Ethics and Heroin Prescription:

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mistake to conflate a person's overriding desires with her values.

Of course, in assessing an addict's decision-making process, we need to worry whether the addiction biases her choice. It makes a great deal of difference what options the addict is choosing between. Consider:

Choice 1
A. A place in a study on an unproven heroin-prescription treatment.
B. A drug-free treatment in a residential treatment center with a good chance of success, but involving a great deal of physical and psychological pain.

Choice 2
A. A place in a study on an unproven heroin-prescription treatment.
B. Returning to life on the streets, funding the heroin seeking by petty crime and begging.

In Choice 1, I would worry that the addiction would bias the addict's choice, leading him to overestimate the possible value of the heroin-prescription treatment and to avoid the difficult process of coming off the drug. But in Choice 2, drug taking is in both options, and there's no reason to think that the addiction makes the addict overestimate the possible value of prescribed heroin and underestimate the value of a life on the streets and petty crime.

Charland comes close to recognizing this in his discussion of the "second strategy," which focuses "on the notion of risk" and the use of a sliding scale of competence. But he quickly dismisses this because "the subjects sought for heroin prescriptions invariably suffer from serious psychiatric disorders other than addiction." But if this is the case, then it is puzzling why he even addressed the original subtle considerations about their competence, since if they have other serious psychiatric disorders, then those conditions are very likely to impair rationality enough to make the subtle considerations of competence beside the point.

I applaud Charland for raising the issue of the competence of heroin addicts to consent to participation on heroin-prescription studies, and for his thoughtful discussion of how addiction affects competence. But he has overplayed some of the empirical characterizations of addiction and underplayed the ability of addicts to think for themselves. I hold more hope than he seems to that it should be possible to find ways in which potential research subjects are not so biased by their addiction in their choices that they are not competent to consent. ■

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Ethics and Heroin Prescription: No More Fuzzy Goals![1]

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Louis C. Charland claims that heroin-prescription trials violate North American standards for clinical research. This may be true, but not necessarily for the reasons he cites. First, without greater attention to the processes and criteria used for subject entry into the trials, Charland does not provide a sufficient basis to determine whether consent was invalid. In this regard we concur with Perring (2002), who notes that Charland has overreached in claiming that heroin addicts can *never* be competent to consent to enrollment into heroin-prescription trials. But perhaps of greater importance, we worry that heroin-prescription trials are especially susceptible to violating ethics and failing informed-consent requirements due to the conflation, confusion, or absence of trial goals. Essential to the ethics of research on heroin prescription, but underappreciated in Charland's article, are the risks of doing research that might primarily benefit society rather than the heroin addict, including research on harm-reduction strategies.

Vulnerability, Exploitation, and Choice

Charland claims that addicts are vulnerable to exploitation if promised free heroin and that this vulnerability negates their capacity to give consent. But vulnerability is most important where individuals are exposed to harm without personal benefit and because of coercion. Exploitation involves placing vulnerable individuals at risk in order to advance goals that the individuals do not share. How vulnerable are addicts and can they share the goals of researchers?

Charland argues that heroin addicts are absolutely vul-

1. The views and opinions contained in this article are those of the authors and should in no way be construed as representing the official policies of the American Medical Association.

nerable—they care too much about heroin to have any other goals. We argue—on the basis of real-life, albeit anecdotal, clinical observations—that heroin addicts often have powerful other goals, including child rearing, job satisfaction, staying healthy, and even dislike for their addiction. Certainly, we believe that failure to act fully on a stated preference does not constitute a repudiation of that preference; otherwise each of us who breaks a New Year's resolution of daily exercise could be accused of having a "true" preference for life as a couch potato. (Indeed, the rhetoric of compulsion and "values collapsing under the whiplash of craving" brings to mind the struggles of some chocolate lovers of our own close acquaintance.)

We also note, however, that if in fact addicts had no other priority but obtaining heroin, it wouldn't really matter much, because the choice offered to addicts in heroin-prescription trials usually is *not* whether or not to obtain heroin. Instead, addicts choose whether to obtain free heroin through the trial. Assuming that addicts operate under compulsion to get the drug, their decisional capacity turns on whether they can make informed decisions about *where* and *from whom* to procure heroin *and at what cost.* Their strongly held preference for heroin itself is not relevant. Rational considerations such as cost, purity of the drug, dosage, necessary accessories, and having some authoritative supervision during one's moments of greatest vulnerability might argue for enrollment in the trial. On the other hand, privacy, personal freedom, and a desire to avoid supervision might argue against enrollment. Indeed, we suspect that some subjects offered enrollment in prescription trials declined—proving that at least some addicts are capable of saying no to "free" heroin.

Exploitation: Reducing Harm for Whom?

There is no doubt that many heroin addicts will see enrollment in heroin-prescription trials as strongly positive from a personal point of view. Addicts may see enrollment as an opportunity to move toward recovery and/or avoid harms associated with addiction, including health risks, financial costs, and the risk of arrest. Yet such benefits to addicts may not be the reason the researchers are doing the trial. A powerful risk of harm-reduction trials is that the goals may be primarily to reduce social harms—such as crime—and not directly to benefit heroin addicts. In our view, it matters whether the primary goal of the trial is to move addicts towards recovery, to maintain addicts in a steady state of addiction, and/or to reduce the social costs of heroin use, and thus the goal should be included in the informed-consent process. Failure to do so would exploit addicts who fall into a therapeutic misconception, believing the trial is primarily for their benefit when this is not the case. In a footnote Charland notes the disconcertingly interchangeable use of terms like *treatment* and *maintenance* in trial reports, which suggests that this problem exists. And the dismal data in regard to moving off heroin after these trials suggest that conveying the impression that heroin prescription is a step towards recovery would be wrong.

If the goals of a trial are primarily social—to reduce commercial sex, illegal drug use, and HIV transmission—then the trial might actually harm enrollees by keeping them in limbo (addicted) in order to cater to societal preferences. Such social goals might or might not be appropriate as grounds for heroin-prescription protocols. Individual volition is not negated by the possibility that a trial aims to benefit society more than enrollees. Many individuals choose to participate in trials with the hope of making a meaningful contribution to society. Moreover, reducing criminal activity and reintegrating into society might well be personal preferences of some addicts. With disclosure and clarity of goals, and mitigation of the risk of exploitation (e.g., by offering standard treatment protocols as an option), we believe that many addicts could consent to participation in prescription trials.

The Problems of Presumed Incompetence

Finally, we note that in Western ethics and law, individuals are almost always held accountable for their choices on a presumption of competence. After all, what would it take to "prove" competence? Further, if addicts cannot consent to trials, how can they competently choose to enter treatment programs where similar, or greater, risks exist? Heroin withdrawal can cause death, all treatment protocols have high failure rates, and some include confinement under so-called "Ulysses contracts." Charland claims that some addicts experience a moment of "clarity" when they commit to recovery, but this raises concern that competency is being seen as related more to the goals of the program than to the "stable" values of the addict.

Although we disagree with Charland's conclusion that all heroin addicts are incompetent to consent to prescription trials unless proven otherwise, we agree that the questions he raises are significant. Addicts *are* particularly vulnerable to exploitation. But assessment of the decisional capacity of individual addicts must be considered only *after* carefully defining the particular and meaningful goals of heroin-prescription trials. ■

References

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