

Heroin Distribution Research Review by Ernst Aeschbach, M.D.

On the Scientific Value of the Research Studies Accompanying Heroin Distribution A Critique . .

For the past eight to ten years, the Citizens of the German speaking sector of Switzerland have been witnessing a highly questionable change of drug policy: open drug scenes, toleration of rising crime rates, and pursuit of "survival aid measures," sometimes known as "harm reduction." These "measures" facilitate addictive behavior instead of behavior which favors the abandonment of drug use and positive perspectives on life.

Though the failure of Swiss drug policy seems obvious, nevertheless, models are still being proposed which more or less advocate the free availability of all drugs. One of these models calls for the distribution of heroin. The common denominator of all these models is the theory that drugs themselves are not dangerous, but rather the way they are used.

Two prerequisites are necessary for the political endorsement of these models. First, the media must disseminate the mistaken notion that drugs themselves are not dangerous, but only the way they are used. And second, the "heroin experiment" must be presented as a "scientific study."

There is no scientific interest or reason for this heroin experiment. The hazards of heroin use have long been proven. Indeed, for the heroin experiment, the term "scientific study" is being used as a subterfuge. This is the only way available for proponents to introduce the broad distribution of heroin in Switzerland.

Federal Council of Switzerland 1992: Drug Abstinence as Primary Goal in May of 1992, the Federal Council of Switzerland voted, under massive political pressure, to allow a temporary experiment to distribute heroin to addicts. It should be noted that the conduct of the experiment contradicted the prevailing narcotics law.

In its implementing decree of October 21, 1992, the Federal Council of Switzerland stipulated that scientific research must accompany drug prevention measures, so that improvements in the health and living conditions of drug addicts, as well as their integration into society, may be analyzed. Drug abstinence was still the primary goal of the prevention and welfare measures.

This decree forms the legal and substantive basis of the General Experimentation Plan, published by the Federal Office of Public Health. The Experimentation Plan delineates the binding guidelines for the establishment and implementation of the heroin experiment. It also explicitly states that drug abstinence is the primary goal, thereby setting forth the primary criteria for evaluating the results. The first project applications for the experiment were submitted

by several cities and organizations and approved by the Federal Office of Public Health in the Fall, 1993. The first experiment began in early December 1993, in Zurich. One of the major components of the project was the trial prescription of heroin. This is an

essential factor for determining scientifically the possible basis for permanent distribution of heroin in the future.

Since the distribution of heroin to addicts represents a fundamental deviation from hitherto proven principles of treatment, it is imperative that a critical analysis of this experiment be undertaken.

Scientific Objectivity: Scientific research demands objective behavior in the formulation of experimentation concepts, as well as in practical procedure. Pre judgment on the part of those responsible could lead to biased results and may later cause erroneous political decisions. When massive political pressure exists, as is the case with this heroin experiment, then at least those who evaluate the individual projects should be neutral. However, in this particular case, the evaluators' neutrality is highly questionable.

As early as 1991, the director of the current heroin project ZokL2, A. Seidenberg, stated the following: "A medicalization of the drug problem, as seen in this experiment, does not represent a definitive solution to the drug problem. Instead, it represents a partial step towards normalization....Even before a broad distribution has been implemented, it is possible to enter

into a discussion concerning additional market-deregulating measures."1

Continuous opposition to the Experimentation Plan has stated:

- * The Experimentation Plan is based on drug-policy, not scientific reasoning.
- * There is a call for broad distribution of opiates to drug addicts.
- * There are exceptionally premature "success reports" by project managers and evaluators.

Making unequivocal drug policy claims, and then trying to substantiate them scientifically, can lead to only seeing what advocates want to see. Internationally accepted scientific standards appear to have been violated.

Flaws in the Federal Office of Public Health's General Experimentation Plan:

The design of the General Experimentation Plan contains methodological flaws and critical errors, some of which are presented below:

1. A major omission is the lack of a control group of drug addicts, to whom narcotics are not prescribed, but who nonetheless receive the same welfare measures. Having a control group would have allowed an analysis of the results, to determine whether the results are due to heroin prescription or welfare measures. Without such a control group, positive results can be due to the quality of counseling and supervision given, and can occur without regard to the prescription of heroin. The use of control groups is a scientific standard which all serious researchers include in order to insure recognition of their work.
2. A major limitation is the unreliability of data collected. Details of physical and mental health, as well as social circumstances, were primarily taken from interviews. This procedure is not in itself invalid, yet a scientist must assure the reliability of collected

data by hard facts and field surveys. Without such reliable data, conclusions can only be speculative. In this case, such supporting information has not been verified. In addition, the collected data are not corroborated by reports from third parties, such as relatives, employers, police, etc. Moreover, easily subjective data have not been collected systematically. For example: although physical examinations were given when participants entered the project, a preliminary report of November 1995, shows that apparently not even systematic laboratory tests were given to determine such important parameters as HIV-status and hepatitis infections.

3. A major contradiction is that quantitative conclusions cannot be drawn from the ambiguous formulation of many questions. For example: according to the General Experimentation Plan, risk behavior with regard to HIV must be examined. However, the criteria for measuring risk behavior remains completely unclear. Since the participants were not required to take routine HIV-tests, no conclusion can be drawn with respect to the frequency of initial HIV infections, not to mention those which may have occurred during the time of participation in the experiment.

4. A major concern is that the majority continued actively in the drug scene and consumed additional narcotic substances during the experiment. Since no records were kept of the drug types and amount consumed, no conclusions can be deemed valid about the relationship between health and consumption behavior or changes in social circumstances during the experiment. This problem could have been avoided by prohibiting participants from taking drugs outside of the experiment and introducing controls such as obligatory random drug tests. Here the Experimentation Plan once again failed to maximize the reliability of the data required for objective evaluation.

5. Some critics, since the beginning of the heroin experiment, have raised the following questions:

* Could the experiment have various negative effects on the drug scene?

* Could a general increase in drug consumption lead to increased drug-induced delinquency?

* Could HIV infection spread further?

According to the General Experimentation Plan, precisely these questions will not be examined in the evaluation. In addition, cooperation by the police has been categorically rejected, and this insures that the impact of the experiment on public safety will not be appropriately verified.

Dubious Changes in the Experimentation Plan: In its decree of October 21, 1992 the Federal Council of Switzerland designated abstinence as the primary goal of the experiment. Moreover, it limited drug prescription to the end of 1996, except for the oral intake of methadone. It authorized only 5 projects with a maximum of 50 participants each, thus setting a ceiling of 250, so that the "scientific experiment with human beings not exceed certain bounds."

These limitations have been attacked by various advocates of the experiment. These advocates essentially called for:

(1) an increase in the number of participants;

(2) authorization of prescriptions for other drugs, for example, cocaine (U. Locher, *Neue Zürcher Zeitung* (NZZ), August 16, 1995); and,

(3) less controlled distribution conditions, i.e., such as the ability to take drugs home (M. Stocker, *NZZ*, August 16, 1995).

These criticisms should be construed as an indication that the advocates themselves do not consider the projects to be scientific research, but rather the means to implement drug policy measures. Unfortunately, the Federal Council of Switzerland succumbed to pressure from the experiment's advocates, and in October 1994, one year after it began, the Council voted to allow the first change in the General Experimentation Plan. The number of participants eligible for heroin prescription was raised from 250 to 500, with those for morphine reduced from 250 to 100 and methadone reduced from 200 to 100. The reason given was that heroin, in contrast to morphine and methadone, was more readily accepted by heroin addicts.

Another rationale for changing the ratio of heroin, morphine and methadone subjects was that initially fewer side effects and incidents were reported with heroin. By greatly increasing the number of heroin subjects and reducing the number of other participants, the results of the study could be artificially altered. This example shows very clearly that the experiment is not based on scientific criteria. Instead, it was designed to accommodate the preferences of heroin addicts.

It is of considerable interest to note that no important successes have been recorded with regard to the experiments' official primary goal, drug abstinence -- the one factor which might have justified any eventual changes in the Experimentation Plan. It seems that the real reason for the change was based on the preference of heroin addicts to take heroin. The second change in the General Experimentation Plan was made in May 1995. This time, the number of participants was increased to 800. With this change, the following three additional research areas were added to the study. The contribution of each one to the scientific validity of the experiment is questionable:

(1) Drug distribution to mentally ill addicts . . . This proposal was made even though clinical evidence demonstrates that providing drugs to such patients is particularly dangerous to their health.

(2) Drug distribution in prison . . . This proposal contradicts policy designed to motivate prisoners to accept long term therapy toward abstinence after physical withdrawal has been completed.

(3) Heroin distribution to patients in already existing ambulatory methadone programs and other therapy centers . . .

This proposal undermines the essence of the methadone programs and mixes heroin and methadone recipients in the same facilities. This is inconsistent with the objective of helping methadone patients stay away from the drug scene and encouraging them to participate in abstinence oriented therapy. Once heroin programs are combined with methadone programs, those receiving methadone face a greater danger of becoming de-motivated in overcoming their drug addiction.

Preliminary Results Justify Abandoning the Experiment: Within the scientific community, it is customary to publish results in scientific journals and thus make them available for verification and discussion. Non-compliance with this discipline violates important scientific procedures. Announcing results for the first time at a press conference is a most unusual procedure among researchers. But this is precisely what the Federal Office of Public Health and the experiment's directors did in November 1995, when they presented the first results at the press conference and deemed them predominantly positive. The feasibility of the experiment and the accessibility of participants within target groups were emphasized. Considering drug addicts' desire for heroin and the very low demands made on them in the experiment, this is not surprising. The preliminary report indicates that the General Experimentation Plan's designated goal of abstinence² has been replaced by a new goal "...to test new approaches in the treatment of drug addicts." This means that the experiment violates the letter and intent of the original 1992 decree of the Federal Council of Switzerland.

Analysis of the individual results presented by the Federal Office of Public Health and the directors of the experiment indicates the following specific failures of the experiment:

1. Improvements in health did not occur within 6 months of the entrance of a participant in the experiment. Physical symptoms such as insomnia, loss of appetite, tiredness and loss of energy (a decrease from 47% to 46%!), nocturnal sweating, dry throat, etc., improved only by a small percentage during the first 6 months -- not enough to meet minimum objectives anticipated for improvement of the participants' health. Indeed, the biggest improvement reported reflects only a better "injection technique", which astonishingly has been included in the list of physical symptoms. Based on the data provided, improvements in physical health are more probably the result of care given than narcotics prescribed. In addition, no comparison was made of the results among the various groups receiving different narcotics. Hence, it is completely inconceivable that researchers could arrive at an optimistic conclusion based on such measures rather than to the supply of heroin. The inclusion of control groups would most probably have substantiated this conclusion.

4. The research directors gave great importance to the high retention rate among the participants 73% until June 1995, with 82% participating for at least 6 months. Such continu incomplete data.

2. The amount of narcotics consumed stabilized after about a month. A significant reduction in dosage and narcotics prescription program can help drug addicts quit the vicious circle of addiction frequency of consumption was therefore not achieved.

3. Improvements in living and working conditions of the participants, as well as their social environment, are to be welcomed. However, it is more likely that these results are due to psycho-social welfare in participation in the program, with continuous access to heroin, must be comparison is deemed a failure in light of the goal of abstinence set for the project. There is little or no information provided about how far the experiment has

been able to attain the goal of abstinence, or the extent to which a controlled (NZZ, November 24, 1995).

5. The high retention rate in the experiment in comparison to in-patient therapy centers was especially emphasized by A. Uchtenhagen, but this invalid and implies erroneous conclusions. A high retention rate in heroin distribution programs is, on the contrary, not an accomplishment if drug abstinence is the ultimate goal.

6. The reported decrease in illegal activities from 53% to 13% is based on information provided exclusively by the addicts who participated in the heroin experiment. Therefore, it cannot be considered as objective proof of the impact of the heroin project on criminal behavior, as alleged by A. Seidenberg (NZZ, No. 228). This data has no value.

Conclusions on delinquent behavior can only be based on verified police records. In the semi-annual report of the Federal Police Bureau of Switzerland, the central narcotics task force noted that "validated scientific findings are lacking, and the only limited information available is based on certain anecdotal observations of the drug scene...." This has occurred primarily because the police have not been included in the heroin projects. Zurich's cantonal police force has also expressed its concern that the evaluation of the experiment will turn out to be biased.

Consequences of Heroin Distribution: The real objective of the Swiss heroin experiment is to introduce a definitive program to distribute heroin to addicts as soon as possible. The planned revision of the narcotics law and the introduction of a new pharmaceutical law will provide the necessary legal framework for achieving this objective. However, the political, social and therapeutic consequences associated with a departure from proven and accepted principles of drug therapy have been ignored to date. In this connection the following considerations warrant careful attention.

* The implications of such a major change in Switzerland's drug policy has not been appreciated beyond its borders.

* Nothing similar is being undertaken anywhere else in the world.

- Even in the United Kingdom, heroin distribution has had universally negative results, reflected by an increase in the number of drug addicts, an increase in the death rate, and extensive health problems.

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Any program distributing narcotics is full of perils. A. Uchtenhagen, director of the Swiss evaluation team acknowledged this when he stated, "The distribution of narcotics to addicts is being undertaken with great caution and restraint throughout the world. In certain cases temporary and very structured methadone programs have been provided as a bridge toward abstinence-oriented treatment." (A. Uchtenhagen, Zrichsee-Zeitung, March 30, 1995.)

Caution in the distribution of narcotics is based on experience. On a societal level and by the addicts themselves, such measures are perceived as acts of resignation. Trust in

established abstinence-oriented treatments decreases. The danger involved in changing this mind set of an addict is frequently not recognized. Often addicts will more willingly fulfill the conditions

needed to receive heroin in a distribution program than decide on a treatment process which is considered to be arduous. Thus, motivation to enter therapy is easily destroyed, and with it the hope for a life without drugs. The negative consequences of drug use have represented the most important reason for an addict to give up drugs. Easy access to drugs and belittling the

consequences of drug use, instead of abstinence-oriented treatment, are counterproductive measures that facilitate drug use and encourage distribution projects.

One of the reasons for launching the Swiss referendum "Youth Without Drugs" in December 1992, was the initiators' concern that the Swiss heroin experiment could be misused to promote the liberalization/legalization of drugs. If the referendum is enacted, heroin projects would be forbidden. At the same time, appropriate and necessary measures would be implemented to aid drug addicts.

It is crucial that a broad and knowledgeable discussion be held on the scientific value of the heroin experiment. For this purpose, the World Health Organization's (WHO) current evaluation of the experiment is too limited. Scientists and doctors beyond Switzerland should be invited to join in a critical professional assessment of this experiment.

<http://www.sarnia.com/groups/antidrug/wrldnews/heroin.html>