Alternatives to the Toxic Drug Supply
An Ethical Analysis

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Introduction

The measure of a social policy is not whether it is popular or practical, but whether it is ethical. This holds true no matter what the social domain in question. Ethical policies, however, are not a matter of mere chance. They are the result of careful and conscientious deliberation that takes into account the relevant factors of real life but at the same time is grounded in ethical principles. It is therefore important to ask whether it is ethically appropriate for society to adopt a policy that offers an alternative to the toxic drug supply that currently results in real misery for its users—misery that extends from adverse reactions and seriously decreased ability to function and even includes the possibility of death—as well as contributes to the presence of a criminal element that subverts and undermines valid social institutions and standards. Further, it is appropriate to ask whether society has an obligation to institute such measures as would be necessary to implement such a policy and, if necessary, to enshrine it in suitable legislation.

What follows is an attempt to address these issues. While it draws on pragmatic and legal considerations, it does so only insofar as this is relevant to the ethical considerations that constitute its main focus. It begins with a brief overview of society's duties towards its members with particular attention to the question whether it has an obligation to provide appropriate health-oriented services, relates this to the issue of addiction and the prevalence of a toxic drug supply to satisfy this addiction, and suggests an answer to some initial questions that were posed by the Ministry of Mental Health and Addictions as lying at the core of the inquiry. These questions are:

1. Is it ethically defensible to separate individuals from the toxic drug supply by providing pharmaceutical quality-controlled substances without requiring a person to have a therapeutic goal of minimizing or abstaining from substance use?
2. Is it ethically defensible to prescribe tablet injectable opioids through a harm reduction approach within the context of continued risk of death rather than not prescribing?
3. Is it ethically defensible for prescribers to provide medication as a harm reduction measure rather than engaging in individualized medical treatment?
4. Is it ethically defensible to provide oral medications rather than medications that are specifically manufactured for injection because it is more cost-effective and, in some cases, preferable to the client?
5. Do the benefits outweigh the harms of providing carries of pharmaceutical quality-controlled substances versus requiring witnessed administration of medication to people with substance use disorder due to potential for diversion?

6. What key measures and processes need to be in place to ensure that pharmaceutical alternatives to the toxic drug supply are ethically defensible?

Two further and in some ways overarching questions that have relevance—and which, incidentally, have far reaching implications even beyond the present context—have been added by the author of this analysis. They are:

7. Should the issue of competence or capacity on the part of people who use drugs be addressed by any policy that is adopted?

and

8. Is it ethically appropriate for society to initiate a toxic drug substitution or replacement programme without at the same time ensuring that adequate professional services designed to institute such a programme in practical terms is available on a consistent basis?

Ethics Preamble

Preface

In order to put the subsequent analysis into proper context, it may be useful to preface it with a brief sketch of the ethical framework that underlies the analysis itself.

It is generally agreed that there are certain fundamental ethical Principles that should structure social interactions. These include the Principle of Autonomy:[1]

Everyone has the right to self-determination subject only to the equal and competing rights of others.

the Principle of Equality:[2]

All persons insofar as they are persons, are equal and should be treated in the same way, and any exceptions to this must always be based on ethically relevant differences in the nature or situation of the person in question.

the Principle of Beneficence:[3]

Everyone has a duty to advance the good of others insofar it is possible to do so without undue risk to oneself, where the nature of the good is in keeping with the competent values of the recipient of the action in question.

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[1] Beauchamp TL and Childress JF. 2001. *Principles of Biomedical Ethics*. New York: Oxford University Press, 3.
[2] United Nations, *Universal Declaration of Human Rights*, Articles 1 and 2; accessed 22/09/2020 at https://www.un.org/en/universal-declaration-human-rights/.
[3] Beauchamp and Childress, op. cit. chapter 5.

and the Principle of Non-Maleficence:[4]

> *Everyone has a duty to prevent harm insofar as this is possible without undue risk to oneself, where the nature of the harm is in keeping with the competent values of the recipient of the action in question.*

While not itself a principle of ethics in the strict sense of the term and while it ultimately has its basis in logic, the Principle of Impossibility also functions as a principle of ethics by limiting the domain of rights and duties on the basis of logical considerations:[5]

> *All rights and duties hold subject to the condition that it is possible to meet them under the circumstances that obtain, where the fact of impossibility lies in the nature of the rights or duties and is not a result of the voluntary actions of the party in question.*

When these principles are applied to the general question of what duties an ethical society has towards its members, it immediately follows that a whole range of services is implicated, where these range from education to defence and include health care. The latter in particular is implicated: Unless any health based differences are ameliorated that prevent members of society from being able to take advantage in an equitable manner of the opportunities that society otherwise offers to its members, the Principle of Equality will be violated. It follows, then, that an ethical society has an obligation to provide its members with appropriate and effective health care modalities.

Framework Considerations

Drug addiction is a medical problem. Moreover, it is well known that satisfying a drug addiction by accessing a toxic drug supply increases the likelihood that an adverse reaction may result and that even death may occur. Therefore, since society has an ethical obligation to provide its members with appropriate health services, and since drug addiction is a medical condition, it follows that if the most effective ways of reducing adverse reactions to drug usage is to provide access to a pharmaceutically controlled drug supply as an alternative to what currently is available through uncontrolled and unsupervised street interactions, then society has an obligation to do so. In more specific ethical terms, and putting it in terms of the ethics framework that was outlined above, the Principle of Equality entails that society has an obligation to ameliorate the situation because it is a health condition, and the Principles of Beneficence and Non-Maleficence entail that it has an obligation to provide an alternative to the toxic drug supply where this alternative would have a greater chance of producing good and reducing harm than what currently exists.

Consideration of Specific Questions

It being clear, then, that society has an ethical obligation to provide an alternative to the toxic drug supply as it currently exists, the question becomes how, ethically, this may be achieved. To this end, the Ministry of Mental Health and Addiction initiated an investigation to address this issue, running under the title of "Pharmaceutical Alternatives to the Toxic Drug Supply." The six questions

[4] Op. cit., chapter 4.
[5] Justinian, *Digest* 50. 18. 185. This is reflected in the case of *Taylor v Caldwell* [1863] EWHC QB J1and has been adopted by all jurisdictions.

that were mentioned at the beginning of this analysis were identified as possibly providing an answer. What follows is an attempt to answer these questions in light of the preceding ethical considerations.

Question 1:

> **Is it ethically defensible to separate individuals from the toxic drug supply by providing pharmaceutical quality-controlled substances without requiring a person to have a therapeutic goal of minimizing or abstaining from substance use?**

Reply:

Since society is ethically bound to structure its policies and injunctions in accordance with the Principles of Beneficence and Non-Maleficence, it has an obligation to structure its health services—which it is ethically obligated to provide on the basis of the Principle of Equality—in such a way as to maximize benefit and minimize harm, where the latter are understood in a health-related sense.

This entrains the above question: namely, whether the access to any services that would be provided under this rubric—namely, pharmaceutical quality-controlled substances— should be on the condition that those who access them should have a therapeutic goal in mind and, specifically, that they should intend to minimize or ultimately abstain from substance abuse.

Ethically speaking, this question can be answered only by framing the issue in terms that apply to an individual's right to access health care services in general because, after all, providing access to such a supply would fall under the rubric of health care services, and consistently in matters of policy should prevail.

There currently is no requirement that individuals who access the health services that are provided by society have a therapeutic self-regarding intent or that they intend to abstain in the future from whatever pharmaceuticals are involved in their interactions. This is clearly illustrated by diabetic persons who suffer from type 2 diabetes that is causally grounded in obesity and inactivity and who access insulin, or by individuals who suffer from health conditions that are grounded in their diet and who require corrective medications, or by individuals whose health condition is grounded in personal practices such as aggressive physical sports and who require medical intervention. These are health conditions, and in their case access to appropriate treatment, medications or interventions is not conditional on the individuals' intent. It is on the basis of their need. Drug addiction is also a health condition. Consequently, and by the same token, access to a safe pharmaceutical supply should also not be on the basis that the individuals who access it have a therapeutic goal or that they intend that the need for such a substance will be reduced and ultimately eliminated.

In reply to this it could be argued that there is a fundamental difference between the need for insulin on the one hand and what is encountered in the case of drug addiction. That is to say, the former is a hetero-induced need. It is not the result of a voluntary act for which the affected individual carries responsibility; whereas drug addiction presents an auto-induced need which

would not exist if the individual who suffers from it did not voluntarily engage in the sorts of actions that led to their becoming addicted.

That, however, would be too facile a reply because it is not correct. Type 2 diabetes is frequently associated with self-induced obesity and inactivity as causal facilitators,[6] where these factors are largely (although not exclusively) under the control of the affected persons. Therefore an auto-induced element seems to be present in such some such cases as well—to say nothing of sports-induced injuries, etc. Consequently, if society chooses to institute a pharmaceutical quality-controlled substance programme it could not ethically make access to such a programme conditional on therapeutic intent unless it was willing to impose the same condition on access to insulin for type 2 diabetes that is the result of diet or inactivity related factors, or indeed make the treatment for all other health conditions that have an auto-induced element conditional on therapeutic intent To single out drug addiction would therefore violate the Principle of Equality.

Question 2:

Is it ethically defensible to prescribe tablet injectable opioids through a harm reduction approach within the context of continued risk of death rather than not prescribing?

Reply:

One of the central ethical issues that are raised by this question centres in the terms "prescribe" and "prescribing" respectively. The implication of this terminology is that the pharmaceuticals that would be involved in the harm reduction programme would be available on the basis of an interaction with a duly empowered and qualified health care professional who would have the authority to prescribe. This, however, entails that, ethically speaking, a fiduciary relationship would exist between the prescriber and the potential recipient of the prescription.[7] This means that the professional in question would be ethically bound to act in accordance with the principles of ethics that were previously identified. From this it follows that the professional who would be involved would have an obligation to reduce harm and act in the best interest of the potential recipient of the relevant prescription. The Principles of Non-Maleficence and Beneficence respectively would here be implicated.

These considerations provide an answer to the question that was raised above. Prescribing pharmaceutically controlled drugs would reduce the risk of the negative reactions that are prevalent in the use of toxic drugs, whereas not prescribing pharmaceutical alternatives would leave the addicted individuals dependent on a toxic drug supply and running the risk of having a negative

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[6] World Health Organization, *Obesity: preventing and managing the global epidemic. Report of a WHO consultation.* World Health Organ Tech Rep Ser. 2000;894:i-xii, 1-253; Kahn SE, Hull RL, Utzschneider KM. Mechanisms linking obesity to insulin resistance and type 2 diabetes. *Nature*. 2006 Dec 14;444(7121):840-6; Caballero AE. Endothelial dysfunction in obesity and insulin resistance: a road to diabetes and heart disease. *Obes Res.* 2003 Nov;11(11):1278-89.

[7] World Medical Association *International Code of Medical Ethics*, accessed 24/09/2020 at https://www.wma.net/wp-content/uploads/2006/09/International-Code-of-Medical-Ethics-2006.pdf; International Council of Nurses, *ICN Code of Ethics for Nurses*, accessed 24/09/2020 at https://www.icn.ch/sites/default/files/inline-files/2012_ICN_Codeofethicsfornurses_%20eng.pdf.

reaction. Consequently prescribing would be consistent with the Principle of Beneficence, and not prescribing would violate the Principle of Non-Maleficence.

Turning, then, to the issue of the continued risk of death, this has to be seen in the context of drugs and drug prescribing in general. As a matter of reality, the risk of death exists with the use of almost any drug no matter how the relevant drugs or pharmaceuticals are accessed, and to some degree this is also true irrespective of the nature of the drugs themselves. After all, drug-related death has a multifactorial basis that does not depend solely on the nature of the substance in question but also on the health state of the individual who uses it, their individual physiological and genetic makeup, and other factors. Therefore the question returns to the issue whether prescribing tablet injectable opioids would reduce the harm that potentially results from the use of non-prescribed pharmaceuticals, and whether it would increase the benefit that would be derived from the use of prescribed pharmaceuticals.

This, however, can be answered only by considering the available data that are relevant to the issue. Consequently, if these data support the conclusion that prescribing tablet injectable opioids would, on balance, reduce the risk of harm, then it would be ethically obligatory to engage in such prescribing even if death might occur on occasion. Failure to prescribe would be to ignore the fact that the likelihood of death or other adverse side effects would be reduced because the drugs that would be used would not have toxic adjuvants. Consequently failure to prescribe would be a violation of the fiduciary obligation of the professionals to act in the best interest of those with whom they interact—in this case people who use drugs —and for society not to institute an appropriate programme would be for society to fail in its obligation to provide appropriate health services. In other words, it would be a violation of the Principles of Beneficence and Non-Maleficence.

To reiterate, the risk of death due to drug usage exists irrespective of the nature of the drug—acetylsalicylic acid and paracetamol are cases in point[8]— and irrespective of whether the drug is a pharmaceutically controlled substance that is provided by a qualified professional or is a toxic substance that is acquired by other means. Therefore the risk of death *per se* should not be the determining factor but whether the risk of death is reduced by acknowledging that drug addiction is a health issue and dealing with it in a medically appropriate manner by prescribing pharmaceutical substances that do not carry the inherent risks of the toxic adjuvants. Given that society has an obligation to provide its members with appropriate health services, and given that appropriate health services involve the supplying of services and substances that reduce health related risks, it follows that it would be ethically appropriate to institute a harm reduction programme that would involve prescribing tablet injectable opioids even though a continued risk of death would remain.

Question 3:

> **Is it ethically defensible for prescribers to provide medication as a harm reduction measure rather than engaging in individualized medical treatment?**

Reply:

[8] Adam D, Stankov G. Treatment of fever in childhood. *Eur J Pediatr*. 1994 Jun;153(6):394-402.

To answer this question, it may be appropriate to address it first in general terms relative to ethical Principles and then to narrow it down to the issue of providing medication as a harm reduction measure without engaging in individualized medical treatment.

In general terms, the answer to the general issue has two parts: one that centres in the Principle of Autonomy, and one that centres in the Principles Beneficence and Non-Maleficence.

Prescribers, being health care professionals, stand in a fiduciary relationship towards those for whom they prescribe. This lies in the nature of a health care professional's interaction with someone in a professional capacity. The individuals for whom they prescribe are, in effect, their patients. Consequently the professionals have an obligation to act in the best interest of the individuals for whom they prescribe and to deal with their health care needs to the best of their ability. This holds true irrespective of whether these individuals are their patients on a long-term basis or simply for the moment, or even whether the relationship is incepted for the sake of engaging in a therapeutic relationship that extends to all aspects of an individual's overall health conditions or simply for a specific issue. In all cases, however, the treatment that the professionals provide should always be specific to the health care needs of their patients. And while it would be appropriate for the professionals to advise their patients of their overall health status and of what this would entail for appropriately addressing any issues that may be raised by the latter, the patients' right of autonomous decision making[9]—which is ethically grounded in the Principle of Autonomy and legally enshrined in the doctrine of informed consent[10]—empowers patients to limit the extent of their relationship to the specific needs as these are identified by the patient on any given occasion.

Nor—and this is the second part of the answer to the general issue—may a professional refuse to prescribe medications that would otherwise be appropriate for the condition of the patient if the patient declines to enter into a therapeutic relationship with the professional that extends beyond their specific need. This is clearly illustrated by the case of someone who enters a walk-in clinic and who suffers from an array of health-related issues including hypertension but who will accept only a prescription for antihypertensive medication. While the professional may—indeed, should—inform the patient of their general health status insofar as the professional is aware of it and should advise them of appropriate interventions, the professional may not refuse to prescribe antihypertensive medication unless such prescription would lead to harm. This is grounded in the fiduciary relationship that exists between a health care professional and a patient, and in the Principles of Beneficence and Non-Maleficence.

Applying these considerations to the specific question of whether it is ethically acceptable for a health care professional to prescribe pharmaceutical quality-controlled substances as a harm reduction measure rather than engaging in individualized medical treatment, a similar conclusion follows. A health care professional would have an ethical obligation to prescribe a medication that

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[9] World Medical Association, *International Code of Medical Ethics*, "Duties of Physicians in General," accessed 25/09/2020 at https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/; Canadian Medical Association, *CMA Code of Ethics and Professionalism*, accessed 25/09/2020 at https://policybase.cma.ca/documents/policypdf/PD19-03.pdf.

[10] Freedman B. A Moral Theory of Informed Consent. Hastings Center Report Vol. 5, No. 4 (Aug., 1975), pp. 32-39; *Criminal Code of Canada* S. 265; *Reibl v. Hughes* (1980) 2 S.C.R. 880; *Ciarlariello v. Schacter* (1993) 2 S.C.R. 119; *Starson v. Swayze* 2003 SCC 32, [2003] 1 S.C.R. 722.

would allow the drug user to avoid having recourse to a toxic drug supply rather than the professional insisting on only prescribing on the condition of engaging in individualized medical treatment that extends beyond what the individual specifically requests. To be sure, any prescription should be attuned to the needs of the drug user, and hence should be individualized in that respect. This follows from the fiduciary duty of the professional. However, as in the case of the walk-in clinic example, insistence on an extended course of therapeutic interventions as a condition of such prescribing would be ethically inappropriate. All the more so since such insistence would be ethically inappropriate unless a similar condition were to be applied in all other areas of health care. This follows from the Principle of Equality. To insist on such a condition in general, however, would violate the doctrine of informed consent and be at variance with the Principle of Autonomy.

Question 4:

> **Is it ethically defensible to provide oral medications rather than medications that are specifically manufactured for injection because it is more cost-effective and, in some cases, preferable to the client?**

Reply:

Answering this question involves several distinct issues: first, whether the material nature of a medication has ethical relevance; second, whether cost-effectiveness considerations are ethically defensible in the context of health care in general and of prescribing in particular; and third, whether patient preference relative to the manner of administration of given medication is relevant to or even determinative of what should be prescribed

As to the first issue, dealing with it involves three distinct and ethically relevant parameters: appropriateness, effectiveness and safety. That is to say, one of the fundamental considerations that, ethically, should guide prescribing is whether the medication that is prescribed is medically appropriate for the condition in question. That is entailed by the very nature of the fiduciary relationship whose inception is necessary for prescribing. Further, it should be effective to some degree or other, since otherwise prescribing it would be ethically inappropriate. It would be a sham. However, safety is also of fundamental ethical concern. Is the substance that is prescribed safe for the individual for whom it is prescribed? Different people will react differently even to the same medication. Moreover, the method of administration falls under the rubric of safety as well: Is the mode of administration of the prescribed substance safe for the individual? After all, different methods of administration may also differ in how they affect even the same patient.

Assuming that these issues are answered in the affirmative, this brings into play to the second issue—whether cost-effectiveness considerations are ethically defensible when prescribing pharmaceutical alternatives to the toxic drugs that would otherwise be accessed by a patient.

This issue, again, cannot be answered directly but has to be considered in the context of health care in general. The reason it has to be considered in the context of health care in general is that society's obligation to provide pharmaceutical alternatives to otherwise available toxic drugs holds only insofar as providing such alternatives falls under the rubric of health care. Therefore any

question of the relevance and ethical acceptability of cost-effectiveness considerations must be consistently applicable to all services that fall under this heading.

Within the context of health care, resources are always limited. This is not a matter of choice but of reality. Therefore, to put it bluntly, what is given to one is taken from the other. This translates into society's obligation to provide health care services in the most cost-effective way possible—the assumption here being, of course, that the services that are chosen are appropriate, safe and effective. On this condition, then, cost-effectiveness considerations are ethically relevant and important.

Applying these general considerations to the present and more specific question, the answer is that cost-effectiveness considerations in principle are ethically relevant when deciding whether to provide oral medications rather than medications that are specifically manufactured for injection. In other words, the question is answered in the affirmative. However—and this should be seen as qualifying this answer—cost-effectiveness should not be seen as superseding medical appropriateness, safety and effectiveness. All other things being equal—this qualification will be addressed in a moment when dealing with patient preference—it is ethically appropriate for society to take cost-effectiveness into account only if oral and injectable prescriptions are equal on that score.

With this, the third issue moves centre stage: Is patient preference relative to the way a given prescription is administered relevant or even determinative of what should be prescribed?

As was pointed out before, the ethically binding rule for the professional should always be to prescribe what is medically appropriate, effective and safe. However, as was also pointed out, the array of medications that can be offered to a patient is limited by the resources that are available to society. This means that a patient's preferences are ethically relevant only insofar as they apply to the array of medications that society can provide. If the manner of their administration is not the patient's preferred manner of administration then, all other things being equal, the patient is always at liberty to refuse the medication. This if grounded in the Principle of Autonomy. However, if there are several distinct medications with different methods of administration or even if the same medication has different methods of administration then, as long as the conditions of medical appropriateness, effectiveness and safety are met and the medications fall within the array of medications that society provides, a patient's preference should be determinative. This would be the case even if these different medications or different methods of administration that fall within the array of services that are provided by society have different degrees of effectiveness, just as long as the patient was informed of this difference and understood this according to applicable standards of informed consent.

Question 5:

Do the benefits outweigh the harms of providing carries of pharmaceutical quality-controlled substances versus requiring witnessed administration of medication to people with substance use disorder due to potential for diversion?

Reply:

This question raises two ethically relevant issues. The first is the overarching issue of harm outweighing benefit; the second is the issue of witnessed administration vs. carries.

Beginning, then, with the issue of harm v. benefit, there are three ways in which the question can be understood: as dealing with harm relative to society, as dealing with harm relative to the individuals who are directly supplied with the relevant medications, and as dealing with the harm to the individuals who might be provided with the medications through diversion by the individuals for whom the substances are prescribed.

As to the issue of harm vs. benefit for society, it is unclear in what sense harm or benefit to society would result from either witnessed administration as opposed to carries unless the notions of harm and benefit are understood in a pragmatic sense. Understood in that sense, however, any answer here would have to be correlated with an answer to the question of which method would reduce the expense to society and hence constitutes the least drain on the limited resources that are available for health care. While that is an ethically relevant issue—as was already pointed out, it is ethically obligatory to use the limited health care resources in the most efficient way possible so that health care services can be designed and delivered in an equitable fashion—there are no valid data that could be used to answer this question. Therefore the issue must remain moot.

As to the issue of whether benefit or harm would result to the individuals who are directly supplied with the medications, it is unclear in what sense a benefit for them would result through their diverting the medications to which they would have access except in the senses that they might sell the prescribed substances or gain another material or personal advantage. Such advantage, however, would not be ethically relevant in the present context unless, through being able to divert the medications, the individuals to whom they were prescribed would be in a position to assume a power relationship over those to whom they diverted the medications. That would be unethical. As to the issue of harm to the individuals who are directly supplied with the medications, the only way that harm would accrue to them would be if the medications that was prescribed for them was strictly limited in quantity and they themselves would have to resort to toxic drugs to satisfy their addiction. In the case, however, diversion would be a matter of their choice, and hence would not in itself be unethical because, by the Principle of Autonomy, everyone has the right to freely harm themselves. This is recognized even in law, as is illustrated by the legal provisions that govern informed consent, and by absence of any legislation that prohibits suicide as an indictable offence.

As to the individuals who would have access to prescribed drugs through such diversion, realistic considerations suggest that their ability to access quality-controlled pharmaceuticals would reduce the incidence of harm that would otherwise be caused by their use of toxic drugs. Consequently in their case benefit would outweigh harm and hence such access, even though it would be through diversion, would be ethically unobjectionable. All the more so since one of the unstated but nevertheless very real objectives of instituting a programme that would supply quality controlled medications as an alternative to using a toxic drug supply is to reduce the harm that results from using the toxic drug supply. Therefore the Principles of Beneficence and Non-Maleficence once more come into play.

This brings into focus the question of witnessed administration vs. carries. The task at hand is not to consider this relative to what in fact is in place. That is a matter of practice: Currently, some pharmaceutically controlled substances will be provided only on a witnessed basis whereas others are provided as carries. The ethics of that practice itself merits investigation but is not currently at issue. Rather, the task is to consider the matter in light of the ethical principles that were identified at the outset of this analysis and in light of the considerations that were raised in the preceding segments of this analysis.

Given what has already been said relative to the issue of benefit vs. harm, it seems reasonable to suggest that ethically there should be no insistence on witnessed administration unless there are overarching ethical reasons why the pharmaceuticals should be supplied only in a witnessed manner. By the Principle of Equality, however, these overarching reasons must be in keeping with polices that are in place across the domain of health care prescribing. In fact, however, there is no consistent protocol that ethically structures witnessed prescribing behaviour in the domain of health care in British Columbia. So, for instance, there is no requirement that pharmaceuticals that are prescribed for high blood pressure, thyroid insufficiency or for the alleviation of pain such as Tylenol 3, hydrocodone or oxycodone require witnessed administration. Yet all of them—in particular the latter—can be diverted. Therefore, unless the protocols for all such medications was revised to require witnessed administration, to require the witnessed administration of pharmaceutically controlled substitutes for toxic drugs in order to prevent diversion would be discriminatory and hence violate the Principle of Equality.

As well, witnessed administration raises the ethical issue of privacy,[11] which is grounded in the Principle of Autonomy. That is to say, everyone has the right to control the amount of information that is gathered about them, how it is gathered, processed or communicated, and who has access to that information. Therefore the witnessed administration of prescribed pharmaceuticals would be ethically (and legally) defensible only on the condition of informed consent. This is also reflected in law.[12]

Furthermore, ethically one should not approach the issue of drug prescribing with the assumption that those who are prescribed the medication would engage in diversion. That would be to assume that the recipients of the prescribed substances would act in what might be considered an inappropriate manner. To assume this, however, would be to pass ethical judgement on the recipients without having adequate evidence for doing so. And here, even statistically valid evidence would not be sufficient for doing so because individuals are not statistics, and it is individuals who would be witnessed. Furthermore, as has already been pointed out, even if diversion were to occur if witnessed administration was not required, it would reduce the overall reliance of other people who use drugs on a toxic drug supply. As has also been pointed out,

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[11] For instance, see Oath of Hippocrates, Loeb Classical Library. 147: 298–299. See also Privacy Commissioner of Canada, Privacy laws in Canada, accessed 29/09/2020 at https://www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/. European Union, Article 8(1) of the Charter of Fundamental Rights, accessed 29/09/2020 at https://www.google.com/search?client=firefox-b-d&q=European+Union%2C+Article+8%281%29+of+the+Charter+of+Fundamental+Rights.

[12] British Columbia, *Freedom of Information and Protection of Privacy Act* [RSBC 1996] CHAPTER 165; accessed 05/10/2020 at https://www.bclaws.ca/civix/document/id/complete/statreg/96165_00; Canada, *Personal Information Protection and Electronic Documents Act* (S.C. 2000, c. 5), accessed 05/10/2020 at https://laws-lois.justice.gc.ca/ENG/ACTS/P-8.6/index.html.

however, that would be ethically consistent with the underlying reason for instituting a pharmaceutically controlled drug supply programme as an alternative to the currently prevalent toxic drug use situation.

Question 6:

What key measures and processes need to be in place to ensure that pharmaceutical alternatives to the toxic drug supply are ethically defensible?

Reply:

If the answers to the preceding questions are ethically valid, then this question can be answered by collating the various points that are contained in them.

More specifically, the pharmaceutical alternatives should be safe, effective and appropriate in response to the needs of the affected person. This follows from the Principles of Beneficence and Non-Maleficence.

Second, access to these alternatives should be on the basis of informed consent, which would mean that any delivery or administration should be preceded by a valid informed consent process. This may involve putting in place a protocol that ensures that the individuals who access the pharmaceutical alternative supply programme are competent and have capacity to give consent. If these persons lack capacity, an appropriate diversion programme of the sort that is in place relative to other health care interventions should be instituted. This follows from the Principles of Autonomy and Equality.

This means that Question 7 which was added to the questions that formed the initial focus of this analysis—namely *Should the issue of competence or capacity on the part of people who use drugs be addressed by any policy that is adopted?* — should be answered in the affirmative, and appropriate protocols should form part of any implementation of the proposed pharmaceutical alternative programme.

Third, a monitoring protocol should be in place so that any adverse side-effects of the pharmaceutical alternatives would be observed as soon as possible and dealt with in an appropriate fashion. This is entailed by the fiduciary obligations of the professionals who would be involved in delivering the programme, and follows from the Principles of Beneficence and Non-Maleficence. This does not, however, mean that contrary to what was said in answer to Question 5 witnessed administration should be the standard. It means that appropriate and effective measures should be developed that allow the identification and reporting of adverse events resulting from the use of pharmaceutically controlled substances.

Fourth, the protocols for engaging in a pharmaceutical alternatives programme should be structured in such a way that the privacy rights of the recipients of the prescribed pharmaceuticals would be respected. This follows from the Principle of Autonomy.

Fifth, the existence of the pharmaceutical alternatives programme should be advertised in an effective manner so that people who use toxic drugs could reasonably be assumed to be aware of its existence and of what would be involved in accessing it. Such advertising, however, should not foster a pejorative impression of those who would access the programme. Drug addiction is a medical condition, and the issue of how that medical condition came about should no more enter the picture than how any other condition that was in principle preventable and that would benefit from treatment came about. This follows from the Principle of Equality.

Sixth, any such programme should take appropriate steps to ensure that access to pharmaceutical alternatives would not be confined to individuals who live in urban or suburban settings that are noted as having a high incidence of toxic drug use. Therefore any such programme should be structured to make it accessible to drug addicted individuals on a geographic basis that is similar to what is in place for individuals who require access to other health care but who live in remote communities. This follows from the Principle of Equality.

Also—and this would bring into play Question 8, which was added to the original group of questions—the measures and processes that would be put in place to actualize the pharmaceutical alternatives programme should ensure that the qualifications and the numbers of professionals who would deliver the programme would be adequate. This again follows from the Principle of Equality.