HEROIN-BASED TREATMENT

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This article describes the history of the heated legal controversy in Germany about prescribing medicinal narcotics. The professional corporations of medical doctors have claimed a right to govern the interpretation and definition of legal terms and for a long time resisted the clinical insights and practical experience about maintenance treatment that had been gathered from abroad. The next logical step was to prescribe heroin — also formerly a licensed medication — in cases where methadone was not accepted or physically tolerated by patients. Slowly the social and political taboos against providing narcotic maintenance to addicts have been removed. The author addresses the question of whether prescribing heroin to addicts can reduce health and social problems and improve the client’s quality of life.

THE GERMAN DISCUSSION REGARDING THE PRESCRIPTION OF MEDICINAL NARCOTICS

After more than ten years of controversial discussions in Germany about medical prescription of opioids, a group of interested cities, German states (Laender), and the Federal Ministry of Health began a cooperative effort in the spring of 1999 to address the issue. The newly elected government declared its support for the initiation of model projects for heroin prescription in Germany.

The Bundesaerztekammer (German Medical Association), police departments in many large German cities (see the Tageszeitung article from June 16, 1998), many trade groups (DHS, akzept, FDR), and an assortment of experts declared that they were in favor of model heroin-based treatment projects, initially described as the controlled prescription of heroin. This topic was not only debated in Germany, but in other neighboring European countries, Canada (Fischer & Rehm, 1997; Rehm & Fischer, 2000; Fischer, 1999), the United States, and Australia (Bammer, Crawford, Dance, Ostioni, & Stevens, 1995; Bammer, 1997) as well.

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The ongoing professional debate about the medical prescription of heroin has been based on the previous British experience of medical prescription of drugs to addicts (Marks, 1992; Bschor, 1980; Krausz, 1999), a practice that began in England in the 1920s. In 1926 the Rolleston Committee recommended “the prescription of heroin and other drugs to drug addicts only if the patient cannot undergo detoxification without serious withdrawal symptoms, if the patient is undergoing a gradual yet slow withdrawal therapy or if the patient needs the drugs to live a useful and normal life.” This last qualification allowed a liberal interpretation of the system (Muehlhausen, 199, p. 33). In the British approach, the earlier treatment goal of abstinence had to be expanded to include the reduction of harmful consequences of drug consumption for the addict and for society as a whole.

An important question relates to whether the medical prescription of narcotics, i.e. diacetylmorphine or heroin, is a suitable treatment for drug addicts, and if so, whether it can be accepted as a routine component of the addiction treatment system. The far-reaching debate over the medical treatment of drug addicts that took place in Germany during the 1980s was based on the model of substitution treatment with methadone. This conflict, often referred to as the “war of beliefs,” has recently subsided. Substitution treatment, namely with methadone, has come to be considered the therapy of choice in Germany; it has been widely used and has produced considerable success with regard to the health and social stabilization of patients (Gastpar, 1999; Kuefner, 1999; BAS 1999; Zerdick, 1999).

In addition to the benefits listed above, the adoption of substitution treatment has also encouraged doctors to assume responsibility for the treatment of drug addicts. In doing so, they have provided basic medical assistance and supplemented the services provided by addiction treatment programs that focus their efforts on psychological and social rehabilitation. Currently, many doctors still have not had experience in the medication-based treatment of drug addicts, although others are now well informed about addiction and drugs. Recently, addiction specialists created the “Deutsche Gesellschaft fuer Suchtmedizin” (German Society for the Treatment of Addiction or DGS, 2000), and a large collection of standard works on addiction treatment is now available (Goelz, 1995; 1998; Backmund, 1999; Poehlke, 2000). The Bundesaerztekammer has also created a specialized course of study on the subject of addiction (BAEK, 1999). In addition, the Third Amendment to the German Law on Narcotics (Drittes BtMG-AendG, p. 303) which went into effect on April 1, 1999, provides that “the prescription of substitution drugs to drug addicts will be dependent upon the fulfillment of the minimum requirements set by the medical doctors who prescribe medications, and the predefinition of the minimum requirements will be assigned to the Aerztekammer.” In this manner, an infrastructure for heroin-based treatment developed.
HEROIN-BASED TREATMENT

Practitioners of somatic medicine have begun to realize some of their limitations and have expanded the professional field to include psychosocial considerations. In doing so, social work is playing an integral role in the provision of social and medical assistance. Social workers are now helping drug clients and supporting them while they access self-help resources, as well as assisting them to free themselves from dependencies on other people. In this respect, the “expansion” of the range of substitution products to include heroin itself does not actually pose a new challenge. Rather, objectifying heroin as a therapeutic substance contributes to the delineation of the goals of opiate addiction treatment.

Given this scenario, embracing heroin treatment as one component of a coherent drug policy will not negatively impact the message of prevention. In this manner, prevention (if it is to be realistic and believable) also means minimizing the health problems and social disintegration caused by the misuse of psychotropic substances. In this regard, the model project for heroin-based treatment compliments, rather than contradicts, these other efforts.

THE SWISS PRACTICE OF PRESCRIBING HEROIN

Recently, the final results of a comprehensive scientific study conducted between 1994-1996 on the Swiss practice of prescribing heroin were made available. A brief overview of the results of this study are presented below:

- Improved accessibility to the target group by offering heroin prescriptions.
- Improvements in the overall medical condition, both physical and psychological, of participants.
- Positive changes in the addictive behavior of clients, including a decrease in the illegal consumption of heroin and cocaine by some.
- Better social integration of clients with respect to work capacity, living conditions, and debt reduction.
- Drastic reduction in the clients’ delinquent behaviors.
- Economic benefits including lowering the costs for criminal prosecutions and detainment as well as for required medical treatments (Uchtenhagen,1998, p. 75; Muehlhausen, 1998, p. 175; Rihs-Middel, 1996; Bundesamt fuer Gesundheit [Switzerland’s Federal Department of Health], 2000).

Based on the study’s outcomes, the researchers recommended continuing a limited program of heroin-based treatment:

The . . . positive results do not imply that we recommend heroin-based treatment as the primary therapy of choice. Rather, it can be
seen as a supplement to the range of treatment, which still includes abstinence-oriented therapies and substitution treatment with oral methadone. (Uchtenhagen, 1998, p. 81)

In this instance the new method was simply treated here as an addition to the available range of therapies – no more and no less (see also Uchtenhagen, Gutzwiller, & Dobler-Mikola, 1994; Uchtenhagen et al., 1999).

The Medical Prescription of Heroin in the Netherlands

The government of the Netherlands has reported that they have a stable, aging population of heroin addicts with long-term use histories, and that these persons seldom take advantage of the comprehensive and easily accessible treatment system that exists there. The number of addicts for the nation as a whole is estimated to be about 24,000 (van der Brink, 2002). Dutch lawmakers first began to consider offering heroin-based treatment in the mid-1990s in response to the publicized results of the Swiss study. The Central Committee for the Treatment of Heroin Addicts (CCBH) was established in 1996 to develop a drug trial protocol for a scientific study of heroin maintenance, with a research design calling for 750 clients. The committee presented the protocol and research design to the Ministry of Health at the end of 1997. A pilot phase was established for 185 patients at the end of 1997 in Amsterdam and Rotterdam, 50 of whom were to receive heroin. The goal of the study was to compare the beneficial and harmful effects of treatment with oral methadone to treatment with prescribed heroin. The study did not concentrate on maintaining abstinence, but focused on fostering improvements in the physical and psychological health and social integration of the participants (see also van Brussel, 1999).

The admissions criteria are: at least 25 years of age, a minimum of five years of dependency on heroin, having experienced failure in other therapeutic efforts (for example, if the previous treatment with methadone was ineffective, the patient must have had a minimum of 50 contacts in a methadone program), health and, or social disintegration, etc. (van der Brink, 2000). Since they began considering patients for admission in July 1998, doctors have recruited 370 patients into the injection project and 160 into a companion inhalation project. No fatalities have occurred, and the patients have not experienced any major difficulties switching from heroin to prescribed methadone. The main results are as follows:

The CCBH concludes that in chronic, treatment-resistant heroin addicts who are already treated with methadone, the treatment with heroin in combination with methadone is more effective than the continuation of methadone alone. With this additional heroin therapy, the patients can benefit from the treatment with respect
HEROIN-BASED TREATMENT

to their health and their social functioning. The registration of heroin as a medical product is recommended (van der Brink, 2002).

CRITICISM OF HEROIN-BASED TREATMENT

The critics of heroin-based treatment have presented arguments similar to those raised earlier by opponents of methadone treatment. These include the claims that, the provision of heroin will prolong the person’s addiction and that prescribing it “capitulates to the addiction.” It is clear from the foregoing comments about the Dutch heroin trials that initial expectations of the program had been too high, as some thought that the results would be similar to those that had been found for substitution treatment. In this sense, maximum success was expected within a relatively short period of time among drug addicts who were older, poverty-stricken and who had long careers of dependence. The idea of harm reduction or damage minimization has been completely disregarded in these criticisms. High expectations have also been held for the possible social effects of these programs. A lesson learned from substitution treatment is that although methadone can serve as a catalyst in improving an addict’s situation, real progress can only be achieved through outpatient psychosocial treatment and efforts to further the addict’s own self-competence. Thus, the idea of a pharmacological panacea is slowly being replaced by more realistic perceptions of the drug problem and the treatment of hard core addicts.

PARALLELS TO METHADONE TREATMENT

Similar patterns may be observed with regard to substitution treatment in Germany (see Huesgen, 1989) and the prescription of heroin in Switzerland and in the Netherlands. In all of these cases exceptionally strict criteria were developed for acceptance into the programs. In fact, some critics have argued that the acceptance criteria are too restrictive, and that many heroin and multiple drug users are being excluded from treatments for which they may be well suited. There are also a number of drug addicts experiencing health and social problems who are younger than 25 years of age, yet they are ineligible for substitution treatment.

Despite such complaints, neither the general public nor the experts have been willing to relax the criteria and offer heroin treatment to all addicts who might profit from it. As noted earlier, these issues parallel those that were encountered with the implementation of methadone treatment in the late 1980s. The nationwide controversy over the introduction of medication-based forms of treatment led to the development of extremely cautious policies. The medication-based treatment forms have recently been linked with other proposed treatment changes. The new
proposals have not yet been adopted, however, and strong regional differences complicate matters.

**Removing Taboos**

The existing taboos against the proposed heroin maintenance efforts will undoubtedly be lessened once doctors actually begin prescribing the drug. Presumably heroin — which people view as a symbol of ill health and social danger — could come to be seen as a substance with therapeutic value, due to the fact that it has achieved medical legitimacy. Under this program, doctors will be able to prescribe the drug as they would any other medication, another routine form of medical treatment. For this system to work, however, there will have to be a fundamental change in the perspective of users. While heroin consumption has traditionally been part of their chosen hedonistic lifestyles, they will now be asked to see themselves as medical patients. It seems likely that a debate about heroin’s status change from an illegal to a legal drug will take place due to the public’s obvious ambivalence about heroin: is it a diabolic substance or a medicine?

Cohen (1998, p. 19) describes the developing dynamic: “A modern, humane and intelligent drug policy needs to recognize the symbolism of drugs, but it can no longer make the symbolism the deciding factor. A modern drug policy must simply make it possible for doctors and addicts to work together to find out which substances need to be used in which situations.” The adoption of a modern drug policy would require that people rethink their positions about other previously illegal substances as well. New forms of assistance and treatment need to be made available to cocaine addicts and frequent users of ecstasy as well. Despite these suggested changes, the current treatment paradigm founded on the notion that drug consumption is entirely hedonistic and undesirable remains intact.

**Social Work and the Heroin Prescription Projects**

Anticipated social work practices associated with the prescription of heroin (Arnold, 1996; Kleiber, 1999) would not be much different from the psychological and social assistance that is offered or prescribed in substitution treatment programs. As is true in methadone programs, social workers could be successful in processing personal and social conflicts and in identifying and developing hidden potential and self-help resources. This would occur because the program participants have access to heroin without the pressure of having to purchase the drug in illegal markets. Ultimately, it is believed that these programs will serve as the basis for the client’s continuing reintegration and normalization. The Swiss heroin maintenance studies have reported similar findings: “A certain euphoria often predominates when the drug is prescribed and everything appears to be working.
HEROIN-BASED TREATMENT

Then depressions suddenly emerge, and the participant is confronted with feelings of sorrow, shame and failure” (Berthel, 1997, p. 3).

While substantial health improvements can often be achieved in a relatively short period of time, a routine of social significance and psychological stabilization often takes a longer period of time to achieve and requires the interdisciplinary cooperation of medical and psycho-social professionals. Those running the German project plan to include a psychosocial component in the treatment setting, although scientifically valid criteria must be developed during the pilot project in order to determine the specific measures that would be most appropriate. This concern with conceptual integration may be traced to the earlier findings of the World Health Organization’s external advisory committee in regards to the Swiss project’s “attempts at prescribing narcotics to drug addicts.” The document states: “These changes represent, within the limitations of the study design, overall meaningful improvements in health status. Those prescribed heroin (alone or in combination with methadone and other medications) evidenced significant improvements in their physical and mental health over 18 months. However, in the absence of data from an appropriate control group it is not possible to conclude that these improvements were caused or enhanced by the prescription of opiates, the provision of ancillary services, or by the combination of these interventions” (Ali et al., 1999, p. 165). In contrast to the studies conducted in other countries, the German research would be the first to examine the results of heroin-based treatment in different settings.

There are two goals associated with the creation of different control groups in the German experiment. The first is to test vis-à-vis the Swiss project the scientific added value of the standard intervention strategy, in this context traditional case management. The second is to provide psycho-educational programs for the opiate dependent group. The various effects are to then be evaluated for both groups.

In contrast to the medical care of opiate addicts, no standards exist for the psychosocial co-treatment, either for procedures or for intensity. In order to evaluate the psychosocial treatment component, two procedures, differing in their conceptions, will be implemented and compared in the course of the project. Both procedures – case management with integrated motivating interviews and psycho-education in conjunction with drug counselling – will be standardized to the extent possible. Concerning case management, it is possible to utilize the experiences of the German model project with this intervention strategy (Oliva, Goergen, & Schu, 2000). The German model project showed that drug addicts with chronic multiple impairments who were previously not reached by the addiction network could be accessed and maintained in care. Positive experiences with the treatment of chronic illness, especially psychoses and chronic physical diseases, show that psycho-
education is a procedure that is easily standardized and that could be an effective addition to the existing variety of treatment programs (Krausz & Farnbacher, 2000). The integration of existing intervention strategies would thus be facilitated (e.g., self help concepts and help offers of local counselling services).

**WILL PRESCRIBING HEROIN AMELIORATE THE PROBLEM OF LIFE-THREATENING INFECTIOUS DISEASES IN DRUG ADDICTS?**

One central expectation may be placed on heroin prescription—and this extends well beyond the framework of the model project. This is that the program should increase accessibility to assistance so that more addicts can establish and maintain stable contact with public health care facilities. Hartnoll (1993) feels that there are other groups experiencing difficulty in trying to access assistance in this AIDS-defined era, especially younger addicts and more controlled, less conspicuous addicts whose drug consumption and lifestyle remain relatively stable. Neither of these groups is to be included in the heroin maintenance program, however, although making offers for contact more attractive could help them avoid significant health problems. If heroin prescription programs are to be effective in preventing HIV and AIDS, the present strict admission requirements will have to be relaxed considerably, as Hartnoll suggests. On the other hand, we must keep in mind that heroin maintenance programs are more difficult to manage than are methadone interventions. The reasons for this include the facts that the patient has to take heroin much more often than methadone, and in most cases they would prefer to inject heroin. Given these demands, the traditional British method of administration is preferred—giving the patient the heroin dosage or prescribing the heroin through the patient's local pharmacy and providing the user with an adequate number of syringes. This procedure is conducive to the emergence of a black market, however, and this would certainly subject the heroin maintenance approach to considerable criticism.

**MEDICALLY CONTROLLED TREATMENT OR LEGAL ACCESS TO OPIATES?**

An engrossing discourse took place with regard to the Swiss heroin prescription projects, and this is certain to be repeated in Germany. Heroin prescription projects have been introduced as medically controlled prescription models, where these practices become a part of routine or accepted medical treatment (“medicalized”). They serve as one component of psychiatric-medical and psychosocial treatment forms that minimally include subsidiary (drug) social work assistance. At the same time, these efforts deny the user the “pleasurable aspect” of consumption and require active participation in self-help groups or similar organizations as conditions of involvement (see Hoelzmann, 2000). This medicalized conception of heroin
HEROIN-BASED TREATMENT

prescription is not new. Christine Bauer and Horst Bossong (Bossong, 1992) were the first to define the medicalized form of heroin prescription as the only realistically achievable method, while advocates of self-help initiatives and user groups clung to their preferred hedonistic conceptions (Winternitz, 1993). Bauer and Bossong wrote:

In view of the high risks involved with intravenous drug use, it appears justified to put low-percentage and non-injectable drugs on the market and on the other hand leave high-percentage and injectable substances to the doctors for medical prescriptions. . . . A scientific experiment on maintenance treatment with heroin on long-term addicts should be conducted as soon as possible to find out whether the medical and psychosocial state of addicts could be successfully improved with such maintenance programs. Such programs could be viewed as the first intermediary step towards the legalization of heroin. (Bauer & Bossong, 1992, p. 87, p. 91)

These conflicting positions coalesced during the debate about the Swiss “DroLeg” Initiative, which was intended to introduce a comprehensive decriminalization of drug consumption and the government’s legalization of drugs. The provisions of this initiative are outlined briefly below.

It was thought, for example, that a “controlled legalization model” would make it easier to access medicinal and therapeutic use of substances that previously fell under the Narcotics Act. Exact regulations were to be developed for the production, trafficking, and sale of substances used as leisure drugs (such as cocaine, heroin, LSD, MDMA, cannabis, Psilocybe mexicana (a.k.a. “magic mushrooms,” etc.). These substances would be sold in specially licensed businesses (head shops, coffee shops, etc.) or pharmacies, and would include age and advertising restrictions. In addition, specialists among the professional staff of drug counseling centers were to be trained to advise users, assign them a personal identity card, and to inform them about low-risk forms of consumption (Maurer, 1998, p. 3). Opponents of these suggested changes, including the controlled prescription of heroin under medical supervision, wanted to forbid the distribution of narcotics without a medical approval. They maintain that there is a serious risk that if adopted, this plan could lead to the spread of drug consumption – with all of its associated social, health, and psychological implications (Gutzwiller, 1998, p. 9). The Dutch model, oriented toward having flexible and damage-minimizing medical policies functioning within existing laws, is seen by many as being more appropriate than the more radical alternative of deregulation (Killias, 1998, p. 14). The DroLeg Initiative is based on
a model of self-determined consumption and is intended to displace the dismal reality of a poverty-stricken addict scene. The danger is that illnesses that require psychiatric treatment will no longer be adequately treated if the medical system relinquishes its responsibility for prescribing opiates. This concern is thought to be especially true with regard to the adequate treatment of HIV and AIDS-related illnesses (Seidenberg, 1998, p. 27; see also Lichti, 1998, p. 32; Pfister-Auf der Maur, 1998, p. 35; Gorge, 1998, p. 37).

This controversy makes it clear that significant differences exist even among proponents of heroin prescription. Contested issues concern the question of prescribing only to so-called “heavy drug users,” as opposed to prescribing it to (even temporary) addicts who have not yet suffered from severe health, psychological or social disintegration; insisting on medical supervision of the prescription or allowing the patient to take the drug on his own terms; prescribing only when the user agrees to submit to additional psychological treatment and not to supplement consumption without demanding that they remain abstinent or in maintenance treatment. Another question is whether the prescription of heroin should be viewed as an extension of the medically substantiated treatment of heroin users or whether it should serve as the first step in a process leading towards the drug’s legalization. In the latter case heroin would be removed from the Narcotics Act, a change fraught with implications.

THE CURRENT IMPLEMENTATION OF A HEROIN-BASED TREATMENT CONCEPT WITHIN THE FRAMEWORK OF A MODEL PROJECT

The research objectives of the German model project for heroin-based treatment include the following: this is a clinical pharmacological trial to test the efficacy of heroin-assisted treatment in comparison with methadone treatment; the project will examine various criteria for heroin-assisted treatment and their relationship to different outcomes, (which groups of heroin-dependent patients profit most?); and an investigation of the feasibility and efficacy of the various medical and psychosocial treatment elements (Degkwitz, Krausz, & Verthein, 1999).

The German model project for heroin-based treatment (Michels, 1999) follows the standard procedure of a clinical drug trial, although it has the unusual addition of research questions that include social science and criminal-political concerns. In doing so, it goes far beyond normal pharmacological studies by looking at the effects of the social and psychological settings surrounding the patients who are taking part. Program planners believe that the social, political, and economic implications of this model project will prove important for the entire addiction treatment service system.
HEROIN-BASED TREATMENT

All patients have agreed that clinical drug trials are necessary and that the pharmacological and political effects of heroin-based treatment should be scientifically investigated, for this substance has not been evaluated in this way before. The results of the project will be reported to the International Drug Control Board (INCB), which is responsible for monitoring international drug trafficking in accord with international treaties and agreements.

THE MODEL AS PART OF A CLINICAL DRUG TRIAL

The general conditions of the regulations in the Narcotics Law specify that a clinical drug trial may only be conducted on human subjects if and so long as the risks involved justify the expected benefits of the drug. In addition, the patients must be informed by a physician of the character, importance, and consequences of the trial and sign a declaration that they agree that their medical data will be recorded and passed on to the supervisory board for review. A physician who has had at least two years of experience conducting clinical drug trials will supervise the clinical study. The drug trial protocol must be submitted to the relevant ethics review committee. In most cases, these trials are conducted according to the international guidelines of Good Clinical Practice (GCP; BAEK, 1997). The trial protocol determines the subject, defines the population parameters, specifies the treatments that are permitted, validates measurement techniques, monitors compliance, randomizes the assignments of the patients to the experimental and control groups, and also contains statements about the evaluation of the results and the documentation that will be required.

The companies interested in marketing a specific drug as a pharmaceutical usually finance these trials. The trials generally take place within the framework of a double blind study, with experimental and control groups and randomized assignment to the two groups. They are also expected to comply with the criteria of the Declaration of Helsinki, which was adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964 and later revised and amended at various other conferences. This experiment binds a physician who is conducting medical research involving human subjects to promote and safeguard the health of the patient above everything else and reminds them that there are risks involved in all diagnostic, therapeutic, and prophylactic procedures. The physician must then assess the benefits and the risks while ensuring that the participant is not harmed and determine that they have given their full consent to participate in the study.

A trial protocol is bound by many prerequisites. Among other conditions, an ethical review committee must approve it, in this case the Bundesinstitut fuer Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices or BfArM), located in Bonn, Germany.
The Model's Objective Targets

There are a number of features of this project that are atypical of drug trials. For example, the group of patients have not used opiates for medicinal purposes and have been forced to purchase the substance in a form that is not subject to any product controls. As a result, street heroin’s composition is unknown, and the drug’s potency can vary greatly. In addition, the drug must be purchased at inflated black market prices, a factor that fosters the commission of criminal acts in order to be able to pay for their purchase. Users are constantly exposed to the pressures of criminal prosecution. Altogether we are dealing with a consumption pattern that is outlawed by society, where users are forced to participate in illegal markets, and which quickly leads to the development of both psychological and physical dependency. Many consider the development of this dependency an illness — as it is defined, for example by the World Health Organization (WHO) — an illness complicated by its criminal status. The scientific model for heroin-based treatment of opiate addicts has emerged as a consequence of the considerable social, health, and security problems associated with the so called “open drug scene.” The serious ramifications of street use, combined with the increasing risk of HIV and hepatitis infections have led to this treatment approach becoming widely accepted by society as well as by the professional community.

The Heroin Project's Guiding Scientific Questions

The following questions have been prepared, queries that are to be answered within the context of the heroin maintenance study:

- What are the substance-oriented effects and side effects of heroin, and which of these may be attributable to different means of administration?
- How can we reduce the heroin user mortality rate?
- How can we improve the physical (somatic) and psychological health of heroin users?
- How can we support decreased risk behaviors?
- In what ways can social and occupational integration be fostered by such treatment?
- Can the subjects achieve medium- to long-term abstinence from opiate consumption or at least reduce their consumption?
- What political effect does such a project have on the existing addiction treatment system?
• What are the social and political implications of such a model with regard to cost-benefit analysis, the effects of prevention or even on the therapy system as a whole? (see also Rihs-Middel, 1999).

**Federal and Regional Participation in the Project**

It is essential that these questions be resolved in ongoing discussions between the participating cities, the state (Laender) and federal governments and with scientists. It is equally important that people who are active in the addiction treatment system and advocates of self-help also be involved. In these interactions, however, the discussion should not be influenced by ideological beliefs and expectations about the successes or possible failures of the program. The outlines for such programs should be worked out locally, as needed by the participating cities, utilizing the models established in Switzerland and the Netherlands (see Lindlahr, 2000).

In the process, the restrictions involved in such a concept must be accepted, because we are talking about the medical prescription of heroin and not about promoting pleasure-oriented consumption.

It is believed that these programs can only be implemented where a differentiated and structured addiction treatment system already exists, for example, where doctors offer less-restricted, methadone-based assistance.

The Federal Ministry of Health, the participating cities (Hamburg, Hanover, Frankfurt am Main, Cologne, Bonn, Karlsruhe, and Munich), and the participating Laender (Hamburg, Lower Saxony, North Rhine-Westphalia, and Hesse) have all discussed the potential structure and financing of a heroin-based treatment project since the spring of 1999. The participating cities are currently developing the needed infrastructure for the project, such as building and renovating treatment facilities to meet the required security standards, hiring and qualifying personnel such as drug trial researchers, doctors, nurses, and social workers. They are also coordinating the on-site project and public relations, in cooperation with the Laender and the federal government.

**Outline of the Research Design**

Different research institutes submitted proposals for research designs in early 2000. The “Zentrum fuer Interdisziplinaere Suchtforschung” [Center for Interdisciplinary Addiction Research] at the Universitaetsklinik Hamburg-Eppendorf [University Clinic in Hamburg-Eppendorf], under the leadership of Michael Krausz, was appointed to head the project in September 2000. Those included will focus on the central concerns of addiction treatment services, such as examining the crucial questions and paradigms of addiction therapy. Gaining, large-scale acceptance of the project is seen as crucial – especially considering the ideological controversies
MICHELS

raised in discussions of the topic. The trial protocol is comprised of information about the research objectives (heroin prescription as an additional method of assistance or the optimization of existing therapies), the general methodology, and the scientific nature of the model project. The project is supposed to continue for approximately three years. During its tenure, the heroin will not be prescribed by a doctor who owns their own practice, but rather by public health departments in (methadone) outpatient and inpatient (psychiatric) clinics. Participant subjects must meet the following criteria: a proven heroin dependency; voluntary participation; a minimum age; and exhibit somatic, psychological, and social deficits. These projects will provide for comparisons of several groups of users. They include the participants who are admitted into the program, the control group being treated with methadone, and a third group who were denied admission into the project. Experimental participants are to be recruited from two groups: those who have previously been unsuccessful in methadone programs and long-term opiate addicts who could not be helped by addiction treatment services or low-threshold approaches such as drug consumption rooms and drug clubs.

The timeline includes a recruitment period of several months to allow for the selection of patients for participation in the project. In this process, the less-restrictive facilities will be told about the various target groups and asked to contact those whom they feel would be suitable candidates and, if necessary, to help motivate them to participate in the project. The supervising physicians are to make the final determination of which patients will participate in the project. The trials are to be randomized for the different treatment groups. In order to increase the likelihood that control group oral methadone participants will not drop out, the physicians have the discretion to allow such patients to participate in the heroin-based treatment group, should spaces become available. All patients will undergo various medical and psychiatric tests, and the results of these tests will be documented and evaluated. Case management requires that regular contacts be maintained in order to create individualized treatment plans to strengthen personal resources, and the effects of psychological treatment are to be tested in a control group.

To summarize, some of the project's objectives include the reduction of illegal drug consumption, an improvement in the subject's health and psychological status, and social stabilization. The feasibility and acceptability of the study, an examination of the maintenance rate, the pharmacology of heroin, and the effects of the project on the addiction treatment system as a whole are also part of the overall study plan. The project will serve as an important step towards the development of a more rational handling of the drug problem in German society.
Heroin-based Treatment

Notes

1 Deutsche Gesellschaft fuer Suchtmedizin (DGS) = German Drug Medication Society, first founded by private practitioners practicing maintenance treatment and later joined by addiction researchers. The association works mainly for the integration of addiction medicine into medical training, practice and continuing education. It also supports reform activities in drug policy. Info: www.dgsuchtmedizin.de

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HEROIN-BASED TREATMENT

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