A CALL FOR SMART REGULATION OF CBD

Position of the Canadian Hemp Trade Alliance and the Canadian Health Food Association on the Removal of Cannabidiol ("CBD") from the Prescription Drug List in Certain Dosages for Use in Therapeutic (Natural Health) Products and Supplemented Foods

EXECUTIVE SUMMARY

The purpose of this Paper is to express concern about the current regulation of cannabidiol ("CBD") as a prescription drug when marketed with therapeutic or wellness claims.

This current approach is not reflective of the risk profile of cannabidiol, will result in a lost opportunity for Canada and Canadian industry to become a global leader in respect of cannabidiol products and research, and will facilitate the continuation of the illegal market, with potential harm to Canadians.

Cannabidiol does not pose a health or safety risk sufficient to justify the current prescription-only status. Among other things, cannabidiol can be safely used by the public under approved and specified conditions of use, in a self-care environment. Canada's current approach to the regulation of cannabidiol is also out-of-step with the proposed and/or existing approaches of other jurisdictions. At this moment in time, Canada is uniquely positioned to establish a global leadership position on the appropriate risk-based regulation of cannabidiol, with great potential benefit to Canadian industry. In contrast, the current approach to regulating cannabidiol for prescription-only use in therapeutic and wellness products will facilitate the continuation of the illegal market that currently exists for these products. The continuation of this unregulated, illegal market poses health and safety concerns to Canadians resulting from non-quality controlled products and a lack of, or provision of improper, information about the safe and effective use(s) of cannabidiol.

It is submitted that, in contrast to the current approach, a regulatory pathway should be opened to permit the inclusion of cannabidiol derived from industrial hemp in natural health products (for example, in dosages up to an appropriate maximum such as 200 to 600 mg/day) and supplemented foods (for example, in dosages up to an appropriate maximum such as 20 to 60 mg/day) with appropriate therapeutic and wellness claims. The Canadian Hemp Trade Alliance and the Canadian Health Food Association request that Health Canada's last-minute decisions to add phytocannabinoids to the Prescription Drug List, and to Schedule 2 of the *Natural Health Product Regulations*, be reversed, and instead, adopt a more appropriate, "smart," regulatory approach that is better suited to the risk profile of naturally-occurring phytocannabinoids derived from industrial hemp.

INTRODUCTION

The Canadian Hemp Trade Alliance ("**CHTA**") was established in 2003 as a national organization to represent Canada's industrial hemp industry. The CHTA promotes Canadian industrial hemp and hemp products globally, disseminates information and coordinates research. It currently has 300 members, including farmers, processors, manufacturers, researchers, entrepreneurs and marketers.

The Canadian Health Food Association ("**CHFA**") was formed in 1964 and is Canada's largest trade association dedicated to natural health and organic products. CHFA's membership is over 1,300 strong and includes manufacturers, retailers, wholesalers, distributors and importers of natural health and organic products, including foods, vitamin and mineral supplements, herbal products, sports nutrition products, health and beauty aids and more.

The CHTA and CHFA are referred to herein collectively as the "**Parties**".

The *Cannabis Act* (the "**Act**") as recently introduced removed cannabis from Schedule 2 to the *Controlled Drugs and Substances Act*, however all phytocannabinoids from the cannabis plant have been added to the Prescription Drug List ("**PDL**"). As set out more fully below, the Parties are concerned about the current regulation of cannabidiol ("**CBD**"), particularly when sourced from the industrial hemp plant for the following three key reasons:

i. CBD does not pose a risk to human health sufficient to justify its inclusion on the PDL at certain doses (for example, up to 200 to 600 mg per day), and instead, is more appropriately regulated pursuant to the natural health product ("**NHP**") or supplemented food pathways, depending on proposed daily dosage and product format;

ii. Canada is uniquely positioned to establish a global leadership position in self care and the rapidly emerging CBD consumer health products industry by regulating CBD in a manner consistent with its risk profile; and

iii. The current approach to the regulation of CBD enables the continuation of the illegal CBD market, with potential harm to Canadian consumers from non-quality controlled products and a lack of information about the safe and effective use(s) of CBD, and harm to the legal hemp and cannabis industries.

BACKGROUND

The Cannabis Plant and Defining Industrial Hemp

The *Cannabis sativa* plant is highly complex, with hundreds of chemical constituents, including over 100 cannabinoids that are produced in the flowers and leaves of the plant. It is generally understood that cannabinoids imitate endocannabinoids (compounds made naturally by the human body) and in this way, have many possible therapeutic uses. Additionally, the *Cannabis sativa* plant contains terpenes, aromatic hydrocarbons that give cannabis its distinctive (sour) smell. Some believe that terpenes have a potential health benefit, and may be part of the "entourage effect" that allows a combination of cannabinoids to work more effectively in the human body.

The most abundant and widely-discussed cannabinoids in the *Cannabis sativa* plant are tetrahydrocannabinol (**THC**) and CBD. As discussed more fully below, THC is the primary psychoactive compound in cannabis, or the compound that results in the "high" or intoxication. In contrast, CBD is non-intoxicating and non-addictive and is understood to have a number of therapeutic properties.

For the purposes of this discussion, we distinguish between two different varieties of the *Cannabis sativa* plant: marijuana and industrial hemp (*Cannabis sativa* L.). Although marijuana and industrial hemp are the same species, they have important differences in genetic make-up, and in particular, the genes for cannabinoid production.

Marijuana contains major genes that allow for the production of THC, while the industrial hemp plant contains genes that only allow for the production of very small amounts of THC. At its most basic: in Canada, *Cannabis sativa* plants that contain more than 0.3% THC in the flowering heads and leaves are deemed to be marijuana and those containing 0.3% or less THC are classified as hemp. In contrast, the marijuana plant often contains between 10% and 20% of the intoxicating cannabinoid, with some cultivars reaching as high as 25% THC.

The cultivation, processing and sale of industrial hemp is regulated pursuant to the *Industrial Hemp Regulations* ("**IH Regulations**") made under the Act. "Industrial hemp" is defined as "a cannabis plant – or any part of that plant – in which the concentration of THC is 0.3% w/w or less in the flowering heads and leaves". The IH Regulations require all hemp acres and producers to be licenced. Therefore, all industrial hemp is grown in Canada under licence from Health Canada, using specific cultivars that have been vetted as low THC-producing varieties. The IH Regulations distinguish between the flowering heads, leaves and branches (often referred to as the "regulated" parts) of the hemp plant, which contain the vast majority of the plant's CBD, and the rest of the plant, which contains negligible amounts of cannabinoids.

THC and CBD

It is well-known and widely acknowledged that THC is the cannabinoid that is responsible for the *Cannabis* plant's psychotropic (i.e. intoxicating) effects. A level of about 1% THC is considered the threshold for *Cannabis* to have a psychotropic effect (i.e. intoxicating potential). An intake of 2.5 mg of THC, dosed twice per day (for a total of 5 mg THC daily) is the level at which one can expect some form of intoxication.

It is also well known that CBD has no psychotropic (i.e. intoxicating) properties. CBD has very low affinity for both CB_1 and CB_2 receptors, and this is thought to explain its lack of psychotropic (i.e. intoxicating) activity. Health Canada has widely acknowledged that CBD does not produce a high or intoxicating effect, including in its most recent publication *All About Cannabidiol (CBD) Information about CBD in cannabis and hemp products under the new Cannabis Act*.

Hemp generally has more CBD than is contained in marijuana, and can often reach 6% concentration in the leaves and bracts, as analyzed according to Health Canada guidelines. A field of hemp, using existing approved cultivars, is estimated to produce over 1 kg CBD per hectare. Of particular interest, researchers have documented that naturally-sourced CBD displays superior medicinal properties compared to synthetic or lab-produced CBD.

Therapeutic Uses of CBD

There is a growing body of evidence supporting the potential therapeutic uses of CBD. It is important to note that this Paper is not advocating for any particular use of CBD. Rather, it is advocating for a pathway (outside of the existing prescription drug pathway) for the approval and marketing of safe, effective and low risk therapeutic and supplemented food products containing CBD. This position is well-supported by the growing body of evidence (which will not be covered in this Paper) that CBD presents much potential for therapeutic uses, with very low risk to health or safety, particularly in the presence of low levels of THC as exist in industrial hemp.

Current Regulation of CBD

Contrary to what was expected based on Health Canada's *Proposed Approach to the Regulation of Cannabis* published in November 2017, CBD is subject to the exact same restrictions as THC, despite the vastly different risk profiles of the two cannabinoids and the vastly different risk profiles of marijuana and industrial hemp.

As set out in the *Proposed Approach*:

> A new pathway is proposed for NHP submissions containing parts of the cannabis plant subject to the proposed Cannabis Act, such as products derived from cannabis flowers containing cannabinoids such as CBD. To minimize the risk of psychoactivity, the same 10 ppm THC limit would be applied to such products. These submissions would be required to demonstrate robust safety and efficacy evidence under the NHP regulatory framework.
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> The 10 ppm THC limit applicable to all NHPs with cannabis would be established in the Natural Health Product Regulations.

However, when the *Cannabis Regulations* (the "**Regulations**") were introduced, there was no new pathway for NHP submissions containing CBD with a 10 ppm THC limit. In fact, the Act and its Regulations do not distinguish between CBD and THC, or between CBD derived from industrial hemp and CBD derived from marijuana.

Instead, CBD was added to the PDL, and the NHP Regulations were amended to add the regulated parts of the cannabis plant to the list of excluded NHP substances.[1] As a result, only limited parts (i.e. the unregulated parts of the cannabis plant) can be used in NHPs, and all cannabis products intended for therapeutic use are regulated as "cannabis drugs".[2] The definition of "drug" in the Regulations specifically excludes cannabis that is a NHP to which

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[1] The following two entries were added to Schedule 2 to the NHP Regulations, Excluded Natural Health Product Substances:

> 7 Cannabis as defined in subsection 2(1) of the Cannabis Act, except for a derivative or a product made from a derivative that is exempt from the application of the Cannabis Act under the Industrial Hemp Regulations and that does not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid
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> 8 Anything referred to in Schedule 2 to the Cannabis Act that contains more than 10 µg/g THC, an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid

As a result of these additions to Schedule 2, only cannabinoids from the parts of the plant listed in Schedule 2 to the Act or that are exempt from the Act per the IH Regulations are permitted to be included in NHPs. These "unregulated parts" of the cannabis plant include derivatives or products made from derivatives of: non-viable seeds; mature stalks without any leaf, flower, seed or branch or fibre derived from any such stalk; and the root or any part of the root of the plant.

[2] "Cannabis drugs" are cannabis products that have been manufactured, sold or represented for a therapeutic use, cannabis that is/will be used as an active pharmaceutical ingredient in a pharmaceutical, and cannabis that is/will be used in a clinical trial. The FD Regulations define a "clinical trial" as an investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug.

the NHP Regulations apply. Instead, the Regulations specify that all cannabis drugs will require a Drug Identification Number (**DIN**), and can only be sold pursuant to a prescription. On October 17th, the PDL was amended to add:

> Phytocannabinoids produced by, or found in, the cannabis plant and substances that are duplicates of such phytocannabinoids, except:
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> > (a) derivatives of cannabis that are exempt from the application of the Act under the Industrial Hemp Regulations and that do not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid, or
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> > (b) anything referred to in Schedule 2 to the Act that contains no more than 10 µg/g delta-9-tetrahydrocannabinol and that does not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid.

Therefore, any cannabis product containing the regulated parts of the cannabis plant and associated with therapeutic claims can only be sold as a "cannabis drug", and all cannabis drugs are regulated as prescription drugs. Health Canada has not distinguished between THC and CBD, despite the very different risk profiles of the two cannabinoids, nor has it distinguished between CBD derived from marijuana and CBD derived from hemp, despite the significant differences in risk profiles of marijuana and hemp.

SUBMISSIONS

The Parties respectfully submit that the current regulation of CBD, particularly when derived from industrial hemp, is not appropriate given the safety / risk profile of CBD, fails to position Canada and the Canadian industry to establish a global leadership position relating to CBD, and will permit the continuation of the illegal CBD market, at risk to Canadians and the legal cannabis industry.

1. CBD Does Not Pose a Health or Safety Risk Sufficient to Justify Prescription-Only Status

As set out above, the purpose of this Paper is not to advocate for any particular therapeutic use of CBD. The Parties do, however, want to advocate for: (i) the removal of CBD from the PDL (in the presence of very low levels of THC) at certain dosages (e.g. up to 200 to 600 mg/day); and (ii) a regulatory pathway for the inclusion of CBD in NHPs (at certain dosages) and supplemented foods at certain dosages (e.g. up to 20 to 60 mg/day).

As set out below, the risk profile of hemp-derived CBD does not justify its prescription-only status. Primarily, there are important differences in the impact of CBD and THC on the body which result in significantly different risks such that regulating them in the same way does not make sense from either a scientific or a regulatory perspective. The result of the current regime is that CBD (and particularly hemp-derived CBD, which exists in the presence of very low, regulated levels of THC) is being overly-regulated.

For example:

- Unlike THC, it is well-established that CBD is neither intoxicating nor addictive;[3]

[3] This position has been well-communicated by Health Canada. Consider too the following excerpts from the World Health Organization's CBD Critical Review Report (June 2018):

> In humans, THC effects are characterised by impairment of psychomotor and cognitive performance, and a range of physical effects including increased heart rate and dry mouth. In general, clinical studies have reported that even high doses of oral CBD do not cause the those effects that are characteristic for THC and for cannabis rich in THC.
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> For example, in a study of healthy volunteers administered 200 mg oral CBD, CBD did not produce any impairments of motor or psychomotor performance. A number of other studies involving high doses of CBD were recently summarized by Grotenhermen et al; they concluded that high doses of oral CBD consistently fail to demonstrate significant effects or demonstrate effects opposite to those of THC. While it has been suggested that further large-scale human studies are needed to explore the gastric conversion and potential

- CBD is well-tolerated, even in daily doses of 1,500 mg/day;[4] and

- There is limited THC-associated risk with hemp-derived CBD because the CBD is produced in the presence of very low levels of THC and because CBD does not convert to THC.

Given the well-established unique safety profile of CBD, it should not be included on the PDL at certain dosages. First, CBD does not meet the criteria for regulation as a prescription drug, and second, the NHP and supplemented food market access pathways provide much more appropriate regulatory oversight for the proposed marketing of products containing CBD at safe and well-tolerated dosages.

i. CBD Does Not Meet the Criteria for Prescription-Only Status

It is well-established that in determining prescription status, Health Canada's objective is to make drugs available in a way that will best prevent harm and optimize benefits in the interest of protecting and promoting health and safety. According to the *Food and Drug Regulations*,[5] the following criteria must be considered in deciding whether to include a substance on the PDL:

i. Supervision by a practitioner is necessary

    a. for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in respect of which the drug is intended to be used; or

    b. to monitor the disease, disorder or abnormal physical state or its symptoms in respect of which the drug is intended to be used, or to monitor the use of the drug;

ii. The level of uncertainty respecting the drug, its use or its effects justifies supervision by a practitioner; or

iii. Use of the drug can cause harm to human or animal health or a risk to public health and the harm or risk can be mitigated by a practitioner's supervision.

Health Canada considers a medicinal ingredient to warrant prescription status when the medicinal ingredient, under the specified conditions of use, meets at least one of the PDL principles or factors. In contrast, Health Canada recognizes non-prescription status for medicinal ingredients that, under the approved specified conditions of use, are considered safe for use by the public in a self-care environment.

CBD does not meet any of the above requirements and can safely be used by the public, under approved and specified conditions of use, in a self-care environment.[6] As set out below, there is sufficient evidence to support the proposed uses of CBD as a medicinal ingredient in a non-prescription therapeutic product at doses up to 200 to 600 mg/day and in a supplemented food at doses up to 20 to 60 mg/day.

THC-like side effects following oral CBD administration it is very unlikely that oral cannabidiol will be shown to result in THC concentrations sufficient to induce any meaningful effects.

[4] The World Health Organization 's CBD Critical Review Report, the WHO noted that "to date, there is no evidence of recreational use of CBD or any public health-related problems associated with the use of pure CBD". Studies using human subjects have supported the claim that the use of CBD, even at daily doses of 1,500 mg is "very well tolerated" while other studies have supported oral administration as an effective pathway for CBD. Additionally, Health Standards Australia New Zealand reviewed 33 studies in its "Cannabidiol Hazard Profile" where it found that "CBD has a favourable safety profile" and "orally administered CBD is well tolerated at doses exceeding 1000 mg/day."

[5] Section C.01.040.3.

[6] In making these submissions, the Parties have taken into account Health Canada's *Guidance Document: Determining Prescription Status for Human and Veterinary Drugs* and Health Canada's *Guidance Document: Data requirements for switching medicinal ingredients from prescription to non-prescription status*. Although this Paper is not intended to constitute a "switch submission", the Parties have considered the requirements for a partial switch, and below we set out the grounds for the removal of industrial hemp-derived CBD in certain dosages and for certain uses from the PDL. It is recognized that marijuana-derived CBD and/or CBD for use in other dosages and for other uses may rightfully remain on the PDL.

Supervision by a practitioner is not necessary for the therapeutic uses of CBD at the daily doses contemplated herein (i.e., up to 200 to 600 mg/day). The use of CBD as proposed is for conditions and symptoms which are easily recognized and can be correctly diagnosed without practitioner supervision which reflect therapeutic uses similar to how NHPs are used generally.

For example:

- There are a large number of NHPs currently approved for use in the treatment and/or management of pain, inflammation and stress relief.

- CBD has been demonstrated to be safe at the levels being proposed herein. There is no evidence of serious adverse reactions or interactions between CBD and food or other drugs and it is well-documented that CBD does not have dependence or addiction potential.

- The use of CBD as proposed herein does not require complex or individualized instructions. Consumers will be able to readily comprehend how the product is to be taken and will be able to easily self-administer treatment. There will not be complicated dosage regimens or instructions for use, no need for dose titration or tailored dosing.

- There is no evidence demonstrating that the use of CBD as proposed herein has the potential to mask other diseases.

- The safety profile of CBD, and particularly CBD derived from industrial hemp is favourable. CBD poses a very low risk to public health and safety. In the dosages contemplated for approval pursuant to the NHP pathway, the consequences of misuse are minor. CBD is non-intoxicating and non-addictive and there is therefore no risk of dependence, abuse or diversion. Perhaps most notable are the following findings of the World Health Organization ("**WHO**"): "In humans, CBD exhibits no effects indicative of any abuse or dependence potential"; "CBD is generally well tolerated with a good safety profile"; and "To date, there is no evidence of recreational use of CBD or any public health-related problems associated with the use of pure CBD".

- There is no evidence of adverse drug reactions in patients using hemp-derived CBD.

Although it is acknowledged that there has been limited market experience with the therapeutic use of CBD as proposed herein, Health Canada must consider the following:

- The years of use of marijuana-derived CBD by registered patients under the medical cannabis regime, with very little (if any) oversight by medical practitioners and no, if any, significant adverse events;

- The significant and growing body of evidence globally supporting the safe and effective use of CBD, without practitioner oversight, for a number of different therapeutic uses; and

- The treatment of CBD (and particularly CBD derived from industrial hemp) in other jurisdictions and its widespread use (again, without significant adverse events reported) in the illegal market.

ii. <u>CBD for Therapeutic Uses in Doses Up to 200 to 600 mg/Day is Most Appropriately Regulated via the NHP Pathway</u>

Despite its recent inclusion on the PDL, CBD is currently used, and will continue to be used by Canadians for health and wellness purposes. As currently regulated, there are two mechanisms through which Canadians can legally obtain CBD: as a prescription drug (once approved) and in the recreational market. The Parties submit that neither

of these pathways are appropriate and that therapeutic and wellness products containing hemp-derived CBD would be best regulated via the NHP pathway.

To date, there have been no prescription products approved in Canada containing hemp-derived CBD as the active ingredient. As discussed above, such products do not meet the criteria set out in the *Food and Drug Regulations* for prescription-only status. In addition to those considerations however, it is important to note that the approval pathway for prescription drugs is not appropriate for naturally-sourced, low risk CBD. The prescription drug approval pathway was designed to test the safety and efficacy of drugs developed in a laboratory. The active ingredient is added to excipients to create a pharmacological formulation and the manufacturer has tight control over the active ingredient and excipients. The prescription drug approval pathway was designed with this drug-development reality in mind.

In contrast, therapeutic products with naturally-sourced active ingredients have some variability. It can be difficult to isolate the active ingredient and perform studies to the standards required for prescription drug approval. This is not to say that safety and efficacy cannot be demonstrated, simply that it is extremely difficult to do with studies that would meet the prescription drug approval pathway requirements. This is, in part, why the NHP pathway was developed, and why it is more appropriate for low-risk CBD products in certain doses.

At the other end of the spectrum is the recreational market. Canadians can currently legally purchase cannabis products that contain unrestricted amounts of CBD, however no therapeutic claims can be made. Given that CBD has no psychotropic (i.e. intoxicating) properties, it is likely that these CBD products are being used for therapeutic purposes. Canadians are thus purchasing cannabis that is high in CBD, and self-diagnosing and self-treating using these products without any guidance from Health Canada or manufacturers as to the proper use of such products (the making of any therapeutic claims in connection with recreational cannabis is strictly prohibited). As a result, Canadians are left to undertake their own research into the possible uses and proper dosage amounts for whatever ailment they are seeking to treat, based on information that has not been considered or approved by Health Canada.

The NHP pathway presents a solution to both of the above-noted issues created by the ways in which products containing CBD are currently available. First, the approval process is more appropriate for a naturally occurring substance. It allows for a wider range of evidence to be submitted while still requiring manufacturers to demonstrate safety and efficacy. Additionally, it would create an opportunity to better regulate how Canadians use CBD for their therapeutic and wellness needs. It would allow for more control over dosing and create clear indications for which individuals can use CBD for self-care. Given that industrial hemp does not contain high levels of THC, the risks associated with THC need not be considered in approving industrial hemp-derived CBD products.

Hemp-derived CBD is more analogous to the herbal products regulated by the NHP pathway than the products listed on the prescription drug list. Given the low risk to health, the need for education on proper use at the dosages proposed herein, and the demonstrated efficacy, the Parties submit that this pathway is an important, and the most appropriate, approval pathway for therapeutic and wellness products containing hemp-derived CBD.

iii. CBD in Food Products with General Health Claims at Doses Up to 20 to 60 mg/Day is Appropriately Regulated Pursuant to the Temporary Marketing Authorization Pathway

Health Canada has defined supplemented foods broadly as pre-packaged products that are manufactured, sold or represented as a food, which contain (among other things) added herbal or bioactive ingredients (defined to include plant material) that may perform a physiological role beyond the provision of nutritive requirements. The Parties submit that conventional food products with added CBD meet the definition of a supplemented food.

Health Canada has a well-established pathway for the marketing of foods that are supplemented with novel ingredients, namely through the use of Temporary Marketing Authorization Letters ("**TMALs**"). The Parties submit that the TMAL pathway is appropriate for the marketing of products that meet the definition of food with regard to product format, history of use, representation to consumers and public perception.

TMALs are issued for pre-packed supplemental foods that are safe to consume during the TMAL period, but are currently non-compliant with respect to the addition of certain ingredients. The purpose of TMALs is to generate

information to support a possible amendment to the *Food and Drug Regulations*. As set out above, it is well-established that CBD is safe for consumption at the proposed doses (up to 20 to 60 mg/day).

The TMAL research requirement will enable the gathering of important data on consumption patterns and consumers' understanding of supplemented foods containing CBD and their use of label information and the effectiveness of product labels as a risk management tool will facilitate the collection and reporting of consumption incidents. Similar to the case with NHPs, this regulatory pathway will facilitate the making of informed decisions by Canadian consumers about consumption of foods containing CBD.

In the alternative to the TMAL process, the Parties submit that Health Canada should consider the novel food pre-market assessment pathway for foods containing CBD in doses less than 60 mg/day.

2. Canada is Uniquely Positioned to Establish a Global Leadership Position

Health Canada's current approach to the regulation of CBD generally, and industrial-hemp derived CBD more specifically, is not consistent with the findings of the WHO, the likely regulation of hemp-derived CBD in other jurisdictions or the increasing awareness around the important distinctions between THC and CBD, and between CBD derived from marijuana and hemp. This is largely because of the lack of distinction in Canada between the regulation of CBD and THC, and the lack of distinction between hemp-derived and marijuana-derived CBD.

Canada has an opportunity to establish a global leadership position by regulating CBD in a manner consistent with its risk profile, by removing low daily doses of CBD from the PDL and instead introducing an evidence-based tiered regulatory regime which enables access to CBD products for Canadians and consumers around the world, but time is of the essence as other international jurisdictions are moving to clarify their regulation of CBD.

By way of example, the United States recently passed the *Hemp Farming Act of 2018* (the "**Farm Bill**") and as a result, hemp ingredients (including plant parts and derivatives of any part of the hemp plant) no longer qualify as controlled substances under federal law and may be eligible for use in food, dietary supplements, cosmetics and personal care products sold in interstate commerce. The Commissioner of the US Food and Drug Administration has noted that the FDA has the authority to issue a regulation that would allow hemp compounds and derivatives, including CBD, to be used in foods and/or dietary supplements, and that the FDA is currently evaluating that process.

In response to the growing body of evidence supporting the therapeutic uses of CBD, regulators in a number of other jurisdictions are also developing pathways for use of CBD and other non-THC cannabinoids for therapeutic and general wellness uses. As set out in the WHO's CBD Critical Review Report (the "**WHO Report**"): "Several countries have modified their national controls to accommodate CBD as a medicinal product for self-selection".

The WHO recently reported on its Expert Committee on Drug Dependence ("**ECDD**") closed door sessions that took place from November 12 to 16, 2018 and during which the Committee reviewed the chemical composition of cannabis and its impact on the body. The 11-strong ECDD committee heard evidence on the effectiveness of CBD which according to the WHO is considered by many to be a "miracle medicine at the heart of the legalisation debate". According to the WHO, the ECDD believes that the "groundswell of support" will result in a downgrading of cannabis at the international level.

As further evidence of the increasing support for therapeutic uses of CBD and increasing awareness of its non-intoxicating and non-addictive properties, the World Anti-Doping Agency[7] has excepted CBD from its list of prohibited cannabinoids

[7] The World Anti-Doping Agency was established in 1999 as an international independent agency composed and funded equally by the sport movement and governments of the world. It's mission is to lead a collaborative worldwide movement for doping-free sport. Its activities include scientific research, education, development of anti-doping capacities and monitoring of the harmonized anti-doping policies in all sports and all countries.

Canada has been a world leader in hemp production and is the largest exporter of hemp products. However, competitors in the US, Europe, Australia, China and other countries could dominate this new and potentially very lucrative market because governments in those countries are amending regulatory regimes to allow for the inclusion of hemp-derived CBD in therapeutic products.

3. Health Canada's Current Approach Will Allow for the Continuation of the Illegal Market, with Potential Harm to Canadians and the Legal Cannabis Industry

The overly restrictive approach to the regulation of therapeutic and wellness products containing CBD does not support the stated objectives of the Act and Regulations, with significant potential harms and cost to Canadians and the legal cannabis industry.

It is well-established that the framework for the legalization and regulation of cannabis was informed by the following five themes: minimizing harms of use; establishing a safe and responsible supply chain; enforcing public safety and protection; medical access; and implementation. These themes were codified in section 7 of the Act, which reads:

> The purpose of this Act is to protect public health and public safety and in particular, to
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> a) protect the health of young persons by restricting their access to cannabis;
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> b) protect young persons and others from inducements to use cannabis;
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> c) provide for the legal production of cannabis to reduce illegal activities in relation to cannabis;
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> d) deter illegal activities in relation to cannabis through appropriate sanctions and enforcement measures;
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> e) reduce the burden on the criminal justice system in relation to cannabis;
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> f) provide access to a quality-controlled supply of cannabis; and
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> g) enhance public awareness of the health risks associated with cannabis use.

The current prescription-only regulation of low risk, safe and effective therapeutic and wellness products containing CBD does not support, and in fact is contrary to, the stated purpose of the Act.

More specifically: the current barriers to entry for NHPs and supplemented foods containing CBD restricts Canadians' access to a supply of quality-controlled therapeutic and wellness products, resulting in a continuation of the robust illegal market for such products. The continuation of this unregulated, illegal market poses health and safety concerns to Canadians resulting from non-quality controlled products and a lack of (or provision of improper) information about the safe and effective use(s) of CBD.

The availability of CBD oils, tinctures, creams and foods on websites shipping into Canada is ubiquitous. A simple web search turns up hundreds of available products, many of which are represented for use in treating a number of ailments. The WHO Report also acknowledges the widespread "unsanctioned medical use of CBD-based products with oils, supplements, gums and high concentration extracts available online for the treatment of many ailments". By falling outside the regulated system, these unregulated and illegal products do not undergo any type of pre-market review by Health Canada: These products are made available to Canadians without manufacturers demonstrating compliance to the safety, efficacy, and quality standards to which regulated NHPs and supplemented foods are required to adhere. Excluding CBD products from the NHP and supplemented foods categories limits the ability of Health Canada to conduct and informed assessment of these products and the facilities they are manufactured in.

Without a properly regulated, legal supply of low risk CBD health products that have been assessed by Health Canada, Canadians will continue to turn to the illegal market, which lacks quality controls. As set out in the Regulatory Impact Analysis Statement that accompanied the Regulations (the "**RIAS**"):

> Other health risks associated with cannabis use include risks associated with the consumption of contaminants that come from growing cannabis under poor, unregulated conditions found in illegal operations. These contaminants can include heavy metals, pesticides, herbicides, fungicides, growth hormones, moulds, and bacteria, as well as toxic solvents, which can all pose various health risks to individuals.
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> …
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> Requiring licence holders to develop and adhere to standard operating procedures and a sanitation program will help ensure that every cannabis product is produced, sampled, tested, packaged, labelled, distributed and stored in a manner that maintains quality. These [Good Production Practices] GPP requirements are anticipated to reduce the health risk to adults of consuming cannabis products with potentially harmful pesticides, chemicals, heavy metals or other dangerous substances, which have been found in illegally sourced cannabis while also providing access to cannabis products of a known potency.

Indeed the RIAS acknowledges that, during consultation, Canadians spoke to the need for the legal industry to be able to offer the same range of products that are currently available through the illegal market in order to be able to successfully compete.

It should be noted that Health Canada's pre-market review for therapeutic products extends beyond safety and quality concerns to assess the *efficacy* of every product for its recommended use(s). Under the proposed framework for cannabis products, low THC / high CBD products in various formats (creams, capsules, tinctures, beverages, chewing gums etc.) will be available on the legal cannabis market under the new proposed classes (cannabis topicals; cannabis extracts, and cannabis edibles), but there is no proposed pre-market review for the *efficacy* of these products (since no health claims are permitted under the proposed framework). These CBD products will be permitted for sale in provincially-authorized recreational cannabis stores as recreational products.

However, due to the previously mentioned lack of intoxicating properties of CBD, CBD products containing less than 10 ppm THC are unlikely to serve a *recreational* purpose: To the contrary, it is likely that consumers seeking high-CBD and low/no THC products in a recreational store would be doing so for the therapeutic benefits consumers associate with CBD as a result of the widely-publicized therapeutic benefits of this molecule. In light of this existing perception by consumers (that CBD is non-intoxicating and has therapeutic benefits) our position is that CBD products with less than 10 ppm THC are better positioned as health products, where they will undergo pre-market review by Health Canada (for safety, efficacy, and quality), ensuring these products are safe and effective for the recommended use(s). Allowing these products to market without pre-market review by Health Canada for efficacy leaves consumers reliant on resources from the unregulated market to self-determine indications for these products.

If regulated as health products, CBD products (with <10 ppm THC) would also be subject to the labelling requirements for this category of product. Part of the pre-market review by Health Canada for therapeutic products includes ingredient-by-ingredient assessment of the risks associated with the formula. These risks can extend beyond those associated with cannabis to risks posed by ingredients in the formula, such as photosensitizing or cross-reactive herbs, or those with potential to interact with other foods or drugs. *Arnica montana* (arnica), for example, exhibits cross-reactivity with plants in the Daisy family: The *Cosmetic Ingredient Hotlist*, which is referenced as a resource for licensed processors to guide selection of ingredients for cannabis topicals, does not prohibit or restrict arnica, but the Natural and Non-prescription Health Products Directorate (NNHPD) monograph for arnica requires a contraindication for consumers allergic to plants in the Daisy family on all topical products containing arnica. Under the current proposed framework, a topical cannabis product containing arnica and CBD would not be required to carry this contraindication, but the same product regulated as a natural health product would require this risk statement. Health Canada's independent assessment of the risks associated with any formula is a valuable safeguard for Canadian consumers.

Finally, the current regulation of therapeutic and wellness products containing CBD is harmful to the legal Canadian hemp industry. The recent amendments to the IH Regulations which allow for whole-plant use were intended to provide significant benefits to industrial hemp producers by providing new opportunities for the sale of high-value plant parts to other licence holders. More specifically, hemp producers are no longer required to destroy the flowering heads, leaves and branches of the plant upon harvest. These parts of the plant are rich in CBD.

The RIAS acknowledges the position of the CHTA:

> The IHR 2018 opens up the market of the whole plant for industrial hemp producers, therefore the entire profits generated from their sale is an incremental benefit. According to the CHTA, in their comments on the proposed Bill C-45, allowing for the harvest, sale and processing of non-psychotropic cannabinoids would bring great financial benefit to Canadian industry, amounting to potential revenues of several hundred million dollars to the industry from a multi-billion dollar CBD market (CHTA, 2017). This market is growing annually.

If Health Canada does not amend its approach to the regulation of therapeutic and wellness products containing CBD, there will be insufficient information about the safe and effective uses of CBD to properly inform Canadians. Additionally, the illegal (and unregulated) market for therapeutic products containing CBD will remain in force and unchecked, with significant potential risk to Canadian consumers and inflated costs to the legal cannabis industry.

NEXT STEPS

The Parties acknowledge that more work is necessary to establish the parameters for the safe and effective use of CBD in therapeutic products and supplemented foods. The purpose of this Paper is to start that conversation with Health Canada with a view to establishing an appropriate regulatory pathway for these products which aligns with the government's intention behind the adult-use cannabis regime: the protection of Canadians, quality control, and disruption of the illegal cannabis market.

APPENDIX "A"

Sources Supporting the Safe and Effective Use of CBD As Proposed

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3. Australia New Zealand Food Authority Final Assessment Report Application A360. Use of Industrial Hemp as a Novel Food.

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