August 18, 2023
One Chance to Grow Up
Response to Congressional RFI on Cannabidiol (CBD)

Dear Chair McMorris Rodgers, Ranking Member Cassidy, Ranking Member Pallone and Chair Sanders,

We applaud the bi-partisan and bi-cameral leadership of the House Energy and Commerce Committee and the Senate Committee on Health, Education, Labor and Pensions for seeking feedback on assessing and devising a regulatory pathway for hemp-derived CBD products "that prioritizes consumer safety and provides certainty to the U.S markets".

One Chance to Grow Up is a national nonprofit based in Colorado, founded by parents who stepped up to look out for kids after marijuana was legalized for adult-use in 2012. Today, One Chance to Grow Up advocates for policies at both the state and federal level to protect our nation's young people from the negative impacts of changes to laws regarding marijuana and hemp and the evolution of those products' markets.

One Chance to Grow Up has engaged over 10,000 parents, hundreds of coalition partners and health experts, to improve outcomes for youth while positively impacting over 26 important pieces of THC (marijuana and hemp) legislation. We have been a trusted resource for media, elected officials, parents, educators, and health and youth serving organizations throughout the country while working to secure key safeguards at the state and local levels. These safeguards include:

- Child-resistant packaging
- Universal THC symbol, THC & CBD potency & package amounts on product labels
- Caps on THC serving size & package amounts (only secured on edibles in the adult-use recreational market; majority of market has no serving size or package amount caps)
- Product testing & limits on certain known harmful pesticides & chemicals
- Important warnings & education (includes posted pregnancy warnings at point of sale)
- Data collection on youth impacts (includes THC toxicology on deaths ages 25 & under - including completed suicide)
- Funding for youth prevention & pregnant & breastfeeding education & research (includes THC Concentration Potency Study)
- Advertising limits (includes local restrictions--distances from schools, hours, etc.)

Most recently we've participated in state policy debates and rulemaking around hemp-derived CBD.

The Request for Information (RFI) contains excellent questions about hemp-derived CBD products that national leaders should also be asking about products being marketed and sold today under the labels of "hemp", "cannabis" and "marijuana". Today's lack of clear and adequate definitions and determinations of what is what, what has or has not been determined safe for human consumption, for what intended use, and how these products are being marketed and sold, has become an urgent public health and safety issue. This particularly affects our nation's most vulnerable populations—pregnant and lactating women, children, teenagers, and young adults (those under the age of 25 as their brains are still developing), who all remain at the greatest risk and harm from federal inaction.

Further, in many states and municipalities that voted or opted to allow commercial "marijuana" sales— high CBD low THC products—were portrayed as the driving force in gaining favorable public opinion. This includes CNN's nationally aired "weed" series that highlighted the Figi family, and why they moved to Colorado to gain access to high CBD low THC marijuana to reduce their daughter's uncontrolled seizures. This message and sentiment spread quickly throughout the country, as few Americans wanted to prevent someone suffering from gaining access to something that could make a difference in their health and well-being. A recent nationwide survey reported by CNN showed that over a third of parents believe CBD and marijuana are the same.

Consequently, federal baseline consumer and product standards and youth safeguards to minimize unacceptable risks and negative impacts are imperative, no matter what a state or local jurisdiction has determined when it comes to allowing for commercial sales. We appreciate the opportunity to weigh in where we have experience and expertise. We look forward to being a valuable resource going forward as more information, data, and research are needed. Please do not hesitate to contact Henny Lasley, Co-Founder and Executive Director, One Chance to Grow Up at Henny@onechancetogrowup.org with any questions you might have.

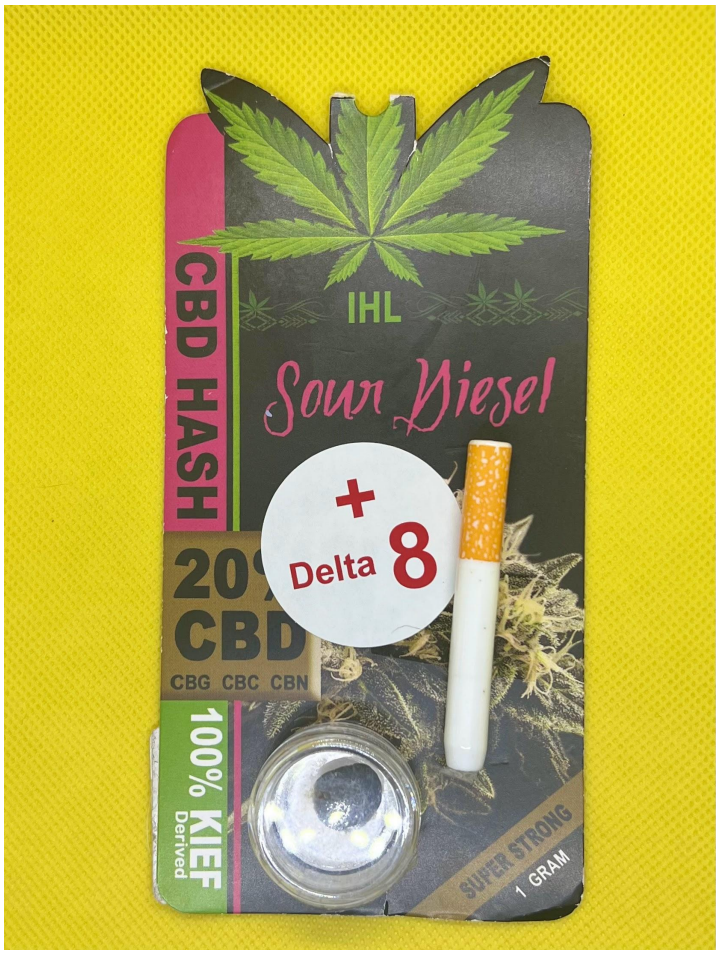
Current Market Dynamics

1. What does the current market for CBD Products look like? Please describe the types and forms of products available, manufacturing practices within the industry, market supply chain, how products are marketed and sold, the types of cannabinoids used in products, the marketed effects of CBD products, and the range of CBD doses currently found in the market.

Because there are no set product standards or regulatory safeguards, a variety of different products are being marketed and sold as CBD or hemp. False or misleading claims and aggressive marketing tactics without adequate product transparency and accountability have created tremendous confusion and harms for far too many, as the lines have become blurred

between what is a safe CBD non-psychoactive product versus a non-safe and/or psychoactive product that shouldn't be allowed to be marketed and sold.

The following page includes pictures and descriptions of products being sold as "hemp-derived CBD" that contain additional compounds whether they are naturally occurring, synthetically, semi-synthetically or biosynthetically produced. The products below were recently purchased online and in a "vape" shop respectively with no age verification. We are happy to provide more pictures and descriptions of products being sold all over the U.S.



Manufacturer: Innovative Health Labs (made in Europe)
Product: Sour Diesel Delta 8 CBD Hash 100% Kief "Super Strong"
Potency: Unknown - Cost $39.99
Net Wt. 1 gram (1000 mg)
Purchase Date: March 9, 2023 (expired in 12/2021)
Title: Delta 8 CBD Hash 100% Kief "Super Strong", came with "own rolled joint" to smoke
Description: 1 gram (1000mg) of Delta 8 CBD Hash Kief with "plastic joint", no amount of THC per serving

Manufacturer: Summit Manufacturing, Denver , CO
Product: Summit CBD Assorted Delta 8 classics gummies- 10 in package
Potency: 100mg per package, 10 mg each
Cost: $ 16.99
Net Wt. none marked
Purchase Date: March 2, 2023

Additional photos of products being sold as "CBD":

These products do not provide standardized warnings and often contain contradicting information. Information on product labeling above includes:

- Therapeutic effects: calming, relaxation, inflammation, pain, euphoria, bliss
- This product is not intended to treat or cure any disease or condition
- Certified European Union testing and regulated below allowed THC level
- These statements have not been evaluated by the FDA or any health authority.
- Not intended for use by anyone under 21
- Not intended for use by anyone under 18
- Do not use this product if you are subject to drug testing
- Contains non-detectable levels of THC
- Consult your doctor before using this product

Products like these and countless others pose an urgent public health and safety risk. They are highly deceptive to consumers who may have no idea of the amount of psychoactive compounds nor other potentially harmful chemicals used in the production of the product and left in the finished product.

Products like the ones above are being sold online, in local gas stations, convenience, beauty stores, garden supply stores and vape shops throughout the US including states such as South Carolina which have not legalized any form of CBD or THC. Typically these products are sold with no age requirements or other basic product standards and safeguards. Accordingly, they are a risk and health threat for consumers and the public as very little research has been conducted on these products yet this is a multi-billion dollar industry that has been allowed to operate with minimal oversight.

The rapid growth in the number and type of these products has increased exponentially and make federal regulations and safeguards around hemp-derived CBD imperative.

The resources below provide additional details about the challenges and the prevalence of this problem:

> Delta-8, Delta-10, HHC, THC-O, THCP, and THCV: What Should We Call These Products?
>
> 5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC | FDA
>
> Shop | Delta 8 Resellers
>
> Here is link to one of many local articles reporting tragic incidents including death involving children and young people

A recent marijuana/hemp trade article also highlights the problem: Study: Illegal Hemp Delta-9 THC Products Are Hiding in Plain Sight

Since 2014 Poison Centers have seen an increase across all ages with big increases in the 5 and under ages category America's Poison Centers - Cannabidiol (CBD)

Adverse impacts as reported by J Cannabis Research Self-reported adverse events associated with Δ8-Tetrahydrocannabinol (Delta-8-THC) Use | Journal of Cannabis Research

Advisory: Cannabidiol (CBD) Potential Harm, Side Effects, and Unknowns | SAMHSA

Warning about false health claims from the American Academy of Pediatrics Beware of health claims about cannabis products | AAP News | American Academy of Pediatrics

2. How has the market changed since passage of the 2018 Farm bill?

The THC limit established by Public Law 115-334, the Agriculture Improvement Act of 2018 ("the 2018 Farm Bill") has been abused by the hemp/CBD industry to sell intoxicating products to the general public.

In as much as the 2018 Farm Bill specifically referenced limitations on Delta-9 levels (.3% by dry weight of the plant material), the industry has broadly taken this to mean that other extracts from industrial hemp were effectively legalized. This has created an unintended, unregulated, commercial market for Delta-9, Delta-8, Delta-O Acetate, Delta-10, Hexahyrdocannabinol (HHC) and many other unregulated hemp-derived intoxicating cannabinoid products. We refer collectively to these products as Frankenstein THC or Copycat THC, as they produce similar or sometimes even higher intoxicating and psychotropic effects than Delta-9 THC. Meanwhile, CBD in its pure form is known to not have any psychoactive effect.

While the potency limit of .3% THC works reasonably well for plants, it doesn't work for a finished or processed product unless only the plant is being sold. Food is measured in ounces and THC is measured in milligrams and potency. For example, a package that weighs one ounce can have 85 mg of THC and meet the statutory limit of .3% (.003 x 28,350). A ten ounce can of soda could have over 850 milligrams of THC.

To put these incredibly large amounts of THC into perspective, the serving sizes of THC medicines prescribed for serious illnesses and conditions start at 2.5mg and don't exceed 10mg. Industry websites claim that intoxicating effects can be felt at 1-2.5mg depending on various factors. A comprehensive THC potency report found that the amount of THC, potency, and frequency of THC consumed; impacts its risks and harms while defining high potency THC at

10% potency. It also found that "inhaling more than 10mg of THC within 10 minutes can lead to a blood THC level above 5ng" which in some states can be used to support a conviction for driving under the influence. The considerable risks associated with concentrated amounts of high potency marijuana can be found on this educational document required at point of sale. The National Institute for Drug Abuse recommended that 5mg be used as a standard unit of THC for research purposes. While the potency of a typical marijuana plant in the 1980's was under 2%, it now reaches upwards of 30% with concentrated products reaching 90% or over, due to today's unprecedented commercial innovations.

And yet, today's hemp/CBD products are being marketed as "marijuana" substitutes and are broadly deemed legal as a result of the 2018 Farm Bill. Where not explicitly prohibited by state law, they are sold in vape cartridges, edibles, concentrates, and tinctures that often come in kid-friendly forms without any safety or product requirements to include consumer warnings, childproof packaging, limits on serving size and package amounts and directions of use, or age restrictions.

Again, these products are sold even in states that have not authorized any form of CBD or THC sales and these products are typically not age gated.

3. How is the lack of national standards for CBD products affecting the market?

National poison centers received 2,362 cases of Delta-8-THC exposure with 41% involving kids under the age of 18 years old between January 1, 2021 and February 28, 2022 and the FDA received 104 reports of adverse events of individuals who had consumed delta-8 THC between December 1, 2020 to February 28, 2022, according to consumer updates on the FDA's website. A SAMHSA Advisory published in February of 2023 provides many details on the current challenges and why urgent action is needed. SAMHSA's Advisory includes the following:

Cannabidiol (CBD) Potential Harms, Side Effects, and Unknowns

- CBD products, except for the prescription medication Epidiolex, are not FDA-approved, so despite being marketed extensively, there are no federal standards for the content, purity or potency.
- The concentration of CBD may be more or less than advertised.
- Manufacturing process may introduce harmful biological and chemical contaminants, including the psychoactive THC.
- The lack of safety standards, accuracy in labeling, and quality control may lead to additional concerns for unintended intoxication, particularly among children.
- Delta-9 may be sold as CBD. Labeling may be unclear or misleading.

The FDA has not approved CBD to be marketed as food additives or dietary supplements. CBD is often advertised as therapies for many health conditions even though these claims are unproven. Nor does the FDA pre-empt or limit state laws on hemp production that are more stringent.

60% of CBD sales are conducted online, allowing for online sales to minors due to no federal age restriction or regulations. There is no requirement that the amount of psychoactive compounds be disclosed and therefore allow minors to access THC and various derivatives in varying psychoactive amounts. CBD is also sold at drugstores, grocery stores, convenience stores and gas stations.

Risks and Harms:

- Adverse events and side effects
- Unreliable dosage and purity
- Unproven health and wellness claims
- Unknown health effects
- Unknown chemicals and compounds

Driving Impairment Risks

Inaccurate information about whether or not these products lead to impairment is being disseminated widely, creating unacceptable risks for consumers and the public. Recently a state transportation agency released information about CBD stating that CBD products are everywhere. That they are sold on-line, in grocery and beauty stores boasting the benefits of CBD and **stated that such products are non-psychoactive and therefore should be safe to drive while using.** It is just one of many examples of dangerous and misleading information being widely disseminated to the public due to the constantly changing landscape around these products.

Our organization sent evidence to the state agency, including pictures of products that we had purchased from local head shops, vape shops, CBD stores and even online (one of our 17 year old's ordered and picked up thousands of milligrams of psychoactive THC purchased via the web) that were labeled CBD, or Delta 8, HHC, THC-O and even Delta 9 (hemp-derived THC), so that the state agency and citizens in their distribution networks could be informed.

Pathway & Scope

> **4. Please comment on the concerns FDA has raised with regard to regulating most CBD products through existing pathways (i.e. conventional foods, dietary supplements, and cosmetics)?**

We support the FDA's recent finding that CBD should not be treated as a dietary supplement or food. As FDA Principal Deputy Commissioner Dr. Janet Woodstock stated, "We have not found adequate evidence to determine how much CBD can be consumed, and for how long, before causing harm." The FDA also pointed to potential strategies to minimize the risks to include: content limits, labeling requirements, minimum age requirements, and oversight on CBD consumption by animals to minimize CBD exposure from consuming animal products such as eggs, meat, and milk.

We also support the FDA's concerns that many products pose special risk to children. "[T]he Agency is particularly concerned that some of your products are in forms that are appealing to children. For example, your CBD Lollipops, CBD Gummies, and Delta-8 THC Gummies are in forms that would be attractive to children and could easily be mistaken for traditional foods that are commonly consumed by children."[1]

Certainly aspects of current FDA pathways could be utilized should CBD manufacturers be required to receive premarket approval based on data demonstrating safety and generally recognized as safe and effective (GRAS/E) for their intended purpose of use. When it comes to CBD or other hemp-derived cannabinoids being sold as a medicine, the manufacturer should be required to go through the same strict requirements and protocols that others must go through in seeking FDA approval for a medication.

As far as Epidiolex and the exclusionary rule, due to the complexities of plant derived CBD, it would seem that different formulations/product types for different intended uses could be used to allow for more diversity in order to better meet the growing consumer demand for truly non-psychoactive high quality hemp-derived CBD products in amounts that have been proven to be safe for human consumption. But again, manufacturers must show data proving their products are safe for human consumption and for widespread public consumption before being permitted to market and sell them. And every approved product should also be required to meet federal baseline product, consumer, and youth safety requirements including appropriate labels and warnings.

5. How should CBD and/or cannabinoid-containing hemp products be defined? What Compounds should be included and excluded from a regulatory framework?

The definition found in the Cannabis Administrative and Opportunity Act (CAOA) could be used with a few clarifying additions to address today's product realities. Please see the language below with clarifying additions in red. We've shared this with U.S. Senate and U.S. House

[1] U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition. Naturally Infused LLC MARCS-CMS 628036 warning letter, November 16, 2022. Retrieved December 7, 2022 from https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/naturally-infused-llc-628036-11162022

Agriculture Committee members and staff as they work on recommended changes to the 2018 Farm Bill.

SEC. __. DEFINITION OF HEMP UNDER USDA DOMESTIC HEMP PRODUCTION PROGRAM.

Section 297A(1) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639o(1)) is amended--

(1) by striking ``The term'' and inserting the following:

``(A) In general.--The term''; and

(2) in subparagraph (A) (as so designated), by striking ``with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.'' and inserting the following: ``and any products made or derived from such plant or parts, with a total tetrahydrocannabinol equivalent concentration of not more than the allowable tetrahydrocannabinol equivalent amount described in subparagraph (C).

``(B) Total tetrahydrocannabinol equivalent.--

``(i) In general.--Subject to clause (ii), in subparagraph (A), the term `total tetrahydrocannabinol equivalent' means--

``(I) any tetrahydrocannabinol, including--

``(aa) delta-8 tetrahydrocannabinol;

``(bb) delta-9 tetrahydrocannabinol;

``(cc) delta-10 tetrahydrocannabinol; and

``(dd) tetrahydrocannabinolic acid; and

``(II) any other substance that has similar effects on the body as a substance described in item (aa), (bb), or (cc) of subclause (I), including through interaction with other substances in the applicable product.

``(ii) Exclusion of isomers.--The Secretary

of Health and Human Services, in consultation with the Secretary of the Treasury and the Attorney General, may exclude 1 or more isomers of tetrahydrocannabinol from the definition under clause (i).

``(C) Allowable tetrahydrocannabinol equivalent amount.--

``(i) In general.--Subject to clause (ii), the allowable tetrahydrocannabinol equivalent amount referred to in subparagraph (A) is--

``(I) for any product intended for human consumption, 1 milligram of total tetrahydrocannabinol per 100 grams on a dry weight basis (or a proportionate amount of any fraction thereof; or 1 milligram of total tetrahydrocannabinol per retail sales unit, whichever is lower; and for which the Secretary of Health and Human Services has --
(a)established a minimum purchase age of 21 for any product from a substance derived from hemp if the Secretary determines that the effects on the body are similar to the effects on the body as a substance described in subsection B(i)(I); and
(b)issued regulations for non-intoxicating CBD products which provides for limits on potency, serving size and allowable amount per retail sales unit as determined to be non-intoxicating and safe for human consumption; prohibitions on harmful ingredients and additives; labeling requirements; marketing restrictions where appropriate, taking into consideration vulnerable populations, including children, pregnant and perinatal women; and the monitoring and reporting on adverse effects; without compromising the incentives and existing regulatory pathways for products receiving FDA approval as a medicine; and

``(II) in the case of any specified plant product not intended for human or animal consumption described in clause (iii), 0.7 percent total tetrahydrocannabinol equivalent on a dry weight basis.

``(ii) Modification; determination with respect to tetrahydrocannabinolic acid.--For purposes of clause (i), under regulations promulgated by the Secretary of Health and Human Services, in consultation with the Secretary of the Treasury and the Attorney General--

``(I) the Secretary may modify the allowable tetrahydrocannabinol equivalent amounts described in clause

(i) if the Secretary determines that the effects on the body of such substance or interaction of substances differ significantly from the effects on the body of delta-9 tetrahydrocannabinol; and

``(II) rules similar to the rules relating to the determination of `Total THC' in section 990.1 of title 7, Code of Federal Regulations (as in effect on the date of enactment),

shall apply in calculating the ratio of tetrahydrocannabinolic acid described in subparagraph (B)(i)(I)(dd) taken into account for purposes of determining the allowable tetrahydrocannabinol equivalent amount.

``(iii) Specified plant product.--A specified plant product referred to in clause (i)(II) is any part of the plant Cannabis sativa L. that does not contain any item described in that paragraph that has been processed, extracted, or concentrated (other than harvesting, drying, curing, or trimming).".

a. Should Congress or FDA limit the amount of intoxicating or potentially intoxicating substances produced in Cannabis sativa L. in food and dietary supplements.

We highly recommend the following:

- Any hemp/CBD products (that are intoxicating or potentially intoxicating) that are permitted to be sold should be capped to 1 milligram of total accumulative THC (in all its determined allowable forms) per finished product (this is a container limit). As an example, Oregon follows .5mg/container.
- Hemp/CBD manufacturers should be required to prove to the FDA that their products are non-intoxicating before products can be sold, FDA must certify the findings that such products are non-intoxicating.
- Congress should not allow for the manufacture and sale of “semisynthetic derivatives” or “biosynthetic cannabinoids” due to the risks involved.

- The FDA should not allow CBD or any substances derived from hemp or cannabis in food products or dietary supplements that appeal to children.
- Banning of products that are known to be dangerous for human consumption; novel cannabinoids should not be permitted to be manufactured for sale until such time as public health experts can declare such products safe.
- Federal rulemaking and agency policy making must restrict conflicts of interests and prevent industry influence.

We agree with recommendations included in SAMHSA's February 2023 Advisory on CBD. These are:

- Work with public health and regulatory agencies and medical providers to disseminate the latest evidence on the risks,
- Educate community partners and community members on the short and possible long-term effects associated with CBD use,
- Implement evidence-based and evidence-informed programs to prevent non-FDA approved CBD use, particularly among adolescents and young adults,
- Encourage additional clinical research on the effects of CBD,
- Learn about potential interactions of CBD with alcohol and prescription and over-the-counter medications, and
- Educate patients on the potential risks and harms associated with CBD use, including interactions with prescription drugs, dietary supplements, alcohol, and illicit drugs.

6. Other non-cannabinoid products are available on the market that have raised safety concerns among some individuals, which FDA has regulated without a substance-specific regulatory framework (e.g. kratom, caffeine, etc.). How has FDA dealt with products containing those substances? How might these products be implicated by a CBD-specific product framework?

Establishing federal minimum product standards to reduce the risks and harms is an approach that can be used for other substances that also don't fit into a substance-specific regulatory framework. Congress and national agencies can apply evidence-based and evidence-informed health and safety approaches, standards, policies, and product regulations that have shown to be effective when it comes to CBD/hemp.

Hemp-derived CBD is such a complex and fast-growing area, having a substance-specific regulatory framework is overdue.

7. How has the absence of federal regulation over CBD created a market for intoxicating, synthetically-produced compounds, such as Delta-8 THC, THC-O, THC-B, HHC-P, and others?

The absence of federal regulation has resulted in an "anything goes" type of unregulated market with states trying to figure it out on their own, without the adequate expertise or authority to handle some of the challenges involved. Consumers and the nation's most vulnerable populations, including kids, are being harmed and put at tremendous risk, unnecessarily.

This differs from other substances due to the complexity of the 2018 Farm Bill legalizing compounds derived from hemp. Below are additional resources highlighting the prevalence and problems around these unintended compounds:

Delta-8-THC craze concerns chemists

The Risks Involved With Using THC-O - Addiction Center

7b. How have FDA and state regulators enforced against products containing these compounds?

The FTC and FDA have sent warning letters about products that look like highly recognizable trademarks such as Cheetos, Nerds and Doritos. The FDA has sent warning letters about products in forms that would be attractive to children and could be mistaken for foods commonly consumed by children. Individual states that are in the know have banned certain products and some have capped THC per serving and package amount. However, it remains an inconsistent patchwork landscape with each state left to navigate their own path, while unregulated manufacturers continue to produce new and different variations of similar banned chemicals/products. Meanwhile, there are still thousands of these types of products being sold all over the country even in states that have product bans in place. No agency has stepped up to properly enforce and protect the public.

7c. How should Congress consider the inclusion of these products in a regulatory framework for cannabinoid hemp products, if at all?

These unknown compounds should be banned until manufacturers can prove they are safe for human consumption and meet consumer and product standards and youth safeguards.

Federal-State Interaction & Safety & Quality

9a. Which product standards relating to warning labels, minimum age of sale, manufacturing and testing, ingredient prohibitions, adverse event reporting, and others have states adopted to product consumer safety and what should Congress adopt?

Congress should adopt the highest standards and safeguards that put public health and safety and protecting young people as their highest priorities. If we've learned anything from our nation's experience with substance misuse, abuse, and addiction, we've learned that prevention and minimizing harms is far less costly to do upfront than to do after the fact.

Certain states have begun to tackle this problem in various ways including banning synthetic and semi-synthetically compounds altogether and capping the amount of THC (in any form) in a serving/container amount if allowing any at all. But again there remains to be tremendous confusion around these products that most states are finding overwhelming to tackle on their own.

Any product containing THC (in any form) if allowed should be age-gated at 21 and under, and have child-resistant packaging including requirement of a universal THC warning symbol, potency caps, limits on total amount of THC (in all its forms) per package, listing of servings per package, directions of use and adequate warnings on the label. Products that appeal to children should be prohibited. Many of the safeguards listed below have been established on THC marijuana regulations by states.

Baseline minimum safeguards should include:

- Minimum purchase age of 21 for any product from a substance derived from hemp/CBD if the Secretary of Health and Human Services determines that the effects on the body are similar to the effects on the body as THC (in any of its forms).
- Congress should direct the Secretary of Health and Human services to issue regulations for non-intoxicating CBD/hemp products which provide for limits on potency, serving size, and allowable amount per retail sales unit as determined to be non-intoxicating and safe for human consumption along with listing of number of servings and directions of use.
- Child resistant packaging and plain and opaque packaging (i.e. no branding)
- Restrictions on allowable product types, shapes, flavors, and additives
- Prohibitions on any product or product types deemed to be "appealing to children" including sugar and flavorings
- Prohibitions on any products that contain alcohol, caffeine, tobacco or other substances

- Restrictions on harmful pesticides, chemicals, solvents, metals, used in cultivation and product production
- Mandatory pre-sale product testing
- Mandatory product recall authority
- Standardized government health and safety disclosures and warnings on labels provided to consumers with each purchase
- Prohibit health-related marketing claims that are not conclusively supported by scientific research
- Significant and enforceable fees and penalties for false claims, lack of compliance, and national reporting of such violations
- Restrictions on advertising and marketing that reaches kids to include: no outdoor advertising, audience composition requirements (15/85) for print, no digital and social media advertising and prohibiting product branding on tangible items associated with children. Ideally advertising would require including health warnings in the advertising itself.

In addition, safeguards should be bolstered by the following resources and actions:

- Funding for nationwide public awareness campaigns to prevent underage use, and targeted adult education regarding the differences between hemp-derived CBD and other marijuana products (as over a third of parents in a recent nationwide survey believe they are the same)
- Direct agencies responsible for national surveys of adult and youth drug use to add questions about CBD use so that ongoing surveillance and health data can be assessed and monitored.
- Direct the CDC to gather data, monitor, assess and publicly report on adverse effects including health impacts of use during childhood and adolescence and women during pregnancy and breastfeeding.
- Dedicate adequate resources to the Health and Human Secretary to implement this new regulatory pathway in a way that prioritizes public health and safety and protecting high risk populations including children, young people, and pregnant and lactating women while providing funds for enforcement and ensuring high compliance.

As recommended in SAMHSA's Advisory:

- Direct appropriate agencies to work with public health and regulatory agencies and medical providers to disseminate the latest evidence on the risks
- Educate community partners and community members on the short and possible long-term effects associated with CBD use
- Implement evidence-based and evidence-informed programs to prevent non FDA approved CBD use particularly among adolescents and young adults.

10. How should Congress consider federal preemption as it works towards a regulatory pathway?

Federal baseline regulations should allow for state laws that are more, not less, comprehensive. States should have the option to continue to build upon them as desired.

12. What actions, if any, should the federal government take to better understand the potential benefits or harms of CBD products and other cannabinoids?

The federal government and relevant agencies should conduct a Cochrane scientific review and convene experts to assess all the latest research and data, and further advise on the potential benefits and harms at different serving size and package amounts particularly when it comes to high risk populations (pregnant and lactating women, children, minors). However, it should not include those representing the industry or those with a conflict of interest.

13. How should a new framework for CBD products balance consumer safety with consumer access?

Any new framework should place mandatory product safeguards including a cap on serving size and amount per package and other youth safeguards as quickly as possible. It should also require manufacturers to provide evidence showing their products are safe for human consumption for their intended purposes and require they meet GRAS/E (Generally Recognized as SAFE and Effective)—so negative unintended consequences can be mitigated.

15. FDA approved Epidiolex, a drug containing CBD, based in part on a data package that included preclinical data from rodent safety models, as well as clinical trials. FDA has received safety data on CBD products from several manufacturers also based on rodent models. How should FDA consider data submitted for a CBD-containing drug as evidence to support that CBD is safe for human consumption in non-drug products, recognizing the inherent differences in the intended uses of such products?

The FDA has data provided in clinical trials by Epidiolex. This data can potentially assist the FDA in confirming what levels and amounts of CBD are safe for human consumption (levels that won't lead to adverse or negative impacts even if the product is used daily) without jeopardizing the standards and integrity of FDA approval for Epidiolex for its intended medical use. Another factor to evaluate is whether CBD like THC in marijuana can have an accumulated effect in the body overtime, and if so what are the risks and effects of that, and how should that be integrated into establishing adequate safety caps on serving size and limits on package/container amounts.

16. Should there be limits on the amount of CBD in foods, dietary supplements, tobacco, or cosmetics?

Absolutely. We strongly recommend as the FDA has concluded that CBD should not be allowed in any amounts in foods, dietary supplements, tobacco, or cosmetics.

16e. How should the experience of states inform the setting of limits on amounts of CBD in products?

Congress should know that at the state level this industry can have undue influence and that consumer and public safety including safeguards for our nation's youth are rarely a factor or driving force in those final decisions due to the powerful lobbying and financial interests involved. State health authorities do not have the expertise or experience to evaluate and set parameters on these products. This is precisely why federal involvement is necessary. Evaluating data that has been collected by states including reported adverse effects from CBD/hemp products could provide valuable insights.

One Chance to Grow Up, based in Colorado, has in-depth knowledge of one particular retailer and manufacturer that has been selling CBD products for years and hasn't been subject to regulations when it comes to product standards and youth safeguards since its inception. It is Charlotte's Web, and is owned by the Stanley Brothers. To our knowledge they are one of the largest producers marketing and selling their products as "CBD" throughout the country. In some states, they have started to lobby for carve out legislation allowing their products to contain higher amounts of THC than other hemp/CBD products, arguing that a certain CBD to THC ratio makes their products safe even when they contain higher levels of THC per serving and container. To our knowledge, there is no peer reviewed, evidence-based science, to support this claim.

The concern here is that, in addition to the lack of product disclosures, safeguards, and minimum age requirements, their THC serving sizes and THC amounts per container exceed levels that many claim can cause intoxicating effects. This can impact unsuspecting parents of children, teenagers, and young adults.

It is imperative that all manufacturers provide adequate data to back-up the safety of their CBD products and that standards can be enforced and applied to the entire industry rather than allowing for unsubstantiated exceptions. Particularly, when as stated earlier, over a third of parents believe that CBD and marijuana are the same thing. The fact that owners of this manufacturer and retailer are also in the business of today's commercial THC may create potential conflicts as well.

17. How should a regulatory framework account for CBD products marketed in combination with other substances that may alter or enhance the effects of CBD (e.g., caffeine, melatonin, etc.)?

Until manufacturers can prove safety in combining CBD with other substances, they should be prohibited.

18. What precedent is there for FDA restricting certain otherwise allowable ingredients in legally marketed products?

One example is Kombucha. To be commercially produced and sold as a non-alcoholic beverage, kombucha must contain less than 0.5% alcohol – a level where someone would have to drink many bottles in a short period of time to feel any effects of the alcohol.

20a. How should such a framework compare to the current Good Manufacturing Practice (GMP) requirements that apply to food, dietary supplements and cosmetics?

Hemp-derived CBD manufacturers should also be required to meet Good Manufacturing Practice (GMP) requirements.

Packaging, Accessibility, and Labeling

23. What is the evidence regarding potential benefits of including a symbol or other marking on product labeling to provide clarity for consumers who would purchase products that contain CBD?

Research found in the National Library of Medicine highlights the importance of product labeling when it comes to the labeling of hemp and hemp-derived CBD products. Researchers conclude: "Accurate and informative labeling of hemp and hemp-derived CBD products is an important public health issue. FDA-regulated product labels are considered an essential tool for protecting consumers and enabling informed decision-making."

Due to the confusion around CBD and other THC marijuana products, having a symbol with the letters CBD is important in differentiating CBD products from other marijuana products that contain THC. Currently, in most states that have allowed for legal marijuana, those products are required to be marked and labeled with a symbol and the letters THC. This can provide an important way to inform, differentiate, and educate consumers and the public on the differences of CBD and THC while preventing harmful or accidental consumption.

24. What are the potential benefits or drawbacks of an additional or substitute standardized label panel for CBD products compared to the current Nutrition Facts Label and Supplements Label?

Because CBD can be complex and there is potential for more cannabinoids to be determined safe for public consumption in the future, it seems forward thinking to put a standardized label panel for CBD products in place.

25. What precedent exists in foods, dietary supplements, tobacco, and cosmetics for requirements of labeling to present risks to special populations in labeling (e.g. children, pregnant and lactating women, consumers taking certain drugs, etc?)

There are many, including warnings on tobacco and those for pregnant women. Warning labeling requirements in the United States cover all kinds of hazards and risks. When it comes to children, such warnings include mandatory simple clear statements of risks and the use of an appropriate symbol to demonstrate those risks. The Fair Packaging and Labeling Act (FPLA or Act) directs the Federal Trade Commission and the Food and Drug Administration to issue regulations requiring that all "consumer commodities"(any food, drug, device, or cosmetic) be labeled to disclose identity of commodity, net contents, and name and place of business of the product manufacturer, etc.

26. Some suggest requiring labels for CBD products to include 'potential THC content". Would THC content be unknown in a particular product? Is there precedent for such a labeling requirement?

If any THC is allowed, the amount of THC (in any permitted form) should be capped on a finished product basis. Each CBD product should be required to disclose on both a weight and potency basis how much THC is contained in a serving size and package amount.

27. How should access to CBD products by children be regulated? For example, would it be appropriate to have an age restriction on the purchase of CBD products?

Until more research is conducted, an age restriction of 21 would be wise. A prescription from a bona fide-physician could then be required for use for those under the age of 21.

28. What specific additional restrictions should apply to CBD products regarding their appeal to or use by children with regard to marketing, packaging, and labeling? Is there precedent in the food, dietary supplement, tobacco, or cosmetics

space for restricting certain product features that would make products appealing to children?

CBD should not be allowed to be marketed or sold in any form of candy, sweets, flavorings, and additives or products that appeal to children. We should err on the side of caution by putting thoughtful safeguards in place proactively rather than reactively.

Examples of restrictions in tobacco include marketing and advertising restrictions, age restrictions, potency caps on nicotine levels, restrictions on flavorings, bans on vending machines, etc. The latest Tobacco Control Act gives FDA authority to take further actions to protect public health. The Poison Prevention Packaging Act, where prescription drugs, over-the-counter (OTC) drugs, household chemicals, and other hazardous products must utilize child-resistant packaging. Dietary supplements containing iron are required to be contained in child-resistant packaging.

29. Some suggest requiring packages with multiple servings to be easily divisible into single servings. Does a framework like this exist today for any other product or substance?

It exists in state marijuana regulations for edibles. And quite frankly it exists with foods that have denoted serving sizes. Due to the on-going unknowns and uncertainties around CBD, it seems only prudent to make serving size easy for consumers to determine, understand, visually see and measure combined with a maximum cap on the allowable serving size and amount of servings per container/package.

If CBD is permitted in foods, which we strongly discourage, the serving size of food should control the final serving. The recent Colorado law, SB 23-271, on hemp takes this position by defining serving size as "Serving means the size or portion customarily consumed per eating occasion, expressed in a common household measure as established in Table 2 of 21 CFR 101.12."
An unfortunate development in both the hemp and marijuana industries has been the disconnection between food serving size and CBD/THC serving size. This has resulted in an increase in reported THC poisonings due to marijuana edibles being accidentally consumed by children. The following pictures are examples of the problem experienced in Colorado in 2014. You can see that a THC sprayed gummy candy was indistinguishable from the food, but one serving of THC (10mg, a cap that many including industry members say is much too high) was in one piece, whereas the stated serving on the package of candy was seven pieces.

Thank you for the opportunity to provide this information to you. We would be happy to provide more details and additional information on the above submission. We look forward to being a trusted resource based on our ten years experience in policy and education on the key issues involved when it comes to better protecting our nation's young people. Again, if you have any questions or comments please do not hesitate to contact Henny Lasley at Henny@onechancetogrowup.org.

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