

How Drug Control Policy and Practice Undermine Access to Controlled Medicines

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Abstract

Drug conventions serve as the cornerstone for domestic drug laws and impose a dual obligation upon states to prevent the misuse of controlled substances while ensuring their adequate availability for medical and scientific purposes. Despite the mandate that these obligations be enforced equally, the dominant paradigm enshrined in the drug conventions is an enforcement-heavy criminal justice response to controlled substances that prohibits and penalizes their misuse. Prioritizing restrictive control is to the detriment of ensuring adequate availability of and access to controlled medicines, thereby violating the rights of people who need them. This paper argues that the drug conventions' prioritization of criminal justice measures—including efforts to prevent non-medical use of controlled substances—undermines access to medicines and infringes upon the right to health and the right to enjoy the benefits of scientific progress. While the effects of criminalization under drug policy limit the right to health in multiple ways, we draw on research and documented examples to highlight the impact of drug control and criminalization on access to medicines. The prioritization and protection of human rights—specifically the right to health and the right to enjoy the benefits of scientific progress—are critical to rebalancing drug policy.

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Background

The international drug control conventions and controlled substances

The international drug control conventions (hereinafter “the drug conventions”) impose varying levels of control on a range of substances based, in theory, on their perceived risk of misuse and medicinal value. Substances are listed in four separate “schedules,” with each schedule determining the requisite level of control for the substance listed within it. The drug conventions serve as the cornerstone for domestic drug laws and impose a dual obligation upon states: to prevent the misuse of controlled substances while ensuring their adequate availability for medical and scientific purposes.¹ The drug conventions further explicitly provide that controlled substances are indispensable for medical and scientific purposes. Indeed, the World Health Organization’s (WHO) Model List of Essential Medicines includes 12 medicines that contain internationally controlled substances, such as morphine, methadone, buprenorphine, diazepam, and phenobarbital.² Essential controlled medicines are used across the spectrum of health care, from childbirth, surgical anesthesia, and pain relief in palliative care (such as for people with end-stage AIDS or terminal cancer), to mental health treatment, drug dependence treatment, and neurological care.

Many controlled substances embody the duality in the drug conventions—that is, they have both licit (medical) uses and uses defined as illegal in some jurisdictions. For example, benzodiazepines, when prescribed by a licensed professional, are used to treat a range of ailments such as insomnia, obsessive-compulsive disorder, and seizures. Outside of this medical context, however, their use is illicit due to the perceived risk of misuse that they carry, and they are included in the drug conventions’ schedules. Despite the mandate that these two obligations be enforced equally, the dominant paradigm—in both the text of the drug conventions and their implementation—is an enforcement-heavy criminal justice response to controlled substances that centers on preventing what is deemed in law to be their misuse. This prioritization of restrictive control is

to the detriment of ensuring adequate availability of and access to controlled medicines and infringes upon the rights of people who need them.

Balancing the medical merits of substances with their likelihood for non-medical use is, in theory, a matter of scientific judgment, and the drug conventions provide that the scheduling of controlled medicines should be based on WHO recommendations.³ To this end, WHO convenes an Expert Committee on Drug Dependence (WHO Expert Committee) to study controlled substances and make recommendations on the level of risk of harm and the therapeutic utility of a substance, which should subsequently be reflected in the substances’ scheduling under the drug conventions.⁴ On several occasions, however, the UN Commission on Narcotic Drugs (CND) rejected the recommendation of the WHO Expert Committee, particularly when it comes to recognizing the potential therapeutic benefits of certain cannabinoids that are controlled (as is discussed below). Independent addiction experts and clinicians repeatedly assert that some controlled substances, including cannabis and 3,4-Methylenedioxymethamphetamine (MDMA), are wrongly placed in the drug conventions’ most restrictive schedules.⁵ Others have concluded that the WHO Expert Committee does not evaluate some substances frequently enough and would benefit from emulating the best practices of some national-level evaluators.⁶

Indeed, not all international scheduling determinations are replicated nationally. For instance, heroin is classified in the Single Convention on Narcotic Drugs, 1961 (the Single Convention) as a Schedule 1 and Schedule 4 substance, the most restrictive classifications, or “particularly liable to abuse and to produce ill effects...not offset by substantial therapeutic benefits.” This judgment is embodied in most national drug laws.⁷ However, a number of countries—including Switzerland, the Netherlands, the UK, and Germany—have, through law or public health regulations, established a licit use for heroin in treating well-defined cases of opiate dependence.⁸ Of note, cannabis and cannabis resin are similarly classified in Schedules I and IV of the Single Convention—that is, they

are seen to be liable to abuse and without redeeming medical benefit. As with heroin, a number of countries have set policies legalizing and enabling access to cannabis for medical purposes, including for pain relief.

The Single Convention codifies the obligation on States parties to make adequate provision to ensure the availability of controlled substances for medical and scientific purposes, and stipulates three minimum criteria to which countries must adhere in national regulations: (a) individuals must be authorized to dispense substances controlled under the Single Convention by license (license to practice medicine or special license); (b) controlled substances may be transported only between institutions or individuals authorized under national law; and, (c) a medical prescription is required for the dispensation of controlled substances. However, the Single Convention also provides that states may impose stricter rules or controls if deemed necessary, and many countries opt to implement additional requirements. The Convention on Psychotropic Substances, 1971, sets out a more limited obligation, requiring that access to psychotropic substances for medical purposes not be unduly restricted.⁹

Surprisingly, there is no provision in the drug conventions to manage the interaction between states' drug control obligations and their responsibility to ensure access to controlled medicines. The focus on drug control and punitive sanctions creates a frame that is heavily oriented toward criminal justice and policing, which can have profound effects even for medicines not currently controlled under the drug conventions. For example, against the advice of WHO, China attempted in 2015 to bring ketamine under international control, which would have severely limited access to a vital anesthetic in developing countries.¹⁰

WHO recognizes the bias of drug policy implementation in preference of control, as does the International Narcotics Control Board (INCB), which first highlighted the challenge as far back as 1989:

legislators sometimes enact laws which not only deal with the illicit traffic itself, but also impinge on some aspects of licit trade and use, without first

having adequately assessed the impact of the new laws on such licit activity. Heightened concern with the possibility of abuse may also lead to the adoption of overly restrictive regulations which have the practical effect of reducing availability for licit purposes.¹¹

That said, the INCB itself has been as much a part of the problem as its solution, often saluting restrictive drug control regimes imposed by governments without paying sufficient attention to the consequences of those regimes on access to medicines.¹²

This paper aims to demonstrate that the prioritization of criminal justice and the desire to prevent non-medical use of controlled substances under the drug conventions undermine access to controlled medicines, and in doing so, infringes upon the right to health and the right to enjoy the benefits of scientific progress (right to science). The impact of drug control will be examined, from the text of the law to the de facto extension of criminalization beyond the scheduling of substances to the health sector, where patients and individuals seeking treatment, health service providers, and researchers are adversely affected. We draw on documented examples to show the interaction between drug control, criminalization, and these rights. The paper concludes that the prioritization and protection of human rights—specifically the rights to health and to science—are critical to rebalancing drug policy.

Access to controlled medicines and the international human rights framework

The right to the highest attainable standard of physical and mental health (hereinafter “the right to health”) has been guaranteed in international law since the Universal Declaration of Human Rights in 1948 (UDHR).¹³ It is now protected in a range of conventions, notably in Article 12 of the International Covenant on Economic, Social and Cultural Rights, 1966 (ICESCR), and Article 24 of the Convention on the Rights of the Child (ratified by every country in the world except the United States of America).¹⁴ Under this right, access to essential medicines, as defined by WHO, is accorded

the highest priority.¹⁵ The ICESCR construction of the right to health expands on the narrower mention in the UDHR of the right to medical services and “security” for people who are ill.¹⁶ Access to essential controlled medicines encompasses not only their availability, accessibility, acceptability, and receipt via high quality health services, but also includes access to information about the function and use of those medicines. Hence, realization of a core component of the right to health is, in practice, impeded by legal, regulatory, and attitudinal barriers (among others) which result from the restrictive manner in which the drug conventions have been interpreted. In reviewing states’ compliance with the right to health, UN treaty bodies have, for example, recommended steps to address barriers and increase access to medication-assisted treatment in Belarus, Georgia, Indonesia, Lithuania, Russia, Ukraine, and Uzbekistan.¹⁷ In a case currently pending before the European Court of Human Rights, applicants have challenged the Russian ban on opiate substitution therapy (also known as medication-assisted treatment) on the grounds of freedom from cruel, inhumane, and degrading treatment, the right to family life and privacy, and the prohibition of discrimination under the European Convention on Human Rights (ECHR).¹⁸

The right to science has similarly been guaranteed since the adoption of the UDHR (Article 27). It is further elaborated in Article 15(1)(b) of the ICESCR, which guarantees the right to enjoy the benefits of scientific progress and its applications.¹⁹ This right includes not only the right to knowledge and information generated from investigation, but also freedom of inquiry, the latter indispensable to scientific research. Despite these provisions—and the fact that independent scientific research is critical to an understanding of a substance, its properties, potential for harm and potential medical use—research into controlled substances is significantly hampered by onerous bureaucratic requirements and undue criminalization.²⁰

Paul Hunt, the former UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental

health (hereinafter “the Special Rapporteur on the right to health”), has commented on the “scant regard” of drug control for international human rights law and the generally disjointed interaction of the two legal frameworks.²¹ This disregard for human rights persists despite their place in the UN Charter, and supremacy of the obligations of UN member states under the charter over any other international agreement.²²

The importance of respecting, protecting, and fulfilling human rights in the context of drug control has been affirmed in a plethora of international commitments and resolutions. As the UN General Assembly agreed in a 2007 resolution and reiterated in the outcome document of the UN General Assembly Special Session (UNGASS) on drugs in 2016, states have a legal obligation to carry out drug control “in full conformity with the purposes and principles of the Charter of the United Nations, international law and the Universal Declaration of Human Rights, with full respect for the sovereignty and territorial integrity of States, the principle of non-intervention in the internal affairs of States, all human rights, fundamental freedoms, [and] the inherent dignity of all individuals.”²³ Similarly, Barrett observes:

*Human rights in international drug control have ... traditionally been absent, and are viewed as a nuisance by many governments and UN agencies ... [T]he system consciously avoids addressing important but controversial issues in order to preserve the appearance of international consensus.*²⁴

In the context of access to controlled medicines for pain relief, Lohman et al. argue that excessive over-regulation by governments and ignorance of health care providers conspire to create a vicious cycle of under-treatment, and conclude that poor prioritization of controlled medicines for pain relief is not a result of the low prevalence of pain but of the invisibility of its sufferers.²⁵

The observations of Hunt, Barrett, and Lohman et al point to the normative gap between the human rights and drug policy frameworks, and the relative power imbalance between those

promoting health and rights, and those with a criminal justice agenda.

Drug policy undermines access to controlled medicines and infringes upon the right to health

Where drug policy disproportionately emphasizes preventing diversion and non-medical use of controlled substances over ensuring their availability and access for medical and research purposes, it risks violating the right to health.²⁶ Independent bodies charged with overseeing the aforementioned treaties have authoritatively interpreted the normative content of the right to health and related obligations. The Committee on Economic, Social and Cultural Rights (CESCR), for example, considers access to essential medicines, as defined by WHO, to be a core obligation within the right to health, meaning that access should be immediately prioritized by all state parties and not just added along the way toward progressive realization.²⁷

Further, CESCR has clarified that the right includes both freedoms and entitlements, as well as immediate and progressive obligations to ensure healthcare facilities, goods and services are available, accessible, acceptable and of sufficient quality.²⁸ Accessibility includes affordability as well as non-discrimination, such that “health facilities, goods and services must be accessible to all, including the most vulnerable or marginalized sections of the population, in law and in fact.”²⁹ The right to health additionally includes obligations to take steps to prevent, treat, and control diseases, and to avoid policies that are likely to result in unnecessary morbidity.³⁰ Consequently, UN treaty bodies have expressed concern at the Russian ban on opiate substitution therapy, and have called on a range of other countries to take steps to ensure access to such therapy.³¹

The global state of access to controlled medicines for pain relief illustrates the detrimental impact restrictive drug controls have on realizing the right to health. The INCB estimates that 5.5 billion people have limited or no access to these

medicines, with 92% of the world’s morphine consumed in countries that constitute just 17% of the global population.³² While there are myriad reasons for this, including economic barriers, prescriber regulations, and marketing practices, it is difficult to overlook the role of overly burdensome regulatory frameworks, which have their roots in emphasis on restrictive control in the regulation of controlled medicines. Indeed, when we consider the effects of the drug conventions on the right to health, we see an incursion of the restrictive control and criminal justice mindset into the medical realm.

De facto criminalization

Punitive sanctions arising from the drug conventions (related to production, supply, and/or possession), efforts to prevent the diversion and misuse of controlled substances, and heavily politicized drug policy have collectively given rise to criminalization over and above the letter of the law. The result is the de facto criminalization not only of controlled substances and those who use them, regardless of their licit use or status, but also of those who prescribe them.

De jure and de facto criminalization weigh heavily upon the work of health professionals. In many jurisdictions, health professionals face disproportionate penalties for errors in the handling or prescribing of controlled medicines; are burdened by onerous security-related storage requirements; and are often subject to law enforcement oversight beyond what is prescribed in law or regulation.³³ Twenty-one countries participating in a 2014 INCB survey indicated that the fear of sanctions or prosecution represented a barrier to the availability of controlled medicines in their country, while a total of 81 countries reported implementing penalties for the inadequate recordkeeping of controlled medicines, varying from fines and license revocation to prison sentences.³⁴ This incursion of criminalization into the sphere of health undermines professionals in the delivery of ethical health care, poses a considerable disincentive to the therapeutic use of controlled substances, and creates an environment

of constant, implicit accusation that health professionals are on the verge of misconduct.³⁵

The negative impact of de facto criminalization reaches beyond health professionals: it is evident in the mistreatment of people who use drugs and people in medical need of controlled substances in non-judicial settings that nonetheless bear the imprint of the law. In the case of people who seek treatment for opioid dependence, the deforming influence of criminalization means that patients in need—like the controlled substance itself—become something to be contained and controlled.³⁶ For example, people may be subjected to humiliating requirements such as having to collect their medicines at a police station, undergoing mandatory urine testing to assess non-medical substance use, being shifted from weekly methadone collection to daily supervision, and not being permitted to touch their medicine (which can only be administered by a physician or nurse).³⁷

Where opioids are used in drug dependence treatment, doctors are required to maintain a degree of control over not only the controlled substances, but the patient's behavior, suggesting a policy that not only pre-empts diversion, but hints that patients and even doctors are not to be trusted. Many countries require patients to attend a clinic on a daily basis for their dose of methadone, rather than making take-home doses available as is the case for most medicines. And, while a number of treatment options for opiate overdose or dependency exist (such as medicines that block intoxication like buprenorphine and medium-term control options such as injectable extended-release naltrexone), treatment choices are often guided by overly punitive and restrictive policies and provider prejudice rather than medical need.³⁸ In the United States, for example, drug courts—meant to offer treatment as an alternative to imprisonment—frequently require that patients pursue treatment with opioid blockers, naltrexone, or enter drug-free treatment rather than using methadone or buprenorphine, two medicines with demonstrated beneficial effect (and psychoactive properties).³⁹ In the UK, Release, the UK center of expertise on drugs and drug law, reports similarly restrictive or punitive measures

including withdrawal of a methadone prescription where a client is deemed to have exhibited behavioral issues (a measure in breach of national guidelines); coerced reduction of methadone or buprenorphine dosage; and conditional methadone prescription, such as requiring patient engagement with other interventions. Release argues that these measures fall short of the UK's commitments under ICESCR and points out, "In no other area of treatment would we see the choice of the individual to be able to access a widely available and evidenced treatment at the expense of political ideology."⁴⁰

The overemphasis on regulating controlled medicines and patients who need them extends beyond those seeking drug dependence treatment. Use of morphine and other opioids for pain relief, for example, is heavily stigmatized in Armenia, Kenya, and many other low- and middle-income countries.⁴¹ Patients may be denied the appropriate medicine, prescribed an inadequate amount to control their pain, or permitted to take home only a small supply of medicine.⁴²

These medicines are mythologized for their capacity to cause dependence. The implication is that a patient becomes criminal should dependence occur, though technically, a patient only becomes a criminal when denied a legal source of controlled substances. Rigid laws also mean that overbearing efforts are made to prevent the diversion of controlled medicines to illicit markets, even when there is a lack of evidence about diversion or the development of dependence in those to whom these medicines are prescribed. A systematic review demonstrates that, among patients with no history of substance misuse who were treated with opioid analgesics, only 0.43% misused their medication, while just 0.05% developed dependence.⁴³ There is little justification, therefore, for restricting prescriptions for controlled medicines or denying their availability. Indeed, such measures undermine the right to health, not only by impeding access to essential controlled medicines, but because they fly in the face of the notion of health as a fundamental constituent of human dignity.⁴⁴

The following case studies further highlight the de facto criminalization of patients and health-

care professionals, in violation of the right to health.

Case study 1

A 2015 Human Rights Watch report on palliative care and access to pain relief in Armenia found that fewer than 3% of those in need of morphine had access to it. Oral morphine is not available, and outpatient (out of hospital) access to injectable opioids is available in limited doses to cancer patients only (as prescribed by an oncologist). In flagrant violation of patient confidentiality, oncologists reported being required to provide written monthly reports to the police disclosing details of patients who receive opioid pain relief, including their names, addresses, and ID numbers.⁴⁵ Human Rights Watch observed that police oversight and control, along with participation in the regular destruction of morphine ampules at health facilities generate “a sense of trepidation among oncologists and pharmacists.”

While steps to reform oncologist reporting practices were initiated in 2016, the de facto criminalization of patients, caregivers, and health professionals continues via excessive regulatory requirements. For example, oncologist prescriptions must be approved by a standing commission of multiple doctors and bear four different stamps of authorization. Patients or their caregivers are also required to return the empty ampules before a new prescription is issued.⁴⁶ These requirements, among others, inculcate a significant degree of stigma around opioid analgesic use and require thousands of people in severe pain to wait for effective pain medication or simply go without it. These barriers unnecessarily limit access to medicines for pain relief, in violation of both the right to health and the prohibition of cruel, inhuman, or degrading treatment.⁴⁷ They additionally indicate disproportionate interference with the right to respect for private and family life.⁴⁸

Case study 2

The overreach of restrictive control into the realm of health also plays out at the international level. While WHO’s health expertise is enshrined in the drug control treaties, it has often been resisted in the CND and opposed by the INCB. Cannabis and

cannabinoids are examples. Delta-9-tetrahydrocannabinol (Δ^9 -THC), a formulation of the main psychoactive ingredient in cannabis, has been reviewed several times by the WHO Expert Committee.⁴⁹ One of the chemical variants of Δ^9 -THC, dronabinol, has been available by prescription in many countries for some years.⁵⁰ In 1989, the WHO Expert Committee recommended that dronabinol be reclassified under the 1971 Convention to a schedule that recognized both its potential for abuse and therapeutic value due to its effectiveness in reducing nausea secondary to chemotherapy.⁵¹ This recommendation was rejected by the CND the first time it was considered, though was eventually approved by the CND in 1991.⁵²

In a later report, the WHO Expert Committee concluded that dronabinol was useful for the treatment of chronic pain, multiple sclerosis, neuropathic disorders, arthritis, and AIDS-associated anorexia, and that other medical uses were likely to be found.⁵³ It therefore recommended that dronabinol be reclassified to a schedule that reflected a greater balance in favor of therapeutic importance relative to potential for harm. The CND declined to vote on the recommendation, deciding instead to request a further review by the WHO Expert Committee.⁵⁴ When it comes to the medical value of cannabinoids as judged in UN mechanisms, it has been difficult for health experts to overcome the politicization of drug control, and the consequent undue restrictions put on access to controlled substances with potentially great medicinal value. Hence, overly restrictive drug control can impede research into the medical benefits of controlled substances, thus infringing also on the right to science, as discussed below. Fortunately, in 2016 the WHO Expert Committee outlined its intention to conduct a pre-review within the following 18 months on whether or not to consider re-scheduling cannabis under the conventions, a move which could influence domestic legal regimes.⁵⁵

Case study 3

Since 2000, the United States has seen a nearly fourfold increase in opioid overdose deaths, in which both drug control policy and a confluence of

other factors have played a part.⁵⁶ There is no single agreed explanation for this phenomenon. In at least some parts of the country, it seems that periods of increased legitimate prescription of opioids for pain relief, perhaps with inadequate monitoring of these prescriptions, led to crackdowns on prescription opioids, which in turn led to the wider use of heroin and other street opioids, of which the purity and toxicity are unknown.⁵⁷ Overly restrictive controls on opioid prescribing, however, are rarely sufficient to tackle misuse, and indeed can unduly limit access to pain relief medications.

Overly restrictive drug control policy may promote overdose deaths in several ways.⁵⁸ First, methadone and buprenorphine maintenance treatment, which reduces additional narcotic usage, remain heavily restricted, not integrated into primary health care, and not sufficiently available in many parts of the country.⁵⁹ Second, most jurisdictions still do not have policies that encourage the ready availability of naloxone for overdose reversal to people who use drugs, their families and friends, as well as first responders.⁶⁰ Third, in spite of its excellent results elsewhere, the US has not adopted heroin-assisted treatment, which could be useful in cases where other treatment has not succeeded, which are, by definition, cases at high risk of overdose. Various human rights bodies have interpreted a requirement to ensure access to medication-assisted treatment under the right to health.⁶¹

Case study 4

In Russia, as mentioned above, methadone and buprenorphine for treatment of addiction are illegal: police can arrest those in possession of the medicines, and prosecutors threaten those who distribute information about these medications with violation of laws prohibiting propaganda about illegal drugs—criminalization which impedes deeply into the sphere of health.⁶² This is despite the fact that WHO categorizes both methadone and buprenorphine as essential medicines. They are among the best-studied and most effective treatments for opioid dependence and have demonstrable benefit in reducing HIV risk via injecting, which accounts for the largest share of Russia's HIV

epidemic. The ban on these medicines is a clear violation of the right to health, and equating education about the medicines with propaganda further violates the right to information. Despite the stance of their government, Russian representatives have served for years on the INCB, sponsor UNODC's informal working group on science, and participate actively in debates on drug dependence treatment and other measures at the CND.

Drug policy undermines access to controlled medicines and impedes the right to enjoy the benefits of scientific progress

The right to health and the right to enjoy the benefits of scientific progress are interrelated and interdependent. The right to science is “sometimes considered a prerequisite for the realization of a number of other human rights” and is explicitly linked to rights to health, the rights of older persons, and development.⁶³ As yet, CESCR has not made a detailed interpretation of the right to science as it has the right to health. The right to enjoy the benefits of scientific progress is enshrined under Article 27 of the UDHR (“Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits”) and Article 15(1)(b) of ICESCR, as well as regional standards in Africa, the Americas, and Europe. Under ICESCR, the right is supplemented by a negative obligation under Article 15(3), which provides that states must respect the freedom indispensable for scientific research. This has been interpreted to mean the state is obliged not to interfere with choices and priorities decided by scientists and not to impose a certain topic or method of research on the academic community.⁶⁴

The right to science is broadly acknowledged to be of great significance in the context of globalization, the communication revolution, and the accelerated pace of scientific and technological development; and yet, it is poorly implemented to the extent it was referred to as a right at “vanishing point” by Schabas in 2007.⁶⁵ In 2009, recognizing the increasing relevance and continued neglect of

the right to science and its applications, UNESCO convened a series of discussions designed to clarify the normative content of the right and enhance its implementation. The conclusions and proposals for the normative framing of the right, captured in the Venice Statement, emphasized freedom of inquiry as a vital element in the development of science, access to the benefits of scientific progress, and the “creation of an enabling and participatory environment for the conservation, development and diffusion of science and technology” as core components of the right to science.⁶⁶ The right to science has since been the subject of increased attention.⁶⁷

The Special Rapporteur in the field of cultural rights stipulated that a prerequisite for implementing the right to science is “ensuring the necessary conditions for everyone to continuously engage in critical thinking about themselves and the world they inhabit, and to have the opportunity and wherewithal to interrogate, investigate and contribute new knowledge.”⁶⁸ The Special Rapporteur also sets out the normative content of the right to science—to paraphrase: access to knowledge and to the benefits of science without discrimination; opportunities to contribute to the scientific enterprise and freedom indispensable for scientific research; information to enable informed decision-making “after considering both the possible improvements offered by scientific advances and their potential side effects or dangerous usages” as well as participatory decision-making in determining what constitutes “benefits” of scientific progress; and an enabling environment.⁶⁹ The two normative conditions most pertinent in the context of drug policy are access and freedom of inquiry, specifically:

In terms of access: the innovations “essential for a life with dignity should be accessible to everyone, in particular marginalized populations.”⁷⁰ This non-discrimination obligation demands eliminating both *de jure* and *de facto* barriers.⁷¹

In terms of freedom of inquiry: freedom of scientific research has been interpreted as “the right or freedom to assess and choose the preferred path of scientific and technological development.”⁷² The Special Rapporteur on cultural rights clarifies that freedom “means ensuring that the scientific

enterprise remains free of political and other interference, while guaranteeing the highest standards of ethical safeguards” and explicitly notes that barriers to scientific research must be overcome.⁷³

In the context of drug policy, the incursion of criminalization and overly restrictive control into research restricts the scope and implementation of scientific inquiry. This frequently occurs via heavy administrative and bureaucratic regulation of controlled substances under the auspices of anti-diversion measures, which effectively impede freedom of inquiry. Below, we argue that disproportionate bureaucratic, legal, or other restrictions may violate states’ obligations under Article 15(3) of ICESCR.

In a similar vein, the American Association for the Advancement of Science reported that scientists participating in its 2013 focus groups remarked that “over-regulation can have the cumulative effect of stifling the freedom indispensable for scientific research and creative activity” and that “[w]hile regulations individually may or may not be reasonable responses to concerns about national security [and] trade ... an accretion of overlapping, vague and contradictory regulations can smother the scientific enterprise.”⁷⁴ When researchers are able to initiate and demonstrate the medical value of a controlled substance—for example, prescription heroin in Canada—the *de jure* criminalization of controlled substances means access to medical treatment and related information may still be impeded.⁷⁵ Even where law reform reflects scientific findings, *de facto* criminalization lends stigma and additional impediments to accessing the substance.

Furthermore, *de facto* criminalization engenders bias and tends to politicize issues related to controlled substances. This impacts judgment and decision-making from scientific review to funding. The Special Rapporteur on cultural rights commented on “the diminishing role played by the State in research and development and the concomitant extensive increase in the involvement of the private sector,” adding that the state should not rely entirely on the private sector and should make all efforts possible to ensure publicly funded research.⁷⁶ We argue that *de facto*

criminalization weakens access to science and its applications, and amounts to a violation of (often vulnerable or marginalized) individuals' rights. Finally, we recognize that scientific freedom is not absolute, "but centers on the nexus of freedom and responsibility."⁷⁷ Any restriction to the right to science must comply with the relevant legal standard. For example, Article 4 of ICESCR provides that rights in that covenant can only be restricted in a manner that is according to law, consistent with the nature of the right, pursuant to a legitimate aim (such as the protection of public health), and strictly necessary for the promotion of general welfare in a democratic society. CESCR has stated that "such limitations must be proportional, i.e. the least restrictive alternative must be adopted where several types of limitations are available."⁷⁸

The following case studies highlight the de facto criminalization of patients and researchers, in violation of the right to enjoy the benefits of scientific progress.

Case study 1

In the UK, researchers require a special license in order to hold Schedule 1 controlled substances (those subject to the most stringent level of control). Obtaining such a license may take up to one year, cost GBP3000 (plus an additional GBP2000 for security equipment and police checks), and furthermore may require additional import licenses, since most suppliers of controlled substances are located outside the UK. David Nutt, psychiatrist and neuropsychopharmacologist, estimates that overcoming these hurdles increases the cost of the research into controlled substances "by about 10-fold."⁷⁹ Consequently, just four hospitals in the UK hold a Schedule 1 dispensing license. As such, research into the medical value of Schedule 1 substances is effectively smothered, closing opportunities for discovery of therapeutic benefit (or harm).⁸⁰ Despite initial case reports suggesting a medical value for MDMA analogues (similar in structure to MDMA) in alleviating dyskinesia (involuntary movements) associated with Parkinson's disease, media hype around potential misuse of MDMA analogues re-

sulted in their blanket classification as Schedule 1 substances.⁸¹ This effectively criminalized both the analogues and the research, as the sites conducting the research could not afford Schedule 1 licenses.⁸²

Similarly, in Canada, it took a research group sponsored by the Multidisciplinary Association for Psychedelic Studies more than four years to be permitted to import MDMA from Switzerland under a special license, even though the group had already obtained approval from the federal department of health and a Canadian institutional review board to conduct research into the therapeutic use of MDMA in post-traumatic stress disorder.⁸³ Nutt notes there are no known instances of diversion of Schedule 1 or Schedule 2 drugs from research labs, "So the law simply censors research rather than protects the public; indeed the limitation to clinical research produced by the regulations almost certainly has done much more harm than good to society by impeding medical progress."⁸⁴

Case study 2

The issue of access to cannabis for medical treatment received a high degree of attention in the US after a series of television documentaries on the beneficial effects of a cannabis derivative for children with Dravet syndrome, or treatment-resistant epilepsies, among other conditions.⁸⁵ Dr. Sanjay Gupta, CNN's chief medical correspondent, documented the story of more than 100 American families who moved to Colorado (which authorized patients and their caregivers to possess, cultivate, and use cannabis for medical purposes in 2000), in order to secure regular access to the substance for medical use for their children. As the law currently stands, these patients and families must stay in Colorado, because transporting their medicine (a non-psychoactive cannabis oil) puts them at risk of criminal prosecution.⁸⁶ Previously, therapeutic benefits of the cannabis extract had not been scientifically evaluated. Critics of overregulation note that this was the result of restrictions on research with cannabis and its derivatives in the US, including licensing restrictions and refusal to reschedule cannabis by the Drug Enforcement Agency, which

retained authority of the decision despite lack of health expertise. These restrictions violate both freedom of inquiry and the requirement for non-discriminatory access to the benefits of scientific progress.

Case study 3

LSD is another case in point. Notwithstanding accounts suggesting that LSD may have considerable therapeutic value for treating alcoholism in some patients, researching the medical value of LSD in Europe is made impossible by the fact that there is no approved source of LSD formulation for human clinical trials.⁸⁷ In this case, marginalized members of European society—people in need of treatment for alcoholism—are denied access to the benefits of research.

Case study 4

In the US, researchers published multiple papers noting that MDMA caused dopaminergic brain damage. The finding was widely circulated, and retracted only after it was revealed that the researchers had mistakenly used methamphetamine—known to impair dopamine function—rather than MDMA, in the experiment. Widespread media coverage of the erroneous finding, along with a lack of appropriate scrutiny of results or interest in replicability, reflects the presumptive prejudice and bias toward detection of harm built into research on psychoactive substances.⁸⁸

Restrictions on the exercise of the right to science such as these need to be carefully considered in light of the permissible limitations of rights outlined in Article 4 of ICESCR, outlined above. Specifically, they should be reviewed to consider whether they are the least restrictive measures in pursuit of a legitimate aim (protection of public health). Given, for example, that the risk of diversion from research laboratories is extremely low, the calculation of proportionality in assessing these restrictions on research should also consider the lost possibility for treatment and medical benefit resulting from drug restrictions. In these circumstances, we argue that draconian restrictions on the

right to science, which have a potentially significant impact on the right to health and which seek to combat a small risk of diversion, are often disproportionate and therefore in violation of ICESCR.

Finally, the bias against psychoactive substances also requires attention to the questions not asked or comparisons not conducted in scientific research. For example, the trial used to approve long-acting naltrexone, an opioid blocker for addiction treatment, compared this medicine to placebo and counseling alone (shown to be inferior to existing treatments in multiple previous studies) rather than to opioids with known medical benefit (and psychoactive effect) used in addiction treatment.⁸⁹ Since approved, the opioid blocker has become the treatment preferred by multiple actors in the US criminal justice system, with respondents from that sector reporting that they prefer it to the psychoactive treatments because of the medical evidence indicating superiority.⁹⁰ This is striking, of course, because there has been no comparative study. Ethicists and researchers have flagged this lapse, and a genuine comparison is now underway between the opioid blocker and the medicines which comprise the gold standard of care.⁹¹ Scientific gaps caused by bias threaten the right to science by undermining the balance of freedom and responsibility in research.

Conclusion

As noted by the Johns Hopkins–*Lancet* Commission on Public Health and International Drug Policy, impediments to access to controlled medicines go hand in hand with other elements of overzealous drug control, such as mass incarceration for minor offenses, even if cloaked in the guise of health concerns. Both are fueled by the demonization of people who use drugs, and by unscientific notions of addiction that dominate the public mind, with health clinics and other non-judicial spaces bearing the imprint of criminal law through what we have referred to as *de facto* criminalization.⁹² The massive denial of opioids and other controlled medicines to people who desperately need them—which remains a quintessential example of global

health inequity—is furthered by the difficulty faced by researchers whose work could explore the therapeutic benefits of controlled medicines but who cannot obtain controlled substances or official approval for their research.

The Johns Hopkins–*Lancet* Commission report suggests ways to emerge from the unscientific demonization of drugs and the futile pursuit of drug prohibition in favor of an approach based on the idea that the harm of psychoactive drugs, like the harms of tobacco, for example, can be controlled by pragmatic public health measures. A truly health-oriented drug policy requires openness by policy-makers, institutional review boards, health professionals, and society to the idea that controlled substances have benefits for human health and human dignity, and that their study and use to promote public health is a worthy enterprise. Indeed, their contributions to health and well-being are as essential to compliance with international law as the regulation of substances that can cause harm. States’ obligations related to the right to health extend to a duty to uphold that right through international cooperation and assistance. This means, for example, that they should respect, protect, and fulfill the right to health in their joint action in intergovernmental bodies such as the CND.

In regular sessions of the CND in recent years, as well as in the 2016 UNGASS on drugs, member states—including some with relatively repressive drug laws—pledged to adopt “public health approaches” to drug control policy that conform with human rights.⁹³ The INCB ended its 2017 session with a press release urging vigilance and cooperation in addressing the world’s drug problems, but “in conformity with human rights.”⁹⁴ In many cases, national level pledges took the form of commitments to treat people who use drugs as patients, not criminals.⁹⁵ It remains to be seen if these commitments have any meaning, or if they will distract attention from unchanged health- and human rights-unfriendly policies under a different banner. If countries or international mechanisms are truly interested in a health-based approach to addressing drug problems, they must prioritize improving access to controlled medicines, thereby

also meeting their obligations to respect, protect, and fulfill the rights to health and the benefits of scientific progress.

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