Notes and Comments

Methadone Maintenance for Heroin Addicts

Tens of thousands of people dependent on heroin are only the beginning. Because of national policies outlawing the distribution of opiates to addicts, our "narcotics problem" now includes an elaborate traffic in illegal drugs, furthering organized crime; an enormous outlay of government resources to control narcotics "abuse"; and a staggering number of property offenses committed by users needing cash to support their habit.¹

Although an effective treatment for addiction has long eluded the medical profession, a breakthrough may be near. Recent medical investigations have shown that methadone, a synthetic addicting opiate, is extremely useful in the rehabilitation of heroin addicts. Research begun in January 1964 by Dr. Vincent Dole and Dr. Marie Nyswander at Rockefeller University in New York indicates that methadone, when administered appropriately, blocks the action of heroin, eliminates the drug craving which drives many detoxified addicts to resume heroin addiction, and produces neither euphoria nor other distortion of behavior. Dole and Nyswander see methadone maintenance as a means by which to draw a patient out of the heroin addict

community, away from a life of crime, and into a productive social role.  
But for a variety of reasons, elements in both the medical and legal communities oppose methadone’s use in a maintenance treatment program for addicts. What follows is a review and critical examination of both the medical and legal controversy surrounding methadone maintenance.

I. The Medical Controversy

The Dole-Nyswander experimental program, currently operating out of several New York hospitals, has essentially two phases. An initial six week in-patient period, during which the heroin addict is withdrawn from heroin and brought to a stabilization dosage of methadone, is followed by an indefinite out-patient period, during which the patient receives regular dosages of methadone and continues to have available a wide array of supportive services.  

2. Basic accounts of the Dole-Nyswander research include: Dole & Nyswander, A Medical Treatment for Diacetylmorphine (Heroin) Addiction, 195 J.A.M.A. 616 (1965); Dole, Nyswander, & Kreek, Narcotic Blockade, 118 ARCH. INTERN. MED. 304 (1966); Dole, Nyswander & Warner, Successful Treatment of 750 Criminal Addicts, 206 J.A.M.A. 2708 (1968) [hereinafter cited as 750 Criminal Addicts], first printed in First National Conference on Methadone Treatment, Proceedings (June 21-22, 1968) [hereinafter cited as Proceedings]. Leading articles and numerous statements about the program have recently been collected in Hearings, supra note 1.  


3. During Phase I, the patient is started on oral does of methadone (dissolved in fruit juice); the doses are increased until a stabilizing dosage of about 100 mg/day is reached. If the medication is given in proper doses there should be no euphoria or undesirable side effects (except mild constipation) during the stabilization period. 750 Criminal Addicts, supra note 2, at 2709. Methadone has been safely used as a painkiller for years; no toxic effects have been observed in its new use. See note 36 infra.

Phase II is the out-patient phase. Out-patients are required to return to the clinic each day to take their supervised oral doses of methadone. The patients give daily urine samples to be analyzed for traces of illicit narcotics and amphetamines. Eventually, if justified by good conduct, patients are provided with several days’ dosage at a time, and return once or twice a week for a urine analysis and other tests. Psychological, social, and vocational support continues to be given.  

Withdrawal from methadone is not, as of now, a part of the treatment. Withdrawal itself is easy, but indications are that once withdrawn from methadone, the patient experiences a return of the narcotic hunger, and reverts to the use of heroin. Researchers believe that gradual withdrawal after several years of stable living might succeed, but this procedure has only begun to be tested and Dole and Nyswander see no necessity for it. 750 Criminal Addicts, supra note 2, at 2710.
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the program had admitted 1300 patients selected according to the following criteria: at least four years of mainline heroin use; failure at previous withdrawal treatment; age 20-50; no legal compulsion to treatment; and no major medical complications such as severe alcoholism, epilepsy, or schizophrenia.

Follow-up statistics show that Dole's methadone maintenance program is effective and safe for the addict population with which he is working, and is a success from both society's and the patient's vantage point. A report prepared in March 1968 by an independent "Methadone Maintenance Evaluation Committee" under contract with the New York State Narcotic Addiction Control Commission indicated that of the 871 men admitted by that date to the several New York hospitals housing Dole programs, 86% had continued in treatment. Detailed study of the two largest hospital programs showed that the 544 men continuing in treatment had made substantial progress toward rehabilitation. None of the patients still under care had become readdicted to heroin. At the time of admission only 28% of the

5. 750 Criminal Addicts, supra note 2, at 2709. The average patient was 33 years old, and had been addicted 10 years. The average age of addicts on the New York City Narcotics Register is 28. The upper age limit in Dole's program was raised from 40 to 50 during the program's third year.
6. The adequacy of any treatment must be evaluated from more than one vantage point. See Etzioni, Shortcuts to Social Change, in THE PUBLIC INTEREST, Summer 1968, at 40-54; Katz, The Right to Treatment (draft of an article to be published in the UNIVERSITY OF CHICAGO LAW REVIEW). Because the current approach to addiction has so many
harmful social consequences, any program that, for example, reduced addict crime could in some sense be called useful, whether or not the patient is helped. However, methadone maintenance not only seems successful from society's point of view, but is highly acceptable to patients and apparently exposes them to few risks. Wieland, supra note 2, at 31-32. For a good subjective and anecdotal account of the Dole-Nyswander methadone program, including a discussion of the patients' enthusiasm, see Hentoff, Profiles: Dr. Marie Nyswander, 41 THE NEW YORKER, June 26, 1965, at 3, July 3, 1965, at 32.
8. Ten per cent were considered failures and were discharged, three per cent have dropped out, and one per cent have died. Id. at 2713. In most cases the conduct that led to discharge involved uncooperative or anti-social behavior, or non-narcotic drug abuse (including alcoholism). Researchers felt that with these patients, for whom stopping heroin use with blockade treatment was not enough to open the way for social rehabilitation, methadone maintenance combined with psychotherapy and sheltered environment might have been successful. 750 Criminal Addicts, supra note 2, at 2711. Evaluation, supra note 7, at 2713-14.
9. Dole and Nyswander remind us that quite apart from the drug problem, their patients were "[f]urther handicapped by the ostracism of the community, slum backgrounds, minority group status, school dropout status, prison records and anti-social companions, and thus they had seemed poor prospects for social rehabilitation." Dole & Nyswander, Methadone Maintenance and Its Implications for Theories of Narcotic Addiction, in ASS'N FOR RESEARCH IN NERVOUS AND MENTAL DISEASE, THE ADDICTIVE STATES 360-61 (1968) [hereinafter cited as D&N Theories].
10. Eleven per cent did, however, demonstrate repeated use of amphetamines or barbiturates, and about five per cent had chronic alcohol problems. Evaluation, supra note 7,
patients held jobs or attended school, but after five months in the program 45% were either employed or in school, and after eleven months the percentage had risen to 61%; for those remaining twenty-four months or more, the figure was 85%. The number on welfare dropped from 40% to 15% over the first two years, and, with the end of heroin addiction and of a need to deal in the expensive illegal heroin market, the number of arrests and convictions among patients decreased dramatically. The Evaluation Committee concluded that for those patients selected and treated as described, the program could be “considered a success.”

These results are all the more remarkable when compared with those from other treatment programs. All of these established programs, which seek to induce drug abstinence, have failed to keep the discharged patient from resuming his heroin addiction, with its associate

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Urine analysis revealed that about fifteen per cent of the patients “use heroin intermittently (e.g., on weekends) even though the euphoric effect was blocked.” 730 Criminal Addicts, supra note 2, at 2711.

11. Prior to treatment, 91% of the patients had been in jail, and all of these had been more or less continuously involved in criminal activity. Since coming for treatment, 88% of the patients have had arrest-free records. The researchers estimate the reduction in crime to be “at least 90%.” 730 Criminal Addicts, supra note 2, at 2710-11. For comparison with a matching “contrast group” selected from an ordinary Detoxification Unit in New York, see Evaluation, supra note 7.

This data supports the belief that much addict crime is not based on any underlying “criminal personality” but is rather a result of our national policy. By forcing the heroin market underground and diminishing the supply of illegal drugs, that policy pushes up the price of heroin and causes addicts to steal to maintain their habit. TASK FORCE REPORT, supra note 1, at 10-11. See generally Chein, Narcotics Use Among Juveniles, in NARCOTICS ADDICTION 125 (O’Donnell & Ball eds. 1966) [hereinafter cited as O’DONNELL & BALL]; Finestone, Narcotics and Criminality, in O’DONNELL & BALL 141; O’Donnell, Narcotic Addiction and Crime, 15 SOCIAL PROBLEMS 374 (1966). A conservative estimate of the amount an addict steals to finance his drug habit is $50 worth of goods per day. TASK FORCE REPORT, supra note 1, at 10. Using a much disputed but widely mentioned figure for the number of addicts in this country—60,000—it would appear that heroin users are responsible for stealing over a billion dollars worth of goods each year. In the Declaration of Purpose written in 1966 for the sections of the Mental Hygiene Law concerning drug addiction, the New York state legislature reported that “[n]arcotic addicts are estimated to be responsible for one-half the crimes committed in the city of New York alone . . . .” N.Y. MENTAL HYGIENE LAW § 200 (McKinney Supp. 1968).

In evaluating Dole’s figures regarding decrease in convictions, it should be recognized that his program makes a lawyer available to patients, and that this could lead to more effective legal representation than the patient would receive were he not affiliated with a treatment program.

12. Evaluation, supra note 7, at 2714. The Evaluation Committee also recommended further investigation. A discussion of this recommendation appears at pp. 1188-91 infra.

13. Comparisons among programs are difficult because these programs have often failed to conduct sufficiently detailed evaluations, and because different programs use different criteria of success. See Cole, Report on the Treatment of Drug Addiction, in TASK FORCE REPORT, supra note 1, at 137-42; O’Donnell, The Relapse Rate in Narcotics Addiction: A Critique of Follow-up Studies, in NARCOTICS ch. 14 (Wilner & Kassebaum eds. 1965). Any complete comparison of programs would take into account cost of the programs, ease of implementation, and acceptability to patients.

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ciated anti-social behavior. The most clearly inadequate of such programs are local “detoxification” units, which typically lack any supportive services and involve only short-term institutionalization to withdraw the addict. Almost without exception, these units merely separate the addict from heroin for a brief period. The two federal narcotics hospitals, like a number of state and local programs, offer longer periods of care and some supportive services to improve the likelihood of continued abstinence after discharge; but the best a recent Presidential Commission was able to say of the federal effort was that “there is growing evidence that [the relapse rate] is not as high as the 94% rate found in one short-term follow-up study.” And even state-run civil commitment programs, despite long periods of institutionalization and sophisticated “treatment” components which go beyond efforts to induce drug abstinence, have had only the most limited success in keeping patients from returning to heroin once released. Synanon, a structured community in which many of the

14. O’DONNELL & BALL, supra note 11, at 178. “[M]ost of us [doctors] consider drug addiction as a chronic relapsing illness and do not really expect long periods of abstinence.” Remarks of Dr. Samuel Slipp of N.Y. Medical College in REHABILITATING THE NARCOTIC ADDICT 69 (Institute of New Developments in the Rehabilitation of the Narcotic Addict, 1960). Compare the remarks of Dr. Slipp with the following from the most recent pamphlet prepared by the Bureau of Narcotics for doctors: “It is well established that the ordinary case of addiction yields to proper treatment, and that addicts can remain permanently cured when drug-taking is stopped and they are otherwise physically restored to health and strengthened in willpower.” BUREAU OF NARCOTICS, TREASURY DEPT., PAMPHLET 56: PRESCRIBING AND DISPENSING OF NARCOTICS UNDER HARRISON NARCOTIC LAW (1966) [hereinafter cited as PAMPHLET 56].

The poor record of other efforts at treating heroin addicts is summarized in TASK FORCE REPORT, supra note 1, at 14-17.


16. TASK FORCE REPORT, supra note 1, at 14. The frequently more sophisticated state and local programs, for which there is virtually no data, are discussed in Cole, supra note 13, at 138-39, 141-43. See also Hearings, supra note 1, at 536-69, A-399-447, 30 (galleys for Part 2A). The highly touted New York State Narcotic Addiction Control Commission rehabilitation program was recently the subject of a lengthy “exposé” article in the New York Times, where the program was described as more like a prison than a rehabilitative effort. April 21, 1969, at 1, col. 5. Recent developments at the federal treatment hospitals are discussed in REHABILITATING THE NARCOTIC ADDICT, supra note 14, at 75-119.

17. This conclusion is reached in a December 1967 report by the research team associated with the California Civil Commitment program at the California Rehabilitation Center in Corona. Kramer, Bass & Berecochea, Civil Commitment for Addicts: The California Program, in Proceedings, supra note 2, at 45-59. About one out of three addicts in the California commitment program remained in good standing after their first release to outpatient status. However, only one out of six has remained in good standing after 3 years. Of those who were returned to the institution and subsequently re-released, only 25% remained in good standing for one year. This, of course, leaves an increasing number of multiple recidivists. The researchers conclude that the California civil commitment program will induce periods of abstinence in some individuals, but in a far fewer number than had been hoped for. They also point to perhaps the most important consequence of a high degree of failure in a compulsory program:

The ultimate effect has been to produce a system into which a large number of ad-
members will stay indefinitely,¹⁸ claims some success, but this method of treatment is suitable for only a tiny part of the addict population.¹⁹

Despite the spectacular results of methadone maintenance, both in absolute terms and in comparison with alternative treatments, there is strong opposition to its expansion as a form of treatment. One of the arguments advanced by critics is that methadone maintenance will create a grave social cost by leading to increased addiction—heroin or methadone—in the general population.²⁰ In a letter to the Yale Law Journal, the Bureau of Narcotics raises the spectre of a general social decline should methadone dependence be accepted by society:

The Bureau does have a vital role . . . to alert society as to the possible pitfalls and to caution against mass acceptance of a theory which could adversely affect our society by increased addiction.

. . .

Will there be any deterrence when potential users are assured that there will be no ill consequences from drugs experimentation; indeed, that addicts may even receive preferential treatment?

dicts are locked, most of them shifting between approximately equal periods of incarceration and parole. Though a small proportion of the population are removed from the system by "succeeding," the majority will either remain in the system until the termination of their commitment or be extruded from the system following suspension. . . . The value of a program like this should not be viewed solely in terms of the number who succeed but also in terms of what happens to the majority who do not.

Id. at 58.

As Chein has pointed out, very little thought was given "to the question of whether psychotherapy is something that can be administered by force." CHEIN, supra note 1, at § 8. Nevertheless, these programs have been heralded as the hope for the future. The TASK FORCE REPORT, supra note 1, at 16, says: "This trend [towards developing civil commitment programs] has broad public acceptance; perhaps it has even assumed the proportions of a movement."

18. Synanon involves "the formation of a unique system in the community, a complete living and working situation, the utilization of residents in the treatment or management of their peers, the absence of direct professional staff in treatment and management . . . ." REHABILITATING THE NARCOTIC ADDICT, supra note 14, at 203.


Much the same must be said for Daytop Lodge, a half-way house for probationers with a history of heroin addiction, which utilizes a method of treatment quite similar to that of Synanon; the program is small and the available data not auspicious in terms of the eventual integration of Daytop members into society. REHABILITATING THE HEROIN ADDICT, supra note 14, at 239-44; Hearings, supra note 1, at 293.

20. Dr. Dole indicates that each year a tiny per cent of the drug seizures made by New York police is methadone, suggesting that a small percentage of the existing addict population uses methadone as the drug of primary addiction. Interview with Dr. Vincent Dole, Feb. 7, 1969.

Although the analogy is inaccurate, the Bureau of Narcotics may be haunted by the fact that when heroin was initially introduced it was "hailed by medical men as a non-habit-forming substitute for opium or morphine or as a cure for drug addiction." A. LINDESMITH, OPIATES AND ADDICTION 208 (1966).
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What will be the result of having no social stigma against addict-proselytizers in our communities?\(^2\)

If the Bureau’s fear of increased addiction stems from a prediction that the expansion of maintenance programs would make methadone more readily available to non-patients, that fear should be quieted by the experience of the Dole program. Careful administration procedures within maintenance programs can successfully minimize drug diversion to potential addicts.\(^2\)

The thrust of the Bureau’s rhetorical questions seems to be that widespread use of methadone treatment will hamper the government’s efforts to deter narcotics addiction in general. The feared weakening in deterrence would presumably arise both from a lessening of the ill consequences of drug experimentation and from a reduction in the social stigma which attaches to addiction. In the absence of needed empirical data, the theoretical debate over the causes of addiction remains unresolved, and thus it is impossible to evaluate the impact which a lessening of ill consequences and a reduction of stigma would have on the creation of new addicts.\(^2\)

But regardless of the underlying causes of addiction, the establishment of methadone treatment would not lessen most of the ill consequences which are presumed to deter potential drug users. The wider use of methadone treatment would leave unaffected the many criminal sanctions now existing in the general narcotics area. In addition, a methadone program promises not legal drug highs, but a lifetime of inconvenient medical management.\(^2\)

Finally, an argument that methadone treatment is undesirable


22. During the outpatient phase, the patient returns to the program daily to receive his dose under the supervision of a physician. Only after the patient has fully demonstrated his reliability is he allowed to take out doses of medication for a number of days. Even during this period, at least once per week “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.” 750 Criminal Addicts, supra note 2, at 2709-10. Thus it becomes impossible for the outpatient to give his drug to someone else without being detected quickly. The danger of drug diversion, however, is a genuine one. As the number of methadone programs increase, care must be taken not to sacrifice vital administrative safeguards, including carefully trained personnel. See Hearings, supra note 1, at 332.

Nor is it likely that methadone patients would be drug proselytizers, as the Bureau’s letter seems to suggest. It is widely believed that addicts convert others to addiction not out of any missionary zeal, but to create a market for drugs they sell in order to get funds to maintain their own costly drug supplies. See Chein, supra note 1, at 376.


24. Furthermore, if new methadone programs continue to adopt Dole’s requirement of

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because it makes heroin use less risky could be used to defeat any attempt to find an effective treatment for heroin addiction.

The suggestion by the Bureau that the social stigma attached to drug use would be weakened by an expansion of methadone treatment is one which cannot be either confirmed or refuted by existing data. It is extremely likely that powerful social stigma would remain for drug use outside a treatment setting; however, even were stigma to be reduced, the other ill consequences of addiction, described above, would continue to exercise a very strong deterrent effect. While it does not then seem likely that a reduction in the stigma attached to methadone maintenance would significantly lower deterrence of narcotics addiction in general, any reduction in stigma would itself be an enormous step toward realization of an equally crucial goal, the rehabilitation of addicts and their reintegration into society.26

The argument most frequently made against methadone programs is that they require maintaining patients indefinitely on an addicting drug. The thrust of this criticism goes beyond the admitted inconvenience to the patient of having to take his daily dosage. Drug abstinence is viewed by many as an indispensable treatment goal for all addicts.

Different treatment programs, of course, use different rehabilitative methods, and have different, even conflicting, treatment goals. A doctor who conceives of treatment only in terms of abstinence, and who runs a treatment program geared to freeing the addict permanently from dependence on any drug, would argue that methadone maintenance merely substitutes one addiction for another and is not “treatment” at all.26 But another doctor, who emphasizes social and vocational

four years of heroin use before admission, any experimentation with heroin that resulted in addiction would condemn the heroin user to a lengthy purgatory.

An interesting footnote to the debate described in the text is the recent finding by Jaffe that the availability of methadone maintenance as a possible method of treatment does not inevitably destroy the motivation of addicts to achieve abstinence by participating in one of the available abstinence-oriented treatment methods. Jaffe 1969, supra note 2, at 5.

25. Even assuming that more addicts are created through a lessening of the occasions for fear, Chein argues that these would be individuals who had already failed to find alternative solutions to their problems and who had not received any effective help in doing so. It follows that the posted line of action would, for them, be adaptive; they would be seeking what seemed the best available treatment for their distress. It may be that, in thus calling attention to themselves and to their problems, they could be helped to find more adequate solutions. But what if not? . . . If the best that our society has to offer them is narcosis, what moral right would we have to withhold it from them? CHEIN, supra note 1, at 380-81.

26. See, e.g., REHABILITATING THE NARCOTIC ADDICT, supra note 14, at 283 (informal remarks of Dr. V. Vogel), 284 (informal remarks of Dr. D. Myerson), 378 (informal remarks of Dr. A. Bassin); N.Y. Times, Feb. 16, 1966, at 88, col. 1 (remarks by Dr. R. Baird, Director of Haven Clinic).
rehabilitation as a treatment goal, might well find the objective of a program like Synanon, in which many of the ex-addicts live permanently in an addict community, to be abstinence without real rehabilitation.27

In support of the abstinence requirement, critics of maintenance often invoke (1) past experiences with unsuccessful heroin maintenance programs; (2) widely held views about the physical and social consequences of addiction; and (3) theories about the causes of addiction.

Controversial heroin maintenance programs that existed in the United States from 1919 to 1923 and now operate in Britain are pointed to by both critics and supporters of maintenance programs.28 The most telling criticism of both heroin maintenance experiences is that drugs were illicitly diverted and that heroin use spread. But two distinctive features of methadone make it more suitable than heroin for a maintenance program. The large drug dispensations in heroin maintenance programs are a practical necessity. Because of heroin's short duration of action, intense withdrawal symptoms appear within hours after intake of the drug; addicts may need several shots a day, and the only feasible solution is to give the addicts drugs for self-

27. Dole and Nysvander write: “Those of us who are primarily concerned with the social productivity of our patients define success in terms of behavior—the ability of the patients to live as normal citizens in the community—whereas other groups seek total abstinence, even if it means confinement of the subjects to an institution.” D & N Theories, supra note 9, at 365.

28. For a clear example of the use of earlier experiences with heroin maintenance programs to support a critical view of methadone maintenance treatment, see AMA Committee on Alcoholism and Drug Dependence, Management of Narcotic-Drug Dependence by High-Dosage Methadone HCI Technique, 201 J.A.M.A. 956, 957 (1967). See also Packer, supra note 1, at 836.


Administrative shortcomings are also cited as one of the reasons for the failure of America's hastily organized and controversial heroin clinics of 50 years ago. Whether these clinics actually failed, and the reasons for their closing, are much debated. A.M.A. Council on Mental Health, Review of the Operation of Narcotics 'Clinics' Between 1919-23, in O'Donnell & Ball, supra note 14, at 180-87; Ausubel, Controversial Issues in the Management of Drug Addiction: Legalization, Ambulatory Treatment and the British System, in O'Donnell & Ball, supra note 14, at 195-209. See also, Comment, Narcotics Regulation, 62 Yale L.J. 751, 784-87 (1953). It should be noted that in neither the British program nor the American clinic plan was drug-dispensing combined with other treatment and rehabilitation components.
administration. Heroin maintenance programs are further complicated because adaptation of the patient's body to certain of the drug's effects leads the patient to demand increasingly large dosages to stay comfortable. Thus, attempts to stabilize the dosage levels of patients are likely to fail. Methadone, however, is a horse of a different color. Unlike heroin, methadone is long-acting; the entire daily dosage can be given under direct observation, eliminating the opportunity for illicit distribution. And methadone patients have been stabilized at constant dosages with no difficulty.

A second class of arguments against the maintenance aspect of methadone programs invokes not past experience, but commonly held beliefs about the consequences of addiction. Some critics believe that all addiction has serious physiologically debilitating effects. Others claim that maintenance on an addicting drug will make social rehabilitation impossible because of the "well-proven personality deterioration and social demoralization that have invariably accompanied addiction." The simple answer to this criticism is that Dole's research

31. Furthermore, "[w]ith progressive escalation of narcotic requirement, any maintenance program would fail to rehabilitate the patients since their energies would remain directed toward drug-seeking. If patients continued to behave and think like addicts, the only result of maintenance would be to shift the source of drugs from the street to the medical clinic. This could not be an acceptable result." Lowinson, The Methadone Maintenance Research Program, in REHABILITATING THE NARCOTIC ADDICT, supra note 14, at 271, 278 [hereinafter cited as Lowinson]. But cf. CHEIN, supra note 1, at 378, and note 42 infra.
32. See note 92 supra.
34. There is dispute whether even heroin has any serious physiologically debilitating effects; these effects may rather be due to "the lack of the drug and the constant preoccupation with obtaining it." Ploscowe, supra note 30, at 69. For example, available evidence indicates that the addict's ability to work is undermined by not receiving his customary dosage of heroin, rather than by the effects of the drug itself; that is, inefficiency is a symptom of the withdrawal syndrome. CHEIN, supra note 1, at 358, 362. In any case, methadone appears to eliminate whatever physiologically debilitating effects heroin might have.

The "personality deterioration" and "social demoralization" associated with heroin addiction seem more a consequence of our legal and social policy toward drug addiction than a consequence of opiate use itself. These policies, not to mention other social policies that breed human misery and may have led the addict to drugs in the first place, force the addict to lead a way of life that quite understandably may involve him in deviant or criminal behavior, and leave him a broken person. Ploscowe, supra note 30, at 46; A. LINDESMITH, OPIATE ADDICTION 87-88 (1947). See generally, PACKER, supra note 1, at 332-37; TASK FORCE REPORT, supra note 1.
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believes it. The source of this particular critical approach may well be in the puritanical spirit which Etzioni finds "still sufficiently strong in American culture so that the use of any substitute drugs ... is regarded as an indulgence." Any reliance on drugs, regardless of important distinctions as to their harmfulness, is seen as weakness—and thus the view that any form of legalized dependency is morally offensive. But this view of drug dependence is not consistently applied; the maintenance of diabetics on insulin, for example, is a form of dependency which is accepted without moral controversy.

36. See pp. 1177-78 supra. See also Lovin, supra note 31, at 277-78; WHO Expert Committee on Dependence Producing Drugs, Fifteenth Report, (W.H.O. Technical Report Series No. 943, at 10 (1966) (methadone maintenance has demonstrated that social rehabilitation of subjects with a drug dependency is possible). Even relatively unfavorable statements on methadone do not charge that methadone has any negative physical effect on patients. The objections by the AMA Committee on Alcoholism and Drug Dependence do not even seem to be on medical grounds. The Committee says that methadone is addicting, but the only significance they attribute to this is that if the drug is withdrawn the addict would experience "severe abstinence" symptoms. However, after citing the failure of what they admit were poorly administered heroin clinics, the Committee concludes without argument, that "Currently no nation not even among the producing countries, considers maintenance to be a satisfactory answer to the drug abuse problem." AMA Committee on Alcoholism and Drug Dependence, supra note 28, at 937.


38. See Ausubel, supra note 35. This view was expressed by a Senate Subcommittee discussing a proposal to reestablish heroin clinics:

The crux of the "clinic" proposal ultimately rests, not upon its practical workability but upon the fundamental moral issue involved. ... We believe the thought of permanently maintaining drug addiction with "sustaining" doses of narcotic drugs to the addict to be utterly repugnant to the moral principles inherent in our laws and the character of our people.

39. In their first article, Dole and Nyswander suggest this analogy between methadone maintenance for heroin addicts and insulin maintenance for diabetics. 195 J.A.M.A. 646-50

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The third class of objections to the maintenance aspect of methadone programs focuses not on the consequences of addiction but upon its causes. "The evidence indicates that all addicts suffer from deep-rooted major personality disorders" and, so the argument runs, maintenance on methadone cannot get to root causes of the disease. This "psychogenic" theory of addiction—that addiction is caused by an antecedent character defect—has come under strong attack. But even if more substantial medical knowledge should eventually prove it correct, methadone maintenance might be thought no less valuable because (1) the program in all its aspects may actually affect those psychological causes or (2) whatever its theoretical defects,

(Aug. 1965). It is arguable that the analogy fails because in the case of heroin addiction the disease is "voluntarily" contracted and, some say, can be cured if the patient has a sufficiently strong character. This has been vigorously debated. See, e.g., note 41 infra. However, the diabetes example proves a basic point, that an across the board condemnation of all drug dependency as immoral is foolish. See also note 25 supra.

40. CHEIN, supra note 1, at 14.
41. See D&N Theories, supra note 9. Dole and Nyswander question the psychogenic theory and propose an alternative theory emphasizing the metabolic aspects of addiction. They believe that the addict is biochemically defective and requires drugs much the same way as the diabetic requires insulin. They reject the idea that all addicts are highly disturbed individuals, preferring the belief that "addict traits" are the consequences and not the causes of addiction. In support of their view, they point to the fact that while methadone patients after stabilization exhibit emotional problems related to external situations (e.g., jobs, schools, family), these patients, whose drug hunger has been relieved, "exhibit [no] residual psychopathology." Id. at 365. Dole and Nyswander do not believe that the supportive assistance which their program provides explains their patients' vocational and social success. Their conclusion is that either the patients we admitted to treatment were quite exceptional, or else we had been misled by the traditional theories of addiction. If, as is generally assumed, our patients' long-standing addiction to heroin had been based on weakness of character—either a self-indulgent quest for euphoria, or a need to escape reality—it was difficult to understand why they so consistently accepted a program that blocked the euphoric action of heroin and other narcotic drugs, or how they could overcome the frustrations and anxieties of competing directly and hold responsible jobs.

Id. at 361.
42. Even if addiction is a consequence of psychological disorders, Dole and Nyswander may simply underestimate the importance of the psychologically supportive aspects of their program, including the therapeutic role played by their presence and enthusiastic attention to their patients. See note 52 infra. Furthermore, by relieving the addict's consuming hunger for drugs, methadone dispensation is a crucial adjunct to the program's supportive services and an effective aid to social rehabilitation. If the addict is a man with many problems, the methadone dispensation may help to meet at least some of them. Chein's analysis of the dynamics of the English system of handling addicts suggests that even "mere" drug dispensation may be important for the addict's psychological rehabilitation:

[T]here is an amazing paradox in the English system. The addict within the system is limited to maintenance doses. But as a consequence of tolerance, he should be having no effect other than the prevention of withdrawal symptoms. Why not, then, get himself humanely detoxified and continue without the threat of sudden withdrawal? Obviously, the addict who stays in the system must be getting something out of it that has nothing to do with the psychopharmacological effects of the drug he is taking. . . . The major gain for the English addict who stays in the system must be that he has someone who is willing to talk to him and listen to his troubles, and who proves that he cares by giving him something, the narcotic.
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methadone maintenance may still be the most effective treatment available from the patient's vantage point as well as from society's.\textsuperscript{43}

The usual danger of symptomatic treatment is that by merely masking the causes of a disease, it allows those causes to fester and destroy the organism. But after stabilization on methadone, the addicts treated by Dole become increasingly healthy and equipped to deal with the demands of everyday life. Even were maintenance on methadone known to restrict the patient's activity more than "full" rehabilitation or abstinence, these other forms of treatment have been tried and have proven unsuccessful for many of the patients in Dole's program. For these addicts the alternative to methadone maintenance is continued heroin addiction and further misery.\textsuperscript{44}

A final objection to Dole's program is that the use of methadone is still in the "research" stage and may not yet be considered established "treatment." The conclusion that flows from this labeling exercise is that methadone maintenance is proper only if programs are kept small and are structured to answer specific questions, rather than to provide therapy.\textsuperscript{45}

The major effect on our urban chronic opiate users... is that it provides an answer to emptiness. Specifically, the addict gets three things out of his involvement with narcotics:... an identity[...]


43. It is possible, of course, that Dole and Nyswander are wrong, and that in fact their treatment masks the symptoms of the deeper disease of an addictive personality. The usefulness of debate over this question is questionable, given our sparse knowledge of the causes of addiction. The important questions are: "In what way does this allegedly symptomatic treatment hinder the patient?" and "What better alternatives do we have to offer?"

It should be pointed out that if methadone is not a "cure," it is reasonable to think that its widespread use will decrease the pressure on society to commit the resources to develop and implement "cure" programs. More importantly, to the extent that methadone maintenance removes the ugly manifestations of drug addiction (e.g., crime), it could decrease the pressure on society to commit resources to eradicate the human misery and poverty that is widely associated with addiction.

44. "If the person is better off with the drug than without it, insofar as it is humanly possible to do something for him, then he ought to have the drug. If we do not like it, we should find better ways of helping him." Chein, \textit{supra} note 42, at 69-70.

45. The Chief Counsel to the Bureau of Narcotics writes:

Some persons claim that adequate "research" has been done, and that a positive "treatment" program may be established. Again, the Bureau has looked to the views of the representative medical bodies, which have concluded that methadone addiction maintenance remains a research undertaking, and that it cannot be considered as established treatment.

In order to be considered as "treatment," it must be more than promising—it must be proven... The Bureau does have a vital role, even if it is only to act as a catalyst against mass acceptance of a theory which could adversely affect our society... Bureau of Narcotics Letter, \textit{supra} note 21.
The essence of this position must be that, given its own articulated goals, Dole's program has not yet been sufficiently tested to be accepted as successful by the medical community and considered as one of the standard therapeutic procedures available to trained physicians treating addicts.\(^4\) Naturally those doctors who oppose the maintenance concept in principle will require especially powerful data before they become convinced of the safety and effectiveness of Dole's program, even within its own terms;\(^4\) while some doctors do not attack the program directly, on the basis of its treatment goals, they take the second-line tactic of stalling for time by proposing additional research questions.\(^4\)

Dole and his supporters do not, of course, maintain that all research relevant to methadone maintenance has been successfully completed. A series of further research questions recommended by the New York State Evaluation Committee refer explicitly to modifications in the

Now several years old, a statement on methadone by a joint committee of the American Medical Association and the National Research Council, calls for "carefully specified and controlled procedures . . . to evaluate adequately the various facets of the program." The AMA-NRC statement is quoted in a later statement about methadone maintenance by the AMA Committee on Alcoholism and Drug Dependence which called for the "application of the most rigid research controls" to the methadone programs. The Committee says: "It is disquieting to those who would like to see this program continue at a properly controlled research level to know that it has since been presented as if it were an established effective treatment method that might be taught to any interested physician." AMA Committee on Alcoholism and Drug Dependence, supra note 28, at 956. See also Jaffe 1969, supra note 2, at 1.

46. AMA Committee on Alcoholism and Drug Dependence, supra note 28.

47. Doctors deeply hostile to the basic goal of methadone treatment may even oppose research. Cf. World Medical Association, Declaration of Helsinki, Recommendations Guiding Doctors in Clinical Research (1964), reprinted in AMERICAN MEDICAL ASSOCIATION, DECLARATION OF HELSINKI AND AMA ETHICAL GUIDELINES FOR CLINICAL INVESTIGATION (undated pamphlet available from the AMA) ("Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject."). This opposition to methadone research is reported and criticized by Dr. Irvine Page, past-President of the American Heart Association and past-Chairman of the AMA Section on Experimental Medicine. Page, Further Evidence on Methadone and Criminal Drug Addicts, 37 MOD. MED., March 10, 1969, at 64. Dr. Page sarcastically contrasts this opposition to "the easy acceptance of such surgical feats as cardiac transplant." See also Jaffe 1969, supra note 2, at 2.

48. Donald Miller, Chief Counsel to the Bureau of Narcotics, indicated in a telephone conversation on April 4, 1969, that the research/treatment debate is "only concerned with public health problems" and "avoids moralistic problems." But clearly the line between research and established treatment could be crossed only when the basic idea of maintenance is itself accepted; and as Dr. F. Richards, a member of an AMA committee evaluating the methadone program, said in a telephone interview on April 2, 1969, "We're still struggling with that, quite frankly."

The Bureau of Narcotics apparently considers the answer to the question of whether addiction will be increased if methadone maintenance is adopted to be one of the things that must be "proven" before methadone is to be considered "establish treatment." Bureau of Narcotics Letter, supra note 21. It is difficult to see how and when empirically "proven" answers to a question like this could be reached, at least in the near future.
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basic Dole program,49 and these modifications are now in the process of being tested across the country. Both for better medical understanding and as a basis for important economic judgments,69 answers to the following questions are vitally important: Will methadone maintenance be as useful for a different addict population, such as for younger or less motivated addicts, or for a prison population?21 What are the therapeutically active components of Dole’s program; for example, could the extremely expensive in-patient phase be eliminated without a significant decrease in the program’s effectiveness?32 After

49. Although the Evaluation Committee explicitly calls Dole’s program a “success,” the Committee emphasizes 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.” Evaluation, supra note 7, at 2714.

The Committee recommended expansion of the current program, and extension of methadone treatment “(e) to other groups, using 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 (b) variations in technique, including induction on an ambulatory basis.” They also recommend continued follow-up and evaluation, and further research on the impact of each component in the program. Id.

50. Although methadone itself may cost “pennies a day,” methadone maintenance is not a cheap form of treatment. An analysis of Dr. Dole’s August 1, 1967-July 31, 1968 budget indicates that the full treatment program costs $1660 per out-patient per year; the six-week in-patient phase itself costs about $2140. Bureau of the Budget of the City of New York, Memorandum: Per Patient Costs of the Methadone Program (dated Aug. 16, 1967). See also Hearings, supra note 1, at 328, 332. An elimination of the in-patient phase or other components of the program would, of course, cut costs. The most sizable saving, however, would come if addicts could be withdrawn from methadone after a number of years. Costly procedures, however, may be justified by their success and by estimates of the costs of not treating the addiction. See Hearings, supra note 1, at 335; note 11 supra.

51. In Jaffe’s Chicago methadone program, patients were taken randomly from a waiting list of chronic narcotic users who had volunteered for treatment in the Drug Abuse Program of the State of Illinois Department of Mental Health. Unlike Dole’s program, patients were not rejected because of legal entanglements, or previous history of psychosis, alcoholism, or non-narcotic drug use; thus it is impossible to say of this sample that potentially difficult patients were screened out, although, of course, the sample contains only those addicts sufficiently motivated to volunteer. Jaffe modifies Dole’s procedure in a number of significant respects, but his results so far are impressive, suggesting that methadone maintenance is an effective method of treatment for a larger part of the addict population than Dole’s sample has allowed anyone to conclude. Jaffe 1969, supra note 2. See note 52 infra.

Dole has conducted a recent small study at Riker’s Island in New York to test the usefulness of methadone for addicts in prison. He has found that addicts in jail are motivated to volunteer for methadone treatment, can begin the rehabilitative process and be stabilized in a prison hospital, and will stay with the program after release. Dole, Report to the Joint Legislative Executive Committee on Methadone Treatment at Riker’s Island (mimeographed paper dated May 15, 1968).

52. The In-patient Phase. Wieland’s initial results from Philadelphia indicate that the expensive in-patient phase is not an essential part of the treatment. Dividing 44 patients into two groups, one beginning with an in-patient phase, the other directly with outpatient (ambulatory) care, Wieland found no difference between the two groups’ results. On the basis of his findings—results were almost identical to those reported by Dole and Nyswander—Wieland plans to treat all subsequent patients in the out-patient clinic,

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several years of treatment, is withdrawal from methadone possible without the patient's return to heroin? 263

But Dole, supported by many other respected doctors, several of whom have repeated his procedures, 264 believes that his basic maintenance program has now been proven medically acceptable for at least that addict population described by his own selection criteria. Research is no longer necessary when a defined procedure, tested over a sufficiently long time period, has yielded enough data to permit an informed judgment by decisionmakers as to the advisability of the program under various circumstances. Since the risks of treatment are believed to be negligible (e.g., no evidence at all of toxicity), 265 since possible

"unless there are significant medical or psycho-social complications which warrant hospitalization." Wieland, supra note 2, at 36.

Jaffe's Chicago program is entirely ambulatory. The other distinguishing aspects of the program are that (1) potentially difficult patients were not screened out; (2) the dosage of methadone administered was significantly lower than that used by Dole and Nyswander; (3) most of the patients were told that they would be withdrawn from methadone after a few months. Seven months after this program began, 75% of the 60 patients were still in treatment, and of the group still in treatment 75% were employed, none was using illegal drugs regularly (15% show occasional use), and there had been one arrest. Jaffe 1969, supra note 2. Clearly, many patients do not appear to need an inpatient phase, although for some a period of hospitalization may be needed to develop a positive relationship between physician and patient, and to prepare the patient for his new life. See Chein, supra note 1, at 382. Jaffe looks to future studies to provide a basis for deciding which patients are best suited for totally ambulatory treatment.

Personalities of Program Operators and Their Relationship with Patients. Jaffe's study has also attempted to resolve the widely discussed question of whether "the benefits of the use of methadone are attributable . . . to the charismatic personalities of those who operated the programs," for example Dole and Nyswander. His limited results suggest that this therapeutic component is not necessary for the program's success. "No single individual or profession has exerted a dominant influence on our program. The rehabilitative aspects of our program were directed by social workers and ex-addicts. . . . Physicians came to the clinics only to prescribe medication and to attend to medical problems. These physicians were intermittently rotated." Jaffe 1969, supra note 2, at 5. Wieland, however, indicates that there is a significant difference between "the potency of methadone alone versus the potency of methadone plus a trusting relationship." He considers a trusting relationship an essential ingredient for successful treatment. Wieland, supra note 2, at 36-37.

Urine Testing. Urine monitoring has been necessary to gather research data. Is the presence of that monitoring itself important in keeping the addict away from the illegal heroin market and in achieving the other successful treatment results? Is it a useful treatment aid, merely a research evaluation component, or a "check" being used in a moralistic way to see that the patient abides by the "rules of the game"?

53. Jaffe and Wieland indicate that they are beginning to attempt withdrawal from methadone with some patients. Jaffe 1969, supra note 2, at 6. Wieland, supra note 2, at 38. See note 3 supra. If the value of methadone maintenance is itself accepted, there is no reason why open questions about ultimate withdrawal from methadone should interfere with expansion of the current efforts; hypotheses about withdrawal can be tested after heroin addicts become methadone patients.


55. See note 36 supra. Of course methadone treatment projects a lifetime of drug maintenance. Thus, although no sign of toxicity has appeared during the first five years of Dole's program, and there is no evidence of toxic effects from methadone's other uses, there is always some possibility that toxic effects will begin to emerge after five, ten, or twenty years of use.

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benefits to both the patient and society are great as weighed against
the likely effects of non-treatment, and since the likely proportion of
treatment failures is predictable and communicable to the patient,
Dole's program should now be considered a valid form of treatment.
What Dole fears is that the call for more research, research which is
not needed before responsible therapy could begin, may be used to
delay the basic changes in national drug policies which acceptance of
methadone treatment would entail.56

When the various medical arguments against a program on Dole's
model have each been considered, the proven results of Dole's program
remain persuasive. The risks described by critics of methadone must be
evaluated in light of the known personal and social costs of current
approaches to addiction. The still point in the debate over the effects,
goals, and proper limits of methadone programs is that methadone
maintenance on the Dole model provides relief significantly more effec-
tive than that provided by any available alternative program for an
important class of the addict population. Since the addict population is
heterogeneous, different treatment approaches may be suitable for dif-
ferent kinds of addicts.57 At a minimum, no sound medical reason can
be given for opposing the expansion of Dole's present program to in-
clude the 1000 properly screened heroin addicts already on waiting lists
who desperately seek his treatment in New York.

II. Problems Under Federal Law58

Assuming that an expanded methadone maintenance program is con-
sidered to be medically and socially desirable, what would be the legal

56. The grounds for impatience with the endless calls for more research in the field
of addiction are summarized by Schur:

It is becoming increasingly questionable whether lack of adequate knowledge about
addiction provides a justification for inaction or complacency about the status quo
in the policy realm. In certain circles it has been traditional to meet all demands for
reform of drug laws with a call for "further research," and obviously no responsible
social scientist is going to oppose properly focused research efforts. Yet in the absence
of some sudden revelation identifying a crucial and hitherto unrecognized causal factor
or some major breakthrough in the development of addiction treatment techniques,
it seems foolhardy to ignore the possibilities of ameliorating at least ancillary features
of the narcotic situation through the adoption of more sensible and humane public
policies.


modality should be thought of in terms of its appropriateness for all addicts. As in usual
therapeutic interventions, the physician treating addicts will have available a number of
treatment procedures, and will select the procedure which he considers likely to be most
effective with the individual patients. (This, of course, assumes some agreement that the
main goal of the therapy is to make possible productive social behavior; as considered
above, some doctors subordinate this treatment goal to a goal of immediate abstinence.)
See note 24 supra.

58. This Note is limited to a discussion of the scope of federal power in present federal
obstacles to its implementation? Both because of methadone's relative newness as employed by Dole and because of its addictive qualities, potential restrictions on its use arise under both the Federal Food, Drug, and Cosmetics Act and the Harrison Act.

A. Under the Federal Food, Drug, and Cosmetics Act

The use of methadone for maintenance presents an unusual set of problems under the Federal Food, Drug, and Cosmetic Act, which establishes procedures to assure that "new drugs" will not be introduced into interstate commerce until their safety and effectiveness have been proven. Before a "new drug" is marketed across state lines, the Food and Drug Administration must approve a new drug application (NDA); where there is not sufficient proof that a new drug is safe


Nor does this Note concern itself with state laws regulating the use of narcotic drugs by physicians. The Uniform Narcotic Drug Act is followed in many states, and, like the Harrison Act, appears to allow doctors wide latitude in treating addicts or other patients with addicting drugs. Section 7 of the Uniform Act allows the physician "in good faith and in the course of his professional practice only" to prescribe, administer, or dispense narcotic drugs to addicts. Thus, an interpretation of the Harrison Act will also suggest an approach for physicians under state law. States, of course, may pass laws stricter than the Uniform Narcotic Drug Act, delineating specific behavior which is proper for a doctor and that which is not. California, for example, has set extremely strict standards for doctors treating addicts. Maximum daily doses to be given during a fixed number of days to achieve withdrawal (the only permissible treatment goal) are written in the statute. CALIF. HEALTH & SAFETY CODE §§ 11390-11396 (West 1964). See especially Elder v. Bd. of Med. Examiners, 50 Cal. Rptr. 304 (1966) (physician's license revoked for dispensing methadone as a substitute for the addict's narcotic, a violation of California statute). Jaffe indicates the uncertainty he felt as to whether Illinois law would allow even research with methadone maintenance. Jaffe 1969, supra note 2, at 2. The Illinois statute explicitly allowed a doctor to administer narcotic drugs only to patients "suffering from a disease . . . other than for addiction." ILL. REV. STAT. ch. 38, § 22-11 (1964). However, at Jaffe's urging, Illinois became the first state to provide specially in its laws for "research and experimental programs involving the administration of methadone," provided approval is received from the State Department of Mental Health. ILL. REV. STAT. ch. 38, § 22-10.1 (Supp. 1969). Cf. N.Y. MENTAL HYGIENE LAW § 204(3) (McKinney Supp. 1968).


60. 21 U.S.C.A. § 335(a) (Supp. 1968). The manufacturer may market without NDA approval any drug he believes to be "generally recognized as safe and effective." The government may then "seize and condemn" such drugs if it can establish by a preponderance of the evidence that the drug is "not generally recognized as safe and effective." See, e.g., United States v. Articles of Drug Labeled "Quick-O-ver", 274 F. Supp. 443 (D. Md. 1967); United States v. Article of Drug Labeled "Wynn 30", 268 F. Supp. 245 (E.D. Mo. 1967). Cf. United States v. Wood, 226 F.2d 924 (4th Cir. 1955). If medical opinions differ, some courts conclude as a matter of law that the drug in question is not generally recognized as safe and effective. AMP Inc. v. Gardner, 275 F. Supp. 410, 415 (S.D.N.Y. 1967) ("For such difference [of medical opinion] indicates precisely the lack of general recognition of the safety of plaintiff's products which brings them within the statutory definition of new drugs."). See also Merritt Corp. v. Folsom, 165 F. Supp. 418 (D.D.C. 1958); United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes, 178 F.
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and effective, an alternative procedure permits the drug's manufacturer or sponsor to claim an investigational new drug exemption (IND) and send the drug into interstate commerce for testing only.\(^1\)

The first question concerning methadone maintenance under the FD&C Act is whether the "new drug" provisions are applicable at all. Methadone is not a "new" drug in the customary sense; the use of methadone as a painkiller is well established, and its use in some aspects of the treatment of heroin addiction—during withdrawal, or for a brief period prior to withdrawal on a maintenance basis—is widely accepted.\(^2\) However, an accepted drug like methadone would require new drug approval if it were marketed in interstate commerce for a new use "not generally recognized as safe and effective."\(^3\)

The manufacturers of methadone have remained aloof from the controversy, making no labeling changes or new claims for the drug, and they have not been required to file a new drug application. It is possible, of course, that the FDA might require methadone manufacturers to change their labeling of the drug to encompass its use in maintenance programs, and also require that a new drug application be filed for that use.\(^4\) However, the FDA's inaction in the face of six years of widely publicized methadone use in maintenance programs suggests that manufacturers will not now be required to follow "new drug" procedures; had the use of methadone in maintenance programs required such procedures, the FDA would seem to have been obligated to act long ago.\(^5\)

Supp. 847 (D.N.J. 1959). Other courts, however, have put a heavier evidentiary burden on the government, holding that the existence of some disagreement among the expert witnesses does not necessarily mean that the safety and efficacy of the drug for that purpose is not generally recognized among qualified experts. United States v. Article of Drug Labelled "Quick-O-ver", 274 F. Supp. 443, 448-49 (D. Md. 1967).


The newness of a drug may arise by reason (among other reasons) of . . . (5) The newness of a dosage, or method of duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition is not a new drug.


64. The regulations provide that a manufacturer must change the labeling on the drug if he receives notice "that a drug . . . introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it."

21 C.F.R. § 1.106(o) (1967).

65. The FDA may recognize the special problems in this situation of proceeding against the manufacturers of methadone. Methadone is an inexpensive drug produced by several manufacturers (the patent has expired), who continue to send the drug through interstate commerce for its customary uses. To require these manufacturers to change the labeling
Since a new drug application may eventually be filed by a manufacturer or sponsor for methadone, a brief discussion of the applicable standards for approval is in order. The standards for new drug approval incorporated in the 1962 amendments to the FD&C Act suggest that approval for methadone in a maintenance use should be granted.\(^6\)

To be approved, the new drug must be "safe for use under the conditions prescribed,\(^7\)\(^6\) and there must be "substantial evidence that the drug will have the effects it purports or is represented to have under the conditions of use prescribed."\(^8\) A "preponderant evidence" test was rejected by the draftsmen of the Act in favor of the "substantial evidence" test, because consensus or even majority rule was felt to be unsound within the medical profession.\(^6\) Since the major dispute over the "effectiveness" of methadone maintenance centers around disapproval of the program's treatment goals rather than its efficacy in achieving those goals, this controversy should not stand in the way of new drug approval. It is not the function of the FDA to pass judgment on treatment goals, but only to ensure that a drug be effective in achieving the purposes claimed for it, and to require that any limitations upon those purposes be clearly stated in the drug's labeling and advertising.

Since the criteria permit and even direct approval where medical opinion is split, FDA approval of methadone in its new use would be at this stage would force them to undergo expensive and lengthy procedures necessary to gain "new drug" approval. This might have the effect of forcing the manufacturers to cease methadone production entirely. See Cavers, The Legal Control of the Clinical Investigation of Drugs: Some Political, Economic, and Social Questions, 98 DAEDALUS 430-34 (Spring 1969).

66. Under FDA regulations, the procedures that must be followed in order to win approval are extraordinarily lengthy. And in practice, the FDA has applied the standards stringently. See Cavers, supra note 65, at 430-34; Remarks of Karl Beyer, M.D., at 1964 FDA-FLI Conference, 20 Food Drug Cosm. L.J. 75, 75-79 (1965); Comment, The Drug Amendments of 1962, 38 N.Y.U. L. Rev. 1082, 1092 n.71 (1963).

67. 21 U.S.C.A. § 355(d) (Supp. 1968). Safety, of course, does not mean absolute absence of risk. Rather, the requirement is for adequate warning to the doctor of a drug's inherent dangers. Furthermore, no medical treatment, especially with drugs, is without risks. Cf. RESTATEMENT (SECOND) OF TORTS § 402A, comment k. See note 128 infra.

68. [T]he term "substantial evidence" means evidence consisting of adequate and well controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

69. The committee recognizes that in the difficult area of drug testing and evaluation there will frequently, if not usually, be a difference of responsible opinion. The committee feels that the existence of such a difference should not result in disapproval of a claim of effectiveness if it is supported by substantial evidence as defined in the manner set forth below . . . .

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justified; further labeling changes could be made at a later time when more data has been collected regarding methadone's effectiveness with a wider addict population or in a different treatment setting. The labeling change would leave no doubt about the manufacturer's right to ship methadone interstate to be used in maintenance programs, and would thus be a crucial step in the general acceptance of methadone maintenance.

If, however, the FDA should be unwilling to classify the use of methadone for maintenance purposes as safe and effective, maintenance programs could still continue under the investigational new drug exemption. That exemption is granted according to strict regulations, and sponsors and investigators are held to rigorous research standards. The National Institute of Mental Health, which, although it is subsidizing five methadone maintenance programs, has no direct control over the drug's supply, has filed an IND for these investigational programs. Presumably, since the statute says "any person" may file a new drug application, the NIMH could file an NDA making an enlarged claim for methadone's use; and since NIMH-supported investigators are testing modifications in Dole's program, the NIMH data could be used to get new drug approval of methadone for a wide range of uses.

B. Under the Harrison Act

According to the Bureau of Narcotics, any doctor who uses methadone maintenance as treatment for heroin addicts violates federal law. The basis for the Bureau's position is the Harrison Act—a federal regulatory measure passed in 1914—which requires the registration of narcotics dispensers, imposes an excise tax on narcotic

71. For the general duties of an investigator who has a sponsor covered by the Act, see 21 U.S.C. § 355(f); 21 C.F.R. § 130.3(c) (1969); 21 C.F.R. § 130.37 (1969). Cf. Turkel v. FDA, 334 F.2d 844 (6th Cir. 1964).
72. An investigator who gets his supply of an established drug on the local market and puts it to a new use is not required to file an IND. 21 U.S.C.A. § 331(d) (Supp. 1968). See Cavers, supra note 65, at 440-43.
73. Whether or not a doctor is directly covered by the FDA regulations, his failure to follow the prescribing information on the package insert could expose him to liability for departing from an accepted norm if there is resulting harm, although the litigation here is minimal. Id.; Sanzari v. Rosenfeld, 34 N.J. 128, 167 A.2d 625 (1961); cf. Toole v. Richardson-Merrill, Inc., 60 Cal. Rptr. 396, 409 (1967).
75. 26 U.S.C.A. §§ 4721-22 (1967). Registrants, which include manufacturers, doctors, pharmacists, etc., are required to pay a small occupational tax and to keep records. The purpose of these provisions is clearly to keep the drug traffic observable.

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drugs (to be evidenced by stamps affixed to the package containing the drugs), and limits the sale and distribution of narcotics to recipients who use a written order form provided by the Treasury Department.

When first passed, the Act did not appear to interfere with the medical treatment of addicts. The obvious targets for prosecution were doctor-pushers and prescription peddlers. Reputable physicians, "treating addicts as they saw fit," were prescribing and dispensing narcotics, and explicit statutory exemptions appeared to protect them in their good faith professional activities. The section requiring use of a written order form, for example, contained a specific exemption for "the dispensing or distribution of any narcotic drugs to a patient . . . in the course of [a physician's] professional practice only." And in a similar vein, a 1919 amendment to the Act, making illegal the dispensing of narcotics not in their original stamped packages, exempted doctors "where said drugs are dispensed or administered to the patient for legitimate medical purposes." Nevertheless, the phrases "legitimate medical purposes" and "in the course of his professional practice only" were not defined, and these apparent qualifications on the physician's exemptions have become a source of legal controversy.

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78. 
79. Ploscowe, supra note 30, at 97.
80. That the statutory exemption left physicians their wide professional discretion was a widely held belief at the time. See, e.g., Simmons v. United States, 300 F. 321, 322 (6th Cir. 1924).
82. 26 U.S.C.A. § 4704(b)(2) (1967). No person, including a doctor, may use an order form to obtain narcotic drugs "for any purpose other than the use . . . in the legitimate practice of his profession." 26 U.S.C.A. § 4705(g) (1967). Persons not registered under one of the relevant provisions of the Act may possess narcotic drugs when they have been "prescribed in good faith" by a physician. 26 U.S.C.A. § 4724(c) (1967). For other similar exemptions, see 26 U.S.C.A. § 4704(b)(1), § 4705(c), and § 4724(b)(5-6) (1967).
83. The development of the "British system" (see note 27 supra) from Dangerous Drug Laws which are quite similar to the Harrison Act, provides a fascinating contrast to the development of our own country's policy, with its emphasis on criminal sanctions and intimidation of doctors. See A. LINDESMITH, THE ADDICT AND THE LAW, 167-70 (1959).
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According to a widely distributed Bureau regulation:

A prescription, in order to be effective in legalizing the possession of unstamped narcotic drugs and eliminating the necessity for the use of order forms, must be issued for legitimate medical purposes. . . . An order purporting to be a prescription issued to an addict or habitual user of narcotics, not in the course of professional treatment but for the purpose of providing the user with narcotics sufficient to keep him comfortable by maintaining his customary use, is not a prescription within the meaning and intent of the act; and . . . the person issuing it, may be charged with violation of the law. 84

In addition to its own rigid standard, the Bureau in recent years has looked to the joint statements of the American Medical Association (AMA) and National Research Council (NRC) for guidance about appropriate medical standards in the treatment of addicts. 85 The AMA-NRC Committee, however, has also concluded that in general "continued administration of narcotic drugs solely for the maintenance of dependence is not bona fide attempt at treatment, nor is it ethical medical practice." 86 Thus by reference either to its own regulation or to the AMA-NRC statement, the Bureau concludes that methadone maintenance treatment programs are illegal; however, since the AMA-NRC statement makes provision for research, the Bureau has allowed limited methadone programs to go forward for investigational purposes. 87

Analysis of case law and administrative history indicates that the Bureau's interpretation of the Harrison Act is improper, and that its current approach to methadone maintenance should be modified to protect the many physicians who believe that methadone maintenance is a sound form of treatment.

The Good Faith Medical Purposes Test. The language of the

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84. 26 C.F.R. § 151.592 (1967). This provision appears at the beginning of a pamphlet which was sent by the Bureau of Narcotics to practicing physicians in March, 1966, in an attempt to “generate interest in treating and curing narcotic addiction” and to apprise physicians of “the policy of the U.S. government” as regards the “ethical” treatment of drug addicts. Pamphlet No. 56; supra note 14, at 1-2. The pamphlet also contains, at 8-21, a reprint of a 1963 statement by the AMA Council on Mental Health and National Academy of Sciences-National Research Council, Narcotics and Medical Practice [herein-after cited as AMA-NRC (1963)].

85. See Bureau of Narcotics Letter, supra note 21.

86. AMA-NRC (1967), supra note 63, at 159 (emphasis in original). This statement is a condensation of a revision of the original AMA-NRC statement of 1963, supra note 84.

87. AMA-NRC (1967), supra note 63, at 140. The Bureau regulation makes no provision for research.
present Bureau regulation\(^8\) is derived from *Webb v. United States*.\(^8\) one of the first cases to interpret the Harrison Act's exemption for physicians. In *Webb*, "professional treatment" was restricted to treatment which attempted to cure the addict's habit.\(^9\) Supreme Court cases decided during the years immediately following *Webb* accepted and even added to the requirement *Webb* had engrafted onto the Harrison Act's exemption.\(^10\) Adapting the *Webb* position, the Bureau regulation states that narcotic drugs cannot be prescribed "to keep [an addict] comfortable by maintaining his customary use," and seems to allow

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88. Quoted at p. 1197 *supra*.
89. 249 U.S. 96 (1919) (doctor who peddled over 4,000 drug prescriptions indiscriminately at fifty cents a piece, sometimes using fictitious names on them, convicted of violating the Harrison Act).
90. The following question was certified to the court in *Webb*:
If a practicing and registered physician issues an order for morphine to an habitual user, the drug not being issued by him in the course of professional treatment in the attempted cure of the habit, but being issued for the purpose of providing the user with morphine sufficient to keep him comfortable by maintaining his customary use, is such an order a physician's prescription under [the provision which exempts physicians from the application of the Harrison Act]? *Id.* at 99. The Supreme Court, four Justices dissenting, answered that "to call such an order for the use of morphine a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required." *Id.* at 99-100.
By structuring their sentences so as to assume that "professional treatment" does not include "providing the user with narcotics sufficient to keep him comfortable by maintaining his customary use," both the question certified in *Webb* and the Bureau regulation attempt to settle the controversial question by begging it.
91. In *Jin Fuey Moy v. United States*, 254 U.S. 189 (1920), the Court held that a doctor could not legitimately prescribe drugs "for the mere purpose, as the jury might find, of enabling such persons to continue the use of the drug," or "to cater to the appetite or satisfy the craving of one addicted to the use of the drug." *Id.* at 193-94. The case clearly involved abuse, the doctor having peddled prescriptions to all comers, many not patients.
In *United States v. Behrman*, 258 U.S. 280 (1922), a most confusing case, the Court affirmed the conviction of a doctor who had written a prescription for narcotics large enough to provide 8000 injections. Although the facts indicated abuse, the case had the effect of taking away from physicians the defense of good faith. In what Rufus King calls a "trick indictment," the government had not alleged that the prescriptions were contrary to approved and proper treatment, but in effect alleged that the drugs were given in a good faith attempt to cure the addict. *King, supra* note 29, at 741. Justices Holmes, Brandeis, and McReynolds dissented, Holmes saying that the indictment alleged that the drugs were administered in good faith in the course of the doctor's practice, and that this brought Behrman within the statute's exemption. He refused to read the statute as "tacitly making such acts, however foolish, crimes,... if the Court deems the doctor's faith in his patient manifestly unwarranted." *Id.* at 290.
Although the effect of the case was to remove the defense of good faith, the Court itself focused on the large dispensation of drugs for self-administration, which the Court said "could only result in the gratification of a diseased appetite for these pernicious drugs or result in an unlawful parting with them to others in violation of the act as heretofore interpreted in this Court within the principles laid down in the *Webb* and *Jin Fuey Moy* Cases" *Id.* at 289. The Court hedged away, however, from saying that all dispensations of drugs for self-administration were prohibited for all kinds of patients as a matter of law: "It may be admitted that to prescribe a single dose, or even a number of doses, may not bring a physician within the penalties of the act . . . . Undoubtedly doses may be varied to suit different cases as determined by the judgment of a physician." *Id.* at 288-89.
Rufus King sums up the impact of these cases by saying that "the Narcotics Division succeeded in creating a very large criminal class for itself to police (i.e., the whole addict-doctor-patient-addict-peddler community), instead of the very small one that Congress had intended (the smuggler and the peddler)." *King, supra* note 29, at 738.
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only the administration of diminishing doses while the addict is undergoing withdrawal. Frequent prosecution and conviction of doctors discouraged most members of the profession from the treatment of addicts.\textsuperscript{92}

However, within 7 years after Webb, in \textit{Linder v. United States}\textsuperscript{93} and \textit{Boyd v. United States},\textsuperscript{94} the Supreme Court had significantly clarified the rights of physicians under federal law to dispense and prescribe narcotic drugs. These more recent decisions have been ignored by the Narcotics Bureau in official pronouncements to doctors.\textsuperscript{95}

The indictment in \textit{Linder} questioned neither the doctor's good faith medical purpose nor his adherence to proper standards of medical practice.\textsuperscript{96} In effect, it simply asserted that Dr. Linder had dispensed one morphine tablet and three cocaine tablets to an addict-informer for the sole purpose of "relieving conditions incident to addiction and keeping [the patient] comfortable,"\textsuperscript{97} on the assumption that this action was sufficient to constitute an offense under the Harrison Act. In reversing Linder's conviction and writing for a unanimous Court, Justice McReynolds repudiated the Webb test, pointing out quite correctly that the Harrison Act says nothing about addicts, and does not purport to prescribe methods for their medical treatment.\textsuperscript{98} Whether the doctor was engaged in "\textit{bona fide} medical practice" was to be determined by looking at "evidence and attending circumstances,"\textsuperscript{99} and thus not simply by referring to a single method of

\textsuperscript{92} A. LINDESMITH, \textit{THE ADDICT AND THE LAW} 6-7 (1965).
\textsuperscript{93} 268 U.S. 5 (1925).
\textsuperscript{94} 271 U.S. 104 (1926).
\textsuperscript{95} See, e.g., \textit{Pamphlet No. 56, supra note 14.}
\textsuperscript{96} 268 U.S. 5, 16-17 (1924). Dr. Linder's indictment was almost identical to that in \textit{United States v. Behrman}, 258 U.S. 280 (1922), \textit{supra} note 91, except for the quantity of drugs involved.
\textsuperscript{97} 268 U.S. at 17. Dr. Linder maintained "that the facts stated [were] not sufficient to constitute an offense." \textit{Id.} at 16. These facts included:

[Petitioner knew that the patient] was addicted to habitual use of these drugs and did not require administration of either because of any disease other than such addiction, and [petitioner] did not dispense them for the treatment of any other disease or condition; they were not administered by him or by any nurse or other person acting under his direction, nor were they consumed or intended for consumption in his presence; the amount was more than sufficient to satisfy the recipient's craving if wholly consumed at one time; petitioner put the drugs into her possession expecting that she would administer them to herself in divided doses over a period of time; they were in the form in which addicts usually consume them to satisfy their cravings; the recipient was in no way prevented or restrained from disposing of them.

\textit{Id.} at 16.
\textsuperscript{98} \textit{Id.} at 18. Throughout the opinion, Justice McReynolds expressed his conviction that limitations must be placed on the power of the federal government to regulate the medical profession by means of a revenue measure.
\textsuperscript{99} \textit{Id.} at 18. The opinion distinguishes and clarifies all cases, usually with a statement to the effect that the "quoted language must be confined to circumstances like those presented by the cause." \textit{Id.} at 20.
treatment, whether approved by the Bureau of Narcotics or anyone else. Using this test, the Court said that it could not possibly conclude that Dr. Linder "acted improperly or unwisely or for other than a treatment purpose."\(^{100}\) A fair reading of \textit{Linder}, then, is that a doctor who dispenses drugs for a good faith medical purpose has not violated the Act.\(^{101}\)

When taken in conjunction with \textit{Boyd v. United States},\(^{102}\) which was decided the following year and is the last Supreme Court pronouncement in the area, the \textit{Linder} test for the legality of a physician's acts becomes clearer: if the doctor dispenses or prescribes the drug "in good faith 'for the purpose of curing disease or relieving suffering,' he should be acquitted."\(^{103}\) The \textit{Boyd} court distinguishes between a prescription of drugs in which the doctor is "treating [confirmed addicts] for addiction or endeavoring to relieve them from suffering incident to it" (legal), and a prescription which "could only have been issued to enable the recipients to indulge their acquired longing for the drug and its effects" (illegal).\(^{104}\) Is the defendant trying to heal or merely to peddle? To be subject to the Harrison Act's criminal liability the doctor must be acting with \textit{no good faith treatment purpose}.

\textit{Linder} and \textit{Boyd} clearly abandon the \textit{Webb} prohibition against the distribution of addicting drugs to persons dependent on them. A doctor acting in good faith in the course of his professional practice may treat addicts as he sees fit and may, in his discretion, administer or prescribe drugs to relieve their suffering or to keep them comfortable; no \textit{treatment} goal or method, including drug maintenance, is proscribed as a matter of law. Despite this clear holding, the Bureau of

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100. \textit{Id.} at 18.
101. The case may also fairly be read to suggest a dual test for qualifying for the Harrison Act exemption: acting for good faith medical purposes and acting in accordance with fair medical standards. Although language about good faith and purpose pervades the opinion, there are two references to action in accordance with "medical standards." \textit{Id.} at 17, 22. Obviously, the two tests are related. See p. 1201 infra. But the thrust of the opinion—especially the concerns the court shows in distinguishing the earlier cases—seems to be a purpose test: had the doctor acted to treat, or had he merely "conspired to sell" drugs? \textit{Id.} at 20. Medical standards provide a useful aid to the court in judging the doctor's purpose, but the court must look at "attending circumstances." \textit{Id.} at 18. The \textit{Linder} court's references to medical standards suggest only that if the doctor had acted for a good faith medical purpose \textit{and} in accordance with medical standards, he could not be convicted. Since the indictment did not allege that Dr. Linder departed from either standard, the Court in its main task of sweeping away the earlier cases did not have to sort out its test as carefully as it later did in \textit{Boyd}. See p. 1201 infra.
102. 271 U.S. 104 (1926).
103. \textit{Id.} at 106.
104. \textit{Id.} (emphasis added).
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Narcotics regulation described above, based on language in Webb which Linder and Boyd repudiate, has never itself been appropriately modified.

In distinguishing between a treatment purpose and, for example, a conspiracy to sell narcotic drugs under the guise of a prescription, courts will naturally look to such factors as individualization of treatment and the care with which large quantities of drugs are dispensed. They will also look to "medical standards," since a departure from a procedure followed by all other reputable doctors strongly suggests the absence of a treatment purpose. But recourse to standards is no more than an evidentiary aid to the crucial determination for decision —whether the doctor acted for good faith medical purposes. Thus in Boyd, where several doses of heroin had been prescribed for self-administration, the doling out of abnormally large prescriptions—with the attendant risk either that the addict would consume all the drugs at once in a thrillseeking or dangerous way, or that he would dispose of the excess through illegal sales—was the basis for a presumption; the size of the prescriptions suggested to the court that the doctor was aiding or acquiescing in a plan to divert the drugs illegally, or else that he cared so little about how the drugs were used as to make the label "good faith" treatment clearly inappropriate. The Supreme Court upheld the doctor's conviction, pointing out that the amounts distributed "were grossly excessive and unreasonable according to any fair medical standard," and that no special reason or occasion was shown to justify the excess.

105. Quoted at p. 1197 supra.
106. PAMPHLET No. 56, supra note 14. Neither Linder nor Boyd is mentioned once in this pamphlet, which is widely distributed to doctors. The Bureau of Narcotics regulation (p. 1197), although it holds physicians to a single standard of practice (an attempt at withdrawal) and refuses to acknowledge other therapeutic goals as "professional treatment," sets out as its major premise a test of purpose: "A prescription in order to be effective in legalizing the possession of unstamped narcotics and eliminating the necessity for the use of order forms, must be issued for legitimate medical purposes." 26 C.F.R. 151.392 (1967).

26 C.F.R. § 151.411 (1967), not reprinted in PAMPHLET No. 56, supra note 14. Neither Linder nor Boyd is mentioned once in this pamphlet, which is widely distributed to doctors. The Bureau of Narcotics regulation (p. 1197), although it holds physicians to a single standard of practice (an attempt at withdrawal) and refuses to acknowledge other therapeutic goals as "professional treatment," sets out as its major premise a test of purpose: "A prescription in order to be effective in legalizing the possession of unstamped narcotics and eliminating the necessity for the use of order forms, must be issued for legitimate medical purposes." 26 C.F.R. 151.392 (1967).

26 C.F.R. § 151.411 is apparently only to tell physicians that they may in certain situations dispense drugs as well as prescribe them. 26 C.F.R. § 151.411 (1967) reads: "Prescriptions unnecessary. Practitioners may dispense narcotic drugs to bona fide patients pursuant to the legitimate practice of their professions without prescriptions or order forms." Although the cases discussed above show a concern for the amount of drugs under the addict's control, cases like Linder and Boyd suggest that the same analysis is required both where the doctor directly dispenses drugs and where he allows the addict to get drugs by means of a prescription.

On the authority of the case law, current methadone programs would appear to be immune from legal attack under the Harrison Act. All indications point to the conclusion that Dole and the other doctors committed to methadone maintenance are dispensing methadone "in good faith 'for the purpose of curing disease or relieving suffering.'"109 The drugs dispensed are in controlled dosages, and the entire administration process is carefully monitored. In contrast to the operations of Dr. Boyd, adequate safeguards exist during all stages of Dr. Dole's treatment program to protect against the potential problems created when multiple dosages are dispensed for self-administration.110 A good faith medical purpose is also indicated by the supplementing of drug dispensation with counselling and other supportive techniques as needed to aid the addict in social and vocational rehabilitation.111

Reference to Medical Standards. Although the determination of good faith medical purpose must be recognized as the crucial element in the adjudication of a physician's claimed exemption under the Harrison Act, reference to objective standards of medical practice will continue to be important. Such reference is necessary both as an aid to the courts, because the subjective determination of good faith medical purpose is so difficult, and because doctors might otherwise be discouraged from treating addicts for fear that their purposes would be misunderstood by law enforcement officials and courts.112

109. Id.
110. See note 22, supra.
111. In discussing Dole and Nyswander's initial research, the World Health Organization uses language similar to that of the cases:

The Committee is of the opinion that insofar as maintenance on methadone is not carried out simply for the gratification of the individual but is used as an adjunct to rigorous efforts toward social rehabilitation, the employment of this procedure under very carefully controlled conditions will be of considerable scientific interest.

WHO EXPERT COMMITTEE ON DEPENDENCE PRODUCING DRUGS, supra note 36, at 9.

This purpose test would exempt from the criminal provisions of the Harrison Act any doctor who acts with a good faith medical purpose (and any patient who possesses drugs "prescribed in good faith" by a physician, 26 U.S.C.A. § 4724(c) (1967)). Departure from medical standards may subject the doctor to professional sanctions, or, in the event of injury to the patient, to a possible malpractice suit. But cf. notes 119 and 125 infra. However there should be no danger of criminal liability. As Justice Holmes said, dissenting in United States v. Behrman, 258 U.S. 280, 290 (1922), "[S]uch acts, however foolish, [are not] crimes."

112. The fear many doctors express of becoming involved with treating addicts at all is in large part caused by the incredible confusion and contradiction in circuit court cases dealing with the dispensation of drugs to addicts. These circuit courts have experienced great difficulty in attempting to reconcile the irreconcilable language in all the Supreme Court's opinions interpreting the Harrison Act. It is often difficult to determine what test these courts are using: a purpose test, a medical standards test, or some variation or combination of the two.

Despite statements by most courts to the effect that the doctor's good faith is a question of fact for the jury, some cases seem to return to Webb's broad language:
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But the particular form of reference to practice advocated by the Bureau of Narcotics is both medically unwise and legally incorrect. The Bureau's position is that a doctor who fails to comply with the single standard of legitimate medical practice laid down by a joint committee of the American Medical Association and the National Research Council forfeits his professional exemption under the

When a licensed physician abuses his professional function by selling or giving away prescriptions for drugs to known addicts, he automatically forfeits the privileges extended to him by § 2552(c)(1) [§ 4705(c)(1)] of the statute. Lindenfeld v. United States, 142 F.2d 829, 831 (2nd Cir.), cert. denied, 323 U.S. 761 (1944). See United States v. Abdallah, 149 F.2d 219 (2nd Cir. 1945). See also Mauk v. United States, 88 F.2d 557 (9th Cir.) cert. denied, 302 U.S. 694 (1937); Nelms v. United States, 22 F.2d 79 (9th Cir. 1927). Any administration to an addict not suffering from a disease other than addiction which requires the drug for treatment is said to be "for the purpose of gratifying the craving for the drug" and not a "legitimate medical purpose." Ratigan v. United States, 155 F.2d 919, 922 (9th Cir.) cert. denied, 301 U.S. 705 (1937). Similarly, a doctor's honest belief that the drugs dispensed assisted a police chief-patient in holding his job or making him comfortable "does not establish good faith nor alter criteria of standard medical practice." McBride v. United States, 225 F.2d 249, 253 (6th Cir. 1955), cert. dismissed as improvidently granted, 350 U.S. 934 (1955).

Some cases attempt to make a distinction between a physician and a seller of narcotics—suggesting a good faith medical purpose test, but strongly implying that all dispensations of addicting drugs to addicts are "sales." Nigro v. United States, 117 F.2d 624 (8th Cir. 1941); United States v. Ratigan, 7 F. Supp. 491 (W.D. N.D. 1934).

Other courts indicate more clearly that they are using a good faith medical purpose test. See, e.g., United States v. Anthony, 15 F. Supp. 555 (S.D. Cal., 1936) (a district court opinion, but perhaps the sanest interpretation of the Harrison Act); Boehm v. United States, 21 F.2d 283, 285 (6th Cir. 1927); Neddleman v. United States, 261 F.2d 892 (5th Cir.), cert. denied, 362 U.S. 600 (1958) (a good faith test, but there had been evidence of a bad faith sale); United States v. Brandenberg, 155 F.2d 110, 111 (2nd Cir. 1946); DuVall v. United States, 82 F.2d 382, 386 (9th Cir.) cert. denied, 295 U.S. 697 (1936). In Teter v. United States, 12 F.2d 224 (7th Cir.) cert. denied, 273 U.S. 705 (1926), the use of a purpose test rather than a medical standards test worked to the detriment of the defendent. Two doctors testified that "in the treatment of addicts it was not improper to give them doses such as appear to have been given to the complaining witness." Notwithstanding this, the court said: "[W]e are satisfied that under all the circumstances it was for the jury to say whether or not these sales of drugs to the complaining witness were in good faith, or were solely for the purpose of pandering to the habit of a drug addict, and selling the drug." Id. at 225-26.

Some courts apparently use a good faith purpose test only to determine whether it was reasonable for the defendant doctor to believe that the addict would not resell the drugs. Bush v. United States, 16 F.2d 709, 710 (5th Cir. 1927). See also Hawkins v. United States, 90 F.2d 551, 553-55 (5th Cir.), cert. denied 302 U.S. 733 (1937) (court also indicating that it was following the Bureau regulation and would not allow any dispensation to addicts solely to treat their addiction).

Strader v. United States, 72 F.2d 869 (10th Cir. 1934), presents the most confusing set of facts. The court distinguishes (as the indictment in Linder did not) between providing drugs to keep an addict "comfortable by maintaining his customary use," and providing drugs "to relieve a condition incident to addiction." Id. at 592. This is an obvious attempt to reconcile Linder with the Bureau regulation, and is complete sophistry. (See A. LINDESMITH, THE ADDICT AND THE LAW 13 (1935): "A doctor who provides an addict with drugs to relieve withdrawal distress necessarily also keeps him comfortable by maintaining customary use.") Apparently building on this distinction, the Strader court continues that the physician must act "in good faith and in accord with fair medical standards," but that "evidence" of medical standards is crucial "because of its bearing upon the intent and purpose" of the doctor. If the doctor's conduct conformed to these standards, it would indicate good faith; but if he deviates from the standards, it suggests commercial purposes. Id, at 592. Strader's conviction was reversed partly because the trial court, holding that certain methods of treatment were not permitted as a matter of law, had refused to allow appropriate expert testimony.
Harrison Act.\textsuperscript{113} The gist of the joint AMA-NRC report, considered by the Bureau as "the authoritative definition of legitimate medical practice,"\textsuperscript{114} is that "the continual administration of drugs for maintenance

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113. Federal law provides the framework within which the medical profession can authoritatively determine what the role of the physician will be in the treatment of addicts and in determining alternative approaches to the addiction problem. . . . Congress has imposed a responsibility upon law enforcement agencies to ascertain whether certain practices by a physician are bona fide, and the courts have said that physicians have no immunity from prosecution outside the scope of professional treatment. . . . [I]n fulfilling the responsibilities imposed by the legislators and the courts, the enforcement agencies have looked to the representative medical and scientific groups for policy guidance. Specifically, we have relied on the pronouncements of the American Medical Association, and more recently the joint statements of AMA and the National Research Council.
\end{quote}


Although the AMA had played a significant role in the development of Bureau of Narcotics policy, that relationship has not been formalized until recently. See \textit{generally}, AMA-NRC (1963), \textit{supra} note 84, at 9; for a discussion of the AMA's role in the hasty closing of the narcotic clinics in this country in the 1920's, see AMA Council on Mental Health, \textit{Review of the Operation of Narcotic "Clinics" Between 1919 and 1923}, in O'Donnell and Ball, \textit{supra} note 11, at 180-87.

Because of inconsistent court rulings and widespread harassment of doctors, many confused and fearful doctors withdrew from the treatment of addicts. In 1961 a widely distributed report by the Joint Committee of the ABA and AMA on Narcotic Drugs pointed out the difficulties and recommended that (1) the determination of standards of good faith and limits of proper medical practice should not "be left to the conflicting opinions of so-called experts, who may have differing views on how to treat narcotic addiction" or to "twelve laymen on a jury" making "an ex post facto judgment;" (2) "the AMA itself should determine the standards of good faith and the limits of proper medical practice in the treatment of addicts." \textit{Placowec, supra} note 30, at 82. The next year the Ad Hoc Panel Report to the 1962 White House Conference on Narcotics made similar recommendations. \textit{PROCEEDINGS: WHITE HOUSE CONFERENCE ON NARCOTIC & DUID ABUSE} 271 (1962). In 1963, the President's Advisory Commission on Narcotics and Drug Abuse recommended that steps be taken to reflect the principle that the medical profession should determine what is the legitimate medical treatment of addicts and legitimate medical use of narcotic drugs. \textit{PRESIDENT'S ADVISORY COMMISSION ON NARCOTICS AND DRUG ABUSE, REPORT 57} (1963). Toward that end, the Commission requested the AMA Council of Mental Health and the National Academy of Sciences-National Research Council to prepare a joint statement as to what in their opinion constituted the legitimate medical treatment of the narcotic addict. The statement (AMA-NRC (1963), \textit{supra} note 84) was printed in the Commission's final report. \textit{Id.} at 83-95.

In that statement the AMA-NRC called for the establishment of "a medical body on a national level to maintain a current 'code' of ethical medical practice with relation to narcotics and narcotic addiction. . . ." AMA-NRC (1963), \textit{supra} note 84, at 16. In 1965, the AMA-NRC "notified [the Bureau of Narcotics] that a joint committee of members from AMA and NRC had been formed to act as an informal advisory body to the Bureau of Narcotics on certain problems relating to narcotics and narcotics addiction . . . ." Letter from Walter Wolman, Director, AMA Dept. of Mental Health, to Henry Giordano, Commissioner of Narcotics (on file at Yale Law Journal). That body continues to function, and in 1967 it released a revision of its 1963 statement, AMA-NRC (1967), \textit{supra} note 63.

114. In 1967, the Presidential Commission on Law Enforcement and Administration of Justice (The Crime Commission) summed up the status of the AMA-NRC statement:

The Bureau of Narcotics accepts it as the authoritative definition of legitimate medical practice against which all medical practice is to be measured. . . . The Commission has no doubt that the AMA-NRC 1963 statement was an accurate expression of the consensus of medical opinion about treatment. . . . Whatever the situation may have been before 1963, there is now no reason for any confusion or apprehension on the part of physicians about their legal right to treat addicts-patients in most circumstances that are likely to arise. \textit{TASK FORCE REPORT, supra} note 1, at 19. It indicates however, that a "minority, composed of reputable men within the medical profession . . . do not consider [the AMA-NRC
of addiction is not a bona fide attempt at cure, nor is it ethical medical treatment. . . . The maintenance of stable dose levels is generally inadequate and medically unsound." 115 Ironically, reliance on the views of a medical group—an approach recommended by the President's Advisory Commission on Narcotics and Drug Abuse and others as a means by which to return the addict problem to the medical profession and to encourage doctors who had been intimidated by fear of Harrison Act prosecution to begin treating addicts 116—has become instead the means by which a number of respectable doctors have been either deterred from treating addicts at all, or harrassed in their efforts to

115. AMA-NRC (1963), supra note 84, at 11, 14. Prolonged administration of narcotics is allowed, however, in a "few unusual circumstances" for patients suffering incurable and painful (but not necessarily fatal) diseases, patients in terminal conditions, and aged and sick addicts for whom withdrawal is dangerous to life.

116. See note 113 supra.
apply a treatment approach not popular with a majority of their profession.\textsuperscript{117}

To take the position of the Bureau that advocates of methadone maintenance must wait "until the consenses [sic] of medical opinion indicates that medical maintenance of addicts is professional treatment,"\textsuperscript{118} is to adopt a concept of government unsuited to a profession in which sharp division over appropriate forms of treatment is the norm. It is generally recognized that a multi-standard approach, permitting a wide range of individual variation, is necessary to prevent stultification in the profession. In civil malpractice suits, for example, a physician is protected as long as he follows a "course of treatment advocated by a considerable number of his professional brethren in good standing in the community;"\textsuperscript{119} at least this much professional discretion should be allowed under a criminal statute which cuts into medical practice obliquely and requires no showing of actual harm to the patient.\textsuperscript{120}

\textsuperscript{117} In an interview on Feb. 7, 1969, Dr. Dole discussed the difficulties his program has had with Bureau investigators. Both Jaffe and Wieland mention in their articles the anxiety caused by the legal uncertainty of their programs. Jaffe 1969, supra note 2, at 2; Wieland, supra note 2, at 33.

In theory, an AMA-NRC statement could be written to reflect the full range of respectable medical opinion—majority school, minority school, and beliefs less widely approved but still held by respectable authority. A doctor would then both know before he acted that he was safe from criminal prosecution, and be free to act according to his best professional judgment in selecting among various treatment approaches. The AMA-NRC statement as written simply fails to reflect that full range of responsible opinion.

In practice, the hope that "impartial" panels will either resolve medical disagreements or reflect all shades of respectable opinion may be naive. Cf. Lambert, \textit{Impartial Medical Testimony} 20 N.A.C.C.A. L.J. 25, 29 (1957) ("If a partisan to one or other school of thought is on the so-called impartial panel, he brings his opinions with him; the wine must taste of its own grapes."); B. Diamond, \textit{The Fallacy of the Impartial Expert}, 3 Arch. Cum. Psychiat. 221 (1959).

\textsuperscript{118} Bureau of Narcotics Letter, supra note 21 (emphasis added).


\textsuperscript{120} At least one lower court judge took this approach towards medical standards in a criminal trial for violation of the Harrison Act:

If reputable physicians honestly hold to two opinions, some justifying the administr-
And the single standard test is as legally unsound as it is medically unwise. Since a study of the case law has shown that purpose is the crucial test for exemption, the legal theory of the Bureau must be that failure to comply with the single AMA-NRC standard creates an irrebuttable presumption of a lack of good faith medical purpose. For a court to indulge in such a presumption would be to return to the discredited *Webb* approach of proscribing certain methods of treatment as a matter of law.

In addition to its general statement on the medical unsoundness of drug maintenance, the AMA-NRC has also issued a special statement on the methadone maintenance programs. Asked by the Narctoics Bureau for advice as to whether the Dole program was “treatment” or “research,” the AMA-NRC responded that it was “a pilot research project to study a relatively new treatment approach,” labeled it “promising,” but called for further evaluation. The Bureau has used this description in a conclusory way. It permits methadone maintenance when it is a “research undertaking,” but will not allow a widespread therapeutically-oriented program. Thus the Bureau has recently made a series of “inspections” of methadone programs to determine whether they are being run “within the limits of ethical medical practice as applied to research,” by which the Bureau apparently means kept small and devoted to information-gathering rather than to the treatment of patients.

It should be pointed out that in 1924 the AMA House of Delegates issued a famous policy statement condemning as improper any method of addict treatment which gave the patient drugs for self-administration. AMA-NRC *(1963)*, *supra* note 84, at 9. This view was clearly not determinative of the issues arising in Harrison Act litigation. *United States v. United States*, 268 U.S. 5 (1925) (physician may prescribe drugs for addict’s self-administration).


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The Bureau has refrained from any action which might restrict research and there are now several research methadone addiction maintenance programs being conducted in the United States. Since such activities must be carried out within the limits of ethical medical practice as applied to research, and since it is still the job of this Bureau to make certain that narcotic drugs are not being diverted into illicit channels, it has been necessary for us to make inspections, seek appropriate explanations, and, when necessary, to recommend corrective action. Some physicians strongly protest a police officer making inquiries into professional practice, and our activities have been interpreted as disruptive. However most researchers recognize the medico-legal problems involved, and we have had a good working relationship with them.
Whichever label the Bureau uses, a doctor should always be safe from Harrison Act liability when he is following treatment procedures approved by other respected doctors; once a doctor has cleared his procedure with an appropriate advisory body, he should have no need to negotiate with the Bureau of Narcotics under threat of legal attack, regardless of whether he calls his program research or treatment. At a time when the medical and legal professions are just beginning to give extended consideration to the complex ethical problems of medical research, it is inappropriate for the Bureau of Narcotics to threaten criminal prosecution for activities not carried out “within the limits of ethical medical practice as applied to research,” both because those “limits” have not been defined in any detail by the profession and because, for historical reasons, the mere presence of Bureau investigators intimidates doctors and arouses their resentment.

124. For example, the use of decentralized, hospital committees to review the judgment of experimenters is now required for any grant under the jurisdiction of the National Institute of Health, which sponsors five methadone research programs. For a general discussion of the role of these institutional review committees and their possible future role in the regulation of medical research on humans, see Calabresi, Reflections on Medical Experimentation in Humans, 98 DAEDALUS, Spring 1969, at 200-405; Curran, Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies, 98 DAEDALUS, Spring 1969, at 542, 576-88; Freund, Introduction to the Issue “Ethical Aspects of Experimentation with Human Subjects,” 98 DAEDALUS, Spring 1969, at x-xi; Jaffe, Law as a System of Control, 98 DAEDALUS, Spring 1969, at 406, 409-10, 419-20; Katz, The Education of the Physician-Investigator, 98 DAEDALUS, Spring 1969, at 494-97.

125. It is widely agreed that the use of an “experimental” procedure is proper when “there is no established procedure for handling the medical problem confronting the physician” or when “the application of established and approved treatments and procedures has failed to bring about an improvement of the patient’s condition.” SHARTEL & PLANT, THE LAW OF MEDICAL PRACTICE 125-23 (1959). The Declaration of Helsinki, perhaps the most important codification of ethical guidelines for medical experimentation, makes an important distinction between therapeutic experimentation and non-therapeutic experimentation, and of the former says: “In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, reestablishing health, or alleviating suffering.” World Medical Association, supra note 47. In one of the few litigated cases in this area, Stammer v. Bd. of Regents, 262 App. Div. 372, 29 N.Y.S.2d 38 (1941), aff’d, 257 N.Y. 959, 39 N.E.2d 919 (1942), the court overturned the suspension of a physician’s license to practice for having used in the treatment of cancer a “secret formula” that was unknown and without support in the medical profession. The court pointed to the doctor’s skill, the patient’s full knowledge and consent, the failure of other known methods, and the need to encourage initiative and originality in the medical profession. For the importance of the patient’s informed consent to liability-free experimentation, see SHARTEL & PLANT, THE LAW OF MEDICAL PRACTICE 38-40, and cases cited therein; Stason, The Role of Law in Medical Progress, 32 LAW AND CONTEMP. PROB. 563 (1967); Blumgart, The Medical Framework for Viewing the Problem of Human Experimentation, 98 DAEDALUS, Spring 1969, at 248, 255-62; Freund, Legal Frameworks for Human Experimentation, 98 DAEDALUS, Spring 1969, at 314; Katz, supra note 124; Jaffe, supra note 124, at 420-22.

In the treatment of addiction, there is clearly no generally accepted, successful method of treatment. In this situation, keeping in mind that in the care of the patient the doctor should always use his professional judgment and weigh risk of treatment against risk of no treatment, the justification for the use of an “experimental” procedure for therapeutic purposes is great.

Furthermore, for the Bureau to say that methadone "research" but not methadone "treatment" will be allowed is to engage in a meaningless labeling game; it is by no means clear that sensible distinctions between therapeutic research and treatment can be made.\(^{127}\) Criteria such as safety, effectiveness, and purpose do not effectively distinguish therapeutic research from treatment,\(^{128}\) nor does calling a procedure "research," as opposed to "treatment," itself determine the scale on which that procedure should be used or the safeguards necessary for the patient.\(^{129}\)

The best distinction between therapeutic research and treatment is one based on "knowableness"; for example, enough data probably exists about Dole's basic program to permit a fully informed judgment on the advisability of its expanded use, whereas variants of his program which eliminate the in-patient phase or accept a larger part of the addict population cannot be evaluated as completely until they have been more thoroughly tested and become more "knowable."\(^{130}\) But once this distinction has been recognized, the most pressing issue regarding methadone maintenance remains: is it wise or proper to use a treatment effort on a large scale when both the risks and effectiveness of the proposed treatment are not fully known?

An expansion of methadone treatment under conditions where risk

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127. See Katz, supra note 124. See also Freund, supra note 124, at viii-ix.
128. The notion that a distinction can be drawn on the basis of safety breaks down when one considers that some accepted "treatments," such as cardiac catheterization and digitalis in the diagnosis and care of heart disease, are every bit as risky as so-called "research." Indeed, medical treatment is always risky in that even the safest of drugs, such as aspirin, may, in particular instances, produce dangerous side effects.

Reference to effectiveness also proves unsatisfactory as a basis for distinguishing between research and treatment. Obviously, a method of treatment may prove ineffective on a patient, regardless of drug labeling or favorable indications before treatment. Some procedures accepted as treatment are applied without much clear indication of likely effectiveness; e.g., heroin addiction treatment methods and programs other than methadone maintenance.

The idea that in research the purpose is to acquire medical knowledge, while in treatment it is to care for the patient, makes little sense since much research takes place in the context of therapy, and since most therapeutic interventions today are considered experimental. See articles cited in note 127 supra.

In addition, it is not correct to say that for procedures called treatment there is a general agreement about appropriateness, or an understanding of the reasons for effectiveness (e.g., shock treatments).

129. The notion that research may not appropriately be run on a large scale falters abruptly when one recalls the widescale testing of the poliomyelitis vaccine.

As Dr. Jay Katz asks, "If consent becomes an important requisite in clinical research combined with therapeutic care, should it be obtained in therapeutic interventions? Does it make any difference whether the same medical procedure is carried out in the context of a research study or not?" Katz, supra note 124, at 497 n.7. A procedure labeled research, of course, usually contains evaluation features.

130. Of course we could have the knowledge that a medical procedure yields 90% success (and thus feel justified in its large-scale use) but still not have a way of determining the risk or prognosis for success for any individual patient.
and effectiveness are not well known raises a range of questions needing the most serious consideration by decisionmakers from the legal, medical, and lay communities, questions which are currently overshadowed by the debate defined by the Bureau of Narcotics.\textsuperscript{131}

The most difficult questions concern procedures affecting the voluntariness of the addict's involvement in treatment. What sort of consent should be required of "volunteers"?\textsuperscript{2132} Since many addicts may not be motivated to seek treatment on their own (this lack of motivation may be part of the disease), what attempts, if any, to recruit addicts for methadone treatment would be proper? What procedures, if any, should be used for enlisting addicts in prison? When addicts are civilly committed, what is the content of their "right to treatment"—for example, when several methods for treating addicts are available, what role should the addict play in the selection of a treatment procedure?\textsuperscript{2133} Given a risk of harm or a possibility of failure, in what situations, if any, may a treatment procedure be compelled, or made a condition of parole?\textsuperscript{2134}

These questions are especially important because a social program promising a reduction in crime may be seized upon by those whose zeal for order can lead to all too casual disregard of the dignity and rights of the individual. Thus it is appropriate to question whose interests planners are considering when they talk of benefits and costs

\textsuperscript{131} The distortion brought about by the Bureau's policy that only methadone "research" programs are allowed is shown by the recent announcement in New York City that a five-year methadone "research" program was being developed (with help of the Vera Institute of Justice) to treat 5000 addicts. New York's purposes would seem clear: with an enormous addict population, a soaring crime rate, and no other proven effective treatment program available, the political leadership has seized on methadone maintenance hoping that it will yield significant results. While this program will be answering significant questions and while there are enough variables to justify the program's size (presumably a program could always be made to look like research, especially if expensive evaluation components were built in), calling the program research is either deceptive or meaningless. The city, after all, will be creating an enormous population dependent on methadone, and could not very easily call its program off at the end of five years. The label "research" is applied by the City not because the word can be given significant content, but because it might bring the program within the Bureau of Narcotics' "research" authorization. Worst of all, the Bureau's approach focuses attention on a word, and diverts attention away from what should be a highly visible consideration of the real issues, which include weighing the risks and benefits to the patient and society of a large program.

\textsuperscript{132} The role of consent in medical experimentation with humans is discussed in the articles cited in note 125 supra.

\textsuperscript{133} For an interesting discussion of the range of problems likely to arise in the development of the right to treatment following Rouse v. Cameron, 373 F.2d 451 (D.C. Cir. 1966), see Katz, The Right to Treatment (initial draft of a paper to be published in the University of Chicago Law Review).

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of a proposed policy; compassion for the addict is not the same thing as pity for ourselves. As a program comes under the control of those whose concerns are primarily to reduce crime, the program may take on the main characteristics of a non-therapeutic research effort, where pursuing a goal of benefit to society may conflict with the best interests of the patient/subject. In such a situation, the need for safeguards is most acute, for the individual's autonomy is most vulnerable.