

# CLASSIFICATION OF PSYCHOACTIVE SUBSTANCES

WHEN SCIENCE WAS LEFT BEHIND

REPORT 2019







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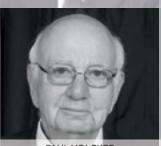
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### **FOREWORD**

A catalogue of some 300 psychoactive substances acts as the foundation for current international and national drug control laws. These substances are placed into specific categories according the degree to which they must be fought, and are banned at a number of levels. Their cultivation, production, manufacture, export, import, sale, possession and consumption are prohibited in all cases except for scientific research or medical use. Some are considered to have no medical benefit whatsoever, without any proof to back such a claim.

When States ratified the drug conventions, gradually instating the international drug control system from 1961 to 1988, they committed to introducing analogous classifications in their national laws. This emphasizes the degree to which it determines law enforcement priorities and sentences handed down by judges, and how deeply it affects the lives of millions of people around the world.

Indeed, this classification or "scheduling" of drugs is the cornerstone of the current repressive approach to drug policy, which has resulted in the "collateral damage" of the "war on drugs" – tragic consequences that the Global Commission on Drug Policy has condemned since its founding in 2011. The effects of prohibition – in terms of public health and security, discrimination and prison overcrowding, the rise in power of criminal organizations and the associated violence and corruption, as well as the lack of access to essential medicines – highlight the urgent need to change course and implement policies that are more effective and more respectful of human rights.

This ninth report of the Commission analyzes the history, procedures and inconsistencies of the current classification of psychoactive substances. One will not find in this classification some of the most dangerous substances – tobacco, alcohol – which escape prohibition and allow established and respectable corporations to make huge profits. In contrast, substances that are listed in the annexes of the international conventions, the so-called "drugs", are seen as necessarily bad; they are supplied by an illegal market that is just as profitable and empowers organized crime.

The sharp distinction that is made between legal and illegal substances is the result of a long history of cultural and political domination. It is not based on any scientific assessment of the substances' potential harms for the people who consume them and for society as a whole, or of their possible benefits for those who use them in a reasonable way. The order in which they are scheduled according to their potential harms, and the degree to which they must therefore be subjected to repressive measures, suffers from a similar lack of scientific assessment. They are considered collectively as evil! This classification is too often influenced by ideology, prejudice and the discrimination of marginalized populations, not to mention the financial interests of the pharmaceutical industry. Science is rarely part of the decision process – and when it is allowed to offer its recommendations, they are rarely taken into account!

Psychoactive substances must be urgently reviewed on a rational basis. The incoherence of the current classification system represents a big hurdle for the reforms that need to be undertaken. It is past high time to accept the fact that a society without drugs is an illusion and that we must now lay the foundations, based on scientific evidence, for their legal regulation. Let us now focus on what constitutes the real legitimacy of drug policy: life, health and security for all.

**Ruth Dreifuss** 

Chair of the Global Commission on Drug Policy

## **EXECUTIVE SUMMARY**

The international drug scheduling system, used to classify psychoactive substances according to their harms and benefits, lies at the core of the international drug control regime. Its proper functioning is the key to balancing the regime's dual objectives: securing adequate availability of controlled substances for medical purposes while preventing their diversion for non-medical or other uses. Before 1961, the global drug control system focused on imposing restrictions on international trade and was designed to accommodate and respect differences between the laws of states. Since the Single Convention on Narcotic Drugs was signed in 1961, however, states have responded to international law with schedules and classification systems that are not evidence-based or rationally linked to the harms and benefits of substances, but rather based on political choices and benefits for policymakers. Such drug control policies have resulted in social and economic problems not only for people who use drugs but also for the general population, including health epidemics, prison overcrowding and arbitrary enforcement of drug laws.

The current system, governed by the 1961 Single Convention and the 1971 Convention on Psychotropic Substances, has gradually brought more and more psychoactive substances under international control. Today over 300 substances are scheduled. Eight schedules have been defined according to the dependence potential, abuse potential and therapeutic usefulness of the drugs included in them – four in each of the 1961 and 1971 conventions. These international drug control conventions recognize only medical use, including the relief from pain, as benefits from the use of psychoactive substances; other cultural, recreational or ceremonial uses are not taken into account, or rather are excluded.

The strictness of control measures depends on the schedule in which a substance is placed. Of the eight schedules, two imply the prohibition of substances they include, including their medical use (with the exception of very limited quantities for research). However, with only a few specified exceptions, all substances scheduled under the conventions for non-medical and non-scientific purposes are effectively banned.

This de facto prohibition is arbitrary. The current distinction between legal and illegal substances is not unequivocally based on pharmacological research but in large part on historical and cultural precedents. It is also distorted by and feeds into morally charged perceptions about a presumed "good and evil" distinction between legal and illegal drugs.

Scheduling decisions are taken by the Commission on Narcotic Drugs (CND), which was established by the United Nations Economic and Social Council. The World Health Organization (WHO) provides recommendations on the advice of its Expert Committee on Drug Dependence (ECDD), which are then submitted to a vote of CND members (a simple majority vote for the schedules of the 1961 convention and two-thirds for the 1971 schedules).

Decisions about scheduling have thus become subjected to political considerations and an inherent bias towards prohibiting new substances. The negative consequences of allowing a drug onto the market that might later turn out to be dangerous are very high, whereas the negative consequences – for decision makers – of keeping off the market a drug that is in fact harmless are minimal. As a result, recommendations to add new substances to the schedules are usually rubberstamped, while recommendations not to schedule substances or to place them under a less strict regime consistently meet significant opposition.

Several substances listed on the earliest schedules of the 1961 convention – including widely used substances such as cannabis, cannabis resin, heroin and cocaine – had never received an expert evaluation or their evaluations were up to 30 years old.

There have been calls to amend the conventions to resolve inherent inconsistencies and to clarify the mandates of WHO, the International Narcotics Control Board (INCB) and the CND in the scheduling process. Proposals have also been repeatedly made to improve the scheduling criteria and to outline a system based on scientific evidence.

An improved scheduling procedure, which strikes a better balance between ensuring availability of controlled substances for legitimate uses and preventing problematic use, would provide a key tool to guide reforms that transform international and national drug control policies from an exclusively prohibitive framework into a flexible model based on regulation.

An evidence-based international scheduling system would allow reform-oriented countries more flexibility to design domestic schedules according to their needs, while improving control over potential illegal exports. It would also be far more effective at gradually steering the drugs market in a direction that causes far less harm. Finally, an evidence-based scheduling system would remove much of the stigma associated with drug use, thus helping people to make more responsible and less harmful choices.

Guiding principles for a more rational scheduling model include:

- ensuring adequate availability of each substance for medical and research purposes;
- abandoning zero-tolerance policies to provide more space for "other legitimate purposes";
- showing more leniency towards milder substances;
- taking into account local social and cultural circumstances;
- conducting a cost-benefit analysis of potential harms and perceived benefits;
- accepting certain risk thresholds comparable to other acceptable societal risks, instead of upholding an absolute precautionary principle;
- weighing carefully the potential consequences of scheduling decisions, taking into account predictable responses of users and markets; and
- making better use of existing medical and consumer safety legal instruments, instead of criminal drug laws.

The Global Commission on Drug Policy calls for a comprehensive and interdisciplinary approach to designing drug control policies. It is time to end the "silo" approach that treats drug control as a single issue and classifies drugs and enforces drug prohibition based on unreliable and scientifically dubious schedules.

The only responsible path is to regulate the market of illegal drugs. Governments should establish regulations and a new scheduling system – adapted to the dangerousness of each drug and based on solid scientific assessments – and monitor and enforce these regulations. For the Global Commission, urgent action is needed to end the inconsistencies of the current scheduling system:

- The international community must recognize the incoherence and inconsistencies in the international scheduling system, and must trigger a critical review of the current models of classification of drugs.
- The international community must prioritize the role of the World Health Organization and interdisciplinary scientific research in further developing evidence-based scheduling criteria based on a rational scale of harms and benefits.
- UN Member States must refocus the international scheduling system on the original impetus
  of controlling transnational trade and allow for innovative national classification systems to
  be developed.



# CLASSIFICATION OF DRUGS: EVIDENCE OR IDEOLOGY?

The scheduling system lies at the core of the international drug control regime, which was established out of concern over "the health and welfare of mankind", as expressed in the preamble of the 1961 and 1971 global drug control conventions. The proper functioning of the scheduling system is the key to fulfilling the regime's dual objective: to ensure adequate availability of controlled substances for medical purposes while preventing their 'abuse' and diversion to the illegal market. "An effective drug control regime that complies with the spirit of the drug control treaties should therefore strike the right balance between the considerations given to these two aims", according to the World Health Organization (WHO).¹ The paradox of international drug control is that "unbalanced laws, policies and practices remain widespread."² This mechanism was put in place to guide international cooperation on drug control. At the domestic level, however, its ideology-driven implementation has resulted in a multitude of negative consequences, from over-policing of certain communities to public health epidemics.

The global drug control regime that unfolded after World War II has gradually brought more and more psychoactive substances under international control (Box 1). Nowadays, over 300 substances are scheduled under the 1961 Single Convention on Narcotic Drugs (as amended by the 1972 Protocol)<sup>3</sup> and the 1971 Convention on Psychotropic Substances,<sup>4</sup> divided over four schedules in each treaty, and under the precursor tables of the third global drug treaty, the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, known as the Trafficking Convention<sup>5</sup> (Figure 1). The strictness of control measures regarding import and export certificates, estimates of requirements, licenses and medical prescription, depends on the schedule in which a substance is placed.<sup>6</sup> The general obligation of the 1961 and 1971 conventions, applicable to all schedules, is "to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs".<sup>7</sup>

#### BOX 1 The international scheduling system<sup>8</sup>

According to the UN Office on Drugs and Crime, "The narcotic drugs and their preparations under international control are grouped and listed in four Schedules, defined according to the dependence potential, abuse liability and therapeutic usefulness of the drugs included in them. Drugs controlled under the 1961 Convention are listed in one of two Schedules (I and II), depending on the relationship between their therapeutic utility and abuse liability. The control provisions applicable to drugs in Schedule I constitute the standard regime under the 1961 Convention; Schedule II consists of drugs which are considered to be less liable to abuse and which are more widely used in medicine. Two additional Schedules III and IV cover, respectively, preparations of drugs in Schedule I and II intended for legitimate medical use, and selected drugs from Schedule I considered to have particularly dangerous properties and rather limited therapeutic utility."

[...] "The control system provided for psychotropic substances is, in principle, based on the one for narcotic drugs. However, in the 1971 Convention, the necessary control measures were categorized in four separate Schedules, depending on the relationship between the therapeutic usefulness and the public health risk caused by abuse of the substances in question. The four Schedules use a sliding scale of these two variables: Schedule I implies high public health risk and low therapeutic utility and, therefore, the strictest control measures; whereas Schedule IV implies the opposite, i.e. lower public health risk and higher therapeutic utility."

The preambles of the drug treaties underscore that the medical use of most substances is "indispensable" and that their availability should not be unduly restricted. The only categories of drugs that the conventions recommend states to "prohibit" are the substances in Schedule IV of the 1961 Convention and Schedule I of the 1971 Convention. "Prohibition" in this sense means prohibiting them for medical purposes and only allowing very limited quantities for research purposes. For drugs in Schedule IV of the 1961 Convention, including cannabis and heroin, full prohibition is recommended but optional; a party is only required to do so "if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare". For substances in Schedule I of the 1971 Convention, including LSD, MDMA and the psychedelic compounds of hallucinogenic mushrooms and cacti (psilocybin, mescaline), the prohibition of "all use except for scientific and very limited medical purposes" is obligatory. The prohibition of "all use except for scientific and very limited medical purposes" is obligatory.

Today's hegemonic concept of drug prohibition only became predominant at a global level after World War II. Earlier documents, such as the key recommendations of the 1894-1895 Indian Hemp Drugs Commission, read today as sophisticated drug policy reform proposals, similar to the models only recently adopted by countries such as Uruguay and Canada.<sup>11</sup> (Box 2)

#### **BOX 2 Key recommendations of The Indian Hemp Drugs Commission Report (1895)**

- 1. Total prohibition of the cultivation of the hemp plant for narcotics, and of the manufacture, sale, or use of the drugs derived from it, is neither necessary nor expedient in consideration of their ascertained effects, of the prevalence of the habit of using them, of the social and religious feeling on the subject, and of the possibility of its driving the consumers to have recourse to other stimulants or narcotics which may be more deleterious (Chapter XIV, paragraphs 553 to 585).
- 2. The policy advocated is one of control and restriction, aimed at suppressing the excessive use and restraining the moderate use within due limits (Chapter XIV, paragraph 586).
- 3. The means to be adopted for the attainment of these objectives are:
  - Adequate taxation, which can be best effected by the combination of a direct duty with the auction of the privilege of vend (Chapter XIV, paragraph 587).
  - Prohibiting cultivation, except under license, and centralizing cultivation (Chapter XVI, paragraphs 636 and 677).
  - Limiting the number of shops for the retail sale of hemp drugs (Chapter XVI, paragraph 637
  - Limiting the extent of legal possession (Chapter XVI, paragraphs 689 and 690). The limit of legal possession of ganja or charas or any preparation or mixture thereof would be 5 tola (about 60 grams), bhang or any mixture there of one quarter of a ser (a quarter of a liter).

A New York Times article in 1892 predicted that the idea of total prohibition of "stimulants and narcotics" to prevent problematic abuse, would be "as feasible as would be the plan of preventing railroad accidents by urging travelers to stay at home". 12 But the latter plan was basically the direction in which the international drug control system gradually developed. With only a few exceptions, today all non-medical and non-scientific purposes of substances scheduled under the UN treaties are banned. 13

For centuries, opium and cannabis (in Asia, Africa and the Middle East) and coca (in the Andean region) have been widely used for cultural, ceremonial and traditional medicinal purposes. But the only benefits from the use of psychoactive substances that the conventions recognize are the treatment of disease or the relief from pain. "The mere pleasure-giving quality of a drug does not count, or rather counts as a negative", according to Mark Kleiman, "as widespread voluntary non-medical use is treated as evidence of 'abuse potential'." With regard to scheduling decisions, according to an anonymous administrator quoted by Kleiman, the consequence of that premise is: "If it's fun, it's Schedule One". 15

The zero-tolerance approach towards any non-medical drug use that is embedded in the international control system has created distorted and morally charged perceptions about a supposed "good-and-evil" difference between legal and illegal drugs. "The distinction between legal and illegal substances", however, the UK Home Office acknowledged in 2006, "is not unequivocally based on pharmacology, economic or risk benefit analysis. It is also based in large part on historical and cultural precedents". '6 According to a draft document on reviewing the UK classification system, many young people have "problems in understanding the rationale behind controlling drugs such as cannabis and ecstasy when their misuse contributes less overall harm to society than widely available drugs such as alcohol and tobacco." The UK drug strategy at the time recognized that alcohol plays an "important part in the cultural life of this country". 18

#### FIGURE 1 Schedules under the UN Drug Conventions

#### 1961 Single Convention on Narcotic Drugs

#### SCHEDULE I

Substances that are highly addictive and liable to abuse, and precursors readily convertible into drugs similarly, addictive and liable to abuse (eg. cannabis, opium, heroin, methadone, cocaine, coca leaf, oxycodone)

#### SCHEDULE II

Substances that are less addictive and liable to abuse than those in Schedule I (eg. codeine, dextropropoxyphene)

#### SCHEDULE III

Preparations containing low amounts of narcotic drugs, are unlikely to be abused and exempted from most of the control measures placed upon the drugs they contain (eg. <2.5% codeine, <0,1% cocaine)

#### SCHEDULE IV

Certain drugs also listed in Schedule I with "particuarly dangerous properties" and little or no therapeutic value (eg. cannabis, heroin)

#### 1971 Convention on Psychotropic Substances

#### **SCHEDULE I**

Drugs presenting a high risk of abuse, posing a particularly serious threat to public health with little or no therapeutic value (eg. LSD, MDMA, cathinone)

#### SCHEDULE II

Drugs presenting a risk of abuse, posing a serious threat to public health, which are of low or moderate therapeutic value (eg. dronabinol, amphetamines)

#### **SCHEDULE III**

Drugs presenting a risk of abuse, posing a serious threat to public health, which are of moderate or high therapeutic value (eg. harbiturates, puprenorphine)

#### **SCHEDULE IV**

Drugs presenting a risk of abuse, posing a minor threat to public health, with a high therapeutic value (e.g. tranquillizers, including diazepam)

#### 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances

#### TABLE I

Precursors of psychotropic substances, such as ephedrine, piperonal, safrole, phenylacetic acid, lycergic acid; and a few key regeants such as acetic anhydride used in the conversion of morphine into heroin and potassium permanganate used in the extraction of cocaine

#### TABLE II

A wide range of regeants and solvents that can be used in the illicit production of narcotic drugs and psychodropic substances, but also have widespread licit industrial uses, including acetone, ethyl ether, tonuene and sulphuric acid

Considering a "more logically consistent approach to substance abuse" was deemed impossible, however, because a "classification system that applies to legal as well as illegal substances would be unacceptable to the vast majority of people who use, for example alcohol, responsibly and would conflict with deeply embedded historical tradition and tolerance of consumption of a number of substances that alter mental functioning (ranging from caffeine to alcohol and tobacco). Legal substances are therefore regulated through other means." But that argument would apply equally to the "deeply embedded historical tradition and tolerance" in other countries for cannabis, coca or opium. Colonial cultural prejudices and Western pharmaceutical concepts have shaped the global drug control regime. They are still deeply embedded in misperceptions about "illegal" drugs and their comparative harmfulness.

In a 2009 article that would cost him his job, David Nutt, then head of the UK agency responsible for advising the government on the classification of drugs, challenged those distortions arguing that "the drug debate takes place without reference to other causes of harm in society, which tends to give drugs a different, more worrying, status." He compared the risks of ecstasy use with the substantial risks of horse riding, to point out the fundamentally different social attitudes and policy responses. Prohibition of recreational horse riding has never been considered, in spite of the many accidents and deaths among youth.



This photo shows some of the natural drugs covered by the UN conventions on international control of narcotic drugs, including Laudanum, Cocaine, Morphine, Opium, Bella Donna. © UN Photo/MB.

Nutt also compared the number of deaths related to ecstasy use with the much higher number of paracetamol overdose deaths and the gross disparity in media coverage between them: "the likelihood of a newspaper reporting a death from paracetamol was 1 per 250 deaths, for diazepam it was 1 in 50, whereas for amphetamine it was 1 in 3 and for ecstasy every associated death was reported."' His conclusion: "The use of rational evidence for the assessment of the harms of drugs will be one step forward to the development of a credible drugs strategy."<sup>21</sup>

In its 2018 report "Regulation: the Responsible Control of Drugs", the Global Commission on Drug Policy underscored the need for "an improved scheduling procedure that strikes a better balance between ensuring availability of controlled substances for legitimate uses and preventing problematic use". <sup>22</sup> In this 2019 report, the Commission proposes a tiered, more rational model for responsible classification and scheduling.

#### BOX 3 Political interference in scientific research, "the WHO 1995 Cocaine Project"



In 1995, WHO and the United Nations Interregional Crime and Justice Research Institute (UNICRI) announced the results of the largest global study on cocaine use ever undertaken, involving more than 40 researchers from around the world. The study concluded that the use of coca leaves appears to have no negative health effects and has sacred and social functions for indigenous populations. The study called for more research on the positive therapeutic uses of coca leaves. The study found also that the harmful effects of cocaine use are less widespread than those of legal drugs such as alcohol and tobacco, and are concentrated among high-dosage users.

Once the results of the study were known to Member State delegates, US officials opposed its publication, since according to one of its representatives to the World Health Assembly, this project: "headed in the wrong direction (...) undermined the efforts of the international community to stamp out the illegal cultivation and production of coca". The US representative made clearer the position of his country, stating: "If WHO activities relating to drugs fail to reinforce proven drug-control approaches, funds for the relevant programs should be curtailed". This political interference in scientific research has resulted in the end of the project, the rest of its process being never completed, and its full research outcomes never published.<sup>23</sup>



# THE INTERNATIONAL SCHEDULING SYSTEM

#### HISTORY OF THE GLOBAL DRUG CONTROL REGIME

The idea of banning any "recreational" use of certain psychoactive substances was inspired by the growing influence of Anglo-American Christian puritanism and the anti-alcohol Temperance movement in the late 19th and early 20th century, which in the United States also led to prohibition of alcohol between 1920 and 1933. The drive towards prohibition was also fueled by racist sentiments towards Chinese and Mexican immigrants who used opium and cannabis. "Addiction" originally focused on symptoms of people consuming opioids. Cocaine was not considered addicting because it did not produce the same effects as opioids upon its introduction in the mid-1880s. It was also presumed non-addicting because it was considered Western medicine and "did not carry the stigma of 'old' pre-modern drugs." 24

Attempts to internationalize the aspiration to root out what were perceived as "moral evils" were initially not very successful. In the first international agreement, The Hague Opium Convention of 1912, some basic rules were agreed to regulate the international trade of opium and to limit manufactured drugs (morphine and cocaine) to "medical and legitimate" needs. Those "legitimate" needs included the widespread local traditional use in the countries where those plants were cultivated. The 1925 Geneva Convention still maintained "legitimate purposes" of raw opium and coca leaves (Chapter II), but restricted manufactured drugs "solely for medicinal or scientific purposes" (Chapter III).

"The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the antiwar left and black people. You understand what I'm saying? We knew we couldn't make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did."

John Ehrlichman (in 1994), Assistant to US President Richard Nixon for Domestic Affairs (1969-1973)

The European colonial powers controlled profitable monopolies in the trade of opium, coca and cannabis in their overseas territories. The first international drug control treaties were strongly influenced by colonial interests as well as cultural biases: alcohol and tobacco were the socially accepted drugs in the home countries of the main negotiators, so were never seriously considered as drugs to be put under international control. Colonial monopolies supplied the local opium markets in Asia and the cannabis markets in North Africa – thus recognizing traditional uses – as well as many opiate, cannabis and cocaine preparations for the European medical market.

The principle of scheduling drugs into different categories was first introduced in the 1931 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, after the German delegation argued that codeine was a safer therapeutic substance than opium, morphine or heroin, and that it would be unable to sign up to the treaty if its provisions did not differentiate between them. At the time, the German pharmaceutical industry was the leading manufacturer of codeine. Hence, a system of dual scheduling was devised with different levels of controls and restrictions. "Most also agreed that utilizing the drug with the least addictive propensity was generally the proper course to follow, and therefore codeine was preferable to morphine when possible. But if all drugs suffered under the same level of control – that is, all were equally difficult to procure and required the same amount of paperwork to account for – physicians and pharmacists would have less incentive to opt for newer, potentially less problematic substances such as codeine." Under German pressure and faced with a plausible argument, delegates reached a compromise by creating a two-tiered regulatory structure: Group II drugs were exempted from retail reporting requirements and could be sold as over-the-counter medicines without prescription.

The 1931 convention introduced another important principle: "it applied control measures not only to drugs which were dangerous by themselves, but also to substances which were 'convertible' into such drugs". 26 Drugs "capable of producing addiction" were placed in Group I, while drugs convertible into such drugs were placed in Group I, sub-group (b), if they were of limited medical use, and in Group II if they were widely used in medicine.

Before 1961, the global drug control system focused on imposing restrictions on international trade and was designed in such a way that it accommodated and respected national differences between the laws of states. The primary objective was "to prevent the uncontrolled export of certain substances to states that have prohibited those substances. This tolerance of difference was fundamental to the origins of the international control system prior to 1946, until a transformation of the system was undertaken in the post-War period which culminated in the 1961 Convention. It involved the attempt to convert what had been essentially a 'reciprocal' system into a morally charged 'absolute' principle of prohibition."<sup>27</sup>

The two pillars of the international control system – the import and export authorization system established by the 1925 Convention, and the system to balance global licit production with estimates of global requirements established by the 1931 Convention – are still in place, administered by the International Narcotics Control Board (INCB). According to Adolphe Lande, who played a key role in the design of the UN drug control treaty system after World War II, those administrative systems to control international trade had the intended result that by the 1950s "only very insignificant amounts" from legal production sources were still diverted into illicit channels through international trade.<sup>28</sup> "The illicit traffic is a consequence of the control",<sup>29</sup> however, according to Lande, and "[c]landestine factories which could acquire opium or coca leaves with relative ease had taken the place of legal manufacturers as suppliers of the illicit traffic."<sup>30</sup>



In the 19th century, psychoactive substances that are illegal today were sold as cures for a number of ills, for instance cocaine to treat depression. Archive image.

Cultivation and traditional uses of the three plants whose derivatives were initially the main focus of concern in attempts to construct an international control regime, had before 1961 not been subjected to the guiding rule of the present system: strict limitation to medical and scientific purposes. In Asia, Africa and the Middle East, opium and cannabis, and in the Andean region coca, have long been widely used and socially accepted for cultural, ceremonial and traditional medicinal purposes. For the UN Commission on Narcotic Drugs (CND), in 1955, this represented "a serious gap which the Commission set out to close when it undertook to elaborate the Draft Single Convention. The Commission, therefore, did not allow for any exceptions to this rule when deciding to include it among the permanent rules on the Draft Single Convention." 31

In the midst of reconstruction and global decolonization struggles after World War II, negotiations started to strengthen the international regime by creating a new "Single Convention" under the auspices of the United Nations, replacing the earlier treaties. The 1961 Single Convention intended to consolidate the multiple pre-War treaties into a "single" legal instrument but was also meant to close the control gaps for the sources of the illicit production and trade that had emerged as a consequence of the effective measures against the diversion from licit sources.

The British, Dutch and French colonial powers, which had previously resisted the imposition of stricter prohibition rules, had lost control of their profitable legal monopolies over opium, coca and cannabis production in their former colonies, such as India, Burma, Indonesia and Morocco. The newly independent states were less successful than their former colonial rulers in resisting U.S. pressure to establish a global drug prohibition regime; the balance of power had shifted. Proposals to allow the continuation of some of those centuries-old practices by broadening the wording of the treaty's general obligation "to limit exclusively to medical and scientific purposes" by adding "and other legitimate purposes" (as in the 1912 and 1925 treaties) were rejected.<sup>32</sup> After difficult negotiations, the Single Convention obliged countries to extend national control to the cultivation of opium poppy, coca and cannabis, to impose criminal sanctions on illicit cultivation and to ban all traditional uses.<sup>33</sup>

The 1961 Single Convention "embodies the general strategy of the developed drug consumer states to curtail and eventually eliminate the cultivation of drug producing plants, objectives that could only be achieved at some cost to the developing countries where these plants were grown". All traditional uses of cannabis and coca had to be abolished within 25 years, the "quasi-medical" uses of opium within 15 years. Controversially, cannabis ("the flowering or fruiting tops of the cannabis plant") and cannabis resin were listed under Schedules I and IV, the latter reserved for substances with "particularly dangerous properties" and little or no recognized therapeutic value. This stringent classification was made without a proper assessment by WHO, advised by its Expert Committee on Drug Dependence (ECDD), the body mandated by the convention to recommend on the scheduling of substances. Adolphe Lande has said that cannabis "is defined as one of the 'narcotic' agricultural products whose control undoubtedly represents the weakest point of the international regime."

The inclusion of coca leaf in Schedule I, alongside cocaine, was also done without a proper scientific review by WHO. The criteria informing the classification of substances under the Single Convention include the "similarity principle" (if a substance resembles one that is already controlled, it warrants similar control) and the "convertibility principle" (if a "precursor" substance can be easily converted into a drug already under control, it warrants similar control). Those criteria perpetuated the historical bias embedded in the system and led to applying the same controls over raw plant materials and extracted alkaloids.

#### INCONSISTENCIES MAR THE CURRENT SYSTEM

Structural inconsistencies in the scheduling system worsened when the treaty structure further developed with the 1971 and 1988 Conventions. A scientifically dubious distinction was made between so-called 1961 "narcotic" and 1971 "psychotropic" drugs to allow for more lenient controls over a range of pharmaceutical drugs, including amphetamines, barbiturates and tranquillizers. As the UN International Drug Control Programme (UNDCP) – which has become the UN Office on Drugs and Crime (UNODC) – stated in a commentary to its 2000 Model Drug Law, "the international classification into narcotic drugs and psychotropic substances according to whether the substance is governed by the 1961 or by the 1971 Convention has no conceptual basis. The legal definition of many psychotropic substances is entirely applicable to narcotic drugs, and in many cases, the reverse is true." <sup>37</sup>

Scandinavian governments started to raise the alarm over increasing problems with amphetamine abuse in the 1950s. "Efforts to control domestic distribution proved unsuccessful because neighboring states in Western Europe, especially West Germany, imposed no significant export controls. Similar to the situation with regard to opiates a half-century earlier, differences in national regulation fostered a traffic considered illicit by one government but licit by a neighbor." The initial proposal was to bring those substances under international control by adding them to the Schedules of the 1961 Convention.

According to WHO officials, the ill effects of amphetamines could indeed "be considered 'similar' to those of cocaine, both causing central nervous system stimulation [and] the ill effects of barbiturates which are addiction producing and of those tranquilizers which are also addiction producing could also for this purpose be considered to be similar to the ill-effects of morphine, all of these drugs producing central nervous system depression. The reason why the World Health Organization cannot assume this similarity is not necessarily technical, but legal." <sup>39</sup>

William McAllister has said that "multinational drug companies influenced governments the world over to take a more permissive position regarding psychotropics than had traditionally been adopted toward opiates and coca products." Hence the decision to negotiate a separate protocol for these substances, which became the 1971 Convention on psychotropic substances. Many countries "copied the existing schedules from the international treaties wholesale, or with few modifications. Thus, the schedules' configuration would substantially affect pharmaceutical firms' ability to sell their products in potentially lucrative overseas markets."

During the negotiations, the representative of India expressed the hope "that just as the opium producing countries had, over the past several decades, accepted strict control on opium in the interest of all mankind, the developed countries manufacturing psychotropic substances would also now co-operate in ensuring truly effective measures of control on these substances." The controls imposed over non-pharmaceutical substances in Schedule I (LSD, MDMA, psilocybin, mescaline) are indeed as strict as, if not stricter than, those of the 1961 Convention. The control regime of the other three 1971 schedules, however, is significantly more lenient, even though a number of ECOSOC resolutions have later called on parties to adopt stricter measures than those required by the treaty. The WHO ECDD has called attention to the problems this has created in the scheduling process (Box 4).

#### BOX 4 Ambiguous effects (WHO Expert Committee on Drug Dependence)45

"In essence, similarity in terms of abuse and ill effects to drugs already controlled is the criterion applied to narcotic drugs. In accordance with the 1961 Single Convention on Narcotic Drugs (hereinafter referred to as 'the 1961 Convention'), the ECDD, when deciding whether to recommend international control, first determines whether the substance under review has morphine-like, cocaine-like, or cannabis-like effects or is convertible into a scheduled substance having such effects. If so, the Committee then determines if the substance is liable to similar abuse and produces similar ill effects to the substances in Schedule I or Schedule II, or confirms that it is convertible into a substance already in one of these Schedules.

However, no specific guidance is given in the Guidelines as to how similar to the original drug a substance must be for it to be considered as morphine-like, cocaine-like or cannabis-like. The lack of specific guidance on this matter poses considerable difficulty for the ECDD when the drug under review has some similarity for example to both a narcotic drug and a psychotropic substance, because the scheduling criteria in the 1971 Convention on Psychotropic Substances (hereinafter referred to as 'the 1971 Convention') also include a similarity rule. The decision as to whether to control analgesic and stimulant drugs under the 1961 or 1971 Convention is a major problem. Most potent analgesics are controlled under the 1961 Convention, but a few are controlled as psychotropic substances under the 1971 Convention. Of the stimulants of the central nervous system, cocaine is under the 1961 Convention, whereas amphetamines are under the 1971 Convention. Thus, the criteria for choosing between the two Conventions are ambiguous for these classes of drug".

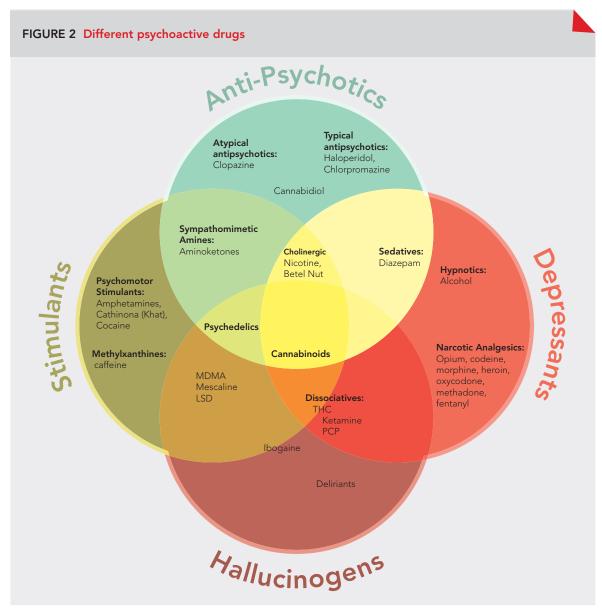
Another inconsistency that emerged was that while the 1961 Convention included herbal raw materials and other precursors, the 1971 Convention deliberately excluded these "convertible" substances. This gap was closed with the 1988 Convention which includes precursors for "psychotropic substances" but not for "narcotic drugs" (already covered under the 1961 Convention), and chemical reagents and solvents often used in the illicit production of both. A corresponding partition arises between the treaty bodies: WHO issues recommendations on precursors for narcotics and the International Narcotics Control Board (INCB) on precursors for psychotropic substances.

The 1971 Convention also includes a "principle of non-acceptance" with regard to all scheduling decisions. A party is permitted to submit a notification explaining why, "in view of exceptional circumstances, it is not in a position to give effect with respect to that substance to all of the provisions of the Convention" (Article 2.7). This gives some more flexibility compared with the 1961 Convention for national deviations from the UN schedules.

In the 1931 Convention, the authority to add other drugs produced from alkaloids of opium or coca to either Group I or II was given to the Health Committee of the League of Nations. After World War II, under the United Nations, that authority was handed over to WHO "acting on the advice of an expert Committee" and expanded to any substance which had morphine-like or cocaine-like effects or which was "convertible" into such a substance. 46 Scheduling decisions were thus initially taken by the specialized health agencies mandated by the international community. The 1961 Single Convention, however, transferred that authority to the CND, subjecting the adoption of WHO recommendations to a simple majority vote of CND Member States. To some extent, decisions about scheduling recommendations based on WHO scientific expert advice thus became subjected to political considerations of Member States.

According to the official Commentary, which provides guidance to member states on how they should interpret the 1961 Convention, the CND "should in principle accept the pharmacological and chemical findings of the World Health Organization. When it does not accept the recommendation of the World Health Organization, it should be guided by other considerations such as those of an administrative or social nature." The CND can only accept or reject a WHO recommendation, not choose another schedule, and "[i]n no case can the Commission decide to extend control to a substance if the World Health Organization has not recommended to do it". 48

Similar provisions apply under the 1971 Convention, stating that WHO's assessments "shall be determinative as to medical and scientific matters",<sup>49</sup> with the Commentary explaining that those "must be accepted by the Commission, which is not authorized to base its decisions on other medical or scientific views".<sup>50</sup> Decisions on changes in the 1971 schedules, however, are adopted by a two-thirds majority vote, and the CND can decide to add a substance to another schedule as the one recommended by the WHO, "bearing in mind the economic, social, legal, administrative and other factors it may consider relevant".<sup>51</sup>



#### **FAILED BALANCE: ACCESS TO CONTROLLED MEDICINES**

The international drug control regime is built on the principle of striking a balance between securing access to controlled medicines and preventing their diversion. The control system succeeded in curbing the diversion of legally produced pharmaceutical opiates and cocaine into illicit distribution channels, which was taking place on a large scale before World War II. WHO maintains that the "universal adoption of the treaties and their implementation continue to be highly effective in preventing the diversion of drugs from licit to illicit markets in international trade". Most illicit diversion of pharmaceuticals now occurs at the national level, according to the INCB: "Since the diversion of narcotic drugs and psychotropic substances from international trade has almost stopped, the diversion of such substances from licit domestic distribution channels has become a major source used to supply illicit markets." <sup>53</sup>

The unprecedented overdose epidemic in the United States is a dramatic reminder of the importance of maintaining a proper balance between enabling adequate access to pain medicines and curbing the risks of an increase in problematic use and overdose in the absence of effective controls. The epidemic is supplied from various sources: illegally imported heroin mainly from Mexico and Colombia; pharmaceutical painkillers obtained with medical prescription; diversion of pharmaceuticals into illicit distribution channels; sales over the internet, either via "grey" sites with low prescription barriers or via illegal crypto-markets; and the recent phenomenon of highly potent fentanyl-type substances entering the market, including Mexican heroin cut with fentanyl.

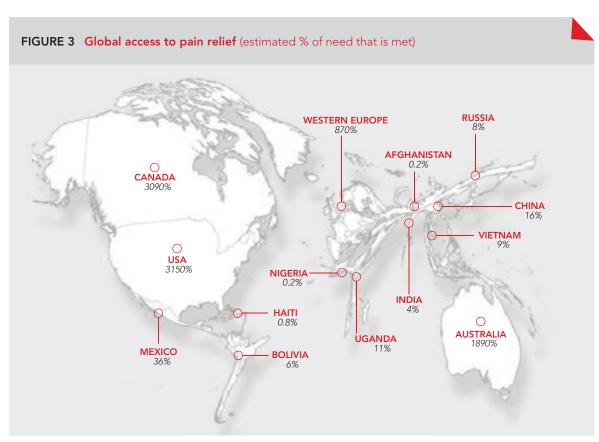
Aggressive marketing of pharmaceutical painkillers included deliberate misrepresentation, such as claims that the risk of dependence was low. Such tactics increased sales, particularly of OxyContin introduced by Purdue Pharma in 1996,<sup>54</sup> making "large quantities of oxycodone hydrochloride readily available for inhalation and intravenous injection".<sup>55</sup> This was a major factor triggering the epidemic, the end of which is not yet in sight due to a chronic lack of effective harm reduction responses.<sup>56</sup> While the crisis has reached alarming proportions, the circumstances that enabled it are specific to the United States, including irresponsible behavior by pharmaceutical companies, unregulated private medical practices, and fraudulent prescription and distribution channels that operate with impunity. The Global Commission examined the crisis in detail in its position paper "The Opioid Crisis in North America" in 2017.<sup>58</sup> In reality, most of the world's population suffers from a diametrically opposed crisis in public health and human rights: an epidemic of untreated pain and a chronic lack of access to essential medicines. This lack of access is particularly problematic for several controlled medicines that are made of or contain "narcotic" drugs.

#### BOX 5 Attempts at international scheduling of ketamine

Ketamine is an anesthetic used in both veterinary and human surgical procedures and is often the sole anesthetic agent available across large areas of the Global South. Ketamine is easy to use, especially in under-developed, rural and emergency settings where clinical controlled conditions are unavailable; it does not suppress the respiratory function and is safe in terms of overdose when used under medical guidance. For those reasons, ketamine is included in the WHO Model List of Essential Medicines. At the same time, ketamine due to its dissociative effect is also consumed recreationally as a hallucinogen, a form of consumption that has grown in recent years, prompting moves from China, with support from other Asian countries and the INCB, to control the substance under international law. The WHO ECDD, however, reported that concerns were raised "that if ketamine were placed under international control, this would adversely affect its availability and accessibility. This in turn would limit access to essential and emergency surgery, which would constitute a public health crisis in countries where no affordable alternative anesthetic is available".<sup>68</sup>

At its birth, the scheduling system was justified as a mechanism necessary to improve access. "In providing for a lenient regime for drugs in Group II the authors of the 1931 Convention were guided by consideration of the fact that availability of widely employed useful drugs of relatively little abuse liability should not be made too difficult, and that in establishing controls both the need for prevention of abuse and for facilitating legitimate use should be taken into account." A similar rationale lay behind the more lenient control regime established under the 1971 Convention: "The authors of the [1971] Vienna Convention thought they could not provide for very strict controls of very widely employed medicines because it would reduce the ease of their availability for therapeutic purposes. Instead, they emphasized the usefulness of knowledge of the dangerous properties of the substances involved and of education in the fight against drug abuse." 60

According to WHO, "the obligation to prevent abuse of controlled substances has received far more attention than the obligation to ensure their adequate availability for medical and scientific purposes, and this has resulted in countries adopting laws and regulations that consistently and severely impede accessibility of controlled medicines."



Source: Knaul, F., Bhadelia, A., Rodriguez, N., Arreaola-Ornelas, H., Zimmermann, C. "The Lancet Commission on Palliative Care and Pain Relief —findings, recommendations, and future directions", The Lancet, March 2018.

Recognizing the dramatic failure of the system, in 2007 WHO launched the Access to Controlled Medicines Programme (ACMP) to help governments identify and remove key barriers to access.<sup>61</sup> In 2011 WHO published guidelines on ensuring balance in national policies on controlled substances;<sup>62</sup> in 2015 the INCB devoted a supplement to its report to the availability of controlled medicines;<sup>63</sup> and the outcome document of the 2016 UN General Assembly Special Session (UNGASS) on drugs contained a special section on the issue.<sup>64</sup> Despite these increased efforts, according to the latest progress report by the INCB, in most countries in Africa, Asia, Latin America, the Caribbean and Eastern Europe, access to opioid analgesics and several essential psychotropic substances remains inadequate or has even been declining: "People are still suffering; such people range from those who have to undergo surgery without anesthesia to those without access to the medication they need and those who are dying in unnecessary pain."<sup>65</sup> The consequences of this "deep-lying imbalance", which favors punitive approaches over ensuring access to controlled medicines, have been detailed in the 2015 Global Commission report, "The Negative Impact of Drug Control on Public Health: the Global Crisis of Avoidable Pain."<sup>66</sup>

This deeply entrenched imbalance appears difficult to overcome, as became apparent in recent controversies around the scheduling of tramadol and ketamine (Box 5). In both cases, after repeated reviews, WHO recommended against international control, arguing that scheduling would hamper access for medical use. At the same time, the INCB supported calls from countries in favor of international control and advised countries to at least impose controls under national drug control legislation. It demonstrated the difference in attitude between the WHO ECDD and the INCB secretariat, and the INCB attempt to intrude on what is clearly a treaty mandate of WHO.<sup>67</sup>

#### **RECOMMENDATION**

The international community must recognize the incoherence and inconsistencies in the international scheduling system, and must trigger a critical review of the current models of classification of drugs.

The negative consequences of the current international schedules for drug control can no longer be ignored. They range from the scarcity of essential medicines in low- and middle-income countries to the spread of infectious diseases and injuries, higher mortality and the global prison overcrowding crisis. The international community must face these challenges, and measure and correct the negative consequences of current schedules.





# LESSONS FROM (SEMI)LEGAL MARKETS

#### NON-SCHEDULED PSYCHOACTIVE PLANTS

The 1961 Convention was built around substances derived from the three principal plants—opium poppy, coca and cannabis—and also imposed controls on the plants themselves. Several other psychoactive plants, however, have escaped being subject to international control. In its report for 2010, in a special topic on "Plant material containing psychoactive substances", the INCB drew attention to the fact that "although some active stimulant or hallucinogenic ingredients contained in certain plants are controlled under the 1971 Convention, no plants are currently controlled under that Convention or under the 1988 Convention".<sup>69</sup> The INCB recommended "that Governments should consider controlling such plant material at the national level where necessary".<sup>70</sup>

The inclusion of the active compounds of khat (cathinone, cathine) and ayahuasca (DMT) in the 1971 Convention, and of ephedra (ephedrine, pseudo-ephedrine) as a precursor for methamphetamine in the 1988 Convention, has created legal uncertainties around these plant materials in several countries. In many other countries, however, the cultivation and use of these and other herbal stimulants and psychedelics is fully legal. In the case of kratom (*Mitragynia speciosa*), its principal alkaloid mitragynine is not under international control either. The spread of some of these herbal substances from their original traditional cultural settings to new markets has created legal challenges as well as interesting opportunities.<sup>72</sup>

The chewing of khat is widely practiced for its mild stimulant effects in East and Southern Africa (especially Ethiopia, Somalia and Kenya), Madagascar, the Arabian Peninsula and by diaspora communities in Europe and North America. The psychoactive compounds in the khat plant have been under international control since 1988: cathinone in Schedule I and cathine (norpseudoephedrine) in Schedule III of the 1971 Convention, and norephedrine under the 1988 Trafficking Convention as a precursor used in the illicit manufacture of amphetamine. Khat itself has also been considered for inclusion in the drug control treaty schedules, but WHO concluded in 2006 after a critical review that "the potential for abuse and dependence is low and the level of abuse and threat to public health is not significant enough to warrant international control." After WHO recommended against it, the INCB continued to call "upon the authorities to consider taking appropriate measures to control its cultivation, trade and use". To

Norway, Sweden and the United States banned khat shortly after cathinone was included in the strictest Schedule I of the 1971 Convention. Since then, bans have been implemented in Canada and in the majority of European countries – most recently in 2013 in the Netherlands and in 2014 in the United Kingdom, where a ban was enforced not on the basis of scheduling advice from the competent national agencies but rather because they "no longer wanted to be out of step with neighboring countries that had criminalized khat [..] and to avoid the countries becoming commercial khat hubs for the rest of Europe". Against the advice of WHO, khat has thus become a controlled substance in a growing number of countries, with as yet unclear consequences. There is a risk that history will repeat itself, including the cultural insensitivity and anti-immigrant sentiments that marked the early days of prohibition.

In the Horn of Africa, meanwhile, the production, trade and consumption of khat remain legal, and the market has expanded. In 2017/18, in Ethiopia alone, according to the government's Central Statistical Agency, there were almost 3 million small-holder farmers growing khat on an estimated 260,000 hectares? (in comparison, the total area under coca bush cultivation worldwide in 2016 was 213,000 hectares<sup>78</sup>). While most of the khat is consumed within Ethiopia, roughly 20 per cent (about 50,000 tons) is exported, mainly to neighboring Somalia and Djibouti but also to the East African diaspora and to new markets including China, which represents around 9 per cent of Ethiopia's total export value.<sup>79</sup> Since the stimulant qualities of khat diminish within three days of harvesting, it must be moved to those far-away markets quickly by airplane, making the international trade to countries where khat has recently been banned highly vulnerable to police and customs interdiction. "Inevitably, these farmers will be affected by an expanding number of prohibitions on khat consumption emerging in countries around the world. [..] As a result, the Ethiopian government faces legislative and policy dilemmas regarding its khat industry. It has few enviable choices: disregard such bans and condone the export of a substance deemed illicit in many countries, essentially becoming complicit in illicit trafficking and smuggling, or opt to control and restrict the production and consumption of a crop that underwrites the livelihood of millions of Ethiopians and contributes hundreds of millions of dollars to annual spending and potentially incite political instability."80

The surprisingly fast-growing international market of kratom is another example of an emerging international legal twilight zone. Kratom (*Mitragynia speciosa korth*), a tropical tree indigenous to Southeast Asia,

produces broad leaves that have long been used for medicinal and recreational purposes.<sup>81</sup> Kratom is not under international control, but has been banned in Australia, Malaysia, Myanmar and Thailand, and the United States and some European states are considering measures to counter its widespread availability on the internet. The U.S. market has grown exponentially in the past decade, with estimates for 2016 about "several million consumers purchasing products from more than 10,000 retail outlets with an estimated annual market of 207 million US dollars".<sup>82</sup>

The U.S. Drug Enforcement Administration (DEA) announced in 2016 that it intended to include kratom in Schedule I, arguing that "especially concerning, reports note users have turned to kratom as a replacement for other opioids, such as heroin. In the United States, kratom is misused to self-treat chronic pain and opioid withdrawal symptoms, with users reporting its effects to be comparable to prescription opioids." The announcement triggered a massive public response that led the DEA to reconsider its action and allow time for more consideration. <sup>84</sup>

A survey among kratom consumers confirmed that for many, "their kratom use was meant to address symptoms including pain, low energy, depressed or anxious mood. Additionally, a large proportion, if not the majority, of use was intended as a means to reduce or abstain from prescription or over the counter drugs to treat ailments for which kratom's side effect profile was more tolerable". Moreover, "banning the availability of kratom through scheduling could precipitate public health problems that do not presently exist or are at very low levels, because this would shift the marketplace from a largely lawful retail market to illicit manufacturers and distributors with no regulated labelling, purity or content standards, or effective ability to remove adulterated products from the market."

Instigated by the American Kratom Association, states such as Georgia, Nevada and Utah have introduced a Kratom Consumer Protection Act, considering that "research of the benefits and safety risks of kratom and its role in battling opioid addiction is important to the public welfare of the citizens". <sup>87</sup> The act sets an age limit of 18 years for kratom sales. It requires clear labeling of kratom products showing the amount of mitragynine and 7-hydroxymitragynine, clear directions for use and precautionary statements on the drug's safety and effectiveness. These local legislative initiatives represent a promising regulatory alternative to the DEA initiative.

In the south of Thailand, kratom is used by more than a million people who chew the leaves or use them to make various drinks as an alternative to alcohol. Since the 1943 Kratom Act prohibited its use, there have been regular campaigns by the police, who have cut down kratom trees in people's backyards and arrested thousands of kratom users, stoking anti-government sentiment among the region's predominantly Muslim communities. After an in-depth academic survey and an experiment with "community control" of kratom instead of criminalization, the Thai Parliament approved several drug law amendments in December 2018 that permitted traditional medical uses of kratom.<sup>88</sup>

#### **LEGAL REGULATION OF CANNABIS**

Medical use of cannabis has been legal for more than two decades in several U.S. states, starting with California in 1996, and in some European countries and Israel. This expansion of the medical cannabis market has accelerated in recent years; almost every month another country joins the trend. In the past few years, rapid expansion has taken place across Europe (Czech Republic, Germany, Greece, Luxembourg, Poland and Slovenia) and Latin America (Argentina, Chile, Colombia, Mexico, Peru, Uruguay), in spite of many shortcomings in the regulatory frameworks in most of these countries. This trend is also beginning to become visible in the Caribbean (St Vincent and the Grenadines, Jamaica), Africa (South Africa) and Asia-Pacific (India, New Zealand, Thailand).<sup>89</sup>

Beginning in 2012, ten U.S. states plus the District of Columbia have approved ballot initiatives or passed laws to regulate cannabis beyond medical use, and Uruguay (2013) and Canada (2018) have approved national cannabis regulation laws. These new regimes that legally regulate the whole cannabis market, including non-medical or "recreational" uses, are contributing to fresh debate elsewhere in the world. Cannabis regulation is on the agenda of Mexico's and Luxembourg's incoming governments, and in New Zealand the governing coalition has committed to a referendum by 2020 on whether to legalize non-medical cannabis.

The Dutch government will be permitting local experiments in regulated cannabis production to supply the "coffee shops" where purchase and use is tolerated. Within the United States, additional state ballot initiatives are being planned, and more state legislatures are considering cannabis regulation bills.

The Regional Commission on Marijuana established by the Caribbean Community (CARICOM) recently concluded that the prohibitionist regime for cannabis "is not fit for purpose" and recommended "significant changes to the laws of the region to enable the dismantling of this regime [...] that has proven to be ineffective, unjust and caused more harm than it sought to prevent". The Commission was mandated to "conduct a rigorous enquiry into the social, economic, health and legal issues surrounding marijuana use in the Caribbean and to determine whether there should be a change in the current drug classification of marijuana thereby making the drug more accessible for all types of usage (religious, recreational, medical and research)."

In its report, the Commission accepts the evidence that the original classification of cannabis was made without the benefit of scientific research and data. "Given the key finding that now establishes that cannabis/marijuana has several beneficial effects, cannabis/marijuana can no longer be accurately classified in law as a 'dangerous drug" with 'no medicinal or other value' ".92 The Commission was unanimous in its view that "the current legal classification appears obsolete and idiosyncratic" and "can no longer be supported as a justification for law-making and should be rejected, as it undermines the legitimacy of the law itself."93 Furthermore, "the incongruity of the harsh laws and inaccurate classification of cannabis/marijuana is exacerbated by the fact that other harmful substances are not similarly treated under the law, leading to claims of inherent unfairness and injustice in the legal system."94

It is still too early to draw firm conclusions about the impact of legal regulation of cannabis markets. But the potential of these new regulatory regimes to serve public health and criminal justice can be glimpsed by looking at the success and challenges of tobacco control policies. The strong evidence that "comprehensive tobacco control programs are effective in reducing tobacco use among adults and young people", "5 in sharp contrast with the lack of evidence of any effectiveness of criminalization approaches towards cannabis, has inspired regulators in Canada, Uruguay and several U.S. states. "The key recommendations to reduce tobacco use include increased unit price, smoke-free policies, comprehensive control programs, community mobilization, mass-reach health communications, and strict retailer licensing and enforcement" according to the Community Guide, which also recommends "increased taxes, limited hours of sale, regulating retail outlet density, and enhanced enforcement of licensed retailers". "6"

#### **NEW PSYCHOACTIVE SUBSTANCES**

Myriad new psychoactive substances (NPS) are appearing on the global drugs market, "promoted aggressively as 'legal highs' and distributed through global internet-based traders, at a rate that is straining traditional control systems", "7 prompting states and international institutions to rethink their current scheduling systems.

The differences in the scheduling decision processes for pharmaceutical drugs and emerging psychoactive substances are striking. Accompanying review processes of pharmaceutical drugs, there is "a well-financed and effective lobby for both sides of the regulatory decision debate for pharmaceuticals developed by pharmaceutical manufacturers. The manufacturers are often very large corporations, anxious to recoup investments that may run to the hundreds of millions of dollars. The consumer side is often represented by well-organized NGOs, provided with information from other government agencies that gather relevant data. Egregious errors are likely to generate effective protest by the injured party."<sup>98</sup>

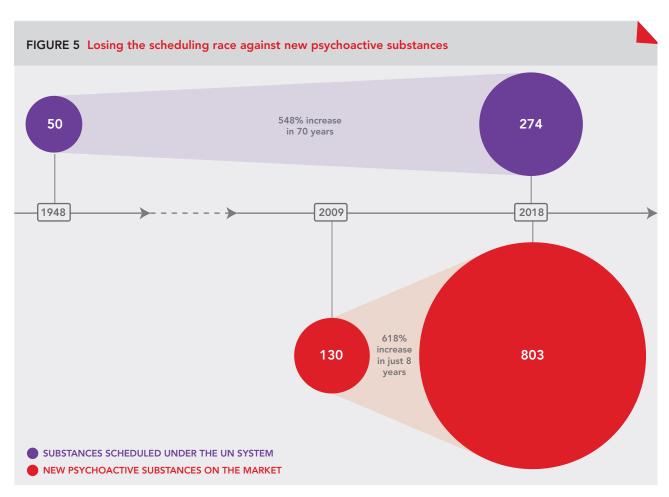
In the case of new psychoactive substances, to the contrary, "there is an inherent, perhaps inescapable, bias in the system towards prohibiting new substances about which little is known. The negative consequences to decision makers of permitting on the market, in any way, a drug that later turns out to be dangerous are very high. The negative consequences to decision makers of keeping off the market a drug that is in fact harmless, even if the resulting prohibition worsens the problems related to that drug, are minimal." 99

The regulatory panic triggered by the unmanageable avalanche of new substances led some countries to design new catch-all control systems, like the 1988 U.S. Analogue Act, which automatically prohibits

a substance if it is "substantially similar" in structure and effect to an already prohibited drug; or the UK 2016 Psychoactive Substances Act, which bans any psychoactive substance which "by stimulating or depressing the person's central nervous system ... affects the person's mental functioning or emotional state". While their simplicity may seem attractive to policy makers eager to stay ahead of the curve of new NSP constantly appearing on the market, such broad definitions of similarity or psycho-activity run into many conception-related and operational difficulties. The UK Bill covers an extraordinarily broad range of substances but also specifies a list of exempted substances, including alcohol, caffeine, nicotine, and some foods, medicines and substances already controlled under the Misuse of Drugs Act. The Bill "does not make harm or potential for dependence a criterion by which a psychoactive substance is either included or exempted from its scope". 101

This exclusion of the concept of harm is intended to avoid the need for lengthy deliberation on potential harms before a substance is banned, following the rationale provided by the Bill. However, "that panel also recognized the possibility of a future substance being discovered that is minimally harmful and is of enough clinical, commercial, cognitive enhancing, or (dare we say) recreational value that legal supply would be warranted." 102 Accordingly, the panel recommended a "safety valve" provision through which such substances could be placed on the exempted list, 103 but no such provision has been included in the Bill. Without it, "legislative control is irrevocably decoupled from any assessment of the risk of harm". 104

Some jurisdictions have adopted faster mechanisms to classify new substances under existing drug control legislation. Others, tellingly, "have enforced consumer safety or medicines legislation to stop the open sale of these products", and though more rigorous evaluation is required, "first results suggest that these have been effective, while avoiding criminalization of users. [..] It seems to be more efficient to enforce medicines or consumer laws against suppliers and distributors than to prosecute many individual users under criminal drug laws." <sup>105</sup> According to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA),



Source: WHO, INCB and the World Drug Report 2018

"a range of other potential legislative controls, many already in existence and some already employed by European member states to control new psychoactive substances, might also have a legitimate and effective role to play in the field of drugs control". 106

Using food safety or consumer protection regulations to control drugs can pose risks, however. The researchers Peter Reuter and Bryce Pardo, looking at the experience with "weight loss products" containing psychoactive substances, have pointed at the "fact that these products are distributed in a legal market provides false reassurance about government regulation", since many people believe such products "are approved for safety and efficacy before they can be sold to the public", which is not the case. 107 There have been successful examples of the use of medicines legislation in some European countries to pull NPS (especially mephedrone) off the market by classifying it as a medicine but withholding market authorization. 108 However, in 2014 the European Court of Justice ruled against using medicines laws to control NPS after two individuals in Germany convicted of "unlawful sale of unsafe medical products" filed suit, arguing that this did involve an obvious artifice since "the substances involved were never intended to serve as medicines". 109

New Zealand did include an exemption schedule in its 2013 Psychoactive Substances Act, establishing temporarily a regulatory framework for "low risk" psychoactive substances. Under the scheme, manufacturers and distributors seeking to legally sell new psychoactive substances were required to gain pre-market approval by demonstrating that their product posed a "low risk of harm" based on six criteria: toxicological effects, risk to public health, potential to cause death, potential to create dependence, likelihood of misuse and appeal to vulnerable populations. New Zealand had experienced a previous legal episode with BZP "party pills" (containing mixtures of benzylpiperazine): "at its height in the mid-2000s the BZP party pill industry in New Zealand was estimated to have sold as many as 200,000 party pills per month". 110 This unregulated lucrative phase, during which "party pill producers invested considerable energy in many of the same pro-consumption activities seen with alcohol and tobacco, such as advertising and marketing", ended in 2008 when BZP was scheduled as a class C drug under the Misuse of Drugs Act.<sup>111</sup> The industry responded to the ban on BZP by shifting production to non-BZP party pills and synthetic cannabinoids and many of those entered an interim regime that was established in 2013 while regulations for the scheme were still being developed. In May 2014, however, the interim regime was brought to an abrupt end by a Parliamentary amendment to the Psychoactive Substances Act due to on-going reports about irregularities around retail stores and adverse effects from synthetic cannabinoids.

One of the concerns with the 2013 exemption schedule was whether the regulatory framework underpinning access to legal highs would be "capable of withstanding the pressures that will inevitably emerge once a legal high industry develops the capacity to push its own interests". It Interviews with key industry stakeholders "espoused an idealistic mission of shifting recreational users of alcohol, tobacco and illegal drugs towards 'safer alternatives'", but also revealed an increasing "tension between profit and idealistic motivations". While stakeholders distanced themselves from "Big Alcohol" and "Big Tobacco", Marta Rychert and Chris Wilkins conclude that "[r]ules for engagement with new 'addictive consumption industries' are required to clarify the role they are permitted to play in the development of regulatory regimes for new psychoactive substances". It

#### **RECOMMENDATION**

The international community must prioritize the role of the World Health Organization and interdisciplinary scientific research in further developing evidence-based scheduling criteria based on a rational scale of harms and benefits.

States must also address the increasingly blurred distinctions between legal and illegal drugs and markets, by requesting from multilateral mechanisms more flexibility in the adoption of different scheduling rules and guidelines at the domestic level. Such a process depends on re-balancing the role of stakeholders in designing scheduling models, with more prominence needed for science, health and social professionals. Such a process would also allow to lift the existing barriers to scientific research on the essential medical uses of these substances.



## **CHALLENGES AND REFORM OPTIONS**

#### **IMPROVING THE CURRENT SYSTEM**

"If a captain's only concern were the safety of his ship, as the saying goes, he would never leave port. Likewise, if international drug treaties were only concerned with preventing diversion into illicit trade, they would simply ban the use of all drugs with potential for abuse. Of course, the captain's goal is not only the safety of his ship, but also the timely delivery of his cargo. So it is with the international drug control regime, which aims to ensure that controlled substances are available in necessary quantities and timely delivered to those authorized to receive them, while at the same time minimizing the diversion of those substances into illicit trade." 115

The current drug scheduling system governed by the UN treaty regime is fraught with historical biases and inconsistencies almost beyond repair. According to a group of experts who have been involved in the WHO review process, "the present situation in which several important substances (e.g., cannabis, cannabis resin, heroin and cocaine) were never evaluated or were evaluated up to eight decades ago seriously undermines and delegitimizes their international control. In addition, their historic evaluation no longer represents current scientific information." 116

In recent decades, calls and proposals from within the UN system itself have repeatedly been made to improve the scheduling criteria, to amend the treaties to resolve some inherent inconsistencies and to clarify the mandates of WHO, the INCB and the CND. The INCB, for example, in its Evaluation of the Effectiveness of the International Drug Control Treaties in 1994, proposed to harmonize the scheduling criteria and process of the 1961 and 1971 conventions, which "would lead to the elimination of contradictions, to transparency and to easier scheduling decisions, while reducing the costs of the evaluation process." 117,118

The WHO guidelines for the review process have been subject to periodic changes, the latest having been adopted by the Executive Board of WHO in January 2010. The new rules include specific requirements intended to enhance the evidence base and transparency of the process. "It is not expected that this revision will result in the substances currently controlled under the two Conventions being removed from their schedules ("Un-scheduling"). However, the revision will allow for a more precise and scientific assessment in the review of substances in the future." 119

The WHO review of cannabis in 2018 can be seen as a test case for those improved scheduling guidelines. The ECDD's recommendations include some clearly positive points, especially acknowledging the medicinal usefulness of cannabis by removing it from Schedule IV of the 1961 Single Convention and clarifying that cannabidiol (CBD, one of the active ingredients in cannabis) is not under international control. The unprecedented review process also provides a wealth of up-to-date information based on a thorough review of the available scientific evidence and will surely be an authoritative reference for years to come on all aspects of medicinal uses of the various cannabis-related substances. However, the outcomes of the ECDD process also reveal the difficulties to overcome the inherent inconsistencies of current scheduling procedures (Box 6).<sup>120</sup>

#### **BOX 6 WHO's Critical Review of Cannabis**

Concluding a five-year review process, the ECDD released in January 2019 its recommendations for rescheduling cannabis-related substances.<sup>121</sup> WHO clearly acknowledges the medical properties of cannabis, but the outcomes also reveal a questionable rationale for keeping cannabis under strict international control. "The evidence presented to the Committee did not indicate that cannabis plant and cannabis resin were particularly liable to produce ill-effects similar to the effects of the other substances in Schedule IV", <sup>122</sup> the strictest schedule reserved for drugs with "particularly dangerous properties" (Art. 2, § 5-a) such as heroin and fentanyl. "Use of all these substances is associated with a significant risk of death, whereas cannabis use is not associated with such risk," and, in addition, "preparations of cannabis have shown therapeutic potential for treatment of pain and other medical conditions", therefore the ECDD recommends deletion from Schedule IV. <sup>123</sup>

Based on this "similarity principle", the Expert Committee then had to assess whether cannabis is "liable to similar abuse and productive of similar ill effects as the drugs in Schedule I or Schedule II" (Art. 3, § 3-iii), and whether it should remain in Schedule I (e.g., on a par with morphine and cocaine), be transferred to Schedule II (e.g., on a par with codeine) or be deleted from the schedules altogether. The ECDD arrives at the conclusion that "[w]hile the Committee did not consider that cannabis is associated with the same level of risk to health of most of the other drugs that have been placed in Schedule I, it [..] recommended that cannabis and cannabis resin continue to be included in Schedule I", noting the "high rates" and "global extent" of cannabis-related health problems. This is a dubious argument that seems difficult to align with the scheduling criteria established in the Convention or with the latest WHO guidelines.

According to the Commentary on the 1961 Convention, substances "which are comparatively less dangerous and widely used in medical practice may therefore often be proposed for inclusion in Schedule II". 125 Or, as the ECDD concluded in the cases of khat, tramadol and ketamine, for example, they should not be placed under international control at all. Amid rising diplomatic tensions over recent changes in the cannabis policy landscape, the ECDD seems to have made a deliberate choice to limit its recommendations to condoning medical uses but to abstain from making any recommendations that might have further fueled political tensions over the policy trend towards legal regulation. Letting political considerations slip into its recommendations, however, compromises the scientific evidence-based WHO mandate within the UN drug control treaty system.

Keeping cannabis in Schedule I (and transferring there the cannabis constituent THC and its synthetic equivalent dronabinol), and only exempting under Schedule III certain mixtures "compounded as pharmaceutical preparations", risks providing a limited number of patented pharmaceutical company products with preferential treatment over a wide array of more natural cannabis products with similar medicinal properties. Moreover, in an attempt to stay away from political controversy, the ECDD with its recommendation to keep cannabis in Schedule I – supposedly grounded in a review of the latest scientific evidence – effectively ratifies the highly dubious arguments on the basis of which cannabis entered the treaty schedules in the first place. While it is important that WHO has finally recognized the medical usefulness of cannabis, the ECDD recommendations demonstrate the incapacity of the current scheduling system to correct historical errors and to ensure that scientific evidence prevails over ideology. At this critical juncture for the future of the global drug control regime, evidence-based guidance from the mandated UN bodies is needed more than ever.

#### A RATIONAL SCALE OF HARMS

"Strong arguments exist for the need to seek synergies between drug and alcohol policies, not least of which is the fact that they will often be targeting the same populations and settings. Current policy models are also challenged by the growth of the 'legal highs' market, as well as the misuse of pharmaceutical products [..]. From a public health perspective, this highlights the need for a more comprehensive approach, encompassing both illicit and licit substances, and possibly other behavioral addictions. The challenge is two-fold: to consider to what extent this overarching vision is justified, and how this perspective might be translated into an appropriate regulatory and control framework." 126

Serious efforts have been undertaken in the European Union, the Netherlands, New Zealand and the United Kingdom to design an evidence-based scheduling system, which is not an easy task. The most advanced attempt thus far is the "multicriteria decision analysis" of drug harms in the United Kingdom by Professor David Nutt and his colleagues at the Independent Scientific Committee on Drugs. 127

One major complication, however, is that "[u]nlike in the early days of substance evaluation, scientists today are aware that dependence-producing properties are not only a function of the substance, but also include the route of administration and the dosage form. Therefore, dependence liability may vary for the various preparations of the same substance." 128

Another critique, from Peter Reuter, is that "the harms are assumed to be intrinsic to the drug rather than the result of the drug and its regulation. That is clearly false. For example, the mortality associated with heroin use is much lower if it is purchased in known quantity of specified purity from a pharmacy for injection with a sterile needle rather than purchased in a clandestine transaction with unknown adulterants to be injected with a used needle." 129

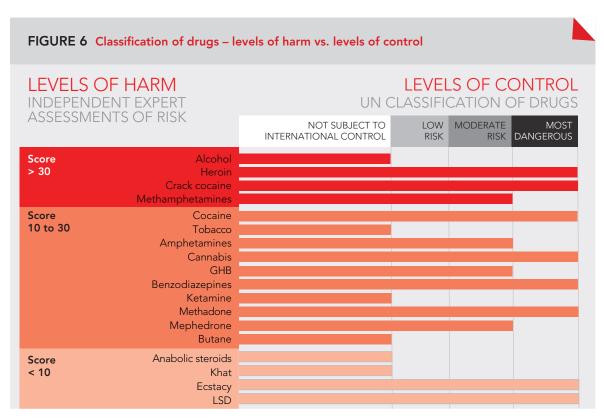
The incorporation in the scheduling decision of a prediction about market responses is difficult yet crucial for the effectiveness of an evidence-based scheduling system. If a certain substance is made less available on the illicit or grey drugs market, what alternatives may consumers resort to – and are they better or worse than the substance being pushed out of the market? "The size of the existing user base is another factor that can affect the choice between prohibition and regulation. Turning a large number of otherwise law abiding citizens, who are habitual users, into criminal offenders is not a decision to be taken lightly." 130

Insufficient attention has been given to a wide range of other potentially useful control mechanisms and legal instruments that have been applied already in Europe with some effect for specific psychoactive substances. According to a UK report on responses to NPS, "it would be worth exploring these and evaluating the different outcomes. This includes potential long-term reform to provide a comprehensive framework for dealing with all psychoactive substances": 131

"A new Harmful Substances Control Act or framework could be developed [to] consolidate a wide range of existing legislative provisions covering controlled drugs with those at least for alcohol and tobacco and even perhaps those covering the control of medicines and poisons. This has the advantage of de-cluttering the current drug control legislation and providing an opportunity to remove anomalies that have grown up over the years." 132

The issue of the inconsistency with tobacco and alcohol control has in fact appeared on the ECDD agenda. A critical review of tobacco in 1999 concluded that "smoking tobacco is dependence-producing, causes serious public health problems and has no therapeutic use. However, judging from the control measure provided for, the scheduling criteria specified and the substances already under control, existing international drug control measures for narcotic drugs and psychotropic substances appear to be unsuitable for controlling tobacco, a dependence-producing natural substance widely used for non-medical purposes at the time of adoption of the relevant conventions. Even though new information indicates health risks greater than those previously known, tobacco would not meet the criteria for scheduling under the existing international drug control conventions. Furthermore, once scheduled, total prohibition would be the only control measure applicable to tobacco, since the regulated supply of controlled substances is not allowed for non-medical and non-scientific purposes." 133

WHO therefore instead "initiated a procedure to develop a framework convention that includes a strategy for Member States to adopt a comprehensive tobacco control policy and to deal with aspects of tobacco control that transcends national boundaries", 134 which led to the adoption in 2003 of the WHO Framework Convention on Tobacco Control. 135 Similarly, in 2012, there was "a brief discussion as to whether ethanol (ethyl alcohol) should be considered for pre-review". However, noting that a process towards a WHO Global Strategy to Reduce the Harmful Use of Alcohol had already been put in motion, the Expert Committee referred the matter for consideration at a future meeting. 136



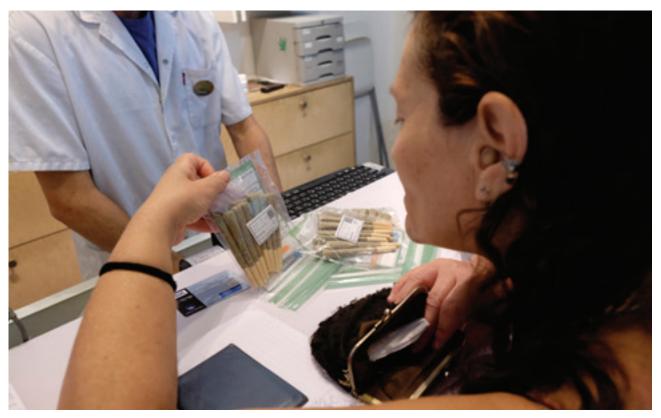
Source: This graph is based on the scientific modelling made by David Nutt et al. (Drug harms in the UK: a multicriteria decision analysis, The Lancet, https://doi.org/10.1016/S6-61462(10)6736-0140), and their assessment of the various harms of drugs used for recreational purposes in the UK, using multi-criteria decision analysis (MCDA), and, Schedules of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, as at 16 May 2018 (ST/CND/1/Add.1/Rev.4) and Schedules of the Convention on Psychotropic Substances of 1971, as at 11 November 2018 (ST/CND/1/Add.2/Rev.4).

#### REGAINING NATIONAL FLEXIBILITY FOR LEGAL REGULATION

The medical cannabis boom is justifiable under the existing UN drug control regime, in spite of its inclusion in Schedule IV and the accompanying recommendation of full prohibition including for medical purposes, which WHO recently proposed to delete.<sup>137</sup> There can be no doubt, however, that the legal regulation of non-medical markets is out of compliance with provisions of the UN drug treaties.

As more jurisdictions move in this direction, treaty tensions will increase, and states will be obliged to explore options to reconcile such policy changes with their obligations under international law. In its 2018 report "Regulation: The Responsible Control of Drugs", the Global Commission outlined possible reforms to modernize the international drug control system, which are equally relevant for the scheduling system. The first option would be to work progressively towards a new framework single convention that replaces the three existing conventions and is designed to meet the contemporary needs and aspirations of all member states. The replacement convention would include an improved and more coherent scheduling procedure that strikes a better balance between ensuring availability of controlled substances for legitimate uses and preventing problematic use. A second option would be the amendment of current treaties by a negotiated consensus between all parties; or the removal of a particular drug from the treaty schedules following a WHO recommendation adopted by a majority CND vote.

The Global Commission has already pointed out that the polarized nature of views on regulation make it unlikely that a new consensus could be easily found, and since its previous report the polarization only seems to have increased. The Global Commission has also called previously to review and to consider the deletion of cannabis from the schedules of both the 1961 and 1971 Conventions. But the prospects of the recently concluded WHO review process leading to the removal of cannabis from the treaty schedules are not looking promising either, for reasons explained earlier in this report. There are other options, however, for countries that want to move forward with reforms in spite of this stalemate at the global level.



An Israeli prescription-carrying patient purchases medical marijuana at a dispensary in Tel Aviv. © Eddie Gerald/laif/Redux 2016

A unilateral option would be for a country to withdraw from the relevant treaties, and then re-join with a reservation on the specific articles preventing the legal regulation of a given drug, as Bolivia did regarding the coca leaf (Box 7). In a more coordinated manner, several like-minded countries could agree to modify certain treaty provisions among themselves by negotiating an "inter se" agreement. Such a move could resolve, for example, the legal conflict of the domestic cannabis regulation regimes with the UN treaties. <sup>138</sup> Such an inter se agreement could also accommodate international trade in cannabis between regulated jurisdictions for non-medical purposes.

### BOX 7 The Bolivian reservation on coca leaf

Bolivia's derogation from its treaty obligations regarding the coca leaf represents a successful example of a country claiming the right to make an exemption for an internationally scheduled substance based on special national circumstances. After an aborted attempt in 2009 to amend the Single Convention, which places coca leaf in the same schedule as cocaine and obliges parties to abolish coca leaf chewing within 25 years, in June 2011 Bolivia became the first country to denounce the treaty. Early 2013 Bolivia re-acceded to the Single Convention, reserving "the right to allow in its territory: traditional coca leaf chewing, the consumption and use of the coca leaf in its natural state; for cultural and medicinal purposes; for its use in infusions, and also the cultivation, trade and possession of the coca leaf to the extent necessary for these licit purposes". At the same time, the reservation made clear that Bolivia "will continue to take all necessary measures to control the cultivation of coca in order to prevent its abuse and the illicit production of the narcotic drugs which may be extracted from the leaf". 139

Despite U.S. lobbying and the INCB arguing that Bolivia's move "would undermine the integrity of the global drug control system", <sup>140</sup> the number of objections from treaty parties fell far short of the one-third (62) required to block it. <sup>141</sup> The fact that none of the objecting states considered the reservation to be an obstacle for the re-entry into force of the Convention between them and Bolivia, <sup>142</sup> however, could be interpreted as a tacit agreement that treaty provisions regarding specific substances are in principle "separable from the remainder of the treaty with regard to their application", <sup>143</sup> one of the criteria for the permissibility of a reservation or inter se modification to derogate from certain treaty obligations. <sup>144</sup> The acceptance of Bolivia's unilateral defection from the international scheduling status of the coca leaf by the other treaty parties has created an important precedent.

The reservation has effectively resolved Bolivia's legal conflict between its domestic coca market and its treaty obligations. The INCB now refers to Bolivia as a "licit producer of coca leaf": "The cultivation of coca bush in that country for the chewing of coca leaf and the consumption and use of coca leaf in its natural state for cultural and medicinal purposes, such as preparing infusions, is allowed, in accordance with the reservation made by the country in 2013". 145 Export of Bolivia's now legally produced coca products, however, remains restricted to the limited licit purposes recognized by the Single Convention. Export of natural coca products that contain the cocaine alkaloid for other purposes (tea, energy drinks, liquors, mild stimulant, food supplement) would only be allowed if the coca leaf were deleted from the treaty schedule after a WHO review process, or once importing countries had obtained a similar reservation or had reached an inter se treaty modification agreement that allows international trade between its parties.

The Global Commission's 2018 Regulation report states that different drugs will require different approaches:

"More risky drugs clearly justify a greater level of government intervention in the market, and tighter restrictions. The ability to vary the intensity of regulatory controls allows for the creation of a 'risk-availability gradient' according to which the availability of drugs is further restricted as their risks increase. [...] Legally regulated supply should not, therefore, be seen as inevitably leading to increased drug availability, but instead as enabling responsible authorities to assume control over which drugs are available, where and how. Maintaining prohibitions on the most potent and risky drugs – such as synthetic opioids like carfentanil that can be deadly in the tiniest of doses – will remain a health imperative, and can be further justified by the availability of less potent, less risky alternatives."

It will be difficult to reach a consensus on the variety and flexibility of control mechanisms appropriate for different substances. The above-mentioned examples of khat and kratom, however, which are not controlled under the international drugs conventions but are subjected to widely varying degrees of national controls and prohibitions, do provide evidence for the possibility of co-existence in practice of fundamentally different control regimes for the same substance.<sup>146</sup>

### RECOMMENDATION

UN Member States must refocus the international scheduling system on the original impetus of controlling transnational trade and allow for innovative national classification systems to be developed.

Market restrictions on distinctly milder, less harmful and less potent substances should be loosened, including for "other legitimate uses" beyond medical and scientific purposes, opening space under domestic legislation to allow for traditional, religious, self-enhancement or social uses.

### **CONCLUDING REMARKS**

### THE INCOHERENCE OF THE CURRENT SCHEDULING SYSTEM

The initial efforts to control drugs in the first half of the 20th century established a comprehensive system focused on controlling international trade while maintaining a certain flexibility for domestic policies, including for "other legitimate use". Those efforts succeeded in taming the unbridled commercial trade that was largely in the hands of colonial powers and companies, and in curbing diversion from those profitable legal sources onto the illegal market.

The subsequent tragedy of the international drug control system is that it proved incapable of preventing the consequential emergence of large-scale illicit production and trafficking. The prohibitive and overly punitive ethos that dominated post-World War II negotiations on the Single Convention took the UN drug control regime in the wrong direction, with devastating consequences: "The end result of all this is that the model on which drug control policies have been based historically appears to be, if not broken, then at least in serious need of repair." The scientifically dubious nature and politicization of several crucial early scheduling decisions, subsequently perpetuated on the basis of the "similarity" and "convertibility" scheduling criteria, and the structural scheduling inconsistencies added by the 1971 and 1988 conventions, led to a dysfunctional scheduling system.

The zero-tolerance position of a significant group of UN Member States and the generally status-quo friendly multilateral drug control bureaucracy (CND, INCB and UNODC) block attempts to make corrections to the current system, as evidenced by opposition to, and sometimes interference with, WHO scheduling recommendations. Recommendations to add new substances to the schedules are usually rubberstamped, while recommendations to move substances to a less strict schedule or refrain from scheduling certain drugs are consistently confronted with significant opposition. As the UK Home Secretary said, "Where there is a clear and serious problem, but doubt about the potential harm that will be caused, we must err on the side of caution and protect the public." In practice, application of such a precautionary principle leads to "an overriding bias in the decision-making process towards the prohibition of new psychoactive substances". 148

According to Adolphe Lande, one of the key architects of the global regime, "the way in which a country deals with its problems of drug abuse is (from the viewpoint of international drug control) normally no international interest as long as that country effectively prevents the illegal export of internationally controlled drugs from its territory into other countries." Re-focusing international drug control efforts on that original primary objective, of allowing countries to control their illegal exports while establishing domestic schedules according to domestic needs, would provide countries more flexibility in designing evidence-based scheduling systems. Differences between jurisdictions in the levels of control for certain substances can co-exist within a global regime as long as international cooperation is based on mutual respect for such variations. The two principal international drug control mechanisms, the import certificate and export authorization system and the administration of estimates and requirements, are capable of dealing with national variations and were in fact designed for that purpose.

The Global Commission calls for a comprehensive and interdisciplinary approach to designing drug control policies and an end to the "silo" approach that treats drug control as a single issue, classifying drugs and enforcing drug prohibition based on unreliable and scientifically dubious schedules.

A new UN-system Coordination Task Team of interested UN system entities has been established within the framework of the Secretary-General's Executive Committee, led by UNODC, to "support the development and implementation of policies that put people, health and human rights at the center", "call for changes in laws, policies and practices that threaten the health and human rights of people", "ensure human rights-based drug control and address impunity for serious human rights violations in the context of drug control efforts", "enhance access to controlled medicines for legitimate medical and scientific purposes, including the relief of pain and treatment of drug dependence" and "provide Member States with a necessary evidence base to make informed policy decisions and to better understand the risks and benefits of new approaches to drug control, including those relating to cannabis". The UN system common position on drug policy, the first shared position of the Coordination Task Team, pushes the global policy trend to move towards "a human-centered and rights-based approach firmly anchored by the 2030 Agenda", highlighting the critical importance of "science-based and evidence-based policy decisions to realizing such an approach". The UN system common position of the critical importance of "science-based and evidence-based policy decisions to realizing such an approach".

### THE GLOBAL COMMISSION'S APPRECIATION OF THE CURRENT SITUATION

Distinctions between legal and illegal drugs and markets are not sharp. Drug markets are fluid; consumers tend to have a drug of preference, but can shift back and forth between pharmaceutical and illegal sources – depending on availability, quality, safety and price – and sometimes resort to non-scheduled substances such as kratom or NPS. The reasons for using drugs can also differ widely: treating dependency, self-medication for pain or illnesses, self-enhancement, staying awake or getting to sleep, spiritual experience or to seek pleasure. Most people who use drugs recreationally are not risk-seekers, like people who engage in rock climbing or other extreme sports. They want to use drugs as safely as possible and to avoid problematic patterns of dependence. Few of them will require treatment or other forms of health care assistance. As the Global Commission has reminded on several occasions, only 11 percent of people who use drugs experience problematic use, and need social or medical support.

In the case of those people with problematic patterns of use, "a self-medication motive is one of the more compelling reasons for overuse of and dependency on drugs". "Rather than simply seeking escape, euphoria, or self-destruction," argues Edward Khantzian, they are often "attempting to medicate themselves for a range of psychiatric problems and painful emotional states. Although most such efforts at self-treatment are eventually doomed, given the hazards and complications of long-term, unstable drug use patterns, [..] the short-term effects of their drugs of choice help them to cope with distressful subjective states and an external reality otherwise experienced as unmanageable or overwhelming." <sup>152</sup> A better understanding of those different reasons and patterns, and of the choices people make when using drugs, is key for developing more effective policies. A non-stigmatizing and evidence-based scheduling system can influence and guide people to make more responsible and less harmful choices.

### PRINCIPLES FOR BETTER CLASSIFICATION SYSTEMS

For the Global Commission, the only responsible answer to this complex topic is to regulate the market ofillegal drugs, starting by establishing regulations and an ewscheduling system adapted to the dangerousness of each drug and based on solid scientific assessments, and to monitor and enforce these regulations. This is already the case for food, for legal psychoactive substances, for chemicals, for medications, for isotopes and many other products or behaviors that comprise a risk of harm.

While the international community continues to struggle to find a new consensus, countries should move forward with designing and implementing a more rational policy of scheduling, controlling and regulating psychoactive drugs.

Guiding principles for such an approach should include:

- ensuring adequate availability for medical and research purposes;
- abandoning zero-tolerance policies to provide more space to "other legitimate purposes";
- showing more leniency towards milder substances;
- taking into account local social and cultural circumstances;
- conducting a cost-benefit analysis of potential harms and perceived benefits;
- accepting certain risk thresholds comparable to other acceptable societal risks, instead of upholding an absolute precautionary principle;
- weighing carefully the potential consequences of scheduling decisions, taking into account predictable responses of users and markets;
- making better use of existing medical and consumer safety legal instruments, instead of criminal drug laws.

A scheduling system built on such principles could become a key tool to guide policy changes away from an exclusively prohibitive framework and towards a flexible regulation model, as well as a tool for gradually steering the drugs market in a less harmful direction.

# **TESTIMONIES**



### CAROL KATZ BEYER | A mother's account of losing her sons to prohibition

### **United States of America**

As a mother and healthcare professional who is grappling with the loss of two children to fentanyl-related overdose, I know too well the impact of harmful drug policy. I have interviewed countless families whose stories call for a paradigm shift, embracing comprehensive care and solutions rooted in science, compassion, and public health. I co-founded Families for Sensible Drug Policy to advocate for drug policy reform, while educating helping professionals about harm reduction strategies and solutions.

A growing number of families like mine are harmed by the scheduling of drugs as controlled substances. Draconian drug policy encourages an unrealistic and punitive model that requires abstinence, making no room for youthful experimentation that can occur for a variety of reasons. Yet focusing on substance use as the primary problem not only devalues the unique journey, strengths, and resources of each family, it also unwittingly moves our loved ones from experimentation to problematic use.

My own sons, Bryan and Alex, were no different than countless other young adults around the world. They played sports, loved music, went to parties and concerts with friends, and experimented with drugs. Since their high school had a "zero tolerance" policy, they were drug-tested, got a positive screen for cannabis and cocaine, and were forced into an intensive outpatient program with people who used drugs that were older. They were told to identify as powerless addicts, then kept from sports, extracurricular activities, and their peers. Their condition got worse, but "hitting bottom" was considered part of recovery. They were taught that I was "codependent" and an "enabler" for showing love and advocating for their well-being.

When their substance use became more harmful we were told to send them to a 28-day inpatient rehab program in Florida. Afterwards, Bryan and Alex cycled between detox, jail, rehab, and sober living facilities. They maintained stretches of sobriety, and seemed to be maturing out. Bryan attended Johnson and Wales University, started a business, and got married! Alex graduated from Full Sail University, returned home to New Jersey to be closer to family, and pursued his career! Tragically, since the streets are flooded with fentanyl and there are no safe consumption spaces to manage relapse, my beautiful boys lost their lives to preventable overdoses. The loss is unfathomable to family and friends. It was not the plan for my youngest son, Devin, to visit his brothers' graves on the day he graduated from college.

Current prohibition-based drug policies interfere with people's human rights, as well as individual and family safety. As a mother, I believe that the US government's stance toward drugs contributed to my sons' deaths. The War on Drugs marginalized them, telling them their lives did not matter.

Family support is an integral part of recovery and a healthy relationship with substances. We know that problematic use results from an interaction of psychological, biological, and sociocultural variables. Addiction gets called a "disease", but that is a misunderstanding. Through programs like Family Drug Support, families are empowered to work through the issues contributing to problematic use together. People who use drugs and their families deserve support that treats them with dignity, individuality, and respect.

### CONNIE VAN STADEN | From Dealer to Leader

### Human Rights and Advocacy Officer, SANPUD, South Africa

I was born in 1975 in an average income-earning home, west of Pretoria in South Africa, during a period of political upheaval. One aspect of my growing up that I wish I could have changed was the fact that my parents were both alcoholics. My father worked as a gas inspector for a large refinery plant and my mother worked in the funeral sector. They were both hard-working, functioning, and we were never exposed to violence or any of the other stereotypical "children of alcoholics" rhetoric. Contrary to the usual narrative, our home was filled with love and there was always enough food and plenty of laughter! For the most part we were a very happy family. Unfortunately though, both succumbed at a relatively young age to the bottle. My mother passed away in 2008 (age 49) and my father in 2007 (age 53).

When I was 15 I started going to clubs in Pretoria and experienced my first interactions with psychoactive chemicals, namely ecstasy and LSD. The very next day after using LSD I tried heroin and absolutely fell in love! I loved what the drug did for me. It took all away all the pain, all the heartaches, and it didn't matter that people said "You're a worthless junky, you have no discipline, you're a criminal, you have no ethics." There was nothing that could bother me.

I became the person that parents warned their kids about! I was the Popular One, the guy everybody wanted to know, the life of the party. Of course a lot of the "heavyweights" in the clubs noticed this and asked me to sell drugs to the clubbers. This became a great way for me to support my own (now quickly forming) habit.

For many years I was a functional user. I was able to work, engage with family and friends, maintain regular social contacts... I even managed to finish high school grade 12 in 1994 but did not go on to tertiary studies. When I was around 21, I tried to stop heroin but couldn't. Not only was it a barrier between the harsh world and myself, I had also become physically dependent on it, experiencing terrible withdrawal when it was unaccessible.

When my father passed away in 2007, I increased my use, lost my job, ran away from home and ended up living on the streets. Fear and the lack of resources and facilities all inhibited my choice to make changes. Many doctors at the time were unaware of how to correctly administer medication like Suboxone and methadone. Stigmatized drug use and social exclusion only served to keep me further from getting proper help. I believe a lot of this stems from lack of education, not only with doctors and nurses but also within our communities.

In 2015, a new organization in Pretoria called Step Up started to provide health care services to heroin users and sex workers residing on the street. I got involved as I felt I had valuable life lessons that I could contribute. At the same time I started a drug user network called DUG, Drug users of Gauteng, providing for the first time in South Africa a platform for local substance users to have a voice and a sense of belonging. I was then the very first person to be initiated in the Step Up project and the NSP program. Today we have over 3,000 people accessing the program and our network has 175 registered members in the city center alone.

In 2016 Step Up hired me as a paid employee and thus for the first time I was given an opportunity to really change my life. A lot of people ask me what made me decide to change? It is the mere fact that a complete stranger showed me unconditional love and respect. This organisation didn't judge me no matter what I decided to do with my life and that made me think: If a complete stranger can treat me like this maybe I deserve better. From that day on I started to make better health and self-care decisions for my life.

Today I earn a good salary, I am engaged in a methadone programme, I have my own accommodation, my own laptop, my own cell phone. I conduct engagements with substance users, police officers, health care workers and university professors. I am proud of my life changes and I hope to continue to be an Ambassador for the substance using population in our country.

### DAVID NUTT | A method for the holistic assessment of substances

### Imperial College London, United Kingdom

I am a psychiatrist and psychopharmacologist. My expertise is using drugs/medicines to explore brain function in healthy volunteers and people with psychiatric disorders. Because the brain is a neurotransmitter-driven organ and drugs act to change neurotransmitter function, I believe this approach provides the best way of interrogating brain function, especially if used with neuroimaging techniques such as PET and fMRI.

Over a career of nearly 40 years, I have studied almost every class of drug in humans. These include some potent, dangerous and often abused drugs such as opioids (heroin, hydromorphone, methadone and buprenorphine), as well as benzodiazepines, ketamine and alcohol. I am able to use these because they are either medicines or legal drugs. However, when I wanted to study psychedelics and cannabis I found my path was blocked because of the Schedule I status. The UK government treats these as much more dangerous or desirable (from the consumer perspective) than those others already mentioned despite overwhelming evidence that psychedelics are very safe (almost no deaths) and are rarely abused. Cannabis is also relatively safe having been a medicine in the UK until 1971.

The impact of this on my research has been immense. To store and research either psychedelics or cannabis I need to have a special, higher-level police check than the one I am required to have before I can prescribe opioids. I also need to get a special license from the Home Office, which is expensive in terms of time (it can take up to a year to obtain) and cost (around £3000 plus an annual retention fee). There are no special licenses required to hold or research the opioids mentioned above, nor for benzodiazepines or ketamine. This clearly reveals that the purpose of the Schedule 1 restriction is not to reduce supplying drugs for money, since heroin and methadone have significantly more street value. Also, in the UK, there has never been an example of a researcher selling Schedule I drugs; the fear of diversion is a ploy to justify the current status of drug control.

In our first study of psilocybin\* in the treatment of resistant depression, I calculated that because of the extra costs incurred by the Schedule I status of psilocybin, each dose cost around £1500 – more than ten times the amount if the restrictions were not in place. This money is taken from research grants and so undermines their financial viability and reduces their extent. It also took us over 2 years to get the permissions to conduct the research, which represents a huge lost opportunity cost.

Perhaps if the current scheduling did reduce recreational drug use or harms one might be able to accept the stifling effect it has on research and clinical treatment. But there is absolutely no evidence that it does this. So now it's time to change so we can all benefit.

<sup>\*</sup> A naturally occuring psychedelic compound produced by certain species of mushroom

### GILLES FORTE | WHO's mandated role in the drug control conventions

### Secretary to the WHO Expert Committee on Drug Dependence

The World Health Organisation (WHO) has an important role in setting global standards by providing public health guidance and recommendations that are scientifically robust, transparent, and independent.

WHO has a special mandate that is given by the international drug control conventions for recommending the level of international control for substances with psychoactive effects. It does this through the Expert Committee on Drug Dependence (ECDD), an independent scientific advisory body to WHO. WHO's work in reducing the supply of harmful psychoactive substances has become a core part of the international drug control system and has shown how important it is to protect the health of the most vulnerable.

The ECDD is a cornerstone for tackling the opioid crisis and has recommended the international control of many new psychoactive substances that have emerged onto the illicit drug market since 2014. In some parts of the world, particularly in high-income countries, the overprescribing of opioid medicines has led to increased rates of dependence and to a shift towards the use of more potent synthetic substances such as fentanyl analogues that have contributed to increased overdose deaths in the world.

One of these potent synthetic opioids is carfentanil, which is used as an adulterant to heroin and can produce lethal effects at extremely small doses. The ECDD recommended placing carfentanil under the strictest level of international control, therefore limiting its supply and potentially saving lives.

Though many psychoactive substances that cause public health harm do not have legitimate medical uses, many psychoactive medicines with proven therapeutic uses, such as opioid analgesics and benzodiazepines, can be harmful when not used appropriately. An unintended consequence of controlling substances with proven therapeutic use is that it would restrict access for legitimate use to people who need these medicines that could save lives and relieve pain and suffering. WHO estimates that 83% of the world's population lives in countries with low or non-existent access to controlled medicines for the treatment of moderate to severe pain.

The ECDD has played an important role in providing balanced recommendations in the international control of psychoactive medicines. These include anaesthetics like ketamine, whose excellent safety profile means that it can be administered without the usual level of anaesthesia monitoring, therefore making it widely used in low income countries and emergency situations. It also includes medicines such as tramadol, one of the few opioid pain medications available in generic form. It is widely used in many low- and middle-income countries and in crisis situations where access to other opioids for the management of pain is limited or not existent.

As ECDD intensifies the number of harmful synthetic cannabinoids, amphetamine-type stimulants and fentanyl analogues that are placed under international control, it also ensures that international control measures do not restrict access to essential and life-saving medicines.

# NEIL WOODS | "Tough on drugs" only breeds more violence: a police officer's perspective Law Enforcement Action Partnership, United Kingdom

They were using gang rape as a method of control and intimidation.

Police in Northampton had had some success against the local heroin dealers. This opened the door for the notorious Birmingham gang, the Burger Bar Boys, to take over. The Burgers knew the fundamental drug war truth that "the most brutal gangs are the hardest to catch" – and let people know that any collaboration with the police would be endangering not just themselves, but their wives and sisters.

That's why I was sent in undercover. I spent months buying heroin from these young men. It's the heroin trade that is the most brutal market because it attracts the biggest sentences in court. It is a Class A Drug and judges are told it's the one to punish most. The bigger the risk, the bigger the pushback in the never ending arms race of the drug war.

One day D didn't pull up in the usual sports car but in a mini van. There were four others with him. D said "What do you think?" one of them replied, "Yeah he's fucking Five-O...fucking do him bro, just fucking kill him now". I was shown a Glock handgun and told to take my shirt off, then my pants. As they stood around me laughing I wondered if they were really suspicious, or if this was just their standard way to terrify and control their customers.

After seven months of work I had enough evidence against the gang and their whole support network. 96 people were arrested, many of them in a huge series of raids with support from four different police forces. An Intelligence Officer later told me that for all that effort, the heroin and crack supply had been interrupted for maybe two hours.

The Burger Bar Boys each got 10 years in prison in a public celebration of "getting tough on dealing". All the next gang learned was to be even more vicious to evade capture.

"Successes" like mine are not in isolation. Police across the world are really good at catching drug dealers. But this is part of the problem. Where the threat of prison is high, then police action makes the street gangs more brutal, in a simple Darwinian process.

In the U.K. the scene is deteriorating fast, precisely due to police success. Children are now used as a buffer zone between the gangsters and cops. Kids as young as 12 are exploited to be proxy dealers. Often they are filmed in sexualized situations to blackmail them, all the easier to make them carry bundles of heroin in the rectum, and sell the product to other vulnerable people criminalized by The State.

This is the never-ending arms race of the drug war, forever fuelled by "tougher sentences". It will only end when society can no longer stomach the corruption it entails. How bad does it have to get?

### PEDRO ARENAS | The harms of forced crop eradication

Observatory of Growers and Cultivations Considered Illicit (Observatorio de Cultivos y Cultivadores Declarados Ilícitos, OCCDI Global), Colombia

My name is Pedro Arenas. I was born on the banks of a river in the southeastern part of Colombia. In the early 1980s, as I was finishing primary school, my father did not find further schooling for me. In this rural area there were no secondary schools. Therefore, like many other adolescents, I went to work in the field collecting coca leaves from crops that were grown in the region. I was barely 13 years old and started earning my own income.

I remember the adults commenting that growing this crop was an illegal activity, and therefore we could be arrested by the authorities at any time. Faced with this fear, farmers increasingly moved into more remote and more environmentally important areas of the forest. So I continued my work as a coca leaf collector south of Guaviare, a region that today faces the highest rate of deforestation in the Colombian Amazon region.

In the 1990s, aerial fumigations against coca crops with the herbicide glyphosate generated losses of legal crops, broke family economies that were based on this activity, and led to human rights violations. My mother also lost her cultivation and had to leave the countryside and all that she owned to move to the nearest city and start her life over.

We carried out protests as peasant organizations. I reported to several authorities the damages caused by the fumigations to families, their food security and the environment. Nevertheless, the state continued to fumigate for another 21 years, ignoring the complaints, and did not investigate human rights violations. There were also threats, attacks, and assassinations of protest leaders. I myself have suffered threats, persecution, and two attacks that almost cost me my life.

Since then, I have worked to defend the human rights of indigenous people, farmers and Afro-descendants who grow coca for traditional and cultural purposes, as well as those families who do it to obtain coca paste. I have seen campaigns that stigmatize that plant and persecute the farmers who make a living from it.

I can say that farmers have been punished with forced displacement and even imprisonment for undertaking an activity that is seen by us as normal. Forced eradication has only had negative consequences for families and does not provide sustainable results. For this reason, I say that we should not have policies for drugs that are only measured by the area under cultivation and areas eliminated every year, but not against overcoming poverty and advancing development.

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### **ADDITIONAL RESOURCES**

www.anyoneschild.org

www.beckleyfoundation.org

www.druglawreform.info

www.drugpolicy.org

www.genevaplatform.ch

www.hri.global

www.hrw.org

www.intercambios.org.ar

www.icsdp.org

www.idhdp.com

www.idpc.net

www.inpud.net

www.incb.org

www.menahra.org

www.ohchr.org/EN/HRBodies/HRC/Pages/

WorldDrugProblem.aspx

www.politica dedrog as.org/PPD

www.sdglab.ch

www.talkingdrugs.org

www.tdpf.org.uk

www.unaids.org/en/topic/key-populations

www.unodc.org

www.wola.org/program/drug\_policy

www.wacommissionondrugs.org

www.who.int/topics/substance\_abuse/en/

### REPORTS BY THE GLOBAL COMMISSION ON DRUG POLICY

(http://www.globalcommissionondrugs.org/reports/)

War on Drugs (2011)

The War on Drugs and HIV/AIDS: How the Criminalization of Drug Use Fuels the Global

Pandemic (2012)

The Negative Impact of the War on Drugs on Public Health: The Hidden Hepatitis C Epidemic (2013)

Taking Control: Pathways to Drug Policies That Work

(2014)

The Negative Impact of Drug Control on Public Health: The Global Crisis of Avoidable Pain (2015)

Advancing Drug Policy Reform: a new Approach to

Decriminalization (2016)

The World Drug Perception Problem: Countering Prejudices against People Who Use Drugs (2017)

Regulation: the Responsible Control of Drugs (2018)

# POSITION PAPERS BY THE GLOBAL COMMISSION ON DRUG POLICY

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The Opioid Crisis in North America (October 2017)

Drug Policy and the Sustainable Development Agenda (September 2018)

Drug Policy and Deprivation of Liberty (June 2019)

### **ACKNOWLEDGEMENTS**

### **Technical Coordination**

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### **GLOBAL COMMISSION ON DRUG POLICY**

The purpose of the Global Commission on Drug Policy is to bring to the international level an informed, science based discussion about humane and effective ways to reduce the harm caused by drugs and drug control policies to people and societies.

### **GOALS**

- Review the base assumptions, effectiveness and consequences of the punitive drug policies
- Evaluate the risks and benefits of different national responses to the drug problem
- Develop actionable, evidence-based recommendations for constructive legal and policy reform.

