Ethical Evaluation of Heroin-Prescription Research: An Insider's View

Dominique Sprumont

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tion. I wonder if the delirium simply masks authentic values rather than destroying them. Still, the result would be the same: the addict no longer has access to authentic values with which to evaluate the option of entering a heroin-prescription research program.

This conclusion about authenticity worries me because it effectively eliminates the category of the "unwilling [heroin] addict" (Frankfurt 1989, 68). Such an addict has a desire to refrain from using heroin and also a desire to consume it; but she only wants the first desire to constitute her will (i.e., to motivate her actions). Therefore, arguably, she has authentic desires and may have the capacity to choose rationally. However, on Charland's model of heroin addiction, such addicts are anomalous. The paradigm of the heroin addict is the "wanton," that is, an addict who has no concern for

> whether the desires that move him to act are desires by which he wants to be moved to act. If he encounters problems in obtaining the drug or in administering it to himself, his responses to his urges to take it may involve deliberation. But it never occurs to him to consider whether he wants the relations among his desire to result in his having the will he has. (Frankfurt 1989, 68)

Unless the addict has always expressed such "wanton lack of concern" (Frankfurt, 68), he is no longer himself (as Charland would say). He is like the terrorized victim of a hijacking who is so beside himself that his identity is lost, if only temporarily.

At times, it seems clear that Charland *would* accept that some heroin addicts are not pure wantons; some maintain real values of their own, which they might wish to constitute their will, but their desire for heroin overrides that wish. At other times Charland suggests that by virtue of being heroin addicts, addicted persons have no authentic values and therefore no competency to consent. Whether Charland's presumption of incompetence is warranted depends on the severity of the effects of heroin-induced delirium. If the effects do not usually negate authenticity, then the presumption will have to be revised. It could still be a presumption against the ability of heroin addicts to consent to heroin prescription; after all, voluntariness is a requirement for consent, and an addict cannot choose such a prescription voluntarily. However, the presumption of incompetence could not be grounded in the blanket assertion that heroin addicts lack authenticity and hence competency to consent. ■

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Dominique Sprumont, Institute of Health Law, University of Neuchâtel and Fribourg (Switzerland)

In exploring Cynthia's Dilemma, Louis C. Charland (2002) argues that heroin addicts should be treated as incompetent unless proven otherwise. He concludes that heroin-prescription research violates existing North American ethical standards for clinical research. Yet, recognizing that there is a strong need for investigating the medical prescription of heroin as a treatment alternative, he suggests two strategies for conducting such research: first, the use of a surrogate decision-making procedure; second, a focus on the notion of risk that builds on the idea that competence should be assessed using a sliding scale.

The fact that Charland refers exclusively to North American ethical standards in his conclusion should be underlined. Indeed, the context in which the heroin and cocaine prescription-research program was launched in Switzerland is crucial to understanding how it was evaluated at the time. In 1992 large cities such as Zurich were confronted with an acute drug problem. The situation was growing out of control, in both a sociocriminal and a public-health perspective. Thus it was first a political decision to prescribe heroin and cocaine under medical supervision as an alternative treatment for drug addicts. The purpose of the program was to investigate heroin and cocaine prescription as a prevention and assistance measure, with the understanding that abstinence was the final goal. The Ethical Review Commission of the Swiss Academy of Medical Science was invited to evaluate the ethical acceptability of

the program only after it was introduced by an ordinance of the Federal Council.

The fact that the research subjects were severely addicted and had experienced repeated treatment failure was acknowledged from the beginning as impairing their competency to consent to the research. It was indeed foreseen that the number of dropouts would be very low, as the subjects themselves would not be able to resist participating. As Charland puts it, heroin addicts care too much about heroin to say no. Raising doubts about the competency of the research subjects, the Commission even requested that the Federal Office of Public Health cover all damages caused by the subjects to third persons during the study.

There were two main concerns in the evaluation of the program: first the overall medical and ethical acceptability of prescribing heroin and cocaine to drug addicts; and second, the scientific merit of the program. The Commission did not reach a consensus on the first issue. A strong minority maintained that as a matter of principle, heroin and cocaine prescription could not be considered medical treatments but were instead tantamount to denial of treatment. The issues were not much different from those typically raised in debates between North American and European experts on the proper goals for drug policy. Nonetheless, the majority of the Commission voted in favor of the program. The main argument was that there was too little information available to refuse a priori to evaluate the benefit of heroin and cocaine prescription. Under Freedman's principle of equipoise it was thus ethically acceptable, if not necessary, to conduct such a program.

One key argument in reaching this conclusion was the limited risks to which the research subjects would be exposed. Because the inclusion criteria limited participation only to severely addicted persons with repeated treatment failure, the conditions under which the heroin and cocaine would be prescribed were actually said to benefit subjects. In other words, it was argued that the program in itself lowered the risks that the subjects confronted daily.[1] This is important, as it is a fundamental requirement that research with incompetent subjects present only minimal risks to the subjects.

This brings us back to the issue of competency. Charland's argument is certainly convincing. Theoretically, it seems reasonable to affirm that unless proven otherwise severely addicted heroin addicts should be deemed incompetent to consent to participate in heroin-prescription studies. However, such considerations are in contradiction with the law, including the Swiss Federal Civil Code, which asks us to consider persons competent unless proven otherwise. Legally, the capacity to consent should always be understood *in concreto.* When there is doubt, the competency of a person should be assessed through a medical examination. Such an assessment may lead a judge to appoint a legal representative to act as surrogate for the subject. It would then be the responsibility of the legal representative to weigh the subject's interests and decide whether or not the subject should be included in the study. As the Commission admitted, given that the research risks in the proposed study were thought to be very limited and the benefits looked rather promising, the choice of a legal representative would likely mirror the subjects choice.

Also relevant to this debate is the patients' rights movement's defense, in Switzerland and elsewhere, of the principle that psychiatric patients should not be treated differently than somatic patients, particularly in terms of competency. This viewpoint is in fact accepted in most cantonal law on patients' rights. According to the Swiss Federal Civil Code, anyone over 18 should be considered competent unless proven otherwise. Considering participants incompetent a priori would have contradicted this policy.

Even if Charland's arguments appear fundamentally correct, their application to the Swiss program would have been ethically unacceptable. As mentioned above, the interests of subjects should be assessed on both an individual and collective level. Surrogate consent would have led to the same conclusions about the best interest of the subjects. However, surrogate consent could also have jeopardized the program by further stigmatizing the drug addicts in the community. The favorable opinion of the Commission of the Swiss Academy of Medical Science came after a careful and thorough evaluation of the program. It was not an easy decision, but it was a courageous one. Even if controversy remains surrounding the scientific merits of the program, it has proven to be beneficial for the participants, leading to a dramatic decrease in the number of overdoses and an overall improvement of health status and quality of life for most participants.

Further research is needed. Currently, approving such research appears to be more a matter of political dogma than biomedical and social science. Yet, if the decision to conduct the Swiss trials was first based on political motives, the research projects were then carefully assessed both on their scientific and ethical merits. In other countries, such as in the USA, one could regret that due to the politcal agenda, investigators and IRB are not even allowed to consider such scientific and ethical evaluation. ■

1. At one point the Commission was even criticized for being too strict and thus denying "therapy" to several hundred "patients."

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