# Using Neuropharmaceuticals for Cognitive Enhancement: Policy and Regulatory Issues

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**Abstract**

This chapter provides an overview of policy and regulatory issues relating to the use of neuropharmaceuticals for cognitive enhancement in normal persons without a cognitive disorder. It draws on experience with a range of policy and regulatory approaches to alcohol, tobacco, pharmaceutical drugs, and illicit drugs and focuses on approaches that target rates of drug use in the population as a whole. The focus on regulatory interventions for the control of neuropharmaceuticals is important because a range of pharmaceutical drugs is often reportedly used and advocated for enhancement purposes. We also examine how more public health interventions such as awareness raising, education, and stigmatization could be used as preventive strategies to reduce the use, and harm associated with the use, of neuropharmaceuticals for cognitive enhancement.

## Introduction

The recent increase in neuroscience research on human cognitive functioning has prompted speculation about the potential for developing new interventions, such as neuropharmaceuticals, that will enhance cognitive function in persons whose cognitive performance is normal, that is, unimpaired by disease or injury. This speculation has been encouraged by research reporting improved cognitive performance in "healthy controls" in response to drugs intended for use in the treatment of cognitively impaired patients, e.g., persons who have suffered strokes or head trauma.

This chapter provides an overview of unique policy and regulatory issues raised by the proposed use of pharmaceutical drugs for the purpose of cognitive enhancement in persons without cognitive impairment. Current discussions about the possibility of this type of cognitive enhancement focus on the use of neuropharmaceuticals to improve executive function, memory, attention span, concentration, and alertness. The literature cites some empirical evidence that students, particularly those at elite colleges in the USA, use prescription stimulants such as Ritalin (methylphenidate) or dexamphetamine/mixed amphetamine salts (Adderall) as study aids (DeSantis et al. 2008; Teter et al. 2006). Illicit drugs may also be used for cognitive enhancement purposes, but this chapter will focus on policy and regulatory interventions for the control of neuropharmaceuticals. This is because there is an increasing call for the prescription of neuropharmaceuticals for cognitive enhancement purposes. However, such a policy change could trigger a rapid growth in drug use that may lead to unanticipated harm including addiction. This chapter draws on experience with a range of policy and regulatory approaches to a variety of psychoactive substances that include alcohol, tobacco, pharmaceutical, and illicit drugs. An assessment of different approaches to controlling or regulating

these substances can provide useful insights in designing practical regulatory approaches to the emerging enhancement use of neuropharmaceutical drugs.

Neuropharmaceuticals putatively used for cognitive enhancement can be framed in different ways that reflect similarities between their patterns of use and the use of illicit drugs, prescription drugs, and "lifestyle" drugs. Different fields use different competing frames or discourses to capture the phenomenon. These range from the paradigm of drug misuse and prescription drug abuse (that is often encountered in the public health literature) to the paradigm of "cognitive enhancement" most often encountered in interdisciplinary bioethics discussions (Forlini and Racine 2012; Racine 2008). We also examine the possible roles of public health interventions such as awareness raising, education, and uses of stigma that could be used to prevent use and reduce harm arising from neuroenhancement use of these drugs.

## Claims Made for the Enhancement Use of Neuropharmaceuticals

The safety and effectiveness of using neuropharmaceuticals as cognitive enhancers in healthy individuals remains uncertain, but this pattern of use has nonetheless been sympathetically discussed in leading scientific (*Nature*) and medical journals (*BMJ*, *Neurology*). This proposed use of prescription medications raises regulatory and public health policy challenges that need to be carefully considered.

The lack of scientific evidence on the safety and efficacy of neuropharmaceuticals when used for enhancement presents a major challenge to those seeking to make recommendations about policy and regulatory approaches. Nonetheless, professional bodies have attempted to develop policies in the UK (Academy of Medical Sciences 2008; British Medical Association 2007) and Canada (Government of Quebec 2009). The American Academy of Neurology, for example, has published guidance for neurologists on how to respond to patient requests for a prescription to improve their memory, cognitive focus, or attention span, on the assumption that such requests are already common in neurology practice (Larriviere et al. 2009).

## Regulatory Options

A recent paper in the Lancet argued that the aim of drug policy should be to "promote the public good by improving individual and public health, neighbourhood safety, and community and family cohesion, and by reducing crime" (Strang et al. 2012, p. 71). Models of drug regulation vary according to the type of drug and the jurisdictions involved. This section examines the strengths and weaknesses of applying these different models of regulation to the use of neuropharmaceuticals for cognitive enhancement. Table 69.1 provides an overview of approaches and their major strengths and weaknesses.

**Table 69.1** Summary of regulatory and public health approaches and their major strengths and weaknesses[a]

| Approach | Description | Strengths | Weaknesses |
|---|---|---|---|
| Free market | No restrictions on the adult use of neuropharmaceuticals for cognitive enhancement | Promotes personal choice to engage in cognitive enhancement | Potential dangers if safety has not been established |
| | | | Resources wasted if efficacy is not established |
| | | | Incompatible with current regulation of putative enhancers |
| Market regulation | Psychoactive substances regulated through various measures including taxes and limits on sales and promotion | Avoid the potential negative consequences of prohibition while controlling use | Commercial interests selling these drugs have an interest in limiting the effectiveness of the system to maximize profits |
| Licensed users | People demonstrate an understanding of the risks and capacity to use the drugs responsibly before being allowed to use for enhancement | Promotes informed consent | Not currently feasible |
| | | | Challenging given varying levels of health literacy in society |
| Prescription system | Only licensed physicians can prescribe a drug which must be dispensed by a pharmacist | Supervision by health-care professionals | Possibility of diversion |
| | | Ensures access for approved medical purposes | Availability through Internet pharmacies which are difficult to regulate |
| Prohibition | Unauthorized trade in psychoactive substances, whether illicit or medicinal, is a criminal offence | Clear regulation on nonmedical uses of medications | Creation and expansion of black markets |
| | | | Creates challenges because current putative enhancers are used as treatment for legitimate medical conditions |
| Public health education approaches | Reduce or delay initiation and prevent regular and dependent drug use | Cost-effective | Not very effective for prevention of use of illicit drugs, tobacco, and alcohol |
| Mass media and information campaigns | Use warning messages about the health impact of drug to influence attitudes and behaviors | Potential for widespread diffusion of information | Potential source of misinformation |
| Stigmatization and denormalization | Use of stigma to create a negative image for use of neuropharmaceuticals for cognitive enhancement | Not restricted to health agencies | Unintended consequences and collateral stigma of illness |
| | | Can involve social control that is exerted by family and friends | Potential impact on users' self-esteem and societal acceptance of diversity |

[a]See text for full details

## Free Market Approaches

Some bioethicists have argued for a laissez-faire approach towards neuroenhancement. They have recommended a free market, suggesting that there should be no restrictions on the use of neuropharmaceuticals for cognitive enhancement (Sandberg and Savulescu 2011; Savulescu and Bostrom 2009). Greely and colleagues argued that easier access to cognitive enhancers should be allowed and no legal penalties be imposed on those who wanted to use neuropharmaceuticals without a prescription. Furthermore they suggest that the use of drugs should be viewed "in the same general category as education, good health habits, and information technology – ways that our uniquely innovative species tries to improve itself" (Greely et al. 2008, p. 702).

Bostrom and Sandberg have advocated a similarly liberal view in suggesting that treating nontherapeutic neuropharmaceutical use as misuse is inconsistent with the shifting border between therapy and enhancement. Bostrom and Sandberg (2009) argue that:

> To make the best use of new opportunities, society needs a culture of enhancement, with norms, support structures, and a lay understanding of enhancement that takes it into the mainstream cultural context. Consumers also need better information on risks and benefits of enhancers, which suggests a need for reliable consumer information and for more studies to determine safety and efficacy. (p. 333)

This liberal approach is inconsistent with international drug control treaties. The United Nations Drug Conventions are clear that unauthorized trade in psychoactive substances, whether illicit or medicinal, should be a criminal offence and consequently recreational drug use must be strictly controlled (Hughes and Winstock 2012). Furthermore, free market approaches are inconsistent with other regulatory approaches to the regulation of pharmaceutical drugs in developed countries, as we discuss below. The use of prescription neuropharmaceuticals without a prescription – including those used for cognitive enhancement – is illegal in most developed countries that are signatories to these international treaties.

## Market Regulation

If the use of neuropharmaceuticals without a prescription was to become legal, the market could be regulated in different ways. For example, markets could be regulated in the same way as markets for other legal drugs such as tobacco or alcohol. The use of alcohol and tobacco is not prohibited and does not require a prescription, but their use is controlled by methods including the imposition of taxes, limiting availability, age limits on use, and restricting promotion of their use and when and where they may be used. These approaches have had reasonable success in limiting availability and controlling the use of some drugs. For example, raising taxes and limiting the availability of alcohol are moderately effective in

reducing levels of alcohol consumption and rates of alcohol-related problems (Babor et al. 2010; Room and Hall 2012). Regulatory controls on smoking in public places, workplaces, bars and restaurants have contributed to reductions in community smoking prevalence (Room and Hall 2012).

A major weakness with a legal regulatory system is that the companies who market the commodities have a major commercial interest in limiting the effectiveness of the system or in using the system to their advantage, e.g., by limiting competition to current market participants ("regulatory capture"). The continued effectiveness of regulatory systems depends on the vigilance and preparedness of governments to operate these systems in the public interest (Room and Hall 2012).

## Licenses for Use

Some bioethicists have suggested a licensing system for the use of neuropharmaceuticals for cognitive enhancement. Bostrom and Sandberg have suggested that "enhancement licenses" be issued to people who demonstrate an understanding of the risks and a capacity to use these drugs responsibility. This would mean that users would be able to give informed consent and that any adverse effects of their use could be properly monitored (Bostrom and Sandberg 2009). Dubljevic proposes an "economic disincentives model" whereby users would be licensed, first paying fees for a course about effects and side effects, proving their knowledge by passing an exam, becoming registered as an enhancement user, and obtaining additional medical insurance (Dubljevic 2012).

This idea is not currently feasible under drug regulatory systems in developed countries. It seems reasonable to expect that such a licensing system would require a minimum demonstration of the safety and efficacy of putative enhancers to meet the requirements of informed consent and other criteria of moral acceptability (Racine 2010). It is not clear who should fund research to demonstrate this or whether consent could be free from coercive pressures to use a cognitive enhancer.

## Prescription System

Prescription systems are designed to manage the medical use of drugs that have potentially adverse and beneficial health effects. Many illicit drugs were first used for medical reasons, and some illicit drugs (or drugs with similar effects) are still used as medicines, e.g., opioids and stimulants. Prescription monitoring systems can reduce irregular prescribing and patient utilization while allowing patients to access these drugs for appropriate medical purposes (Strang et al. 2012). Under prescription regimens, only licensed physicians can prescribe a drug which must be dispensed by a pharmacist, often in limited quantities to limit diversion. However, prescription regimens do not eliminate nonmedical use of neuropharmaceuticals because these drugs may be diverted to nonmedical use, e.g., by giving drugs to family or friends or selling the drug on the black market. This can make reduction of supply through traditional law enforcement difficult (Strang et al. 2012).

The prescription system can allow greater control by regulators. For example, in the USA the 2011 Prescription Drug Abuse Prevention Plan was introduced to reduce misuse and diversion of prescription drugs. The plan includes mandatory education for physicians who prescribe and pharmacies that dispense. Such programs are designed to prevent doctor shopping and drug diversion by allowing physicians and pharmacists to access patient records at the time of writing a prescription or dispensing a drug to ensure that the patient is not receiving multiple prescriptions from different doctors (Holmes 2012).

The emergence of Internet-based pharmacy services makes control of prescription drugs less effective and more challenging (Fischer et al. 2010; Strang et al. 2012). Websites may require a prescription but "rogue" websites may provide drugs without one (Nielsen and Barratt 2009). Online pharmacies are difficult to regulate closely because sites may only be available temporarily, they are difficult to trace, and their operation may cross international boundaries and jurisdictions (Orizio et al. 2011). Real-time monitoring may provide much-needed data about the prevalence of acquiring prescription drugs from online pharmacies and even reduce the overuse of prescription medications. Online monitoring of trends in drug use may also provide better information about broader patterns of "off-label" prescription drug use (Nielsen and Barratt 2009).

Regulation of online pharmacies is challenging, but it is even more difficult to regulate Internet sites where people may access information or supplies of pharmaceutical drugs. For example, social networking websites such as MySpace and Facebook have become a common marketplace for the buying and selling of prescription drugs (Stone and Merlo 2011). There are also websites advising users on how to simulate a disorder in order to persuade a doctor to provide a prescription.

It appears that prescription monitoring systems may reduce overall use, but their impact on reducing diversion or nonmedical use of pharmaceuticals is unclear (Fischer et al. 2010). Diversion is not likely to be effectively targeted by law enforcement approaches. It is likely to be more effective to put in place measures to reduce the overall use of the drug while ensuring that when it is used it has been prescribed appropriately (Fischer et al. 2010).

Strang and colleagues note two weaknesses with the regulation of drugs via a prescription system. Firstly, reduced rates of prescription of some drugs can produce an increased use of other prescription drugs with similar effects, as nonmedical users find alternative drugs to use when distribution of their preferred drug has been restricted. Secondly, restrictions on prescribing have the potential to deny medications to patients who require them for treatment (Strang et al. 2012).

## Off-Label Use

Off-label use occurs when a prescription is provided by a physician for a reason other than the licensed purpose of the drug but generally for medical indications. The American Academy of Neurology guidelines adopt a laissez-faire approach that permits off-label use of enhancement, but this view does not capture the fact that off-label therapeutic uses of a drug are warranted under the proviso that physicians are using a drug to treat a patient (Larriviere et al. 2009). The Academy

of Neurology guidelines have been criticized for not providing helpful guidance to health professionals that is consistent with commitments to evidence-based medicine and socially responsible medical practice, and it is also at odds with the general understanding and justification of off-label prescription (Racine and Forlini 2010).

## Explicit Enhancement Use of Neuropharmaceuticals

It has been argued that the use of neuropharmaceuticals for cognitive enhancement could be readily dealt with by incorporating explicit enhancement use into existing systems of pharmaceutical regulation (Greely et al. 2008). Bostrom and Sandberg argue that the present system for licensing drugs and medical treatments is overly constraining because it does not allow for the development and marketing of drugs that have a solely enhancing function (Bostrom and Sandberg 2009). They suggest that the "medicine-as-treatment-for-disease" framework creates problems for pharmaceutical companies and users who have to doctor-shop to find a physician who is willing to bend the rules by prescribing a drug for enhancement purposes. Some students admit simulating psychiatric symptoms in order to get prescriptions for drugs that they intend to use for enhancement purposes (Carroll et al. 2006).

Dubljevic proposes a system whereby a government agency would offer a licensing system for pharmaceutical companies to develop drugs that would be used for cognitive enhancement, on the condition that these drugs were first used to treat cognitive disorders (Dubljevic 2012). He suggests that pharmaceutical companies would be interested in this opportunity because of the large potential market for cognitive enhancers. However, given that pharmaceutical companies already have large markets for their products, it is not certain that they would be willing to take on the extra expense and medicolegal risk involved in marketing neuropharmaceuticals to healthy people for cognitive enhancement purposes. Previous attempts to market stimulants for cognitive enhancement have been abandoned (Bell et al. 2012). It is unlikely that pharmaceutical companies would be eager to fund studies to demonstrate the safety and efficacy of drugs to enhance cognitive performance in healthy people. The legal liability involved in providing drugs to healthy people would also be a deterrent because there may be less social tolerance for side effects and adverse events of drugs used electively for nontherapeutic reasons.

## Prohibition of All Enhancement Use

In contrast to laissez-faire approaches, prohibition is a policy position which bans enhancement use of a drug. A parallel may be drawn between this approach and the anti-doping policy in competitive sports. In this model, athletes submit to a testing regime targeting a range of identified substances, and there are severe penalties for those who are identified as drug users.

An example of the application of this model to cognitive enhancement could be to drug test students for the use of drugs for cognitive enhancement. However, as in the case of illicit drugs, there is no compelling case for the effectiveness of

school-based drug testing in discouraging drug use by students (Roche et al. 2009). The neuropharmaceuticals used for cognitive enhancement purposes may be exactly the same substances used for the treatment of legitimate medical conditions, and it would therefore be very difficult to work such an anti-doping system in practice. Furthermore, a rigorous testing scheme is no guarantee against the use of performance-enhancing substances.

There are a number of other important reasons that make it hard to justify using drug testing to deter use of cognitive enhancers in educational settings. It may lead to the criminalization of such behavior. The resulting stigma and illegality of such use may deter patients from using these drugs for appropriate medical purposes. It may also unwittingly send the message that drug use is common and in fact normalize use. Furthermore, implementing a drug testing system would be costly and divert resources away from other activities such as education and treatment.

## Public Health Approaches

Public health approaches to reducing drug-related harm include measures designed to deter individuals from using substances in ways likely to harm themselves or others. These approaches follow from a policy of prohibiting harmful use of a substance while recognizing that legal and regulatory prohibitions will not prevent all use. Measures to prohibit use or regulate markets, as described above, function to protect public health. However, more general prevention approaches also aim to stop people from starting drug use, delay initiation, or dissuade them from becoming regular and dependent drug users.

Examples of such measures include laws that prohibit driving while under the influence of alcohol or drugs, the public use of drugs, or being intoxicated in public places; public education about the risks of drug use; and the stigmatization of certain drug use or patterns of drug use (and thereby the people who use these drugs in these ways). Public health approaches can be implemented in a variety of settings, such as schools, the mass media, community settings such as the workplace, and in primary health care. Environmental interventions aim to limit the availability of dangerous substances, while educational interventions aim to raise community awareness and knowledge of the adverse effects of drug use.

Knowledge and awareness campaigns are generally ineffective in preventing the use of illicit drugs, tobacco, and alcohol (Babor et al. 2010). More effective strategies include psychosocial developmental interventions (e.g., resilience building programs in schools) and information campaigns to correct community misperceptions (e.g., about the prevalence of use of some types of drugs) (Strang et al. 2012). The latter is particularly relevant in the case of neuropharmaceutical use for cognitive enhancement because US college students perceive the prevalence of this type of drug use as much higher than the actual prevalence (Forlini and Racine 2009; McCabe 2008).

Targeted preventive interventions to curtail stimulant abuse among college students have been recommended. These include efforts to educate students about the dangers of illicit stimulant use, using a denormalizing approach, combined with health education to debunk myths and expose the risks involved while encouraging more appropriate study habits (Rosenfield et al. 2011). One limitation of this approach is that it places the onus on university administrations and neglects the role of physicians in prescribing these drugs (Forlini et al. 2013) and the societal pressures that encourage their use.

The mass media are important vehicles of public information (or misinformation) about the prevalence and risks of drug use. Mass media deserve special attention because of their overestimation of the extent of neuropharmaceutical use for cognitive enhancement (Forlini and Racine 2009; Partridge et al. 2011). Media guidelines may raise awareness of this problem. For example, the Australian Press Council has put forward recommendations on how the mass media should avoid certain messages when reporting on drug use (Australian Press Council 2001). Reports should avoid glamorizing drug use or unintentionally providing information on how to obtain a drug or how to use it in risky ways. Unfortunately these guidelines are not always followed when reporting on enhancement use of neuropharmaceuticals (Partridge et al. 2011).

Stigmatization and denormalization of the use of neuropharmaceuticals for cognitive enhancement deserve more attention given their fundamental role in policy and public health approaches to drug use. Current anti-tobacco campaigns which represent an example of the effects of stigmatizing smokers could tempt policy makers to use a similar approach to enhancement use of neuropharmaceuticals. Room and Hall (2012) argue that the main lesson from global experience with prohibitions of psychoactive substances is that such prohibitions are most successful when there is a strong community norm of abstinence. This approach contrasts with the free market arguments for the normalization (or at least the destigmatization) of cognitive enhancement use of neuropharmaceuticals (Bostrom and Sandberg 2009; Greely et al. 2008).

Denormalization and stigmatization are likely to be difficult approaches to implement in the context of cognitive enhancement in the face of markedly different stakeholder attitudes towards cognitive enhancement. For example, health-care providers condemn the nonmedical use of stimulants for academic performance enhancement, while college students may be more tolerant of such use among their peers (Forlini and Racine 2009). It will be difficult to change the very different mindsets of these groups with stigmatization campaigns.

## Challenges in Assessing Regulatory Options

### Lack of Evidence on Prevalence, Efficacy, and Harms

The lack of good quality evidence about the cognitive enhancement use of neuropharmaceuticals is a major challenge in assessing regulatory options. Early in the bioethics discourse about cognitive enhancement, there were recommendations

made for policy approaches on the basis of assumptions that the substances under discussion were being used widely across the population and they actually enhanced cognitive performance and were safe to use. However, there is an increasing awareness that such assumptions lack an evidence base and, in fact, may be false (Lucke et al. 2011).

Critics have questioned evidence from US studies of student drug misuse that have been used to justify claims that the use of neuropharmaceuticals for cognitive enhancement is widespread. The interpretation and relevance of these findings for cognitive enhancement has been questioned (Lucke et al. 2011). Other results emerging (Franke et al. 2011) show that the prevalence may be much lower than claimed. Media reports perpetuate the impression that prevalence of use is already high and increasing (Partridge et al. 2011). Data are needed from large-scale focused studies of cognitive enhancement to provide data that will inform appropriate policy development.

Recent reviews of the effects of putative neuroenhancing drugs, such as the stimulants, antidepressants, and acetylcholinesterase inhibitors, have not found convincing support for their efficacy (Lynch et al. 2011; Repantis et al. 2008, 2010a, b). In normal healthy people without any impairment, such as sleep deprivation, stimulants have a very modest impact on memory, and gains are more likely among those with lower baseline ability (Smith and Farah 2011).

Neuropharmaceuticals are regulated because of their potential to adversely affect health. Regular users may develop acute tolerance to the subjective effects of stimulants and often respond by increasing their dose, thereby increasing the risks of toxic side effects and of abuse and dependence. In the USA almost 1 in 20 nonmedical users of prescription stimulant medications meets criteria for stimulant dependence or abuse. Medical complications of acute stimulant intoxication include an altered mental state (from euphoria to psychosis), seizures, and cardiac arrhythmia (Kroutil et al. 2006). Debates about the cognitive enhancement use of neuropharmaceuticals have been criticized for ignoring the potential for abuse and addiction (Bell et al. 2012; Swanson et al. 2011). Concerns about minimizing the potential health effects of neuropharmaceuticals should be paramount in discussions about appropriate policy and regulatory frameworks.

## Lack of Evidence of Effectiveness of Methods of Regulation

Drug policy is often contentious, operating in "a complex political terrain characterised by intense controversy, mixed opinion and unrelenting media attention" (Fraser and Moore 2011, p. 505). Ideally, evidence about the effectiveness of policy approaches should be underpinned by good scientific evidence about the effects of the substance in question. But as Strang and colleagues note, policy is often formulated to deal with problems of perceived immediate public importance (such as the emergence of a new type of psychoactive drug or a highly publicized drug-related death of a celebrity), rather than on the basis of scientific knowledge about the prevalence of

the drug's use or its likely harms (Strang et al. 2012). Public debate in drug policy is also driven more by values and politics than by scientific evidence. This context means that even with good evidence, emerging knowledge about neuropharmaceuticals may only be tenuously related to public perception, patterns of use, and approaches to policy and regulation. Evidence about the effectiveness of different policy approaches and their cost-effectiveness can nonetheless help both the public and policy makers to select policies that achieve the goals they desire (Strang et al. 2012).

The rationale for public health approaches may be debatable at this point in time. Outram and Racine have noted that there is a lack of empirical data justifying public health interventions. There is a risk that governments may act on the grounds of probable health risk instead of epidemiological data (Outram and Racine 2011a). Outram and Racine have noted the lack of critical reflection on the underlying rationale for reports that cognitive enhancement practices are rampant. They suggest that these reports constitute important actions from a social standpoint:

> ... as it currently stands, cognitive enhancement is constituted in a way that challenges the creation of coherent and effective policy recommendations. The different approaches taken to the subject of cognitive enhancement appear to reflect this lack of cohesion. However, policy makers should not simply wait and hope that on balance the benefits turn out to be greater than the risks or to wait for definitional consensus. Some components of cognitive enhancement could be reduced down to clearly identified targets to be further examined. Then, if appropriate, policy should be created that is normative and, amongst other criteria, beneficial to the majority of the population. (Outram and Racine 2011b, p. 323)

## Future Directions

So what is the most probable policy approach to the use of neuropharmaceuticals for cognitive enhancement? In the absence of a good evidence base on the safety and efficacy of such drug use, prohibition is likely to be the default position. This position is a precautionary one that aims to reduce the risk of adverse health outcomes.

The neuropharmaceuticals that appear to be used for cognitive enhancement are medicines that are already controlled through prescription systems. Patterns of use described in the bioethics literature as cognitive enhancement are achieved through the diversion of neuropharmaceuticals from their medical use, which is defined as a criminal offence in most countries. Examples include the fraudulent presentation of symptoms to a physician for the purpose of obtaining a diagnosis in order to obtain a prescription for a stimulant, or obtaining neuropharmaceuticals without a prescription, either from a friend or through the Internet. A physician who prescribes a neuropharmaceutical off-label for enhancement purposes to someone without a disorder is also acting illegally.

There is no simple answer to the best way forward in formulating policy approaches to the use of neuropharmaceuticals for cognitive neuroenhancement. Every approach has advantages and disadvantages, but international deliberations about policy must start from the basis of existing systems (Racine and Forlini 2009).

The feasibility and effectiveness of approaches may differ across jurisdictions and vary with the characteristics of the specific neuropharmaceutical under consideration and those who use it. Policy approaches to regulating covert drug use are challenging. It is especially difficult to regulate the use of neuropharmaceuticals which may have been obtained through diverse channels – including a prescription for off-label use that may be given in good faith by a physician or illegally accessed via the Internet without a prescription or manufacture and supply via the black market.

It is important to explore all logically possible options. Potentially useful strategies include targeted public health interventions, professional self-regulation to support existing guidelines for prescription, and developing more effective guidelines for medical professionals. Further examination may be warranted of the potential role that denormalization (or stigma) may play in discouraging enhancement use of neuropharmaceuticals. The framing of any such public discourse will be important if we are to avoid making it more difficult for people to access treatment and obtain help for psychological or health concerns arising from such drug use.

Public debates about the possible benefits and harms of using pharmaceuticals for neuroenhancement provide the best chance of developing sensible policies towards such use (Hall 2004). Meaningful deliberation about the ethical acceptability or regulation of neuroenhancement should not be based on speculation and poor-quality estimates of the prevalence, efficacy, and safety of the use of neuropharmaceuticals for cognitive enhancement. Ideally policies should be evidence based and informed by monitoring and evaluation of their impacts. However, in the absence of such evidence, many important ethical challenges can be addressed within the regulation of the use of neuropharmaceuticals for cognitive enhancement through the existing regulatory systems that govern illicit and pharmaceutical drugs.

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