning: (1) operations which are known or suspected to constitute, or which seem likely to give rise, to illicit traffic in narcotic drugs or psychotropic substances, (2) persons known to be engaged in or suspected of engaging in operations referred to in paragraph 1, and vehicles, ships, aircraft and other means of transport used, or suspected of being used, for such operations, (3) new means or methods used for illicit traffic in narcotic drugs and psychotropic substances, and (4) products which are newly developed or used as narcotic drugs or psychotropic substances and which are the subject of illicit traffic;

Points out that this exchange of information should be conducted in such a way as to reinforce the activities of the other authorities competent to take action against the abuse of narcotic drugs and psychotropic substances.

Invites Members to consider the possibility of concluding bilateral or multilateral agreements with a view to intensifying action to combat illicit traffic in narcotic drugs and psychotropic substances. Such agreements might be based on the Council's model bilateral Convention on Mutual Administrative Assistance for the prevention, investigation and repression of Customs offences.

Requests Members who accept this Recommendation to notify the Secretary General of their acceptance and of the date from which they will apply the Recommendation. The Secretary General will transmit this information to Members' Customs Administrations.

Mr. ROGERS. Thank you very much for your statement, Mr. Rossides.

(The following letter was received for the record:)

DEPARTMENT OF THE TREASURY,
Washington, D.C., November 2, 1971.

HON. PAUL G. ROGERS,
Chairman, Subcommittee on Public Health and Environment,
Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.

DEAR MR. CHAIRMAN: In my testimony to your subcommittee on October 27th, I presented preliminary statistics on heroin seizures during the first 9 months of 1971. Enclosed for submission for the record of the hearings are the final statistics on heroin and other drug seizures by the Treasury Department's Bureau of Customs during the first 9 months of 1971. 1050.97 pounds of heroin, worth about \$456 million at street prices, were seized. During the same period last year only 25.65 pounds of heroin were seized. The \$456 million figure is based on a street price of \$6 for the approximately 76 million 100 milligram doses of 5% heroin that could have been produced by the seized narcotics.

Sincerely,

EUGENE T. ROSSIDES,
Assistant Secretary.

Enclosure.

NARCOTIC AND DRUG SEIZURES 1ST 9 MONTHS OF CALENDAR YEAR 1971—TREASURY DEPARTMENT, BUREAU OF CUSTOMS

	1971	1970	Percentage change
Number of seizures:			
Heroin.....	192	400	108.33
Opium.....	63	96	52.38
Cocaine.....	93	159	70.97
Other narcotics.....	222	199	-10.36
Marihuana.....	4,761	4,623	-2.90
Hashish.....	851	1,205	41.60
Dangerous drugs.....	1,074	1,142	6.33
Total.....	7,256	7,824	7.83
Quantity in pounds:			
Heroin.....	25.65	1,050.97	3,997.35
Opium.....	22.39	42.57	90.13
Cocaine.....	137.18	102.56	-25.24
Other narcotics.....	15.86	76.04	379.45
Marihuana.....	110,191.50	143,827.74	30.53
Hashish.....	3,330.20	4,569.68	37.22
Dangerous drugs (5-grain units).....	8,449,214	3,569,315	-57.76

Mr. ROGERS. Dr. Carter?

Mr. CARTER. I want to compliment the distinguished gentleman on a very informative statement. It shows that our Government and the present administration is vitally interested in suppressing the drug traffic. It shows the worthwhile actions taken to eradicate this traffic. That is all I have to say.

Mr. ROGERS. Dr. Roy?

Mr. ROY. First let me thank you for what I would judge to be a comprehensive statement. We appreciate that.

I want to ask you about a statement on page 2.

It says, "In my judgment this program has arrested the United States incredible downward slide into drug abuse."

How can you support that statement?

Mr. ROSSIDES. I can as my own judgment, Congressman. This is a personal judgment. I believe that through the actions of the adminis-

tration, with the full support of the Congress and the activity of the Congress, combined with enforcement and education, we have definitely, in my judgment, peaked in the heroin problem.

Just as an example, my own college dean gave a report that this year there is no question of the downturn of the use of heroin on the campus. I would submit that if you called 100 colleges that the vast majority, in fact maybe much higher, would say the same thing.

Education on heroin, in my judgment, has been a crucial part of that turning point. Not just enforcement. We do not know statistics. All the statistics—forget it. There is no base and even if there is a base, you cannot say how much is getting in.

But 1,000 pounds in this 9 months, that is a fact. So there had to be an impact on the supply as well as on demand. The youth are no dopes. They are smarter than we were when we were young.

Heroin they are turning off. They are not convinced about marijuana. So it is in that general phase, Congressman.

I have heard this from a number of people but that does not mean that we do not have a long, continuing job. The only problem I had in whether I should make that statement—and I have made it for the last few months—was the possibility of complacency. I don't believe we will have that problem of complacency. This is a tough one. We have a long way to go to combat it.

Mr. ROY. I suspect you may be correct about the college campuses. Yet we continue to get figures that admissions to our jails and prisons are addicts or have evidence of using heroin.

Then we get into higher percentages if we take the entire prison population, those that are coming back for a second and third time.

You spoke of full cooperation of the government in South Vietnam with regard to this problem. What happened to the deputy that was picked up at the airport bringing in something like 8 kilos of opium from Thailand? Have these people been dealt with effectively?

Mr. ROSSIDES. I believe they have cracked down on that I might pass that to Mr. Gross. But at one point there was one official—whether he was a Deputy in the Parliament—is that what you are referring to?

Mr. ROY. Yes, sir.

Mr. ROSSIDES. I don't know what has happened since he was apprehended. I will try to find that and submit it for the record.

(The following information was received for the record:)

Most recent information indicates that the Deputy, Pham Chi Thien is being held in the Chi Hoa National Correction Center in Saigon.

Reportedly, he has not resigned from the Lower House.

Mr. ROY. You have had experience with Interpol. The other question is, why are we having such great difficulties with the laboratories in France and is any progress being made in this area?

Mr. ROSSIDES. Mr. Gross can expand on that.

I think progress is being made with France. Ambassador Watson has done a tremendous job in giving the drug problem the highest priority. I had two sessions with the Ambassador. There is no doubt in his mind this is number one priority. He worked closely with French officials in Marseille. There has been an increase in French enforcement on figures. The problem of labs is a difficult one—they are tough to find. Certainly more has to be done and hopefully it will be. The labs are easily concealable and movable.

Another greater problem, Mr. Congressman, on which there should not be any misunderstanding, is the thought that all you have to do is get labs in Marseille and it is over. The labs are not just in Marseille. They are throughout Europe. We hope there would be more pressure put on.

I think Mr. Gross could expand on that.

Mr. ROY. What is the estimate of the total number of pounds of heroin being brought into this Nation at the present time to meet the needs of 250,000 to 300,000 addicts?

Mr. ROSSIDES. I do not know. I have seen the estimates of our own officials. They can range from 3,000 or 4,000 pounds to 10,000 pounds. I just don't know.

Mr. ROY. What is your best estimate as to what percentage of it you are picking up?

Mr. ROSSIDES. We have been having some remarkable success in the last 9 months, but I don't know if we can keep that up. We hope to. I think we are catching a lot more. I would not want to give a percentage figure but let me put it this way—because this is the more important point following the essence of your question—for the first time we are now contending with the smuggler on the basis that he may get hit.

In the past, forget it; 99 out of 100 times he would be in and he could care less about one seizure. Now he may be getting into a financial risk and it may be very expensive when he gets caught at our borders.

Why? Because he has paid a lot of money by that time. It does not cost him if they stop him at the source. I don't know what percentage is being caught. We are not up to 50 percent, I would not want to say, 10, 15, or 20.

I am saying this, though, that I think as part of the multidimensional approach everything has to be tried. Attacking it at the source, in transit, the smuggling, internationally, and so on. But I think our experience in the Customs Service the last 2½ years shows we can be more successful than we realize at our borders.

One of the new elements that stems from the recent appropriation is the fact that a significant loophole was at the border with the light planes. So part of our appropriation would be for equipment to combat that. For the first time we can foresee getting to the 50-50 mark.

This means something.

Mr. ROY. If you can get close to that, that is a big deal. Couldn't you make another interpretation that more is being brought in and you are picking up the same percentage?

Mr. ROSSIDES. You could but there are a lot of interpretations. I think it is the interpretation I put on it.

Mr. ROY. I have no other questions.

Mr. HASTINGS. Mr. Chairman, I am particularly delighted to welcome my fellow New Yorker here in this capacity. I am aware of the efforts you have made. I have only one question.

Are you aware of the statement made, I believe, by a BNDD official in Paris, John Cusak, I believe, that if three to five top French millionaires hiding behind a sole legitimate screen were eliminated, we could do away with the heroin traffic in Europe.

Mr. ROSSIDES. I am aware of the comment.

Mr. HASTINGS. Do you have any comment?

Mr. ROSSIDES. I have no comment on the comment.

Mr. HASTINGS. I guess I will have to get Mr. Blount here to ask him.

Mr. ROSSIDES. Yes.

Mr. HASTINGS. I have no further questions, Mr. Chairman.

Mr. ROGERS. Mr. Kyros?

Mr. KYROS. I regret that I did not hear all of your testimony, but I will certainly read it carefully.

We made certain agreements with Turkey but it is rumored that this year's crop is still going to be harvested and that the agreement does not apply to it. Is there any truth in it?

Mr. ROSSIDES. Yes, and no, Congressman. The agreement that was entered into between the Government of Turkey and the United States announced by Prime Minister Imr and President Nixon was that 1 year hence—because there was a Turkish law that required 1-year notice, or leadtime, about planting—as of June 30, 1972, there will be no further legal planting of opium poppy in Turkey. So they were allowed to harvest and plant. However, part of the agreement was that there would be the special efforts by the Turkish Government because it is a Government monopoly to collect fully the crop that was being harvested in June and July. That is the harvest period. And further there would be a full effort to buy up on the U.S. plan of purchase so that they do not plant and if they do plant, then to purchase the crop that is to be planted during October, which is this month. This current crop which is being planted will be the last legal crop that can be harvested.

So both of those aspects the administration and the Congress should keep their eye on.

Mr. HASTINGS. Besides the excitement—and I think it merits excitement—about those agreements, do you really feel these laws and agreements can be enforced by the Turkish Government?

Mr. ROSSIDES. Congressman, we hope so. But again there should be no misunderstanding and no complacency as if this was an end-all, and I think that is the gist of your question. Absolutely not. This was a major step forward, a major advance, the psychology, the symbol to the world and the Turkish Government deserves credit for that. We hope they will be successful in stopping the trafficking, illegal trafficking in the current harvest, and they will be successful in collecting the harvest that is planted.

Mr. KYROS. On page 5 of your statement, you comment on the possibility of new sources becoming even more important, for example, in Southeast Asia, Burma, Laos, and Thailand. The chairman took the subcommittee over there and that is the feeling we have returned with. I don't know how you are going to control drug traffic with our military apparatus in Southeast Asia that provides lines of communication, provides money, and provides resources for transportation performance because we have military forces in Southeast Asia.

Mr. ROSSIDES. It is difficult. I would say this, that the President recognizes this and we are ahead of the game for the first time on the question of there being a substitute supply for the United States. For the U.S. troops there, yes, but that is being worked on vigorously. Hopefully with the number of troops being out of there by next June, that aspect will be reduced significantly.

Mr. KYROS. I recall that during the last congressional recess, in

August, you and I were on the U.S.S. *Saratoga* together and got catapulted off the carrier. You were moved then to advise me that you were going to Lebanon and other nations nearby. What did you learn there, Mr. Rossides?

Mr. ROSSIDES. They are a major source of production of hashish and they pledge their full effort. They said they needed assistance and that kind of thing. Everyone needs assistance. I think the key point that the President is trying to get around is the same concept as the military, everybody must carry their fair share of the burden.

Mr. KYROS. Will they cooperate?

Mr. ROSSIDES. Definitely. The Lebanese will cooperate. I also visited Israel. Israel is not a producing country but they were a transporting country and they pledged full cooperation.

Mr. KYROS. How does it get into Israel?

Mr. ROSSIDES. We said there is no excuse for it getting in with their tight security.

Mr. KYROS. Syria lets people go back and forth.

Mr. ROSSIDES. There is some smuggling. There should not be. We pointed out they have the best security available, if the Army takes care of the land border, and customs takes care of the sea border. They have pledged full cooperation.

They made some seizures since that visit.

Mr. KYROS. We have no trouble with Egypt?

Mr. ROSSIDES. Not that I know of.

Mr. KYROS. I am delighted to see you before the committee. When I traveled with the subcommittee, and even before that, I found your Customs people alert, active, and very cooperative. A group of very fine men, I thought, throughout the world.

When I traveled in Asia I was amazed at their grasp of the problem and their realistic approach. I want to commend you for your efforts.

Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Rossides, I am not sure I understand the difference between your operation and the Bureau of Narcotics and Dangerous Drugs. As I understood it, they have been given the lead agency function overseas.

Mr. ROSSIDES. That is correct, Mr. Chairman. In a certain sense they are responsible for working with the Government on the sources. Our responsibility is the smuggling. And theirs is internal in the United States.

Mr. ROGERS. They are not involved in smuggling?

Mr. ROSSIDES. There is some overlapping in that area. However, that is being worked on by the Cabinet Committee on International Narcotics Control because the President gave that committee the mandate to coordinate all overseas policy including the policy on enforcement. We will work out an adequate operational procedure.

Mr. ROGERS. So this is being worked on?

Mr. ROSSIDES. Yes, sir.

Mr. ROGERS. Who resolves it? Suppose there is a question between you and the Bureau. It was my understanding from previous testimony that the final say so was in the Attorney General.

Mr. ROSSIDES. I read the previous testimony. There is no specific problem that has gotten to that point. Since that testimony that appeared before your committee, the President set forth the Cabinet

Committee on International Narcotics Control. Also attached for the record is a copy of that directive and order.

Now it is the Cabinet Committee that decides all questions on the international law enforcement policy.

(The President's directive referred to follows:)

THE WHITE HOUSE,
Washington, D.C., August 17, 1971.

Memorandum for : Hon. John B. Connally,

Secretary of the Treasury,

Subject: Cabinet Committee on International Narcotics Control.

Drug abuse, particularly narcotics addiction, has grown to crisis proportions in the last several years in the United States. It is imperative that the illicit flow of narcotics and dangerous drugs into this country be stopped as soon as possible. In order most effectively to coordinate this effort, which encompasses diplomatic, intelligence, and law enforcement functions, I am hereby establishing a Cabinet Committee on International Narcotics Control.

The Cabinet Committee will be chaired by the Secretary of State and include: Secretary Rogers, Secretary Connally, Secretary Laird, Attorney General Mitchell, Ambassador Bush, Director Helms, and such others as become necessary in the opinion of the Chairman.

The Cabinet Committee will be supported by a Working Group to be composed of personnel from each of the concerned agencies. The Executive Director of the Cabinet Committee and Chairman of the Working Group will be Egil Krogh, Jr.

The Cabinet Committee shall be responsible for the formulation and coordination of all policies of the Federal Government relating to the goal of curtailing and eventually eliminating the flow of illegal narcotics and dangerous drugs into the United States from abroad. To the maximum extent permitted by law, Federal officers and Federal departments and agencies shall cooperate with the Cabinet Committee in carrying out its functions under this directive and shall comply with the policies, guidelines, standards, and procedures prescribed by the Cabinet Committee.

More specifically, the Cabinet Committee shall—

(1) Develop comprehensive plans and programs for the implementation of these policies.

(2) Assure that all diplomatic, intelligence, and Federal law enforcement programs and activities of international scope are properly coordinated.

(3) Evaluate all such programs and activities and their implementation.

(4) Make recommendations to the Director of the Office of Management and Budget concerning proposed funding of such programs.

(5) Report to the President, from time to time, concerning the foregoing.

RICHARD NIXON.

Mr. ROGERS. So it is not decided simply by Justice.

Mr. ROSSIDES. That is our interpretation of the agreement. That is what we are working out now.

Mr. ROGERS. Does Justice interpret it the same way you do?

Mr. ROSSIDES. I assume so but I have not asked them. It is a question now of the President asking for action. We are moving ahead working enormously well in the various subcommittees and a working committee of the Cabinet committee. We have a meeting this afternoon and one of the agenda items is this question.

Mr. ROGERS. What are the main questions that have to be resolved? Who picks up an investigation, where, and how far he carries it? Is that basically it?

Mr. ROSSIDES. That is exactly it.

Mr. ROGERS. Where does Treasury start?

Mr. ROSSIDES. Treasury starts wherever there is smuggling and the conspiracy to smuggle starts overseas and continues into the United States.

Mr. ROGERS. Do you follow it in the United States?

Mr. ROSSIDES. Yes, sir.

Mr. ROGERS. What does the Bureau of Narcotics do then? Why are they involved overseas at all?

Mr. ROSSIDES. They work with the foreign governments on eliminating the sources. And they also work on the smuggling cases that they initiate that we have not already initiated. They work on this. This is part of the overlap we are working out. In the past it was an atrocious relationship.

Mr. ROGERS. But you think it is beginning to work? Your agreements have not yet been finalized?

Mr. ROSSIDES. Under the new Cabinet committee directive we are working on it.

Mr. ROGERS. How many men do you have now working on enforcement, Bureau of Customs?

I notice you talked about increases?

Mr. ROSSIDES. I will submit the figures for the record with the authorization. We will have close to 4,000 inspectors. They are not all in straight enforcement but they are in this total effort that we make as far as customs goes.

That inspector today is more conscious of drugs than anything else. (The following information was received for the record:)

NUMBER OF MEN WORKING ON ENFORCEMENT (BUREAU OF CUSTOMS)

Customs enforcement personnel presently total 5,097 out of an authorized number of 5,453.

Mr. ROGERS. You did have, when this started out, what, 300 and some?

Mr. ROSSIDES. We started with maybe 3,000 inspectors at the beginning of this administration. With agents we started with 350 and now we have 980, a significant and substantial increase.

We have increased customs patrol officers up to maybe 600. That was a major deficit. There is no substitute for manpower. The customs bureau had not had an increase in manpower for 40 years, back to the midtwenties. No periodic increases.

Mr. ROGERS. So you have 980 that are actually enforcement people?

Mr. ROSSIDES. Nine hundred and eighty agents authorized on board.

Mr. CARTER. That is three times the number approximately that we had at the beginning of this administration.

Mr. ROSSIDES. Correct, sir.

Mr. ROGERS. I think the President has done a good job in this and, of course, the problem has grown significantly within this period of time, hasn't it?

Mr. ROSSIDES. Well, when you say grown, it has become one of the things, Mr. Chairman.

Mr. ROGERS. You don't think the drug problem has grown within the last 3 to 5 years?

Mr. ROSSIDES. Three to 5 years. What I am saying is that in December of 1968 before the national debate, the national discussion, all the facts and figures had not been brought out. The Congress and the President initiated this. It has been all to the good. You could hardly have had a proper discussion in December of 1968. Now you can and this is fine.

We are discovering things we had not discovered before and a lot of statistics we did not have before.

Mr. ROGERS. I agree. What I am saying is we have increased manpower and you have increased some interception now. That has gone up considerably.

Mr. ROSSIDES. And education and research.

Mr. ROGERS. What I am concerned with is how does what we are doing now compare to solving the problem? I don't see any great reduction in the number of drug users according to statistics. For instance the U.S. district attorney in New York said the recent seizures there, commendable as they are—

Mr. ROSSIDES. I would like to tell you off the record what I think about his statement.

Mr. ROGERS. He said it did not even affect the presence of heroin in New York.

Mr. ROSSIDES. He is wrong. He does not know. I disagree with his statement, and the statement reported in the press was stronger than was his interview with Mr. Rozell. This is some of the myth that gets perpetuated. He is asked a quick question. "Well, it does not show a ripple," or some comment like that. He does not know. He does not know all the facts. For him or anyone else to say that 1,000 pounds of pure heroin has not had an effect, they do not know what they are talking about.

So all I am saying is that is a disservice to the men and women of the customs service, and it is a disservice to the Congress and others who have worked hard on this. He does not have an overall view on that.

My point is that there may have been a supply. There may have been an inventory. It may be that less are using it and more using something else. In the District of Columbia the reports from the police department is that the addicts are getting cheated because when they buy the bag there is less heroin in there. The reports we have are that the percentage of heroin in the stuff seized is less. So we are making an impact and these off-the-cuff comments, frankly, annoy me.

Mr. ROGERS. I wanted to get your reaction on it because this concerns me, too. We are making all this effort, tripling our manpower and yet the District Attorney, who is involved probably in the most heavily drug-infested area says it has not made a ripple.

This causes us concern.

Now, are you familiar with the report of the customs advisor, I am not sure how to pronounce his name, Kovoriac, dated February 8?

Mr. ROSSIDES. Yes, sir.

Mr. ROGERS. Let me quote a statement here.

On January 9, 1968, a report entitled "Treatment of Professional Smugglers" was submitted by Mr. J. F. O'Neil, Advisor at Tan Son Nhut Airport in Vietnam. This outlined shortcomings of personnel at the airport and their reluctance to stop the flow of goods into Vietnam.

This is their customs people.

We were advising trying to improve it. The operation on January 9, 1971, three years later, has deteriorated to the point to where Customs are for all practical purposes totally ineffective and have no control whatsoever over the goods that arrive at Saigon's International Airport.

He goes on to say that the situation exists in spite of advisory teams' efforts to build an effective customs operation in the area:

During the past three years innumerable suggestions and reports have been made and meetings held with the Chief of the passenger terminal, Director of Customs, Vice Minister of Finance, Minister of Finance. These gentlemen, with-

out exception listen with extreme politeness, agree a bad situation does exist and that something must be done, but after three years of these meetings and countless directives being issued at all levels the Customs operation at the airport has not only not improved, but it has reached a point to where the Customs' personnel of Vietnam are little more than lackeys to the smugglers mentioned in the above report.

The same people that were operating three years ago are still in business and more powerful than ever. The sole function of Customs at the airport seems to be to assist these smugglers to bring in their contraband without hindrance and the advisors at the airport are not looked upon as advisors but as policemen.

What comment do you have on this?

Mr. ROSSIDES. Are you reading from the New York Times report?

Mr. ROGERS. I don't know where it came from. This is excerpted from the report.

Mr. ROSSIDES. Correct.

Mr. ROGERS. I got the impression everything was rosy from your report.

Mr. ROSSIDES. Oh, no, no, no. Not only not rosy but I say that at least we are making the effort in the Far East that we had not thought of before. Part of the reasons—

Mr. ROGERS. 1968 is 3 years.

Mr. ROSSIDES (continuing). We concentrated on Turkey, that was the major source. How we moved in there and part of it has been—and I am proud of the fact—it has been the customs that was sounding the alarm. It was the team that was there under our agreement. They were sounding the alarm and the bell on smuggling and blackmarketing and so on.

I happened to be there before this report leaked, but I was not involved in any leak. I met with the Embassy. We had taken action before February.

In the fall of last year, the President moved in on this. I am pleased to say that they have made changes. I don't want to get into discussions. Mr. Gross may want to make future comment.

The customs chief was put out by the Government of Vietnam, Ambassador Bunker got into this and Ambassador Burger, who has the Irregular Practices Committee at the Embassy. He is a top man. Burger is a tough cookie and he has done a tremendous job in my judgment regarding corruption and smuggling in drugs. They went right to the Government. The Government did act. I don't say more should not be done.

Mr. ROGERS. When did they act?

Mr. ROSSIDES. Within 2 or 3 months after that report was in the paper they removed the chief of customs.

They moved a few other people. Tan San Nuit is now in much better shape.

Mr. ROGERS. What about International Airport?

Mr. ROSSIDES. That is the one. Tan Son Nhut International Airport. There is a problem with other situations. They have a long way to go but there has been improvement.

When I say "rosy," I am saying at least half the battle is to know what the problem is.

Mr. ROGERS. Now, as I understand it, it would be BNDD that would carry on the negotiations with the Government and not you?

Mr. ROSSIDES. No. The Ambassador is responsible and he will do it.

Mr. ROGERS. I want to get clear in my mind this function.

As I understood, you said that BNDD is the lead agency?

Mr. ROSSIDES. That is for enforcement.

Mr. ROGERS. I presume this is enforcement.

Mr. ROSSIDES. This is Customs to Customs. They don't have dealings with our fellow Customs Service.

Mr. ROGERS. So they would not get into that at all.

Mr. ROSSIDES. That is our role.

The customs services of the world have been neglected and yet the substances have to go across the border. BNDD will deal with the national police of Vietnam, Thailand and so on.

Mr. ROGERS. You would deal——

Mr. ROSSIDES. With the customs. And Mr. Gross can report to you further on some of the programs that are being developed by the State Department on a team basis.

Mr. ROGERS. What improvements have been made since February of 1971? If you could furnish that to us? We have just been there and it was not very encouraging.

Mr. ROSSIDES. We will do the best we can.

(The following information was received for the record:)

IMPROVEMENTS OF CUSTOMS CONTROLS AT TAN SON NHUT AIRPORT

Customs controls at Tan Son Nhut Airport have been markedly tightened up. Known smugglers have been excluded from the Customs areas, and large quantities of commercial merchandise are no longer passed through the passenger terminal without collection of import duties.

The United States Customs Advisory Team working through the Embassy was finally successful in having GVN Customs enforce the joint Finance-Economy Decree of December 4, 1970, which requires that import licenses for all commercial merchandise be obtained prior to the fact of importation. Previously such shipments were being licensed after arrival at Tan Son Nhut, sanctioning their purchase through illegal financial transactions.

A shakeup of SVN Customs in May 1971, reflecting Embassy representations, brought about the removal of the Director General of Customs and the transfer of several other corrupt GVN Customs officials. As a result, goods detained and cases established at Tan Son Nhut showed a marked increase due principally to the efforts of the Customs advisors and the new and capable Airport Terminal Chief and Airport Fraud Repression Chief, both of whom received Customs training in the U. S.

At this time Tan Son Nhut is no longer believed to be a major entry point for commercial or narcotics smuggling. Although the situation is greatly improved, problems still remain, and they will continue to receive attention.

Mr. ROGERS. When this committee visited Vietnam we were not encouraged about what they said about the smuggling.

Mr. ROSSIDES. All I am saying, I am encouraged in that the problem was recognized. Ambassador Bunker and Ambassador Burger acted. The Government acted just at the beginning. At least we are finished with the beginning.

Mr. CARTER. Certainly I think that the agreement you made with Turkey was, or the administration made with Turkey, was quite tremendous. I believe it will be fruitful. You have accomplished much in this area.

Again last year I believe you interdicted seven times as much drug coming into the United States or as much as had been interdicted in the past 7 years, is that correct?

Mr. ROSSIDES. That is correct.

Mr. CARTER. And in the international field, international commu-

nity, you have done more work and received more cooperation in the past 2½ years than in the past 25 in our history, is that correct?

Mr. ROSSIDES. This is my judgment, sir. That more has been accomplished.

Mr. CARTER. You have also increased your IRS agents, too, is that not correct?

Mr. ROSSIDES. That is correct.

Mr. CARTER. So that you can get on these dealers?

Mr. ROSSIDES. For the first time we initiated this program.

Mr. CARTER. Really it has been a great program, hasn't it, and personally I think you are doing a wonderful job. You made a great presentation here. This shows that the administration is going forward and advancing wonderfully in its fight against drugs.

Now, the sad thing about Vietnam is actually that the agents there are Vietnamese and under Vietnamese control, is that not correct?

Mr. ROSSIDES. Yes, they are their own agents; yes, sir.

Mr. CARTER. Just as their army there is under the control of South Vietnam. Most people do not realize that but we don't make military moves without approval of Thieu and his people.

Mr. ROSSIDES. Correct.

Mr. CARTER. And we are phasing that out. In 1968 we had how many people in there?

Mr. ROSSIDES. In January of 1970 we had 542,000, we reduced that over 60 percent.

As of December 1 there will be 182,000.

Mr. CARTER. We feel combat people will be removed and that so far as the military is concerned this drug problem will vanish. At least we hope so.

I think you made a wonderful presentation. I want to thank you.

Mr. KYROS. One more question, in light of the testimony this morning.

When I think of the Bureau of Narcotics and Dangerous Drugs and the work that you are doing, I wonder why you do not take your drug activities and combine them under the Special Action Office.

Give me a reason for not doing that, please.

Mr. ROSSIDES. Let me give at least a couple of reasons, Congressman.

You know the administration's position that the bill regarding the Special Action Office excludes law enforcement. I would only say that I obviously support that position but I want to say that nothing could be worse than to try to put law enforcement in that office for a number of reasons. Not so much that a doctor is heading it now. He does not have to be a doctor to head it. Law enforcement is a straight line operation.

The last thing we need to do and the last thing we need to think about is national police forces operated from the White House. This administration is unalterably opposed to it. I personally think it would be a disaster. It is that bad.

I know there is a concern and urgency. Proper coordination is being worked out. So you have some bumbling here and there, you have some problems, but you work them out.

We now have the mechanism of the Cabinet Committee on International Narcotics Control but the last thing Congress would want is the concept that someone in the White House has some direct-line

leverage on agents. I am not sure that that point has been released before but it just does not work.

Mr. KYROS. I think you made that pretty clear.

Thank you very much, sir.

Mr. ROSSIDES. Thank you, Mr. Chairman.

Mr. ROGERS. Thank you very much, Mr. Rossides.

If you will let us have this information, I think it will be helpful.

Mr. ROSSIDES. We will supply it promptly, Mr. Chairman.

Mr. ROGERS. I think the President has made greater effort in this field. I think the circumstances called for it and he is responding. This committee wants to do everything it can. We appreciate what you are doing and you have many friends on this committee who commend you for what you are doing.

Mr. ROSSIDES. Thank you, Mr. Chairman. I will pass those comments along to the White House.

Mr. ROGERS. Our last witness this morning is Mr. Nelson Gross, Senior Adviser to the Secretary of State and Coordinator for International Narcotics Matters.

Mr. Gross, we are sorry you had to be detained so long before we could hear your testimony.

We are happy to have you.

STATEMENT BY NELSON GROSS, SENIOR ADVISER TO THE SECRETARY OF STATE AND COORDINATOR FOR INTERNATIONAL NARCOTICS MATTERS, DEPARTMENT OF STATE

Mr. GROSS. I appreciate the opportunity to be here.

I will file my statement with you.

Mr. ROGERS. Without objection it will be made a part of the record at this point.

(Mr. Gross' prepared statement follows:)

STATEMENT BY NELSON GROSS, SENIOR ADVISER TO THE SECRETARY OF STATE AND COORDINATOR FOR INTERNATIONAL NARCOTICS MATTERS, DEPARTMENT OF STATE

RECENT ACTIVITIES IN INTERNATIONAL DRUG CONTROL

Mr. Chairman, the President has declared drug abuse to be the number one non-economic domestic problem facing the United States today. In his message to the Congress on June 17, he pointed out that our efforts to control the traffic and dry up the demand for drugs and narcotics at home cannot succeed unless the problem is attacked on an international plane. What is today a serious situation in the United States could well move into other countries unless a total battle is waged. The President appealed, therefore, not only for more effective measures on the national front but for a world-wide cooperative effort.

I am pleased to report that there has been a significant upsurge in our efforts to broaden and strengthen controls over narcotics and other dangerous drugs, both domestically and internationally. It is further gratifying that these efforts are generating support in the attack against drug abuse from other nations.

The Department of State is continuing its lead role in the area of international controls. On September 7 the White House announced the establishment by the President of the Cabinet Committee on International Narcotics Control. The Committee is under the chairmanship of Secretary of State Rogers and includes Attorney General John N. Mitchell; Secretary of Defense Melvin R. Laird; Secretary of the Treasury John B. Connally, Jr.; Ambassador George Bush, U.S. Representative to the United Nations; and Richard Helms, Director of the Central Intelligence Agency. Other Federal agencies cooperate with the Committee, as appropriate.

The Cabinet Committee is charged with the formulation and coordination of all policies of the U.S. Government relating to the goal of curtailing the flow of narcotics and dangerous drugs into the United States. Specifically, the Committee will: (1) develop comprehensive plans and programs for drug control; (2) assure the coordination of all activities of international scope; (3) evaluate all such activities and their implementation; (4) make recommendations to the Director of the Office of Management and Budget concerning funding of activities; and (5) make periodic reports on the progress of its operations to the President. The first formal meeting of the Cabinet Committee was held on September 28, and a number of specific options and projects centering on Southeast Asia are currently being developed for policy consideration and action.

The capacity of the Department of State for dealing with the drug problem has been strengthened and its activities intensified through the upgrading and expansion of the Secretary's Office of Narcotics Matters. Moreover, the regional and functional bureaus in the Department have designated drug control coordinators, and many of our missions have appointed control officers to coordinate the Country Team efforts abroad.

The Department's East Asian Bureau chairs an interagency narcotics task force with representation from State, Agency for International Development, Bureau of Narcotics and Dangerous Drugs, Treasury, Defense, Central Intelligence, and United States Information Agency. This group developed instructions for negotiating a comprehensive program with the Government of Thailand. The task force has also prepared a concept paper setting forth an integrated approach to narcotics control in East Asia to guide missions in preparing country and regional programs.

The Thai program and the East Asian concept paper will be prototypes for cooperative programs in other geographic regions. The accent is on measures of immediate impact to suppress the traffic and smuggling, to close illegal processing plants, and to lay the basis for rational solutions to illegal production and addiction. The emphasis is on local responsibility and mutual aid and on the integration of national, bilateral and multilateral programs. The Washington approach is being matched in the field by Country Team evaluation and program recommendations with coordination facilitated by regional meetings of missions at the ambassadorial and working levels.

The Middle East Bureau has also established an interagency task force. Suggested programs from our Embassies in Afghanistan and Pakistan relating to opium production and traffic in those two countries are currently under consideration by the inter-agency group. Iran, which resumed opium production in 1969 and appears to have its production under effective control, has publicly declared it will discontinue production when its neighbors do so.

The problem in Latin America is one of an increasing flow into the United States from that area of heroin from Europe and cocaine of native origin. The need is for tighter drug controls, better law enforcement and closer cooperation between foreign and U.S. narcotic control agencies. The Latin American Bureau has requested area missions to evaluate the drug control situation and to make program recommendations which will be given interagency review.

In the European area, the challenge is two-fold, to strengthen cooperative action against the illicit traffic and to marshal European technical, financial and moral support for more effective drug control in Southeast Asia and the Middle East.

Worldwide, the Department and Foreign Service are supporting the expansion of the personnel required to improve intelligence and provide advice and assistance to foreign drug control and enforcement agencies.

The U.S. Government interagency effort is proceeding both bilaterally and multilaterally against the illicit drug traffic and the supplies that feed it. Bilateral cooperation has been most close with countries which have a special relationship with us or to the problem of drug control as it affects us. Collaboration with Canada and with Mexico is especially important because of our common frontiers. Cooperation with France is essential because morphine from Middle East opium processed into heroin in clandestine laboratories in southern France is a major source for the U.S. addict population.

A Franco-American Intergovernmental Committee on Drug Control has been meeting periodically to review the cooperative arrangements and to discuss how to improve them. At the invitation of the Americans and French, Canadian representatives from the Royal Mounted Police have also participated in the work of the Committee since November 1970. During and between meetings of

the Inter-governmental Committee, Working Groups meet to exchange information on cases under investigation, to present progress reports and to consider specific ways in which the three enforcement agencies may assist each other.

The primary objective of this trilateral cooperation effort is, of course, the discovery and closing of heroin conversion laboratories in southern France and the interception of the illicit heroin traffic from France to North America. It is difficult to find and close heroin laboratories. They are undercover, relatively simple to operate and easily moved to another location. However, the French with all our full cooperation and with such assistance as we can give are making a determined and sustained effort against the illicit traffic. An agreement signed with France in February of this year provided for French agents to operate in the U.S. and for U.S. to operate agents in France. The cooperative effort has been demonstrated by the recent substantial heroin seizures made by French and American police.

The governments of the United States and Mexico have been actively cooperating in narcotics trafficking programs since 1969 when a Joint Working Group was established. The United States has provided helicopters and fixed-wing aircraft to locate clandestine crops of opium poppies and marijuana, the cultivation of both of which is in violation of Mexican law. Our cooperative effort has resulted in the seizure and destruction on Mexican soil of large quantities of narcotics and psychotropic substances aimed at the illicit market.

On June 30, Turkish Prime Minister Erim announced that Turkey would ban the production of opium. A decree specified that production will be restricted to only four provinces for the fall 1971 planting, and that complete abolition of opium production will go into effect when the crop is harvested in June of next year. Since that announcement, two additional actions have been completed by the Government of Turkey. The first was the passage of a strict opium licensing and control law. The bill passed the National Assembly on June 21, the Senate on August 18, and became law on August 25. Secondly, the Turkish opium monopoly has completed purchases of opium gum from this year's harvest. The collection of 149 tons, which was more than double last year's 61 tons, was larger than any annual collection in the past eight years and represents a significant reduction of leakage into illicit channels.

In response to the Turkish decision to ban opium production, the United States Government has sent a high level agricultural team to provide technical advice on agricultural and agro-industrial development in the area where poppy growing will be eliminated. Secretary of Agriculture Hardin will arrive in Turkey on November 2 to review the team's report and discuss it with the Turkish Government. We have assured Turkey of our readiness to provide financial assistance to help prevent foreign exchange losses from legitimate exports of opium gum and poppy products. These assurances also included assistance to help establish development activities in the affected areas.

The agreement with Turkey was particularly significant in that it will remove a major source of opium for heroin marketed in the United States. We are interested in similar cooperative arrangements with governments of other countries along the illegal trade route which runs from the Middle East through Europe to North America and increasingly through South America.

As I indicated earlier, we are focusing on plans to cooperate with the governments of countries in southeastern Asia where there is substantial illegal or uncontrolled production of opium. That is the area to which the illegal traffickers will turn increasingly as existing sources of supply in the Middle East are closed to them. Two major plus items can already be cited. On September 28, the United States and Thailand signed a Memorandum of Understanding by which the two countries pledged mutual action against the supply and trafficking of illicit narcotics and dangerous drugs. Of equal significance was the promulgation by royal ordinance on September 23 of a narcotics law which for the first time in Laotian history prohibits the growing, processing, trading and use of opium and the opiates. These actions will form the basis for cooperative efforts between the two countries and the United States to combat the drug problem in Southeast Asia and reduce the flow of heroin to American servicemen in the area.

In the international field we have also been working multilaterally, within the United Nations and other international organizations and within the framework of the international drug control system established and operating under treaties. International efforts to bring opium and other narcotics under effective control have a long history and have in fact been successful in controlling the

legal manufacture of narcotic drugs for medical use. Although world requirements for morphine have increased more than five times since the 1930's, there is no evidence of leakage to the illicit traffic from the licensed factories. Now the challenge to the international control system is to bring the illegal and uncontrolled production of narcotic raw materials under equally effective control and similarly to extend control over psychotropic or so-called mind bending substances.

On the multilateral scale, the United States is working to promote three principal initiatives: (1) the strengthening of the 1961 Single Convention on Narcotic Drugs, (2) the United Nations Expanded Program and Fund for Drug Abuse Control, and (3) the UN Convention on Psychotropic Substances.

U.S. amendments to strengthen the 1961 Single Convention were proposed in March of this year. At our initiative the UN Economic and Social Council scheduled a plenipotentiary conference for March 1972 to consider all proposed amendments to the Convention. We have conducted extensive diplomatic consultations throughout the world over the past several months in an effort to obtain support for our proposals.

The Single Convention in its present form calls for essentially voluntary restraints on Parties with respect to cultivation of the opium poppy, production of opium, manufacture of opium-derived drugs, and the import and export of these substances. The adoption of the U.S. amendments would give the International Narcotics Control Board sufficient powers to provide enforceable and obligatory international controls over cultivation, production and trade of narcotics and limit such activities to the minimum essential medical and scientific needs. Among other things, the U.S. proposed amendments would: require full information on the cultivation of the opium poppy and the production of opium; order reduction in cultivation or production where there is a significant danger of illicit diversion or where world needs are already being met; order worldwide remedial measures to be taken, including a partial or full embargo on the export or import of drugs to or from an offending country; and make the narcotics offenses already enumerated in the Single Convention immediately extraditable.

One year ago the United Nations Commission on Narcotic Drugs adopted a resolution introduced by the United States and cosponsored by 8 other countries for the establishment of a United Nations Fund for Drug Abuse Control.

In March 1971, the Secretary General established the Fund, and on April 1 the United States representative to the United Nations delivered to the Secretary General a letter of credit for one million dollars as the first payment on the United States initial pledge, endorsed by the Congress, of 2 million dollars to get the Fund started. It is expected that at least \$5 million would be donated each year by governments, non-government organizations, and private sources. Annual contributions would hopefully increase to \$20 million once the Fund becomes firmly established.

Among the programs which will be financed by the UN Fund are: Expansion of research and information facilities of United Nations drug-control bodies; technical assistance in pilot projects for crop substitution purposes; establishment and improvement of national drug-control administration and machinery; training of personnel; creation and expansion of research and training centers to serve national or regional needs; enlargement of capabilities and extension of operations of United Nations drug-control bodies; promotion of facilities for treatment, rehabilitation, and social reintegration of drug addicts; and development of educational material and programs suitable for use on high-risk populations.

Cooperation in control of dangerous drugs works both ways. While the sources of our chief narcotics problem are foreign, the United States is a contributing source for illegal traffic in psychotropic drugs which afflict other nations. If we expect other governments to help stop the flow of heroin to our shores, we must act to prevent equally dangerous substances from going into their nations from our own. Accordingly, the United States is a strong supporter of the Convention on Psychotropic Substances developed by a United Nations Conference in Vienna early this year. This is the first international instrument adopted for the purpose of combatting the abuse of psychotropic substances and the illicit traffic to which it gives rise. Under the terms of the Convention, substances such as LSD and other hallucinogens, the amphetamines, barbiturates and tranquilizers will be brought under rigorous controls similar to those envisaged for narcotic drugs under a strengthened Single Convention. Three months after 40 nations have ratified it, the Convention can come into force. The Convention

was signed by the United States on February 21 and submitted by the President to the Senate on June 29 for advice and consent to its ratification.

International cooperation in the world-wide campaign against drug abuse was strengthened considerably during the month-long meeting in Geneva of the UN Commission on Narcotic Drugs concluded last Thursday. The U.S. Delegate John E. Ingersoll reports that the session laid a solid basis for the plenipotentiary conference scheduled for March. He stressed that wide agreement was reached among the delegations on the common objective of eliminating the illegal traffic in narcotic drugs, but noted that only time would tell to what extent the plans worked out by the experts and technicians attending the Geneva meeting will be translated into effective actions by their governments.

Among the key results of the Commission was the call for strengthening international drug legislation contained in a 14-nation resolution passed without a dissenting voice. The resolution calls attention to the critical proportions of the drug problem, noting it constitutes "a menace to which no country can feel immune." The key part of the document puts the Commission on record as believing "that a review of the 1961 Convention on Narcotic Drugs is warranted" and it recommends that all nations invited to the plenipotentiary conference in March of next year give urgent consideration to the proposals made to amend that convention. In addition to the proposals from the United States, suggested amendments to the Single Convention have also been put forward by France, Peru, and Sweden.

In action to strengthen regional cooperation against illicit drug cultivators and traffickers, Iran, Pakistan and Turkey took steps to set up a subcommittee of national representatives that will meet between regular sessions of the full Commission. The decision was taken by means of a resolution that declared stronger cooperation among Near East and Middle East governments to be essential in the struggle against drug traffickers.

During the meeting the Commission also examined the comprehensive action plan against drug abuse drawn up by the Secretary General. Many delegations expressed their general satisfaction with the short and long-range projects listed in the document.

These then are the principal recent initiatives in drug abuse control. We look for a much broader campaign internationally to prevent the further spread of a rapidly growing menace. Certainly the U.S. Government agencies have embarked upon a strong concerted effort to alleviate the problem. The job calls for determination and a constant effort on all fronts.

Mr. GROSS. Secretary Rossides has covered much of the ground and my statement is a rather general one.

I want to repeat that the President has established the Cabinet Committee on International Narcotics Control, which I think includes all of the personnel who should properly be on such a committee.

In case you are not informed on the workings below the actual Cabinet members, the Cabinet Committee has a working group with Mr. Egil Krogh as its executive director, and there are subcommittees within that group. I chair the subcommittee on Diplomacy and Foreign Aid. Mr. Ingersoll chairs the Subcommittee on Enforcement. Dr. Jaffe is a member of the working group on the demand side, so to speak.

Mr. ROGERS. I think it would be well if you could let us have for the record the organization of the Cabinet Committee and its subagencies and their jurisdiction.

Mr. GROSS. We will let you have that.

(The following letter was received for the record:)

DEPARTMENT OF STATE,
Washington, D.C., November 8, 1971.

HON. PAUL G. ROGERS,
House of Representatives,
Washington, D.C.

DEAR MR. ROGERS: During the testimony by Mr. Nelson Gross on October 27, you asked for further details on the Cabinet Committee on International Narcotics Control. The information is provided herewith.

The Cabinet Committee was established on August 17, 1971, and announced by Secretary Rogers at the White House on September 7. The membership as announced was as follows:

William P. Rogers, Secretary of State (Chairman).

John N. Mitchell, Attorney General.

Melvin R. Laird, Secretary of Defense.

John B. Connally, Jr., Secretary of the Treasury.

Richard Helms, Director, CIA.

George Bush, U.S. Representative to the UN.

Membership was subsequently extended to include Secretary of Agriculture Clifford M. Hardin. Other agencies will be asked to participate in the work of the Committee, as appropriate.

As indicated in Mr. Gross's statement, the Cabinet Committee is responsible for the formulation and coordination of all U.S. Government policies relating to the goal of curtailing and eventually eliminating the flow of illegal narcotics and dangerous drugs into the United States. Specifically, the Committee is charged with developing comprehensive plans and programs for international drug control; assuring the coordination of all diplomatic, intelligence, and Federal law enforcement programs and activities of international scope; evaluating all such programs and activities and their implementation; making recommendations to the Office of Management and Budget on proposed fundings; and providing periodic progress reports to the President.

The Cabinet Committee is supported by a Working Group composed of high-level personnel from each of the member agencies (e.g. Nelson Gross from State) plus the Special Action Office for Drug Abuse Prevention. The Working Group is chaired by Egil Krogh, Jr., of the White House staff; Mr. Krogh also serves as Executive Director of the Cabinet Committee.

The Working Group has seven subcommittees to deal with special subject areas and to coordinate on-going activities. There are six functional subcommittees as follows (agency chairmanship is given in parentheses): Intelligence (CIA), Law Enforcement (Justice), Public Information (White House), Diplomacy and Foreign Aid (State), Congressional Relations (White House), and Rehabilitation, Treatment, and Research (Special Action Office for Drug Abuse Prevention). The seventh subcommittee to the Working Group, known as the Coordinating Subcommittee, reviews outgoing communications, coordinates the narcotics control activities at the staff level among interested agencies and departments, and carries out all the necessary staff work on questions raised at the Working Group level. The Coordinating Subcommittee members are in close liaison with the Regional Interagency Task Forces on Narcotics Control which have been established by the geographic bureaus in the Department of State.

As Mr. Gross indicated, the first formal meeting of the Cabinet Committee was held on September 28. A number of specific options and projects growing out of that meeting are currently being developed for policy consideration and action.

I hope this information will be helpful. If I can be of further assistance, please let me know.

Sincerely yours,

DAVID M. ABSSHIRE,

Assistant Secretary for Congressional Relations.

Mr. ROGERS. How often does the Cabinet Committee meet?

Mr. GROSS. The Cabinet Committee thus far has had only one meeting. That was the meeting held on September 28 at which Secretary Rogers announced that Secretary Hardin would go to Turkey to head an agricultural mission.

He also announced at that time the agreement which was signed afterward between the United States and the Government of Thailand, a broad memorandum of understanding which will be implemented in various stages with help from BNDD, Customs, and ATD; there would be crop substitution and the rest of it.

Also he announced at that time—I don't think it had been publicly acknowledged—that Laos had within a day or two before passed a law for the first time banning the production of opium and trafficking in opium and its derivatives.

In case you have not heard, Laos has gone one step further. A law has just been passed banning the use of acetic anhydride, which is an ingredient for heroin. I think that is another good and constructive step forward.

Mr. KYROS. How are they going to make rubber and glass? I understand that for rubber, glass, and paper, you need acetic anhydride.

Mr. GROSS. Acetic anhydride is a widely used chemical. It makes a myriad of different products, plastics of all kinds, products you just mentioned. But in Laos, evidently, industry does not require that particular product. So at least for this period of time they have banned it. If later on they acquire uses for it, I assume the machinery would be there for proper regulation and licensing, which is what we would be looking for.

I might mention—because I don't think it has been made public—that Secretary Rogers, as Chairman of the Cabinet Committee, met yesterday with the Ambassadors involved in the Golden Triangle area, that is the Ambassadors from Burma, Thailand, South Vietnam, and Laos. I attended the meeting, as did Marshall Green, and we discussed such things as whether other countries might also be interested in the regulation of acetic anhydride as well as any other cooperative and regional efforts which they might be able to exert.

Mr. ROGERS. What reaction did you get?

Mr. GROSS. Very good. We spent considerable time, and I would say that the Ambassadors, as they expressed the views of their governments, were quite anxious to move ahead.

They are not anxious to establish a new regional entity, but perhaps some informal liaison at a ministerial level between and among those governments to handle problems which obviously cross borders. Air trafficking is one example. Day-to-day border control is another example.

I think the Ambassadors might get together on their own. Of course, we volunteered our assistance wherever we could be helpful.

Mr. ROGERS. That is commendable.

Mr. GROSS. Thank you.

Just by way of giving you the organization on this, the State Department has obviously led in the development of the programs in Southeast Asia, the Thai program specifically. Mr. Masters, who runs the East Asian task force, is here with me today. It was his task force which originated the thinking on this. Agencies represented on the group include State, AID, BNDD, Treasury, Defense, CIA, and USIA.

Mr. Masters is conducting these meetings on a two-a-week basis, but sometimes 4 to 5 meetings weekly. The task force is in the process now of implementing the United States-Thai Memorandum of Understanding so that we can have detailed agreements in each of the enforcement areas. It is also beginning to discuss country programs for the other countries, Laos and the rest.

Mr. ROGERS. I wonder if you have had an opportunity to look at the subcommittee's report that has been issued on their trip?

Mr. GROSS. Yes, sir.

Mr. ROGERS. We were concerned about Thailand there and the help that is needed, particularly in the border areas. I think if you do have an opportunity to review that, it would perhaps be helpful.

Mr. GROSS. The particular program which you cite as No. 3 in your subcommittee recommendations, of course, was taken up by the State Department immediately. That has been approved. In fact, when I went to Thailand myself I carried the approval for that as an illustrative program earmarking a certain amount of money and indicating that more would be made available as, when, and if the various subagreements were formalized with particular priority on the enforcement projects that we envisioned.

Mr. ROGERS. And you know the border police. I guess you are aware of that problem. We visited them and they had wanted to get M-16 rifles. They have the old Springfield rifle and the AID mission there will not allow them to have it because there is a police category in their name. They will give them to the armed services but simply because they have police, someone here has a hangup on that.

What they are doing is trying to secure the sovereignty of the area there and until they get to that they are certainly not going to do anything about drugs.

I think you need to give some attention to that area.

Mr. GROSS. I, myself, met, along with Ambassador Unger, with Minister Prepot who, as you know, is the national commander, if that is the proper word, of the border patrol police as well as the Army, too. He indicated to us that the anti-insurgency effort was their main concern at this time.

We tried to counter by indicating that the insurgents very often profited from the opium trade and indeed with the elimination of the opium trade, it would help their efforts in the anti-insurgency. I think the real problem here—I am not sure I should say it is a problem—but what has to be done is to get the Thai themselves, in the military level, on the border patrol police level, and on their national police level, to begin to implement, to begin to effect controls on narcotics.

It is all well and good that we have a few BNDD agents, but they can only provide some leads.

Mr. ROGERS. I think the point we made in the report was, and that we were concerned with on the trip there, that it is not possible for them to devote their efforts and energy to the drug problem as long as they are out trying to secure a village and save people's lives, and unless we give them some help to do that, we are not going to make any headway.

Mr. GROSS. We are working on that directly now, too. As I understand it, there is a contract with a German munitions operation which would provide them essentially with an equivalent weapon.

Mr. ROGERS. They need some weapon to respond to the insurgency.

Mr. GROSS. AID had a meeting here in Washington of all of their regional people, including their representatives in Thailand, South Vietnam, and Laos, just last week in an effort to gear them up, and this point was stressed.

Mr. KYROS. Mr. Gross, I looked over your statement and listened to your remarks. I think the State Department is doing everything it possibly can and I have a lot of admiration for those people. That is why I am puzzled by the fact that on page 6, you point out in depth the cooperation we have with the French Government, and what a great job they are doing.

At the same time, in our own Government, Postmaster General Blount says that we ought to have a ban or a boycott on French goods.

Do you really know what you are doing? Is this really cooperation, or are we going to try to bludgeon the French?

Mr. GROSS. I think the statement of Mr. Blount was totally unauthorized and unexpected.

I was in Europe at the time and received immediate calls from the White House, as did Ambassador Watson, and it was stressed that Mr. Blount was a former member of the Cabinet, which, of course, he is. He had no reason to do this in terms of anticipation of White House or Government reaction.

I think, frankly, that he has gone too far in this and I don't think the remarks are justified and appropriate, particularly, in my own opinion, considering the fast developing beefing up of the forces in the French Government. I must say that President Pompidou and Interior Minister Marcelin have gone even further here. They are proposing initiatives within the EC community and going beyond, and at the Geneva narcotics meeting they proposed some other devices.

Mr. KYROS. Have we officially indicated to the French that the remarks were irresponsible and not representative of this Government's opinion about what the French Government is doing about narcotics control?

Mr. GROSS. The State Department has not but I believe the Cabinet Committee, that is Mr. Krogh, has sent the message.

Mr. ROGERS. We have second bells.

Now, could you let us know what progress is being made in working out the differences between BNDD and Customs and how your group settles this?

Mr. GROSS. The Cabinet committee group has the ultimate responsibility to settle it because it is charged with the responsibility to see that we have effective controls. So, therefore, if there is an impediment along the way we try to do something about it. We will get back to you on it.

Mr. ROGERS. I think this would be good to let us have this.

(The following letter was received for the record:)

DEPARTMENT OF STATE,
Washington, D.C., December 3, 1971.

HON. PAUL G. ROGERS,
House of Representatives,
Washington, D.C.

DEAR MR. ROGERS: With reference to your question concerning the resolution of any differences that may appear between Customs and BNDD, please be advised that a new program has been instituted by the Cabinet Committee as follows:

The Cabinet Committee has initiated the preparation of narcotics control action plans for those countries considered to have a current or potential involvement in the production, processing, consumption, or transiting of illicit hard drugs. The project is focusing on world supplies, trafficking, and smuggling of heroin and cocaine destined for the U.S. market or U.S. personnel abroad. Selected Foreign Service posts have been asked to prepare preliminary action plans without consultation at this stage with host governments. Such plans will include a description of the drug situation, a statement of goals, the strategy to achieve such goals, estimated costs, priorities and a general time-table for actions. The plans will be reviewed by the Department's regional Interagency Narcotics Control Committees and, where appropriate, submitted for approval to the Working Group to the Cabinet Committee. The approved narcotics control action plans will then be forwarded to posts abroad to serve as a basis for opening discussions with host governments for the negotiation of bilateral narcotics control action programs.

Clearly the expertise of each agency will be reflected at each level of evaluation. Should differences arise between the approach of any one agency from that of another, the issue will be settled at the higher level. Ultimately the Cabinet Committee itself will be the final arbiter in determining the final formulation of the plan for a given area.

Sincerely yours,

NELSON GROSS,
*Senior Adviser and Coordinator for
International Narcotics Matters.*

Mr. ROGERS. Do you feel that it would be helpful in the White House along with rehabilitation and treatment, to maybe have a deputy there that would oversee enforcement activities and at least try to coordinate them?

Mr. GROSS. I cannot comment on the domestic side of it because that is a matter for Mr. Ingersoll and Mr. Rossides. I am inclined to go along with what Secretary Rossides said.

On the international side, I would most strongly echo what he said. I do not believe that the Action office would be oriented to do it. It think that if the State Department is geared up properly, and I think that it is now, that it is the job of our own Department through our Ambassadors and through our country teams to develop these programs. It has to be done through the Ambassador.

If you have—and I notice in your report, if I can allude to it—a suggestion for BNDD people not being connected with the Embassy, I think you are going to create great difficulty. I don't think the BNDD would get the same kind of reception they get when they talk to local foreign government officials. When they go in, if they are not sent by the Embassy, they are not going to be received in the same way and they would be scattered all over the place.

Mr. ROGERS. Yes; I understand unless it was with the blessing of the Embassy.

We got some feedback that it is very difficult for BNDD to go in and try to have a tough line when some of the Embassy people are saying, "Well, you know, we have to keep things going pretty well along."

Mr. GROSS. You will always have that kind of debate within an embassy.

Mr. Masters, by the way, is going to be the DCM in Bangkok shortly. He is very familiar with this.

Mr. ROGERS. Thank you. We appreciate your being here.

I am delighted to see this offensive, in effect, that you have mounted. I think it is going to be effective. We certainly hope so.

Thank you, Mr. Gross.

The committee stands adjourned.

(Whereupon, at 12:30 p.m., the subcommittee adjourned, subject to the call of the Chair.)

SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION

MONDAY, NOVEMBER 8, 1971

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND ENVIRONMENT,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to notice, in room 2123, Rayburn House Office Building, Hon. Paul G. Rogers (chairman) presiding.

Mr. ROGERS. The subcommittee will come to order, please.

Our hearings today concern themselves with reports that the Food and Drug Administration is planning to change the drug methadone from its existing status of an experimental drug to an approved drug.

Since the obvious outlet for methadone would be in the area of drug addiction centers and the President's proposed legislation would establish Dr. Jaffe as the man responsible for the Nation's efforts in detoxification and rehabilitation of these addicts, that office would most probably be the most directly in contact with the use of methadone. For that reason, we have invited, in addition to Dr. Edwards from FDA, Dr. Jaffe.

As we all know, the drug subculture and the world of crime are almost indistinguishable and we feel that comments from the Justice Department would also be more relevant. John Ingersoll, representing the Justice Department, has also been invited. When this committee began hearings there was a general assumption that methadone was the wonder weapon which society could use to transform drug addicts into useful, productive citizens. In our desire to find some solution we, as most interested citizens, were all too ready to accept any promising solution, and surely methadone was one.

But there has developed a growing concern as we traveled to centers in cities all over the Nation that methadone, far from being the magic bullet, posed a potential problem almost equal to heroin itself.

In the general order of things, if a drug is classified as an investigational one, there are relatively few men licensed to experiment with that drug.

In the case of methadone, however, there are more than 300 licenses. The actual number of people handling this may be double or even triple that figure.

And in the case of methadone, we have seen that the majority, if not the entire number of licensed investigators, are not really investigating this drug, but are simply dispersing it. This, of course, is contrary to the protocol for IND's and I think a matter which FDA would immediately halt if another drug or substance were at issue.

But I have been told that FDA has not even let a single contract to investigate methadone, and that the scanty reports forwarded so far are totally inconclusive as to its effects.

I think that the fact that the long term effects of methadone use have never been studied, nor have the side effects or the effects on expectant mothers and their offspring, would be basis enough to reject approval of any drug. The fact that methadone has the potential and the history of being lethal is an added factor and one which should also weigh heavily.

I do not accept the fact that methadone is a very useful drug for detoxification, and in some instances may be used for maintaining a hard addict.

But for the Federal Government to give its official sanction to this drug as being safe and effective for curing addiction via and approved drug status, would cause great concern. And I have grave reservations about the Federal Government maintaining a portion of the population in a state of addiction.

Our concern over reported FDA approval of methadone for wider distribution does not rest only with the question of whether the drug is effective as a cure to heroin addiction. We know that, while methadone is safe if taken as prescribed, the overall question of safety is a shadowy area. Indeed, a few would contest this committee's findings during road hearings that the present means of controlling the distribution of methadone are wholly inadequate. Under present controls, methadone's potential for death is alarming. In New York State alone, between January 1970 and August 1971, 126 methadone related deaths were reported. Twenty were due to overdoses, six involved accidental poisonings of children.

It is not our intention to seek a total ban on the distribution of methadone, but to encourage only bona fide, well controlled methadone programs. It is our hope that the hearings today can serve as a vehicle to achieve this goal.

I know that the problem of distribution of methadone is of particular concern to our colleague on the committee, James Hastings, who has devoted considerable study to the problem nationally and to its impact on his home State of New York.

I might say that we have received a telegram, as I understand it, and I will be glad to yield at this time.

Mr. HASTINGS. Thank you, Mr. Chairman.

I would like for the record to indicate that as of October the New York Public Health Council sent a telegram to Dr. Edwards expressing their concern. I would like to read that for the record:

"New York State Public Health Council at monthly meeting today expressed serious concern over rumored removal of IND status of methadone. This would result in lack of control that would be possible for any one State to regulate and jeopardize successful programs."

I have received word that Governor Rockefeller has sent a telegram to you, Mr. Chairman, and I believe to Dr. Edwards and to Secretary Richardson, and the text of the telegram is:

"This is to support the action of New York State Public Health Council which recently expressed serious concern over present IND

status of methadone. Changing status will result in a lack of control, would make regulation by any one State impossible, and jeopardize the present successful program."

So my State, the State of New York, expresses serious concern over the possible approval of the FDA on methadone. I personally feel there is a definite therapeutic need for methadone in the maintenance program.

My concern is one of control. I am sure that is a concern that is shared by all of us. I would hope that would be the purpose of this hearing.

Thank you, Mr. Chairman.

Mr. ROGERS. Without objection the telegrams from the Governor and the New York Public Health Council will be made a part of the record.

(The telegrams follow:)

[Telegram]

ALBANY, N.Y., November 8, 1971.

HON. ELLIOT RICHARDSON,
Secretary, Health, Education, and Welfare,
Washington, D.C.:

This is to support the action of the New York State Public Health Council which recently expressed its serious concern over removal of the present IND (investigational new drug) status of methadone. This change in status would result in a lack of control that would make regulation by any one State impossible and would jeopardize present successful programs.

NELSON A. ROCKEFELLER.

(Cc: Mr. Paul G. Rogers, U.S. Representative.)

[Telegram]

ALBANY, N.Y., October 22, 1971.

DR. CHARLES C. EDWARDS,
Commissioner, Food and Drug Administration, Department of Health, Education and Welfare, Rockville, Md.:

New York State Public Health Council at its monthly meeting today expressed its serious concern over rumored removal of present IND status of methadone. This would result in lack of control that would be impossible for any one State to regulate and would jeopardize present successful programs.

NORMAN MOORE, M.D. *Chairman,*

Public Health Council, New York State Department of Health.

(Cc: President Nixon.)

Mr. ROGERS. I should like to read from a letter from Dr. Neil Solomon, secretary of health and mental hygiene of the State of Maryland.

DEAR MR. ROGERS: It is my opinion that methadone should only be administered under most rigidly controlled conditions. I believe there should be nationwide regulation similar to the ones proposed by the State of Maryland, which will make it unlawful for any physician to prescribe methadone except as part of controlled methadone maintenance programs or legitimate medical need. If this is not done, I predict a nationwide problem will develop with methadone that will be of the same magnitude as the one we now have with heroin. There were four deaths this year in the State of Maryland due to overdoses of methadone. These deaths could have all been avoided if we had stricter control over this drug.

Our first witness this morning is Hon. Charles Edwards, Commissioner of the Food and Drug Administration.

We welcome you to the committee, and will be pleased to receive your testimony.

STATEMENT OF DR. CHARLES C. EDWARDS, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY DR. ELMER H. GARDNER, DIVISION OF NEUROPHARMACOLOGICAL DRUGS; PETER HUTT, GENERAL COUNSEL; AND DR. JOHN S. ZAPP, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH), HEW

Dr. EDWARDS. Thank you, Mr. Chairman.

I would like to introduce on my left, Dr. Elmer Gardner, head of the Division of Neuropharmacological Drugs.

On my right, Mr. Peter Hutt, General Counsel, and next to Mr. Hutt is Dr. John S. Zapp, Deputy Assistant Secretary for Legislation (Health).

Mr. ROGERS. We welcome you gentlemen to the committee.

Dr. EDWARDS. We appreciate this opportunity, Mr. Chairman, to discuss with you the background information leading to our current consideration of a new drug application submitted on June 28, 1971, by Eli Lilly & Co. for a Disket formulation of methadone hydrochloride to be used in the long-term treatment of heroin addiction. Until the submission of this data in this NDA, we could not take any position on the safety and efficacy of methadone in treating drug addiction. I wish to emphasize that this NDA is still under consideration. It has not yet been approved or disapproved. My remarks today, therefore, do not represent any final FDA or Department position.

I also want to emphasize that methadone is an addictive narcotic drug. It is certainly not a cure-all or panacea for the treatment of heroin addiction. We at FDA also are fully aware that its use must be very closely monitored and very closely controlled.

The extent of the drug abuse problem and heroin addiction, in particular, has been a cause of increasing public concern. A variety of non-drug-treatment approaches has been utilized over the past several years. They range from long-term hospitalization, to residential programs such as Synanon, to outpatient psychotherapeutic efforts. The time, manpower, and money required in all of these have resulted in only limited success. Accordingly, a chemical therapeutic agent has become an attractive alternative.

This has resulted in a search for an effective medication for addicts. Through such an agent, the addict might be freed of his craving for heroin.

The drug that has been most widely investigated and used for this purpose is methadone, a synthetic narcotic. Methadone has been approved and widely used as an effective analgesic since it was synthesized at the end of World War II. It has also been approved and widely used for more than a decade, in low oral doses, to allay opiate withdrawal symptoms. But not until 1963 was it first observed that this drug could possibly be of value in the treatment of heroin addiction.

Maintenance treatment of heroin addiction with methadone has, since 1963, been in an investigational status. Thus, the drug is not yet approved for general use for maintenance therapy. The investigational

use of methadone under the IND regulations began on a national scale following a publication by Dole and Nyswander on the "Successful Treatment of 750 Criminal Addicts" with methadone in the *Journal of the American Medical Association* on December 16, 1968. A copy of that article is attached to this testimony (see p. 1502).

To collect the type of scientific data needed to support approval of any new drug, it is necessary that the programs using the drug follow proper protocols and keep adequate records. Moreover, investigational studies of methadone present problems not encountered in studies with other types of drugs because it is an addicting narcotic with a proven capacity for abuse.

Therefore, to protect the community from the hazards of diversion and abuse, and to assure the development of valid data, guidelines for methadone maintenance studies were developed through the cooperation of the National Institute of Mental Health, the Bureau of Narcotics and Dangerous Drugs, and the Food and Drug Administration.

These guidelines were published in the *Federal Register* on April 2, 1971. A copy is attached to this testimony (see p. 1509).

Prior approval of both the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs, Department of Justice, is required before any new IND program involving methadone can be initiated.

We have now approved approximately 298 IND sponsors for methadone maintenance programs—representing approximately 380 individual treatment units. New sponsors are sending in plans at the rate of more than one per day.

I would like to emphasize this; more than one per day.

Some sponsors, particularly NIMH and the Veterans' Administration, monitor 20 or more programs. Since publication of the April 2, 1971, regulations, each applicant for a methadone maintenance program has been subject to inspection by BNDD and must receive approval by both BNDD and FDA. Every applicant has been asked to correct any major deficiencies in his protocol before he can initiate this program. We have not approved applications unless BNDD and FDA are convinced that the sponsor can conduct an adequate study. Thus, few private practitioners have been granted IND's for methadone maintenance since April 2.

In considering the new drug application pending before us, and the obligations of the Secretary under section 4 of the Comprehensive Drug Abuse Act of 1970, we have consulted widely among the medical profession.

Among those with whom we have talked 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 FDA/NIMH Psychotomimetic Advisory Committee, several other leading experts, and the FDA Drug Abuse Advisory Committee, chaired by Dr. D. Henry Brill.¹

¹ Committee members: Dr. William Bloom (Tulane University), Dr. Sidney Cohen (UCLA), Dr. Max Fink (New York Medical College), Dr. Daniel X. Freedman (University of Chicago), Dr. Robert Millman (Rockefeller University), Dr. Maurice SeEVERS (University of Michigan), Dr. Eddie L. Way (University of California, San Francisco).

We have met on numerous occasions with representatives of Dr. Jaffe's Special Action Office, the National Institute of Mental Health, and have maintained close liaison with the Bureau of Narcotics and Dangerous Drugs and all Federal agencies. Finally, we have discussed the matter thoroughly with the companies which presently produce and market methadone products.

As one would expect on any controversial subject, there is a wide diversity of opinion about this matter. There appears, however, to be a very strong consensus that the IND status of methadone is no longer defensible, and that an NDA is approvable as long as an acceptable control mechanism is available to make certain that the drug will not be misused.

As is true with some nonopiate drugs, the method of distribution and use is a very important factor in considering whether this drug will be safe under its conditions of use, and must therefore be considered in determining whether it can be approved for marketing under an NDA.

In the opinion of the best medical experts with whom we have consulted, including our advisory committee, and in the opinion of our own staff who have reviewed the data, there is currently substantial evidence that methadone is safe and effective for its pharmacologic effect.

Methadone, in contrast to heroin and many other narcotics, produces its pharmacologic action when taken orally as well as by injection. Oral methadone relieves the craving for injecting heroin for reasons that are not completely understood. When taken orally by the stabilized individual, methadone produces no euphoria or other mental effects and no impairment of functional capacity. Methadone is longer acting than heroin and has less severe withdrawal effects. The individual stabilized on methadone has little or no desire for heroin and, in contrast to the person needing intravenous heroin, is not on an emotional roller coaster which moves from euphoria to beginning withdrawal, and to drug seeking behavior, several times a day. In many instances, moreover, a patient stabilized on oral methadone who injects heroin does not experience the usual euphoria and thus may be dissuaded, therefore, from the use of heroin.

The question whether this will have a major impact in the rehabilitation of narcotic addicts, using various social criteria and indicators, is still open to debate and may not be resolved for some time to come. We have, therefore, been advised that, if the drug is to be approved, it should be approved only for its demonstrated pharmacological effect.

This would follow the procedure we used when we approved antiacid drugs with indications for use in treating of symptomatic relief in peptic ulcer and other conditions for which control of gastric hyperacidity is required. Approval of methadone for its pharmacologic effect would therefore be consistent with normal FDA practice.

Some additional information on the safety of chronic use of methadone in animals and humans may be needed. Approval may therefore be conditioned upon development of such information, as well as further data on the type of patients who best respond to this drug. This is similar to our recent approval of an NDA for L-Dopa, where further studies have been required.

It is always possible, of course, that drugs might later be found that will be safer and more effective than methadone. If methadone is approved for maintenance therapy and subsequent evidence develops that this is the situation, we would then take steps to revoke our approval of methadone. Again, this is a normal situation for FDA. In our recent NAS/NRC review of prescription drugs, we found many situations where a drug that was once considered the drug of choice has become, through the development of better therapeutic agents, either a poor drug at best or even one that must now be removed from the market.

At the moment, however, we know of no drug that has been demonstrated to be as safe and effective as methadone for combating heroin addiction. We must also face the fact that the drug is presently being used not as an investigational drug, but as a regular part of the physician's armamentarium in combating the heroin problem. This may, indeed, have been the situation for over a year. Finally, we must face up to the fact that, with the exception of long-term data on the chronic use of methadone, the data now available on this drug appear fully to demonstrate its safety and effectiveness for treating heroin addiction.

The acceptance of methadone by the medical profession is demonstrated by the very recent statement of the AMA Council on Mental Health on Narcotic and Medical Practice, just published in the October 25, 1971, issue of the *Journal of the American Medical Association*. A copy of that statement is attached to this testimony (see p. 1513).

The council has set out, in that statement, its opinion that methadone may properly be used in the practice of medicine for maintenance as well as detoxification under specific conditions.

Because of methadone's addicting potential, this agency and every individual or group with whom we have consulted believes that a closed system must be established for the close control of the distribution of the drug. Adequate medical care standards must be established for the use of methadone for maintenance treatment.

The new drug provisions of the Food, Drug, and Cosmetic Act permit us to establish strict procedures for the distribution of this drug. Section 4 of the Comprehensive Drug Abuse Act of 1970 permits us to determine proper medical practice in the use of methadone, which can in turn be enforced through the NDA procedures.

The usual approval of a drug for marketing permits prescriptions by an individual licensed to practice medicine. A drug under the schedules of the Comprehensive Drug Abuse Act of 1970 can be prescribed only by a practitioner registered with BNDD. Criminal proceedings are usually necessary to revoke a physician's registration.

In contrast to this typical marketing approval, an NDA could provide the standards for dispensation of this drug so as to limit its distribution to direct shipment from manufacturer to programs approved for maintenance treatment of addiction and to hospital pharmacies for its analgesic use. Addiction treatment programs and hospitals could be approved after submitting a form of certificate detailing the standards of care to which they would adhere. This mechanism would, in essence, provide a licensing system and civil rather than solely criminal procedures to control distribution of the drug.

If a program was unacceptable or did not adhere to its stated standards, drug shipment could be terminated. State health agencies or their designees could assist FDA and BNDD in evaluation of programs for approval and in monitoring the approved programs.

This system of control would have some elements of the investigational controls over a new drug. Under both, there is strong control and accountability.

To minimize diversion, the heretofore approved indications—analgesia, antitussive and opiate detoxification—for methadone might be curtailed or eliminated. This would be done to protect the public against unsafe use of the drug. Under the Food, Drug, and Cosmetic Act, we are required to determine the conditions under which the drug may safely be used, and widespread availability in pharmacies may simply be found not to meet that statutory standard. Similar limitations have been placed on other drugs and thus are not contrary to past practice.

The IND status is intended under the statute to be used solely to permit true clinical investigations and research. It was never intended to be used for exerting regulatory control over a safe and effective drug. With every passing day it is apparent that methadone is being retained on IND status solely for control purposes, contrary to the intent of our statute and regulations. We have now reached the point where we must either approve the drug or revoke IND's for the vast majority of the existing methadone treatment programs throughout the country and return to a handful of true research studies.

The proposal to approve methadone that we are now considering contains regulatory control mechanisms that are at least as strong as those available under the present IND status, and indeed in my opinion are probably stronger. Using the authority of the Comprehensive Drug Abuse Act of 1970 as well as the Federal Food, Drug, and Cosmetic Act, we have been able to formulate an approach that will reduce, as far as possible, the possibility of diversion and misuse. It is this approach that we have been discussing with all of the individuals and organizations mentioned above.

We are aware that there is concern that new legislation may be necessary to achieve a sufficient degree of control to prevent misuse and abuse of methadone. As I have already indicated, the NDA approach we are presently considering, provides at least as strong control and accountability as the IND approach. We are, however, participating with the Special Action Office and BNDD in the active consideration of possible new legislation. We would of course most assuredly endorse any needed new legislative controls.

We fully recognize that FDA cannot do the important job of surveillance over the use of methadone by itself. We have worked closely with BNDD in the surveillance of methadone and under its IND status and the same cooperation will exist if and when the drug is approved. We have in the past withdrawn approval of an IND plan for methadone whenever requested to do so by BNDD. We would give the same serious consideration to any such request by BNDD in the future.

In short, the matter of control is every bit as important as whether safety and effectiveness have been established. Whether the drug is

retained on IND status or is approved, regulatory control will remain the principal focus.

Whatever conclusion is reached on this matter, the decision will be published in the Federal Register with ample time for consideration and comment by interested persons. We realize that it is difficult for this committee to consider the matter on the basis of the discussion we are able to present today, without being able to review a concrete proposal. We can therefore assure you that if any concrete proposal does emerge, Congress, interested professionals, and, indeed the public at large, will have ample opportunity to make known its views before any final action is taken. As with the IND protocol, full opportunity for presentation of opinions will be given. We do not wish to rush into any new approach without full and adequate consideration by all who are interested.

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

Mr. Chairman, that is the conclusion of our prepared statement.

(The attachments referred to follow :)

[From Journal of American Medical Association, December 16, 1968]

Successful Treatment of 750 Criminal Addicts

Vincent P. Dole, MD; Marie E. Nyswander, MD; and Alan Warner, PhD

A four year trial of methadone blockade treatment has shown 94% success in ending the criminal activity of former heroin addicts. The majority of these patients are now productively employed, living as responsible citizens, and supporting families. The results show unequivocally that criminal addicts can be rehabilitated by a well-supervised maintenance program.

In November 1963, on the initiative of the Health Research Council of New York city, a study of heroin addiction was started at Rockefeller University Hospital. The council recognized the need for new methods of treatment. Thousands of heroin addicts were filling the jails of New York city. It seemed reasonable to ask whether some medication might control the drug hunger of these criminal addicts, and enable them to live in the community as decent citizens.

See also page 2712.

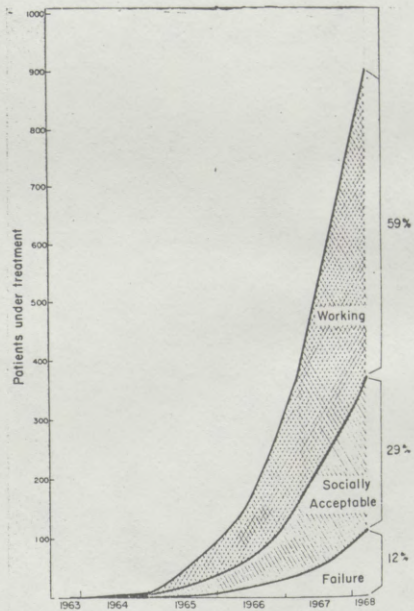
Clinical studies conducted in the metabolic ward during 1964 and extended to Beth Israel Medical Center in 1965 suggested that this result might be achieved by using the familiar drug methadone hydrochloride in a new way. By establishing tolerance to methadone, and subsequently maintaining the tolerant state with a constant daily oral dose, we found it possible to block the action of heroin, and eliminate the hunger for narcotic drugs.¹ Patients, thus blockaded, felt no narcotic effects, but lost their compulsive desire for heroin. They stopped being criminals, and in the majority of cases became productive members of society. A preliminary report of the clinical findings was published in 1965.²

At the time of this report, the potential value of treatment for large scale use remained indeterminate. The results, although encouraging, were lim-

From Rockefeller University and Beth Israel Medical Center, New York.

Read before the Section on Preventive Medicine at the 117th annual convention of the American Medical Association, San Francisco, June 19, 1968.

Reprint requests to Rockefeller University, New York 10021 (Dr. Dole).



1. Growth of the methadone maintenance treatment program. In addition to patients in treatment, approximately 1,000 addicts are awaiting admission to program.

ited to the treatment of a few patients for a few months. The present report summarizes the much more extensive experience of the past four years (Fig 1). The number of criminal addicts who have been rehabilitated with methadone treatment is large enough to empty a moderate sized jail, and there are at least 1,000 more addicts waiting for treatment. Detailed records of medical and social status have been kept for all patients, and analyses of urine for narcotic drugs, barbiturates, and amphetamines have been made at least weekly.³

All patients admitted to treatment from the beginning of the research (January 1964) to the time of this report (June 1968) are included in the statistics, except for a special group of patients who received combined treatment for addiction and tuberculosis, and a few patients who had been started on methadone therapy elsewhere and were accepted as transfers. For some analyses, such as measures of social stability and productivity, the tabulation has been limited to patients who have been in treatment for more than three months.

A notable feature of the treatment program has been the absence of compulsion or confinement. It has not been found necessary in the methadone program to apply prison techniques for control of behavior. Some addicts who had been notorious troublemakers in prison-type programs have become ordinary patients with methadone treatment. Not all have responded favorably, of course; some patients have been discharged for disruptive behavior, or because of nonnarcotic drug abuses. All of these failures—including patients who had been in treatment for only one day—are included in the statistics (Table 1).

Procedure

Addicts with a history of at least four years of mainline heroin use and repeated failures of withdrawal treatment were admitted to treatment in the order that they applied, subject to the following conditions: age 20 to 40 (upper limit raised to 50 in the third year of the study), no legal compulsion (ie, methadone treatment not a condition of probation or parole), no major medical complication (eg, severe alcoholism, epilepsy, schizophrenia), and resident of New York city. During the first 18 months only men were admitted to the program; subsequently a woman's unit has been in operation, with admission by the same procedure except that the intake office attempts to bring in married couples to the two units at approximately the same time.

The treatment program is divided into three phases, related to the progress of rehabilitation with methadone maintenance continuing throughout. During phase 1, a six week period of hospitalization on an open medical ward, the patients are brought to a blockading level of methadone. The new patient should be given this medication in relatively small, divided orally administered doses (eg, 10 mg twice daily), and brought to mainte-

Table 1.—Discharges From January 1964 to May 1968*

Cause	Time on Program, mo				
	<1	1-6	6-12	>12	
Behavior	5	23	13	13	(50%)
Drug abuse	0	0	0	0	(0%)
Heroin	2	2	0	5	(8%)
Nonheroin	4	8	7	8	(25%)
Medical	2	1	5	1	(8%)
Disability	2	2	1	5	(9%)
Death	2	2	1	5	(9%)
Voluntary	(14%)	(33%)	(24%)	(29%)	

*There were 863 total admissions and 109 total discharges (13% of admissions).

nance level (80 to 120 mg/day) gradually, over a period of four to six weeks. Some experience in regulation of dose is necessary: if the medication is increased too rapidly, the patient will become over-sedated during the first few weeks, and may experience urinary retention and constipation, whereas if the dose is inadequate, a patient who had been using a large amount of heroin will have unnecessary withdrawal symptoms. There appears to be a wide margin of safety in administration of methadone to patients who have been heroin addicts, but of course the physician must avoid giving an excessive dose to a new patient. When in doubt, the safe rule is to give the medication in divided doses and observe the effects over the first 24 hours.

As the dose is gradually increased over a period of four to six weeks, the medication makes the patient refractory to narcotic drugs and eliminates (or greatly reduces) any narcotic drug hunger, presumably by maintaining a blockade of the sites of narcotic drug action. There should be no euphoria or other undesirable side effects (except mild constipation) if the medication is given in proper dosage. If the patient appears to be sedated during this induction phase the dose of methadone should be held constant or reduced until further tolerance is developed.

More recently, we have been testing a strictly ambulatory treatment, and have obtained favorable results, confirming the previous reports of Brill and Jaffe⁴ and of Wieland.⁵ New patients are started on small doses of methadone and are gradually brought up to stabilization level, as closely supervised outpatients. This is much less expensive than hospitalization and, with proper supervision, equally successful.

Phase 2 begins for the patients when they are discharged to the outpatient clinic, and continues for at least a year. The newly discharged patients return for medication to the outpatient clinic each weekday, and are given medication to take home for the weekends. Later, as justified by good conduct, the patients are permitted to come at less frequent intervals, taking out doses of medication for the intervening days. At least once per week (with rare exception) each patient is required to drink a full dose of the medication in the clinic, and thus demonstrate that he has maintained his

tolerance by taking medication during the intervals. Each time that a patient comes to the clinic he is required to leave a urine specimen for analysis.

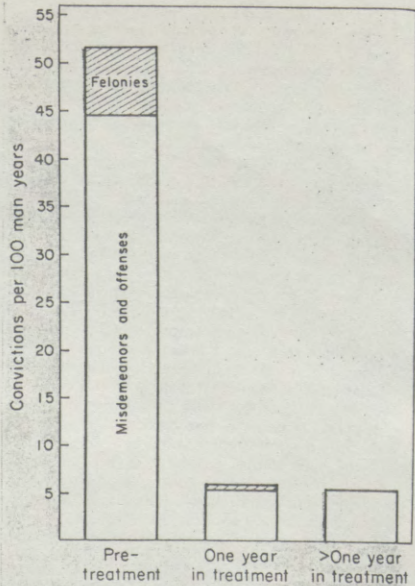
Phase 3 is reached when the subject has become a stable and socially productive member of the community, and can be treated as an ordinary medical patient. To be classified in this category, he must be acceptably employed (either in a job or at school, or if a woman, as a homemaker), and have no further problems with drugs or alcohol. The stability of rehabilitation must be proven by one year of normal life in the community. Medically the treatment of these patients remains the same as the treatment of patients in phase 2; they also take at least one dose of medication in the clinic each week, and leave a urine specimen.

Patients who have been discharged for misconduct, or who have asked to leave the program, have been withdrawn from medication by gradual reduction in dose over a period of about a month. This is done easily and without discomfort. We have not, however, considered it desirable to withdraw medication from patients who are to remain in the program, since those who have been discharged have experienced a return of narcotic drug hunger after removal of the blockade, and most of them have promptly reverted to the use of heroin. It is possible that a very gradual removal of methadone from patients with several years of stable living in phase 3 might succeed, but this procedure has not yet been adequately tested.

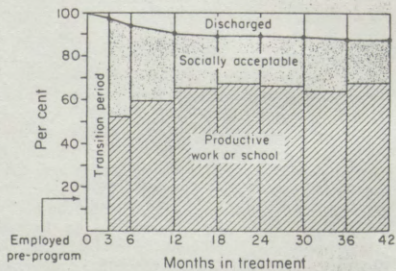
The supportive services provided by the methadone program and community agencies have been related to the needs of the patients. Some patients, when freed from the burden of heroin addiction, have ceased all antisocial activity; they obtained jobs without further assistance and began to support their families. These exceptional individuals needed nothing from the program except medical supervision. More frequently, the slum-born, minority group criminal addict needed help to become a productive member of society. Many of these individuals came to us from jail with no vocational skills, no family, and no financial resources. They were further handicapped by racial discrimination and by their police records.

Results

Drug-related crime has been sharply reduced by the blockade of narcotic drug hunger. Prior to treatment 91% of the patients had been in jail, and all of them had been more or less continuously involved in criminal activities. Many of them had simply alternated between jail and the slum neighborhoods of New York city. The crimes committed by these patients prior to treatment had resulted in at least 4,500 convictions (for felonies, misdemeanors, and offenses), a rate of 52 convictions per 100 man-years of addiction. The figure is obviously a minimum estimate of their pretreatment criminal activity since convictions measure only the number of times an addict has been caught. For every con-



2. Reduction in criminality of 912 former heroin addicts, as measured by 90% drop in rate of convictions.



3. Status of 723 male addicts admitted to methadone treatment. Rehabilitation was measured by productive employment and crime-free status over four-year period.

viction, the usual addict has committed hundreds of criminal acts for which he was not apprehended.

Since entering the treatment program, 88% of the patients show arrest-free records. The remainder have had difficulties with the law. Some of these individuals, however, were arrested merely on suspicion, on charges such as loitering, or by inclusion in a group arrest. In such cases, if the charges were

Table 2.—Convictions* of 912 Patients on Methadone Therapy, January 1964 to May 1968 (939 Patient-Years)

	Felony	Misdemeanor	Lesser Offenses
Narcotics	3	10	0
Dangerous drugs	0	4	0
Nondrug crimes	0	27	7
Rate per 100 patient-years	0.3	4.4	0.7

*Convictions for offenses committed while patients were receiving treatment. Pretreatment conviction rate (all offenses) was 52 per 100 patient-years.

subsequently dismissed, the episode has not been considered a criminal offense in our statistics. The remainder, 5.6% of the patients, were guilty of criminal offenses, and were convicted. In all, there have been 51 convictions in 880 man-years of treatment experience (a rate of 5.8 convictions per 100 man-years). Table 2 shows a more detailed analysis of these data.

We believe that the record of convictions of patients in treatment is essentially complete since a patient receiving methadone cannot absent himself for longer than a week without being missed. Moreover, legal representation is available for arrested patients. It provides both an accurate definition of the charge, and an incentive for the arrested person to report his difficulty. As to the estimate of arrests and convictions of patients before treatment, we have only a minimal and incomplete figure. The reduction in crime, therefore, is at least 90% (Fig 2).

All patients convicted of crimes and removed from treatment by imprisonment were discharged from the program. Some of them have been, or will be, readmitted on completion of their jail sentences. A few other patients were discharged voluntarily. Of a total of 863 admitted to treatment, ten (1.2%) were discharged from methadone treatment at their own request because they wished to leave New York; these patients are not considered either successes or failures since their outcome is not definitely known. The remainder (12%), all of whom we report as failures of the program, can be classified both by the length of time in treatment and the reason for discharge (Table 1). In most cases the misconduct that led to discharge involved uncooperative or antisocial behavior, or nonnarcotic drug abuse (including alcoholism). For these individuals—fortunately the minority—stopping heroin use with blockade treatment was not enough to open the way for rehabilitation. Possibly more elaborate programs, combining blockade treatment with psychotherapy and sheltered environment, might have succeeded.

Since blockade with methadone makes heroin relatively ineffective, a patient cannot use heroin for the usual euphoria, nor will he experience abstinence symptoms after an experiment with the drug. He can, however, remain drug-oriented in his thinking, and be tempted to return to heroin. Many patients have made sporadic attempts to use heroin again, especially during the first six months of treatment. Their habits of association with ad-

dicts, and of heroin taking in certain environments, were not eliminated by the blockade. For such individuals, the negative experience of experimenting with heroin and feeling little or no euphoria may contribute to the extinction of conditioned reflexes that underlie drug-seeking behavior." Needless to say, the staff does not encourage such dangerous experiments, but we recognize that for some individuals this type of self-experimentation might be a necessary step in reeducation and should not be regarded as a failure of treatment. Fortunately, experiments of this kind were the exception rather than the rule. The majority of patients have stopped heroin use completely after starting methadone treatment. This fact has been verified by repeated analyses of urine. For example, in a group of 174 patients, in which the analyses were done three times weekly for the first year of treatment, 55% did not show a single positive for self-administered narcotics. On the other hand, a minority of these patients, about 15%, continued to use heroin intermittently (eg, on weekends) even though the euphoric effect was blocked. These tended to be isolated, schizoid individuals who were unable to find new friends or participate in ordinary activities.

The greatest surprise has been the high rate of social productivity, as defined by stable employment and responsible behavior (Fig 3). This, of course, cannot be attributed to the medication, which merely blocks drug hunger and narcotic drug effects. The fact that the majority of patients have become productive citizens testified to the devotion of the staff of the methadone program: physicians, nurses, older patients, counselors, and social workers. The success in making addicts into citizens also shows that an apparently hopeless criminal addict may have ambition and intelligence that can work for rather than against society when his pathological drug hunger is relieved by medical treatment.

This investigation was supported by grants from the Health Research Council (City of New York Department of Health) and the New York State Narcotic Addiction Control Commission.

Generic and Trade Names of Drug

Methadone hydrochloride—Adanon Hydrochloride, Althos Hydrochloride, Amidone Hydrochloride, Dolophine Hydrochloride.

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Special Communication

Progress Report of Evaluation of Methadone Maintenance Treatment Program as of March 31, 1968

Methadone Maintenance Evaluation Committee*

The Methadone Maintenance Program, under the direction of Vincent Dole, MD, and Marie Nyswander, MD, has now been in operation for approximately four years. It was initiated by a grant from the New York City Health Research Council, has been continued and expanded by a contract from New York City Department of Hos-

See also page 2708.

pitals through the Inter-departmental Health Council to Beth Israel Medical Center and, as of Oct 1, 1967, the program has been funded through the State of New York Narcotic Addiction Control Commission. This program is an outgrowth of work at Rockefeller University which indicated that methadone maintenance offered hope as a treatment modality in the rehabilitation of "hard core" heroin addicts.

The charge to the Evaluation Unit at the Columbia University School of Public Health and Administrative Medicine has been to attempt to evaluate the results of this program in an objective manner and to make recommendations based on this evaluation.

1. Percentage distribution by age of patients in methadone program and New York City Narcotics Register.

*Henry Brill, MD, Chairman. For a complete list of members of the committee, see page 2714.

This report was recommended for publication by the AMA Council on Mental Health.

Reprint requests to Pilgrim State Hospital, Box 22, West Brentwood, NY 11717 (Dr. Brill).

Description of Patients

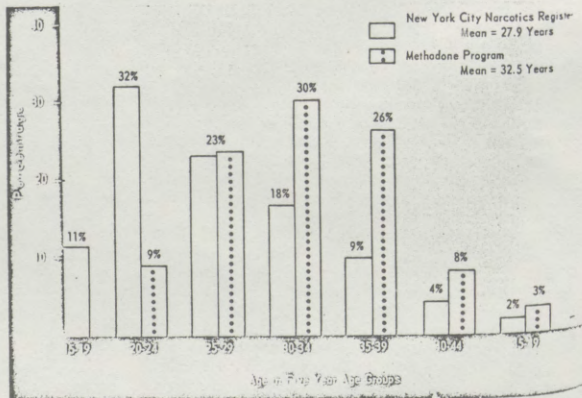
The patients in the Methadone Maintenance Program have all been well-established heroin addicts, for an average of ten years prior to admission to the program. They are between 20 and 50 years of age with an average age of 33 years as compared with an average age of 28 years for addicts reported to the New York City Narcotics Register.

Sixty-eight percent of the patients in the program are over the age of 30 contrasted with 34% of addicts reported to the Narcotics Register (Fig 1). The ethnic distribution of patients in the program compared with that of addicts known to the Narcotics Register is shown in Fig 2. The proportion of white patients is considerably higher in the program (48% vs 25%) and the proportion of Negro and Puerto Rican patients is lower (33% vs 47%) and (18% vs 27%). Approximately half of the patients did not finish high school, and practically all of them have well-documented histories of repeated previous arrests, jail terms, and repeated treatment failures.

The patients all enter the program voluntarily, and each one signs a consent form prior to starting treatment.

Program

The program is in two phases. Phase 1 is an inpatient phase of approximately six weeks during which the patients are given methadone hydrochloride in increasing doses until they are built up to a stabilizing dose of between 80 and 120 mg daily. During their hospital stay, the patients are given a great deal of personal, social and psychological support, as well as necessary medical and dental care. This care is provided by a team of physicians, social workers, nurses, and counselors. Research assistants who are former addicts, currently being



maintained on methadone, also play an essential supporting role in the program.

Although available, formal psychiatric treatment has been required by only a small group of patients.

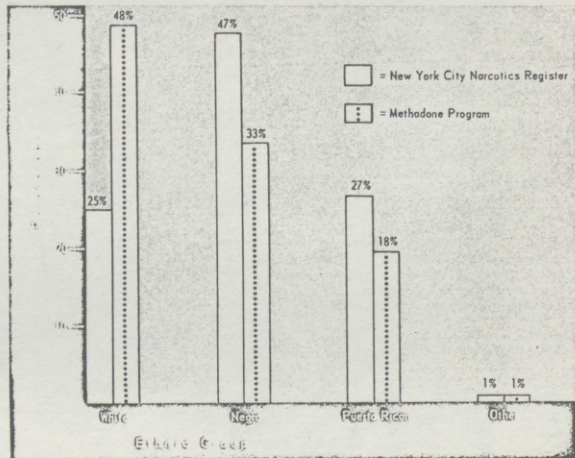
Phase 2 is the outpatient phase. In the early part of phase 2, the patients appear daily for medication and urine testing for indication of heroin usage, or use of other drugs. After a few months those patients who appear to have made a good adjustment are provided with medication for several days at a time and return to the clinic once or twice a week for urine testing. Physical examinations are given periodically, psychosocial, vocational, and legal support is available, as needed. The major emphasis is in assisting the patients towards (1) getting a job, (2) returning to school to complete the equivalent of a high school education, (3) increasing their skills by taking additional technical training (ie, TV repair, auto repair, beautician).

Results

As of March 31, 1968, a total of 871 patients had been admitted to the program. One hundred and nineteen or 14% have left the program. Of these, 87 or 10% have been discharged, 3% have dropped out, and 1% have died. The Table shows the census for each of the groups which are currently being followed. Experience with the Van Etten Tuberculosis group, the Rockefeller University Ambulatory treatment group, and the group from Riker's Island is limited both in numbers and in length of follow-up; therefore, this report will focus on the results obtained in the two largest groups with the longest experience who are being treated under the program contract with Beth Israel Medical Center. This group includes 375 men from Morris J. Bernstein Institute and 169 men from Harlem Hospital who have been in the program three months or longer.

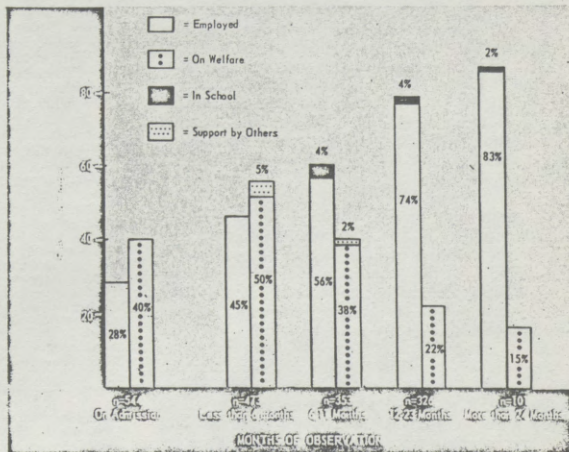
Among these 544 men only 28% were known to be gainfully employed at time of admission and 40% were known to be re-

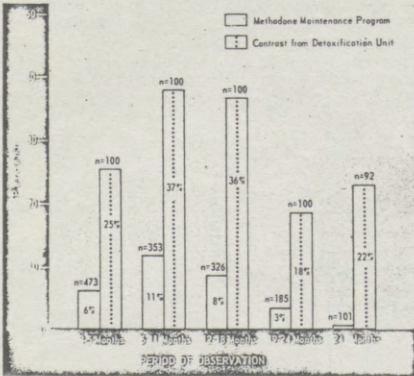
ceiving welfare support. The progress of these patients is shown in Fig 3. After five months in the program 45% are employed, after 11 months 61% are either employed or in school and among those remaining 24 months or longer, 85% are employed or in school. The proportion of patients receiving



2. Percentage distribution by ethnic group of patients in methadone program and New York City Narcotics Register.

3. Employment status and school attendance for 544 men in Methadone Maintenance Program three months or longer as of March 31, 1968, according to months of observation.





4. Percentage distribution of arrests for 544 men in Methadone Maintenance Program three months or longer as of March 31, 1968, and for contrast group according to months of observation.

Methadone Maintenance Research Program Census as of March 31, 1968

Facility	No. Admitted Through 3/31/68		No. Discharged*		Discharged, %		No. in Program as of 3/31/68	
	M	F	M	F	M	F	M	F
MBI†	486	105	72 (4)	18 (1)	15	17	414	87
Harlem	207		16 (2)		8		191	
Van Etten	35	8	12 (1)	1	34	13	23	7
Other	20	4	...	...	...	...	20	4
Rikers Island	6		...	...	...	...	6	
Subtotal	754	117	100	19	13	16	654	98
Total		871		119 (8)		14		752

*Number in parentheses represent deaths, overall death rate is 1%.
†MBI represents Morris J. Bernstein Institute.

welfare support shows a progressive reduction from 50% at five months to 22% after one year and 15% after two years. The experience with the 79 women who have been in the program for three months or longer shows a similar pattern.

None of the patients who have continued under care has become readdicted to heroin, although 11% demonstrate repeated use of amphetamines or barbiturates, and about 5% have chronic problems with alcohol.

Another measure of rehabilitation is a decrease in the number of arrests. Figure 4 shows the proportion of men in the methadone program who have been arrested in each period of observation contrasted with the proportion of arrests in a contrast group selected from patients admitted to the Detoxification Unit at Morris Bernstein Institute and followed up over the same period of time. This contrast group was matched with the methadone group only by age, ethnic group, and month of admission, and therefore, is not, in any sense, a control group. The recent arrest experience of those who have been dropped from the program resembles that of the group from the Detoxification Unit.

A relatively small percentage of those gainfully employed are employed in the program. This is often a transient phase in the process of rehabilitation. All patients are continuing on maintenance doses of methadone. Periodic medical examinations have demonstrated no evidence of toxic effects of the drug in either liver or kidney function tests, and no evidence of decreased motor functioning.

Conclusions

The results of this program continue to be most encouraging in this group of heroin addicts, who were admitted to the program on the basis of precise criteria. For those patients selected and treated as described, this program can be considered a success. It does appear that those who remain in the program have, on the whole, become productive members of society, in contrast to their previous experience and have, to a large extent, become self-supporting and demonstrate less and less antisocial behavior. It should be emphasized that these are volunteers, who are older than the average street addict and may be more highly motivated. Consequently, generalizations of the results of this program in this population to the general addict population probably are not justified. There remain a number of related research questions which need further investigation.

Recommendations

As a result of the most encouraging results demonstrated thus far, we recommend:

1. Continued intake of new patients as rapidly as current facilities will allow.
2. Expansion of the program to other units which can provide all elements of the current program.
3. Extension of the program to other groups, with different criteria for admission such as younger patients, or a prison population, in order to determine the applicability of this treatment program to a broader segment of the addict population, and variations in technique, including induction on an ambulatory basis.
4. Further research on the impact of each major component of the program.
5. Continued follow-up and evaluation of all patients currently in the program and in any new programs to be developed in order to assess the long-term effects and results.

Members of the Methadone Maintenance Evaluation Committee include Paul Densen, DSc; Jack Elinson, PhD; Herman Hilleboe, MD; Lawrence C. Kolb, MD; Donald B. Louria, MD; Harold Meiselas, MD; Samuel P. Oest III, MD; Dickinson Richards, MD (Emeritus); Cecil G. Sheps, MD; Ray Trussell, MD. Ex-Officio Members: Efrén Ramirez, MD; Florence Kavalet, MD; Maurice Bachrach. Staff: Frances R. Gearing, MD, Director, Evaluation Project; Mrs. Frieda Karen, Field Supervisor.

This report was submitted to the State of New York Narcotic Addiction Control Commission by Columbia University School of Public Health and Administrative Medicine under terms of Contract Number C-26978.

Generic and Trade Names of Drug

Methadone hydrochloride—Adanon Hydrochloride, Althose Hydrochloride, Amidone Hydrochloride, Dolophine Hydrochloride.

(Reprinted from Federal Register of April 2, 1971; 36 F.R. 6075)

Title 21—FOOD AND DRUGS**Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare****SUBCHAPTER C—DRUGS****PART 130—NEW DRUGS****Conditions for Investigational Use of Methadone for Maintenance Programs for Narcotic Addicts**

A notice was published in the *FEDERAL REGISTER* of June 11, 1970 (35 F.R. 9014), proposing establishment (21 CFR 130.44) of acceptable guidelines for programs for the investigation of methadone in the maintenance treatment of narcotic addicts. The guidelines of the Bureau of Narcotics and Dangerous Drugs, Department of Justice, were also proposed June 11, 1970 (35 F.R. 9015). In response, a substantial number of comments were received from the medical community through the American Medical Association, Student American Medical Association, American Psychiatric Association, National Academy of Sciences-National Research Council, known authorities in the treatment of drug addiction, and from individuals and municipalities currently operating methadone maintenance programs.

The majority of the comments are in the form of objections to provisions of the protocol and the regulation, as follows:

1. The criteria in the protocol for the exclusion of subjects from the studies: Pregnancy, psychosis, serious physical disease, and persons less than 18 years of age.

2. The requirement in the protocol that no more than a 3-day supply be given to a subject at one time.

3. The necessity for making records available to the Food and Drug Administration and to the Bureau of Narcotics and Dangerous Drugs and the lack of a guarantee of confidentiality of patient records.

4. The requirement that one of the objectives of the studies be a return to the drug-free state.

5. The requirement that the dosage level be limited to 160 milligrams per day.

6. The necessity of obtaining prior approval from the Bureau of Narcotics and Dangerous Drugs.

7. The requirements for weekly urine analysis and other laboratory tests and examinations.

8. The classification of the use of methadone in the maintenance treatment of narcotic addicts as an investigational use.

9. The regulation being overly restrictive and not in the best interest of the public.

The Commissioner of Food and Drugs, having considered the comments and having met with representatives of in-

terested groups, associations, and individuals for further discussion, finds that:

1. The majority of the comments are a result of interested persons interpreting the proposal as restricting investigators to the suggested protocol. This is a misinterpretation since the protocol is intended only as a guide to assist the profession, municipalities, organizations, and other groups who are interested in sponsoring programs for the investigation of methadone in the maintenance treatment of narcotic addicts. It is not intended that every methadone program be confined to the limits of this protocol. Modification of the protocol and completely different protocols will be accepted, provided they can be justified by the sponsor. Modifications and completely different protocols consistent with public welfare and safety will be approved.

2. Since the suggested protocol is intended as an aid to those who wish to sponsor programs for the investigation of methadone in the maintenance treatment of narcotic addicts, it is recognized that it would be to the benefit of the Food and Drug Administration, the Bureau of Narcotics and Dangerous Drugs, and the sponsors of the investigations to have a suggested protocol that would be acceptable to the majority of sponsors while satisfying the requirements of the two aforementioned agencies. Accordingly, the following revisions have been made in the regulation as adopted below:

a. The provision of the protocol "Criteria for exclusion from the program" has been changed to "Patients requiring special consideration." Pregnancy, psychosis, serious physical disease, and being less than 18 years of age are not reasons for automatic eliminations from a program but are conditions that merit special considerations which are detailed.

b. A provision has been added to the protocol to permit the investigator to exceed the dosage of 160 milligrams per day when the investigator finds it essential to do so and describes the considerations leading to such dosage levels in his protocol.

c. The requirement for laboratory examinations at 6-month intervals has been changed to 1-year intervals.

d. The objectives of the study have been clarified.

3. The remaining comments concerning the protocol and not mentioned above deal primarily with problems that can be met by submission of a modified protocol to be judged on individual merit.

4. Regarding the objection that the recordkeeping requirements and the necessity for making records available to the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs could violate the confidential relationship between the patient and the physician: The Federal Food, Drug, and Cosmetic Act provides for promulgating regulations that require the sponsor of the drug investigations to maintain adequate records and that these records be made available to authorized

personnel of the Food and Drug Administration. These records must be adequate in the event that followup on adverse reaction information requires identification of the patient. The Bureau of Narcotics and Dangerous Drugs is authorized to have access to these records under the Harrison Narcotic Act.

5. Methadone used in the maintenance treatment of narcotic addicts is an investigational use drug because, despite recent research gains, there remains inadequate evidence of long-term safety and of long-term effectiveness for this use to permit general marketability of methadone for maintenance treatment under the Federal Food, Drug, and Cosmetic Act standards for new drugs.

6. It is necessary that prior approval for methadone maintenance programs be obtained from the Bureau of Narcotics and Dangerous Drugs as well as the Food and Drug Administration because of this drug's potential for abuse. The Bureau of Narcotics and Dangerous Drugs' approval will be based on the existence of adequate control procedures to prevent diversion of the drug into illicit channels. Since the applications will be submitted only to the Food and Drug Administration and reviewed simultaneously by the two agencies, the inconvenience to the sponsor and the delay of approval will be minimal.

Therefore, 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 under authority delegated to the Commissioner (21 CFR 2.120), the following new section is added to Part 130:

§ 130.44 Conditions for investigational use of methadone for maintenance programs for narcotic addicts.

(a) There is widespread interest in the use of methadone for the maintenance treatment of narcotic addicts. Though methadone is a marketed drug approved through the new-drug procedures for specific indications, its use in the maintenance treatment of narcotic addicts is an investigational use for which substantial evidence of long-term safety and effectiveness is not yet available under the Federal Food, Drug, and Cosmetic Act standards for the general marketability of new drugs. In addition, methadone is a controlled narcotic subject to the provisions of the Harrison Narcotic Act and has been shown to have significant potential for abuse. In order to assure that the public interest is adequately protected, and in view of the uniqueness of this method of treatment, it is necessary that a methadone maintenance program be closely monitored to prevent diversion of the drug into illicit channels and to assure the development of scientifically useful data. Accordingly, the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs conclude that prior to the use of methadone in the maintenance treatment of narcotic addicts, advance approval of both agencies is required. The approval will be based on a review of a Notice of Claimed Investigational Exemption for

a New Drug submitted to the Food and Drug Administration and reviewed concurrently by the Food and Drug Administration for scientific merit and by the Bureau of Narcotics and Dangerous Drugs for drug control requirements.

(b) No person may sell, deliver, or otherwise dispose of methadone for use in the maintenance treatment of narcotic addicts until a study providing for such use has had the advance approval of the Commissioner of Food and Drugs on the basis of a Notice of Claimed Investigational Exemption for a New Drug justifying such studies.

(c) An abbreviated Notice of Claimed Investigational Exemption for a New Drug shall be submitted in four copies to the U.S. Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852. Forms entitled "Notice of Claimed Investigational Exemption for Methadone for Use in the Maintenance Treatment of Narcotic Addicts," suitable for such a submission may be obtained from the above address. The submission should be signed by the person in charge of the maintenance program who will be regarded as the responsible party and sponsor for the exemption. If the sponsor is a manufacturer or distributor of the drug, the regulations as outlined in § 130.3 should be followed, except where the guidelines set forth below in this section are appropriate. The notice shall contain the following:

(1) Name of sponsor, address, and date and the name of the investigational drug, which is methadone.

(2) A description of the form in which the drug is purchased (for example, bulk powder or tablet or other oral dosage form), the name and address of the manufacturer or supplier, and a statement that the drug meets the requirements of the United States Pharmacopoeia or the National Formulary if recognized therein. If it is in an oral form designed to minimize its potential for abuse, and is not recognized in the U.S.P. or N.F., assurance that the drug meets adequate specifications for its intended use should be provided. This information may be obtained from the manufacturer. If bulk powder is used, a statement detailing how it is to be formulated, the name and qualifications of the person formulating the dosage form, and the address of where the formulating will take place if it is to take place at any location other than the principal address of the sponsor.

(3) The name, address, and a summary of the scientific training and experience of each investigator, and all other professional personnel having major responsibility in the research and rehabilitative effort, and individuals charged with monitoring the progress of the investigation and evaluating the safety and effectiveness of the drug if the monitor is other than a physician-sponsor. An investigator, other than a physician-sponsor (and investigators immediately responsible to a physician-sponsor and named in his submission) who has signed a form FD-1571 or the form entitled "Notice of Claimed Invest-

igational Exemption for Methadone for Use in Maintenance Treatment of Narcotic Addicts," is required to sign a form FD-1573, obtainable from the Food and Drug Administration.

(4) A description of the facilities available to the sponsor to perform the required tests including the name of any hospital, institution, or clinical laboratory facility to be employed in connection with the investigation.

(5) A statement regarding the number of subjects to be included in the program.

(6) A statement of the protocol. The following is an acceptable protocol; however, it is not to be construed that this protocol must be adhered to in order to obtain clearance by the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs. This protocol is intended primarily as a guide for investigators who wish guidance in what said agencies consider acceptable. Investigators who wish to do so may submit modifications of this protocol or other protocols; these will be judged on their merits.

PROTOCOL

A. Objectives. 1. To evaluate the safety of long term methadone administration at varying dosage.

2. To evaluate the efficacy of oral methadone per se in decreasing the craving for other narcotic drugs and in minimizing their euphoriant effect.

3. To evaluate the efficacy of methadone as a pharmacological moiety in facilitating social rehabilitation of narcotic addicts.

4. To determine which addicts are capable of returning to an enduring drug-free state.

B. Admission criteria. 1. Documented history of physiological dependence on one or more opiate drugs, the duration of which is to be stated.

2. Confirmed history of one or more failures of treatment for their physiological dependence on opiates.

3. Evidence of current physiological dependence on opiates.

An exception to the third criterion (current physiological dependence on opiates) is allowable in exceptional circumstances for certain subjects for whom methadone maintenance may be initiated a short time prior to or upon release from an institution. This procedure should be justified on the basis of a history of previous relapses. In these circumstances, appropriate descriptions of the facilities, procedures, and qualifications of the personnel of the institution are to be included in the application filed by the sponsor.

Subjects who wish to do so may be transferred from one approved program to another.

C. Patients requiring special consideration—1. Pregnant patients. Safe use of methadone in pregnancy has not been established. There is limited documented clinical experience with pregnant patients treated with methadone, and animal reproduction studies have not been done. It is therefore preferable that pregnant patients be hospitalized and withdrawn from narcotics. If such a course is not feasible, pregnant patients may be included provided the patient is informed of the possible hazard. To minimize the risk of physiological dependence of the new born, or other complications, pregnant women should be maintained on minimal dosage. The investigator should promptly report to the Food and Drug Administration the condition of each infant born to a mother in a methadone maintenance program.

2. Patients with serious physical illness. Patients with serious concomitant physical

illness are to be included in methadone maintenance program only when comprehensive medical care is available. Such patients require careful observation for any adverse effects of methadone and interactions with other medications. The investigator should promptly report adverse effects and evidence of interactions to the Food and Drug Administration.

3. Psychotic patients. Psychotic patients may be included in methadone maintenance programs when adequate psychiatric consultation and care is available. Administration of concomitant psychotropic agents requires careful observation for possible drug interaction. Such occurrences should be promptly reported.

Investigators who intend to include in their programs patients in categories 1, 2, and/or 3 above should so state in their protocols and should give assurance of appropriate precautions.

4. Patients less than 18 years of age. It is imperative that adolescents be afforded the benefit of other treatment modalities whenever possible and that those with minimal histories of physiological dependence be excluded from methadone maintenance programs. Investigators who wish to include adolescents in the program are therefore required to submit special protocols for this purpose. These protocols should state in detail the number of such patients to be treated, the alternative treatment methods available, the criteria for selection, the screening procedures, and the ancillary procedures to be employed.

D. Admission evaluation. 1. Recorded history to include age, sex, history of arrests and convictions, educational level, employment history, and past and present history of drug abuse of all types.

2. Medical history of significant illnesses.

3. History of prior psychiatric evaluation and/or treatment.

4. Assessment of the degree of physical dependence on and psychic craving for narcotics and other drugs, and evaluation of the attitudes toward and motivations for participation in the program.

5. Formal psychiatric examination in subjects with a prior history of psychiatric treatment and in those in whom there is a question of psychosis and/or competence to give informed consent.

6. Physical examination.

7. Chest X-ray.

8. Laboratory examinations to include complete blood count, routine urinalysis, liver function studies (including SGOT, alkaline phosphatase, and total protein and albumin globulin ratio), blood urea nitrogen, and serologic test for syphilis.

E. Procedure—1. Dosage and administration. The methadone is to be administered in an oral form so formulated as to minimize misuse by parenteral injection. The initial dosage is to be low, for example, 20 milligrams per day. Subsequently, the dosage is to be adjusted individually, as tolerated and as required, up to 160 milligrams per day. In exceptional cases, investigators may find it essential to exceed this dosage to obtain the intended effect. If such cases are encountered, the initial protocol or an amended protocol should include the maximum dosage to be administered, the number of patients for whom such dosage is required, and a description of the considerations leading to such dosage levels. The methadone is to be administered under the close supervision of the investigator or responsible persons designated by him. Initially, the subject is to receive the medication under observation each day. After demonstrating adherence to the program, the subject may be permitted twice weekly observed medication intake with no more than a 3-day supply routinely allowed in his possession. Additional medication may

be provided in exceptional circumstances, such as illness, family crisis, or necessary travel, where hardship would result from requiring the customary observed medication intake for the specific period in question.

2. *Urinalysis.* Urine collection is to be supervised; urine specimens are to be analyzed for methadone, morphine, quinine, cocaine, barbiturates, and amphetamines; urine specimens are to be pooled or selected randomly for analysis at intervals not exceeding 1 week.

3. *Rehabilitative measures.* Rehabilitative measures as indicated may include individual and/or group psychotherapy, counseling, vocational guidance, and job and educational placement.

4. *Abnormalities.* There shall be adequate investigation and appropriate management (including necessary referral and consultation) of any abnormalities detected on the basis of history, physical examination, or laboratory examination at the time of admission to the program or subsequently, including evaluation and treatment of intercurrent physical illness with observation for complications which might result from methadone.

5. *Repeated examinations.* Physical examination, chest X-ray, and laboratory examinations conducted at the time of admission are to be repeated annually.

6. *Discontinuation and followup.* Consideration is to be given to discontinuing the drug for participants who have maintained satisfactory adjustment over an extended period of time. In such cases, follow-up evaluation is to be obtained periodically.

7. *Records.* Adequate records are to be kept for each participant on each aspect of the treatment program, including adverse reactions and the treatment thereof.

8. *Other special procedures.* Within the limitations of personnel, facilities, and funding available and in the interest of increasing knowledge of the safety and efficacy of the drug itself, the following procedures are suggested as worthwhile, to be carried out at baseline and periodically in randomly selected subjects: EKG, EEG, measures of respiratory, cardiovascular, and renal function, psychological test battery, and simulated driving performance.

9. *Voluntary and involuntary terminations.* Subjects who have demonstrated continued frequent abuse of narcotics or other drugs, alcoholism, criminal activity, or persistent failure to adhere to the requirements of the program are ordinarily to be terminated and their records should reflect that they are treatment failures. If they are continued indefinitely in the program, the reasons for so doing should be stated in the protocol.

10. *Results.* 1. Evaluation of the safety of the drug administered over prolonged periods of time is to be based on results of physical examination, laboratory examinations, adverse reactions, and results of special procedures when these have been carried out.

2. Evaluation of effectiveness or rehabilitation is to be based on such criteria as:

- a. Arrest records.
- b. Extent of alcohol abuse.
- c. Extent of drug abuse.
- d. Occupational adjustment verified by employers or records of earnings.
- e. Social adjustment verified whenever possible by family members or other reliable persons.

f. Withdrawal from methadone and achievement of an enduring drug-free status.

3. Evaluations are to be recorded at predetermined intervals; for example, monthly for the first 3 months, at 6 months, and at 6-month intervals thereafter.

4. *Evaluation group.* Whenever possible, a locally oriented independent evaluation committee of professionally trained and qualified persons not directly involved in the project nor organized by the sponsor will inspect facilities, interview personnel and selected patients, and review individuals' records and the periodic analysis of the data.

(d) The sponsor shall assure that adequate and accurate records are kept of all observations and other data pertinent to the investigation on each individual treated. The sponsor shall make the records available for inspection by authorized agents of the Food and Drug Administration. The Bureau of Narcotics and Dangerous Drugs is also authorized to inspect these records under the Harrison Narcotic Act.

(e) The sponsor is required to maintain adequate records showing the dates, quantity, and batch or code marks of the drug used. These records must be retained for the duration of the investigation.

(f) The sponsor shall monitor the progress of the investigations and evaluate the evidence relating to the safety and effectiveness of the drug. Accurate progress reports of the investigation and significant findings shall be submitted to the Food and Drug Administration at intervals not exceeding periods of 1 year. All reports of the investigation shall be retained for the duration of the investigation.

(g) The sponsor shall promptly notify the Food and Drug Administration of any findings associated with the use of the drug that may suggest significant hazards, contraindications, side effects, and precautions pertinent to the safety of the drug.

(h) The physician-sponsor or individual investigators in admitting addicts to the investigational treatment program

are required to give to the addict an accurate description of the limitations as well as the possible benefits which the addict may derive from the program.

(i) The physician-sponsor or each individual investigator of this program shall certify that the drug will be used and administered only to subjects under his personal supervision or under the supervision of personnel directly responsible to him; a statement to this effect shall be included in the notice. The signing of the form "Notice of Claimed Investigational Exemption for Methadone for Use in the Maintenance Treatment of Narcotics Addicts" by a physician-sponsor or the form FD-1573 by an investigator will satisfy this requirement.

(j) The physician-sponsor or each individual investigator shall certify that all participants will be informed that drugs are being used for investigational purposes, and will obtain the informed consent of the subjects and shall include a statement to this effect in the notice. The signing of the forms as indicated in paragraph (i) of this section will satisfy this requirement.

(k) Failure to conform to the protocol for which approval has been received from the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs will be a basis for termination of the claimed investigational exemption.

(l) The sponsor of a "Notice of Claimed Investigational Exemption for a New Drug" already on file with the Food and Drug Administration should review and amend his submission to bring it into accord with the acceptable protocol where appropriate within 60 days after the effective date of this section. All differences in his protocol from the suggested protocol should be justified.

(m) Provisions under the Harrison Narcotic Act enforced by the Department of Justice are applicable to this use of methadone.

Effective date. This order is effective upon publication in the FEDERAL REGISTER (4-2-71).

(Secs. 505, 701(a), 52 Stat. 1052-53, as amended, 1055; 21 U.S.C. 355, 371(a))

Dated: March 25, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

(Reprinted from Federal Register of April 2, 1971; 36 F.R. 6081)

Title 26—INTERNAL REVENUE**Chapter I—Internal Revenue Service,
Department of the Treasury****SUBCHAPTER A—INCOME TAX****[T.D. 7100]****[Treasury Decision 7076]****PART 151—REGULATORY TAXES ON
NARCOTIC DRUGS****Administering and Dispensing
Requirements**

On June 11, 1970, there was published in the *FEDERAL REGISTER*, 35 F.R. 9015, 9016, a notice of proposed rule making amending §151.411 of Title 26 of the Code of Federal Regulations in order to make clear the conditions upon which practitioners may administer or dispense narcotic drugs in the course of conducting clinical investigations in the development of methadone maintenance rehabilitation programs. Essentially, the proposal would require that practitioners obtain approval prior to the initiation of such an investigation by submission of a Notice of Claimed Investigational Exemption for a New Drug to the Food and Drug Administration which would then be reviewed concurrently by that agency for scientific merit and by the Bureau of Narcotics and Dangerous Drugs for drug control requirements.

This proposal was published in conjunction with a notice of proposed rule making published by the Commissioner of Food and Drugs for addition of a new section to Part 130 of Title 21 of the Code of Federal Regulations. Among other matters this notice contained acceptable criteria and guidelines agreed upon by the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs for the conduct of clinical investigations of this nature. Since the original publication of both of these notices, two extensions of 30 days each have been granted for the receipt of additional written comments. After extensive review of the written comments received, both agencies have agreed upon certain alterations in the proposed criteria and guidelines which are designed to facilitate

further research and to accommodate the diverse needs and interests of the scientific community. These changes have been effected by appropriate modification of the new section to be added to Part 130 of Title 21 of the Code of Federal Regulations published elsewhere in this issue of the *FEDERAL REGISTER*. Inasmuch as the bulk of comments received concern the criteria and guidelines appearing originally in that proposal, no modifications of the proposed amendment to §151.411 of Title 26 of the Code of Federal Regulations as published on June 11, 1970, have been undertaken.

As previously set forth, it is recognized that the investigational use of methadone, a class "A" narcotic drug requiring the prolonged maintenance of narcotic dependence as part of a total rehabilitation effort, has shown promise in the management and rehabilitation of selected narcotic addicts. In addition, it is a drug which has been shown to have a significant potential for abuse. The amendment which follows is designed to clarify the conditions under which it may be used for the specific investigational purpose indicated until such time as the results of present and future clinical investigations may indicate the necessity for reevaluation of current uses and control mechanisms. It does not authorize the prescribing of narcotic drugs for any such purpose, see 26 CFR 151.392. Moreover, it does not affect any other uses of narcotic drugs, or waive any requirements concerning the control, security, use, transfer, or distribution of narcotic drugs imposed by other Federal narcotic laws or regulations. The amendment shall become effective as of the date of this publication; however, those practitioners currently engaged in the operation of a bona fide clinical investigation shall have a period of 60 days in which to submit or resubmit a Notice of Claimed Investigational Exemption for approval.

Accordingly, under the authority previously cited in the notice of proposed rule making published in the *FEDERAL REGISTER* on June 11, 1970, 35 F.R. 9015, 9016, the word "Dispensing" preceding §151.411 of Part 151 of Title 26 of the

Code of Federal Regulations is hereby deleted and §151.411 is amended to read as follows:

§151.411 Administering and dispensing.

(a) Practitioners may administer or dispense narcotic drugs to bona fide patients pursuant to the legitimate practice of their profession without prescriptions or order forms.

(b) The administering or dispensing of narcotic drugs to narcotic drug dependent persons for the purpose of continuing their dependence upon such drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be deemed to fall within the meaning of the term "in the course of professional practice" in sections 4704(b)(2) and 4705(c)(1) of title 26 of the United States Code: *Provided*, That approval is obtained prior to the initiation of such a program by submission of a Notice of Claimed Investigational Exemption for a New Drug to the Food and Drug Administration which will be reviewed concurrently by the Food and Drug Administration for scientific merit and by the Bureau of Narcotics and Dangerous Drugs for drug control requirements; and provided further that the clinical investigation thereafter accords with such approval; see 21 CFR 130.44. The prescribing of narcotic drugs is not authorized for any such purposes.

Effective date. This Treasury decision shall be effective when published in the *FEDERAL REGISTER* (4-2-71).

Dated: March 25, 1971.

[SEAL] JOHN E. INGERSOLL,
Director, Bureau of Narcotics
and Dangerous Drugs, Department of Justice.

RANDOLPH W. THROWER,
Commissioner, Internal Revenue Service, Department of the Treasury.

Approved: March 25, 1971.

EDWIN S. COHEN,
Assistant Secretary
of the Treasury.

Narcotics and Medical Practice

Medical Use of Morphine and Morphine-like Drugs and Management of Persons Dependent on Them

Drug dependence of the morphine type is a diagnosable and treatable disorder. The physician must be involved with the entire continuum of treatment and rehabilitation, making selective use of consultation and referral as indicated. Management of morphine-type dependence through oral methadone maintenance holds promise for certain drug dependent persons, but it should be employed by physicians only in well-defined settings and under certain circumstances. Although the prospect of drug dependence always must be taken into account, the physician should not hesitate to consider the use of morphine and morphine-like drugs when such use is clinically indicated for the comfort and well-being of patients who require analgesia or other symptomatic relief.

In a statement in 1963,¹ the American Medical Association and the National Academy of Sciences-National Research Council set forth guidelines of ethical medical practice with respect to narcotics, and outlined principles of treatment and management of persons dependent on these drugs. The organizations also indicated in their statement that it is the duty of the medical profession to review its expressed opinions on this subject regularly to assure their continued validity. In line with that view, the statement was updated in 1967, and a condensation was published in *THE JOURNAL*.² The rapid advances of research and clinical experience since 1967, coupled with new federal legislation, make this current revision desirable.

One of the major points of a report of the President's Ad Hoc Panel as presented to the 1962 White House

Conference on Narcotics³ was that the statutory and regulatory measures for the control of narcotic drugs are not intended to interfere with administration of such drugs in legitimate medical practice. The report of the Ad Hoc Panel also contained a reminder that expressions of prevailing medical opinion have a profound impact not only on medical practice but also on laws, regulations, and judicial proceedings.

The purpose of this revised statement is to identify currently accepted medical principles and to describe the elements of "legitimate medical practice" in the use of narcotic drugs in medicine and in the treatment and management of persons dependent on them.

This statement will be limited to consideration of the morphine-like drugs, even though legal usage of the term "narcotics" includes cocaine and cocaine-like agents. This legal usage is at variance with medical terminology and pharmacological facts, but it is included in the Comprehensive Drug Abuse Prevention and Control Act of 1970,⁴ major international narcotics conventions, and

most state drug abuse laws. This usage has led to much confusion because the cocaine-like drugs, being stimulating and not depressant, have a very different action from that of the morphine-like drugs. They have entirely different clinical indications and provide different patterns of dependence and different characteristics of withdrawal.

An additional source of confusion has grown up around the term "addiction," which is used inappropriately in many instances. This statement will, as did the previous two statements, follow the suggestion of the World Health Organization in using the term "drug dependence of the morphine-type" rather than the older expression "morphine addiction." (It is strongly recommended that the reader review Eddy et al⁵ to understand fully the reasons for the suggested change in nomenclature.)

Use of Morphine-like Agents in Medical Practice

Administration to Patients With Pain.—One of the primary functions of the physician throughout history has been the control and alleviation of acute and chronic pain of physical or psychological origin. It is the physician's responsibility to relieve pain by eliminating its cause if possible. Although several nonnarcotic analgesic medications are available, in many instances a morphine-like agent is clinically indicated. In these cases, regular by-the-clock administration should be avoided. Recurrence of significant pain should be the indication for medication.

In the treatment of patients with chronic or incurable painful condi-

¹ Report of the AMA Council on Mental Health and its Committee on Alcoholism and Drug Dependence and the National Academy of Sciences-National Research Council Committee on Problems of Drug Dependence.

² Reprint requests to AMA Department of Mental Health, 535 N Dearborn St, Chicago 60610.

tions, it is ethical practice to administer morphine-like drugs over a prolonged period when all reasonable alternative procedures, including the administration of other analgesics, have failed. Prolonged administration of morphine-like drugs is most frequently found necessary in cases of terminal disorders, but, in certain unusual circumstances, they may also be employed in nonfatal illnesses. It should be recognized that with prolonged administration, especially if parenteral, tolerance eventually will develop to the therapeutic effects of the drug, as will some degree of dependence.

Special note should be made of those patients who have a morphine-type drug dependence, or a history of such dependence, and who have other medical or surgical problems. If there is a bona fide symptomatic need demonstrated by adequate diagnostic evaluation, it is the physician's responsibility to prescribe analgesic medication as he would for any other patient. Thus, in the treatment of such patients with significant postoperative pain, for example, morphine-like analgesics may be administered. The physician, however, must remain constantly alert in such situations to certain considerations:

1. He must assure himself of the real need for the administration of morphine-like agents. This can be accomplished only by adequate evaluation of the total person who is his patient. Persons dependent on morphine-like drugs are astute at simulating other disease conditions. The physician should be particularly cautious if the patient in effect makes his own diagnosis and demands the "only" remedy—a dependence-producing drug—which will provide him with relief.

2. He must be aware of the fact that he is dealing with a person who has established a particular type of relationship to taking a morphine-like drug, a kind of compulsive reliance on the pharmacological effects of the drug which performs a particular psychological function for him. This type of craving must be interpreted along with all other clinical evaluations. The physician does not help the patient by catering to his drug dependence.

3. He must take the factor of tolerance into account with the actively drug-dependent patient—a factor which might influence the effective dose level. The drug-dependent person, however, tends to overestimate his illicit drug intake; his need and his tolerance may not be so great as

his story might indicate. Also, tolerance, especially to respiratory and analgesic effects, disappears rapidly during abstinence, so that the time elapsed since the last drug-taking is important. If it can be established that many weeks have passed, it is likely that the factor of tolerance can be ignored.

4. He must remember that abrupt withdrawal can increase morbidity or result in death if the patient who has an established dependence on a morphine-like drug undergoes major medical or surgical trauma. Appropriate medical management includes maintenance of the drug dependence until the patient begins to recover from his other illness; only then should a regimen of gradual withdrawal be considered.

5. He must recognize that occasionally cases of drug dependence of the morphine type involve aged and infirm persons so severely ill that withdrawal of the drug may be dangerous to life. In such cases it is proper and necessary to maintain a supportive level of medication.

Some or all of these considerations are applicable to patients who have established dependence on drugs other than morphine-like agents. States of mixed drug dependence which include morphine-like drugs also may exist, where the same considerations of personality structure and function hold true.

Administration for Other Than Analgesia.—Other indications for the administration of morphine-like agents will include sedation and sleep when sleeplessness is due to pain or cough, preoperative sedation in anesthesiology, antitussive effect in the control of cough, relief of certain forms of dyspnea, control of diarrhea, and gastrointestinal muscle spasm.

Characteristics of Drug Dependence of the Morphine Type

Epidemiology.—Drug dependence of the morphine type as it exists in the United States can be described as an interplay of three epidemiological factors:

1. **The Agent.**—Heroin used to be the drug of choice of a great many drug-dependent persons in the United States, but there is now a definite trend toward use of other dependence-inducing drugs and the combined use of heroin and such drugs. This mixed pattern results in part from availability. Tolerance tends to build up less rapidly with interspersed or mixed-drug-type depen-

dence because of the reduction in amount and frequency of administration of heroin. Mixed dependence does not, however, diminish either the drive to continue drug abuse or its attendant behavioral responses. The drugs most commonly interspersed with heroin or other morphine-like drugs are cannabis, barbiturates, amphetamines, and alcohol.

2. **The Host.**—A majority of the patients are young adult males, but many are older. In recent years, there has been a striking increase in the number of teen-agers involved. The number of females dependent on heroin also has been increasing. Previous cultural and ethnic distinctions have lessened considerably.

3. **The Environment.**—Drug dependence of morphine type, or of mixed type, until recently was a problem chiefly in certain large cities, and particularly in the lower socioeconomic areas. Today, however, it has spread widely to other parts of metropolitan areas and to smaller communities as well, and it includes all socioeconomic classes.

Some Psychiatric and Psychosocial Factors.—Although disturbances of personality and other psychiatric problems are thought to precede, and be predisposing of, the development of drug dependence rather than result from it, the expression of any underlying psychopathology may be aggravated by the abuse of drugs. Full-blown psychoses are rarely associated with the use of morphine-like drugs. If psychoses are present, they are likely to be endogenous psychoses or toxic psychoses caused by intoxication with, or withdrawal from, non-opiate drugs used concomitantly.

Drug-dependent persons, or even just those who have dependence of the morphine type, do not constitute a homogeneous group. It is inappropriate to generalize freely because much depends on the individual's psychic structure, his social and cultural background, and his total physiological and psychological resources. Additional variables of age, sex, peer group identity, academic and employment achievement history, family structure, marital relationship, etc., will reflect variations in personality structure and behavior, thus emphasizing the individualized nature of the development of drug

dependence. Opinions should not be based on general statements that purport to relate uniformly to all drug-dependent persons. Adequate evaluation and understanding of the individual patient are necessary to prepare a course of remedial action.

Certain characteristics of dependence of the morphine type, however, will be shared by most, if not all, such patients. There will be a psychological dependence, a reliance on the drug, which may manifest itself as an overpowering drive or compulsion to procure and continue taking the drug and to obtain it by any means. The degree of this dependence, however, can range from very mild to extremely severe. There also will be manifest an early physical dependence which increases in intensity as dose and frequency of administration are increased. Physical dependence will develop on continual administration of the same drug, or another morphine-like agent. There is a specific and definite syndrome of morphine-like drug withdrawal. The development of tolerance to the drug necessitates that dosage be increased to obtain the initial pharmacologic effects.

Frustration tolerance tends to be unusually low in persons dependent on morphine-like drugs. Ordinary delays and inconveniences of daily living are experienced almost as crises and, if possible, are avoided or escaped through impulsive action. These persons are frequently of dependent personality structure and are adept at manipulating those around them to conform to their needs for support. There is usually a strong identification with the drug-taking group, frequently assuming the form of a drug-taking subculture. Association with the group—dependence on it—becomes almost essential to the individual's sense of well-being.

Diagnosis of Dependence of the Morphine Type

The mere use of a psychoactive drug or violation of any of the drug abuse control laws cannot be equated with drug dependence, even if the use is periodic. In each case a specific medical diagnosis will be required.

The diagnosis of dependence of morphine type is based primarily on history, physical examination, and

clinical observation. Urine testing is useful, but the presence of morphine-like drugs in the urine does not necessarily indicate dependence.

Diagnosis of drug dependence usually is not difficult. Frequently the patient admits to his dependence and his need for drugs. Even so, adequate history must be procured to substantiate the patient's statements. History will be important also in the determination and assessment of the degree of dependence, patterns of drug use, and motivation.

In addition to a general medical history, a specific history must be sought covering the introduction to drugs and the development of drug abuse which led to the state of dependence. The patient's description of routes of administration, of drug effects, and of experiences of any previous withdrawal, together with the circumstances, characteristics, and intensity of such withdrawal, also will provide important information regarding the dependence status. So will information about living arrangements, including how time is spent and how expenses are met. Description of previous attempts at treatment will likewise be contributory. These substantiating observations become particularly important when the patient is seeking some type of drug-administration support in the treatment of his purported state of drug dependence.

Additional elements of general medical history should include questions of previous episodes of hepatitis, bacterial endocarditis, abscesses, and other instances of complications which frequently accompany drug dependence of the morphine type.

Physical examination findings that are especially pertinent to a diagnosis of drug dependence of the morphine type include evidence of needle marks, indurations, and scars of abscesses along routes of intravenous administration. These signs should be sought in antecubital spaces, forearms, hands, groin, and neck, although there may be evidence almost anywhere a vein can be found.

Most clinical laboratories now have facilities to do urinalysis for detection of various drugs such as barbiturates, amphetamines, some tranquilizers, and free morphine, which is also

an indicator of heroin. Heroin is rapidly deacetylated in the body and therefore is not found in the urine. The presence of quinine and its metabolites also can be detected. Such a finding may suggest heroin-taking because heroin obtained on the street is often "cut" with quinine.

It is particularly important to determine whether the patient has been taking barbiturates in combination with morphine-like drugs. Determination of the degree of barbiturate intake must be made because uncontrolled withdrawal from barbiturates can produce delirium, convulsions, and even death.

In addition to all of the above, conclusive proof of drug dependence of the morphine type is established by the appearance of the specific and characteristic abstinence syndrome induced by abrupt cessation of drug administration, or by the administration of one of the specific opiate antagonists.

Clinical Course of Dependence of the Morphine Type

Once established, drug dependence of the morphine type has the characteristics of a chronic, relapsing disorder. Periodic withdrawal to a drug-free state is accomplished by many drug-dependent persons even without medical assistance, but repeated relapse to drug use is common, and the duration of periods of abstinence usually is short.

The total course of dependence can be influenced by adequate treatment, for which physicians have a direct responsibility. Regardless of any treatment difficulties, the physician must continue to apply all knowledge available to him in attempting to eliminate the syndrome of drug dependence and to treat any associated psychopathology.

Recovery from drug dependence can include, but is not equated with, the concept of cure. Recovery occurs either spontaneously or as an outcome of a formal treatment program, and criteria can be posited to determine the existence of such recovery and to assess its degree.

Progress toward recovery may be measured by the following events:

1. The period of abstinence becomes greater than any previous period of abstinence, and periods of relapse become sig-

nificantly shorter, as determined by careful history-taking.

2. The primary or secondary effects of the drug-dependent state are markedly reduced in number and intensity.

3. The patient believes that his ability to function is enhanced without resort to the chronic abuse of drugs.

4. The physician, or the therapeutic team, believes that the patient functions more adequately in his present drug-free or drug-reduced state than he had functioned prior to the onset of treatment.

A person who has been dependent on one or more drugs may be considered recovered if he fulfills each of the following criteria:

1. He remains continually abstinent from the drug on which he had been dependent for a period of three years. An occasional minor relapse in the course of treatment does not constitute therapeutic failure, inasmuch as drug dependence is a chronic, relapsing illness.

2. He remains, during this time, free of abuse of other psychoactive drugs, including abuse of alcohol, and uses only those drugs which may be medically prescribed and taken according to a physician's instructions.

3. He does not suffer significantly from drug-related social and economic disability or incapacity.

4. He does not suffer from a psychological disability which represents a continuation of the psychodynamics of his drug dependence. A major psychiatric disorder which preceded or was precipitated by drug abuse, such as schizophrenia, is not considered to represent a continuing drug dependence, even though it may appear to have replaced it.

Recovery does not require that the person must be able to demonstrate a capacity to use his drug of dependence in moderation.

It is valid to speak of "social recovery" when an individual, as part of a treatment program, is maintained in a drug-dependent state through the administration of a substitute substance, such as methadone, or is given an antagonist, such as cyclazocine, neither of which interferes with his social and economic functioning and adjustment.

Treatment of Morphine-type Dependence by Withdrawal Methods

This method of treatment of the patient with morphine-type drug dependence should have the combined goal of drug abstinence, resolution of general medical and psychiatric prob-

lems, and social rehabilitation; but it should be remembered that motivation for treatment must exist before withdrawal can be successfully undertaken. The initial step in this treatment procedure is withdrawal from the dependence-producing drug (detoxification). The physician also will seek consultation, or make referrals, when needed to obtain the psychiatric and other medical evaluation necessary for instituting additional specific treatment measures. Furthermore, sociological studies and assessment by competent professionals will point to those areas of living problems requiring continuing attention and help as part of the patient's social rehabilitation.

These various efforts are viewed as being parts of a single therapeutic continuum, individualized for the particular patient, and aimed at accomplishing the stated therapeutic goals. Mere withdrawal from the morphine-like agent does not constitute complete treatment of the drug-dependent patient.

There never has been any legal or medical question of the right and duty of a physician to administer limited quantities of the drug on which the patient is dependent, or one of a like nature, to relieve acute withdrawal symptoms. In most cases of morphine-type drug dependence, management of the acute withdrawal state is best accomplished in a hospital or other secure setting reasonably certain to be drug-free. Some communities have specialized facilities, although under certain conditions withdrawal can be carried out in other institutional settings. These conditions include the following: (1) few cases are involved, (2) the patient is well-evaluated, (3) good environmental control is maintained, and (4) the physician has acquired skill and experience in this work. Nonspecialized institutional settings may include (1) psychiatric wards of general hospitals; (2) a properly selected ward (usually sick bay) of a public or private mental hospital; and (3) in select cases, certain general hospital beds.

Abrupt, complete withdrawal ("cold turkey") as routine "treatment" is inhumane, unnecessary, and distinctly contraindicated, even if the patient is in jail. Frequently, when abstinence phenomena are not severe, mild seda-

tion or administration of tranquilizers, together with the kind and reassuring presence and attention of medical and other personnel, provides adequate support. Alternatively, treatment is the oral administration of methadone, with its subsequent gradual withdrawal. Various schedules of administration are available. Methadone should be used not routinely but only if the abstinence phenomena are particularly disturbing. Clinical observation of the patient will be the determinant.

Ambulatory (outpatient) withdrawal is usually difficult and should be undertaken with care, preferably in consultation with or under the supervision of a physician who has special skill and experience in the management of drug-dependent persons. With adequate social support and control of the dispensing of medication, ambulatory withdrawal can be feasible, especially for persons whose dependence is not long-standing. Withdrawal should be completed within a three-week period.

A drug-dependent woman who is pregnant should undergo withdrawal treatment prior to delivery. If delivery has to be accomplished before withdrawal, the physician should be alert for signs of drug dependence in the neonate, and institute proper care immediately.

It is unrealistic to believe that the physician's role in the treatment of the drug-dependent patient ends when withdrawal from the drug has been completed. In many respects, it is just beginning. This is true even if there are no general medical or surgical problems during hospitalization which might require outpatient follow-up care and treatment.

The most critical therapeutic efforts begin when the patient is ready to leave the hospital and reenter his community. Continuing contact and help are essential at this point. If such help is not forthcoming, relapse to the use of drugs is almost inevitable. An adequate aftercare program is vital to the patient. Such services must include psychotherapeutic attention of a directive and supportive type, individual, group, or both. Supportive social service contact with the patient, and in almost every instance with the patient's family or spouse, also should be provided in the

community or neighborhood. Various social agencies will have to be utilized to deal with the many ramifications of readjustment problems.

Physicians should play an important role in the mobilization of social and economic resources for aftercare on a community-wide basis and in providing supervision and follow-up treatment. It is, additionally, the physician's responsibility to his patient to assure that contact be made with such services.

Another resource in many communities which the physician can utilize with some drug-dependent patients is the self-help group. Among the well-known groups are Synanon, Narcotics Anonymous, Day Top Village, Gateway House, Odyssey House, and Phoenix House. Such groups now function in most metropolitan areas, and the physician should familiarize himself with their programs. Evaluation of them will determine which, if any, may be suitable for each of his patients.

Absolutely vital to the successful treatment of the drug-dependent person is the nature of the interpersonal relationship that develops between the physician and his patient. Winning the trust, confidence, and respect of the patient constitutes the first major task to be accomplished. This cannot be achieved unless the physician and other personnel involved adhere strictly to the tenets of confidentiality. Even implied threats of reporting to police officials, of cross-examining in search of source of drug supplies, or of alerting parents and family, except under extreme emergency conditions, may completely destroy the basis required for continuing therapy.

The physician must show an active interest in the patient and an alliance with him in his struggles. The physician must identify and acknowledge positive aspects of the patient's personality and behavior, so that the patient does not look upon him as just another critical member of the "establishment." Drug-dependent persons have been lectured to and scolded, often for years, by parents, spouses, friends, employers, probation officers; they are hypersensitive to criticism, which has come to signify rejection. Careful choice of words is required in establishing commu-

nication and in avoiding an implication of condescension or hostility.

Oral Methadone Maintenance Techniques in the Management of Morphine-type Dependence

Over the years, since its inauguration by Dole and Nyswander in 1964,¹ the concept of "methadone maintenance" has come to mean many things. Each mode of oral use of methadone in a maintenance program, however, would still seem to be oriented primarily toward social rehabilitation and toward voluntary participation by the patient. Some aspects of the program have been clearly established; others are still on a research basis.

In its 18th report, the World Health Organization Expert Committee on Drug Dependence stated: "Methadone maintenance [in the pharmacological sense] is the continuing daily oral administration of methadone under adequate medical supervision, the dose being adjusted (a) to prevent the occurrence of abstinence phenomena, (b) to suppress partially or completely any continuous preoccupation with the taking of drugs of the morphine-type, and (c) to establish a sufficient degree of tolerance and cross tolerance to blunt or suppress the acute effects of such agents."²

Some modalities include the indeterminate administration of methadone, perhaps for life, while others include a therapeutic goal of attaining drug abstinence at some appropriate time.

There are differences in dose levels of methadone administration. Some programs are based on high dose to attain high tolerance levels, while other programs utilize moderate or small dose levels. The original Dole-Nyswander program and those patterned after it incorporate a variety of allied services, such as general medical evaluation and care, psychiatric services, and a host of social rehabilitative techniques, in varying combinations and ranging to all-encompassing care. Some programs have tried a modality of simply providing methadone without any of the allied services. The results should reflect the feasibility of this modality and its consistency with the goal of rehabilitation.

Other variables that exist from program to program include differing criteria for patient selection, as well as differences in age, sex, drug history, history of criminal activity, employment record, education level, family structure, and general medical and psychiatric status.

In view of these considerations, the American Medical Association and the National Research Council make the following recommendations:

1. Methadone maintenance programs should include at least the following elements in order to constitute proper medical practice: (a) adequate facilities for the supervised collection of urine and for frequent and accurate urine testing for the presence of morphine and other drugs, (b) general medical and psychiatric services, (c) hospital facilities as needed, (d) adequate staff, and (e) rigid controls of methods of dispensing methadone to prevent diversion to illicit sale or to possible intravenous use.

2. Care should be exercised in the selection of patients to prevent the possibility of causing the person who has not been dependent on heroin to become dependent on methadone.

3. There should be continued evaluation of the long-term effectiveness of methadone programs for persons who are stabilized on an inpatient or an ambulatory outpatient basis.

4. Where feasible, staff members of new methadone maintenance programs should be trained in this technique in an established effective program.

5. Continuing research is essential particularly with reference to (a) the use of properly trained practicing physicians as an extension of organized methadone maintenance programs in the management of those patients whose needs for allied services are minimal. These patients should remain in contact with the methadone maintenance programs for periodic evaluation, including urine testing; (b) the role of methadone maintenance in the treatment of heroin dependent patients under age 18 years; and (c) the use of methadone maintenance in combination with other approaches to the treatment of morphine-type dependence.

These recommendations are essentially in agreement with the recom-

mendations made by the Methadone Maintenance Evaluation Committee of New York, as enunciated in that committee's report to the Third National Conference on Methadone Treatment in New York, Nov 4, 1970, and are consistent with the Federal Regulations titled "Conditions for Investigational Use of Methadone for Maintenance Programs for Narcotic Addicts," published in the *Federal Register* (36:6075-6077, 1971).

Methadone maintenance is not feasible in the office practice of private physicians. The individual physician cannot provide all of the services for the various therapeutic needs of the patient. The individual physician also is not in a position to assure control against redistribution of the drug into illicit channels, to maintain control of doses, or to establish the elements for proper evaluation of the treatment. Practicing physicians, however, should cooperate with methadone maintenance programs in their communities and offer whatever services they may be able to provide.

The Physician's Role in Prevention

Teaching about drug abuse in the public schools is mandatory in most states, but relatively few school districts have developed comprehensive curricular material geared to the modern day needs of students and to their increased level of sophistication. Qualified physicians can make a singular contribution by offering factual information on pharmacology, diagnosis, and therapy for use in creating such materials, and in training teachers and prospective teachers. Physicians are best used as resource persons, rather than as instructors: the task of teaching should be left in the hands of educators who are skilled in the techniques of public instruction.

In his own practice, the physician can play an essential preventive role by exercising good judgment in administering and prescribing psychoactive drugs, so that both diversion to illicit use and the creation of drug dependence are avoided.

Research

There is continued need for multifaceted research on all aspects of drug dependence of the morphine type. Especially needed is the development of reliable criteria for select-

ing treatment modalities to match the requirements of the individual patient. A correlative need is meaningful evaluation of the efficacy of various treatment and rehabilitation techniques, both singly and in combination, as they relate to different types of drug-dependent persons, such as the young, the "criminal addict," and the multiple-drug abuser.

For example, can therapeutic communities be combined with other types of programs to provide an optimum prognosis for certain patients? Is there a way to predict which persons may benefit more from compulsory treatment than from voluntary treatment, and under what circumstances? Can a longer-acting narcotic, such as acetylmethadol, be substituted on a large scale for methadone in maintenance programs to make ambulatory maintenance more practical and less subject to diversion of drugs to illicit traffic? These are some of the questions which require further investigation.

In the area of drug effects, there are unresolved issues relating to the interplay of the drug, the physical and psychological make-up of the user, the environment in which the drug-taking occurs, and other factors.

Still unanswered in the etiology and development of drug dependence are questions such as whether a drug-dependent personality type does in fact exist and can be identified, why some persons resort to drugs while others with similar psychological and social histories do not, and why some persons "mature out" of their dependence on morphine-like drugs while others do not.

It can be expected that findings from research on these and other topics will make necessary further revisions of our current concepts of what constitutes ethical and effective medical practice in relation to morphine-like agents and the dependence they produce.

Legal and Regulatory Aspects

A physician must comply with federal, state, and local narcotic laws and regulations. Copies of the federal law and regulations should be obtained from the Bureau of Narcotics and Dangerous Drugs of the Department of Justice, Washington, DC, or from the nearest district office of the Bu-

reau. Information on state and local regulations can be obtained from state and county medical societies.

At this time, the methadone maintenance procedure is subject to special regulations by guidelines of the Food and Drug Administration and the Department of Justice, and in many instances it is subject to state regulations as well.

Responsible medical bodies should be developed in each state to promote coordination between law enforcement and medical treatment, and to advise appropriate federal, state and local enforcement agencies when questions arise as to whether a physician is prescribing and administering narcotics and other controlled drugs in accordance with accepted medical practice.*

References

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CORRECTION

Reference Omitted.—Reference 8, inadvertently omitted from the EDITORIAL titled "New Therapies in Paget's Disease of Bone," published Sept 6 (217:1383-1384), is as follows:

8. Smith R, Russell RGG, Bishop M: Diphosphonates and Paget's disease of bone. *Lancet* 1:946-947, 1971.

Mr. ROGERS. Thank you very much, Dr. Edwards, for your statement, and for giving us this information and the thinking of the Food and Drug Administration.

Mr. Nelsen.

Mr. NELSEN. Just one question: If methadone were to be approved by law as you indicate, is there a possibility that some one may start to peddle it and cause addiction by the sale of it, or will it be tightly enough handled so this could not occur?

Dr. EDWARDS. Mr. Nelsen, under the plan we are proposing, all methadone would be withdrawn from all pharmacies and it would be shipped directly from the manufacturer to programs that had been approved by the Bureau of Narcotics and Food and Drug Administration, and to hospital pharmacies. There would be no methadone in the pharmacies throughout the country. So our judgment is that at the present time most of the diversion of methadone comes from the prescription use of the drug.

This would eliminate that, and in our judgment would provide greater controls than we currently have.

Mr. NELSEN. Of course, the profit motive in heroin is the thing that really propels it, and we would want to be very sure that in no way would methadone be moving into that same sort of rut. I am pleased to receive your testimony, as usual. Thank you.

Thank you very much, Mr. Chairman.

Mr. ROGERS. Mr. Preyer.

Mr. PREYER. Thank you, Mr. Chairman.

It is good to see you, Dr. Edwards, and I appreciate your testimony. We can understand your problem better after hearing your testimony. You are saying that your real function at FDA is to look into the question of safety and effectiveness, and you really are not the policeman in what is happening on methadone as we are trying to regulate the control of it under the guise of keeping it in the IND status.

So you do have a problem. I can see why you feel you shall have to go ahead and make some decision.

You say that none will be available to pharmacists. How about private practitioners?

Dr. EDWARDS. There would be none available to private practitioners except through hospital pharmacies; there only. It would be for inpatient use for analgesic effects of the drug or as antitussive.

Mr. PREYER. The private practitioner could only use it for inpatient treatment?

Dr. EDWARDS. For inpatient use, that is correct. And of course to the physicians that we are directly involved with in the licensed programs, but these physicians would have to be approved by the medical center or whatever group happened to have the license. So the practicing physicians would be able to use it but only if they were part of licensed programs.

Mr. PREYER. So that if someone, for example, a young man returning from Vietnam had become a drug user there, if he went to his local family doctor for help, the doctor would have to refer him to one of the licensed programs? The doctor himself could not put him on methadone?

Dr. EDWARDS. He would have to get him into a licensed program, that is correct. I would want to also mention, Mr. Preyer, that while

granted our main responsibility is approving the safety and efficacy of the drug, we also have to take into very serious consideration how the drug is used. In other words, we can't pass on the safety and efficacy if we are not convinced the drug can be used satisfactorily and efficaciously.

Mr. PREYER. That is the point that concerns this committee, I know, is how safely it can be used. This drug is in a tablet form?

Dr. EDWARDS. That is correct. It is in several forms. Under the new drug application it would be in tablet form and it is also in powder form.

Mr. PREYER. Well, in any of the forms you are considering, can it be injected? Is it soluble in water or whatever you have to do to inject it?

Dr. EDWARDS. One of the advantages of the tablet form is that it takes a great deal of liquid to dissolve the tablet and as a result of which makes injection very difficult. The powdered form can in fact be injected but we have worked with Eli Lilly Co. and we feel that this tablet form does at least to a degree eliminate this particular risk.

Mr. PREYER. The craving for the drug is an awfully strong one, and we have found a number of instances in the methadone clinics where the drug user is ingenious in pirating away some of the methadone which is either sold on the street or is used to inject. Even if it is painful, they will inject it.

One thing we ran into in Richmond was a form of methadone that was solid in its state. You had to scoop it out of the bottle to use it. They used it on the weekends when the clinic would not be open and they could not go on daily basis. This form could not be injected so that it could not be sold on the street.

Do you think there is any possibility of technical developments of a type of methadone tablet which could only be taken orally?

Dr. EDWARDS. I would be hopeful. However, I must agree with you that some addicts are very ingenious to say the least, and whether or not we will ever develop a system that will handle some of the use is questionable in my mind, but we certainly must be moving in the direction of hopefully taking care of those as well.

Mr. PREYER. One other question along that line: We have had suggestions that some addicts may use methadone in this fashion. If he is a heroin addict and has gotten to the level where he either can't afford enough heroin to get a high, or he has reached a point where it is almost impossible for him to get a high from heroin, and all he is doing is using the drug to fight off withdrawal symptoms, can he then go on the methadone program and thus bring down his heroin tolerance so that rather than having to spend a hundred dollars a day to get a high on heroin, he can go off methadone and go on heroin and for \$20 a day begin to get the heroin high again?

In other words, does methadone reduce your heroin tolerance?

Dr. EDWARDS. Mr. Preyer, I would like to ask Dr. Gardner to answer that question. He is much more familiar with specific pharmacology than I am.

Dr. GARDNER. It would be very difficult for him to do that, Mr. Preyer. The cross-tolerance between methadone and heroin would tend to prevent any euphoria that he would receive from the heroin so he would have a great deal of difficulty in using both at once. If he

tried to take large amounts of each, that might be even somewhat harmful to him.

Mr. PREYER. If you are on methadone during the week and go over on the weekend and use heroin, are you not able to get a heroin high under those circumstances?

Dr. GARDNER. Certainly not at least for a day, and it might even be somewhat longer than that depending on the dose of methadone that somebody was on and again the amount of heroin that he was taking. In most programs and in the kind of protocol we are proposing, only people who have been stabilized for quite some time on daily methadone would even be allowed to be on a twice a week schedule.

Mr. PREYER. From what we have heard, I think that is a very good provision. If you stayed on methadone for, say, a month or two, and then went off of it altogether and went on heroin again, would your heroin habit be less expensive than before you went on methadone? Would you be able to again get a heroin high which you may have lost?

Dr. GARDNER. You could if you stayed off methadone after a few days or more.

Mr. PREYER. So you would in a sense get a fresh start on the heroin habit. That is an unfortunate result, I am afraid.

Thank you very much, Dr. Gardner and Dr. Edwards.

Mr. ROGERS. Dr. Carter.

Mr. CARTER. Thank you, Mr. Chairman.

Doctor, I believe you mean to license methadone to be used in hospitals and in drug treatment centers; is that correct?

Dr. EDWARDS. That is correct.

Mr. CARTER. And to no other physicians?

Dr. EDWARDS. There would be no other physicians, other than physicians that were involved in these particular programs.

Mr. CARTER. Yes. Can you get a methadone high or rush after taking methadone intravenously?

Dr. EDWARDS. Certainly to a far, far lesser degree than with heroin.

Mr. CARTER. To a lesser degree. How long will this program last? How long will you continue this patient on methadone, the one you have shifted from heroin to methadone?

Dr. EDWARDS. Again I think the important thing is for us to emphasize that in a treatment program, it isn't just a methadone program, per se. There are other rehabilitation efforts that have to go along simultaneously with the methadone and I think how long an individual was maintained on methadone would be an individual thing entirely depending upon how he was reacting to his rehabilitation, how he was progressing, what kind of motivation the individual had. There are a number of factors that would have to be considered in answering your question.

Mr. CARTER. We have been using methadone for how long, in the treatment of addiction, heroin addiction?

Dr. EDWARDS. Since about 1963 or 1964.

Mr. CARTER. For heroin addiction. Now what percentage of those who have been on maintenance having been cured of addiction?

Dr. EDWARDS. I certainly don't have an answer. I don't think there are any answers available.

Mr. CARTER. You don't have any figures on that?

Dr. EDWARDS. No.

Mr. CARTER. But you think it would be essential for us to develop those to find out how successful methadone maintenance is or has been?

Dr. EDWARDS. They would be extremely helpful figures. They are figures that are difficult to obtain and figures that would be difficult to keep current. The cure of an addict is something that may last for a month or 2 months or a year, and the number that eventually go back into an addictive life is difficult to determine. But they would be helpful figures to have, certainly.

Mr. CARTER. Methadone then is sort of a crutch to keep him from criminal activities, and so on; is that correct?

Dr. EDWARDS. That is right. What we are approving with methadone, we are referring to as a substitute for heroin, which has certain specific advantages over heroin. In other words, we are suggesting the possibility of approving it for its pharmacological uses only and we feel as a substitute for heroin it has many, many advantages over heroin. It is certainly not by any stretch of the imagination a panacea for treatment of heroin addiction and we are not setting it up as such.

Mr. CARTER. Do you find that people who are on maintenance programs with methadone frequently go out and get heroin or buy heroin and use it?

Dr. EDWARDS. Again, these figures are difficult to come by but it is our feeling, that while this is done, there is no question about it, but I don't think certainly by any stretch of the imagination the majority of patients do this. I think it is the exception.

Mr. CARTER. Well, I have been to some different clinics. In fact, I remember distinctly one in London where the addicts who were on methadone maintenance admitted that when they did get hold of a little money, they went out and got heroin because to them it was the drug which would give more euphoria. You don't know what percentage would be cured by methadone maintenance?

Dr. EDWARDS. May I ask Dr. Gardner if he might want to speak to that.

Dr. GARDNER. It is difficult to talk about cure, but we do know the percentage of patients who stop taking heroin; we also have figures about people who are at least functioning adequately in the community. The addicts who take heroin while on methadone do so early in the treatment program; as the addict stays on methadone his craving for heroin seems to diminish. As people continue in the program, the number taking heroin while still on methadone decreases, and after 1 year less than 5 percent of patients in the adequately controlled programs are still taking heroin.

Mr. CARTER. Less than 5 percent are still taking heroin. But we don't know how long they will be maintained on methadone. In fact, it is addictive, too; is it not?

Dr. GARDNER. Yes; it is addictive and many perhaps would have to be taking methadone for a long time, maybe many years but that would be the case with almost any pharmacologic agent that would be used in the treatment of a chronic condition.

Mr. CARTER. What is the standard reply that a heroin addict gives to you when you ask him, "If you had all of the heroin you wanted, would you ever quit? What is the standard reply to that?"

Dr. GARDNER. I don't know that there is any standard reply. I have talked to a lot of addicts and have received different replies.

Mr. CARTER. I have talked with Dr. Severs, who is in the department of pharmacology, or was, at Michigan, and the universal reply is that "I would never quit."

And Dr. Brill, also, of New York gave the same answer. I have heard that all over and I have heard all of them say that. If you ask them I believe most of them will tell you, "If I had all the heroin I wanted, I would never quit."

And I hope that that does not hold with methadone. Of course methadone does have that advantage in that it keeps people from their criminal activities. Now if we gave heroin freely to these people, do you think it would have the same effect concerning their deplorable habits and criminal activities?

Dr. GARDNER. No; I think there are other advantages to methadone besides the fact that it can be provided through legal means. It is much longer acting than heroin. It does not have to be taken intravenously as heroin does and when it is taken orally it does not produce the mental effects that intravenous heroin produces. So the individual is not constantly in need of a drug and spending almost all of his time in drug seeking behavior.

Mr. CARTER. Just supplying it. That was the first thing I stated. If you supplied heroin to him, if you did that, would he still have the same criminal tendencies?

Dr. GARDNER. No, he would not. But if you were supplying heroin, you would have to be supplying it every 4 to 6 hours.

Mr. CARTER. This is done in some countries, is it not, in England in particular?

Dr. GARDNER. Yes. But England is changing to methadone now.

Mr. CARTER. Well, they are on both. I was over there this year, and they do. They try to emphasize methadone but they do give heroin to some of them and they find out that many of those on methadone maintenance, a large percentage, I would think, actually when they can they get out and get heroin when it is possible, and use that.

Dr. GARDNER. There are probably some proportion of addicts who want the euphoric effects of heroin and methadone——

Mr. CARTER. That really is the basis of using it in the first place, or one basic reason. And I think the big one, the euphoria which one reaches.

Dr. GARDNER. That would be one basis, but there is also a large part of the addict population in which this is not the only or major factor.

Mr. CARTER. What are the factors, then?

Dr. GARDNER. Once the addicts start taking the drug, whether for euphoric or for other reasons, they become involved in a culture that fosters drug-seeking behavior. That and the craving makes it difficult for the addict to stop.

Mr. CARTER. This is quite true but that is not the basis for using it until after they get the habit. The main thing they use it for is the euphoria which they get.

I thank the chairman.

Mr. ROGERS. Mr. Hastings.

Mr. HASTINGS. Thank you, Mr. Chairman.

Dr. Edwards, in the statistical information that you have received from the various IND's and methadone maintenance clinics, do you have any indication as to whether these statistics would show an in-

crease in the use of alcohol or psychotropic drugs by those people who are on methadone maintenance?

Dr. EDWARDS. Again, I would like to refer that question to Dr. Gardner, who is in charge of this program.

Dr. GARDNER. Yes, we do. There is some increase in the use of alcohol and other drugs such as barbiturates and amphetamines. A large proportion of addicts are multidrug users. It is difficult to know whether the increase in other drugs use is simply better recordkeeping for those individuals in the program or an actual increase while on methadone. There probably is some tendency for individuals on methadone to turn toward alcohol and other drugs to obtain a high or get even more relaxation.

Mr. HASTINGS. Several of the directors of methadone clinics that I have talked to have indicated that they thought there was increased use once they went from heroin to methadone. This suggests that there is something that is not fully and totally available with methadone that is available with heroin, that requires them to go on to something else, again recognizing the fact that there may be better statistical figures available. But have you come to a definite conclusion regarding this.

Dr. GARDNER. Yes; there will be some proportion of the addicts on methadone programs or any program like that who will then turn to other drugs such as alcohol and will not be successful in that sense. Even though they will be off heroin, they will be addicted to something else. But again, when we speak of success we are talking only about the relatively small portion of the addict population who might be successfully treated with methadone or anything else, for that matter.

Mr. HASTINGS. Would this NDA, if approved, allow methadone to be utilized for pregnant women or people under the age of 18?

Dr. EDWARDS. The users of methadone in pregnant women and younger elements would still have to seek IND.

Mr. HASTINGS. That would still be under IND status?

Dr. EDWARDS. Yes.

Mr. HASTINGS. That would suggest there are still some things we don't know about methadone, then.

Dr. EDWARDS. In that age group there are still things we don't know and we feel it would not justify it. Because of this unknown, it would not justify us giving a new drug approval for these uses.

Mr. HASTINGS. Does NDA include any language relating to central registration in cities?

Dr. EDWARDS. Peter, do you want to speak to that?

Mr. HUTT. The approval we are proposing would provide where there is central registration, it would be utilized. There is not a central registration mechanism in every community.

Mr. HASTINGS. In fact, very few, has been my experience. But NDA would say where it is in effect it must be utilized. It does not say that there must be in every city a central registration.

Mr. HUTT. There is no final NDA approval at this time. We are still considering this. We would foresee difficulty in requiring it as prerequisite before there could be any program. It might mean there would be no programs. However, this is one thing we could certainly consider further.

Mr. HASTINGS. It would seem to be one of the weaknesses in the

clinics that I have observed, that the lack of central registration allows a methadone user to go to one, two, three, or four different maintenance clinics and we see in each one of them is supplied methadone.

Mr. HUTT. It might be possible to require that central registry be put into effect within a given period of time.

Dr. GARDNER. We have at least proposed some wording which would allow for that if a central registration system were available. I know Dr. Jaffe has considered making such a system available to all communities.

Mr. HASTINGS. I see Dr. Jaffe here, so we can reserve the rest of that question until we talk with the doctor.

The question of weekend privileges on the IND, do you take any position on them now?

Dr. GARDNER. Initially we are advocating that for a period of 3 months there will be no weekend privileges. It would have to be taken under observation daily.

Mr. HASTINGS. This then would be approval over IND as they are operated today; is that correct?

Dr. GARDNER. Yes.

Mr. HASTINGS. That is where absence of central registration bothers me the most. If there is going to be weekend privileges, I can understand currently if a man goes on freedom of clinics. But if we are going to get to this weekend privilege situation, which I presume we are, while we have IND, I assure there must be some control in the central registration.

Dr. EDWARDS. I think your point is well taken. Obviously, in any final document that would be put together, that would be given serious consideration.

Mr. HASTINGS. In both page 9 and 10 when you comment that NDA could provide standards for dispensation, can I anticipate that language would be in the NDA? You say it could provide standards for dispensation of this drug.

Dr. EDWARDS. It very definitely would be; yes.

Mr. HASTINGS. Your language is a little bit weak. On page 10, to minimize the diversion, you say might be curtailed or eliminated.

Dr. EDWARDS. No, that would be a prominent part. That is a good point. We feel very strongly that is an essential ingredient.

Mr. HASTINGS. How long would it be from the time of your approval of the NDA to the date that it could be effective?

Dr. EDWARDS. Well, this is a hard figure to come by because when you say our approval, this is obviously a program that not only requires approval of the Food and Drug Administration but Dr. Jaffe's office, Bureau of Narcotics, and it is very complicated procedure getting everyone on board, everybody in agreement. I would guess that once a definite decision by Food and Drug Administration was made on this subject, that it would be at least another 2 months before we would really be ready to move on it.

Mr. HASTINGS. The reason I ask the question is that my grave concern is a question of control, and although you pointed out rather adequately that controls will be built into the NDA, I still have an overriding fear that we should certainly act legislatively. I think you have mentioned that ultimately you feel we must do that anyway. I think I will direct these legal questions to Jack Ingersoll, which I think are rather im-

portant as to whether or not the Congress will have time to act legislatively before the NDA was approved and available.

Dr. EDWARDS. Well, I think obviously we would not move on this until we felt we were ready to implement the total program and again the Food and Drug Administration has not spent a great deal of time contemplating new legislation. That is the responsibility of others. We obviously feel that this system we are proposing or discussing this morning would provide stronger control and whether or not additional legislation would be needed remains to be seen, but we think this does provide the safeguards that are absolutely essential. I would also want to emphasize that when this is approved by the appropriate groups within Government, it would be published for comment in the Federal Register for a period, so we would be sure that everyone interested had an opportunity to make constructive comments.

Mr. HASTINGS. The reason I asked these questions is that, again, I think there is a definite therapeutic use for methadone maintenance clinics but again I will continue to insist that we have such strong controls that I feel are necessary to control it. I think we too should arrive at a point that we should at least be honest with ourselves that in a large majority of the cases what we are really doing is keeping people on an opiate drug legally, and the country is going to be legal drug pusher, because most of the clinics that I talked to run the clinics and most of the addicts utilizing methadone look forward to a lifetime use of methadone.

The great rehabilitation that you mention would hopefully in the future be successful, the state of the art today in that area is such that we are talking about the British system of maintaining heroin addicts, because it is not as dangerous as heroin and has, as you point out, Dr. Gardner, many attributes that heroin does not have. We are talking about maintaining addicts on an opiate and doing it at Government expense. I think that is the broad picture we are talking about. We ought to be honest with ourselves and if that is what we want to do, say so, and go ahead and to it.

Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Kyros.

Mr. KYROS. No questions.

Mr. ROGERS. Mr. Schmitz.

Mr. SCHMITZ. No questions.

Mr. ROGERS. Are you aware of the studies which have been done by National Treatment Administration here in the District?

How do those studies jibe with your statements today that methadone is a blocking agent for heroin?

It is my understanding that they found that about half of the patients on long-term high dose methadone maintenance are still using heroin and other illegal drugs?

Now the theory on which they were administering those drugs and all other methadone programs around the country operate is that people on high dose methadone maintenance have their desire for heroin blocked. And here we have facts showing, and this study has just been released on October 26, that shows that this simply is not the case. Furthermore, I guess you are aware of the Philadelphia study with Dr. Chambers.

Dr. GARDNER. Yes, sir.

Mr. ROGERS. He also substantiates that same position and also Dr. Dobbs. Are you aware of Dr William Dobbs' study of 100 people in his clinic?

Dr. GARDNER. Yes.

Mr. ROGERS. He found that 3 out of 4 of the patients were continuing to use heroin while on the methadone program. If this is such a blocking agent and stops a desire, why are these new statistics not substantiating that position at all?

Dr. GARDNER. Mr. Chairman, we have not said that this is a blocking agent. It does reduce or in some instances, depending on dosage level, even prevent the euphoria that would occur with intravenous heroin. That is a matter of dosage as well as other things.

Mr. ROGERS. Suppose you shoot methadone, does that give any euphoria?

Dr. GARDNER. That does give some euphoria. That is why we have promoted in preparations which would be difficult to shoot.

Mr. ROGERS. If it is not a blocking agent, what are you going to make the drug safe and effective for?

Dr. GARDNER. It substitutes for heroin and reduces the craving for heroin. It does reduce the euphoria depending on the dosage used. The results obtained in any study depends on the time that you study a population. Early in the course of treatment many addicts continue to occasionally use heroin. This gradually diminishes and disappears as the addict continues on methadone. In the NTA study and the study by Dr. Dobbs followup was short and addicts were studied only during the early phases of treatment. The study by Dr. Chambers had deficiencies in the methods for collecting the urine samples.

There are other studies such as those by Dr. Dole, Dr. Jaffe and Dr. Goldstein which have adhered more closely to good experimental design. In these the number of addicts that are shooting heroin drops off over time. Initially in the program some of the addicts do try to still shoot heroin.

Mr. ROGERS. In this National Treatment Administration program here, they have just gotten these figures out on a study that was made. They say that about 17 percent of the patients, just under 600, had been in the program as long as a year. That in 8 months from August 1970 until April 1971, more than 5,000 people signed up but more than 4,000 people then dropped out.

Now, if this methadone is the substitute that it is supposed to be, and is blocking all of this desire, why do people drop out like that?

Dr. GARDNER. Well, that depends on a number of factors. Methadone is not the substitute for all heroin addicts. Nobody contends that. Part of it does depend on motivation.

Mr. ROGERS. Now wait a minute, right there. Aren't you about ready to say it is approved as a new drug treatment, it is safe and effective?

Dr. GARDNER. That is right.

Mr. ROGERS. For all heroin addicts?

Dr. GARDNER. No; that doesn't mean that all heroin addicts would take it; no.

Mr. ROGERS. Well, they may be given it.

Dr. GARDNER. They might; yes.

Mr. ROGERS. What study leads you to come to that conclusion that it is safe and effective?

Dr. GARDNER. Studies by Dr. Dole, Dr. Jaffe, Dr. Goldstein, Dr. Kleber and many others in which there have been over 2,000 patients studied, many of whom were under treatment for up to 5 years or more.

Mr. ROGERS. How many dropouts did they have?

Dr. GARDNER. In one study there were as many as 20-percent dropouts.

Mr. ROGERS. How often were urinalysis given?

Dr. GARDNER. Weekly or more frequently.

Mr. ROGERS. How many days does a urinalysis give you proof of?

Dr. GARDNER. It depends on how it is taken. If the urinalysis is acquired on a random basis, then it can give you an indication of more than 1 day's experience.

Mr. ROGERS. About a day or maybe a little over. But now I think they can go up to 72 hours, they claim, but that is not a very confined study.

Dr. GARDNER. No study collects daily urine samples for a year or more but instead—

Mr. ROGERS. That is what I am saying.

Dr. GARDNER. Conduct random sampling of pooled urine samples from each individual.

Mr. ROGERS. Why haven't you required this in your investigational use?

Dr. GARDNER. We have.

Mr. ROGERS. You can require a daily urine sample given?

Dr. GARDNER. We have required frequent urine samples though daily samples are not needed.

Mr. ROGERS. I am talking about studies. Have you got any results of that?

Dr. GARDNER. Yes; Dr. Dole conducted such a study.

Mr. ROGERS. You have how many?

Dr. GARDNER. This was about 1,000 people.

Mr. ROGERS. And what period of time?

Dr. GARDNER. Approximately 1 year or often longer?

Mr. ROGERS. When was this made?

Dr. GARDNER. That sample was completed about 2 years ago.

Mr. ROGERS. About 2 years ago.

Dr. GARDNER. Yes.

Mr. ROGERS. How often did he give his tests?

Dr. GARDNER. His tests were done, I believe, at least twice a week.

Mr. ROGERS. So a couple of days were covered there, but not daily.

Dr. GARDNER. No.

Mr. ROGERS. Well, I don't see how you can overlook these recent studies that have just been made, and just been released on an actual program here in the District.

Dr. GARDNER. We haven't overlooked them, Mr. Chairman. There have been studies like them in the past.

Mr. ROGERS. But you don't recognize them as being legitimate or what?

Dr. GARDNER. No; but it depends on when the patients were studied in the course of their treatment, the study method used and the proportion needed to consider a program successful.

Mr. ROGERS. It is not a large number, it is only 600 in a year out of 5,000.

Do you think that is a large number staying with the program?

Dr. GARDNER. No; not in that study, but 2,000 out of somewhere near 3,000 or 3,500 is a large number, given other kinds of therapeutic efforts with opiate addiction. This is again better than what is available to date, but by no means the ideal kind of treatment that we would want.

Mr. ROGERS. What about Dr. Chambers' and Dr. Taylors' comment that:

The frequency of the illegal drug use was much greater than one would expect. The data suggests that methadone maintenance can be expected to prevent euphoria from small doses of narcotics but it cannot be expected to block out higher illegal doses. The high rate of drug abuse among patients who had been on methadone maintenance for at least 1 year indicates that drug craving most certainly had neither been extinguished nor significantly diminished.

And in what we are doing, has there been any study made to see that you get them on a certain maintenance? Maybe you are requiring them to go out and steal more if they have to have more heroin to overcome, to get the euphoria? Has any such study been made?

Dr. GARDNER. Well—

Dr. EDWARDS. Again, Mr. Chairman, I think it is important to recognize that when we get into a new drug category which carries with it, because of the law, the fact that this drug is safe, but more importantly, is effective in the treatment of heroin addiction.

Mr. ROGERS. This is our concern, that the American people will think this, when we get into a new drug category which carries with it, because of the law, the fact that this drug is safe, but more importantly, is effective in the treatment of heroin addiction.

Dr. EDWARDS. I think as far as the American public is concerned, of course, under the program we are discussing, that the restrictions on the use of methadone would be sufficiently important and the public would be sufficiently aware of them that we would certainly hope that this public reaction would not occur but I know exactly what you are saying.

Mr. ROGERS. Yes.

Dr. CARTER.

Mr. CARTER. If you would yield, Mr. Chairman.

On this article printed in the American Medical Journal, it shows that there was 94-percent reduction in crime rate of those who were on methadone maintenance. And also that these people or many of them became productive and good citizens.

Mr. ROGERS. Thank you.

Mr. CARTER. Thank you for yielding.

Mr. ROGERS. The Commonwealth Attorney of Fairfax County, Robert Horan, testified before the Senate District Committee,

Methadone addiction appears to be growing in my jurisdiction at a faster rate than heroin addiction. Our drug treatment program over the past year found it necessary to engage in medical detoxification of 39 patients. Fifteen of these were detoxified for heroin habit and 26 were detoxified for methadone habit. A large majority of those detoxified were below age 20.

What comment do you have on this?

Dr. GARDNER. We too have that kind of concern about addiction to methadone. Much of that abuse comes from prescription use, and this is why we want a tighter control system than that which now exists.

Mr. ROGERS. I thought it was in the investigational status.

Dr. GARDNER. It is, but it can be used for other indications and is in the pharmacies throughout the country.

Mr. ROGERS. Couldn't you still keep this in the investigational status and control that in the pharmacies throughout the country on the other use of it?

Mr. HUTT. Mr. Chairman, this would raise a severe problem for two reasons. If we were to take it out of the pharmacies, it would then be unavailable either for its analgesic use, which is apparently, as we understand it, an important medical concern. It would also be unavailable in many areas of the country for detoxification for which I believe everyone agrees it must be necessary.

For example, there are many States where there are no IND programs whatever. If we were to take it out of the pharmacies without approving NDA, it would then be unavailable for any use there.

Mr. ROGERS. I thought you already said it was approved for NDA for those other uses.

Mr. HUTT. But as I understood your hypothesis, it was to take it out of the pharmacies for those uses.

Mr. ROGERS. No; from what I understood you were taking it out of the pharmacies under your new proposal when you make it a new drug.

Mr. HUTT. Because it would then be available as an approved NDA for detoxification, maintenance and in limited use in hospitals for analgesia.

Mr. ROGERS. So there will be none in the pharmacies, is that what you are saying?

Mr. HUTT. Except hospital pharmacies, and program pharmacies that are approved by FDA.

Mr. ROGERS. Why can't you currently do that? You are saying that you are taking it out of the pharmacies. You are going to take it out of the pharmacies; aren't you?

Mr. HUTT. Only because it will then be available through restricted channels of distribution.

Mr. ROGERS. I understand that. Why under your new drug procedures can you not bring from the pharmacies where it presently exists under the new drug that presently exists for its effect as an analgesic, bring that back into your hospital pharmacy, which I presume is what you are planning to do, and still keep this under investigational status as to use for detoxification or for maintenance programs, and so forth.

This is what you are getting at, isn't it, for maintenance?

Mr. HUTT. Yes; that would be one alternative. We could, in short, as I understand your suggestion, simply take it out of pharmacies other than hospital pharmacies.

Mr. ROGERS. Well, sure, you could do that currently and you could still keep this in an investigational status as to the maintenance problem.

Mr. HUTT. Yes; but we would then have additional problems as the Commissioner has pointed out earlier, Mr. Chairman, that we are presently using the IND mechanism in a way for which it was never built and never intended to be used; namely, to go far beyond the investigational research stage and to encompass true therapeutic on-going treatment programs.

Mr. ROGERS. What I am saying, and what concerns me is that just because it may be used that way, I don't see any evidence that you have that it is really effective with these latest studies, unless you ignore them, and say we are not going to look at that.

Dr. EDWARDS. I would say, Mr. Chairman, that these latest studies, I don't know all of the details of them, although I am aware of them, I tried to emphasize in my testimony that we have pulled together at least the best minds in the business that we could find and I think I can say without any hesitation whatsoever that by far and away the majority of these have recommended in the direction that we are proposing, and that this drug is in fact safe and effective for the pharmacological effects that we have—

Mr. ROGERS. Here is my concern: I don't know why you don't require, in these people dispensing methadone on an investigational basis, proper reporting, proper evaluation, proper investigation with strict control.

Mr. EDWARDS. Because we are. As you know, we are now at about 100 in terms of the programs that we have inspected very intensively. We have put out of operation approximately 20 programs, so we are moving in this direction with the IND and will certainly continue to do that until a better program is forthcoming.

Mr. ROGERS. Yes; but I thought before you would let anybody get into investigational stage you made them show you a protocol.

Dr. EDWARDS. We do, without any question.

Mr. ROGERS. And require the testing, the reporting, so we will have evidence to go on to know whether this ought to be approved as a safe and effective drug for maintenance if this is what you are approving.

I don't see that you have any real evidence from your IND work because these latest reports cause me great concern when three out of four are still using heroin while they are still at the same time using methadone.

Dr. GARDNER. I think, Mr. Chairman, we have as much evidence of the efficacy of this drug in its pharmacological action as we do with many drugs. In the testing of many drugs, there are always some studies that will give contradictory results.

Mr. ROGERS. Well, 75 percent is a heavy contradictory result.

Dr. GARDNER. It depends on the kind of studies. Some studies were not controlled adequately. We do have a number of studies which have convinced all the experts with whom we have talked that efficacy has been demonstrated. That doesn't mean that there won't be studies that may be contradictory. That occurs with every drug and depends on how the studies are conducted.

Mr. ROGERS. To this extent?

Dr. GARDNER. Yes.

Mr. ROGERS. This isn't just a single study you know?

Dr. GARDNER. Yes; even to that extent.

Mr. ROGERS. Dr. Chambers as well. New York State has said they are concerned about it and Maryland is concerned about it. The Commonwealth attorney over here where you have methadone black-marketing and the deaths there and the cases there.

Dr. GARDNER. They are concerned about the control aspects of it and we are concerned about that too. In New York State they are not talking about the efficacy but about the control.

Mr. ROGERS. Yes; what is this efficacious for?

Dr. GARDNER. Again it is efficacious in substituting for heroin use and providing a kind of pharmacological action which will permit somebody to be functional in society in contrast to the state the individual is in while he is taking intravenous heroin.

Mr. CARTER. Mr. Chairman, if the distinguished gentleman would yield further?

Mr. ROGERS. Yes.

Mr. CARTER. Attached right to this is an explanation and an answer to what you are saying. Successful treatment of 750 criminal addicts. Now this includes criminals, the mainliners of 4 years and usually between ages of 20 and 40, and this is a summary of what their findings are:

Four years trial of methadone blockaid treatment has shown 94-percent success in ending criminal activity of former heroin addicts. A majority of these patients are now productively employed, living as responsible citizens and supporting families. The results show unequivocally that criminal addicts can be rehabilitated by a well supervised maintenance program.

Dr. GARDNER. I would like to read this in the statement of our indications for this.

Oral methadone is indicated in the treatment of heroin addiction to methadone maintenance program. Oral methadone produces cross-tolerance for opiates such as heroin and thus substitutes for injected heroin, reducing and preventing both desire, craving and euphoria for injected heroin.

Mr. ROGERS. What about injected methadone? You said that gave some euphoria.

Dr. EDWARDS. We also said with injected methadone we believe that is a problem that is soluble by use of the diskette, so called, a large tablet.

Mr. ROGERS. They can't melt it down?

Dr. EDWARDS. It is very difficult to melt down without using excessive amounts of liquid to do it, so much so that it would make injection extremely difficult. It becomes very syrupy and very thick and viscous and makes injection very difficult.

Mr. HASTINGS. How many total addicts are being treated today under all IND in this country? Do you have an idea?

Dr. GARDNER. About 40,000 to 50,000 under these programs. There are probably that many being treated unofficially in other programs which have not even obtained Federal approval.

Mr. HASTINGS. What we are staying is if we don't get NDA with proper type of control and you start revoking IND, we are throwing that many heroin addicts out on the street.

Dr. GARDNER. Closer to a hundred thousand.

Mr. HASTINGS. Which reiterates my strong concern for NDA, but with safe, effective total control. I would be very concerned that we would take any action that would force your hand into revoking these IND's. It is no panacea and I recognize that, but rather than having

them on the street pursuing their criminal activity for heroin purposes, I certainly would not want to terminate the programs we have in existence.

Thank you, Mr. Chairman.

Dr. EDWARDS. I think you have stated our case quite well. I think we are faced, we are literally being faced with a problem of receiving at least one application per day for new methadone programs. And it is obvious that this is going to continue and we have to turn it off some place as long as we are going to categorize it as an investigational new drug. And again this very tentative proposal we have made this morning is an attempt to come to grips with that without in fact doing away with meaningful programs that are doing a useful public service.

Mr. SCHMITZ. Will the gentleman yield for a question?

Mr. HASTINGS. Yes.

Mr. SCHMITZ. Dr. Edwards, maybe you can answer this. I am not a psychiatrist or psychologist and I can't give the reason why people start drugs, but do you think if the Government got into the methadone business it would act as a catalyst for some people who might start taking up heroin simply because they say to themselves: The expense won't be very great because I can always switch over to methadone and have the Government pick up the tab on my habit.

In other words, is the economic factor a deterrent to going on heroin? Would the ability to switch over to methadone take away at least one barrier to a person taking drugs? To get back to Dr. Carter's question, if 94 percent of the people are successful in going from heroin to methadone and these 94 percent stop their criminal activities, that could give a counterargument to those of us, including Dr. Carter, who regard socialism as a form of theft, collective though it may be. We could argue that what we are really doing when the Government picks up your dope tab, is switching from private theft to collective theft, or socialism, with regard to who pays for your dope habit.

Mr. CARTER. Mr. Chairman, since the gentleman mentioned my name, I would like to say that you can call it collective theft or any other kind of theft that he wants to. Actually, what methadone maintenance does and has done in these cases, it has prevented 94 percent of these addicts from their criminal activities and has saved our country billions of dollars in doing that, and saved us from crime on the street, and so many other things.

And I think no matter where we get the money, it is certainly worthwhile that we do it.

Mr. ROGERS. Thank you.

I have not seen the actual studies here on reduction of crime directly related to methadone treatment in Washington. I don't know that we have had adequate studies yet. Let me ask you this: Are you aware of the International Journal of Addictions, an article by Dr. William R. Martin? I believe Dr. Martin is head of the Lexington Hospital. Let me read you what he says, after this International Conference on Methadone:

Methadone is a dangerous drug and doses used for maintenance are highly toxic to the nontolerant individual. Methadone is narcotic and produces in nontolerant patients a type of euphoria whether injected or administered orally in orange juice, which is qualitatively similar to heroin. Further, it produces a type of tolerance and physical dependence that is indistinguishable from heroin

or morphine. In all probability, it produces, like morphine, long lasting physiological and psychological abnormalities.

Now, is this correct?

Dr. GARDNER. Yes; at least in some individuals. Dr. Martin was one of the individuals with whom we have consulted and who has agreed to our NDA approach.

Mr. ROGERS. Well, he is a part of the administration. I guess he would be controlled—

Dr. GARDNER. No; we don't control Dr. Martin very easily.

Mr. ROGERS. Well, they just removed a man out in Washington State from his position in the Public Health Service because he didn't think they ought to close that hospital out there. This is not very encouraging for people to be independent in their thinking.

Dr. GARDNER. But Dr. Martin, along with us, realizes that this is not the only answer but at least is an answer.

Mr. ROGERS. He does conclude by saying systematic studies should be undertaken to assess potential and known undesirable effects of methadone maintenance as well as its desirable action to assist in social judgment that will have to be made at some future date as to advantages or disadvantages of the maintenance in methadone.

Dr. GARDNER. Yes; that article was written a couple of years ago.

Mr. ROGERS. 1970. And I am surprised that studies were not done in the meantime that would have substantiated one way or the other.

Dr. GARDNER. There have been studies ongoing through these years and again, Mr. Chairman—

Mr. ROGERS. I would like to have you submit for the record those studies on which you are basing any action.

Dr. GARDNER. We will.

Mr. ROGERS. In fact, all studies that you think will have a bearing on this would be helpful.

(The following material was received for the record:)

SUMMARY OF BASIS OF APPROVAL FOR No. 1 DISKET—METHADONE HYDROCHLORIDE

Date of Summary : August 3, 1971.

NDA : 17-058.

Firm : Eli Lilly and Company.

Trademark : No. 1 Disket—Methadone hydrochloride.

Nonproprietary Name : Methadone hydrochloride.

Therapeutic Claim : Maintenance treatment of heroin addiction.

Form Available : Dispersible tablet 40 mg., cross scored for breaking into 4-10 mg. sections—for oral use.

I. SAFETY

Approval of this application for safety is based on :

Animal Studies

1. Reproduction studies—no teratogenicity or embryotoxicity.
2. Toxicity studies not required—reference is made to data in NDA 6-134.

Human Studies

Safety information from 2 clinical studies.

Literature Reports

Published scientific literature.

II. EFFECTIVENESS

Approval of the application for effectiveness is based on :

1. Clinical Studies

(a) Dole, Vincent, and coinvestigators Marvin Perkins and James W. Robinson. The curriculum vitae are satisfactory.

Location: Rockefeller University Hospital, Bernstein Institute of Beth Israel Hospital and Harlem Hospital all in New York City.

Date.—Patients treated for varying length of time between 1964 and April 15, 1970.

Type of Study.—Open label. $N=1435$ —*diagnosis*—heroin addiction:

Males, 1240, average age 33.4.

Females, 195, average age 33.1.

Duration of Addiction.—Males, 14.4 years; Females, 13.6 years.

Results.—At one year—91.3% of urines tested were "clean."

(b) Jaffe, Jerome, the investigator is Director of Drug Abuse Programs, State of Illinois. His qualifications are acceptable.

Location.—Though not stated it is presumed the Chicago area was the setting for the study.

Date.—1967 to April 15, 1970, patients treated for varying lengths of time.

Type of Study.—Open label. $N=576$ —*diagnosis*—heroin addiction:

Males, 459, average age 35.0.

Females, 117, average age 33.1.

Duration of Addiction.—Males, 11.8 years average; Females, 8.7 years average.

Results.—At one year, 87.7 percent of urines tested were "clean."

Statistical Consultation.—Statistical evaluation is not applicable to these data.

Advertising Consultation.—Not yet requested.

Chemical Controls.—Summary not yet available.

Background.—Methadone hydrochloride is a synthetic narcotic analgesic with actions and effects resembling those of morphine. As a marketed drug it has been available in a powder form. In this NDA the clinical data are based primarily on information from patients who were maintained on methadone powder. A special study was conducted to compare both clinical results and bioavailability of the powder and the Disket. Results indicate that the formulations produce comparable results.

REVIEW OF DATA

Preclinical Data

Pohland, Albert, Harold E. Boaz, and Hugh R. Sullivan. Synthesis and Identification of Metabolites Resulting from Biotransformation of DL-methadone in Man and in the Rat. (*J. Med. Chem.* 1971, Vol. 14, No. 3.)

The metabolites were obtained from bile of rats receiving 20 mg/kg of methadone HCl. s.c. In addition to methadone two metabolites were identified. Human urine was the source of the same metabolites which resulted from N-demethylation. The metabolites did not exhibit agonist or antagonist properties in the rat-tail-jerk assay.

Toxicity

No acute toxicity, subacute toxicity or chronic toxicity studies were conducted by "prior agreement with FDA."

REPRODUCTION AND TERATOLOGY

Study 1. A teratology study was conducted in Dutch Belted rabbits.

Dosage

15 females as controls 5 ml/kg distilled water.

15 females—20mg/kg.

15 females—40 mg/kg given during days 6 through 18 of the gestation period.

Results

(1) Food consumption decreased—greatest in 40 mg/kg group.

(2) Two of the 40 mg/kg did not complete the study. One died of a respiratory infection—one aborted on day 25.

(3) No drug related reproduction changes.

(4) Sedation occurred in some.

It was concluded that Methadone HCl had no teratogenic or embryotoxic effects on these rabbits.

Study 2. A teratology study in the rat. (Harlan rats)

Dosage

The rats were gavaged with distilled water, 20 mg/kg or 40 mg/kg in groups of 25 on gestation days 6 through 15.

Results

- (1) Food intake was reduced.
- (2) Weight gain was less in those receiving methadone.
- (3) Hypertonia of skeletal muscles was produced within one hour of dosing. In the 40 mg/kg animals it persisted 4 hours with catalepsy respiratory depression and ataxia.
- (4) Death occurred in 5 at 40 mg/kg, in 3 at 20 mg/kg and one control.
- (5) 19/25 in 40 mg/kg were pregnant. Increased resorption was due to maternal toxicity.
- (6) No other drug related effects were seen. Fetal abnormalities were considered incidental.

ACCEPTABILITY AND BIOAVAILABILITY

Special studies were reported to show clinical acceptability of the Disket and bioavailability in humans.

1. Disket acceptability

196 patients (Dole-150 and Jaffe-46) were switched from Methadone powder to Diskets. There were no complaints suggestive of withdrawal.

In a second study forty patients (Dole-35 and Jaffe-15) were started on the Disket rather than the powder. There were no complaints relative to lack of efficacy.

2. Bioavailability

Dr. William R. Martin and Dr. Donald R. Jasinski of the Addiction Research Center, Lexington, Kentucky, studied bioavailability in humans. Six subjects were given once-daily doses of methadone up to 100 mg per day. The peak dose was reached on day 7 or day 9. After 84 days the Disket was substituted for the powder and continued for 6 days after which all subjects were returned to the powder.

Twenty-four hour urine specimens were collected as follows:

- 1 week after 100 mg dose was reached.
- 1 month after 100 mg dose was reached.
- 3 days after the switch to Diskets.
- 4 days after the switch to Diskets.
- 5 days after the switch to Diskets.

Urine was examined for methadone and 2 metabolites (N-demethyl cyclopyridine and N-desmethyl pyrolidine). The means of determination for the 6 subjects for the 5 fractions listed above were: 15.08, 18.99, 21.97, 21.85, 21.75 as mgs in the total urine sample. The investigators stated that since only 15-20% of a maintenance dose is recoverable in the urine, the larger amounts recovered when the patients were on Diskets is of little significance.

PREGNANCY EVALUATION

Dr. Dole's records contained information on twenty-two women (23 pregnancies):

- 16 pregnancies occurred during treatment. Treatment was continued.
- 6 were pregnant on admission.
- 1 diagnosis was uncertain on admission.

There were 15 living infants, 3 of which had withdrawal symptoms at birth.

No congenital abnormalities were noted.

A literature reference reported on 100 consecutive deliveries in women receiving methadone maintenance therapy (Blinick). There was an increased incidence of low birth weight, meconium and breech presentations. Maternal complications were said to be "few".

No data in regard to pregnancy were found in Dr Jaffe's records.

Social Data

Data from Dr. Dole's patients were collected in the categories of behavioral problems, self-administered drugs, alcohol problems, legal status, housing, employment, means of support, school attendance.

These patients completed one to thirteen weeks of therapy. Of the 1,234 patients the figures showed that 76 had at least one episode of destructive behavior, 9 were assaultive and 132 had other problems. The data were not analyzed since social rehabilitation was not proposed as an indication in this NDA.

Dose-range Studies

None.

Controlled Studies

None—all data were obtained retrospectively. Historical control provided.

Reports of Investigations

A. Dole, Vincent P. The study was designated as "open-label" with no control agents provided. The drug used was methadone powder dissolved in water or a citric acid vehicle. The locale of treatment was at one of Rockefeller University Hospital, Beth Israel Hospital, Harlem Hospital.

Patient Selection Criteria

1. 20 years of age or over.
2. Addiction for 5 years.
3. History of previous arrests and conviction.
4. Previous failure to "kick the habit".
5. Residence in a New York City Borough.
6. No overt psychiatric or medical problem.
7. Willing to sign a formal consent for long term medical treatment.

Diagnosis

Primary.—heroin addiction.

Secondary.—the most common in this category were subcutaneous abscess, bronchitis, dental caries and toothache, backache, asthma, alcoholism, nasopharyngitis, sore throat, headache and edema.

Age and Sex Distribution

N=1,435.

Male=1,240 ages 19–86 years (av. 33.4).

Female=195 ages 19–56 years (av. 33.1).

Degree of Addiction

1–5 bags/da, 20.4 percent.

6–10 bags/da, 35.9 percent.

11–15 bags/da, 22.7 percent.

16–20 bags/da, 5.7 percent.

21–50 bags/da, 13.7 percent.

51 bags/da, 1.6 percent.

Time on Study

(Cut off date April 15, 1970.) Average 85.9 weeks (one to 309 weeks).

Dosage

Average: 100.7 mg.

Range: 10 to 250 mg.

Criteria of Effectiveness

Disappearance of morphine and its metabolites in the urine (absence of abused drugs and presence of methadone).

The urine was collected at the clinics and pooled by patient for several days or weeks and tested for morphine, quinine, methadone, amphetamines, barbiturates.

Results

PERCENT OF CLEAN URINE

	Morphine	Quinine	Amphetamine	Barbiturates
By time:				
1 week.....	83.9	58.8	97.8	98.1
2 to 3 weeks.....	95.1	84.5	97.0	98.8
4 to 6 weeks.....	94.9	88.9	96.6	98.6
7 to 13 weeks.....	91.6	86.3	97.3	98.8
14 to 26 weeks.....	91.8	84.3	96.4	98.2
1st year.....	91.9	84.3	96.5	98.5
2d year.....	93.0	86.3	96.6	98.1
3d year.....	95.0	90.4	97.7	98.6
4th year.....	96.0	92.6	98.3	98.4
5th year.....	95.6	93.2	97.4	98.1
6th year.....	99.0	100.0	99.0	99.0
By dose of methadone:				
0 to 60 milligrams.....	91.4	79.1	96.9	98.6
80 to 120 milligrams.....	92.4	85.4	97.1	98.4

For methadone the "clean" urine is represented by the presence of methadone in the urine. The percentages ranged from 17.2% in the first week to 4.0% in the sixth year.

Drop-outs

There were 182 drop-outs during the study. The reasons are noted: Discharged, 10.3; resigned, 20; adverse reaction, 0; death, 12; moved, 4; jailed, 30; unknown, 13.

360 patients were transferred to a clinic other than the the 3 in the study.

In patient vs Out patient.—955 patients started therapy as hospitalized patients and 480 began therapy as out patients. The percentages of clean urines were comparable in the 13 to 26 week observation period. Drop outs were 141 of the in-patients and 41 of the out-patients. The most of the out patient drop outs occurred during the 2nd year, the in-patient drop outs were greatest during the 2nd quarter. Those "fired" or discharged were 81/144 in patients and 22/41 out patients. None were terminated because of adverse reactions.

Harlem Hospital Out Patient Data

The population in this clinic was said to be comparable to that of the Chicago (Jaffe) study.

Total, N=117 all males.

Age, 36.7 years.

Time on heroin, 15.8 years.

Mean bags/da, 8.9.

Dose on methadone maintenance, 100.0 mg.

Duration of treatment on methadone maintenance, 28.8 weeks.

Terminated, 12.0 percent (all but one in 1st year) of those terminated 33 percent were discharged and 50 percent were jailed. 17 percent resigned.

Adverse Reactions reported were categorized as follows:

<u>Organ/system</u>	
Body/abdomen	abdominal pain
/general	abscess (NOS)
	fatigue
	fever
	malaise
	chest pain (NOS)
Cardiovascular/venous	varicose vein
Digestive/buccal	glossitis
/functional	flatulence
	dyspepsia (NOS)
enterocolon	diarrhea
Metabolic nutrition/vitamine	avitaminosis
water balance	edema-general
	edema-peripheral
Musculo-skeletal/joint	Arthralgia
Nervous system/CNS Brain	abnormal dream
" Consciousness	syncope
/peripheral	neuritis
Psychiatric/general	libido decrease
"	nervous
psychoneurotic	anxiety
Skin/dermatoses	dermatitis (NOS)
" erythema	rash (NOS)
" "	erythema
dermatosis	urticaria
Special senses/eye/vision	amblyopia
" "	diplopia
ear	pressure
Urogenital/female/vagina	leucorrhea
male/penis	discharge (NOS)
" /seminal vesicle	abnormal ejaculation

The following reactions were not to be coded or tabulated: poor appetite, cramps, running nose, tears, gooseflesh, dizziness, clulls, shaking, sleeplessness, restlessness, dry mouth, constipation, sweating, urinary hesitancy, vomiting.

Concurrent therapy

By agreement with FDA (July 9, 1970 meeting) only CNS drugs were to be tabulated. The simple listing provided information that 43 drugs were administered during the study. These included analgesics, hypnotics, tranquilizers, antidepressants, narcotics and anticonvulsants. It is doubtful if the administration of these drugs had an effect on the claimed effectiveness of methadone in a maintenance program. The list will not be reproduced in this summary.

Statistical Analysis

The statement "the data do not lend themselves to statistical analysis". No analysis was presented.

B. Jaffe, Jerome H. The data presented here are from an "open-label" study using no control agents. The drug used was methadone powder dissolved in water or a citric acid vehicle such as orange juice or a prepared mix.

Criteria for patient selection

1. Completion of the Illinois Drug Abuse Program Intake Forms.
 - (a) Consent to treatment.
 - (b) Social and medical interview.
 - (c) Research instruments and procedures in use at time of contact.
2. Evidence of 12 months or more of daily opiate use.
3. History of at least 1 attempt at detoxification. (Verified by counselors where appropriate.)
4. Urine at time of intake to be positive for opiates or their metabolites.
5. At least 18 years of age—or if younger to have written permission of the clinical Director.

No one not currently addicted (unless abstinence is without consent) should be given methadone. If the medical/legal history indicates chronic abuse, methadone may be used prophylactically.

Age-sex distribution

N, 576.

Males, 459 ages 18–67 years (average 35 years).

Females, 117 ages 18–58 years (average 33.1 years).

Degree of Addiction

Males, 11.8 years.

Females, 8.7 years.

Degree of Addiction

Only 7 reports made available information on the number of bags of heroin used daily. No tabulation was made.

Secondary Diagnosis

The most frequent reported were:

Syphilis	46	Duodenal ulcer	23
Nasopharyngitis	42	Dental caries	24
Essential hypertension	41	Headache	23
Bronchitis	27	Hemorrhoids	21
Obesity	24		

Criteria of Effectiveness

Disappearance of morphine (or metabolites) in the urine of patients.

Dosage of Methadone

Average 47.6 mg (range 5–160 mg) 84.8% of the patients took 0–70 mg.

Urine Tables—results of treatment

The primary means of determining the effectiveness of methadone in a methadone maintenance program is the absence of abused drugs and the presence of methadone in the urines of patients being treated.

Urines were tested for morphine, quinine, methadone, amphetamines and barbiturates.

Results

PERCENT OF CLEAN URINES

	Morphine	Quinine	Methadone	Amphetamines	Barbiturates
By time:					
1 week.....	55.9	61.3	36.6	0	90.0
2 to 3 weeks.....	67.5	66.6	9.6	66.7	86.9
4 to 6 weeks.....	73.2	75.4	11.4	90.9	92.6
7 to 13 weeks.....	81.5	83.6	10.9	92.8	93.0
14 to 26 weeks.....	84.7	85.6	12.0	92.8	91.4
1st year.....	81.7	81.5	12.7	92.3	92.7
2d year.....	88.8	87.2	17.5	96.7	94.9
3d year.....	83.9	92.9	16.1	100.0	100.0
By dose of methadone:					
0 to 60 mg.....	82.5	81.5	17.8	91.4	93.1
80 to 120 mg.....	90.5	90.0	16.4	100.0	91.0

Terminations

A total of 193 were terminated of these 178 were for reason unknown. 1 was transferred, 1 jailed, 1 death (tuberculosis), 11 resigned, 1 moved.

The largest percentage of drop-outs (65 patients) were in the 21-30 mg. dose range.

Adverse Reactions

The following were reported: abdominal pain, dyspepsia (NOS), arthralgia, rash (NOS), amblyopia.

Concurrent Therapy

Analgesics, antidepressants, hypnotics, anticonvulsants, major and minor tranquilizers and barbiturates were used concomitantly with methadone. There was no report indicating that these drugs affected the efficacy of methadone maintenance.

Statistical Analysis

The data were said to be such that they do not lend themselves to statistical analysis.

SUMMARY OF DATA CONCERNING EFFICACY

Population Data

N, 2,011 (Dole 1435; Jaffe 576).

Males, 1,699 (Dole 1240; Jaffe 459).

Females, 312 (Dole 195; Jaffe 117).

Duration of Addiction (Mean)

Males, 13.7 years; females, 11.8 years.

Degree of Addiction (1,228 addicts)

Bags daily, 13 (range 1-125), 56 percent used 10 bags or less daily.

An analysis of 132 street samples revealed a concentration of 1 to 77 percent. Twelve samples contained no heroin.

Duration of Therapy

Mean 71.6 weeks (1 to 310 weeks)

Doles group 85.9 weeks (1-310)

Jaffees group 35.9 weeks (1-120)

60 percent were on maintenance for less than a year.

The variation in duration of therapy may reflect the fact that Doles patients started treatment at an earlier date.

In Doles group 2 percent reached maintenance dose in a week as compared to 35 percent in Jaffes group. At the end of 6 weeks 67 percent of Doles patients and 58 percent of Jaffee were at maintenance dosage.

Dosage

Mean maintenance dose=85.5 mg. (5-250 mg range) :

Dole=101 mg (10-250 mg range)

Jaffe=48 mg (5-160 mg range)

0-60 mg=81 percent of Jaffes patients

81-120 mg=84 percent of Doles patients

There was no reported correlation between degree of addiction and maintenance dosage.

Urine Data

Both investigators pooled urine.

Morphine

The percentage of clean urines was reported to plateau out at 85-95 percent. At one year (percent of clean urine): Dole, 91.3 percent; Jaffe, 87.7 percent. Relationship between clean urines and dosage.

60 mg or less=84.2 percent.

80-120=92.2 percent.

The figures for Jaffes group reflected a lower percentage of clean urines but his maintenance dose was lower. When Jaffe increased the dosage to 90 mg the figures more nearly approached Doles.

Quinine

At one year both groups were 84 percent clean.

Methadone

Absence of methadone in the first few weeks was explained by the small dosage employed and the estimation that less than 15% is excreted in the urine. The methods of detection were said to be unable to pick up small amounts in the urine.

9.3 percent of urines in both groups were free of methadone at a dosage of 80-120 mg.

Amphetamines

Less than 4 percent exhibited this in Doles group. There were no conclusions concerning Jaffes patients.

Barbiturates

Less than 2% in Doles patients. No valid conclusions were drawn concerning Jaffes group.

Termination Data

Of the 701 patients leaving the two programs, 327 were transferred to other programs. 374=drop outs for the following reasons: Discharged, 103; resigned, 31; death, 13; moved, 5; jailed, 31; unknown, 191.

A tabulation of active patients compared to drop outs were presented.

	Active	Drop outs
Number.....	1,637	374.
Percent:		
Male.....	84.2	85.6.
Female.....	15.8	14.4.
Mean age:		
Male.....	33.9 years.	33.5 years.
Female.....	33.5 years.	31.5 years.
Mean years on heroin:		
Male.....	13.9	12.9.
Female.....	11.9	11.3.
Bags per day.....	13	15.4.
Methadone maintenance dose.....	89 milligrams.	69.9 milligrams.
Duration of maintenance dose.....	60.6 weeks.	31.3 weeks.
Time to reach maintenance dose.....	14.3 weeks.	10.5 weeks.

CONTROL DATA

Historical Control provided by the Task Force Report: Narcotics and Drug Abuse, Report on the Treatment of Drug Addiction, by Jonathon O. Cole, May 1966. This provided a summary of the then available information on the treatment of opiate addicts.

Involuntary Treatments

1. Imprisonment.
2. Imprisonment plus parole.
3. Probation.
4. Involuntary commitment.
5. Voluntary commitment (in lieu of trial and imprisonment).

Voluntary Treatments

1. Medical-psychiatric.
2. Synanon-type programs.
3. Addicts anonymous.
4. Religious programs.

Ancillary treatments to ensure abstinence

1. Nalline testing.
2. Urine testing.
3. Cyclazoline.
4. Methadone.

Ancillary treatments to ensure rehabilitation

1. Individual psychotherapy.
2. Group psychotherapy.
3. Milieu treatment.
4. Special living arrangements.
5. Vocational rehabilitation.
6. Family and Social Services.

OUTCOME OF TREATMENT

The report stated that there was a lack of sound and detailed evaluations of treatment efficacy.

In a follow up study on 673 offenders referred to the New York State division of parole between November 1, 1956 and December 31, 1961, 27% were said to be abstinent and without further criminal record as of December 1962. It was said that unsupervised patients in 90% of the cases relapse in six months. Figures quoted from a 1966 report of Vallant showed that 67% of long-term imprisonment followed by parole of a year resulted in abstinence lasting longer than 1 year. It was concluded that "the relapse rate following simple institutionalization (medical or penal) and release without after care or rehabilitation is very high."

At the Public Health Service hospitals both voluntary admissions and prisoner patients are treated for an average of 6 weeks. About 10% were reported to stay drug-free for the first year after release." Of 1,912 patients who were referred from Lexington Hospital to the NIMH New York Demonstration Center during the period July 17, 1952 to December 31, 1955, 87.3 per cent were readmitted within 12 months of discharge.

SUMMARY OF EFFICACY DATA AS PRESENTED

The overall conclusions from the 2 studies organized and presented by the firm give figures which purport to indicate efficacy.

DOLE STUDIES

Total Addicts treated 4,376 (13 inpatient and 16 outpatient facilities).

Rate of discharge, 20 percent.

Follow up of 281 patients 6 months after discharge: Of those leaving voluntarily 10 percent arrested or jailed, as compared to 26 percent of those who were discharged for cause.

Follow up of 198 up to a year after discharge showed that 13 percent of the Voluntary group and 28 percent of the discharged group were arrested or jailed. After a year the figures were 18 and 30 percent respectively.

Figures for 100 person years compared the arrests and incarcerations for 3 years prior to and 4 years following admission to a maintenance program and compared these data to those for detoxification patients.

Before admission to treatment there were 168 arrests and incarcerations in the maintenance group and 183 in the detoxification group. Following treatment the figures were 5.5 and 197 respectively.

Published reports were cited to demonstrate crime reduction from 4,500 convictions (750 criminal addicts) to 51 convictions. Following admission to the Methadone Maintenance Program 88 percent had arrest-free records and it was concluded that there was a 91 percent reduction in crime rate.

A 1969 publication by Dole reported on a controlled evaluation involving inmates of the New York City Correctional Institute. Follow up for 50 weeks:

N, 28.

12 received methadone and continued on maintenance.

None of the 12 who continued treatment became re-addicted to heroin and 9 had no further convictions. Of the untreated group—15/16 were convicted of new crimes. All became readdicted.

A further published report on social data on 990 men treated at the Bernstein and Harlem units revealed that employment rose from 25 to 92 percent at 36 months of treatment and the number requiring welfare decreased from 51 percent at 6 months of treatment to 8 percent at 36 months.

JAFFE STUDIES

Use of illegal drugs dropped from 100 to 149 percent in the first 60 patients treated. Incarceration rate decreased from 29.9 to 4 percent. Employment increased from 58.4 to 75.0 percent. Those on welfare remained the same.

OTHERS

Statistics from studies by *Weiland* and *Dupont* showed similar trends.

SUMMARY OF EFFICACY

Using the criterion of freedom of the urine from illicit drugs, chiefly morphine, the data presented in this NDA support the effectiveness of methadone as used in a maintenance program for the treatment of heroin addiction.

The dosage used to produce successful outcome of treatment varies with the investigator. But it appears from the data that 80 to 120 mg given once daily maintains a large number of addicts in optimal condition. The patients started as outpatients compare favorably with those who were hospitalized.

Social and vocational rehabilitation while not measures of effectiveness to be presented in this NDA, were documented from (Dr. Dole's tales) as additional support and presented as computerized tabulations without summary.

CLINICAL SAFETY DATA

Adverse Reactions

The known adverse effects from methadone were obtained from its use as an analgesic and cough suppressant. In addition to the list of reactions not coded by prior agreement other known reactions are agitation, disorientation, drowsiness, euphoria, faintness, flushing of face, headache, light headaches, palpitation, pruritus, sedation, and weakness.

In addition to the known reactions, 31 adverse effects were recorded and submitted in the NDA and are summarized as follows:

	First 6 weeks	Total		First 6 weeks	Total
Abdominal pain.....	35	61	Pressure in ears.....		1
Abscess (NOS).....	3	6	Fever.....	7	18
Amblyopia.....		2	Flatful.....	15	17
Anxiety.....	24	31	Glossitis.....	2	2
Arthralgia.....	102	142	Leucorrhea.....	3	3
Avitaminosis.....	1	1	Decreased libido.....	7	16
Chest pain (NOS).....	8	17	Malaise.....	43	66
Dermatitis (NOS).....	2	4	Nervous.....	1	1
Diarrhea.....	36	62	Peripheral neuritis.....	4	4
Diplopia.....	1	1	Penis disorder (NOS).....	2	3
Abnormal dream.....	45	57	Erythema.....	1	1
Dyspepsia.....	137	178	Rash (NDA).....	101	127
General edema.....	6	8	Syncope.....	1	2
Peripheral edema.....	40	56	Urticaria.....	2	4
Abnormal ejaculation.....		5	Anal varicose vein aggravated.....	2	2
Fatigue.....	4	7			

The computerized list of reactions characterized as "severe" anxiety (3 patients), arthralgia (1), abnormal dream (3), dyspepsia (1), fatigue (3), fever (2), penile discharge (1), peripheral edema (1) and aggravation of anal varicose vein (1). The severity was unspecified in a large number of instances and the outcome was not precisely stated.

LABORATORY SAFETY DATA

No baseline laboratory data were in the two retrospective studies reported. It was stated that there was no controlled population available for comparison of the treated group with a healthy group who would be receiving methadone. The following laboratory tests had results given over time. The figures given represented observations, not totals of patients. Those with abnormal findings were tested more frequently.

Hematocrit

At 13 weeks: 146 below normal, 13 above normal.

Normals: Dole 36-51; Jaffe 37-54.

At 91-130 weeks: none above normal, 4 below normal.

Hemoglobin

At 13 weeks: 87 above normal, 124 below normal, 1,469 normal.

Normal: Dole 12.0-18.0; Jaffe 11.5-17.5.

At 91-130 weeks: 2 above, 4 below, 69 normal.

WBC

At 13 weeks: 253 above, 220 below, 1,301 normal.

Normal: Dole 4,500-11,500; Jaffe 5,000-10,000.

At 91-130 weeks: 7 above, 4 below, 44 normal.

Bands, Neutrophils, lymphocytes

All normal or above.

Normals:

Neutrophils, Dale 30-50; Jaffe 50-65.

Bands, Dale 01-08; Jaffe 01-05.

Lymphocytes, Dale 15-50; Jaffe 25-40.

Alkaline phosphatase

Normals: Dale: 1.0-5.0 Bodansky; Jaffe: 0.8-2.3 Beesey-Laury.

91-130 weeks (Kreek-Dole) 21 readings above normal.

91-117 weeks (Jaffe) 33 readings above normal.

There were no increases in abnormal laboratory values as a function of time.

Abnormal liver function tests were to be expected in patients addicted to heroin over a period of years.

EKG

At 1-13 weeks: 16 normal, 3 abnormal.

Serology

At 1-13 weeks: 495 positive, 1,210 negative.

Special laboratory surveillance was carried out at 3 month intervals Bernstein Institute (Dale) and at Harlem Hospital (Dale). Physical examinations were performed on admission and 6 months or a year later. The data were presented in 3 publications.

I. Summer, Ruth, Seth Kane, and Joanna Knobler. "Clinical Status of Patients on Chronic Methadone Therapy." Preceptor, Mary Jeanne Kreek, M.D. The purpose of the study was to investigate the medical aspects of chronic methadone administration on the first 214 patients admitted. There were two phases to the research.

1. Retrospective reviewing of Medical Charts.

2. Comparison of information with the data gained from current blood and urine samples.

Résumé of the program

The patients spent the first 6 to 8 weeks in Bernstein Institute or Harlem Hospital. The first seven spent over a year in Rockefeller University Hospital. Results at admission compared to those 3 months later were noted. Particular emphasis was placed on liver function tests (bilirubin, alkaline phosphatase, SGOT and SGPT). Blood counts, serology tests, basic urinalysis and blood protein levels were done.

Of the 129 patients remaining in the program, 98 were interviewed and 78 blood samples taken. Patients were questioned as to physical condition, sexual function, bowel function, sleep, appetite, sweating, alcohol use, hepatitis and hospitalizations.

Results of Laboratory Evaluations

Two points in time were used for comparison of data, admission and the summer of 1969. The findings were:

1. Increase in mean hemoglobin.
2. Lower hematocrit (normal).
3. WbC remained normal. There was a decrease in neutrophils and an increase in lymphocytes.
4. There were fewer patients with increase in eosinophils (more than 3).
5. Decrease in BUN with more uniformity.
6. Blood sugar remained normal.
7. SGOT and SGPT remained essentially the same—both values above normal.
8. Slight increase Alkaline Phosphatase (but within normal limits).
9. Total Bilirubin the same.

Results from interviews

1. Men tend to have reduced sexual desire (lasting 6–18 months).
2. Excessive sweating noted.
3. High alcohol consumption (esp. Harlem) and liver damage.
4. $\frac{20}{61}$ were hospitalized for other than detoxification, trauma, obstetrics, gynecology.
5. $\frac{1}{60}$ had clinical hepatitis.
6. Most of those interviewed used laxatives for the first 6 months.
7. Discharge from the program was generally for alcohol and non-heroin drug abuse. None for heroin use.

II. Dodes, L., M. Davidson, G. Lowen, and M. Kreek. The emphasis in this paper is on the measurement of liver toxicity because of the high dose, long-term use of Methadone.

Method

Charts of the initial 135 consecutive, unselected patients admitted to Bernstein Institute MMTP were reviewed for results of tests during the first 14 months. Six patients had no data and were eliminated. Tests reviewed were FBS, BUN, WBC, total protein, albumin, total globulins, SGOT, SGPT and alkaline phosphatase. Values were noted at admission, up to one month, 4 months ± 2 , 8 months ± 2 , and 12 months ± 2 .

Results

A majority (74 percent) had elevated transaminases but none had more than a moderate elevation of the three measures, SGOT, bilirubin and alkaline phosphatase. Population skewed toward the abnormal with respect to liver function. Data which were available showed no significant change in FBS, BUN and bilirubin. SGOT and SGPT values above normal were found in 13 percent more patients following chronic methadone administration.

III. Kreek, M., Lance Dodes, Seth Kane, Joanna Knobler and Ruth Martin. This paper dealt with "The Effect of Long-Term Methadone Maintenance Therapy on Liver Function." This study was similar to No. II. 129 of the first 214 heroin addicts were still in therapy after 3 years.

Problem

To determine if methadone (80–140 mg/da) had undesirable effects on patients with and without liver disease. In this group 23 percent had a past history of hepatitis, 32 percent had moderate abnormalities of liver function tests and up to 49 percent had abnormalities of some protein tests at some time during the study.

Results

By July 1, 1969, 85 patients had been discharged. There were 9 deaths, none due to liver disease. Of 11 heavy alcohol users 4 showed moderate and 5 minimal liver function abnormalities. These increased in 6, showed no change in 4 and returned to normal in 1. Of 12 moderate alcohol users, 4/7 continued to have moderate abnormalities. One patient with increased alcohol consumption showed abnormalities in 1969 for the first time.

None were hospitalized for liver disease.

On admission 43% had normal SGOT and 51% had normal SGPT.

These figures became 49% and 65% in 1969.

Alkaline phosphatase and bilirubin were essentially unchanged.

Conclusions

The authors concluded that there is no evidence that moderate to high doses of methadone (80–140 mg/da) exerted hepatotoxic effects with or without pre-existing liver disease. The possibility that liver damage could be due to a direct effect of heroin in addition to hepatitis damage considered. It was felt that "street drugs" containing a variety of foreign substances may play a part in any toxic effects.

Summary of Data Concerning Safety

No patient in the two studies reviewed was discontinued because of adverse reaction to methadone.

No serious side effects were reported.

No progression of liver abnormalities which were present before methadone treatment.

Methadone showed no teratogenic tendency in rats and rabbits.

In humans there were no fetal abnormalities in offspring of mothers on methadone during 23 pregnancies with 15 living infants.

Diskets could be substituted for methadone powder on a milligram for milligram basis.

No comparison can be made between effects of methadone in addicts and healthy non-addict population.

SCIENTIFIC LITERATURE

Two volumes of reprints of a published papers were included. These contribute to the evaluation of both efficacy and safety. A review of these revealed that pertinent information was found in the following:

1. Statement of AMA Committee on Alcoholism and Drug Dependence. JAMA, September 18, 1967, Vol. 201, No. 15. In discussing the Dole-Nyswander programs for the management of Narcotic drug dependence by high-dose methadone technique, the Committee recommended the Continuation at a properly controlled research level, rather than as an established treatment method.

2. *Baden, M. M.* Methadone related deaths in New York City Int. J. Addic. 5(3)489–498 September 1970. In 1968, in New York City Narcotism was the leading cause of death between the ages 15 and 35 years with more than 730 related to heroin addiction. The report is concerned with 32 methadone related deaths of which 24 were on a maintenance program. Of these 12 died of abuse of alcohol, barbiturates or amphetamines, one of intravenous heroin, 4 traumatic deaths, 2 hepatitis, 1 cirrhosis, 1 meningitis, 4 of natural causes, 8 not in the program died of methadone abuse. Autopsies revealed no specific findings attributable to methadone. Death rate among "street" users and those in maintenance programs was about 1% each.

3. *Blachley, P. H.* Progress report on the Methadone Blockade Treatment of Heroin addicts in Portland. Northwest Medicine—March 1970 172–74.

The program started in April 1969 and patients were added at a rate of 2–6 per week. Seventy-five were in treatment at the time of the report. Age range, 21–83, $\frac{1}{4}$ of them women. Most of the patients became legitimately employed within 2 months. Four were started on methadone a week before discharge from jail. Stabilization dose ranged from 10 mg to 250 mg. No formal psychotherapy given. The goal of this program was stated to be control of, but not cure of drug usage.

4. *Blinick, George.* Menstrual function and pregnancy in narcotic addicts treated with methadone. Nature. Vol. 210, July 1969.

This report originated from the department of OB and Gyn at Beth Israel Hospital. Seventy-six women were admitted to the MMTP.—50 were amenorrheic while on heroin, or were menstruating irregularly. Of the 63 women remaining in treatment, 54 had menstrual function and 43 of these began to menstruate regularly within 1 to 2 months. Eight became pregnant 2 to 18 months after treatment was instituted. There was no evidence of malformation in the offspring and minimal evidence of withdrawal.

5. *Bloom, W. A. and E. W. Sudderth.* Methadone in New Orleans: Patients, Problems, Police. Int. J. Addic. 5(3) 465–487 Sept. 1970.

Anti social activity and illegal drug taking continued among 500 patients treated at 3 independent clinics. The police were useful in confronting patients with rumored illegal behavior before an actual arrest occurred.

6. *Kleber, H. D.* The New Haven Methadone maintenance program. Int. J. Addic 5(3) pp 449–463 September 1970.

Patients were placed on a day-hospital status for 4-6 weeks, with group therapy three hours daily as the maintenance dose was gradually built up. In the 15 months since 1968—68 patients entered the program. Of these 56 (83%) continued. Medium age—32, years of addiction—10½, males 7%, blacks 85%, employed 77%. The author lists the issues for the future of methadone.

What features hinder or encourage patients in getting off and remaining off methadone.

Are there long-term physical effects (now appear essentially negative. Research should continue).

What is the quality of a patient's life while on methadone?

How applicable is the program to drug users under 21?

He emphasizes psycho-social involvement with patients and patient participation in running the program. Naloxin is used in tapering off methadone.

8. *La Rouché, M. Land, Patrick T. Donlon.* Heroin addiction. A Comparison of Two Inpatient Treatment Methods.

At the Lafayette Clinic in downtown Detroit a non-medical form of inpatient psychiatric treatment was compared to a prospective study of methadone maintenance—10 patients in each group.

(A) The non medical group were in a locked ward for 6 weeks with substitution withdrawal, psychotherapy, milieu therapy, social service work (family) and rehabilitation planning all became re-addicted.

(B) The Dole-Nyswander technique was used during 6 weeks of hospitalization. Three resulted in failure—5 responded favorably.

The authors concluded that:

Methadone did not eliminate the drive to criminal behavior, but the addicts were not compelled to sociopathy to finance the habit.

Wide spread administration to all addicts is impractical (addicts do not wish to be free of drugs).

Indiscriminate prescribing to an addict has no therapeutic value.

If it is successful, methadone maintenance is part of a carefully planned rehabilitative program.

9. *Martin, W. R.* Commentary on the Second National Conference on Methadone treatment. *Int. J. Addic.* 5(3) 543-552 September 1970.

Lack of comparison of treatment results with an appropriate control group was said to be regrettable. The author feels that Methadone maintenance should be used only as a last resort and only when the consequences of the treatment are less detrimental than continued illicit drug taking. He recommended continued data gathering both as to safety and effectiveness during long term use.

10. *Yale Law Journal* V 78:1175. Notes and Comment.

What appeared to be a long editorial stressed the rationale of the program based on therapeutic qualities. They were listed as: few debilitating effects from long-term treatment, reduces or abolishes drug craving, tolerance to methadone produces a cross-tolerance to heroin, and patients behave normally. The questions were raised 1) what better alternatives are there, 2) are patients better off with the drug than without it. The benefit/risk to the patient and to society needs to be considered. The article stated that the program should be carried out by a practicing physician in association with organized programs in all institutionalized or team settings.

11. *DuPont, R. Land, R.N. Katon* Development of a Heroin Addiction Treatment Program. Effect on Urban Crime. *Jama* May 1971.

Before 1966, heroin addicts comprised less than 3 percent of the admissions to the D.C. jail. In August 1969, 45 percent were addicts and only 27 percent of those identified were on the list of 1200 known addicts. It was then estimated that there were at least 5,000 addicts in D.C. A later estimate of 10,400 was made on the basis of drug death rate.

By November 1970, 2,300 addicts were treated in various drug programs with 70 percent on Methadone maintenance. Arrest rate was 4.5 percent for those who remained in the program and 33 percent for dropouts.

12. *Goldstein, Avram.* Blind Controlled Dosage Comparisons with Methadone in two hundred patients presented at Third National Methadone Conference Nov. 1970.

The report covered 8 months of operation of the Santa Clara County Methadone Program, no exclusions for alcoholism, multiple drug addiction or psychosis were made. The primary aim was to stop heroin use, with rehabilitation a secondary goal. The 206 patients treated showed about the same results after a month with dosages of 30 mg, 50 mg or 100 mg. The larger dose suppressed

heroin use more rapidly. Side effects were difficult to assess since most of the complaints were present while the patient was taking heroin. Dose related effects were dermatitis, constipation, impotence and feeling "loaded". Excessive use of alcohol and other drugs remained about the same as before Methadone was instituted except for barbiturates, which declined with Methadone treatment. Because of the shorter action of Methadone in some patients a split dose provided better results.

13. *Committee on Alcoholism and Drug Dependence*. *Jama* Oct. 19, 1970.

In this statement the Committee stated that recovery from drug dependence may be considered a "social recovery". When, as part of a program an individual is maintained in a drug-dependent state through the administration of a substitute substance, e.g. methadone or cyclazocaine, which does not interfere with social and economic functioning.

The numerous publications of Dole and Myswander have not been noted here. Jaffe's articles have been omitted also. Both of these investigators are represented in the data reviewed for safety and efficacy as represented in the retrospective studies.

Discussion

As presented in this NDA, Methadone hydrochloride in the form of a diskette is indicated for the maintenance treatment of heroin addiction. The basis for estimating efficacy is primarily the absence of abused drugs in the urine with sociological considerations being secondary. In support of claimed efficacy, Eli Lilly and Company present data comparing the use of their Diskette No. 1, with methadone hydrochloride powder on a milligram for milligram basis. An equivalent effect is essential since the body of clinical data is largely based on the use of the powder form. Information from two investigators, Dale and Jaffe furnish the basis for claimed effectiveness. Neither "study" represents a controlled investigation in the randomized, double-blind concept of control.

Statistical analysis of the data to show superiority of the treatment over some other type of treatment is not a feasible approach. Control data, where present, is of a historical nature.

It is advisable to distinguish between the efficacy of the drug, methadone in clearing an addicts urine of abused drugs and the efficacy of the concept of Methadone maintenance programs as they effect the lives of the addicts and the effect on society as a whole.

The question to be answered by the data in this NDA is: Will (or does) Methadone hydrochloride serve to eliminate abused drugs from the urine of addicts during long-term maintenance administration? With this in mind conclusions have been reached after reviewing the data in the NDA. Reference was made to the specific requests made to the firm by FDA in conferences held prior to the submission of the NDA.

Conclusions

1. Safety (pre-clinical): The safety of methadone as demonstrated in the animal data in NDA 6-134 (Methadone as an analgesic and anti-tussive) is such that no toxicity studies were required for this NDA.

Reproduction studies in rats and rabbits revealed no evidence of teratogenicity or embryo toxicity.

2. Safety (Clinical): No congenital abnormalities were observed in newborns of mothers in a Methadone maintenance program (Dale). There were 3 instances of withdrawal symptoms in the newborns. Low birth weight, meconium and increased incidence of breech presentations occurred in 100 consecutive deliveries (Blinick-Doles program).

Adverse Effects: Constipation and sweating are the common effects during both short-term and maintenance administration.

Severe reactions reported from long term use are anxiety, (3), arthralgia (1), abnormal dream (3), dyspepsia (1), fatigue (3), fever (2), penile discharge (1), peripheral edema (1) and aggravation of anal varicose vein (1). No patient was removed from treatment because of adverse reactions.

Dose related adverse effects (Avram Goldstein) are dermatitis, constipation, impotence and "loaded" feeling.

Laboratory safety data

Laboratory measurements are not adversely affected by long term methadone administration (Dale-first 214 patients).

No progress was reported in liver function abnormalities which were present prior to methadone treatment (Dale).

In methadone related deaths there were no autopsy findings related to methadone treatment (Baden).

Efficacy

1. Efficacy of methadone as administered in the programs of Dale and Jaffe has been demonstrated for the primary claim, e.g. elimination of morphine and its metabolites from the urine of heroin addicts.

2. The dosage required to produce the success of methadone maintenance varies from program to program. A once daily dose of 80 mg to 100 mg maintains a representative number of patients.

3. Results in those started as outpatients compare favorably with who are hospitalized initially.

4. Published reports as well as data from Dale and Jaffe's studies show a decrease in crime and an increase in rehabilitation and employment in patients remaining on a methadone maintenance program.

Effectiveness for the Disket is equivalent to that of methadone powder.

Recommendation

Approval of the Application.

IRMA B. HOBART, M.D.

Mr. ROGERS. Any other questions?

Mr. CARTER. What is the least addictive substitute for heroin? There is no nonaddictive substitute for heroin.

Dr. GARDNER. If you are talking of a substitute, methadone is least addictive.

Mr. CARTER. That is the answer I thought you would give, and the answer I believe to be correct.

Dr. GARDNER. There are blocking agents that are not in a sense substitutes, and we hope will be available in the near future.

Mr. CARTER. A substitute is one that can be used in place of, and you would say then that methadone is the least addictive?

Dr. GARDNER. Yes.

Mr. ROGERS. Are you saying that methadone is less addictive than heroin when taken over a period of time?

Dr. GARDNER. Yes, in some ways. It does not produce the effects heroin does since heroin has to be taken intravenously. So it has those advantages. It is not, again, without defects but it is the less addictive substance we have available.

Mr. CARTER. Heroin is the most addictive of the opiates as far as I know. By one injection, people have been known to become addictive.

Mr. ROGERS. And I think when heroin was developed as a substitute—for what addictive drug?

Dr. GARDNER. Well, it was developed as a substitute for morphine.

Mr. ROGERS. To get people off morphine.

Mr. CARTER. On that very thing, in 1914 we outlawed heroin because it was so addictive and it has not been used legally in the United States since that time but morphine continued to be used.

Mr. ROGERS. But it was brought about as a substitute and this is my concern that here we are going to shift everybody to another addicting substitute rather than finding a nonaddicting substitute and really having a crash program to do this.

Dr. GARDNER. There are many substances that have been developed for morphine, some of which, like heroin, have been more addictive. There are still many being developed. But there are also substances being developed that are less addictive and also hopefully substances that have no addictive potential.

Mr. ROGERS. What is Food and Drug doing to bring about a drug that is nonaddicting that is blocking and would be helpful?

Dr. GARDNER. We have been working with the Special Action Office and NIMH in their meetings with industry to expedite the development of other drugs such as the blocking agents.

Dr. EDWARDS. We haven't funded any because we haven't the funds to fund, but we are trying to work with them.

Mr. ROGERS. You are thinking of setting this forth in the Federal Register 180 days before it would go into effect?

Dr. EDWARDS. We haven't put any specific time frame on it yet.

Mr. ROGERS. What would be your thinking generally?

Dr. EDWARDS. I would say at least 3 or 4 months would be given for comment and hearings.

Mr. ROGERS. Suppose Congress wanted to take some action. I think probably some time should be given.

Dr. EDWARDS. We will give whatever time is necessary.

Mr. Chairman, I think it is important to recognize, although there are complexities associated with the addicting drugs like methadone, I think it is important to recognize that most drugs that we approve are not effective for 100 percent of the population for which they are used. And the number of patients for which we approve depends on what the drug is used for. You mentioned motivation. Motivation is a key factor in this whole thing but we are not by any stretch of the imagination suggesting that methadone is going to cure all or even half of the addicts that we are talking about. But to this point in time, it is the only effective substitute that we know of whose safety and efficacy have been reasonably well established.

Mr. ROGERS. And addictive?

Dr. EDWARDS. And it is addictive, right.

Mr. ROGERS. So it is a maintenance program of addiction, simply a substitute on the other.

Just one last question. Suppose a woman was maintained on methadone and became pregnant. What would happen to that child, probably?

Dr. EDWARDS. We don't know for sure. We don't have all of the information we want on this particular aspect of the use of methadone and that is why we would keep the use of methadone in pregnant women on an IND basis, continued on an investigation.

Mr. ROGERS. Normally the child would probably be addictive.

Wouldn't that be the general result?

Dr. GARDNER. There have not been enough pregnant women tested to arrive at conclusions, but from what we do know to date, children undergo some withdrawal symptoms. These are usually mild. There has been no other ill effects observed. Numbers are still not large enough.

Mr. ROGERS. You just have not done the studies on it.

Dr. GARDNER. There are not enough patients since it is difficult to obtain enough patients.

Mr. ROGERS. Well, I think the committee would like to see the studies because I am very much concerned about proving it safe and effective as an addictive drug, where its use may be tremendous in this country where you say 50,000 and 60,000 are already on it. So I think it would be helpful to the committee in its judgment to have those studies.

Any other questions?

If not, thank you for being here.

Our next witness is Mr. John E. Ingersoll, Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice.

Mr. Ingersoll, we welcome you back to the committee, and your associates, and we are pleased to receive your statement.

STATEMENT OF JOHN E. INGERSOLL, DIRECTOR, BUREAU OF NARCOTICS AND DANGEROUS DRUGS, DEPARTMENT OF JUSTICE; ACCOMPANIED BY DONALD E. MILLER, CHIEF COUNSEL

Mr. INGERSOLL. Thank you, Mr. Chairman.

Mr. Chairman, and members of the subcommittee:

It is a pleasure to appear before you again; this time to present the Justice Department's views on the issue concerning the control of methadone and its use in the treatment of narcotic addicts.

The traditional narcotic drug control policy of the Federal Government in the past has been to eliminate sources of narcotic drugs used for other than approved medical purposes. The use of drugs to maintain addiction while attempting to reintegrate the addict into society was not regarded as an approved use in earlier days. Regulatory controls which covered the flow of narcotic drugs from manufacturer to physician were normally regarded as adequate to insure against large-scale sales of drugs by physicians to illicit traffickers. This scheme did not, however, insure against direct sales of the drug to a consumer under the guise of "medical treatment." Therefore, a policy was determined in the 1920's that physicians who claimed to be treating addicts in supplying them with narcotic drugs should be presumed to be engaged in illegal distribution.

This led to prosecutions and intimidations, which were sufficiently successful to eliminate the interest of the medical profession generally in engaging in the treatment of addicts other than in the two approved Federal hospitals at Lexington and Fort Worth. Government policy was broadly supported by existing medical opinion and seems to have achieved the desired end. It was, however, a policy which succeeded in terminating both the sincere and insincere efforts without distinction.

In the last two decades there has been a growing consensus that the voluntary institutional approach to the treatment of narcotic addicts represented by the facilities at Lexington and Fort Worth has failed. In the same period, informed opinion has increasingly supported the view that addiction is a public health problem which should receive the attention of the medical profession. New theories of treatment and new chemotherapeutic agents have proliferated in this period. Most particularly, the use of methadone has been popularized as a result of experimental work begun in the mid-1960's by Drs. Dole and Nyswander in New York.

Their work departed from officially approved notions in two important particulars. First, they were not working within one of the approved Government treatment centers; and, secondly they were supplying drugs for the purpose of maintaining the patient's addiction rather than as a means of facilitating withdrawal. It was, nevertheless, clear that their intentions were bona fide in nature and that

their activity was in no way typical of the kind of physician activities which were traditionally regarded as illicit distribution. Drs. Dole and Nyswander, and others with similar commitments, proved successful in publicizing their efforts and in attracting others to similar work. It was at this time that the weakness in the Government's legal and regulatory apparatus became apparent.

The old Bureau of Narcotics, one of our predecessor agencies, had responsibility for the regulation of narcotic drugs. Any distribution of these drugs by a physician other than "in the course of professional practice" was treated as a criminal offense. Suddenly, the meaning of this phrase "professional practices" had lost its definition. Medical thinking had entered a period of innovation and uncertainty and would no longer support the simple distinction of the past. Dr. Dole could not be arrested and treated as a common criminal nor could the other sincere physicians who began to follow his path. But, the Bureau lacked any legal authority to articulate standards differentiating an acceptable methadone program from an unacceptable one. Such distinctions have to be made with clarity, and on unquestioned authority, if they are to stand in a court of law.

The result of this inability was a proliferation of programs of varying degrees of quality. These were soon followed by blatant profiteering activities of a few unscrupulous physicians, who likewise masqueraded under the guise of methadone treatment programs. The result is, and has been, an escalating amount of methadone diversion and abuse; a growing rate of methadone overdose deaths across the Nation; and the threat of the creation of a new drug problem that previously never existed. A total of 138,181 dosage units of methadone have already been purchased or seized in the first 9 months of this year from the wholesale illicit market. It should also be kept in mind that BNDD does not operate at the street level where most of the illicit traffic in methadone occurs. State and local police also provide anecdotal evidence of the increasing presence of methadone at the retail level of illicit traffic. Those who became emboldened by Government weakness have also taken to the prescribing of Demerol, Numorphan, and other narcotics under the guise of treatment.

We recognized the dilemma at a reasonably early stage. In mid-1968 we turned to the Director of the National Institute of Mental Health for assistance in constructing a regulatory scheme that could differentiate promising medical efforts from damaging and criminalistic activities. An interagency meeting was held in September of 1968 in which representatives of NIMH and FDA and our Bureau participated. The consensus of concern that was then established did not lead to an immediate plan of action, and I, therefore, determined that BNDD should proceed on a fact-finding investigation to explore the regulatory problem in depth.

This was done over a period of months in which leading methadone programs around the Nation and in Canada were visited by a team of Bureau lawyers, a social scientist, and its Chief Medical Officer. Dr. Jerome Jaffe's program in Chicago was one of those visited. The findings, together with a review of the medical literature and individual consultation with national authorities, culminated in a report detailing problems and recommendations for their solution. This report was subsequently made available to the Secretary of HEW, the Commissioner of FDA, and the Director of NIMH.

The FDA recognized the fact that they had never approved the use of methadone for the maintenance treatment of narcotic addicts. This was in line with the policy position taken by the former Bureau of Narcotics that such activities were research only and not treatment. They, therefore, made known to us their desire to cooperate in a joint regulatory effort based on the investigational status of methadone maintenance. This led to a series of negotiations between our two agencies which finally resulted in the publication of the proposed regulations in June of 1970. The proposals contained a model protocol articulating both medical standards determined by FDA and control standards determined by our own Bureau. The model protocol was further complemented by a regulation of our giving it the force of our own law.

A period of comment was allowed which, likewise, became protracted. In the course of these months of negotiation and receipt of comment, FDA took the position, in which we concurred, that maintenance programs were investigational and required an IND number. As a result, a great many IND applications were received and issued prior to the enactment or enforcement of any standards. Finally, on April 2, 1971, the regulatory proposals came into effect and we inaugurated our own program of enforcement.

At the present, our figures show a total of 298 programs operating under IND's at 380 locations. These contain an estimated 25,000 patients though no exact figures exist. Of this total, we have investigated 125 programs. Thus far, seven have been closed, usually through joint BNDD/FDA investigations. Another 14 have voluntarily terminated operations as a result of inadequacies.

The IND control mechanism has not proven adequate to the task. This is hardly surprising in view of the fact that we are really attempting to deal with a totally new concept in the treatment of addiction utilizing laws which were never designed for such a purpose. One of the major loopholes which has developed is the fact that the scheme does not extend to so-called detoxification programs. The use of the drug for this purpose has long been approved though the conditions and requirements remain vague and unenforceable. What we are finding is that some dishonest physicians continue their activity under the guise of detoxification when their privilege to operate under an IND is terminated.

The experience in Great Britain suggests that a major drug problem can quickly arise from the practices of but a few wayward physicians. Instances of this kind are coming to light in virtually every major city within the Nation. We recently made undercover purchases of over 70 exhibits of methadone from a physician who was supplying several hundred addicts. Although profits were high, controls were virtually nonexistent and the drugs were being sold in many parts of the city. One program, recently terminated in New York, boasted 3,800 so-called patients. Reportedly, a \$2 million apartment house had recently been purchased with clinic proceeds.

This has also happened in Washington where one doctor was arrested after several undercover purchases by the Metropolitan Police. Maryland health authorities conducting bona fide methadone programs have complained to us that their effectiveness is being disrupted by this type of illegal activity. The District of Columbia Medical Society has asked

its members to abstain from prescribing methadone to addicts in private office practice. Thus far, prosecutions have not been achieved in any of these cases in spite of intensive police efforts. A further weakness in the IND system is the advisory nature of the present protocol and the fact that so many exceptions have been permitted to grow up. Nevertheless, a degree of control has been imposed under the IND procedure in a situation marked by chaos and growing diversion of methadone.

We are now advised that the IND procedure is no longer a justifiable control mechanism, and that it is being improperly used. We can appreciate that the volume of activity with methadone has exceeded that which is customary in bona fide research investigations. This, of course, is due to the fact that so many IND numbers were issued without imposition of any standards prior to the coming into effect of present regulations. We are also aware that the influential body of medical opinion feels that methadone-maintenance programs have now demonstrated their worth for certain classes of hard-core addicts. This is also the opinion of Dr. Jerome Jaffe, the President's principal adviser on matters of treatment and rehabilitation; and we are willing to accept his medical judgment. The question for us is rather one of how the activity is to be controlled. If controls are inadequate, nothing can result but increasing diversion, national scandal, and a total inability to make any sense of the real utility of this technique.

We are willing to accept the fact that the granting of an NDA approval for methadone maintenance is medically justified. We do, however, recognize our responsibility as the agency charged by Congress with regulating the use of narcotic drugs to insure that they are not diverted to unjustified uses with consequent deleterious effects on the Nation's health and welfare. At present, all of our regulatory controls are predicated on the IND status of methadone and any effective regulatory action of ours following the NDA approval will require new legislation.

At the request of the Special Action Office, we have rendered advice concerning this great problem of controls and are preparing concrete proposals for new laws. As the agency possessing principal expertise in this area, we are convinced of the necessity of new legislation. We would further suggest that this legislation must specifically assign the setting of medical standards to the Government's medical authorities and the setting of control standards to the Department of Justice, each, however, acting after consultation with the other. The legislation of itself would be complex and important. We, therefore, do not feel that it should be handled as an additional issue in context with the legislation currently pending before your subcommittee. We think that is likely only to confuse issues and to result in some injustice to each. We would expect, and look forward to working closely with you in the immediate future in promulgating such legislation.

In the interim period the question of granting the NDA for methadone must be dealt with by the Food and Drug Administration. They feel that action may become necessary because of other considerations which are natural to that agency, and which we respect. In the interim they have advanced proposed administrative and regulatory measures which they feel would aid in controlling the drug after the granting of an NDA. We agree that for a short period of time their measures,

coupled with a voluntary restraint by the industry, could preserve the situation until Congress acts. We have signified to Dr. Jaffe and to representatives of the Food and Drug Administration that we will participate in such an effort to the best of our ability while legislation is in progress before the Congress.

Mr. Chairman, in closing, I want to emphasize that our agency does not presume to determine medical standards. We do possess unique expertise and responsibility for the determination and enforcement of control standards. The two overlap in some particulars, but are nevertheless separable. We realize the serious control problem with which the Nation is now confronted regarding the use of narcotic drugs with addicts. One of the greatest disservices that we could do is to acquiesce in the appearance of a system of controls which lack substance. This would falsely mislead the public and court eventual scandal and embarrassment. Moreover, we realize that inadequately regulated methadone programs will eventually increase the addiction problem with which we already have to contend. We do not relish the prospects of having to sweep up the mess of diversion which judicious action can prevent.

All who have asked know our position. We have cooperated with Dr. Jaffe in developing these ideas; and we have talked at length with the leaders of organized medicine; and we have sought every possible cooperation with other agencies. We know a broad basis of support exists in virtually all knowledgeable circles for our ideas. Our cooperation can be counted upon in any eventuality. We are willing to mount any interim measure that promises not to waste the taxpayers' resources. Any lasting solution depends, as I have indicated, on the action of Congress. I shall be pleased to respond to any questions you may wish to ask of me.

Mr. ROGERS. Thank you very much, Mr. Ingersoll, for your statement.

As I understand it, you basically feel, then, that after doing the study you have done on possible diversion of methadone, that perhaps an approach that will be needed is an additional law setting forth certain responsibilities and control features?

Mr. INGERSOLL. I think that is basically correct, sir, but I think that is a matter that is unique and should be dealt with on its own merits.

Mr. ROGERS. Yes, rather than including it in the special drug abuse office legislation?

Mr. INGERSOLL. Yes, sir.

Mr. ROGERS. Mr. Kyros?

Mr. KYROS. No questions.

Mr. ROGERS. Mr. Hastings?

Mr. HASTINGS. Thank you, Mr. Chairman.

I appreciate your cogent statement. It clarifies my position, but I have one question. If you felt that we could get 180 days from the time of the approval of NDA before it became effective, this would give us enough time to consider the legislative study that would be necessary and take us through, like, next May?

Mr. INGERSOLL. That is a difficult question for me to answer, Mr. Hastings. I can recall by previous experiences in advocating certain legislative proposals.

Mr. HASTINGS. You can say that you would do it but you question whether we could or not? From your point of view, do you think that would be adequate time?

Mr. INGERSOLL. From my personal point of view; yes, sir.

Mr. HASTINGS. Thank you.

No further questions, Mr. Chairman.

Mr. ROGERS. I wonder, could you furnish this committee with a copy of your study and findings?

Mr. INGERSOLL. Yes, sir; I will be happy to do that.

Mr. ROGERS. I think that might be helpful to us. It would appear from your findings that there has been quite a bit of diversion of methadone already.

Mr. INGERSOLL. The study itself, Mr. Chairman, related to the programs and the kinds of controls that would be necessary to prevent diversion. It is quite true that there has been a growing rate of diversion, and we feel that this is the preeminent source of illicit use of methadone. We have had only one instance in the last several years of a clandestine manufacturing operation. There may be some, but they are very, very insignificant at this time.

(See "Recommendations of the Bureau of Narcotics and Dangerous Drugs Study Group on Methadone Maintenance Research," p. 1558, this hearing.)

Mr. ROGERS. Let me ask you this just to help in this whole consideration. And you can submit a statement and answer it, if you want to. I am interested to know for the committee what part of the FBI and IRS agents play in the drug control programs. Are they being fully utilized, and so forth? What is their actual authority, and so forth?

If you could submit that for the record.

Mr. INGERSOLL. I would be happy to.

(The following letter was received for the record:)

DEPARTMENT OF JUSTICE,
OFFICE OF THE ATTORNEY GENERAL,
Washington, D.C., November 12, 1971.

HON. PAUL G. ROGERS,
Chairman, Subcommittee on Public Health and Environment, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR CHAIRMAN ROGERS: This letter is in response to your letter of November 2, 1971, which requested my reaction to two proposals your Subcommittee has under consideration in connection with H.R. 9264, legislation establishing a Special Action Office for Drug Abuse.

The first proposal would establish in the Office of the Director of the Special Action Office a Deputy Director for law enforcement, who would have, with respect to law enforcement activities of the Federal government, authority similar to that provided the Director with respect to non-law enforcement activities. I do not believe it is necessary or desirable for the Special Action Office to have any direct policy or management control over law enforcement activities. Activities in the law enforcement area of drug abuse are functionally discrete from those in the medically-oriented treatment, rehabilitation, and research areas. The skills and training for each function are totally different. It would be as inappropriate for an office devoted to law enforcement to direct treatment and rehabilitation activities, as it would be for the Special Action Office, devoted to the treatment and rehabilitation areas, to direct law enforcement activities.

It is, of course, essential that law enforcement activities relating to the drug problem be coordinated with efforts by the Director of the Special Action Office in areas of treatment, rehabilitation, education and research. To assist in this coordination, I think it would be very helpful for one of the senior assistants of the

Director of the Special Action Office to be designated specifically for this purpose. He would have direct responsibility for working closely with law enforcement officials and for insuring a continuous interchange of ideas and information. In fact, since creation of the Special Action Office by Executive Order in June, such a close working relationship has been established; and we look forward to its continuation after the passage of H.R. 9264.

The second proposal in your letter would provide for the use of the facilities, resources, and personnel of the Federal Bureau of Investigation and of the Internal Revenue Service in carrying out law enforcement activities of the federal government with respect to drug abuse. I take it that this suggestion would not be intended to change any of the present primary responsibilities relating to enforcement of the federal drug control laws. If such is the case, a specific provision in the law is not necessary. Personnel of the Federal Bureau of Investigation now have general arrest authority and can be used to enforce any federal law. For reasons of administrative efficiency and orderly division of responsibility within the Department of Justice, the FBI does not ordinarily undertake investigative efforts in areas for which the Bureau of Narcotics and Dangerous Drugs is responsible, but the authority to do so is there. Regarding the Internal Revenue Service, it is presently investigating tax cases against violators of the federal drug laws and no new legislative authority in this area appears needed.

I want to express my appreciation for the prompt manner in which you and your Subcommittee commenced hearings on H.R. 9264, and I assure you that we desire to cooperate with you to expedite enactment of this essential measure.

Sincerely,

JOHN MITCHELL,
Attorney General.

Mr. ROGERS. Thank you very much.

(Testimony resumes on p. 1577.)

(The following material was received for the record:)

RECOMMENDATIONS OF THE BUREAU OF NARCOTICS AND DANGEROUS DRUGS STUDY
GROUP ON METHADONE MAINTENANCE RESEARCH—DECEMBER 1969

I. THE BUREAU'S RESPONSIBILITY FOR REGULATING THE DISTRIBUTION OF NARCOTIC
DRUGS AND THE SELECTION OF A SPECIAL STUDY GROUP

The Bureau has the responsibility for eliminating illicit sources of narcotic drugs and insuring that such drugs are not diverted from lawful channels into the illicit traffic. The Bureau's efforts, therefore, consist primarily of enforcement activity aimed at the apprehension of underworld drug traffickers and regulatory activity designed to insure that legitimate points of manufacture and distribution do not become sources of illicit supply. The latter function has traditionally required some modest degree of regulation with regard to the prescribing, dispensing and administering activities of medical practitioners. Such persons are granted a special access to narcotic drugs and therefore become possible sources of diversion. This may arise as a result of an individual practitioner's corruption, negligence or disagreement with prevailing standards of medical practice. In each of these cases, the skill and knowledge which society intended to place between the citizen and the use of narcotic drugs is negated.

In the past, one of the Bureau's predecessor agencies, the Bureau of Narcotics, occasionally encountered physicians whose prescribing and dispensing of narcotic drugs constituted a source of supply for numbers of addicts merely seeking the gratification and maintenance of their addiction. In such cases, a bona fide effort to treat the addict was totally absent and the practitioner was merely taking advantage of his special access to narcotic drugs in order to divert them into illicit channels. Within recent years, we have witnessed the growth of a new type of experimental program in which addicts are supplied with quantities of methadone, a synthetic narcotic drug, sufficient to maintain their status of addiction for a prolonged period of time. In this sense, such programs bear a similarity to the practices of those physicians who abuse their special access to narcotic drugs. However, unlike such abuses, the practitioners initiating these new programs appear to have a sincere interest in developing a new treatment modality and have incorporated within them other important therapeutic elements aimed at the treatment and rehabilitation of the addict patient. For this reason it has become imperative that a set of criteria be evolved by which sincere research efforts may be clearly differentiated from illegal prescribing and dispensing practices. Moreover, because these programs involve supplying drugs

to a segment of the addict population, they present numerous opportunities for abuse and are therefore proper objects for the exercise of the Bureau's regulatory authority.

In order to fulfill the Bureau's responsibility in this area and to insure that regulatory powers are employed in such a fashion as to encourage responsibility research efforts, it was determined that a thorough study of major methadone maintenance programs currently in operation should be undertaken. Because of the need for both scientific and legal expertise in the evaluation of these facilities, the Director appointed a special study group consisting of representatives of the Bureau's legal staff as well as representatives from its scientific offices. Those selected were Edward Lewis, Jr., M. D., Chief Medical Officer of the Bureau, Jean Paul Smith, Ph. D., psychologist and then Director of the Division of Drug Studies, and Mr. Gene R. Haislip and Mr. Robert Graham, from the Office of the Chief Counsel. Representatives of the Food and Drug Administration and the National Institute of Mental Health were also invited to participate in the study but declined to do so.

The study group was assigned the task of making site visits to some of the more prominent programs in the United States and Canada, and of presenting realistic recommendations to the Director with regard to an official Bureau position concerning the use of narcotic drugs in programs of this type. After the designation of the study group, permission for on-site visitation was obtained from the following project directors of six selected maintenance programs:

Dr. Herbert D. Kleeber,
Mental Health Center,
New Haven, Connecticut.

Drs. W. A. Bloom and
E. W. Sudderth,
D. R. Clinic,
New Orleans, Louisiana.

Dr. Jerome Jaffee,
Community Health Center,
Chicago, Illinois.

Drs. Harold Trigg and
J. Robinson,
Beth-Israel Medical Center,
New York City, New York.

Dr. Raymond Knowles,
Superintendent,
State Hospital,
St. Louis, Missouri.

Dr. H. R. Williams,
Narcotic Addiction Foundation
of British Columbia,
Vancouver, B.C.

In addition, the study group also consulted with the Methadone Maintenance Evaluation Committee established under contract with the New York State Narcotic Addiction Control Commission for the purpose of evaluating the methadone program being undertaken at the Beth-Israel Medical Center.

The program operated under the auspices of the Beth-Israel Medical Center in New York was selected for review because it is the oldest and largest such program in the nation. It was also originally organized by Doctors Dole and Nyswander whose efforts greatly aided in triggering scientific interest in methadone maintenance as an adjuvant in the total rehabilitation of the addict.

The Mental Health Center in New Haven, Connecticut, was selected because it was an NIMH grantee, and the program was designed with what appeared to be a considerable degree of expertise. This center was equipped with a fairly high ratio of staff members to patients, and had various excellent resources because of its affiliation with, and physical proximity to the Yale Medical Center.

The program in New Orleans was selected for a number of reasons. Of primary interest was the fact that it was a new project, and was completely without financial support. The two co-directors of this program were extremely enthusiastic and seemed professionally capable. The clinic had laboratory and volunteer support from Tulane Medical Center, with which both of the physicians were affiliated. Also of importance was the fact that other poorly controlled, loosely operated programs had existed in the same area. This program seemed to be attempting to fulfill a community need in a much more controlled and acceptable fashion.

The program in St. Louis was selected for several reasons, also. It was an NIMH grantee and again was a very new center for methadone administration. It was considered important to examine a program which was just starting, with the idea that observations could be made of the difficulties encountered in such a new venture. The St. Louis program was of further interest because

it was actually functioning under the auspices of, and physically within a state mental hospital.

The program in Chicago was chosen because Dr. Jaffee, its director, is one of the pioneers in methodology of drug maintenance programs, and he has spoken and written extensively on the subject. Funding was not felt to present a problem to this particular program, and there was good ratio between staff members and patients.

Finally, the Vancouver, B.C. center was chosen because it represented the largest and oldest such center in Canada, and it was felt that since it was outside the United States, some of the more problematical areas might be more freely revealed and discussed with officials from the United States.

In concluding its review, the study group has sought to fulfill two major objectives. These are first, the setting forth of an analysis of the major factors which the Bureau must consider in discharging its responsibilities in this area. This includes a brief summary of each of the programs visited and an explanation of the current state of knowledge and practice in the field of methadone maintenance research. Secondly, a number of specific recommendations for Bureau and Governmental action have also been developed. These include recommended statements of policy explaining the Bureau's position with regard to maintenance programs, recommended regulations to govern the operation of such programs, and recommended guidelines to aid interested persons in the development of programs which will comply with projected Federal regulations and with the best practices observed throughout the country.

In formulating these recommendations, the study group has been particularly mindful of the positions adopted by the American Medical Association, the National Academy of Sciences/National Research Council and the World Health Organization concerning maintenance research. Each of these organizations have recognized the need for continued research and the possibility that a useful mode of therapy may be developed for certain classes of narcotic dependent persons.

The principal objective of the study group has been to suggest controls which would be sufficiently broad to permit continued innovation and scientific research, and at the same time sufficiently specific to insure that such programs may not serve to aggravate the existing problem of narcotic drug dependence. Finally, the study group is of the opinion that sufficient data does not exist to permit a sound determination of the efficacy of narcotic maintenance therapy as a treatment for addiction and that Government must concern itself with the collection and correlation of data which will permit such a determination in the not too distant future.

II. THE PHARMACOLOGY OF METHADONE AND ITS CURRENT USAGE WITH NARCOTIC DEPENDENT PERSONS

Methadone was originally synthesized by the Germans, and its clinical use began around the end of World War II, at which time the drug came to the attention of American medicine. Chemically, methadone is 11-(6-dimethylamino-4,4-diphenyl-3-heptanone hydrochloride. In spite of the fact that structurally it only vaguely resembles morphine, pharmacologically its properties are qualitatively similar to those of the natural alkaloid. The analgesic action of methadone may be somewhat greater, and its sedative, respiratory-depressant, and smooth muscle stimulating actions are somewhat weaker than those of morphine.

Specifically, single doses of methadone are less hypnotic than comparable doses of morphine. However, upon repeated administration, marked sedation is noted, possibly due to a cumulative effect. In equivalent doses, methadone produces about the same amount of respiratory depression as does morphine. Methadone has definite antitussive effects, and similar to morphine, it produces hyperglycemia, hypothermia, and a release of anti-diuretic hormone.

In the intact experimental animal, methadone, like morphine, causes an increase in intestinal tone, diminishes the amplitude of contractions, and decreases the propulsive activity of the intestinal tract. In the human, methadone is constipating, but less so than morphine. Methadone causes biliary spasm, and the ureters supposedly become quiescent. The uterus at term is not appreciably affected by usual therapeutic doses. Of course, it must be recognized that in methadone maintenance situations, dosages are usually greater than the usual analgesic doses, and are obviously administered over a much greater period of time than was intended by the manufacturers in their conception of this drug as an analgesic. It should also be recognized that methadone, like other opiates, has

the potential for causing fetal respiratory depression, which could be harmful to the newborn and result in central nervous system damage, and a variety of problems.

Effects of methadone on the cardiovascular system are not striking. The drug is capable of producing peripheral vasodilation; this can contribute to orthostatic hypotension. Except for sinus bradycardia, methadone is not known to interfere with cardiovascular reflexes.

Significant concentrations of methadone can be demonstrated in the plasma within minutes after subcutaneous injection. The drug is also well-absorbed from the gastrointestinal tract. Methadone quickly leaves the blood and localizes in lung, liver, spleen and kidney. A very small fraction of the drug enters the brain. Methadone appears to be firmly bound to tissue protein and the action can best be accounted for by assuming that there probably is a gradual cumulative effect, followed by slow excretion.

Methadone undergoes extensive changes, mainly in the liver. A large proportion of methadone appears in the urine and feces in the form of biotransformation products. Something under ten percent of the drug is excreted as metabolites in the bile.

The side-effects produced by methadone are similar to those of morphine, and include dizziness, drowsiness, mental clouding, pruritis, nausea, sweating, and occasionally vomiting. These side-effects are felt to occur more frequently after oral than after parenteral administration, and more often in ambulatory than in bed patients. It must be remembered, however, that these effects have been described in patients who have had the drug administered for analgesic purposes, on a short-term basis, and not in patients who have had long-term oral maintenance therapy with a significant tolerance having developed. Delirium, transient, hallucinations, and hemorrhagic urticaria have been reported. The primary danger of overdosage is a decrease in pulmonary ventilation.

The abuse-liability of methadone and its congeners has been fairly well assessed. Volunteer post-addicts who received subcutaneous methadone four times a day developed tolerance to the analgesic, anorectic, nauseant, miotic, sedative, respiratory-depressant, and cardiovascular effects of methadone. Tolerance to methadone develops more slowly than to morphine, especially with regard to the depressant effects.

However, this may be related not so much to slow development of tolerance as to the cumulative effects of the drug. Market sedation with concomitant slowing of the electroencephalogram occurs, during the first few days of experimental addiction. There is no tolerance to the constipating effect of methadone. The behavior of the methadone addict has been observed to be strikingly similar to that of the morphine addict.

Development of physical dependence during the chronic administration of methadone can be demonstrated by drug withdrawal or by the administration of nalorphine. Subcutaneous administration of ten to twenty milligrams of methadone in former narcotic addicts produces definite euphoria which persists somewhat longer than that caused by morphine. Many addicts actually *prefer* the effects of methadone to those of the natural alkaloids, according to one authority. Nevertheless, the overall abuse of methadone has been less than that of morphine.

One must note, that unlike morphine, and most of the narcotic analgesics, methadone is quite effective when given orally. This fact may have two-fold significance. On the one hand, it might make it more convenient, less risky, and require less frequent searches for a "fix," but on the other hand it may have no appeal for the particular type of addict who gains a large portion of his pleasure merely from the sensation of veinpuncture.

The abrupt withdrawal of methadone, even after relatively large doses produces a syndrome which, although qualitatively similar to that of morphine, is slower to develop, less intense, and is more prolonged. This could represent an advantage to the methadone addict in contrast to the morphine addict. The withdrawn addict has minimal symptoms until about the third day, and then he may undergo anxiety, weakness, anorexia, insomnia, abdominal discomfort, headache, diaphoresis, and hot and cold flashes. Even when the syndrome is at peak intensity, which may be as late as the sixth day, vomiting and diarrhea are not prominent, and muscular aches and cramps are usually absent. The addict, however, is usually distressed, and purposive behavior is prominent. Generally, symptoms subside gradually, and are minimal by the tenth to the fourteenth day. Anorexia and a feeling of lethargy, however, may persist for longer periods.

Regarding the addiction liability, methadone is felt to produce a mixed euphoria in non-addicted patients. But in addicts and former addicts, a large dose of the drug can produce a euphoria which is equally as intense as that produced by morphine and other potent opiates, and the euphoria may persist for an even longer period of time.

The untoward effects of methadone, such as nausea and vomiting, constipation, dizziness, dryness of the mouth, sweating, and mental depression, are considered to be more severe and more frequent in ambulatory patients than in those who are hospitalized.

With the aforementioned similarities and differences between methadone and other potent, injectable opiates in mind, let us consider the rationale behind its use in the treatment of narcotic addiction. Impending withdrawal symptoms can be avoided by the substitution of varying amounts of oral methadone for the narcotic which was previously taken. Prolonged oral administration of methadone causes the development of tolerance and also produces a physiological cross-tolerance to other opiates, including heroin and morphine. Since withdrawal symptoms are only moderate in intensity and are slower to appear with methadone, the conclusion has been drawn that methadone would be an effective means of minimizing the intensity of the abstinence syndrome resulting from withdrawal of morphine and heroin in addicted individuals.

For the above reasons, methadone has become a drug of choice for the alleviation of the withdrawal pains of newly abstinent heroin addicts. This is a short-term use of the drug which clearly falls within the scope of use for which was originally approved by the Food and Drug Administration. It is also a use which has been approved by the Bureau of Narcotics and Dangerous Drugs, and its predecessor agency, the Bureau of Narcotics, for many years.

More recently, methadone has been employed in an experimental fashion for the purpose of eliminating the heroin-seeking behavior of selected addicts by taking advantage of the phenomenon of cross-tolerance. This is accomplished by the daily administration of large doses of oral methadone for an indefinite period of time. The individual thus maintained becomes dependent upon, and tolerant to the methadone and at the same time, cross-tolerant to the effects of subsequently administered doses of heroin which do not exceed a certain level. It is claimed that a corresponding reduction of the addict's ability to achieve the desired subjective effects of heroin injection also occurs and his heroin-seeking behavior is thus extinguished. The end result is the elimination of the addict's compulsive necessity of participating in the illicit drug traffic and the criminal acts associated with it.

According to this hypothesis, once relieved of the burden of producing illicit drugs, the patient's energies can then be directed toward the development of more constructive pursuits. He is further motivated to this end by careful exploitation of his dependence on the clinic personnel who encourage his use of the rehabilitative services which they make available. In theory, the patient can eventually be brought to a level of maturity and successful adjustment sufficient to permit his final and complete withdrawal from narcotic drug dependence, including dependence on methadone.

Doctors Vincent Dole and Marie Nyswander were early pioneers of this method in the city of New York. They have claimed great success in the alleviation of heroin-seeking behavior among their patients with a corresponding reduction in criminal behavior and increase in productive enterprise, i.e. gainful employment, scholastic achievement, etc. Thus far neither they, nor other physicians conducting similar research have succeeded in withdrawing any significant number of persons from dependence on methadone.

Doctors Dole and Nyswander have discussed at length what they feel is the almost complete ineffectiveness of mere detoxification of the majority of narcotic addicts, even when accompanied by various kinds of attempts at rehabilitation. Achieving a drug-free existence and social and vocational rehabilitation are all desirable, but it must be decided which has priority. Doctors Dole and Nyswander seem to lean heavily on rehabilitation.

Dole and Nyswander published their original description of the methadone maintenance technique in 1965. They have emphasized that their technique is not merely sustaining an addiction, but rather than their goal is the overall rehabilitation of the addict. The administration of methadone is one of the tools used to accomplish this goal. Since the publication of these studies by Dole and Nyswander, many individual practitioners, clinics, and health departments have indicated to the Bureau of Narcotics and Dangerous Drugs their interest in

establishing methadone maintenance rehabilitation programs. Additional impetus has been given these programs in many areas by State and Local officials who envision methadone maintenance programs as a significant contribution to the nationwide effort to reduce crime. It is, therefore, of utmost importance that this developing mode of therapy be subjected to thorough review so that Government may provide stimulus to further responsible research and, at the same time, protect the public health and safety.

III. METHADONE AS A DRUG OF ABUSE

The use of methadone with heroin addicts in a therapeutic setting and the publicity which has surrounded the development of methadone maintenance programs has tended to obscure the fact that it is also a major drug of abuse. When abused, it is normally taken by intravenous injection in the same fashion as heroin or morphine. Recent evidence of the diversion and sale of oral methadone preparations clearly establish that it is also abused in the form in which it is used in maintenance programs. Evidence of such diversion and abuse is as yet uncommon among well-controlled programs such as those visited by the study group. However, Bureau Regional Offices have reported very substantial abuses in New Orleans, Baltimore, Miami and Washington, D.C. in connection with poorly organized ventures. In a recent monthly regional report, methadone was reported to be running a close second to heroin abuse.

In June of 1969, an investigation of several months duration by agents of this Bureau resulted in the arrest of two persons involved in the operation of a clandestine laboratory at Tupelo, Mississippi, for the manufacture of illicit methadone. Ten kilograms of methadone were seized at the time of arrest and evidence was obtained that the drug was being manufactured and shipped for distribution to Eastern metropolitan areas. A similar incident occurred in New York in the late 1950's during which large quantities of illicit methadone were manufactured and sold to addicts who purchased and used it as heroin. Methadone is also commonly involved in drug store burglaries and doctor's bag thefts.

Because the drug is abused more or less interchangeably with other narcotic drugs, private physicians are often approached with requests for methadone prescriptions. In some cases these requests have led to the establishment of so-called methadone programs which consist of nothing more than centers for the distribution of narcotic drugs to addicts with resulting abuses, diversions, and unverified reports of death by overdose. Such centers are known to have been operated in New Orleans, Miami, Washington, D.C. and possibly elsewhere. In one such case, a combination of Federal and local pressure became necessary in order to safeguard the community's welfare.

The central fact which emerges is that methadone as a drug has erroneously been touted as a panacea for heroin addiction. In many cases, this misunderstanding has been perpetuated by otherwise competent and responsible researchers. This is so in spite of the fact that all major researchers in this field are quite specific in their insistence that methadone is merely one of several necessary elements within a successful program. Administration of the drug alone will not, in the great bulk of cases, result in the addict's return to a useful and law abiding social adjustment. Indeed, it has been found in some cases that an addict may seek to utilize participation in a program as a means of reducing his illicit drug costs and as an umbrella to exacerate his criminal activity. In this connection it must be remembered that the majority of heroin addicts appear to have become involved in criminal activity prior to their heroin addiction.

IV. PROPOSED STATEMENT OF POLICY

The following are proposed statements of policy which the Study Group recommends that the Bureau should issue in conjunction with its proposed regulations and guidelines for the operation of methadone maintenance programs. Essentially, these statements are designed to set forth the present judgments of the Bureau with regard to the nature of this activity.

Policy statement A generally endorses the need for research in the area of the treatment of narcotic drug addiction.

Policy statement B makes clear that methadone maintenance programs, as a form of research, will be encouraged within the framework of proper controls. It also makes clear that such programs are regarded as research only and not treatment, and that their ultimate goal should be to cure the addict of his dependence on narcotic drugs of any type.

Policy statement C is designed to evidence the Bureau's willingness to cooperate with persons conducting such research and to make clear that no special legal immunities should be given to methadone patients merely because of their participation in a program. Other law enforcement agencies are requested to adopt a similar policy. This is regarded as desirable in view of the occasional reports that local police have extended special consideration to such patients in the past. Such a practice could tend to mask the continued criminal involvement of some methadone patients.

Policy statement D sets forth the necessity of engaging in audits of records required to be kept pursuant to the operation of methadone programs and it serves to further dispel doubts as to the purposes for which such audits are to be conducted. Finally, all concerned agencies are requested to aid in supplying and collecting relevant data concerning the impact of such programs on their community.

The Bureau of Narcotics and Dangerous Drugs should issue a comprehensive statement detailing the Government's policy with regard to the initiation and operation of narcotic maintenance programs. This should include the following assertions:

A. The Bureau of Narcotics and Dangerous Drugs recognizes the necessity for the exploration and development of new therapeutic techniques in the treatment of narcotic drug dependence.

B. The Bureau of Narcotics and Dangerous Drugs recognizes that research in the development of methadone maintenance therapy in which methadone, a synthetic narcotic drug, is administered to narcotic drug dependent persons in combination with other intensive rehabilitative therapy has indicated promise in the rehabilitation and management of certain narcotic drug dependent persons and should be further pursued within the framework of responsible controls designed to protect the public health and safety and to develop scientific data which will enable eventual medical determination of the efficacy of such programs in returning the narcotic drug dependent person to a useful drug-free life within the community.

C. It is the intention of the Bureau of Narcotics and Dangerous Drugs to adopt a policy of cooperation with those practitioners engaged in bona fide research in the field of methadone maintenance and to aid such practitioners, or their administrative representatives, by supplying such assistance, advice, and information as its authority and resources will permit upon request. Such cooperation will in no way extend to the granting of special privileges or immunities to patients of such programs who may be arrested for the commission of crimes or who may become the subject of a criminal investigation. The Bureau of Narcotics and Dangerous Drugs further calls upon all Federal, State, and local police authorities to adopt a similar policy.

D. The Bureau of Narcotics and Dangerous Drugs recognizes that responsible decisions in the exercise of Governmental regulatory powers concerning the use of narcotic drugs must be based upon known and ascertainable medical and scientific knowledge. It is, therefore, necessary that this Bureau and other concerned Federal agencies engage in appropriate record checking, recordkeeping and data collecting activities to insure compliance with existing regulations and to form a basis for required future alternations. To further insure the integrity of the operation of narcotic drug maintenance programs, it is the policy of this Bureau that information collected in the exercise of its regulatory powers will not be used for the purpose of investigating persons who participate as patients in such programs. This Bureau further calls upon all Federal, State, and local agencies which are concerned with the problems of crime and narcotic drug dependence to cooperate with it in terms of collecting relevant data; of making such data available to the scientific community, and in submitting their views and opinions concerning the impact of such programs on the problems of crime and drug abuse within their communities.

V. PROPOSED REGULATIONS

The following are proposed regulations for the control of narcotic drug maintenance research submitted by the study group. If these proposals are found to be acceptable, it will only be necessary to rephrase them in appropriate mandatory language. It is further desirable that both the Food and Drug Administration and the National Institute of Mental Health be apprised of the Bureau's intentions and issue such policy statements and additional regulations as may

be necessary. The study group feels that it would be of considerable benefit if, in addition to traditional techniques of law enforcement, a provision for injunction could be designed to enforce compliance with the regulations. Such an injunction procedure could perhaps be designed within the framework of Section 705 of the Controlled Dangerous Substances Act and utilized in those cases in which a criminal prosecution is not desired. Should it become necessary to curtail the practices or operation of any particular narcotic maintenance program, some delay would be required in order to withdraw its patients or place them within another facility.

The prescribing, dispensing and administering of narcotic drugs to persons for the purpose of maintaining their dependence upon such drugs or for the purpose of gratifying their appetite for such drugs should be recognized as permissible within the scope of professional practice in either treatment or research. Practitioners should be permitted to prescribe, dispense or administer narcotic drugs to persons dependent on such drugs:

(A) In the course of professional treatment for illness or infirmity other than dependence on narcotic drugs.

(B) Pursuant to the withdrawal of a patient from his status or narcotic dependency.

(C) Pursuant to the making of final arrangements for the commitment of such narcotic dependent person to a suitable facility for withdrawal from his status or narcotic dependency.

(D) Following a determination by the practitioner that withdrawal of such patient from the status of narcotic dependency would endanger the patient's life.

(E) Pursuant to the operation of a narcotic drug maintenance program conducted in compliance with appropriate Federal regulations following approval of the practitioner's application for registration to engage in such a program in accordance with the appropriate Federal regulations.

In setting forth the Bureau's proposed regulations with regard to the conditions under which the administering and dispensing of narcotic drugs to addicts by virtue of their participation in a methadone maintenance program may be permitted, it may be first desirable to delineate the perimeter within which a practitioner may prescribe, dispense or administer to such persons. The proposed regulation is designed to take into account those areas of permissible practice which are already recognized under the present Bureau regulations and guidelines contained in Pamphlet Number 56 and, in addition, to set forth the new basis on which such practices may be undertaken pursuant to the operation of a bona fide narcotic drug maintenance program.

A special registration should be required of practitioners who wish to administer or dispense narcotic drugs to narcotic drug dependent persons participating in a narcotic drug maintenance program. Such registration should be made contingent upon the submission of evidence of qualification under State law and of a protocol setting forth the manner in which the program is, or will be structured to comply with applicable Federal regulations.

A special certificate of exemption should be required of officials of the United States, the District of Columbia, any State, Territory, or insular possession of the United States, or any county, municipality, or other political subdivision who wish to administer or dispense narcotic drugs to narcotic drug dependent persons participating in a narcotic drug maintenance program. Such exemption should be made contingent upon the submission of a certification by a superior official stating that the official is required by his duties to engage in such activity, and the submission of a protocol setting forth the manner in which the program is or will be structured to comply with applicable Federal regulations.

To insure compliance with the Bureau's proposed regulations for the use of methadone maintenance research therapy, it is necessary that physicians seeking to engage in such activity be required to register for that specific purpose. This will insure that the Bureau is informed of the existence and location of each such program. Moreover, the special registration can be used as the vehicle to insure that provision is made for compliance with Federal regulations. It is envisioned that the application for registration would be accompanied by a protocol describing the nature and goals of each program. Should the program design be considered defective in any particular, the applicant can be so informed and permitted to file an amended protocol. Those physicians seeking to participate in an existing program may be permitted merely to refer to the previously approved protocol. Thereafter, a renewal of registration would be required each

year and would be accompanied by information related to any substantive changes in the previously approved protocol.

The proposed registration requirement could be brought within the framework of the present Class VI registration for the purposes of engaging in research with narcotic drugs. A similar method could be incorporated within the structure of the Controlled Dangerous Substances Act following its passage. This would seem to be entirely appropriate in view of the current medical opinions that maintenance therapy should be regarded as research and not practice. However, this approach is subject to at least two important criticisms. The problems which are inherent within the operation of maintenance programs are essentially independent of their classification as research or treatment. It is, therefore, misleading to imply that the regulatory requirements imposed are predicated solely upon a judgment of this nature. Secondly, many of the practitioners currently involved in the operation of methadone maintenance programs feel that the technique has been perfected to the point that it should be regarded as accepted medical practice. Such persons might take the position that regulations designed to govern research activity are without application to their own treatment activity. Thus, a potential series of arguments and conflicts can be avoided by basing the registration requirement on the particular nature of such programs without reference to their status as treatment or research.

Under present Federal narcotic laws, Federal, State and local officials who are required by their duties to administer or dispense narcotic drugs are exempt from registration and instead are required to file an application for a certificate of exemption. A similar procedure has been incorporated within the proposed regulation to insure that programs initiated, or participated in, by such officials will also accord with Bureau regulations. It may be desirable to continue such exemptions following enactment of the Controlled Dangerous Substances Act in which case this section would still be needed.

Narcotic drugs should be administered or dispensed to a person who wishes to participate in a maintenance program only after it has been established that he, (1) has given an informed and voluntary consent to participation in such program, (2) is currently physically dependent on the use of narcotic drugs, and (3) has a documented history of at least one previous withdrawal treatment failure.

One of the dangers inherent in the operation of methadone maintenance programs is that persons who are only peripherally involved in the use of narcotic drugs may seek to enter such programs either out of a mistaken notion of their nature or as a means of obtaining an inexpensive source of high quality drugs. To insure against such abuses, the Bureau should enact regulations requiring a thorough screening of applicants. Since participation involves subjecting the individual to a severe level of physical dependence on narcotic drugs, the project directors should be required to obtain the informed consent of the applicant in writing. In the case of persons who have not attained majority, such a consent should be required from the applicant's legal guardian.

The regulations should also require a determination based on oral and physical examination and the development of the applicant's history, that he is presently dependent on the use of narcotic drugs. This proposal is based on the judgment that only persons who are already drug dependent should be permitted to participate in a program which entails the maintenance of a severe narcotic dependency. All programs examined presently employ methods of making such a determination. It has been suggested, however, that persons with a history of addiction should be admitted into maintenance programs even though not dependent on narcotic drugs at the time of application. This suggestion has been made with particular reference to individuals with histories of narcotic addiction newly released from prison or confinement. In such cases, it is believed that they will relapse to the use of narcotic drugs in any event, and may as well be accepted into a program prior to relapse. This contention has a certain amount of statistical support. However, in view of the possibility that at least some of these persons may abstain from drug use, it is suggested that program directors be required to establish a current narcotic dependency prior to admission.

At the present time, methadone maintenance therapy is viewed as a research modality which should only be employed with persons who have not otherwise responded to treatment. This view would seem prudent not only because of the research nature of the undertaking but also because of the level of addiction to which the individual is subjected in their operation. To insure that only such persons are accepted for participation, the regulations should require that the

project directors determine that an applicant has failed to benefit from withdrawal treatment on at least one occasion prior to his application.

Of the programs examined only two, the Mental Health Center in New Haven and the Narcotic Addiction Foundation in Vancouver, currently insist upon such a determination. According to the literature, the Dole-Nyswander program in New York also insisted upon this determination until recently.

Those project directors who do not employ this criterion are of the view that conventional withdrawal treatment is such a failure that it is pointless to insist upon a demonstration of previous treatment failure prior to admission. However, in view of the fact that a significant percentage of addicts do benefit from such treatment and that this form of treatment is now being combined with extensive periods of aftercare as provided for in the Narcotic Addict Rehabilitation Act of 1966 and similar State Statutes, it is recommended that a demonstration of at least one previous treatment failure be required.

Practitioners should be permitted to dispense or administer narcotic drugs to persons participating in a narcotic drug maintenance program only in an oral solution or form which renders the drug unsuitable for self-injection and prepared in such a fashion as to render the processing of the drug for purposes of self-injection impractical.

The claimed efficacy of narcotic drug maintenance as a treatment and rehabilitation modality is believed to be closely bound up with the particular pharmacological properties of methadone hydrochloride. These are principally its ability to produce cross-tolerance to other narcotic drugs, the relative length of its physiological activity, and its potency in oral dosage forms. In addition, a very limited amount of maintenance research has been conducted utilizing cyclazocine, a presently uncontrolled drug. The use of an oral dosage form is necessary in order to wean the addict patient of the habit of needle injection so closely associated with the use of heroin. Oral consumption is also believed to eliminate the "suphoric flesh" associated with narcotic drug injection. Finally, the preparation of the drug in a suitable suspension vehicle from which it cannot be readily separated renders it less desirable to the street addict and less subject to abuse by the patient. The use of oral preparations, therefore, re-enforces the program's therapeutic goals and decreases the probability of diversion of the drug into illicit channels.

All programs examined insisted upon the use of oral methadone preparations with their patients. It seems entirely proper to conclude that orally administered methadone is the only form of narcotic drug which currently has a bona fide use in maintenance research. However, in view of the rapid developments in the science of pharmacology, we must envision the possibility of the synthesis of other narcotic drugs which might possess characteristics superior to those of methadone. In addition, there is a possibility of the development of so-called "reservoir" or "depot-type" drug vehicles which would enable periodic administration or implantation as a substitute for present techniques. For these reasons, the suggested regulation has not been framed so specifically as to require the use of oral methadone only. However, it does accomplish the principle objective of insuring that injectable preparations are not employed, or made available to patients. The guidelines which accompany the regulations will explain that oral methadone is the only drug form currently in use.

Practitioners should be permitted to administer narcotic drugs to narcotic drug dependent persons participating in a narcotic maintenance program for supervised consumption on premises under the practitioner's control, and should further be permitted to:

(A) Dispense an amount of narcotic drug equivalent to a two-day supply for self-administration to those patients who have evidenced their ability to function within the program, and

(B) Dispense an amount of narcotic drug, for self-administration, sufficient for the duration of any verified personal illness, family crisis, necessary travel, vacation or holiday, or such as may be necessary in exceptional cases where special hardship would be occasioned by requiring clinic visitation with customary frequency.

The use of narcotic drugs in maintenance programs provides new sources of high quality narcotic drugs to a segment of the addict population. One of the greatest dangers to society from the operation of such programs is the possibility of the diversion of these drugs into illicit channels for use by other addicts or non-addict experimenters. Such diversions could serve to maintain the existing illicit traffic or to introduce new persons into the addict's subculture. It is, therefore, of primary importance to examine this facet closely.

In the maintenance programs which have been observed, new addicts are uniformly required to report each day to a clinic facility for receipt and consumption of their daily narcotic maintenance doses. Safeguarding the drugs from diversion in this stage requires only that adequate security be maintained over stocks and that consumption be supervised. However, after initial phases of treatment, a more liberal policy is adopted in terms of supplying the patient with his daily dosage. Practices differ among observed programs but in New York and Vancouver certain patients are required to visit the clinic facility only once a week at which time they consume a daily dose and receive doses for consumption during the next six days. Other addicts may be required to attend the clinic facility as often as three to five times a week and all programs intend to extend weekend carrying privileges to patients who are progressing satisfactorily.

The practice of granting carrying privileges to patients involved in such programs determines the extent to which diversions may occur. Our examination of major programs did not disclose the existence of any significant problems in this area. However, there are reported cases of patients selling their oral methadone medication. This was admitted by the Methadone Maintenance Evaluation Committee in New York which believed the street value of one maintenance dose of methadone to be approximately \$18. The Vancouver program directors and Vancouver police authorities also agreed that some sales of oral methadone had occurred but had not constituted a significant problem.

In seeking to determine the possibility of such diversion becoming significant, it is necessary to consider the state of affairs which might arise with the continued growth of maintenance programs. Moreover, there are indications that the incidence of diversion may be higher than our review of programs would suggest. In undertaking our study, we were careful to select only the most expertly organized programs for review. We do have reports from officers in the field that a number of other programs are being operated in a much looser fashion and that significant diversions may have occurred. At this time it is impossible to empirically establish the amount of diversion taking place. Such information would probably serve as a poor guide for action in any case.

There are two conflicting considerations to be balanced in determining the wisdom of permitting carrying privileges. The project directors explain that such privileges must be extended to patients to minimize the degree of inconvenience which participation in the program entails. There is unanimous agreement that such privileges should only be extended to patients who appear to be making a successful adjustment. A further argument is that long-term patients should be permitted this privilege in order to minimize their formal contacts with the clinic and the addict population which it serves. It is felt that patients who have made successful social adjustments should not be brought into constant contact with newer patients who are still members of the addict subculture. The question to be answered is whether these advantages are of such importance as to offset the risks of diversion which arise from the granting of carrying privileges.

An examination of the recent history of the narcotic addiction problem in Great Britain leads us to believe that the dangers of diversion are very great. Dr. Glatt has reported that most of the new addicts in Great Britain first obtained their initial doses from addicts who had lawful prescriptions for narcotic drugs. The practice of selling a portion of these lawfully obtained drugs is believed to be directly responsible for the tremendous increases in narcotic addiction in that country. In his letter of March 10, 1969, to the Director of the Bureau of Narcotics and Dangerous Drugs, Mr. Peter Beedle of the British Home Office stated that, "in order to guarantee that there will be no diversion of the drug into illicit channels, it is clearly essential that it should be administered to the addict not supplied to him for self-administration." He also noted that there is evidence of increasing addiction to methadone in Great Britain. At this time, the privilege of prescribing narcotic drugs for addicts in Great Britain has been limited to certain clinic facilities and certain specially licensed practitioners who provided the patient with a prescription on a daily basis.

The directors of all methadone programs examined were in agreement that some limitation must be imposed on the quantity of drug which any patient may be given for self-administration. In attempting to determine the proper limit, it is necessary to balance the very real danger of diversion against the degree of inconvenience which it is desirable to impose on the patient. In terms of his former life style, almost any legal access to narcotic drugs imposes insignificant inconvenience. It does not, therefore, seem unreasonable to require frequent visits to a clinic facility for the purpose of obtaining a medication. New patients

should be required to visit a facility each day for the consumption of medication. Patients who continue to demonstrate an improved adjustment should be granted the privilege of receiving not more than a two-days supply of medication for self-administration with proper allowances for illness, family crisis, necessary travel, or vacation. If the project directors are concerned with minimizing the contact of successful patients with new patients, a special facility can be employed for this purpose. The possibilities of diversion under such a regime would most probably be negligible.

Practitioners should be permitted to dispense or administer narcotic drugs to persons participating in a narcotic drug maintenance program only upon condition that a randomly selected urine specimen voided under the supervision of an attendant be collected and analyzed at least once weekly for the purpose of determining the patient's abstinence from the use of other controlled substances. In addition, other appropriate procedures should be utilized for determining the patient's progress in achieving an improved individual and social adjustment.

One of the principal benefits which is believed to result from the use of narcotic maintenance therapy is the improvement of the addict's individual and social adjustment, and particularly his abstinence from participation in the illicit drug traffic and the criminal activity associated with it. In order to verify the patient's progress in achieving this goal, it is necessary to employ appropriate monitoring procedures which will provide evidence of his improvement. There are a number of techniques which may be utilized to this end such as the collection of pay-check stubs and the development of information from the patient's family and acquaintances. To date, the most reliable of these is the frequent collection of a supervised urine specimen for the purpose of analyzing its content for traces of drugs other than those prescribed. This will provide the project director with an index of the patient's improvement, and also with evidence of whether the patient is using the methadone dispensed to him or diverting it into illicit channels. Moreover, the patient's knowledge that his behavior can be monitored in this fashion is in itself a deterrent to misconduct and diversion. All of the programs examined were collecting and analyzing urine specimens with the exception of the program in St. Louis which was collecting specimens but had not yet succeeded in setting up a system of analysis. All project directors were of the view that frequent urine analysis was an indispensable technique of a bona fide narcotic maintenance program.

The proposed regulation is designed to require the taking of a supervised urine specimen. The word "supervision" is used to convey the notion that the specimen should be voided in the presence of an attendant. It would seem prudent at this time to permit project directors flexibility in devising suitable supervision. The proposed Bureau guidelines should suggest efficient possibilities. The regulation is also designed to require that the urine specimen be examined for the presence of other controlled substances. This requirement is intended to convey the notion that the urine specimen is to be analyzed at least for the presence of methadone, heroin residuals (morphine), cocaine, amphetamine and barbiturates, the principal drugs of abuse. It seems prudent at this point to leave the precise determination of the drugs to be included in this analysis within the discretion of the project director since local patterns of abuse may differ. This matter should also be the subject of recommendations in the Bureau's guidelines and specific approval at the time of submission of an application and protocol. The extent to which various drugs can be detected in the urine is largely governed by economic and technological factors which are subject to rapid change. Some flexibility must, therefore, be preserved at the present time.

Practitioners should only be permitted to administer or dispense narcotic drugs to narcotic drug dependent persons for the purpose of maintaining their dependence upon such drugs incident to their participation in an organized program which incorporates other facets of treatment and rehabilitation including medical care, vocational counseling, and individual and social therapy in accordance with the patient's individual needs.

It is universally conceded by knowledgeable authorities that the use of methadone in maintaining a subject's narcotic dependence is merely one element of a bona fide narcotic maintenance program. Maintaining the subject on daily doses of methadone serves to bind him to the program so that other rehabilitative techniques may be applied. Therefore, if the program is to succeed in bringing about substantial improvement in the addict's individual and social adaptation,

it must take advantage of the bond thus created through the use of methadone by utilizing other vocational and rehabilitative techniques. These techniques consist of supplying individual and social therapy, medical attention and job training and placement. All of the programs examined employed these elements extensively and maintained a competent professional staff for such purposes.

Practitioners should be permitted to administer or dispense narcotic drugs to persons participating in a narcotic maintenance program upon the condition that such persons be withdrawn from narcotic drug dependency as soon as may be medically and psychiatrically possible within the practitioner's sound medical judgment or at such times as it becomes clear that the patient is not favorably responding to participation in the program.

Withdrawal from narcotic drug dependency has always been viewed as the ultimate goal in the treatment and rehabilitation of the narcotic addict. The proposed regulation seeks to make clear that achieving the patient's successful withdrawal still remains the ultimate responsibility of the practitioner and that maintenance is only justifiable for the length of time necessary to effect the patient's rehabilitation, or to determine that his rehabilitation cannot be affected through this technique. Because of the variable responses of individual patients and the differing problems with which staff personnel must deal, it does not seem prudent at this time to prescribe some maximum period for which a participant may be maintained. Moreover, it may be found that some persons of long-standing addiction can never be successfully withdrawn.

The medical profession has always recognized that exceptionally severe cases of long-standing narcotic addiction may require permanent maintenance. The former Bureau of Narcotics adopted this view in concluding that the maintenance of an addict's status of dependency was legally permissible in those cases in which withdrawal would result in endangering the patient's life. Should maintenance programs prove successful in achieving the greatly improved social adjustments which are claimed, it may become desirable to expand upon the exceptions presently permitted to the extent of recognizing the indefinite maintenance of narcotic dependent persons in those cases in which withdrawal cannot be accomplished without appreciable injury to the patient's welfare in terms of his individual and social adjustment.

Practitioners who administer or dispense narcotic drugs to narcotic drug dependent persons participating in a narcotic drug maintenance program should be required to maintain adequate records which include the patient's identity, medical and social history, consent to participation, drug dosages administered and dispensed, results of urine analysis and evidence of progress within the program. This information should be open to inspection, and made available to appropriate government agencies which should provide by policy or regulations that such information will not be used as a basis for the investigation, prosecution or harassment of patients participating in such programs.

This proposed regulation is the natural concomitant of those which have previously been set forth. It is necessary that directors of maintenance programs maintain such records in order to evidence their compliance with substantive regulatory requirements. In addition, any commission or committee which may be established for the purpose of evaluating the overall efficacy of maintenance programs, must have this information readily available to it. Two major objections to this proposal may be envisioned. The first will undoubtedly be based upon the asserted need for confidentiality of the identity and progress of participating patients in order to give them assurance that such participation will not lead to harassment by police authorities.

In view of the experiences of the programs observed in New Orleans and in Vancouver, this kind of assurance to the patients is unnecessary. In both of these programs, the names of all new applicants are submitted with their knowledge to local police authorities for a report and record check. The project directors both report that knowledge of this practice has in no way reduced the size of their waiting lists. In order to provide some measure of such assurances, however, it is suggested that this matter be further clarified through regulation or statement of policy.

Finally, imposition of such record keeping requirements will probably be regarded as an unwelcome burden on the program staff and resources. This objection is deserving of no greater weight than usual.

Practitioners who wish to administer or dispense narcotic drugs in the course of bona fide research in a manner which may not accord with Federal narcotic regulations in some particular should be permitted to request the Attor-

ney General or his delegate, in writing, for a waiver of such specific regulatory requirement. In exceptional cases, such a waiver should be granted after review and comment by the Secretary of the Department of Health, Education, and Welfare and a finding that the proposed research would not endanger the health and safety of the research subjects or the public and would otherwise accord with Federal narcotic laws.

The regulatory scheme which the Study Group has recommended is designed primarily to deal with relatively large scale research programs of a more or less permanent nature. It is recognized that this scheme may prove too rigid for certain otherwise valuable and bona fide research efforts involving small numbers of subjects for short periods of time. The above regulation has been designed to provide a mechanism which will permit such research in exceptional cases.

There should be established a permanent governmental committee for the purpose of collecting and disseminating data derived from the operation of narcotic drug maintenance programs and other relevant sources. This committee should undertake a continuing evaluation of the efficacy of such programs and the effect of their operation upon existing patterns of crime and drug abuse within society. The committee should be composed of representatives of the Bureau of Narcotics and Dangerous Drugs, the Food and Drug Administration, and the National Institute of Mental Health. The committee should be vested with the authority to receive opinion and data from all relevant government agencies including extensive data from each maintenance program, either directly or indirectly.

Methadone maintenance research programs appear to have offered some promise in the management of narcotic addicts and the improvement of their social adjustment. Thus far they have offered little promise in actually curing narcotic drug dependence. None of the directors of programs visited have claimed any appreciable success in actually withdrawing patients and producing a drug-free pattern of adjustment. Some of these researchers emphatically believe this goal to be attainable while others candidly admit that this aim is secondary and may be altogether unattainable. In any case, the number of programs continue to proliferate and the number of persons involved in them to multiply. We are witnessing, in essence, the creation of more or less permanent clinical bureaucracies based on the dispensing of methadone, and not the more execution of transitory experiments. Their success or failure depends on both the correctness of the theoretical postulates on which they are based and the degree of skill with which they are conducted.

The operation of methadone maintenance programs is a complex and expensive endeavor of uncertain outcome. At this time, their effect on the patients involved, on the illicit drug traffic, and on society at large cannot be determined. Although we must recognize some degree of promise in their initial achievements, many important questions remain unanswered. We do not know when or what percentage of the patients involved will be successfully withdrawn from narcotic dependence. The effects of protracted maintenance on high doses of methadone are unknown nor is it clear to what degree normal mental and physical processes are immediately impaired, if at all. The manner in which the illicit drug traffic is affected remains equally unclear. In this context it must be remembered that the use of methadone does not, of itself, deter the abuse of the other illicit non-narcotic drugs. It is possible to imagine methadone patients turning their efforts to the acquisition and use of other drugs such as cocaine, amphetamine or barbiturates. Also, it is believed that a sufficient dose of heroin or morphine can overcome the methadone blockade. It is, therefore, theoretically possible that the cost of a patient's illicit narcotic habit could be driven up rather than eliminated.

Finally, we do not know how the operation of such programs on an extensive scale will affect the general incidence of drug dependence within the national population. They may conceivably help to accomplish the isolation of the narcotic addict and the fragmentation of his subculture or, alternatively, serve simply as vehicles of permanent and severe dependency into which young persons of uncertain addiction are introduced. Will they prove merely to be inexpensive sources of drug supply which the abuser can manipulate to his own whims? Moreover, will the existence of such programs appear to sanction narcotic drug dependence and eliminate important social deterrents to experimentation? Do they in fact represent attempts to change our basic mores concerning drug use, or are they bona fide efforts to find a cure for addiction? These are the serious questions to which answers must eventually be obtained.

Because of the issues presented, it is absolutely necessary that programs be required to incorporate sound monitoring procedures by which their efficacy may

be determined. Urinalysis testing is absolutely essential to insure that the patient has ceased to participate in the illicit drug traffic. It is equally necessary to provide adequate techniques for determining his employment status and lack of subsequent involvement in criminal activity. If the programs are unable to demonstrate marked improvement in these three areas, there is little basis for their justification.

The programs examined employed varying procedures for the determination of these behavioral improvements. The strongest area of verification was in the employment of urinalysis testing. In this case the soundness of the procedure depends upon the frequency of specimen collection and testing, the procedures for insuring that the specimen belongs to the subject, and the kinds of drugs for which it is analyzed. It appears that such testing may not be a reliable indicator if the patient is not required to void the specimen in the presence of an attendant. Greater deficiencies exist in the verification of employment and lack of continuing criminal involvement. It would appear impossible for the program directors to determine a lack of criminal involvement without the benefit of constant working liaison with local police authorities. We found this type of liaison to exist in only one program; that of Doctors Bloom and Sudderth in New Orleans. Other project directors evidence a negative attitude with regard to such liaison.

The incorporation of sound monitoring procedures can be assured in some degree by the enactment of appropriate regulations as recommended in the study group's report. These recommendations have of necessity been overgeneralized in certain particulars in order to permit flexibility and to take into account the plastic state of the art. Certain aspects are intrinsically difficult to regulate such as the criteria for the selection of patients. At the present time, there is no scientific way to determine the degree or extent of an applicant's addiction. In any case the monitoring procedures employed within a program cannot be adequate for the determination of the important questions previously presented. Many of the factors to be determined such as the impact of the program on the total society are beyond the scope of the project director's interest. Moreover, they lack availability to all of the pertinent sources of information needed for such larger determinations. There is, therefore, a need to establish a national commission or committee within the Federal Government for the purpose of collecting data from all relevant sources so that these determinations may be made. Because of the breadth of the issues involved, it would appear that no single Government agency has the expertise or can marshal the resources necessary to effectively perform this evaluation. Therefore, the better approach would seem to be the formation of an inter-agency committee composed of representatives of all concerned agencies with direct access to the skills of each participating agency and the information collected by it.

The committee should receive a continuous flow of data from the operation of methadone programs. At a minimum, this must include the names and addresses of all patients together with race, age and sex determinations, the results of urine testing and verifications of employment and the subsequent incident of anti-social behavior. This information would be further correlated on a continuous basis with information derived from other official sources such as national, State, and local health and police authorities. The committee could perhaps be given the power to conduct, or instigate, on-site investigations of various programs for the purpose of checking the reliability of the incoming data. Finally, the committee should also serve as a clearing house for information to be supplied to researchers and Government officials upon request. This could be effectively used to guard against the possibility of a single patient participating in more than one program. The committee should state or make clear by regulation that information which it receives will not be made available for the purpose of prosecuting or arresting persons who become patients in such programs.

VI. PROPOSED GUIDELINES

The following is a tentative suggestion for proposed guidelines which are designed to aid the practitioner in organizing a methadone maintenance research program which will comply with Federal regulations. The guidelines are considerably more specific than the proposed regulations and have been formulated primarily on the basis of the best existing research practices and not on the basis of the most desirable legal requirements. These guidelines are intended to be advisory only and the researcher will be permitted to adopt his

own practices so long as they do not conflict with the basic regulatory requirements. We can expect that most researchers will in fact adopt and abide by the proposed guidelines. It therefore serves as an instrument for insuring uniformity in bringing about the use of the most desirable practices and, at the same time, preserves a maximum of flexibility. As time permits, it may be desirable to expand them to include recommended patient-staff ratios, dosage levels, patient-facility ratios, record keeping forms, consent forms, data on program design and organization, available urine tests, and the like. The guidelines, of course, can be modified without the necessity of hearings, publications or legal action.

OFFICIAL GUIDELINES FOR THE CONDUCT OF METHADONE MAINTENANCE RESEARCH
UNDER FEDERAL NARCOTIC LAWS AND REGULATIONS

It is the policy of the Bureau of Narcotics and Dangerous Drugs to encourage responsible research in the development of new approaches to the treatment of narcotic drug dependent persons. One such approach which is currently receiving the attention of some medical researchers is the development of experimental "Methadone Maintenance Research Programs" in which the synthetic narcotic drug methadone is administered and dispensed to narcotic drug addicts in oral doses sufficient to create and maintain a high level of tolerance and dependency. Normally, the supplying of narcotic drugs to persons for the purpose of maintaining their state of narcotic dependency or to satisfy their desire or appetite for such drugs is contrary to Federal law. However, special exception has been made for the conduct of maintenance research in which drugs are supplied in a therapeutically controlled regime within the context of a comprehensive program of rehabilitation aimed at returning the narcotic drug dependent to a rewarding and socially acceptable drug-free life within the community.

Research of this nature is predicated on a number of as yet unproven assumptions concerning narcotic drug dependence and the anti-social behavior which so frequently accompanies it. The achievement of the ultimate therapeutic goals rests upon the correctness of these assumptions and also upon the organization and skill with which program resources are applied. The execution of such research requires a considerable degree of specialized knowledge in the handling and treatment of narcotic addicts and the focusing and structuring of a number of inter-disciplinary skills and services. Practitioners who are interested in initiating or participating in such programs should consult the increasing body of technical literature which is available regarding the subject.

Because of the dangers of diversion and misapplication of narcotic drugs inherent within such research, the Bureau of Narcotics and Dangerous Drugs has enacted appropriate regulations to govern and facilitate this activity and to guide the practitioner in the discharge of his duties under Federal law. These regulations, a copy of which is attached, should be studied in detail by the interested practitioner and the following guidelines have further been provided as an aid in understanding and meeting their requirements. The interested practitioner should also become thoroughly familiar with the applicable laws and regulations of the Federal Food and Drug Administration which require the filing of an Investigational New Drug Application.

REGISTRATION AND SUBMISSION OF PROTOCOL

Federal regulations require that all practitioners who wish to dispense or administer drugs pursuant to the operation of a methadone maintenance program must submit a special application for registration. This application must be accompanied by a research protocol setting forth the manner in which substantive Federal regulations governing this area will be complied with. It is envisioned that a single detailed protocol will be submitted with regard to each individual research program. Where two or more practitioners are engaged in initiating the same program, the application of each may incorporate by reference the single protocol submitted. In those cases in which a practitioner is joining an existing program, he may incorporate by reference the previously submitted protocol concerning that program.

The research protocol will promptly be referred to the Bureau's Methadone Maintenance Research Protocol Evaluation Committee which will determine its adequacy in terms of complying with Federal regulations. The committee will draw upon such sources of medical, scientific and legal expertise as are necessary

for this determination. If it should be found that the protocol is insufficient in some particular, the applicant will be notified accordingly and given an opportunity to submit an amended protocol. The Bureau will also provide consultation and advice regarding the manner in which such deficiencies may be cured. Upon approval of a final protocol, the applicant will be registered and may commence his activities.

A new registration is required on or before July 1, of each year. The application for renewal must be accompanied by a copy of the previously approved protocol or an amended protocol if substantial organizational changes are envisioned. In the event that changes are envisioned or have been made, the Bureau's Methadone Maintenance Research Protocol Evaluation Committee will make a determination as to their sufficiency in complying with Federal regulations. Until such determination is made, the practitioner may continue the mode of operation which he is currently following.

The submission of a protocol does not of itself evidence compliance with the Bureau's regulations; however, it does provide a mechanism to insure the initial legal sufficiency of the proposed research project. It should primarily include an explanation of the intended organization and function of the program and the manner in which the applicable regulatory requirements will be

ADMISSION CRITERIA

Federal regulations place certain restrictions on the selection of persons who may be permitted to participate in methadone maintenance research as patients. The practitioner must first obtain an informed and voluntary consent from the prospective patient. In order to meet this requirement, the practitioner or his agent should carefully explain that the applicant will be required to submit to a regime which involves the continuous consumption of the narcotic drug methadone and that this will result in the development of a physical dependency similar to that produced by any other narcotic drug. Moreover, the applicant should be advised that his level of dependency may be of greater severity than that to which he currently is subjected and that such dependency will be of uncertain duration. He should further be informed that the effects of the continuous consumption of methadone have not been determined. After having so informed the applicant, his voluntary consent should be obtained, preferably in a signed statement. If the individual has not reached majority, the consent must be obtained from his lawful guardian.

Since participation in a maintenance program involves a substitute form of addiction which may in fact create physical dependency beyond that to which the patient was formerly subjected, Federal regulation requires a clear determination of a present status of physical dependency on narcotic drugs. This can only be accomplished by utilizing several techniques. These should include: (1) a physical examination of the applicant for the presence of needle marks, scars, "tracks" and other physical symptoms; (2) an oral history concerning the applicant's length and nature of narcotic drug abuse; and (3) some verification of his history by reference to official records, police reports, neighborhood acquaintances, and hospital and medical records. Protracted clinical observation, temporary in-patient treatment, or use of narcotic antagonists such as nalormorphine, may also be of substantial value in establishing dependence.

The regulations also require that the practitioner or his agent take pains to document at least one previous withdrawal treatment failure in the applicant's history of drug use. This is a further precaution designed to insure that persons of uncertain severity of addiction have had at least one opportunity to withdraw from narcotic use. This reflects the judgment that prolonged administration of large doses of a narcotic drug such as methadone should only be employed as a rehabilitative modality in those cases in which the applicant has demonstrated his present inability to make a drug-free adjustment. The documentation may relate to any previous medical treatment, hospitalization, or institutional confinement which would have necessitated withdrawal and abstinence from drug use for a suitable period of time following the patient's initial addiction to narcotic drugs. The number of years of addiction which an applicant must show in order to obtain admission is a matter of discretion within the judgment of the practitioner. It is recommended that practitioners accept only those applicants of chronic long-standing addiction for participation in methadone maintenance programs.

PREPARATION OF DOSAGE

Federal regulations provide that patients participating in a maintenance program may be administered or dispensed narcotic drug in a non-injectable preparation prepared in such a fashion as to not readily permit separation of the narcotic drug for purposes of self-injection. At the present time, methadone hydrochloride is the only narcotic drug having a recognized use in maintenance research. In order to render the drug non-injectable, the methadone hydrochloride powder or tablet is mixed with a liquid solution of some innocuous beverage such as orange juice. This procedure complies with Federal requirements and accomplishes the additional objective of making it difficult for the patient to estimate the amount of drug which he is receiving.

For purposes of insuring the accuracy of dosage measurement, it is recommended that the methadone powder be mixed in a moderately weak concentration such as five or ten milligrams of methadone per cubic centimeter of dilutant. It is usually desirable to have the pharmacist prepare a specified quantity of homogeneous solution from which individual doses can be measured and withdrawn by syringe. The amount of the dosage which the patient receives relative to that which is received by fellow patients may be further disguised by mixing each individually measured dose with additional dilutant so that a uniform "quantity" of solution may be administered to everyone.

In each area where narcotic drugs are compounded, stored, administered, or dispensed, adequate security measures must be employed. Past experience has indicated that not more than one day's supply should be maintained at the administering and dispensing centers with the pharmacy stocks remaining securely in the background. Possibilities of pilfering, theft or armed robbery must be envisioned.

The restrictions on the preparation of dosage forms relate only to the use of methadone to maintain the individual patient in the course of his participation in the program. Therefore, it is permissible for practitioners to utilize injectable preparations in some initial stage of the patient's participation or a subsequent emergency. The purpose of the regulation is to insure that the patient does not gain control of a narcotic drug for purposes of self-injection. Any oral dosage form administered to a patient and orally consumed by him under supervision is sufficient under these regulations.

ADMINISTERING AND DISPENSING NARCOTIC DRUGS

One of the common dangers of supplying narcotic drugs to segments of the addict population is the possibility of diversion into illicit channels. These are drugs for which a ready market exists and in which all narcotic addicts have participated in one role or another. For this reason, Federal regulations place some restriction over the quantity of drugs which may be dispensed or administered to such patients. They require that drugs administered to the patient directly must be consumed under proper supervision to insure that they are not carried away and diverted by the patient. Proper supervision for these purposes would mean consumption under the direct observation of a practitioner, nurse, or professional or administrative official participating in a maintenance program. The use of employed patients regardless of their position or of lay persons without administrative authority would not be regarded as proper supervision.

To minimize the inconvenience of participation to patients, the regulations further provide that a quantity of narcotic drug equivalent to a two-day supply may be dispensed for self-administration by the patient after he has evidenced his ability to function within the program. Although this requires accepting some risk of diversion, the risk is minimized in those cases in which the patient has achieved some degree of successful adjustment. The regulation envisions that all new patients would be required to report at more regular intervals for consumption of their narcotic dosage during the initial stages of their participation. After a patient has become stabilized and has established a pattern of acceptable performance, he may be extended the additional carrying privilege.

A further exception is permitted in the case of verified illness, family crisis, necessary travel, vacation and holidays, or special hardship, where it would be unreasonable to require the patient to report to the program facilities for the receipt of dosages with the customary regularity. The granting of such exceptions obviously entails greater risks of diversion and should only be employed with caution and close scrutiny. The practitioner, or his agent, is expected to verify

any request for additional carrying privileges under this section by making checks within the community to establish the validity of the patient's representations. Excessive dispensations under this section will also be regarded as a matter of official concern.

REHABILITATIVE SERVICES

Perhaps the most important single advantage of supplying methadone to narcotic addicts through a clinic facility is that it brings the patient in daily contact with a therapeutic effort and gives the program directors the leverage needed to apply rehabilitative techniques. But for this leverage and the accompanying programs, the dispensing of narcotic drugs in such a fashion accomplishes little more than providing the addict patient with a cheap source of drugs to maintain his habit. There is no magic in the drug itself, and investigations have shown that methadone is a frequent item of illicit commerce among the addict population. It is for this reason that Federal regulations provide that narcotic drugs may only be supplied to the addict on an indefinite basis as a part of a broad well-organized program of rehabilitation.

There can be no specific delineation of the kind and quality of services which must be offered to comply with regulatory requirements. It is recognized that each individual patient has different needs and problems with which the program must seek to deal. Providing vocational counseling and job placement services are of utmost importance for those patients who are unemployed. The program can accomplish nothing if the patient uses it as a cheap source of drugs while continuing his criminal activity. This process usually requires step-by-step coaching and continuous follow-up. The program should also be accompanied with adequate individual psychiatric and social therapy to deal with the patient's problems of developing acceptable patterns of social behavior. The regulation is intended to permit maximum flexibility in designing and providing rehabilitative services; however, these are regarded as of utmost importance in evidencing the bona fide nature of the research effort.

MONITORING PROCEDURES

It is important that maintenance research programs incorporate adequate monitoring procedures to determine the progress of participating patients. Of these, the most important is the frequent collecting of urine specimens for analysis. Federal regulation requires that these specimens be collected at least once weekly and analyzed for the presence of other major drugs of abuse. It is recommended that that these specimens be collected and analyzed at more frequent intervals than required, particularly during the patient's initial stages of participation.

The results of the urinalysis tests will serve to inform the program staff of the patient's progress in abstaining from other drug use and participation in the illicit traffic. Since this is one of the principal objectives within such a program, it is of great importance that this data be developed and collected. The tests should include examination for traces of methadone to insure that the patient is consuming the drugs supplied to him, and for morphine (heroin residuals), barbiturates, amphetamines, and cocaine. When it is known by the program directors that local patterns of abuse include other drugs, the consumption of which can be monitored through urinalysis, these should also be included in the analysis. The patient's awareness of the fact that diversion, heroin relapse, or abuse of other drugs is capable of such objective monitoring tends to discourage such failings and reinforce desirable behavior patterns.

The collection and analysis of specimens at predictable and infrequent intervals is fraught with the danger that patients may conceal their illicit drug taking by abstaining during the period immediately preceding specimen collection. The possibility may be minimized by adoption of either of the following methods: (1) collection and analysis of urine specimens at frequent intervals, such as on alternate days, or every third day; (2) collection of urine specimens at frequent intervals with a random selection of not less than one per week for analysis; or (3) random collection and analysis of not less than one specimen per week. It is desirable to incorporate all or some combination of these procedures within the program structure so that patients may be moved from one modality into another according to the degree of drug-free adjustment they have achieved.

The regulations further require that the taking of a urine specimen be adequately supervised to insure its integrity. Experience has shown that patients

often devise ingenious means for deceiving program staff members by substituting someone else's specimen for their own. It should be understood that the patient shall be required to void the specimen in the presence of a staff assistant. In no event should program patients be employed for the performance of such duties.

Other monitoring procedures should also be employed in the operation of a program. Contacts with the patient's employer, members of his family or neighbors and acquaintances will aid in determining the progress of his social adjustment. Frequent liaison with local police authorities is of great importance in establishing the patient's abstinence from criminal and anti-social behavior. Such liaison has been developed with unique success in the operation of a number of programs. The collection of paycheck stubs at regular intervals will also serve to verify claims of employment. The development of sound monitoring techniques is limited only by the imagination of the project directors. Again, the intention of Federal regulations is to permit maximum flexibility, but the presence of sound monitoring techniques will be regarded as important indicia of a bona fide research effort.

WITHDRAWAL FROM NARCOTIC DEPENDENCY

The rationale behind the use of methadone on a maintenance basis as a part of a total rehabilitative effort is to bring the addict patient into daily contact with a therapeutic program, to wean him from the habit of heroin injection and to develop a rewarding and socially acceptable personal adjustment which will enable his eventual cure of narcotic drug dependence. In all cases, withdrawal from dependence is viewed as the ultimate goal of the patient's participation in the maintenance program. It is anticipated that individuals will differ in their progress within such programs and in the time required to achieve this ultimate goal. Therefore, Federal regulations leave the matter of withdrawal within the discretion of the individual practitioner but place on him the duty to accomplish this objective as soon as may be.

In addition, the regulations require that patients who repeatedly fail to respond to participation in the program be withdrawn from narcotic dependency and discharged by the practitioner. In any event, the practitioner is expected to accept the responsibility of providing proper withdrawal treatment for the methadone dependency which patients have developed as a result of their participation in the program whenever such participation is to be discontinued.

RECORDKEEPING REQUIREMENTS

Federal regulations require that adequate records be maintained regarding the participation of each patient in a methadone maintenance program. This record-keeping requirement is imposed with two objectives in mind. The first of these is to provide a basis for determining the program's compliance with existing regulatory requirements. Secondly, and of equal importance, such records serve as the raw material by which social and scientific evaluations relating to project design and efficiency may be finally evaluated. Every practitioner should take upon himself the responsibility of developing and exchanging scientific data which will further society's objectives in the treatment and rehabilitation of narcotic drug dependence. It is hoped that dedication to this goal will result in the collecting and recording of scientific data well in excess of the basic requirements of Federal regulation. At a minimum, practitioners should maintain records relating to the individual patient's history, documentation of his status of addiction, previous treatment failure, identification, voluntary consent, narcotic doses administered and dispensed, results of urinalysis and evidence of progress within the program. Evidence of progress within the program may consist of the daily or weekly reports of staff members, the notation of community contacts or collection of paycheck stubs and information received from State and local police, and health and welfare authorities. It is the stated policy of the Bureau of Narcotics and Dangerous Drugs that any information with regard to a particular patient collected in the discharge of its regulatory functions will not be used as a basis for investigation, prosecution, or harassment of such patient and will not be made available to others for any such purpose.

Mr. ROGERS. We have a call of the House. If members could make an attempt to answer and return, because Dr. Jaffe has a 2 o'clock ap-

pointment that he must keep, so we will recess for 10 minutes, and our next witness will be Dr. Jaffe.

The committee stands in recess.

(Brief recess.)

Mr. ROGERS. The subcommittee will come to order, please.

Our next witness is Dr. Jerome Jaffe, Special Consultant to the President for Narcotics and Dangerous Drugs.

Doctor, we welcome you to the committee.

**STATEMENT OF DR. JEROME JAFFE, DIRECTOR, SPECIAL ACTION
OFFICE FOR DRUG ABUSE PREVENTION, EXECUTIVE OFFICE OF
THE PRESIDENT**

Dr. JAFFE. Mr. Chairman, members of the committee, it is a pleasure to be here.

Since the establishment of the Special Action Office for Drug Abuse Prevention in June 1971, representatives of this Office have met on many occasions with representatives of FDA, BNDD, NIMH, AMA, NMA, other relevant medical organizations, representatives of the pharmaceutical industry, as well as Representatives of Congress, including members of this committee, in order to help to define a rational approach to the problem of heroin addiction. Obviously, a significant issue in our discussions has been the proper role of methadone and other opiate drugs in the treatment of the heroin addict.

In recent years, the use of methadone for ambulatory detoxification, as well as for methadone maintenance, has increased significantly. The use of methadone as a maintenance drug has been controlled under an IND or investigatory new drug procedure which was worked out jointly by officials of the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs. 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. As the years passed, the IND procedure, in practice, became an expedient to assist officials of the Bureau of Narcotics and Dangerous Drugs in limiting the spread of poorly controlled programs, pending a more definitive definition of acceptable medical practice in this area by relevant Federal health officials and professional medical associations.

The original goals for which the IND procedure was established have been met. Methadone as a maintenance drug has been proved both efficacious and safe when used in the proper environment and correctly administered. Since 1968, the evidence accumulated on the efficacy of methadone maintenance treatment for significant numbers of heroin addicts has led to published statements by the World Health Organization and statements by the American Medical Association specifying the conditions which maximize the benefits of this type of treatment. The last 2 years of clinical practice has further demonstrated that when used properly, methadone is a safe drug; but, when diverted to the black market or accidentally ingested or otherwise improperly administered, there is a risk of drug overdose in non-tolerant individuals.

Thus, the control of diversion is a significant factor. The IND mechanism has proven itself of limited value in controlling the quality of programs. There has been some inadequate medical care in some notable instances, and to the dismay of all groups interested in responsible programs, the IND mechanism also has not proven to be sufficiently effective in preventing diversion. The problem is further complicated by the fact that methadone is available on prescription through pharmacies in most States, properly labeled for detoxification of heroin addicts, for cough suppression, and for analgesia. The distribution system, therefore, is an open one which may be abused by naive, well-meaning physicians or the occasional practitioner interested primarily in monetary gain. Obviously, it is time to develop a new approach to the use of methadone in the treatment of opiate addiction which maximizes its therapeutic efficacy while adequately controlling the risk of diversion. At the same time we must deal with the problem of methadone detoxification—a standard procedure in which methadone is administered over a period of a few days to 2 or 3 weeks in gradually decreasing dosage to persons addicted to opiates in order to minimize withdrawal symptoms. Detoxification may take place in a hospital setting or on an ambulatory basis, but in either case, in absence of further care following the withdrawal process, the relapse rate to heroin self-administration over the following 12 months is exceedingly high. By referring to their treatment as ambulatory detoxification, maintenance treatment has been carried out by individual practitioners who are not licensed under the IND procedure. Moreover, it has, in some instances, been carried out by individuals who have lost their IND licenses because of questionable procedures. Neither the FDA nor the BNDD currently possess mechanisms for the control of methadone when it is being used for ambulatory detoxification. This represents a significant gap in the Government's ability to control diversion of methadone.

Methadone as a maintenance drug has been found to be effective in decreasing the use of heroin or eliminating it altogether in the majority of individuals under treatment. Moreover, significant numbers of patients are able to cease criminal activities and to assume socially acceptable behaviors which are of benefit to them as individuals as well as to their communities. Currently, according to FDA estimates up to 50,000 patients are actively being treated in methadone maintenance programs. In New York, New Haven, Philadelphia, Washington, D.C., Chicago, and many other cities, data gathered on patients confirms the wide-scale acceptability of methadone to the patient population as well as its efficacy in the reducing illicit drug use and criminal activity, and facilitating social and vocational adjustment.

Acceptable treatment requires the continuing daily oral administration of methadone in a form which discourages illicit use. With adequate medical supervision the dose is adjusted to prevent the occurrence of abstinence-phenomena, to reduce craving for opiate drugs and to establish a sufficient degree of tolerance and cross-tolerance to these drugs so as to blunt or suppress the acute effects of such agents. A typical daily dose range is between 80 and 120 milligrams. In most programs patients receive their medication daily in a clinical setting for at least 3 months of treatment before they are allowed to

take a weekend dose away from the institution. Generally, the most effective programs do not allow the taking home of medication until the patient has demonstrated significant social improvement based upon the absence of illicit drug taking and social adjustment. The problem of diversion can occur only when patients are permitted to take medication from the clinic. In some programs there has been experimentation with the 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-term or even lifetime maintenance on methadone while other individuals will be able to undergo eventual withdrawal after they have gone through successful rehabilitation.

Most clinicians who have worked with addicts feel that methadone alone does not constitute an adequate service. Supportive services, including adequate laboratory facilities for urinary screening, should be available. Trained staff, in adequate numbers, are needed to administer these programs, and patients must be screened for evidence of opiate dependence before placement in a methadone maintenance program.

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. One can look at such drugs as methotrexate, which is used to treat various types of cancer. This drug can be deadly if used incorrectly. Even with penicillin, we take the risk that a patient may have an unknown allergy, and that allergy can lead to a fatal reaction. One could go on and on, until drugs such as aspirin, sleeping medicines, tranquilizers and insulin are noted, all of which may cause overdose deaths.

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 the possible benefits. On balance, methadone for maintenance use, just as methotrexate, penicillin, aspirin, sleeping medicines, tranquilizers and insulin for their specific uses, must be considered safe. It is neither inherently safe, nor inherently dangerous. But as with most drugs, methadone must be evaluated in context; it can be dangerous if improperly used, but it is sufficiently safe when administered properly to individuals who would otherwise be likely to continue using intravenous heroin.

The movement to an NDA at this time will accomplish several things. It would eliminate a credibility gap under which we have been operating. The conditions under which methadone may be safely and effectively administered have been defined. It is difficult to continue to refer to a procedure that is being used with 50,000 people as an investigation. The inadequacy of the IND mechanism as an instrument for adequately controlling program quality has been apparent, and the problem has been compounded by the fact that methadone has been approved for many uses other than maintenance, and is thus widely distributed and available on prescription by the general physician. The NDA would limit the distribution of methadone to specific

facilities that meet the criteria required for the treatment of heroin addicts under methadone maintenance. Detoxification would also be limited to facilities that met the criteria. In making these changes, the use of methadone as an analgesic would be somewhat limited. At the same time, the use of methadone maintenance for the treatment of pregnant patients and persons under the age of 18 would remain under the IND mechanism since in these two patient populations the relative safety and efficacy of methadone maintenance continues to be under investigation. It is possible under the FDA regulatory procedures to allow whatever period of comment is desirable prior to the implementation of NDA regulations. We can assure you that there will be an opportunity for this committee to hold hearings if it should so desire, before any final regulation is adopted. This would also provide time for BNDD, the FDA and SAODAP to work together to develop adequate procedures to monitor treatment programs while working in concert to develop whatever legislation may be needed.

Obviously, there are other drugs which can be used for either withdrawal or maintenance in the same way that methadone is currently being utilized. The regulation of treatment facilities would be an important step in enabling the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs to meet their responsibilities in monitoring these treatment services. FDA as a health and regulatory agency, and BNDD as an enforcement agency, have complementary roles which must interdigitate if we are to maximize the efficacy of treatment and minimum potential problems.

The Special Action Office for Drug Abuse Prevention, in reviewing the question before this committee, is of the opinion: (1) that methadone maintenance has been proven efficacious; it does reduce drug abuse, decrease crime and increase social adjustment; (2) when properly administered and in the context of the traditional concept of balancing need versus risk, methadone maintenance is safe; and (3) control of methadone under an NDA with a view toward the eventual regulation of treatment facilities so as to regulate the use of similar drugs, would assure, more effectively than the IND, that maintenance is carried on only under prescribed conditions.

Therefore, the Special Action Office endorses the development of an NDA and supports the effort to develop proper legislation.

In view of the complexity of the problems and issues involving the dispensation and control of methadone for maintenance purposes, we strongly urge that this committee address the question of the legislative regulation of the use of methadone separately from the legislation now pending before you; namely, H.R. 9264, the bill to establish a Special Action Office for Drug Abuse Prevention. To do otherwise would confuse the issues, and possibly delay the enactment of legislation which is needed if we are to develop a coordinated approach to the problems of drug abuse and drug addiction.

Mr. ROGERS. Thank you very much, Dr. Jaffe.

Mr. Preyer?

Mr. PREYER. Thank you, Dr. Jaffe, for your testimony. I notice that on page 7 you point out that as part of any effective control methadone program there should be screening of all of the patients for evidence of opiate dependence before they are placed in a methadone maintenance program. How is that accomplished?

Dr. JAFFE. Currently, I believe it varies from program to program. This is one problem that is inherent in IND, it permits a number of people to propose their own investigations.

Some programs require at least two consecutive urines positive for opiates. That is something we did in the early stages of our program in Illinois.

Other programs require evidence of needle marks for physical dependence. Some programs do not require that and rely on history given by the patient as being adequate evidence that the individuals are indeed dependent. There is some variability and none of these particular procedures are entirely satisfactory either from the point of view of the people running the programs or from the view of the people seeking treatment.

To send somebody out who says he is an active heroin user and tell him to use heroin for several more days to prove to you that he is an active user condemns him to do crime, and, second, as has happened to a number of people in this field, you get a note back from his relatives that he has died of an overdose.

We have no fully satisfactory way to do this. I think most people sincerely try, however.

Mr. PREYER. This is a point of some concern, the fact that there is no good test for the dependence beforehand. I think what worries this committee, for example, is the returning Vietnam veteran who is probably only mildly addicted from smoking or snorking pure heroin over there. In fact, I think the rehabilitation rates over there run something like 80 percent which is way above what you get when you are injecting heroin. This man comes back to the States. His family suddenly finds he is on heroin; they panic and the doctor will put him on the methadone treatment when he is possibly a man you could break of the habit without too much trouble. Yet, when you put him on the methadone treatment you create an addict for life. So it is so important that somebody knows what they are doing.

Dr. JAFFE. I could not agree with you more. There is a major gap in our armamentarium. Methadone is not suitable for people who do not have long histories of addiction. I am not sure it is a catastrophe to put some people on it, but clearly this is not necessarily the ideal way to treat them.

The difficulty in many situations is that not only is there very little alternative, but treatments that are available do not seem to be particularly appealing to a younger heroin user who finds excitement in his situation. If the only alternative you present to him is psychiatric hospitalization, he may elect to stay on the street awhile longer and during that time get into serious legal problems, if not do permanent injury to his health.

Although I am very, very ill at ease when I see well-meaning physicians putting people on methadone, I can in some way sympathize with their distress in having little else to do. It is currently a situation that nobody feels is satisfactory.

We are pushing ahead to develop an alternative, but I can tell you frankly that it is very sad that we are only now beginning to really push ahead.

Mr. PREYER. I notice that you refer to well-meaning but naive physicians. I hope we do get the message across to them to be very careful, you should not put everybody automatically on methadone.

Dr. JAFFE. One of the advantages of the NDA as it is currently being proposed is that it will not be available to the entire range of physicians. Right now, theoretically because of the availability of methadone in pharmacies, many practitioners will put somebody on methadone for a week or two pending examination. We now have a quarter of a million people who are eligible to prescribe methadone, and the probability of being able to educate all of them fully as to the nuances of this problem is very low. The hope is to create more specialized centers where people are able to adequately evaluate the problem and to use alternatives other than methadone.

Mr. PREYER. I hope that your programs will have in them firm controls about going into the history of these patients. I wish there was a mechanical test that would show how heavily or lightly addicted someone is.

Dr. JAFFE. Well, that is not impossible, but it has its own disadvantages, which are both technical and ethical, and I would be happy to go into it if you would like.

Mr. PREYER. We don't have the time to go into it now, but I hope we can devise standards somehow, whether mechanical or going into history, that will make sure we don't get the mildly or lightly involved drug user in the methadone program.

Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Hastings?

Mr. HASTINGS. Thank you, Mr. Chairman.

Thank you, Dr. Jaffe. I am delighted that in your statement you indicate your support of the development of NDA and also your support of an effort to develop proper legislation on controls. I think this is very helpful as far as those members who have a great concern over the lack of control.

There are a couple of areas that I would like to just question you a little further on. On page 6, you mention support of services, including adequate laboratory experience, should be available. I am concerned in some of the clinics I have visited to find that laboratories were less than adequate. In one case, Los Angeles, the doctor indicated he had sent the urine of his 12-year-old son and 9-year-old neighbor to a laboratory, and they both came back positive on heroin addiction, neither of which was true.

Dr. Jaffe. When I said adequate, I could very well have underlined the word "adequate." One of the major tests of the office is to rationalize the current system which develops small, little laboratories which are not subject to quality control, and we want to make some corrections in that. We anticipate if we are going to treat drug users and we are successful in moving to make treatment readily available to them, we will perhaps be treating more than 100,000 people. Urinary controls are just as important for other forms of treatment as they are for methadone, and they have to be adequate and inexpensive and reliable.

We are taking steps to try to correct many of these deficiencies, and I would hope that within the next few months we will be able to tell you some of the steps we are taking, which may improve the situation very significantly.

Mr. HASTINGS. Does NDA language itself refer to the laboratory facilities?

Dr. JAFFE. We are told by FDA that we can build into NDA any set of requirements, including use of laboratory and uniform records that will make the accounting systems inventories of the drug easy for those people who conduct their onsite inspections. It may also include participation in some kind of regional data system to prevent multiple registration in several different programs. This is another sort of illicit diversion.

Mr. HASTINGS. In order to accomplish a lot of this, I trust you must have Special Action Office legislation, however.

Dr. JAFFE. I believe it would be rather difficult to coordinate all of the pieces without some form of legislation at this point.

Mr. HASTINGS. A matter of trained staff, too, I found to be a serious weakness throughout the country.

Dr. JAFFE. Without trained staff, all of these things are ideas and identification of needs, but without the means of implementation. I think it is critical that we have legislation so that we can begin to recruit the people to correct the deficit that most people are seeing is so obvious, whether it be urine testing or registration of patients in clinics or training of adequate staff, so that the kinds of difficulties we have pointed out in these programs can be corrected. They are potentially correctable, but it is going to require some massive coordination because, as you know, a medication such as methadone is not being used merely by one group supported by Government. We now have some VA programs using it; we have State supporting programs, OEO programs using it. If we really want to bring this under control, all of these programs must be coordinated.

Mr. HASTINGS. I agree with you. I read an article of yours in JAMA on l-methadyl acetate. That is a longer lasting drug.

Dr. JAFFE. It lasts from 48 to 72 hours.

Mr. HASTINGS. What is the current status of this?

Dr. JAFFE. I have been interested in the problem of diversion of methadone for almost 6 years. I submitted to NIMH for a grant in 1965 on the use of l-methadyl acetate. For a number of reasons, the support for these kinds of things were not such that I could get it started then.

I then moved to Chicago in order to further carry out some of these studies. We were first able to get the drug studied in 1968, and I think we published finally in 1970.

Mr. HASTINGS. NIMH has not come up with any conclusion at all about the efficacy?

Dr. JAFFE. A doctor at NIMH was successful in having the manufacturer make available 4 kilograms of the drug. To the best of my knowledge, they have been unable to stimulate any further research on it.

Mr. HASTINGS. This would seem to indicate the diversion problems that you have indicated.

Dr. JAFFE. With that drug and with agreement that people with a serious illness such as heroin addiction perhaps can be obliged to come to a clinic several times a week, we could virtually eliminate the type of illicit diversion and everything that goes with it.

Mr. HASTINGS. I would hope we could get NIMH to devote more time and money and effort in that direction.

Thank you very much, Dr. Jaffe.

No more questions, Mr. Chairman.

Mr. ROGERS. What is the difference in control features between the investigational new drug setup and a new drug as such? Are you saying you can have stricter controls with a new drug approval than with an investigational new drug?

Dr. JAFFE. That is the major purpose of moving into NDA at this time.

One issue is that the IND, frankly, and with most people's full knowledge, has been somewhat subverted into a control mechanism which it was never designed to be. We are reluctant to begin to use something that was designed to permit researchers freedom to investigate as a mechanism to say that you must do that, and you must do this. This would inhibit and crush research. If we feel that in order to get control of the illicit diversion we want to very carefully specify the conditions under which this must be done, then we don't want to create a precedent which says in an IND we will tell every single person what it has to give and when it should give it. The IND was designed to facilitate research. At this particular time we are looking for mechanisms to get control over the illicit diversions.

It seems to me it would be in some ways inappropriate to use the IND for that. It is already causing a major credibility gap. To further try to specify how to use the IND mechanism, I am afraid would create a precedent which would in many ways begin to say that the Government will tell ethical researchers the hour and time to give out medication and conduct research and that, I think, can have long run implications that most ethical scientists would rather avoid.

Mr. ROGERS. The only concern I have is I wonder whether your studies have reached the point where you can make these judgments.

Dr. JAFFE. Pardon me, sir?

Mr. ROGERS. I was saying, from the information I have received, I wonder if we are at the stage where we have sufficient knowledge to make the judgment on making it a new drug rather than from an investigational status?

Dr. JAFFE. There are many areas which obviously are still under investigation and which would require further data. I think we don't know the best way to handle the pregnant addict. There are other areas where we are really uncertain and where data must be gathered. I think many reputable people, even those who began as extreme skeptics with respect to methadone, now believe there is at least some group of hard core addicts who benefit and who will lead useful and productive lives when so treated but who do not seem to be able to make it in any other kind of situation. In that sense, this would then constitute efficacy. They do show a reduced use of heroin. When I say reduced, I don't mean eliminated. In many situations, and most people view heroin addiction as a life-threatening phenomenon, if we had a cancer cure, and you found a situation where previously 95 percent of people succumbed and you had a new drug that got it down to 80 percent, you would say we had made a tremendous improvement in the probability. Here is such a situation.

Mr. ROGERS. Yes; except we are not substituting another disease for cancer which is what we are doing here.

Dr. JAFFE. Mr. Chairman, I think there are many physicians that, if they could substitute a milder syndrome for cancer [and talk to the

cancer patient as to whether they would rather have some other incapacitor death-dealing disease] the answer would be that, "I will take whatever you have in exchange." Nobody is saying we are doing anything more than substituting, Mr. Chairman.

It is an honest open statement. It is a substitution method but for the purpose this is offered, it is a difference between life and death.

Mr. ROGERS. Well, except this, now. You rule out the alternative of trying to get him off, an abstinence.

Dr. JAFFE. Absolutely not. I have done this. I was perhaps the first person ever to do this. We did this in Illinois. We wrote this paper saying we never made a commitment to people they would stay on indefinitely, that they could be withdrawn at any given time, and we pointed out to those people who were very concerned, once you put somebody on methadone, he will never want to get off, therefore you must put them in abstinence programs because methadone is so seductive that no one will ever want to get off.

What we found was the opposite. If you put people in treatment programs with methadone, we hope he will get himself together, get a job, but he may or may not want to stay on this. In fact, in our first studies we told people, "some of you we will insist will come off." What we found was that within time everybody wanted to come off. Nobody wants to take medicine indefinitely, not even the addict.

Mr. ROGERS. Not only that, we found out from recent studies that three-fourths of them here in Washington wanted to go off it all right, but they wanted to go back on heroin.

Dr. JAFFE. That is a problem but—

Mr. ROGERS. Sure. So what are we really talking about? We are spending \$5,500 on the program here in Washington for each one. You have 4,000 drop out of 5,000 and only 600 at the end of the year.

Dr. JAFFE. One of the considerations in reading some of these studies, and we have had the same difficulty when we build a program, a program that offers various kinds of treatment to different kinds of people and we lump the dropout data together, we come up with strange dropout figures. I understand from Dr. du Pont who published these that these are the overall figures. You will find the dropout figure for methadone is the lowest of all. The dropout figure from detoxient units is highest, close to 90 percent. This is a general finding in most programs using a range of services. We have therapeutic communities and at the end of the year 10 to 15 percent of those who enter are still there. In our withdrawal unit where we try to use short-acting programs and aftercare in a residence, we had 90 percent drop out. In a methadone unit, almost identical. We perhaps had 50 percent drop out.

Nobody is pretending that we have answers. I am saying on balance for the kind of people we were seeing, people stayed longer in that particular treatment than any other. I can't speak to the details of Dr. du Pont's findings, but I can say we should look carefully into what specifically that dropout was and if it was really an overall rate, the methadone treatment may look more favorable.

Mr. ROGERS. Here is my concern. Here we are moving in a drug saying it is safe and effective and yet these figures are coming up to show it is not very effective at all.

Dr. JAFFE. Again, I think the public and most people in medicine interpret the term effective, at least I hope the public interprets it the way people in medicine do, if medicine is effective, it is better than no treatment at all. It is certainly no guarantee that every person will be helped and this is true of every single drug that has been approved in the last 10 years. They insist you compare it to no treatment and to placebo, a medication which has no effect. If it does better than nothing, then you say it has some effectiveness. It may only be 10-percent effectiveness.

Mr. ROGERS. But maybe if we kept it in the investigational stage until we investigate it more and find more about it and get the proper information, then we could make some more intelligent judgments.

As it is recommended from the wrapup of this conference, I think you were a participant in it, and here was the wrapup and it was done by Dr. Martin from the Lexington Clinic. The final sentence:

If we are to avoid meaninglessness, and frequently destructive process, based on undocumented authoritative pronouncements, sound and well established principles of clinical investigation must be used in studying the efficacy of methadone maintenance.

Dr. JAFFE. We endorsed that. Dr. Martin is one of the most careful, methodical people in the world with respect to the way he approaches a problem. I believe that was his comment about the 1969 second national methadone conference. Without doubt he had good evidence for that statement. The point that we are addressing ourselves to is what are the tradeoffs? It is my belief, and I am willing to be persuaded otherwise, that we have to have a more effective regulatory mechanism to prevent obvious diversion of methadone in the poor practice that crops up as people try to cope with narcotic addiction in their communities. The problem is that to use IND for that purpose creates a precedent of saying that if you have an investigation the government is permitted to tell you to the milligram, to the day, to the hour precisely how you must proceed with your investigation. So, if it is an investigation, it is an awfully hard investigation and many of the people who are participating in it are not trained to do investigations.

Mr. ROGERS. This can be changed and make them abide by law. This is one of our concerns, that this has gotten to a point where we are supposed to be doing investigations and yet simply because we say it is a little out of hand here, so we will eliminate everything we are doing and make it a new drug and make it approval of the government for safe and effective—

Dr. JAFFE. That is not the intent of the NDA.

Mr. ROGERS. I understand the intent, but what I am saying is the facts. Now, this is the concern I have, that once the public gets the idea that we have said there has been sufficient research to let us make this determination, that it is safe and effective.

Dr. JAFFE. For some small group of narcotic users.

Mr. ROGERS. You don't say that.

Dr. JAFFE. The NDA will say that.

Mr. ROGERS. Say what?

Dr. JAFFE. For a specific subgroup of hard-core heroin addicts.

Mr. ROGERS. Will you tell them to whom it may be prescribed?

Dr. JAFFE. Yes, sir. It is my understanding they will be saying

the people for whom previous treatments have failed, certain kinds of people will still be considered investigational. The issue here——

Mr. ROGERS. Wait a minute. If it is good to say we don't know enough about some of them and it ought to be investigational, you are talking about all of this control, why should that not be included in the new drug approach, too?

Dr. JAFFE. The nature of approving NDA's, and this has been the case for, I believe, almost 10 years, is that one approves a drug not in toto but for specific circumscribed uses, thus methadone is now totally approved for analgesia. It is even approved for cough medicine and perhaps in some instances other specific kinds of things.

NDA does not mean a drug is efficacious for everything one might use it for. Indeed, if somebody came up with an idea that a new drug which is well established such as penicillin were good for something nobody thought of before, even that well established drug would now require an IND first.

Mr. ROGERS. Let me ask you this. Then are you leaving the drugs in the drug stores for cough medicine?

Dr. JAFFE. We have talked to the manufacturer about this. We feel that the situation has gotten to the point that we would like concomitantly with introduction of an NDA to work with the manufacturer to remove most of the other forms of methadone from the drug list.

Mr. ROGERS. The proposal is that you take it all out of the pharmacies, don't you?

Dr. JAFFE. We will be taking most of it out.

Mr. ROGERS. Are we or are we not?

Dr. JAFFE. The issue is that they will put forth an NDA proposal and there will be lots of time for everyone to make comment. Now, what will happen at the end of that, obviously, we can't predict.

Mr. ROGERS. But I understand it is being proposed to take it all out of the pharmacy.

Dr. JAFFE. Yes, sir, that is the initial proposal.

Mr. ROGERS. Therefore, you are saying we are not permitting what has normally been approved and accepted as safe and effective for a cough medicine.

Dr. JAFFE. It is not that it will no longer be approved; it is that it will no longer be available.

Mr. HASTINGS. Will the gentleman yield?

Mr. ROGERS. Yes.

Mr. HASTINGS. If I understood correctly, Dr. Edwards indicates that the cough medicine may very well remain in the pharmaceutical drug stores.

Dr. JAFFE. That is still not clear. That is correct.

Mr. HASTINGS. With only one exception.

Mr. ROGERS. I understood in the pharmacies in the hospitals——

Mr. HASTINGS. I think in the cough medicine there may be an exception.

Dr. JAFFE. The drug for analgesia will be left in the pharmacies.

Mr. ROGERS. The last sentence on page 10 indicates a necessity for some authority of Special Action Office over law enforcement provisions where it is tied in very closely here with maintenance.

Dr. JAFFE. I don't think that that was the intent to imply that, sir.

Mr. ROGERS. In other words, you don't think there is any point in having any control there?

Dr. JAFFE. Well, it was not the intent to create an office with control of law enforcement. We have been acting as a mediator, if you will, as we try to work out a smooth lineup of responsibilities of the Bureau of Narcotics and Dangerous Drugs and the Food and Drug Administration.

Mr. ROGERS. I am sorry, I said page 10; it is page 9. "FDA and BNDD have complementary roles which must interdigitate if we are to maximize the efficacy of treatment and minimize potential problems," which I would think builds the case rather forcefully for some say-so by your office to make sure that they interdigitate correctly.

Dr. JAFFE. We have been working with the Bureau of Narcotics and Dangerous Drugs and FDA.

Mr. ROGERS. I was thinking in setting up authority for you to make sure that you could do this under authority of law.

Dr. JAFFE. Well—

Mr. ROGERS. I guess you have no strong objection if the Congress does that.

Dr. JAFFE. I have learned that my strong objections don't hold a great deal of weight, Mr. Chairman.

Mr. ROGERS. Well, they do in this committee.

There is a vote on. I think we have gotten generally the picture of what is being contemplated. There will be assurances of additional time so the Congress could act if we think it is not sufficient.

If you would submit any studies you think might be helpful to the committee in this regard, we would be pleased to receive them.

Dr. JAFFE. I want to emphasize that in the opinion of all concerned, NDA does not mean that we have an answer. It is a small, partial answer that we think should be available to those who need it, sir.

Mr. ROGERS. Thank you, Dr. Jaffe. We appreciate it.

The committee stands adjourned.

(The following statements and letters were received for the record:)

STATEMENT OF JAMES R. KIMMEY, M.D., EXECUTIVE DIRECTOR,
AMERICAN PUBLIC HEALTH ASSOCIATION

Mr. Chairman and Members of the Committee:

I am Dr. James R. Kimmey, Executive Director of the American Public Health Association. Our Association, with its 52 affiliated State organizations, comprises a membership of 52,000 health workers in some 30 disciplines whose daily efforts are devoted to improving the health status of Americans. Not surprisingly, the Association has often taken official notice of the growing problem for the nation represented by drug abuse. Thus we are pleased to be invited to appear before this Committee to present our views on the various proposals for intensifying, and improving the coordination of, drug abuse control programs in the United States.

In our opinion, the problem of drug usage in this country poses an impending national disaster. It demands new priorities, greatly strengthened efforts, and reorientation of programs. Drug abuse is a disease, and in the United States in 1971, it is an epidemic disease. It is an epidemic disease that cuts across social and generational lines to strike at or near the lives and health of millions of families. It is not, as it once was, a disease affecting a hard core fringe element of the society. The day when a "junkie" was a pariah are gone. It is not, as it once was, a disease that involves a small number of specific drugs. The suburban housewife who uses an amphetamine to get "up" in the morning and a barbiturate to "calm down" at night is equally a drug abuser with the

heroin addict in a "shooting gallery" in the inner city. Any solution to the problem of drug abuse in the United States must encompass this breadth of definition if it is to succeed. Narrowing the definition to only those who use the so-called "hard drugs" fosters punitive and rehabilitative approaches to the exclusion of badly needed control on production and public education.

In viewing any epidemic disease, the public health oriented individual looks not only to the effects of the disease once it is manifest, but also to the vectors—the agents that carry the disease—and the causative organism. Thus it is that public health programs direct themselves not only toward the treatment of manifestations but also concern themselves with control of the vectors and eradication of the causative agents. As it is with malaria, tuberculosis, or venereal disease, so it should be with the drug abuse problem. Treatment and rehabilitation programs, such as methadone maintenance, are one essential part of a total societal program for dealing with this problem. "Vector control" in this case encompasses stringent enforcement of laws which punish those who sell such drugs. A less obvious but important aspect of "vector control" is the problem of educating prescribers of drugs to the danger of over-prescription or inappropriate prescription of drugs with a dependency hazard. Finally, control of the causative agent in this case is a complicated procedure involving both sensitive negotiations with foreign governments who permit the production of the raw materials for the opium family, and regulatory control of domestic production of dangerous drugs which are produced in quantities far exceeding the therapeutic need. Undergirding the entire control program must be continued research activities relating to the drugs themselves and the dependencies they evoke, as well as public education activities which stress the price at which pleasure is sought by the drug user.

In support of these general concerns, the American Public Health Association has made several specific recommendations:

1. Control of importation into the United States of drugs of all types and strict exclusion of illegal drugs;
2. Action against illegal distributors of drugs especially organized criminal groups;
3. Elimination of surplus production in excess of prescription demand;
4. An attack upon unnecessary drug demand through education in the schools, and elimination of advertising which stimulates the excessive use of drugs;
5. Encouragement of further experimentation with organized maintenance programs using methadone and similar compounds, subject to appropriate supervision and evaluation;
6. Use of the services of former drug addicts in assisting with the rehabilitation of others; and
7. Encouragement of medical care facilities to develop adequate staff and equipment to render emergency and post emergency care.

One of the major weaknesses to date in mounting an effective program to control drug abuse has been the fragmentation of responsibility for various aspects of a total approach. Many of the programs that we feel would be desirable exist, but are placed in a variety of Federal, State and local jurisdictional bodies. This type of fragmented activity, so characteristic of our approach to health problems, is a continuing hindrance to effective solutions. The proposal for creation of a Special Office for Drug Abuse Control as single focus for coordination for Federal efforts in the drug area is a reasonable and proper one, and is directed toward the fragmentation problem. In addition, the increased visibility of attempts to solve the problem attained through such an office has value.

A recognition of this need for stronger coordination at the policy, planning, and administrative levels is expressed in a number of specific bills that have been introduced in the Congress. In our view, each of these bills has considerable merit and differ only in relatively minor areas. Generally, H.R. 9264, the *Special Action for Drug Abuse Prevention Act* provides the most flexible yet specific approach to the coordination problem of any of the proposals. There is, however, one area of exclusion in H.R. 9264 that should be carefully considered by the Congress. In Sec. 5. (b) and in subsequent Sections law enforcement activities and legal proceedings are excluded from the authority of the Director of the *Special Action Office for Drug Abuse Prevention*. Although we recognize that the technical and legal aspects of law enforcement are properly beyond the purview of the Director, we would challenge complete exclusion of law enforcement activities as proposed in H.R. 9264. If one is to approach drug abuse pre-

vention and control as a health problem, then the participation of the health-oriented director in matters of policy, planning and coordination of enforcement activities seems to us essential. As long as society judges the sick individual who is a drug abuser as a criminal, the standards applied in his arrest, detention, and treatment while in the jurisdiction of legal authorities is a health matter. The law enforcement phase of the total drug abuse program should be viewed as such—a phase of a total program—and should be coordinated with other activities such as production control, public education, management of acute crises, and rehabilitation of the addicted individual. We would hope that the exclusion of law enforcement activities from any oversight by the director of the *Special Action Office for Drug Abuse Prevention* would be reconsidered and that he would be given a definite and continuing coordinative role that would allow him to place law enforcement in perspective with other, ultimately more important approaches to this serious national problem.

We urge your favorable consideration of the important initiative toward a more rational program for drug abuse control as suggested in H.R. 9264. The problem is not simple; but the current approach is needlessly complex. Better coordination will not, of itself, solve the drug abuse control problem, but it would represent a significant step towards focusing resources that are now directed diffusely.

STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY

INTRODUCTION

This statement is submitted by the American Association of Colleges of Pharmacy to support bills which establish drug abuse prevention and education programs for servicemen and their dependents.

The American Association of Colleges of Pharmacy consists of 74 schools and colleges of pharmacy. All are nationally accredited. Seventy-three of our member schools are located in 44 States and the District of Columbia; the remaining school is in Puerto Rico. More than 2,000 full-time and part-time teachers are engaged in the instruction of approximately 19,000 undergraduate and 2,100 graduate students.

The curriculum leading to the professional degree in pharmacy requires a minimum of five academic years. Two schools offer only a six-year curriculum leading to the professional degree, doctor of pharmacy, and nine others offer the longer program on an optional basis, in addition to the minimum program.

In the five-year program, at least three years of work in the professional subjects are required in addition to the two-year basic science program. In the six-year curriculum, four years are mandatory beyond the two years of basic science.

Thus, today's pharmacy graduate is a thoroughly educated drug scientist.

Pharmacy schools have been actively engaged in organized drug abuse education programs for the general public for at least five years. Many individual faculty members and students were involved in drug education programs long before that date, but on a nation-wide basis, most of the 74 schools have been involved since 1966.

HISTORY OF PHARMACY SCHOOL DRUG ABUSE EDUCATION

We attach an article from the September 1967 *Journal of the American Pharmaceutical Association* (Attachment A) to show how some of our schools started their drug education programs for the public.

Since 1967, pharmacy students and faculty members have conducted thousands of information programs for college students, high school and junior high school students, PTA's, civic clubs, and other groups. We believe several hundred thousand people have learned something about drugs through these programs.

We do not believe our member schools have done enough. We do not believe that pharmacists have done enough. We believe we can do more, particularly with regard to preventing drug abuse in the Armed Services.

EXAMPLES OF CURRENT PHARMACY SCHOOL DRUG ABUSE PROGRAMS

Two of our deans have prepared statements describing the drug abuse education programs, courses, and projects at their schools. These are representative of

activities at most schools of pharmacy. The deans are: Arthur E. Schwarting, Ph.D. (Attachment B), School of Pharmacy, University of Connecticut, and President of the American Association of Colleges of Pharmacy, and George P. Hager, Ph.D. (Attachments C, D, E and F),¹ School of Pharmacy, University of North Carolina, and member of the National Health Resources Advisory Committee.

This Association urges that the subcommittee consider these articles as evidence of the ability of many young pharmacists to participate in drug abuse education programs in the military. If there are insufficient pharmacists available in the Armed Services, the Association suggests that a special call be made under the Selective Service Act to obtain the pharmacists to do the job. The Association believes that many of our recent graduates are now serving in the Armed Services. They have participated in drug abuse education programs and have a strong desire, as patient-oriented professionals, to assist the public in any way possible.

We suggest that the subcommittee request the Department of Defense to identify these individuals and commission them for the purpose of mounting drug information programs. Combined with sociologists, psychologists, physicians, psychiatrists, and law enforcement personnel, these pharmacists could assure the military of proper informational programs. Pharmacists are the only health care professionals whose exclusive specialization is in the health area of drugs, including drugs of abuse.

ATTACHMENT A

ON THE CAMPUS . . . DRUG ABUSE PROGRAMS*

(By Dale W. Doerr, Hugh F. Kabat, William J. Sheffield and William J. Skinner)

Pharmacists are aware of the current publicity being devoted to drug abuse on the nation's campuses. Newspapers, magazines and other media abounded with reports on drug misuse among America's college students.

Unfortunately, these reports rarely give an objective appraisal—a true picture—of the situation. The press has a tendency to magnify a provocative problem out of all proportion, and this overzealous coverage seems especially evident where drug abuse on the campus is concerned. From any press reports on the subject, the casual reader would have to conclude that glue, "pep pills," cough syrups and LSD are as much a part of the college curriculum as Western civilization or English literature, as physics or chemistry.

To a degree, the college drug abuse problem has suffered from such journalistic exaggeration. But only to a degree. Careful studies have shown that drug abuse does exist in many, if not most, American colleges and universities. At this time the problem appears to be confined to relatively few students in any one institution, but if sensational press reports continue to be the only communication to college students on the subject, the problem will not be confined much longer. Experience has shown that drug abuse is a highly contagious disease and the kind of publicity the problem has been getting—publicity that often makes drug abuse sound glamorous and exciting—can only help spread the contagion.

To combat the campus drug abuse problem effectively, somebody has to talk to students about it without glamorizing it—without making it sound like the "in" thing to do. Perhaps what is needed is a balanced drug abuse education program for college students which explains in an objective manner the benefits of legitimate, medical drug use and the dangers of illegitimate, abusive drug use. This paper describes a unique method of providing such education—a promising new program in which pharmacy students play the key role.

¹ Attachments D, E, and F may be found in the committee's files.

Attachment D—"Better Living Thru Chemistry," 1971 USAF Pharmacy Seminar, Brooks AFB, Texas (Capt. Dean Peyton and Capt. David Stevenson).

Attachment E—"Teacher Drug Abuse Education Project—Proceedings," July 13-17, 1970; July 27-31, 1970; August 10-14, 1970. Sponsored by School of Pharmacy, University of North Carolina, and North Carolina Department of Public Instruction.

Attachment F—"Kids 'n Drugs" by Leonard Berlow, School of Pharmacy, University of North Carolina, Chapel Hill, N.C.

*Presented before the Academy of General Practice of Pharmacy at the meeting of the American Pharmaceutical Association, in Las Vegas, Nevada, April 10.

About a year ago, in Dallas, Texas during the APhA annual meeting, we discussed the drug abuse problem on the nation's campuses. Our discussion led to these conclusions—

Students on college campuses must receive a more balanced presentation of the use and abuse of drugs than they now receive.

Students just won't be preached to—they won't respond to being told only that drug abuse is harmful and against the law (they already know that).

Students respond to a balanced presentation of the facts, without overtones of authority, and then make up their own minds.

Students will listen more readily to other students than to faculty members on a topic of this nature; therefore, whatever educational program is developed would be more effective and generate more student enthusiasm if it were organized and conducted by students themselves.

Since the students responsible for any drug abuse education program must be well versed in the use and abuse of drugs themselves, pharmacy students would appear to be the ideal group for the task. If they want to enlist the aid of other student groups, this step would be fine. But pharmacy students alone should be responsible since drugs are the tools of their chosen profession.

Subsequent to the Dallas meeting, we agreed to set up pilot programs on our respective campuses to test the new drug abuse education idea. The proposed programs were explained to the pharmacy school deans and their permission to proceed was obtained. After we found student organizations which were active, imaginative and self-starting, to sponsor the test programs, we helped the students organize and develop their particular programs. To help with the planning, Smith Kline and French Laboratories of Philadelphia prepared a special *College Drug Abuse Manual*. The manual, an 8½- by 11-inch binder, contained several valuable suggestions and ideas. Following the guidelines set forth in the manual and the advice of the faculty, we put the programs in effect. Implementation of the new drug abuse education idea varied slightly on each campus.

MINNESOTA—THE ICE CREAM HABIT

The drug abuse program at the University of Minnesota was developed after discussions with the student activities bureau, dean of students, student union director and dean of the college of pharmacy. The consensus was that the project must include student participation from the beginning. Consequently, the APhA student chapter was given the responsibility for planning, publicity and programming. The Union Board of Governors (UBOG), a student executive group, agreed to co-sponsor the program and to devote \$150 to publicity. Kappa Epsilon, Phi Delta Chi and Kappa Psi each devoted manpower for the project as part of their professional activities.

The sponsors agreed upon a two-day afternoon conference. The time of day was an important factor since 75 to 80 percent of the students are commuters who leave the campus after their last class. October 25 and 26 were selected since these days followed homecoming by 10 days and preceded mid-quarter exams by about a week. The UBOG, which sponsors regular noon-hour programs in the ballroom, permitted use of that facility for the program.

Plans called for a film to be shown during the noon hour of the first day, with the main presentations, a series of talks followed by a panel discussion, to be given the following day. The idea behind a film-only program the first day was that it would serve as a publicity device for building an audience for the next day's major presentations.

Since student advisors felt that a catchy title for the program was necessary, the planners came up with "The Ice Cream Habit," a drug-abuse term, meaning a small, irregular habit. During the summer, members of the university staff made arrangements for speakers, most of whom were drawn from the school of medicine.

In publicizing the program, 30 two-by three-foot tagboard signs were placed in major campus buildings, residence halls and eating establishments. An exhibit was set up in a large display window at the Minnesota Union. One hundred and fifty 8½- by 11-inch notices were placed on campus bulletin boards, each housing unit counselor read an announcement at the unit's regular meeting. WMMR, the university residence hall station, taped an interview with the student chapter president and a press release from the university news service aided the advertising and word of mouth communication.

The film, *Narcotics, The Decision*, which had been obtained from the university's extension film library, was shown twice during the first day of the program,

at 11:30 and 12:30. The first showing drew about 500 students, the second between 350 and 400. Though rather dated, this film was selected because it portrayed the abuse of non-narcotic drugs. A student introduced the film before each showing and explained the purposes of the two-day conference.

The main program featured seven half-hour talks followed by a one-hour panel discussion. Each speaker was introduced by a different student chapter representative. The subjects discussed were—

Growing problem of drug abuse, drug taker personality, use and abuse of narcotics, use and abuse of stimulants—depressants, use and abuse of alcohol, use and abuse of hallucinogens, and human cost of drug abuse.

The panel, moderated by a student and composed of representatives of government, medicine, police, the religious community and campus officials, discussed the subject "Drugs on Campus." Each person who attended the program was given a copy of the SK and F brochure, *The Empty Life*. More than 1,900 were distributed.

A tape recording was made of the conference with portions used on WMMR and KSTP, the NBC radio affiliate. News accounts of the proceedings appeared in the *Minneapolis Star* and the campus newspaper, the *Minnesota Daily*.

In evaluating the two-day program, the sponsors made the following recommendations—

1. For maximum impact, the entire program should be presented in one day. This conclusion was based on the drop in attendance from the first to the second day.
2. The one-day program should be no longer than two and a half hours. It was felt that the individual presentations had been too long and that the four talks on use and abuse could have been given as one presentation.
3. A follow-up program for residence units would carry the message to smaller groups in a more intimate setting.
4. The program should be presented every other year.

TEXAS—DRUG ABUSE ON CAMPUS

Lambda chapter of Phi Delta Chi, the professional pharmacy fraternity at the University of Texas, sponsored the program, a symposium during which five speakers each made 20-minute presentations. A question and answer period followed the last talk. The program ran from 7:30 p.m. to 10:30 p.m. in the student union ballroom. The audience, including pharmacy students, numbered between 350 and 400.

Four of the speaker were drawn from the university faculty; the fifth speaker was the director of the Dallas office of the Bureau of Drug Abuse Control. The faculty members were an associate professor of pharmacology, assistant professor of psychology, assistant professor of sociology and the director of the student health center, a psychiatrist. The moderator was W. J. Sheffield, associate professor of pharmacy.

Press releases were distributed personally to the student newspaper, to newspapers in Austin, Dallas, San Antonio and Houston, to the wire services and to area radio and television stations. All news media were also sent a letter describing press facilities at the program and inviting coverage. Four radio stations used their "Community Bulletin Board" to announce the program from three to five days in advance. One tv station carried some film of the program while it was still in session.

Approximately 120 cardboard signs, 14 by 22 inches, were tied on trees and posted on bulletin boards around campus. The signs, printed on a Line-O-Scribe machine, carried the following copy—

Phi Delta Chi, Pharmacy Fraternity Presents Drug Abuse on Campus, An Objective Symposium On College Drug Abuse Today, Wed. Feb. 8—7:30 p.m., Union Ballroom.

An eight- by eight-foot painted wooden sign with similar copy was placed on the west mall, one of the most trafficked areas on campus. Faculty members, of the college of pharmacy and other schools, were encouraged to make announcements concerning the program in their classes.

The sponsors were disappointed by the small turn-out which they attributed to the overabundance of student-sponsored programs, the lack of well-known speakers and a small advertising budget (\$15). They concluded, therefore, that a successful program depends on well-known speakers, a topic of vital interest and heavy advertising.

Sponsored by the Phi Delta Chi fraternity at Butler University, the program, "Pop Drugs—Drugs for Kicks," consisted of group discussions in housing units climaxed by a formal symposium. The total program ran one week.

In January and February of 1967, the president of the local chapter of Phi Delta Chi, met with the Pan-Hellenic Council (governing body of the university's sororities), the interfraternity council and residence hall presidents to arrange the times and dates for group discussions on drug abuse.

Before their visits, the Phi Delta Chi men spent approximately three hours in group preparation, with special attention to the pharmacology of amphetamines and barbiturates. The 21 pharmacy students involved were either fourth- or fifth-year students with previous apprentice employment.

From February 16 to February 22, each housing unit was visited by a three-man team from the pharmacy fraternity. These men led group discussions on drugs, their use and misuse and at the same time, explained the purpose of the program to stimulate attendance at the symposium. Each presentation averaged a half hour, followed by a question and answer session. Some of the students brought along charts and diagrams to highlight the discussions.

The speakers—a psychiatrist, pharmacologist, research specialist and inspector for the Indiana State Board of Health—were originally contacted by Dale Doerr, co-advisor for the chapter. Prior to the meeting, the panelists met three times to exchange ideas and make preparations.

The university's public relations director handled initial contacts with the two television stations and two city newspapers. As a result the program received both newspaper and TV coverage. Local and university radio stations gave spot announcements during the week prior to the symposium. Based on the near-capacity attendance and on audience reaction, the program was judged to be a success. Much of the success was attributed to the preprogram visits which reached one-fifth of the students and helped build considerable interest in the subject of drug abuse.

SUMMARY

What was learned from these pilot programs? Several things. First, the programs represent an ideal way to counter the sensational—and often negative—publicity that the college drug abuse problem has been receiving. Second, that such programs attract the favorable attention of other communities and other campuses to the pharmacy schools involved. Third, the programs highlighted some of the practical problems (*e.g.*, in content, length, publicity and visual aids) which must be ironed out to assure maximum success in the future. Fourth, the programs demonstrated the keen interest of college students in drug use and abuse. Finally—and perhaps most important of all—the programs demonstrated that pharmacy students relish the chance to talk about drugs, the tools of their profession, in real-life situations.

So far, the new pharmacy-oriented drug abuse education program has been extremely successful. This isn't the first program designed to educate college students about drugs; but this is the first educational program designed to be organized by pharmacy students, promoted by pharmacy students and actually run by pharmacy students.

As practicing pharmacists you can do a great deal to extend this educational effort. First, you can offer your support to the campus drug abuse education programs that are getting underway. During the next few months, we will be contacting pharmacy deans across the country and asking them to approve such programs on their campuses. Several pharmacy educators have already written us to ask for assistance in developing such programs.

You can support these efforts by writing to the dean of the pharmacy school in your community to let him know that you recognize the need for more balanced drug education on our campuses; that you know about and approve the new drug education programs being developed by pharmacy students. Your encouragement and support will mean a lot to him—and to the success of the program. Nominal financial support to the student organization for publicity costs would be helpful in some instances.

There is, however, a much more important contribution you can make—you can extend the same balanced drug education message to the young people in your own community. Today, your time-honored role as a dispenser of medication is being expanded. More and more, the modern pharmacist is called upon to dispense

drug information as well as medication. And rightly so. As pharmacists, you have a better opportunity than any other member of the health team to educate the public about the drugs they take. The late W. W. Charters underscored this fact when he once said—"A well-informed pharmacist is the best single individual to disseminate information about public health."

Nowhere is the need for such information more critical than it is with the nation's youth. Existing facilities for educating them about drugs leave a lot to be desired. Smith Kline & French Laboratories has been involved for the past few years in providing drug abuse education and instruction to law enforcement officers throughout the country. This work has carried them into contact with several state agencies responsible for developing the educational materials used to teach children about drugs. As a result, they have had many opportunities to see the materials teachers are using in various parts of the country to teach this subject. Much of the material they examined was outdated, incomplete, misleading, one-sided or—even worse—totally inaccurate! In many instances, educational agencies had no material on the subject.

This is why your efforts on this behalf are so vital. You have a professional duty to see that the children in your community get the right information about drugs. There are several ways to do this—speaking engagements before high school groups, grade school groups, church groups and other youth organizations; checking on the kind of drug education being offered in your community schools and, if you feel it needs improvement, working with the local parent-teacher organization to improve it. Above all, you should promote your own drug expertise to your patrons. To the average layman, especially the impressionable youngster, drugs are exotic, mysterious substances. He may read or hear that some drugs are capable of producing pleasant effects on his mind, but he doesn't know much more. Because of your professional training, you are better able to explain to him both the good and bad properties certain drugs have, thus keeping them in their proper perspective.

Today's problem of drug abuse among young people, combined with your emerging role as health educators, constitutes a clear call to action.

BIBLIOGRAPHIES

Dale W. Doerr, professor of pharmacy administration at Butler University, earned his BS at Drake University, MS at the University of Illinois and PhD in pharmacy administration at Purdue University. Doerr, a registered pharmacist in Iowa and Illinois, is a member of APhA, Academy of Pharmaceutical Sciences, Academy of General Practice of Pharmacy and Indiana Pharmaceutical Association. He is chairman of the pharmacy administration section of the AACP conference of teachers and is active in Rho Chi and Phi Delta Chi.

Hugh F. Kabat, associate professor of pharmacy and director of the hospital pharmacy graduate program at University of Minnesota, has been active in hospital and community pharmacy as well as in the educational field. He earned his BS and MS from the University of Michigan and his PhD from the University of Colorado. Professor Kabat has held several consultantships and is a contributing editor to *Drug Intelligence*. Among his professional memberships are APhA, Academy of Pharmaceutical Sciences, AACP and ASHP.

William J. Sheffield is associate professor at the University of Texas college of pharmacy. His pharmacy degrees, a BS, MS and PhD, were earned at the University of North Carolina. From January 1943 to November 1945, Sheffield was a pilot in the U.S. Army Air Force and at present holds the rank of major in the U.S. Air Force Reserve. APhA member Sheffield has been secretary-treasurer and chairman of the section on pharmaceutical technology, Academy of Pharmaceutical Sciences, and also active in AACP, AAAS, Phi Delta Chi and Rho Chi.

William J. Skinner, manager of consumer production at Smith Kline and French, is a native of Indiana. He earned his BS at Butler University and his JD at Indiana University school of law. He is a registered pharmacist in Indiana and Pennsylvania and was admitted to the Indiana and federal bars in 1965. Skinner is on the advisory panel of Columbia University's Respect for Drugs project, on the board of directors of the Greater Philadelphia Council on narcotic and dangerous drug abuse and a member of APhA and ASHP.

ATTACHMENT B

THE PHARMACIST AS AN EDUCATOR IN DRUG ABUSE

(By Arthur E. Schwarting)

Arthur E. Schwarting, Dean, University of Connecticut School of Pharmacy, and President, American Association of Colleges of Pharmacy.

Education of our youth in high schools and colleges about drug use, misuse and abuse has taken many forms. One of the most effective forms has been a program using pharmacy students as educators. They are uniquely *qualified*, many have an intense *interest* in the problem and they are *youthful*. All three of these attributes are necessary for an effective program.

QUALIFICATION

Any effort to deal with the drug abuse problem, regardless of its location, must be based on recognition of two rather separate and distinct topics—*why* a person uses drugs and the *nature* of the drug that is used. The person who uses amphetamines to lose weight is unlike the person who uses that drug to "speed." The physiological response and the toxic effects of alcohol are unlike those of LSD. Both parameters—reasons and agents—are amenable to education programs conducted by different qualified personnel.

The pharmacist, and similarly the pharmacy student, makes his greatest contribution to this effort through his knowledge of drugs—their chemistry, their action, their metabolism and their toxic effects. Pharmacists have been given the legal and moral responsibility to oversee the distribution of all legal drugs and to provide authoritative drug information to the public and the health professions. All presently-abused drugs (except marihuana) fall into pharmacological classes which have been studied in depth by pharmacists.

Pharmacists have no bias in their presentation of drug information. They can present accurate information about drugs and the dangers associated with irrational use without emotion. It is quite apparent that most youth reject receiving information from individuals who can be identified as possessing a preconceived bias, as with the clergy (it's immoral, don't do it), the police officer (it's illegal, don't do it), the ex-addict (look what it did to me, don't do it), the school principal (I'll tell your parents, don't do it) or the military commander "I'll bust you, don't do it).

INTEREST

For several years, pharmacy students across the country have volunteered their services in drug abuse programs directed to high school and college groups. At the University of Connecticut students in the second and third professional classes volunteer during the first weeks of classes and demonstrate their sincerity by attending evening training sessions. This program serves to focus their attention on those aspects of their education which best fulfill the needs of pending audiences. Those students with previous experience in the programs discuss successful methods of presentation and pitfalls that should be avoided. Additionally, these students are provided the most recent information on abuse of drugs and are appraised of problems in the communities in which they will appear. Finally, these students are brought to one of the area's drug rehabilitation houses to speak with recovering addicts and to observe rehabilitation techniques.

In their first exposure at a school setting, the pharmacy students meet with a dozen students representing a cross section of the student body to learn of the general level of drug interest, types of drugs being used and special interest topics. The pharmacy students then work in teams of couples with 20-30 students in an existing class makeup so that the audience members are familiar with each other. While these discussions proceed (1-6 hrs.) the faculty advisor to the pharmacy students meets with teachers and school administrators to educate these persons and to describe the program that is in progress.

The goal of the pharmacy student is to provide critically needed information about drugs before they are encountered on the street. They also try to dispel any mysticism surrounding drugs by describing in simple terms the physiological and toxicological effects of drugs. In this way they tend to discourage the user.

Although the overt purpose is not to prohibit drug use, the students make a special effort to thoroughly reveal the irrational nature of this behavior.

The program at the University of Connecticut was composed of 44 visits during the school year 1970-71 by from 4-10 students each. There was no compensation for this labor.

An additional program by the School of Pharmacy is conducted in the campus community. A two-credit course entitled "Elements of Drug Use" is available, without prerequisite, to all students in the University. This course, taught by a young and youthful instructor, provides elementary and accurate information about drug action and toxicity and concludes with the drug abuse problem. This service course is always oversubscribed and is utilized as an elective for students in education, physical education, and by majors in family relations and child development. It, however, attracts students from all areas.

This course is under constant evaluation, and changes in content and manner of presentation have been numerous. Information obtained in this way is used in the pharmacy student program to the high schools.

YOUTH ASPECTS AND TRUST

The best form of drug education seems to occur through peer association. The college sophomore has little reason to distrust another college student or youthful instructor. The high school student does not question the motives of a college student. Our program takes advantage of this inherent trust of one's peers—we have been unsuccessful in any departure from this philosophy.

PHARMACISTS IN THE MILITARY AS DRUG ABUSE SPECIALISTS

Major emphasis on the drug abuse problem in the military has been on enforcement. Very little effort has been directed to programs of education. Education is one of the important keys to prevention and programs of education must be provided. It is essential that the service man be educated about the physiological and toxicological implications of drug misuse.

In the emerging programs that focus on education of military personnel, the pharmacist is an essential component of the educational team. With five or six years of education that is centered on the physical-chemical properties, the pharmacological action and the toxicology of drugs, and with an understanding of people and disease, he has an expertise that is unique and effective and one that will complement psychological, sociological and other medical contributions to the program. His skill and intellect can be utilized at all levels in an educational program. Moreover, because of his background in analysis of drugs, he could serve on programs concerned with detection of drugs. The pharmacist is the only health professional whose exclusive specialization is drugs and their action—including drugs of abuse.

Few pharmacist are given commissions, and no pharmacists have ever been drafted. The Department of Defense must be informed of the needs of our servicemen with regard to adequate drug delivery services and the utilization of the pharmacist as a component of a health education team concerned with drug misuse.

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ATTACHMENT C

STATEMENT PREPARED BY GEORGE P. HAGER, DEAN, SCHOOL OF PHARMACY, THE
UNIVERSITY OF NORTH CAROLINA

The abusive use of drugs in the Armed Forces, as elsewhere, is a many-faceted problem which requires a multilateral solution involving various types of professionals and specialists in the Military. *Crisis intervention and treatment* constitute a medical problem and require the supervision and services of physicians. Behavioral scientists should be primarily responsible for *rehabilitation*. *Prevention and control* of drug abuse, involving both *education and regulatory procedures* is a principal and, perhaps, most productive measure for dealing with the drug abuse problem. The *pharmacist* should have primary responsibility for the *education* phase and, in the *control* phase, he should work very closely with legal and police personnel and he should consult regularly with physicians regarding prescribing practices that may predispose toward abusive utilization.

The pharmacist is qualified for a leading role in *prevention and control* of drug abuse for a number of reasons: (1) the nature of his drug distributive mission requiring his surveillance of the utilization of many controlled substances and providing to him an insight into developing drug abuse problems at an early stage; (2) his education (B.S. in Pharmacy) and his daily experience with drugs; and, perhaps, most importantly (3) his sensitivity to the drug abuse problem and his motivation to contribute toward its solution.

The pharmacist's motivation is clearly demonstrated by the active involvement of schools of pharmacy and of practicing pharmacists at the local level in efforts aimed at the relief of the problem. One specific example will be presented as an indication of the general situation. At the end of the academic year, 1968-69; under the aegis of the local Student Branch of the American Pharmaceutical Association, a group of twenty upper classmen in the School of Pharmacy, The University of North Carolina, indicated a desire to engage in a drug abuse education program during the following year. A carefully selected compilation of drug abuse information materials was given to each of them for study during the summer. During the first six weeks of the fall semester, 1969, seventeen of the students were provided intensive training by experts on the drug abuse problem. Through the remainder of the year, 1969-1970, the specially trained students, usually in small groups, made 65 presentations throughout the State and reached substantial numbers of junior and senior high school students. At a meeting of the heads of various State departments in the spring of 1970, the official representing the North Carolina Department of Public Instruction stated that the pharmacy students' project at that time was the principal thrust in the secondary schools toward preventive education of secondary school students in the area of drug abuse. Because of this experience, the North Carolina Department of Public Instruction requested the School of Pharmacy to provide an intensive training program for a cadre of secondary school personnel in the summer of 1970 and also requested that specially-trained pharmacy students make presentations at all of the 500 secondary schools in North Carolina. A DRUG ABUSE EDUCATION PROGRAM, including a TEACHER DRUG ABUSE EDUCATION PROJECT and a STUDENT-TO-STUDENT DRUG ABUSE EDUCATION PROJECT, was planned as a cooperative effort of the School of Pharmacy, the N.C. Department of Public Instruction, and the N.C. Pharmaceutical Association. Support for the PROGRAM was provided by the Z. Smith Reynolds Foundation. Partial support of the TEACHER DRUG ABUSE EDUCATION PROJECT also came from a grant to the N.C. Department of Public Instruction via the National Drug Education Training Program.

During the summer of 1970, three week-long training programs were held at the School of Pharmacy and they were attended by a total of 173 teachers, counselors, principals, and other administrative personnel, representing almost every school district in the State. A copy of the program appears in APPENDIX A and a copy of "Proceedings—Teacher Drug Abuse Education Project" accompanies this statement. During the academic year, 1970-1971, approximately seventy specially-trained pharmacy students made presentations at 225 secondary schools and reached approximately 55,000 secondary school students (APPENDIX B). The effectiveness of this STUDENT-TO-STUDENT DRUG ABUSE EDUCATION PROJECT is attested by numerous comments of the personnel in the secondary schools visited. A feature of the presentations was a question-and-answer period in which student audiences submitted many of the questions in writing. Some of these have been compiled in the booklet, "Kids 'n Drugs" by Leonard Berlow, the faculty director of the PROJECT (A copy accompanies this statement). Mr. Jesse M. Pike, Jr., as student director of the PROJECT, worked closely with Mr. Berlow. In June, 1971, a day and a half program was presented in three locations in different parts of the State for secondary school personnel as a follow-up on last summer's TEACHER DRUG ABUSE EDUCATION PROJECT (program appears in APPENDIX C). At the follow-up program, attended by a total of 145 teachers, etc., secondary school personnel described local programs in which they were intimately involved pursuant to their training in the summer of 1970. What they have accomplished indicates the effectiveness of the TEACHER DRUG ABUSE EDUCATION PROJECT. The 1971-1972 STUDENT-TO-STUDENT DRUG ABUSE EDUCATION PROJECT is already underway with more than fifty pharmacy students involved at this stage.

The foregoing description of the DRUG ABUSE EDUCATION PROGRAM is an example of similar programs conducted by other schools of pharmacy. It

demonstrates the sensitivity of the pharmacy profession for the drug abuse program and the motivation, in the pharmacy profession, to prevent drug abuse through education. The pharmacy student participants, as they graduate, will swell the ranks of the many pharmacists already in practice who are most active in the education of the people in the communities they serve as a measure toward prevention of drug abuse.

The same motivation of military pharmacists to engage in educational activities that help to prevent drug abuse is exemplified by a presentation by Captain Dean L. Peyton (pharmacy officer at USAF Medical Center, Scott AFB) and Captain David R. Stevenson (pharmacy officer at 317 Tac Hospital, Lockbourne AFB). A copy of their manuscript, "Better Living Through Chemistry", presented at the 1971 USAF Pharmacy Seminar, Brooks AFB, is attached.

Crisis intervention, treatment, rehabilitation, and prevention through education and control require collaboration of physicians, behavioral scientists, legal and regulatory personnel and pharmacists, with the fully trained, professional pharmacist leading the way with regard to *preventive* measures. An assessment of the drug abuse problem locally and an evaluation of relief measures is a component of the program that is often neglected. Accurate assessment of the problem and evaluation of effectiveness would confirm the pharmacist's leadership role in dealing with the drug abuse problem in the Armed Forces—provided military pharmacists, fully qualified by professional education in schools of pharmacy and by the experience (internship) required for licensure are given the opportunity to demonstrate what they can do.

AMERICAN NURSES' ASSOCIATION, INC.,
New York, N.Y., June 28, 1971.

HON. PAUL ROGERS,

Chairman, Subcommittee on Public Health and Welfare, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Washington, D.C.

DEAR MR. ROGERS: The American Nurses' Association, the professional organization of registered nurses, wishes to express its strong support of efforts to attack the critical problem of drug abuse which has become a matter of grave concern in this country.

The causes of drug abuse are linked with the ills of society as a whole. Addiction is a health and social issue that requires rehabilitation measures rather than the punitive approach, the pattern that has commonly been employed in dealing with the addict.

The nursing profession is committed historically to enlighten and compassionate care of those who suffer physically and emotionally. By the very nature of their work and the many settings in which they function, nurses are much involved in the drug abuse problem. Therefore, this association supports legislation which would focus on drug abuse as a health and social issue.

We believe that efforts must be made to separate fact from fallacy about drugs and that programs of public education should be based on the facts and not the assumptions that result in a credibility gap and have the effect of encouraging experimentation with drugs, especially by the young.

We would point out, also, that the present substitutes for opium and opium derivatives—demerol, dilaudid, methadone—are just as addicting as opium. Methadone maintenance programs which have offered a degree of hope for heroin addicts may well be just a stop gap and temporary solution and further investigation into the long term consequences of this approach is essential. Concomitantly, ways and means of assisting people to withdraw from methadone should be initiated.

Funding should be available for drug education programs for children, adolescents, adults and those professionals concerned with resolving the drug abuse problem; for treatment programs that take into account not only the physical effects of withdrawal but acknowledge also the psycho-social dependence on drugs that can be more difficult to cope with; for assistance to help former addicts resume their education or secure job training so they may become productive members of society. Government also has the responsibility for assuring through appropriate legislation that other requirements for physical, mental and social well being such as adequate income, housing and nutrition are met.

The American Nurses' Association has submitted to the Department of Health, Education and Welfare for funding a project to enhance the contribution of professional nurses in the field of drug abuse. Curriculum guidelines would be developed for use by educators in basic nursing programs, graduate programs and continuing education programs for practicing nurses.

Nursing, as the largest of the health professions, does have the potential to be a strong and positive force in combating drug abuse and treating drug addiction. The American Nurses' Association has been committed by its membership to help nurses realize this potential. The following resolution was adopted at the association's 1970 convention in Miami Beach, Florida.

Whereas the Federal Bureau of Narcotics reported 64,000 known narcotic users in the United States on December 31, 1968, the projected figure is now 132,000, and the number of experiments with mind altering drugs is unknown; and

Whereas its causes are inextricably linked with the ills of society as a whole, and its prevention and cure must be seen as an individual as well as a professional responsibility; and

Whereas there is increasing recognition of the fact that addiction is a health and social issue requiring rehabilitation rather than punitive measures; and

Whereas, the challenge in this pioneering period of seeking preventive and therapeutic approaches to this critical issue necessitates that nurses educate themselves about the problem and keep sensitive to the suffering of the drug abuser: Therefore, be it

Resolved, That ANA work at all levels to help develop, collate, and disseminate definitive educational materials on this issue to nurse practitioners; and

Resolved, That nurses seek out and work with related health groups in combating the problem, supporting comprehensive rehabilitation programs and provide effective leadership where none exists; and be it further

Resolved, That nurses support legislation that approaches drug abuse as a health problem.

I respectfully request that this letter be included in the record of your committees hearings on drug abuses.

Sincerely yours,

EILEEN M. JACOBI, R.N. Ed. D.,
Executive Director.

NATIONAL GRANGE,
Washington, D.C., June 28, 1971.

Hon. PAUL G. ROGERS,
Chairman, Subcommittee on Public Health and Environment, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: The National Grange has been very deeply concerned over the widespread use of harmful drugs by children of pre-high school and high school age. Our public elementary and high schools have become the breeding grounds of the future drug addicts.

Early in the '60's the Grange conducted discussions on the drug problem and what the Grange could do to assist in fighting the illegal use of drugs, marijuana, LSD and similar narcotics. These discussions were held in local, state and national Grange meetings and have resulted in the following policy position being adopted as National Grange policy.

As a result of the study and investigation of the "National Grange Committee on Health" the Grange realized that drug use by young people had to be treated as an illness and that the main thrust for control of the use of illegal drugs must be to stop the traffic of drugs rather than to punish the user.

The delegate body of the National Grange, meeting in its Annual Session in 1960, called for heavier penalties for those who deal in or "push" illegal drugs.

"NARCOTICS"

"Whereas, the peddling of narcotics to youth is increasing: Therefore be it *Resolved*, That the Grange demand stronger laws and heavier penalties for first offenders and increased penalties for repeated offenses."

Throughout the following years the National Grange has expressed its concern over the illegal use of drugs and has worked for stricter laws and regulation pertaining to the illegal use of such drugs.

"USE OF NARCOTICS"

"Whereas the punishment for the use of narcotics such as marijuana is being considred to be changed from a felony to a misdemeanor; and

"Whereas, this will make a lesser punishment to a pusher; and

"Whereas, this will create more pushers to further more people to become addicted to narcotics: Therefore be it

"Resolved, That the Grange favors keeping the law a felony; and be it further

"Resolved, That stricter laws be enacted and the punishment for a pusher and user be more severe and better administered; and be it further

"Resolved, That this resolution be for the use of LSD or any kind of drug that causes addiction, unless administered by a lifetime physician."

In spite of increased efforts by law enforcement agencies at all levels of government, illegal drug traffic and their use by people of all ages is on the increase. The information on increased drug by members of our armed forces is indeed disheartening and adds a whole new extra dimension of human suffering to the cost of the war. We applaud the Administration's efforts in this and other areas of illegal drug use and enthusiastically support more activity by the Federal government.

The National Grange, at its 104th Annual Session, held in November of 1970, adopted the following policy statement and resolutions pertaining to drug abuse:

"There is an awareness of the widespread use of harmful and habit-forming drugs with special concern for the alarming number of youth using drugs out of curiosity or for other reasons and without the advice of a doctor. How tragic if numbers of fine young people should be coerced to try certain drugs just for a kick and subsequently became drug addicts.

"We believe there should be a strong and effective deterrent to the sale and distribution of harmful and habit-forming drugs. There should be greater effort to destroy the sources of these drugs by providing necessary legislation and law enforcement and by diplomatic action when the source is beyond our national boundaries.

"We realize that much is already being done to reduce drug traffic and we express appreciation to law enforcement agencies and to the State Department for their efforts.

"We recommend that courses of study be included in the curriculum of elementary schools to inform our children of the dangers of using drugs that are not prescribed by a doctor. We urge all Grange members to use their influence to achieve this objective."

"STOPPING DRUG TRAFFIC"

"The National Grange (1) urges Subordinate Granges to educate its members and the public regarding dangers, symptoms and problems from drug use; (2) recommends congressional legislation to require impounding of all vehicles found in use in illegal drug traffic; increase the number of custom inspectors assigned to search for smuggled drugs; (3) requests intensified efforts by the government through diplomatic channels, to reduce production and export of "hard drugs" from foreign countries; (4) asks subordinate Granges to consider establishing "Halfway Houses" in their communities to assist rehabilitation of young addicts."

"LSD AND MARIJUANA"

"We favor outlawing LSD and marijuana on the same basis as heroin and other harmful or deadly drugs. We also favor action to eradicate the marijuana plant."

The Grange is a family, fraternal, community farm organization with a deep sense of responsibility to God, country and the well-being of our fellow man. As such we recognize that drug abuse is the result of man's inability to relate himself to the society around him. In this respect, we all bear a portion of the blame for contributing to the increased drug problem.

However, changing the values of man is a long, educational process and one in which we all must remain active, as this, in the long run, will be the real solution to the illegal use of drugs.

In the meantime, all efforts should be used to prevent the further increase of illegal drugs by people of all ages. We therefore support H.R. 9264 and similar bills to establish a Special Action Office for Drug Abuse Prevention to concentrate the resources of the Nation in a crusade against drug abuse.

We would appreciate this letter being made a part of the hearing record.

Sincerely,

JOHN W. SCOTT,
Master.

PARENTS FOUNDATION AGAINST DRUG ABUSE,

*Hackensack, N.J., June 29, 1971.**Committee on Interstate and Foreign Commerce, Rayburn House Office Building,
Room 2125, Washington, D.C.*

Att: Mr. W. E. Williamson, Clerk.

GENTLEMEN: We are, unfortunately, unable to make arrangements for a member to appear in our behalf on such short notice, but would like our statement, below, to appear on the record.

It is our sincere wish and desire to eliminate the need and presence of drugs. Removal of the availability would be the foundation for the cure of drug abuse, therefore, our organization's prime dedication is the removal of drugs.

We are helpless to do anything about the drug traffic in this country. Our government, *you*, are our only hope.

The influx of drugs into the country is crippling and killing our children and will affect generations to come.

Drug abuse is claiming more lives than the war. Where are all our representatives who will speak up against drug traffic. Isn't this just as important? It's happening *here* and now.

We want the government to make a concentrated effort to stop the drug traffic. Your recognition of the drug problem in Vietnam and your efforts at rehabilitation is admirable but we know that without lengthy and proper rehabilitation and without ridding the streets of drugs, your efforts will all be in vain.

Some of us are parents of addicts. Other members are simply concerned citizens. We all live in constant fear. We know the pain and misery and heartache first hand.

Please hear our pleas. Today our children are addicts. Tomorrow may be yours.

Very truly yours,

PARENTS FOUNDATION AGAINST DRUG ABUSE,

IRWIN HANDLER,

President.

CITY OF FARGO, NORTH DAKOTA,

BOARD OF CITY COMMISSIONERS,

JULY 1, 1971.

Hon. ARTHUR LINK,

*U.S. Congressman, State of North Dakota,**House Office Building, Washington, D.C.*

DEAR CONGRESSMAN LINK: Enclosed is a Resolution entitled "Resolution Endorsing the Federal Narcotics Treatment and Research Agency" which I offered and was unanimously adopted by the Fargo City Commission at its Regular Meeting held June 29, 1971.

I sincerely hope this Resolution can be presented to the appropriate committees of the Congress resulting in legislation at the earliest possible opportunity.

With kindest regards.

Sincerely,

HERSCHEL LASHKOWITZ,

Mayor and President.

Enclosure.

REGULAR MEETING OF BOARD OF CITY COMMISSIONERS, TUESDAY, JUNE 29, 1971

The Regular Meeting of the Board of City Commissioners of the City of Fargo, North Dakota was held in the City Commissioners' Room at the City Hall at 7:00 o'clock p.m., Tuesday, June 29, 1971.

The Commissioners present or absent were as shown following:

Present: Bromenschenkel, Markey, Schuster, See, Lashkowitz.

Absent: None.

President Lashkowitz presiding.

* * *

RESOLUTION ADOPTED ENDORSING THE FEDERAL NARCOTICS TREATMENT AND
RESEARCH AGENCY

President Lashkowitz relinquished the Chair to offer the following Resolution and move its adoption: (Vice President Markey presiding)

Whereas the explosion of the drug culture among all groups of American citizens poses a serious threat to the health and wellbeing of our Nation; and

Whereas in the United States today drug addiction knows no neighborhood lines, no state, county or city boundaries, and no racial or ethnic distinctions; and

Whereas the shattered minds and hopeless futures of thousands upon thousands of our children are grim testimony to governments' inadequate response; and

Whereas in America today, the narcotics plague ravages our people, fills our streets with terror and our homes with desperation; and

Whereas the Federal Government has a fragmented effort bereft of coordination and hence, local officials waste time and energy attempting to weave the fragmented Federal contributions into a focused local program; and

Whereas the Plague of narcotics addiction will not yield to anything less than a total commitment to treatment and research, focused in a single agency at the national level and funded with real awareness of the devastating human and dollar cost of the narcotic problem: Now, therefore, be it

Resolved, That the City of Fargo, concurring with the United States Conference of Mayors calls upon the Federal Government, both the Congress and the President, to provide for a single, professional, fully-funded Federal Narcotics Treatment and Research Agency with a goal of a billion dollar program in three years providing basic financing for each city to establish a local comprehensive drug treatment program to rid our nation of this evil; and be it further

Resolved, That this Resolution be inscribed upon the permanent records of the proceedings of the Board and certified copies forwarded to the North Dakota Congressional Delegation, the Majority and Minority Leaders of the House and Senate, the President of the United States, the Department of Justice, the Department of Health, Education and Welfare, and to the Department of Housing and Urban Development.

Second by Schuster. On the vote being taken on the question of the adoption of the Resolution Commissioners Lashkowitz, Schuster, Bromenschenkel, See and Markey all voted aye.

No Commissioner being absent and none voting nay, the Vice President declared the Resolution to have been duly passed and adopted and returned the Chair. (President Lashkowitz presiding.)

HERSCHEL LASHKOWITZ,
Mayor and President.

* * *

CERTIFICATE OF CITY AUDITOR

STATE OF NORTH DAKOTA
County of Cass, ss.

I, F. R. Fahrlander, do hereby certify that I am the duly appointed, qualified and acting City Auditor of the City of Fargo, North Dakota; and

That the foregoing is a full, true and correct copy of a Resolution adopted by the Board of City Commissioners of the City of Fargo at a Regular Meeting of the Board held on Tuesday, June 29, 1971; and

That such Resolution is now a part of the permanent records of the City of Fargo, North Dakota, as such records are filed in the office of the City Auditor.

F. R. FAHRLANDER,
City Auditor,
City of Fargo, North Dakota.

ALEXANDRIA COMMUNITY WELFARE COUNCIL,
Alexandria, Va., July 15, 1971.

Mr. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
Rayburn Building, Washington, D.C.

DEAR MR. STAGGERS: My name is Zoe H. Carrigan and I am a citizen member of the Governor's Council on Narcotics and Drug Abuse Control of the Commonwealth of Virginia. My professional occupation is as Regional Director of the Health and Welfare Council of the National Capital Area in the Alexandria region.

I am glad to have the opportunity to speak to you today about a problem which has occupied a considerable amount of my personal and professional time for the past three years. I helped to organize a citizens group in Alexandria which attempted to bring about a comprehensive and coordinated approach on a local level. The leaders of the group eventually became the citizen members of the Alexandria Drug Abuse Coordinating Control Commission. They have attempted to deal with the growing drug abuse problem on a local level with little leadership and no funds from the state and a modicum of funds from federal sources.

The local drug abuse commission is made up of agency representatives from the health, mental health, police, the commonwealth attorney, schools, private agencies and five citizen members. They have made progress in initiating drug abuse education in the elementary schools and have provided some funds for additional officers on the vice squad and for treatment of drug abusers. They have some idea of approaches to the problem. What they need is money.

The same situation pertains on the state level. The State Council is made up of representatives of the various agencies and departments of the state government—health, mental health, law enforcement, the attorney general, Board of Pharmacy, vocational rehabilitation, education, welfare, corrections, youth commission, and four citizen representatives. A state plan has been developed assigning responsibility for various program components to the various agencies. The estimated cost for two years is \$11,025,000 for the treatment aspects alone. This does not include law enforcement or education. The major funds have come from the Law Enforcement Assistance Administration to operate the Council and regional task forces. Some federal funds come from NIMH, from OEO for treatment programs, from Welfare, and some from the Office of Education. We certainly see the need for coordinated comprehensive programming to reduce the multiplicity of funding sources and antagonistic treatment philosophies.

An aggressive law enforcement approach will fill the prisons and jails without adequate funds for treatment and rehabilitation. We have already learned the lesson from the past federal programs that incarceration with little treatment and no follow-up on return to the community results in a cure rate of around 2-5% for narcotic addiction. The newer therapeutic community approach comes closer to 30% and the out-patient methadone programs allows addicts to be productive citizens instead of criminals. We have not even begun to know what to do with chronic drug abusers of non-narcotic drugs.

I would first like to present some general principles that should form the basis of a comprehensive coordinated approach to drug abuse control:

1. The problem of drug abuse is not a police matter, but a problem of our whole society. The amount of drug abuse cannot be documented by the activities of the police.

2. A program should make the best use of available agencies, programs, facilities through expansion of authority and funds rather than multiplication of agencies.

3. A Council is needed on the highest level of authority to assign program responsibility, coordinate program development and evaluate progress.

4. Integration of law enforcement, treatment and education activities and philosophy is needed to ensure effectiveness.

5. Emphasis on community-based programs.

To describe these general principles:

1. STATUS OF DRUG ABUSE

We are a drug-using society and this complicates the purely law enforcement approach. A survey of medical practitioners in Alexandria indicated that drug abuse from their viewpoint was of tranquilizers, sedatives and stimulants. These are obtained legally, but can be just as deadly and just as harmful as illegal drugs. To attack only the abuse of illegal drugs without seeing them as a part of the whole society's use of drugs, including alcohol, would seem to be a misplaced effort. Mankind has been very resourceful at developing substances with which to abuse himself. The only real preventive measure is for each individual to say "No, I do not want that substance in my body." When there are no buyers we won't have to worry about the sellers.

2. USE OF AVAILABLE RESOURCES

The federal approach seems to be to develop a new agency, new facilities and pour large sums of money into new programs which have been inadequately tested. I think we should avoid building huge monuments to drug abuse either in terms of

program empires or marble monuments of treatment facilities. Local hospitals, which are now at 70% capacity, can be used for initial detoxification, mental hospitals and therapeutic communities (in remodeled old buildings) can be used for residential treatment. In the Virginia plan, the major responsibility for administration of treatment programs is given to the Department of Mental Hygiene and Hospitals with local responsibility for planning through the Mental Health Services Boards. H.R. 9059, which uses available mental health centers and public hospitals, is based on this principle of the best use of available resources. Additional funds made available under the Community Mental Health Centers Act could be immediately put to work under present administration departments. H.R. 9264 would appear to establish a new agency with an entirely new bureaucratic set up and another level of red tape between funding sources and program operations.

3. DRUG ABUSE COUNCILS

Both the localities and the state in Virginia have developed the idea of a council charged with overall program development, coordination and planning and with the assignment of areas of responsibility including the three major aspects of drug abuse control—education, law enforcement and treatment. Perhaps the federal government could learn from this model. A Presidential Commission or Council could be designed to provide the overall direction and coordination leaving the operative aspects to agencies already in the business of funding programs. The Health and Mental Health Services Administration under HEW has been set up to plan and develop programs in prevention, treatment and rehabilitation for many other health and mental health problems. The Department of Social Rehabilitation Services, Vocational Rehabilitation and Office of Education are already under the Secretary of HEW. Except for law enforcement, most of the coordination and planning could be accomplished within this one department. A Presidential Council with representatives of the law enforcement agencies, the state department, HEW, and congressional representatives could help to give direction without superimposing another layer of bureaucracy.

4. INTEGRATION OF LAW ENFORCEMENT, TREATMENT AND EDUCATION

Activation of just *one* aspect of drug abuse control can have disastrous impact on other aspects. Each aspect must be developed comprehensively. Arrests of drug pushers or suppliers in a small community sometimes flushes out people in need of treatment when there are no treatment facilities or personnel. In Roanoke a large number of codeine addicts were revealed to public authorities when action was taken against an illegal supplier.

Public education which tells the addict or abuser that help is available without developing the treatment resources is only complicating the problem. Funds for drug abuse control need to be applied to all aspects at the same time in a coordinate manner. Drug abuse councils or authorities at all levels of government can help to provide this comprehensive and integrated approach. H.R. 9264 meets the basic need for integration but I question the mechanism.

5. EMPHASIS ON COMMUNITY PROGRAMS

Treatment or incarceration of the addict relieves the community of the problem for a while, but we have learned that returning an addict to the community without appropriate follow-up just ensures that he will return to his habits. Thus, it is felt that the control of the drug dependent persons, and, hopefully, his rehabilitation, needs to be at the community level. Only for very mentally ill persons or persons who have committed capital crimes does the state need to be involved in long term confinement. Funds from the federal government should be distributed on a matching basis to states and localities so that responsibility is taken at all levels.

Finally, I hope you will act with all dispatch. As more veterans return within the next year, the problem will continue to escalate. Two young persons have died in my neighborhood from abuse of drugs within the past few months. Agencies and schools are attempting to develop programs, but they are a drop in the bucket. What we need is federal funds through already established channels. What we don't need is another agency!

Sincerely,

Mrs. ZOE H. CARRIGAN,

*Regional Director, Alexandria Community Welfare Council, member,
Governor's Council on Narcotics and Drug Abuse Control of the Commonwealth of Virginia.*

NATIONAL ASSOCIATION OF COUNTIES,
Washington, D.C., August 6, 1971.

HON. PAUL G. ROGERS,
*Chairman, Subcommittee on Public Health and Environment,
Rayburn House Office Building, Washington, D.C.*

DEAR CONGRESSMAN ROGERS: On behalf of the National Association of Counties, I wish to advise the Subcommittee on Public Health and Environment of our position on the creation of the Special Action Office for Drug Abuse Prevention.

We support the creation of the Special Action Office for Drug Abuse Prevention with the following amendments: 1) that the legislation establish a National Commission on Drug Abuse to examine the root causes of crimes associated with drug addiction; and 2) that the legislation be coordinated with all existing federal mental health programs which might prove useful to drug addicts.

These amendments were recommended by the National Association of Counties' Crime and Public Safety Steering Committee, a policy-making body, at our Annual Conference in Milwaukee, Wisconsin, July 18-21, 1971.

We would deeply appreciate having our support and amendments reflected in the Subcommittee record.

Sincerely,

LORETTA ANN TAYLOR,
Federal Affairs Assistant.

(Whereupon, at 1:25 p.m., the subcommittee adjourned.)

