VICENTE SEDERBERG LLP

455 Sherman Street, Suite 390
Denver, CO 80203
Tel: 303-860-4501

Austin | Boston | Denver | Jacksonville | Los Angeles | New York

MEMORANDUM

To: International Narcotics Control Board

From: Vicente Sederberg LLP

Date: December 1, 2020

RE: Control of Preparations of CBD under International Drug Control Regimes and Impacts of Potential Reforms

INTRODUCTION

International control of narcotic drugs and psychotropic substances is coordinated between Member States[1] across the globe pursuant to a framework established by three international treaties: the Single Convention on Narcotic Drugs of 1961 (the "'61 Convention"); the Convention on Psychotropic Substances of 1971 (the "'71 Convention"); and the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (referred to hereinafter together with the "'61 and '71 Conventions as the "Conventions"). The purpose and core objective of the Conventions is to limit the production and use of narcotic drugs and psychotropic substances and their precursors to medical and scientific purposes.

Although cannabis and its active component THC have long been controlled under the strictest schedules of the '61 Convention (cannabis) and the '71 Convention (THC), cannabis had never been subject to a formal review until 2019 when the United Nations ("UN") Commission on Narcotic Drugs ("CND") requested the World Health Organization ("WHO") to: (i) provide an updated report on cannabis and; (ii) to undertake in consultation with the International Narcotic Control Board ("INCB"), as appropriate, a review of dronabinol and its stereoisomers when additional information became available. WHO performed its review of cannabis and related substances by carrying out a two-stage process to first determine, through a so-called pre-review, whether there was adequate information about cannabis and cannabis-related substances to justify a critical review, before arriving at six recommendations to revise the placement of cannabis in the control schedules of the Conventions in alignment with WHO's findings. Notably, one of these recommendations clarifies that CBD is not under international control:

• **5.1:** Delete cannabis and cannabis resin from Schedule IV of the '61 Convention.
• **5.2.1:** Add dronabinol and its stereoisomers (delta-9-THC) to Schedule I of the '61 Convention.   ○ **5.2.2:** If 5.2.1 is adopted: Delete dronabinol and its stereoisomers (delta-9-THC) from Schedule II of the 1971 Convention.

[1] The term "Member States" as used herein refers to the signatories of the Conventions.

• **5.3.1:** If 5.2.1 is adopted: Add tetrahydrocannabinol to Schedule I of the '61 Convention.   ○ **5.3.2:** If 5.3.1 is adopted: Delete tetrahydrocannabinol from Schedule I of the 1971 Convention.
• **5.4:** Delete extracts and tinctures of cannabis from Schedule I of the '61 Convention.
• **5.5:** Add a footnote on cannabidiol preparations to Schedule I of the '61 Convention to read: "Preparations containing predominantly cannabidiol and not more than 0.2 percent of *delta*-9-tetrahydrocannabidiol are not under international control".[2]
• **5.6:** Add preparations containing dronabinol, produced either by chemical synthesis or as preparations of cannabis that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that dronabinol cannot be recovered by readily available means or in a yield which would constitute a risk to public health, to Schedule III of the '61 Convention.

These six recommendations are currently being considered by Member States with a vote expected in December.

In response to these recommendations, on June 15, 2020, INCB published an *Analysis of the impact of the WHO recommendations on cannabis and cannabis-related products on the control requirements of the international drug control system* (the "INCB Analysis"), articulating the INCB's position on the recommendations. In the INCB Analysis, INCB asserts:

1. "Cannabidiol (CBD) is not explicitly listed but it is under control as an extract of cannabis under the 1961 Convention."[3]; and
2. The cultivation of cannabis for the extraction of CBD (for any purpose other than a clearly approved medical purpose) is not exempt from control under the '61 Convention because such cultivation does not constitute an "industrial purpose" (fibre and seed) under article 28 paragraph 2 of the '61 Convention.

This memorandum contests INCB's assertion that CBD must be controlled as an extract of cannabis under the '61 Convention, positing instead that the '61 Convention does not mandate this approach. This paper further contests INCB's conclusion that the cultivation of the cannabis plant for "industrial purposes" is limited exclusively to the production of fibre and seed. Rather, both

[2] The WHO, when making its recommendations determined that Member States, in consultation with INCB, could make their own determinations on the standard to apply to the word "predominately" when applied to preparations of CBD. While the WHO appears to understand that Member States maintain unabridged authority to implement the requirements of the Conventions, is creates the inclusion of INCB in this process out of thin air as the treaties contain nothing requiring Member States to consult with INCB.

[3] INCB, *Analysis of the impact of the WHO recommendations on cannabis and cannabis-related products on the control requirements of the international drug control system*, June 15, 2020, at 1.

the control of CBD and the scope of the "industrial purposes" exemption (article 28 paragraph 2 of the '61 Convention) are matters of interpretation by the Member States, many of which have interpreted the Conventions to exempt preparations of CBD from control as an extract of cannabis on various grounds. The interpretation by Member States that preparations of CBD are not subject to control appropriately reflects the fact that CBD is not scheduled in either the '61 Convention or the '71 Convention, is consistent with both the intent of the Conventions and existing precedent, and (as discussed in detail below), is consistent with the findings of WHO as to the safety, lack of potential for abuse, and therapeutic efficacy of CBD.

I. Summary of INCB Position

The INCB Analysis sets forth INCB's current position regarding cannabis-derived preparations of CBD and cannabis plants cultivated for the production of CBD. In this analysis, INCB recognizes that CBD is not explicitly listed as a substance subject to control.[4] This recognition is consistent with the Conventions requirements for changing the scope of control and the findings from the WHO that: (i) there is no evidence that CBD, as a substance, is liable to similar abuse or leads to similar ill-effects to controlled substances in the '61 or '71 Conventions, such as cannabis or delta-9-THC; (ii) CBD has been found to be generally well-tolerated, with a good safety profile and with limited adverse effects; and (iii) therapeutic applications of CBD are being researched for a variety of clinical uses. INCB's position that CBD is not independently controlled under the Conventions is also consistent with interpretations of the many Member States that have implemented laws permitting the production of CBD as an industrial purpose of the cannabis plant.[5]

Despite the lack of explicit control and its demonstrated safety profile, INCB asserts that preparations of CBD derived from an extract of cannabis are subject to control as an "extract or tincture of cannabis," a Schedule I controlled substance under the '61 Convention. This position is grounded in the '61 Convention's control over the parts of the cannabis plant in which CBD is concentrated (flowering tops) and commercially viable to extract. INCB also asserts that the preparations of CBD containing any amount of THC (specifically delta-9 THC) are subject to control in accordance with the scheduling of THC under the '71 Convention.[6] THC, its isomers, and its stereochemical variants are included in Schedule I of the '71 Convention. The isomer delta-9-THC, and its stereo-chemical variants, with one variant being dronabinol ((-)-trans-delta-9-THC), are currently listed in Schedule II of the '71 Convention.

The '61 Convention does not recognize all parts of the cannabis plant as controlled substances but instead includes only certain components of the cannabis plant as substances under control. Cannabis is defined in the '61 Convention as "the flowering or fruiting tops of the cannabis

---

4 INCB, *Analysis of the impact of the WHO recommendations on cannabis and cannabis-related products on the control requirements of the international drug control system*, June 15, 2020, at 1.

5 Many Member States refer to cannabis plants cultivated for industrial purposes as "industrial hemp" or "hemp" and regulated the production of CBD derived therefrom.

6 INCB, *Analysis of the impact of the WHO recommendations on cannabis and cannabis-related products on the control requirements of the international drug control system*, June 15, 2020, at 7 ("cannabis cultivated for the extraction of CBD would have some delta-9-THC content, however small, and this would have to be controlled in accordance with its scheduling.").

plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted…". The flowering tops of the cannabis plant are controlled as both a Schedule I[7] and a Schedule IV[8] substance. Extracted cannabis resin is also subject to control under the '61 Convention as both a Schedule I and a Schedule IV substance. Cannabis resin is defined as "the separated resin, whether crude or purified, obtained from the cannabis plant." Additionally, the "extracts and tinctures" of cannabis and cannabis resin are also designated as Schedule I under the '61 Convention.[9] Thus, INCB asserts that CBD is an extract and tincture of cannabis when the CBD is extracted from the flowering tops and/or purified from extracted cannabis resin.

The cannabis plant is defined separately from cannabis and cannabis resin as "any plant of the genus Cannabis." Unlike cannabis and cannabis resin, cannabis leaves are not specially scheduled as a controlled substance but are subject to various regulatory and reporting requirements. For example, Member States must "adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant" (even though these leaves are not controlled), which entails the use of control measures on the cultivation of cannabis plants for use of the leaves if delta-9-THC is present.

In addition to certain botanical *parts* of the cannabis plant (seeds, leaves) being clearly exempt from control as "cannabis," specific *uses* of the cannabis plant are also exempted from control under the '61 Convention. Article 28 of the '61 Convention expresses this critical exemption:

> *This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.*

This exemption is especially important because, unlike the laws of many Member States, the '61 Convention does not differentiate between high-THC varietals of cannabis and low-THC varietals of cannabis, which are commonly referred to under the laws of many Member States as "hemp." Instead of differentiating control based on THC concentration, the '61 Convention delineates levels of control based on end-use of the cannabis plant, with cannabis plants cultivated for industrial and horticultural purposes exempt from the scope of the '61 Convention. As discussed below, this important distinction provides the legal basis for the industrial hemp programs implemented by Member States, many of which allow for CBD production.

Nevertheless, INCB seeks to assert that CBD production is not a valid industrial purpose of the cannabis plant. In the INCB Analysis, INCB asserts "the cultivation of cannabis for the

---

7 Schedule I is reserved for drugs liable to significant abuse and to produce ill effects, but have potential therapeutic uses.

8 Schedule IV is reserved for drugs listed in Schedule I which are particularly liable to abuse and to produce ill effects, and where such liability is not offset by substantial therapeutic advantages.

9 Notably, per INCB, cannabis and cannabis resin are scheduled under the '61 Convention because they are liable to abuse and to produce ill-effects and do not have therapeutic advantages that offset these effects. However, this rationale is not supported by the findings of the WHO. The WHO concluded that preparations of CBD exhibit no effects indicative of any abuse or dependence potential, that CBD is generally well tolerated with a good safety profile, and that there is evidence that CBD may be a useful treatment for a number of medical conditions (*See* World Health Organization, "*Cannabidiol (CBD) Critical Review Report*," (2018)).

extraction of CBD would need to be monitored under the provisions of the 1961 Convention because it does not meet the definition of "industrial purposes" (fibre and seed) of article 28 paragraph 2." In support of this conclusion, INCB remarks that "the 1961 Convention limits the cultivation of cannabis for industrial purposes to fibre and seed." In other words, INCB interprets the Conventions to permit the cultivation of cannabis plants only for the production of seed and fibre or for medical, scientific, or horticultural purposes and considers the cultivation of cannabis for any other purpose, including CBD extraction for use in *e.g.*, food or beverage products, to be illicit.

In taking this position, INCB seemingly conflates the restrictions under the '61 Convention on *"the cultivation of the cannabis plant for the production of cannabis* [defined as the flowering and fruiting tops] *and cannabis resin*" (article 28, paragraph 1) with the cultivation of cannabis plants in general. This is a critical mistake because only the former is subject to the control mechanism of articles 23 and 28 of the '61 Convention, and the realm of licit purposes is greater than the INCB Analysis suggests. As the Official Records and Commentary on the '61 Convention (the "Commentary") demonstrates, article 28, paragraph 2, does not express the entire realm of "industrial purposes" and is not intended to strictly limit the permitted uses of the cannabis plant as INCB contests. Rather, the provisions of the '61 Convention on cannabis cultivation (articles 23 and 28) apply "*only to the cultivation of the cannabis plant for the production of cannabis and cannabis resin.* ***Cultivation of the plant for any other purpose, and not only for the purposes mentioned in paragraph 2 [(fibre and seed)], is consequently exempted from the control régime"*** *(emphasis added).*[10]

The drafting history of article 28 evidences this key provision of the Commentary. The terms "fibre and seed" were first used in place of "industrial purposes," which would have limited the exemption solely to these two specified uses. However, "fibre and seed" was removed in favor of "industrial purposes" to permit a broader range of uses. The reference to "fibre and seed" was added to the final version of the '61 Convention in its current parenthetical form to provide two examples of many industrial purposes in an effort to help Member States understand the meaning of "industrial purposes" and to provide Member States with the flexibility to address future innovations and the development of other industrial uses of the cannabis plant. Therefore, INCB's inappropriate application of article 28, paragraph 1 to cannabis plants cultivated for CBD production is contrary to the plain language and intent of article 28, paragraph 2 of the '61 Convention.

II. Member States can reasonably interpret, and do reasonably interpret, the '61 Convention such that preparations of CBD are not subject to control as an extract or tincture of cannabis

Member States are tasked with interpreting and enforcing the Conventions' requirements subject to interpretive rules, and latitude is given to Member States to defend and enforce specific positions as they relate to drug control in their home country. As a result, a growing number of Member States, including the United States, have expanded access to preparations of CBD containing low levels of THC by embracing sensible interpretations of the Conventions supporting

[10] United Nations, "*Commentary on the Single Convention on Narcotic Drugs, 1961*," (Aug. 3, 1962), at 312.

self-regulation of such substances. As noted above, extracts and tinctures of cannabis are designated as Schedule I under the ’61 Convention. However, Member States are increasingly interpreting the ’61 Convention such that preparations of CBD are not subject to control as an extract or tincture of cannabis, even when the preparations of CBD are derived from an extract of the flowering or fruiting tops of the cannabis plant. In *Questions and answers relating to WHO’s recommendations on cannabis and cannabis related substances*, November 26, 2019, the UN Office of Drugs and Crime observes that “Some countries hold the interpretation, based on the object and purpose of the treaty provisions, that preparations derived from cannabis that are not psychoactive (*i.e.*, rich in CBD and very poor in THC content), would already now fall outside the scope of control of the Convention.”[11] While the position advanced in the INCB Analysis appears to discredit or ignore this interpretation by Member States, this interpretation is well supported by the ’61 and ’71 Conventions, existing Convention precedent, and the spirit and intent of the Convention.

In such circumstances where INCB’s interpretation is clearly at odds with that of Member States, INCB’s role, as a monitoring body (rather than a guardian of the Conventions), is work to reconcile such differences and review the best approaches that arise from the debate rather than to adamantly defend or enforce its own interpretation. It is the duty of the Member States (and authorities within the UN system) to then defend and enforce specific positions and approaches as compliant. Of course, INCB is well within its rights to defend treaty provisions against an interpretation which does not follow the rules of interpretation by which all parties to the Conventions are bound. Indeed, the authority of Member States to interpret the Conventions is limited by the rules of interpretation set forth in the Vienna Convention on the Law of Treaties, and an interpretation without application of such rules must be challenged.[12]

In the case of the reasonable interpretations of Member States justifying sensible self-regulation of preparations of CBD containing low levels of THC, INCB should assess the most appropriate approach by reviewing and reconciling Member State interpretations along with the science of CBD and its regulation in practice around the globe, rather than setting aside the arguments of Member States and promoting a narrow interpretation that is both at odds with the intent and spirit of the Conventions and untenable in practice.

A. <u>CBD not Scheduled in ’61 Convention.</u>

As more thoroughly discussed below, CBD itself is not scheduled in either the ’61 Convention or ’71 Convention. Thus, CBD is not subject to international control. Some argue that cannabis-derived CBD falls under Convention control as an “extract and tincture” of cannabis, but as explained herein, such control does not conform with the construction or intent of the Conventions. This position is illustrated by a recent decision from the Court of Justice of the European Union[13] holding that “since CBD does not contain a psychoactive ingredient in the

[11] CND, *Questions and answers relating to WHO’s recommendations on cannabis and cannabis-related substances*, (Nov. 26, 2019), at 71.

[12] *Vienna Convention on the Law of Treaties*, 23 May 1969,http://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf.

[13] Note the Court of Justice of the European Union is a court of limited jurisdiction and its rulings are not widely

current state of scientific knowledge …, it would be contrary to the purpose and general spirit of the ['61 Convention] to include it under the definition of 'drugs' within the meaning of [the '61 Convention] as a cannabis extract."[14] In its decision the Court also notes that "CBD, however, is not mentioned in the ['61 or '71 Conventions] and, while it is true that a literal interpretation of the ['61 Convention] might lead to its being classified as a drug, in so far as it is a cannabis extract, such an interpretation would be contrary to the general spirit of that convention and to its objective of protecting 'the health and welfare of mankind'."[15] Preparations of CBD containing a low THC content (*e.g.*, no more than 1%) can therefore be excluded from control because they are not scheduled, are not psychoactive, and not liable for abuse or similar ill effects,[16] and their allowance is implied in Convention precedent.

WHO, in its "*Questions and answers relating to WHO's recommendations on cannabis and cannabis-related substances*", argues that preparations of CBD containing low concentrations of THC should be controlled under the Conventions because such preparations are not specifically exempt from control under the Conventions, leaving ambiguity as to its control.[17] However, it is the explicit inclusion of a substance under the Conventions that subjects it to control, not the lack of an exemption. The regulation of the poppy plant under the Conventions illustrates this control principle in the Conventions. Both INCB and WHO acknowledge that opium poppy varieties rich in noscapine and papaverine are specifically exempt from control of the Conventions, despite the presence of morphine content (which is controlled under the Conventions).[18] Like CBD, noscapine (an alkaloid derived from the opium plant) is a derivative of a controlled substance that is not, itself, controlled under the Conventions. Instead of promoting the scheduling or creating a footnote exception for noscapine and papaverine (as is being suggested for CBD and cannabis), INCB simply requests that countries cultivating this form of poppy report the cultivation. INCB rationalizes this tactic as a way to provide "some control measures to ensure that internationally controlled substances are not diverted or abused."[19] INCB appears to believe that reporting requirements and Member States' self-regulation are enough to prevent the diversion of controlled opiates into the illicit market, so why not the same for CBD, which is a much safer substance?

---

applicable to all Member States nor binding on the INCB. Furthermore, in the cited case the Court opined on provisions of EU law, in particular the provisions on the free movement of goods, in relation to French legislation as applied to specific CBD products derived from all parts of the cannabis plant. Despite these clear limitations on both the jurisdiction of the court and the scope of the court's ruling, this ruling nevertheless ruling provides a contemporary example of how the spirit and intent of the Conventions are interpreted in relation to preparations of CBD.

14 Case C-663/18, B S and C A v. Ministère public et Conseil national de l'ordre des pharmaciens, 2020 E.C.J. 141/20

15 Case C-663/18, B S and C A v. Ministère public et Conseil national de l'ordre des pharmaciens, 2020 E.C.J. 141/20.

16 *See* United Nations, *Single Convention on Narcotic Drugs, 1961: As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961*, Art. 2(9)(a).

17 CND, "*Questions and answers relating to WHO's recommendations on cannabis and cannabis-related substances*," (Nov. 26, 2019) at 27.

18 CND, "*Questions and answers relating to WHO's recommendations on cannabis and cannabis-related substances*," (Nov. 26, 2019).

19 INCB, *Analysis of the impact of the WHO recommendations on cannabis and cannabis-related products on the control requirements of the international drug control system*, June 15, 2020, at 7.

B. Preparations of CBD with low THC are excluded from control under the '61 and '71 Conventions because they are not liable for abuse or similar ill effects.

Cannabis and cannabis resin were included in Schedule I and IV of the '61 Convention because, at the time, it was believed that (based solely on its THC content) cannabis and cannabis resin were liable for abuse and had no therapeutic advantages that offset those effects.[20] However, even with such a limited understanding of cannabis and cannabis resin, the '61 Convention made several exceptions to prohibition (*e.g.*, industrial, medical, scientific purposes, the leaves separated from flowering tops) and did not even contemplate CBD. Even the flowering tops of the cannabis plant, which contain "resin" and are expressly controlled by the '61 Convention, are excluded from control if cultivated for industrial or horticultural purposes.[21]

Unlike the high-levels of THC contemplated by the Convention drafters, which may be present in certain high-THC varieties of the cannabis plant, preparations of CBD, which by nature contain low-levels of THC, were not meant to be under Convention control.[22] "[CBD] shows no potential for abuse or dependence, and any ill-effects are minimal,"[23] and thus CBD does not satisfy the criteria for control. INCB also believes that "there is no evidence that CBD as a substance is liable to similar abuse or leads to similar ill-effect to substances in the '61or '71 Conventions . . . CBD has been found to be generally well tolerated, with a good safety profile and with limited adverse effects."[24]

Additionally, WHO recognizes that cannabis-based preparations containing a combination of dronabinol and CBD have been approved for medical use, and while there are adverse effects related to the use of such medications, they "have not been considered so severe as to prevent medical use."[25] It is therefore quite contradictory to recommend that pharmaceutical "preparations containing dronabinol," which have adverse effects on the consumer, be excluded from some of the Conventions' control provisions while simultaneously trying to control CBD, which has a good safety profile and minimal, if any, adverse effects. By promoting pharmaceutical based preparations of cannabis over naturally occurring preparations of CBD, WHO, at best, misunderstands the '61 Convention's intent, and at worst, simply aims to promote pharmaceutical corporations over local farmers, medical professionals, and small businesses. Unlike many pharmaceutical preparations, high-CBD cannabis preparations containing low-THC elements were

---

20 INCB, *Analysis of the impact of the WHO recommendations on cannabis and cannabis-related products on the control requirements of the international drug control system*, June 15, 2020, at 1.

21 United Nations, *Single Convention on Narcotic Drugs, 1961: As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961*, Art. 28(2).

22 United Nations, "*Commentary on the Single Convention on Narcotic Drugs, 1961*," (Aug. 3, 1962), at 316.

23 CND, *Questions and answers relating to WHO's recommendations on cannabis and cannabis-related substances*, (Nov. 26, 2019), at 65.

24 INCB, *Analysis of the impact of the WHO recommendations on cannabis and cannabis-related products on the control requirements of the international drug control system*, June 15, 2020, at 6.

25 CND, *Questions and answers relating to WHO's recommendations on cannabis and cannabis-related substances*, (Nov. 26, 2019), at 30.

intended to be excluded from Convention control because the levels of THC are so low that they are non-intoxicating and present a minimal threat to the health, safety, and welfare of society.[26]

In drafting the Conventions, several intentional and important exceptions were made to strictly prohibit preparations of controlled drugs. These exceptions highlight the Conventions' intent of promoting the self-regulation and control of prohibited substances by Member States. So long as Member States can regulate and control the misuse and illicit trafficking of controlled substances, Member States have relative autonomy to enforce the Conventions in a manner that promotes the wellbeing of their citizens. As long as a Member State(s) complies with other requirements of the Conventions, article three of the '71 Convention excludes certain

> "preparation[s] containing a psychotropic substance other than a substance in Schedule I [that] is compounded in such a way that it presents no, or a negligible, risk of abuse and the substance cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem . . ."[27]

Additionally, article four of the '71 Convention permits the use of Schedule II substances, such as delta-9 THC, for the manufacture of non-psychotropic substances or products, "subject to the application of the measures of control required by this ['71] Convention until the psychotropic substances come to be in such a condition that they will not in practice be abused or recovered."[28] This critical provision allows for the presence of delta-9 THC in preparations of CBD, so long as the THC cannot be abused or recovered. With respect to potential abuse, recent studies have shown that preparations of CBD containing low-levels of THC (*e.g.*, containing no more than 1% THC) have no psychoactive effects on consumers.[29] This understanding is further enforced by a recent ruling from the Court of Justice of the European Union. In its ruling, the Court notes that "[a] Member State may not prohibit the marketing of cannabidiol (CBD) lawfully produced in another Member State when it is extracted from the Cannabis sativa plant in its entirety and not solely from its fibre and seeds."[30] The Court rationalized its conclusion in that CBD is not controlled under the Conventions, and ". . . according to the current state of scientific knowledge, which it is necessary to take into account . . .the CBD at issue does not appear to have any psychotropic effect or any harmful effect on human health."[31] WHO's own study also comes to this conclusion, stating that

---

[26] United Nations, *Single Convention on Narcotic Drugs, 1961: As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961*, Preamble.

[27] United Nations, *Convention on Psychotropic Substances, 1971*, Art. 3(2).

[28] United Nations, *Convention on Psychotropic Substances, 1971*, Art. 4(b).

[29] Franjo Grotenhermen and Michael Karus, "*Industrial hemp is not marijuana: Comments on the drug potential of fiber cannabis*," (last visited Oct. 12, 2020) http://www.internationalhempassociation.org/jiha/jiha5210.html.

[30] Case C-663/18, B S and C A v. Ministère public et Conseil national de l'ordre des pharmaciens, 2020 E.C.J. 141/20.

[31] Case C-663/18, B S and C A v. Ministère public et Conseil national de l'ordre des pharmaciens, 2020 E.C.J. 141/20.

it would be impossible for a human to ingest a lethal dose of THC, and thus THC has a "large margin of safety."[32]

By clarifying the exclusion of preparations of CBD containing low-THC elements from Convention control, the Conventions would more accurately promote the purpose and concern of the Conventions—to promote the health, safety, and welfare of humankind.[33] The regulation of un-scheduled substances is not the only exclusion by which Member States are permitted to self-regulate with respect to cannabis. Many additional exclusions exist for the production and transfer of cannabis despite the known possibility of diversion, including:

1. Member States may self-regulate and control the production, manufacture, export, import, distribution of, trade-in, use, and possession of substances used exclusively for medical and scientific purposes.[34] In instances where the production and distribution of cannabis and/or cannabis resin is permitted, the Member State is required under articles 28 and 23 of the '61 Convention to designate a national cannabis agency to assume control over the cannabis and cannabis resin within four months of harvest and to maintain exclusive rights for wholesale and foreign trade in the raw materials.[35]

2. Another, important basis by which Member States allow certain cannabis activity arises from the lack of real consequences if a Member State fails to comply with the Conventions. Although INCB can allege that a Member State is in non-compliance, recommend remedial action, or require a meeting with the Member State and suggest a new direction, it has limited authority to penalize Member States for non-compliance. The INCB does have authority under Article 14 of the 61 Convention and article 19 of the 71 convention to impose sanctions (such as trade restrictions or bans) where "the Board has objective reasons to believe that the aims of this Convention are being seriously endangered by reason of the failure of any Party, country or territory to carry out the provisions of this Convention"[36], but such authorities are only used in severe circumstances, and to date, INCB has never imposed actual sanctions. As evident in today's marketplace, many Member States apply the Conventions' requirements in a manner that was not intended—creating a regulated open marketplace for production and sale of cannabis and cannabis-derived products, rather than a monopoly run by a government agency. This shows that Member States are more willing to implement programs through the application of exceptions

---

[32] WHO Expert Committee on Drug Dependence Pre-Review, "*Delta-9-tetrahydrocannabinol: Section 3: Toxicology,*" Section 1.1 (2018).

[33] United Nations, *Single Convention on Narcotic Drugs, 1961: As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961*, Preamble.

[34] United Nations, *Single Convention on Narcotic Drugs, 1961: As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961*, Preamble, Art. 4(c).

[35] Article 23 requires that the state agency has exclusive rights for wholesale and foreign trade in raw opium, while specifying that "Parties need not extend this exclusive right to medicinal opium and opium preparations." Applied to cannabis that would translate to the agency having exclusive rights for wholesale and foreign trade in the unprocessed flowering tops and resin, but not necessarily for "medicinal cannabis and cannabis preparations".

[36] United Nations, Single Convention on Narcotic Drugs, 1961: As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961, Preamble; Art. 14..

rather than adhering to a narrow interpretation of the Conventions. Rather than try and force these Member States to tear down their current programs and implement new programs, INCB, WHO, and UN CND should propose reasonable recommendations that either permit low-THC (*e.g.*,1%) preparations of CBD or allow Member States to regulate and control their own programs, within appropriate limitations. This approach is consistent with the Conventions' intent and reflects what Member States are already successfully and responsibly doing through industrial hemp programs.

C. The occurrence of low levels of THC in a substance does not itself justify control. There is precedent and clear intent in the '61 Convention for exempting from control preparations of CBD that contain low levels of THC.

The '61 Convention excludes from control the "seeds and leaves" of the cannabis plant when not accompanied by the flowering tops,[37] including "'Marijuana' cigarettes containing material derived only from the leaves . . ."[38] The Convention gives control of this substance to Member States even though the leaves were found to be used in the illicit traffic of marijuana because "the leaves are not 'drugs.'"[39] Likewise, the control of preparations of CBD that contain low concentrations of THC, which are not subject to abuse or ill-effects in the consumer, should be left (and was intended to be left) to Member States control. The drafters deliberately excluded the leaves of the cannabis plant (when not accompanied by the tops) from control because they are not drugs, no matter what elements they contain. This exclusion may be justified on the grounds that the tops from which the resin has been extracted contain only a very insignificant quantity of the psychoactive principle (THC). Notably, the leaves and all portions of the cannabis plant contain *some* level of THC, albeit trace amounts, making clear that the presence of trace amounts of THC does not itself warrant control. Since the insignificant quantity of THC present in preparations of CBD, and generally regulated under industrial hemp laws by Member States, is not present in a yield or condition that would be easily recoverable or abused, then preparations of CBD with low-levels of THC, like the leaves of the cannabis plant, were intended to be excluded from Convention control.[40] CBD is never mentioned in the Conventions and is accordingly not subject to control. Since CBD is excluded from Convention control, and it is impossible to produce CBD from cannabis plants without any trace of THC, one can only conclude that preparations of CBD, which by nature contains low-levels of THC, are also excluded from Convention control. This interpretation is further supported by the fact that low amounts of THC (*e.g.*, up to 1%)[41] are non-intoxicating and do not provide a risk of misuse or abuse.[42]

D. Failing to recognize that CBD is not controlled under the Conventions will be catastrophic to the hemp industry and medical cannabis programs around the world.

---

37 United Nations, *Single Convention on Narcotic Drugs, 1961: As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961*, Art. 1(b).

38 United Nations, "*Commentary on the Single Convention on Narcotic Drugs, 1961*," (Aug. 3, 1962) at 3.

39 United Nations, "*Commentary on the Single Convention on Narcotic Drugs, 1961*," (Aug. 3, 1962), at 3, 276.

40 United Nations, "*Commentary on the Single Convention on Narcotic Drugs, 1961*," (Aug. 3, 1962), at 312, 316.

41 The "industrial hemp" laws of most Member States define legal hemp as having .2-1% THC)

42 *See* Franjo Grotenhermen and Michael Karus, "*Industrial hemp is not marijuana: Comments on the drug potential of fiber cannabis*," (last visited Oct. 12, 2020) http://www.internationalhempassociation.org/jiha/jiha5210.html.

A plethora of Member States have already implemented regulated, reasonable, and responsible programs for the cultivation of cannabis and the production of preparations of CBD. INCB should consider this reality and provide practical recommendations that: (i) fit into current regulatory regimes of Member States; (ii) promote consistent implementation of the Conventions across the world, and (iii) facilitate the international trade of preparations of CBD, instead of fostering unreasonable recommendations that will either destroy the current hemp and medical markets established around the world or go ignored entirely, further weakening the UN's authority and position.

III. The "industrial purposes" of cannabis cultivation are not limited to fibre and seed production

Article 28, paragraph 1 of the '61 Convention, requires Member States to implement control measures on the cultivation of the cannabis plant consistent with article *23 only when the cannabis plant is cultivated for cannabis or cannabis resin (drugs)*. Specifically, a designated national cannabis agency must assume control over the cannabis and cannabis resin within four months of harvest, and this national cannabis agency should maintain exclusive rights for wholesale and foreign trade. However, article 28, paragraph 2 clarifies that the '61 Convention does not apply "to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes."[43]

As introduced above, INCB believes that the cultivation of cannabis for the production of CBD mandates monitoring under the provisions of the '61 Convention because its cultivation does not meet the definition of "industrial purposes."[44] In making this conclusion, INCB relies on a clarifying parenthetical (fibre and seed) in article 28, paragraph 2, and narrowly interprets this parenthetical to provide an exhaustive description of industrial purposes. However, the purpose of this parenthetical is widely contested—some Member States argue, contrary to the position of INCB, that this parenthetical is not intended to definitively define industrial purposes, but rather to provide two illustrative examples of many possible industrial purposes. After all, there are speculated to be 10,000 uses of the cannabis plant, and it is impossible to cultivate stalks and seeds without also producing leaves and flowering tops. This interpretation by Member States is supported by the drafting history and the discussion by the Conference of Plenipotentiaries, which show no intention to exclusively limit the exemption to fibre and seed. In fact, the Commentary states in no uncertain terms that "paragraph 1 [of the article 28] expressly states that this regime [(articles 23 and 28)] applies only to the cultivation of the cannabis plant for the production of

---

[43] United Nations, "*Commentary on the Single Convention on Narcotic Drugs, 1961*," (Aug. 3, 1962), at 276 (quoting United Nations, *Single Convention on Narcotic Drugs, 1961: As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961*); INCB, *Analysis of the impact of the WHO recommendations on cannabis and cannabis-related products on the control requirements of the international drug control system*, June 15, 2020, at 7 (citing United Nations, *Single Convention on Narcotic Drugs, 1961: As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961*, Art. 28(2)).

[44] INCB, *Analysis of the impact of the WHO recommendations on cannabis and cannabis-related products on the control requirements of the international drug control system*, June 15, 2020, at 7.

cannabis or cannabis resin. Cultivation of the plant for any other purposes, and not only for the purposes mentioned in paragraph 2, is consequently exempted from the control regime provided for in article 23."[45]

Indeed, consistent with the Commentary, many Member States have already implemented regulated "industrial hemp programs" that take a more expansive perspective on the industrial purposes of the cannabis plant, including to permit the cultivation of cannabis plants for the production of preparations of CBD containing low-levels of THC. To frustrate the cultivation of cannabis plants for non-industrial purposes, Member States have established strict limits on the THC concentration of cannabis plants cultivated for industrial purposes as measured on a dry-weight basis and impose regulatory regimes that include tracking, reporting, registration, and testing requirements. In fact, many Member States, including the United States and Switzerland, have chosen thresholds for acceptable delta-9-THC content that are above the WHO Expert Committee on Drug Dependence's recommended 0.2%. For example, the United States a 0.3% threshold on a dry-weight basis, while Switzerland uses a 1% threshold. The European Parliament recently voted to raise the permitted THC concentration of cannabis cultivated for industrial purposes (*i.e.*, hemp) by farmers applying for EU funding within the European Union from 0.2% to 0.3%.[46] Instead of seeking to stifle the development of similar programs in other Members States, INCB should recognize the authority of Member States to determine what constitutes an industrial purpose of the cannabis plant within their jurisdiction and should pursue a more pragmatic approach that more reasonably addresses the reality of the global industrial hemp industry and economy.

Finally, although INCB asserts that Member States are required to report patient numbers and hectares of cannabis grown for industrial purposes, including the production of preparations of CBD, this reporting obligation is not clear under the Conventions, further casting doubt upon the INCB position. While some Member States may choose to furnish such information to INCB, such reporting is voluntary. Article 19(1)(e) only references opium poppy. It is deliberately silent on cannabis. Additionally, article 28, paragraph 1 on cannabis cultivation only refers to "the system of controls as provided in article 23 respecting the control of the opium poppy" and does not require or incorporate the reporting requirements of Article 19(1)(e). Therefore, the reporting requirements of this article 19 do not apply to the cultivation of cannabis plants. Furthermore, the Commentary specifies that "a [Member State] permitting the cultivation of the [cannabis] plant for the drugs, but also permitted cultivation elsewhere exclusively for other purposes, must apply article 23 to the former, but not to the later."[47] Thus, the cultivation of cannabis plants exclusively for non-drug uses is not subject to control under article 23, and Member States are not required to engage in the associated requirements. Member States that regulate the production of cannabis for industrial purposes are well positioned to collect and report this information to INCB due to reporting and registration obligations included in the regulated regimes of Member States.

---

45 United Nations, "*Commentary on the Single Convention on Narcotic Drugs, 1961*," (Aug. 3, 1962), at 312.

46 The increase applies to farmers applying for EU funding for their hemp cultivation and does not create a harmonized limit that must be implemented by EU hemp Cultivators.

47 United Nations, "*Commentary on the Single Convention on Narcotic Drugs, 1961*," (Aug. 3, 1962), at 314.

However, for the reasons described above, this reporting is voluntary, and the Conventions do not empower INCB to mandate the collection of this information.

CONCLUSION

In sum, despite claims by INCB to the contrary, CBD is not currently under the control of the Conventions. Both the control of preparations of CBD as an "extract or tincture of cannabis" and the scope of the "industrial purposes" exemption on the cultivation of cannabis plants are matters of interpretation by the Member States. While THC is controlled under the '71 Convention, as stated herein, such control was not meant to extend to the low-levels of THC that are inherently present in preparations of CBD and other components of the cannabis plant unambiguously exempt from control. Because the low concentrations of THC within preparations of CBD are non-psychoactive, are not easily recoverable, and pose no risk for abuse, control of such preparations is left entirely to Member States.[48] Therefore, Member States that: (i) interpret the '61 Convention to exempt preparations of CBD from control; and (ii) consider the cultivation of cannabis plants for the production of CBD to be a valid industrial purpose, act well within the scope of their authorities and these positions are supported by the '61 Convention, existing precedent, and the intent of the '61 Convention as expressed in the Commentary. INCB would be well-served to recognize this reality and to adjust its interpretations accordingly.

[48] *See* Franjo Grotenhermen and Michael Karus, "*Industrial hemp is not marijuana: Comments on the drug potential of fiber cannabis*," (last visited Oct. 12, 2020) http://www.internationalhempassociation.org/jiha/jiha5210.html; *see* United Nations, "*Commentary on the Single Convention on Narcotic Drugs, 1961*," (Aug. 3, 1962), at 316.