Cynthia's Dilemma: Consenting to Heroin Prescription

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Heroin prescription involves the medical provision of heroin in the treatment of heroin addiction. Rudimentary clinical trials on that treatment modality have been carried out and others are currently underway or in development. However, it is questionable whether subjects considered for such trials are mentally competent to consent to them. The problem has not been sufficiently appreciated in ethical and clinical discussions of the topic. The challenges involved throw new light on the role of value and accountability in contemporary discussions of mental competence.

Introduction

Heroin prescription involves the provision of medically prescribed heroin in the treatment of heroin addiction. Research undertaken on that treatment modality raises complex ethical problems. One that has not been sufficiently addressed is whether the subjects considered for that research are able to consent to it. There are really two problems. First, how can an individual who is addicted to heroin voluntarily consent to participate in research where their drug of choice is offered free of charge? Second, even granting that voluntary consent is possible, is a heroin-dependent individual mentally competent to make decisions of this sort? When I put these questions to Cynthia, a recovering heroin addict at a local clinic, her reaction was disbelief and amazement. “That’s crazy,” she said, “if you’re addicted to heroin, then by definition you can’t say ‘No’ to the stuff.” Cynthia’s response can be expressed in the form of a dilemma that, in her honor, I will call Cynthia’s Dilemma.

This paper is about Cynthia’s Dilemma and the ethical conundrum it poses for research on heroin prescription. I will argue that the problems raised by the dilemma are serious, but I will also suggest some possible avenues of response. The source of the dilemma lies in the nature of heroin addiction. Heroin addicts suffer from a compulsive need to seek and use heroin. As a result, they have an impaired decisional capacity to make choices about heroin. Ethical and clinical discussions of heroin prescription seem to have missed this point entirely.

Heroin prescription provides an interesting perspective from which to view the role of value in mental competence (Brock and Buchanan 1987). It also shows why competence must involve some sort of accountability (Elliott 1991). There are also interesting parallels between addiction and depression that are relevant. It has been argued that severely depressed patients may not be competent to consent to research because they care too little about risks (Elliott 1997). The problem with heroin addiction is just the opposite. Heroin addicts care too much about benefits. They care too much about heroin. Clinical tests of the competence of depressed subjects to consent to research have recently been carried out (Appelbaum et al. 1999). I will argue that similar tests should be carried out in the case of heroin prescription. The main conclusion of the paper is that we should not presume that heroin addicts are competent to consent to heroin prescription. In fact, we should assume they are incompetent unless proven otherwise.

Keywords
heroin prescription
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Open Peer Commentary

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1. Like many of the authors I will be discussing, I will use the terms addiction and substance dependence interchangeably. There are, however, occasions when it is helpful to distinguish the two, for example, when distinguishing the kind of dependence that occurs when opioids are prescribed for pain relief and when they are used for pleasure-seeking and euphoric effects (Stimmel 1997, 53–56). Furthermore, I will also use the terms decision-making capacity and mental competence interchangeably. As noted in the recent report by the National Bioethics Advisory Commission, they are often used to denote the same thing (National Bioethics Advisory Committee 1998, 13 n. 4). Finally, although heroin can be administered in different forms, the focus of this discussion will be the prescription of injectable heroin.
What is Heroin Prescription?

Heroin prescription\textsuperscript{2} was employed as a treatment modality in the management of opiate dependence in the United States in the early 1900s (Bayer 1976). It has also been available on a limited basis in Britain since the early 1960s (Brewer 1995; Marsden et al. 1998; Metrebian et al. 1998). Indeed, the first controlled clinical trial devoted to heroin prescription appears to have been conducted in Britain (Hartnell et al. 1980). Since then, due largely to an alarming increase in the rate of HIV transmission among injectable drug users, several Western governments and public-health authorities have urged that heroin prescription be investigated more fully. Thus there is now a call to move beyond the use of heroin prescription as a limited form of innovative therapy to possibly wider and more systematic treatment interventions of that type. This is the reasoning that led to the famous “Swiss Trials.” Between 1992 and 1996 the Swiss government undertook a full-scale study of different therapies for treating heroin addiction. A total of 1,146 individuals were originally enrolled in the study, which was spread across 18 sites (Uchtenhagen, Gutzwiller, and Dobler-Mikola 1997). Another large-scale study is currently underway in the Netherlands (Van den Brink, Hendricks, and van Ree 1999). In Australia, extensive preparations for a large-scale trial were finalized only to be aborted by direct political intervention (Wodak 1997). Finally, in Canada calls for research into heroin prescription by public-health authorities have been getting increasingly strident (Fisher and Rehm 1997; Miller 1998; Matas 2001; College of Physicians and Surgeons of British Columbia 1995). A

2. Some authors refer to the medical provision of heroin as “heroin prescription” (Bammer et al. 1999). Others refer to “heroin maintenance” (Perneger et al. 1998) or “heroin substitution” (Jurgen 1997) The terms are often used interchangeably but probably should not be. To characterize what is involved in the medical provision of heroin as “substitution” seems slightly disingenuous. Is the point simply that legal heroin is being substituted for illegal heroin? Or perhaps the idea is that one mode of administration (injection) is being substituted for another (smoking)? Referring to heroin “maintenance” seems more plausible, since subjects in these studies are in fact being “maintained” on heroin. These distinctions become important when the medical administration of heroin is examined in light of the debate between harm reduction and abstinence. The term prescription has the advantage here. It is neutral between the provision of heroin to maintain an individual on opiates and prevent withdrawal (goal: harm reduction) and the provision of heroin where the purpose is to taper the individual off opiates entirely (goal: abstinence).
The Ethics of Heroin Prescription

The absence of any mention of heroin prescription in the NIH Panel consensus statement means that opiate addicts in the U.S. are being denied a treatment modality that is viewed as promising by other Western jurisdictions. This is arguably a violation of justice. There are other important ethical issues raised in the relevant literature. Highlights include the quarrel that pits harm reduction against abstinence (Erikson et al. 1997; Jurgen 1997); the debate over whether addiction should be viewed as a social or a medical problem (ten Have and Spoken 1985); the argument that existing resources are better spent elsewhere (Gaughwin and Ryan 1999); and the worry that there is a risk of promoting the message that heroin addiction is acceptable (Bammer et al. 1999a). These are just a few scattered themes and examples.

Evidently, there is an interesting literature on the ethics of heroin prescription. No resolution of those issues will be attempted here. For present purposes, what deserves mention is what those discussions omit. Nothing is said about whether the subjects targeted for heroin prescription are capable of competent voluntary consent to heroin. Consent is mentioned, but usually only to say it is important to seek it and to stress that subjects must be properly informed (Gaughwin and Ryan 1999; Koran 1973; Ostini et al. 1993; ten Have and Spoken 1985). Everyone appears to assume that competent voluntary consent to heroin use is possible. There is no indication of any serious worry that prescription subjects might suffer from decisional impairments that compromise their capacity to consent. In addition, no mention is made of the fact that individuals like these are particularly vulnerable to exploitation if promised free heroin. There are therefore two serious omissions in discussions of the ethics of heroin prescription. The capacity to give competent voluntary consent is presumed when it should not be, and no allowance is made for the fact that prospective subjects are particularly vulnerable to offers of free and legal heroin.

A good example of how competence to consent and vulnerability have been overlooked in discussions of heroin prescription is the WHO evaluation of the Geneva Trial. The WHO experts note that the project was approved by the Ethics Committee of the Swiss Academy of Medical Sciences. Indeed, the report simply states that “participation in the study was voluntary” (WHO 1999, 4). The...
perspective of the Geneva researchers is no different. Summarizing their enrollment procedures, they write,

during this [initial] visit, the psychiatrist confirmed the patient’s eligibility, explained program procedures, obtained informed consent, performed the baseline assessment, and allocated the patient to either immediate or delayed admission by using computer generated random numbers placed in sealed envelopes. (Perenger et al. 1998, 13)

Again, everyone seems to be assuming that competent voluntary consent to heroin prescription is possible. In the words of an early defender of heroin prescription, “administering heroin to addicts who volunteer for research and provide informed consent would not violate medical ethics” (Koran 1973, 657). If Cynthia is right, however, the presumption that heroin addicts are capable of competent voluntary consent to heroin is simply wrong. Let us see why.

_Cynthia’s Dilemma_

The main premise of Cynthia’s Dilemma is that either

1. prospective heroin-prescription subjects are heroin dependent; or
2. they are not heroin dependent.

If (1) is true and subjects are heroin dependent, then they cannot participate in the trial, since they are incapable of competent voluntary consent. If (2) is true and subjects are not heroin dependent, then they cannot participate in the trial, since they do not qualify. Either way, therefore, subjects cannot participate, from which it follows that the trial cannot be conducted. The key to the dilemma is the claim that because they are heroin dependent, prescription subjects are incapable of competent voluntary consent. To understand the force of this point, we need to look more closely at the nature of addiction.

Why should a diagnosis of heroin dependence preclude the ability to give competent voluntary consent to heroin? The answer lies in the Diagnostic and Statistical Manual of Mental Disorders. There _substance dependence_ is described as “a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues use of the substance despite negative consequences. There is a pattern of repeated self-administration that usually results in tolerance, withdrawal, and compulsive drug taking behavior” (American Psychiatric Association 1994, 176). Compulsive drug-taking behavior is a clinical defining feature of substance dependence. Drug taking in this context extends to seeking as well as using. The individual is completely obsessed with the substance they are addicted to. Virtually all daily activities and relationships are organized around procuring and securing their drug of choice. In the words of Alan Leshner, these individuals suffer from “an uncontrollable compulsion to seek and use drugs” (Leshner 1999, 3).

The notion of compulsion is critical to understanding addiction. It is well known that chronic heroin addicts like those in the Geneva Trial no longer take their drug simply because they want to experience its euphoric effects. They also have powerful cravings for it and need to take it to prevent withdrawal. In Leshner’s words, “continued repetition of voluntary drug taking begins to change into involuntary drug taking, ultimately to the point that the behavior is driven by a compulsive craving for the drug” (3). This is what Cynthia meant when she said that a heroin addict cannot say “No” to heroin. The compulsive drug taking that defines addiction is a direct physiological consequence of dramatic neuroadaptations produced in the reward pathways of the brain (Koob and Le Moal 1997; Nestler and Aghanjanian 1997; Powledge 1999). The powerful reinforcing effect of social and personal factors that accompany drug use only make those compulsions more acute. The fact that in many cases the brain is permanently altered by addictive drugs is worth noting. It means that recovery for some individuals may require years of maintenance on a replacement drug. This is the rationale behind methadone maintenance.

Compulsion is one clinical defining feature of addiction that compromises decision-making capacity (College on Problems of Drug Dependence 1995, 170-71; Gorelick, Pickens, and Bonkowsky 1999, 179; Leshner 1997, 1999). But it is not the only one. Intoxication and withdrawal are two others. When intoxicated the addict is no longer in the throes of active compulsion. They are instead in a state that resembles delirium (National Bioethics Advisory Commission 1998, 6). Withdrawal is also often considered to be tantamount to delirium (National Bioethics Advisory Commission 1998, 6). There are therefore two different kinds of decisional impairment involved in addiction. First, there is compulsion, which compromises the voluntary nature of choice. Second, there are intoxication and withdrawal, which compro-
misse the ability to comprehend choices. Compul-
sion results in volitional impairment, while delir-
ium results in cognitive impairment. A helpful
way to interpret this difference is to say compul-
sion results in disordered desires, while delirium
results in disordered beliefs (Elliott 1996, 2-3).
However, it is important to remember that addic-
tion is a combination of both compulsion and de-
lirium, locked in a tragic alternating cycle. As tol-
erance sets in and greater amounts of the drug are
required to achieve the same effects, the individ-
ual’s life literally spirals out of control (Koob and
Le Moal 1997, 53 fig.1).

So what does a clinical diagnosis of heroin de-
pendence mean? First, it means that decisions that
relate directly to heroin use are susceptible to pow-
erful physiological and psychological compulsions
that usually nullify any semblance of voluntary
choice. This is one reason why heroin addicts can-
not be considered accountable for their decision to
use heroin. Second, even if voluntary choice was
somewhere possible, heroin addicts are still not com-
petent to consent to its use. This is because chronic
heroin addiction results in radical changes in per-
sonal values that make seeking and using heroin
the overriding goal of the addict’s life. Quite liter-
ally, the addict’s brain has been hijacked by the
drug (Leshner 1997). Addicts are no longer them-
-selves and in that sense cannot be considered
accountable for their decision to use heroin.

The decisional impairments that result from
chronic heroin addiction are therefore complex.
They also fluctuate (National Bioethics Advisory
Commission 1998, 7). Compulsion is absolutely
central to the decisional impairments in addiction.
But addiction is not simply a compulsive disorder.
As mentioned above, it also results in fundamental
changes in personal values. These usually last as
long as the person remains actively addicted. There
are interesting implications here for the theory of
competence. Someone whose life revolves around
compulsively seeking and using a drug despite
negative consequences can hardly be considered
mentally capable of rationally weighing the risks
and benefits of using it. Yet the ability to rationally
weigh risks and benefits is generally considered to
be an important condition of competence. We have
seen that addiction lends credence to the view that
competence requires some sort of accountability
(Elliott 1991). It is time to focus on the argument
that addiction compromises competence because it
alters a person’s values (Brock and Buchanan
1987).

Value and Accountability

If the Geneva Trial research protocol were submit-
ted to a North American ethics review board today,
the issue of competency would almost certainly be
raised as a potential problem. Certainly, existing
clinical ethical guidelines suggest that it should
(National Bioethics Advisory Commission 1998;
They specifically warn that special care should be
taken when administering substances prone to be-
ing abused to persons with past or present prob-
lems with substance disorders.

The ethics of research involving the adminis-
tration of alcohol is important to consider in exam-
ining heroin prescription. Numerous concerns
have been raised about research that involves giv-
ing alcohol to subjects who suffer from alcohol
abuse or dependence (Koocher 1991; Modell,
Glazer, and Mountz 1993; National Advisory
Council on Alcohol Abuse and Alcoholism 1998;
Stricker 1991). Surprisingly, although alcohol and
heroin are alike in many relevant respects, similar
reservations have not been expressed in the case of
heroin. Recall how unproblematic the consent of
the Geneva subjects was thought to be. The dis-
crepancy is puzzling. If the competency of alcohol-
ics to consent to research with alcohol is suspect,
then why not the competency of heroin addicts to
consent to heroin-prescription research? In order to
answer that question, we need to specify what
counts as competence. A good place to start is the
MacArthur model developed by Appelbaum and
Grisso (Appelbaum and Grisso 1995; Grisso et al.
1995; Grisso and Appelbaum 1995; Appelbaum
and Grisso 1998). It is one of the most sophisti-
cated models available and has the benefit of hav-
ing been empirically validated. So let us see how
our Swiss subjects would have fared if their eligi-
bility to consent had been assessed using the Mac-
Arthur model.

According to the MacArthur model compe-
tence is comprised of four distinct components:

1. the ability to understand a choice;
2. the ability to appreciate a choice;
3. the ability to rationally manipulate informa-
tion; and
4. the ability to communicate a choice.

Since the Geneva subjects were clearly able to com-
municate a choice, that condition will be ignored
in what follows. There are several important fea-
tures that the MacArthur model shares with other
leading accounts in the field. First, there is the fact that mental competence is held to be decision specific. Dan Brock and Alan Buchanan put the point this way: “a person may be said to be competent to make a particular decision at a particular time, under certain circumstances, but incompetent to make another decision, or even the same decision, under different conditions” (Brock and Buchanan 1987, 18). Second, competence is stipulated to be a threshold concept. Either you are competent or you are not.

Now consider consenting to heroin prescription with the MacArthur model in mind. Understanding in this case revolves around whether or not an individual can be said to comprehend the relevant facts involved in a particular decision. Appreciation builds on what is comprehended in understanding and extends to the acknowledgment that those facts pertain to oneself. Thus it is one thing to understand what heroin dependence is, but quite another to recognize and acknowledge that those facts apply to oneself. In alcohol dependence this distinction is especially pertinent, since alcoholics typically deny they are “alcoholic” even though they may understand perfectly well what alcoholism is. Heroin addicts, on the other hand, generally seem to appreciate the fact that they are addicted, even though they may deny the negative consequences of their addiction. So far, it is not unreasonable to grant that the subjects in the Geneva trial may have satisfied the understanding and appreciation conditions of the MacArthur model. If there is a problem with competence, then it must lie elsewhere. The only possibility left is the ability to manipulate information rationally. This involves

a. reasoning logically from premises to conclusion; and
b. evaluating the risks and benefits of prospective decisions.

This last task requires the capacity to assign preferences to anticipated decisional outcomes as well as the capacity to weigh and balance their respective merits. That requires values.

The role of value in mental competence is controversial. On the positive side there are those who argue it is an essential ingredient of competence. For example, Brock and Buchanan have argued that “a competent decision-maker . . . requires a set of values or conception of the good that is at least minimally consistent, stable, and affirmed as his or her own” (Brock and Buchanan 1987, 25; emphasis in original). According to them, values are required “in order to be able to evaluate particular outcomes as benefits or harms, goods or evils, and to assign different relative weight to them” (25). Reasoning and deliberation, they say, require “applying the decision-makers’ values” (25). Values are also mentioned in the President’s Commission discussion of mental competence (President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research 1982, 47). Nevertheless, despite these important precedents, not everyone is equally impressed with the status of value in competence. In their recent book, Appelbaum and Grisso acknowledge that values play a role in competence. They note that in evaluating risks and benefits “one needs to weigh the desirability of various potential consequences, based on one’s own subjective values” (1998, 55). However, other than that they have little to say about the matter. The case of heroin prescription calls for a more refined examination of how exactly values interface with mental competence.

Brock and Buchanan argue that a stable core of enduring values is required for competence. However, they are careful to allow for lapses in consistency and stability. They limit themselves to a requirement of “minimal” stability and consistency. At the very least, a person must have a limited set of enduring values that count as their own. The reason is that a choice that does not—at least minimally—reflect a person’s real likes and dislikes cannot be said to be their choice. A helpful way to interpret this claim is to say that competence requires some sort of accountability (Elliott 1991). According to Elliott, the essence of accountability is whether “the decision truly belongs to the patient” (169). His point is that “what we really want to know when we ask if a person is competent is whether that person is able to make decisions for which he can legitimately be judged accountable” (169). Now how can a person with no minimally stable real values of their own be held accountable for their decision? It is hard to see how a decision made in such circumstances could reflect a person’s real wants and dislikes. There is an important sense in which a choice made in such circumstances does not really belong to the person who makes it. It is not truly theirs. Therefore, they cannot be held accountable for it. Heroin prescription thus provides an interesting illustration of Elliott’s thesis that competence requires accountability.³ Let us now

³ Elliott appears to identify accountability and responsibility. For example, he writes: “If a person is accountable for
consider how it helps illustrate Brock and Buchanan's claim that an enduring set of values is required for competence.

Consider again our hypothetical competency assessment. Did the Geneva subjects have the requisite core of enduring values to count as competent? And are the values they have really their own? Empirical research on addiction suggests that in both cases the answer is "No" (Koob and Bloom 1988; Leshner 1999). Remember that the brain of a heroin addict has almost literally been hijacked by the drug. The set of values that governs their daily decisions and behavior is no longer really theirs. Everything they decide and do eventually reduces to seeking and using their drug of choice. So if chronic heroin addicts can be said to have enduring values at all, most of them are ultimately controlled and defined by their clinical condition. The drug doesn't always have the first say, but it usually has the last word. It follows that chronic heroin users cannot reasonably be said to have a set of enduring values that is really theirs on which to base decisions about their heroin use. To that extent, they are unable to manipulate information rationally in the sense required, particularly when decisions about their own heroin use are involved. Hence, they cannot be said to be mentally competent when decisions about their drug of choice are at stake.

Caring Too Much

A helpful way to illustrate the decisional biasing that occurs in addiction is to compare it to a related phenomenon in depression. Recall the argument that severely depressed individuals may not be competent to consent to research because they care too little about risks (Elliott 1997). Because of their condition, severely depressed subjects cannot rationally weigh the risks and benefits associated with their decision to consent. The reason is that their sense of value is warped and biased by depression, so risks are underweighted. Their decision is not truly theirs, and so they cannot be held accountable for it. Therefore they are not competent to consent. The heroin addict's situation is just the opposite. Because of their condition, addicted subjects cannot rationally weigh the risks and benefits associated with their decision to consent. But their sense of value is warped and biased by addiction, so benefits are overweighted. Their decision is not truly theirs, and so they cannot be held accountable for it. It follows that they are not competent to consent.

Therefore, like the severely depressed subject, the addicted individual is apparently not competent to consent to research. In both cases the decision in question is not truly their own. The depressed subject is disposed to care too little, while the addicted subject is disposed to care too much. Among other things, both suffer from a marked deficiency in the evaluative capacities that govern emotion (Charland 1998a; 1998b). Their choices do not adequately reflect their real enduring values, because the brain mechanisms and systems that govern evaluation have been disrupted and reoriented. This is a good example of how considerations associated with emotion can be important in assessing competence. Indeed, the relevance of emotion to mental competence is starting to receive increased attention (Appelbaum 1998; Elliott 1999). There are also intimate links between emotion and addiction that deserve further study (Elster 1999).

We have seen that there are good reasons for believing that an enduring set of values is a prerequisite of competence. The values of severely depressed individuals and addicted persons are seriously compromised, which suggests their competence is as well. But in the kind of unipolar depression we are discussing, the reorientation in values that occurs is a relatively entrenched and uniform feature. The resulting impairment in decisional capacity is equally entrenched and uniform. The situation with heroin addiction is markedly different. The impairment in decisional capacity is indeed entrenched, and in that respect depression and addiction are analogous. However, in the case of ad-

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4. One important link is the amygdala, a brain structure that is widely believed to be central to emotion (Damasio 1994; LeDoux 1996; Panksepp 1998). The amygdala is also said to be intimately involved in addiction (Leshner and Koob 1999). The connection is plausible, since both addiction and emotion are closely tied to pleasure and reward. It would not be surprising if they shared some of the same brain systems and pathways.
diction the reorientation in values is not uniform. In the words of the National Bioethics Advisory Committee, substance dependence is a disorder that is characterized by “fluctuating capacity” (National Bioethics Advisory Committee 1998, 7). Thus addiction and chronic unipolar depression are not analogous. The difference arises from the daily dynamics of craving and withdrawal that are characteristic of addiction. This phenomenon is especially prevalent with addiction to a drug like heroin because of its relatively short half-life. Heroin addicts such as the Geneva subjects sometimes have to inject heroin up to two or three times a day.

The philosopher Jon Elster has written eloquently about some of the decision-theoretic options available to model the dramatic shifts in goals and values that characterize addiction (Elster 1999). His discussions of “preference reversal” and “hyperbolic discounting” are particularly helpful in modeling the changes in motivational state that accompany and precipitate relapse. It is because goals and values wax and wane in this way that ambivalence is such a pervasive feature of addiction. Indeed, according to Elster, ambivalence is the hallmark of addiction (10, 74). The addict desperately wants to quit but usually fails. They say they really value and desire a life without drugs but usually end up behaving in a manner that shows they really value and desire the opposite. Life is a relentless seesaw where long term goals and values repeatedly collapse under the whiplash of craving and compulsion.

A Moment of Clarity?
The decisional impairments in heroin addiction fluctuate cyclically even though they also exhibit some uniformity. Insofar as they fluctuate, is it possible there may be a point on the continuum of drug use when an addict is competent to consent to heroin? Is there perhaps a moment of clarity between craving and intoxication? It would be rash to dismiss this possibility a priori. Some, indeed, have argued there are such moments. Let us see how plausible the suggestion is.

Alternative Strategies
I have argued that the research subjects typically sought for heroin prescription cannot satisfy the requirements for informed consent outlined here. By virtue of their clinical condition, they cannot satisfy the third condition for competent choice outlined in the MacArthur Study: the ability to manipulate information rationally. Heroin-dependent individuals do not possess this ability where heroin is concerned. Either they are completely biased in favor of it by compulsion, or they are condemned to seesaw ambivalently, up to several times a day, between intoxication and craving. In the former

5. For example, compare the discussion of cocaine and heroin addiction in Management of Alcohol, Tobacco, and Other Drugs: A Physician’s Manual (2000, 171–88 and 221–82).
case, neither their basic values nor their choices are truly theirs. And in the latter, fluctuations in values and preferences make a decision truly made at one time just as truly nullified at another. It is hard to escape the conclusion that heroin-prescription research violates existing North American ethical standards for clinical research. The only safe assumption is that these subjects are incompetent to consent until proven otherwise.

However, an ethical analysis does not simply end with the declaration that a given treatment intervention or research protocol may be unethical. In many cases much work remains to be done. Heroin prescription is a good example. As we saw, there is apparently a strong need to investigate the medical prescription of heroin as a treatment alternative. In closing, it is interesting to speculate on two possible strategies that might circumvent the problem posed by our dilemma. Because guidelines and regulations governing the medical prescription of heroin and other opiates vary across different jurisdictions, the following remarks will be restricted to general ethical and policy features of the proposed strategic alternatives.

One strategy is simply to grant that prospective subjects for heroin trials are incompetent and then investigate options for surrogate decision making. If prospective subjects considered for heroin trials are willing to enroll, then what harm is there in letting them participate? An appropriate, perhaps independent, surrogate authority could be invoked to certify or deny decisions to enroll. Although adequate follow-up data is lacking, the Geneva Trial participants appear to have had a low-risk experience with important positive benefits. If the risk-benefit ratio of future trials minimizes risks and maximizes benefits in this way, it may be ethically appropriate to permit enrollment using some form of surrogate consent. Willing participants would then be asked to assent to heroin prescription, but their assent would be subject to the approval of a surrogate authority appointed to ensure their best interests are not jeopardized.

A second strategy might be to focus on the notion of risk and build on the idea that competence should be assessed using a sliding scale (Brock and Buchanan 1987, 51-65). Very basically, the sliding-scale approach to competence dictates that when risks are low standards for competence should be low; and when risks are high, standards for competence should be high. There are precedents for this strategy. For example, in a recent discussion on alcohol research, we are told that “the critical ethical issue related to the administration of ethanol to research subjects involves the degree to which the benefits to the subject or society outweigh the risks to the research participants” (Dolinsky and Baber 1997, 1092). We are also told that “almost all of the studies that have evaluated research participants following exposure to ethanol administration have failed to identify adverse effects on subsequent drinking behavior or psychological adjustment” (Dolinsky and Baber 1997, 1092). The implication is that the medical administration of ethanol to alcoholics or problem drinkers may be ethically permissible when the risks to participants are suitably low or nonexistent. Can a similar argument be made for heroin prescription?

Suppose the risks associated with heroin prescription are minimal, or at least not superior to those the addict will encounter in their daily life. What does this mean for competence? According to the second strategy, it means that standards for competence can be set low, since risks are low. Could they be set low enough to permit some form of competent consent? The answer, probably, is no. This is because the subjects sought for heroin prescription invariably suffer from serious psychiatric disorders other than addiction. In Dolinsky and Baber’s discussion of ethanol administration, we are told that “subjects with serious psychiatric conditions are usually excluded from studies because of the potential confounding effect of the psychiatric disorder or the potential for the psychiatric state to be exacerbated” (1093). It is not unreasonable to suggest that this provision should also be applied to heroin prescription. I leave the reader to ponder the merits of these two strategies.

Conclusion

Heroin prescription as undertaken in the Geneva Trial would appear to violate existing North American ethical standards for clinical research. This is because the subjects considered for such trials fail to satisfy the required standards for competent voluntary consent. It follows that the Geneva Trial would probably be unethical according to existing North American standards. I hasten to add that this is not meant to be an indictment of the personal ethics or professional integrity of the Swiss researchers, nor indeed anyone else currently considering or conducting heroin-prescription research. However, it does strongly suggest that the issue of consent to heroin prescription needs to be revisited. Some form of systematic empirical testing of the sort that has been carried out for depres-
sion is probably necessary. In the meantime, we should not presume that heroin-prescription subjects who are active in their addiction are capable of competent voluntary consent to heroin-prescription research. Quite the contrary, we should assume they are incompetent to consent unless proven otherwise. ■

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