

# THOUSAND OAKS CITY COUNCIL



## Supplemental Information Packet

**Agenda Related Items - Meeting of September 10, 2019  
Supplemental Packet Date: September 10, 2019**

**2:30 p.m.**

### **Supplemental Information:**

Any agenda related public documents received and distributed to a majority of the City Council after the Agenda Packet is printed are included in Supplemental Packets. Supplemental Packets are produced as needed, typically a minimum of two—one available on the Thursday preceding the City Council meeting and the second on Tuesday at the meeting. The Thursday Supplemental Packet is available for public inspection in the City Clerk Department, 2100 E. Thousand Oaks Boulevard, during normal business hours (main location pursuant to the Brown Act, G.C. 54957.5(2)). Both the Thursday and Tuesday Supplemental Packets are available for public review at the City Council meeting in the City Council Chambers, 2100 E. Thousand Oaks

### **Americans with Disabilities Act (ADA):**

In compliance with the ADA, if you need special assistance to participate in this meeting or other services in conjunction with this meeting, please contact the City Clerk Department at (805) 449-2151. Assisted listening devices are available at this meeting. Ask City Clerk staff if you desire to use this device. Upon request, the agenda and documents in this agenda packet, can be made available in appropriate alternative formats to persons with a disability. Notification at least 48 hours prior to the meeting or time when services are needed will assist City staff in assuring reasonable arrangements can be made to provide accessibility to the meeting or service.



City Council  
**MEMORANDUM**

2100 Thousand Oaks Boulevard • Thousand Oaks, CA 91362  
Phone 805/449.2121 • Fax 805/449.2125 • www.toaks.org

**TO:** Mayor & City Council

**FROM:** Bob Engler, Councilmember

**DATE:** September 10, 2019

**SUBJECT:** **Ex Parte Communication, Agenda Item 8C – Appeal of Planning Commission Decision Denying Proposed Service Station and Convenience Store**

In compliance with Thousand Oaks Municipal Code Section 1-10.08, the purpose of this memo is to convey that I met as shown below regarding the subject agenda item:

I met with applicant Taylor Megdal, Megdal Thousand Oaks LLC. Mr. Megdal shared his desire for City Council to overturn the Planning Commission’s decision to deny the project.

Mr. Megdal provided a binder of documents to me, which I sent to City Clerk for inclusion in the administrative record.

TO COUNCIL: 9/10/19  
AGENDA ITEM NO.: 8C  
MEETING DATE: 9/10/19



Community Development Department  
**MEMORANDUM**

2100 Thousand Oaks Boulevard • Thousand Oaks, CA 91362  
Phone 805/449.2500 • Fax 805/449.2575 • www.toaks.org

**To:** Andrew P. Powers, City Manager  
**From:** Mark A. Towne, Community Development Director *mt*  
**Date:** September 10, 2019  
**Subject:** **Supplemental #2 – Additional Correspondence Received for Appeal of SUP 2019-70299, Item 8C**

Attached is additional correspondence received for the subject item. Included are 6 emails/letters, all in support of the project, including one from the applicant that provides results from a recent outreach/survey effort performed by “NewNationStrategies” for the applicant.

Attachments

TO COUNCIL: 9/10/19  
AGENDA ITEM NO.: 8C  
MEETING DATE: 9/10/19

**Stephen Kearns**

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**From:** NICK I. Quidwai <concernedcitztoaks@gmail.com>  
**Sent:** Tuesday, September 10, 2019 12:31 PM  
**To:** Mark Towne; Community Development Department; City General Email Account  
**Subject:** Allow 711 on Moorpark rd Please tonite

## **CONCERNED CITIZENS T OAKS** SINCE 1991

PO BOX 19204  
NEWBURY PARK CA 91319  
805-390-2857

TO CITY COUNCIL  
09/10/19

**pLEASE REALIZE THAT FOR SOME REASON STAFF HAS A FETISH TO JUST SAY NO nOT SEE ANY Fer use ACTS bE  
RESONABLE & allow Manager use of his property**

**He has mde so many chnges considering proximity to school & neighbors.  
He has REDUCED the hrs to 21!! A major coup for a 7-11  
No vaping products period!!!  
No junk food but quality lunches.  
Make sure no loitering.  
Work closely with Police Dept.**

**unfairly denied will have accept 100% what a judge says; never e good option.**

**Please be open & allow thia modest proposal to move forward. **11****

Newbury Park CA 91320-1821 USA I.quidwai at gmail.com

<https://www.youtube.com/user/iqidwai/videos>

<https://www.cctoaks.com>

<https://www.facebook.com/iqidwai>

<http://www.cctoaks.com/>

**Twitter: Nick Quidwai**

[@cctoaks](#)

## Stephen Kearns

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**From:** Erika Ralph <bosswoman1979@gmail.com>  
**Sent:** Friday, September 6, 2019 11:21 AM  
**To:** Rob McCoy; Bob Engler; claudia4slowgrowth@roadrunner.com; Ed Jones; Al Adam; Stephen Kearns  
**Subject:** Re: Faculty Member - Support for 7-Eleven

Councilmembers,

I have parents who don't share my opinions - some of them spoke at the Planning Commission. I didn't even have the guts to chime in during the proceeding out of fear of reprisal. I'm so worried about it that I made up this email handle to protect my identity but at least share my opinion.

On Thu, Sep 5, 2019 at 3:45 PM Erika Ralph <bosswoman1979@gmail.com> wrote:

I'm a faculty member and wish to be anonymous since this has become fraught (unnecessarily so in my opinion!) with politics. I overheard this morning a couple of my students choreographing their emails in support of 7-Eleven and thought I owed the decision makers my opinion.

I have tracked this development since its inception and even met with the Developer in its very infancy. I have attended two Neighborhood Meetings to keep abreast of the project and its evolution. Throughout, I have been impressed with how available and transparent the Developer has been. I also think he has operated in good faith proposing to never sell any liquor from the get-go and later agreeing not to sell vape and e-cigarettes.

I speak for the vast majority of the students and faculty, who are thrilled and practically giddy in excitement at the prospect of a small market across from us. My kids have to walk a half hour along Moorpark Road (aka speed-alley) to get a bottle of water, snack, or lunch. For the athletic department, drama program, spirit or others that remain on campus late into the night, it is a long overdue amenity (more like necessity actually). Our only option is unhealthy Dominoes pizza and sodas across the street.

I listened to all the opposition at the Planning Commission and found all of it to be selfish and disingenuous. The opponents were ONLY the adjacent home owners who hijacked worry for our school to advance their own self-centered NIMBY agenda. They aren't concerned about us or the community; the only thing they are worried about is their perceived home property values. Besides, it was a previous gas-station I believe, so their propaganda at our expense is that much more greedy and offensive.

Please don't pander to this small group with blow-horns and purely self-centered motives. Instead, kindly address a urgent underlying need for our High-School population. We outnumber them by a factor of 500 - 1 anyway.

Thank you for your time!

## Stephen Kearns

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**From:** Erika Ralph <bosswoman1979@gmail.com>  
**Sent:** Friday, September 6, 2019 11:23 AM  
**To:** Stephen Kearns  
**Subject:** Re: Faculty Member - Support for 7-Eleven

Its an alias, so I'm fine with it. Thank you for the letting me know.

On Thu, Sep 5, 2019 at 5:59 PM Stephen Kearns <[SKearns@toaks.org](mailto:SKearns@toaks.org)> wrote:

Hello Ms. Ralph,

Thank you for your email. I will forward it to City Council, however, as a city policy, we do not redact information on correspondence to City Council unless personal information, such as a social security number. Your name in the email will appear on the correspondence. Please let me know if you would still like me to forward this to City Council I appreciate you taking the time to submit your opinion regarding the project.

Sincerely,

Steve

Stephen Kearns, Planning Division Manager

Community Development Department

805-449-2315

[SKearns@toaks.org](mailto:SKearns@toaks.org)

**From:** Erika Ralph <[bosswoman1979@gmail.com](mailto:bosswoman1979@gmail.com)>

**Sent:** Thursday, September 5, 2019 3:45 PM

**To:** Rob McCoy <[RMcCoy@toaks.org](mailto:RMcCoy@toaks.org)>; Bob Engler <[BEngler@toaks.org](mailto:BEngler@toaks.org)>; [claudia4slowgrowth@roadrunner.com](mailto:claudia4slowgrowth@roadrunner.com); Ed Jones <[EJones@toaks.org](mailto:EJones@toaks.org)>; Al Adam <[AAdam@toaks.org](mailto:AAdam@toaks.org)>; Stephen Kearns <[SKearns@toaks.org](mailto:SKearns@toaks.org)>

**Subject:** Faculty Member - Support for 7-Eleven

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Thank you for your time!

## Stephen Kearns

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**From:** Pamela Scott <pscott@gpscra.com>  
**Sent:** Monday, September 9, 2019 1:46 PM  
**To:** Stephen Kearns  
**Subject:** Fwd: 2198 North Moorpark Rd

Could you please let them this a TO Blvd commercial property owner? Thank you Steve. Pam Scott

Sent from my iPhone

Begin forwarded message:

**From:** Zaher Hawara <hawara@sbcglobal.net>  
**Date:** September 9, 2019 at 1:26:14 PM PDT  
**To:** "skearns@toaks.org" <skearns@toaks.org>  
**Cc:** "aadam@toaks.org" <aadam@toaks.org>, "rmccoy@toaks.org" <rmccoy@toaks.org>, "bengler@toaks.org" <bengler@toaks.org>, "ejones@toaks.org" <ejones@toaks.org>  
**Subject:** 2198 North Moorpark Rd

Hello Steve, could you make sure the following is disseminated and in the staff report?

This email is in regards to the city council hearing on project located at 2198 North Moorpark Rd.

Dear Sir/Madam

I'm writing in support of the 7-Eleven market and service station. I am a businessman in Thousand Oaks and own a shopping center in the city. I have no doubt this is a good fit for the property for the following reasons:

1 7-Eleven and the developer have made many and enormous changes to their plans to improve what is their typical store, addressing the concerns of the Thousand Oaks High School principal, police, city government and neighbors, not only with design, but most importantly with security measures that address future issues that could potentially arise.

2 The property was a gas station for 40 years, so this use is not atypical along the Moorpark Blvd. corridor. Also, there is nothing wrong with small neighborhood markets. They are a fabric of all communities. I know people have organized opposition, but respectfully ask you to review the applicant's arguments on their true merits: the High School's support, the lengths the applicant's gone throughout working with staff and stakeholders to satisfy community and public concerns.

3 After being receptive to every concern, the owner and applicant find themselves challenged by voices who have never been involved in this long, cumbersome and expensive process, and who, I truly understand what the applicant has offered, how they've accommodated, and the economic value they offer the community. No beer and wine, no vapes, 24 cameras directly tied to the police station, an expensive attractive building, and the limited hours they have proposed are tremendous efforts toward anyone's concerns.

4 The property owner should be allowed to have this use on his property because it is reasonable overall and he has the right to enhance his land vacant for over 10 years. The property is zoned properly, the planned building and project has been gone over in minutiae so that it is extra attractive and safe.

5 And finally, hearing of a handful of neighbors who, surprisingly, expressed concern about "the homeless," where are these homeless? They're not near a freeway, they have the support of public safety, they're installing two dozen surveillance cameras, their trashcans are locked, and therefore wouldn't an attractive, well-lit public market be more a deterrent to vagrants than a dark empty lot?

I sincerely think this use is consistent with the Community Plan and a benefit for all.

Sincerely,  
Jeff Hawara  
Beertown Property LLC

Alvin Cox  
Back Bays Trust  
360 E. First St. #768  
Tustin, CA 92780

September 5, 2019

Rob McCoy, Mayor  
Al Adam, Mayor Pro Tem  
Claudia Bill-de la Peña, Councilmember  
Bob Engler, Councilmember  
Ed Jones, Councilmember  
City of Thousand Oaks  
2100 Thousand Oaks Blvd.  
Thousand Oaks, CA 91362

Re: 2198 N. Moorpark Road, Thousand Oaks, CA

Dear Mayor McCoy and Thousand Oaks City Council Members,

I am writing regarding the property located at 2198 N. Moorpark Road in Thousand Oaks. Our family has owned this property since 1977. The service station which was originally situated on the property was built by Mobil Oil Company and served as a fuel station, auto repair, and convenience store for many decades. It would have continued to operate in this capacity had it not been taken offline for necessary remediation work and clearances from the County of Ventura.

The developer Elliott Megdal & Associates has undertaken extensive outreach within the community in an effort to obtain consensus for development at the site. Due to competing interests, the developer has had to balance the economic feasibility of development, the interests of the nearby residents, high school, businesses, and the community as a whole.

Transforming my family's property from its unsightly state as vacant land to productive use is a pivotal project. The modern 7-Elevens offer new innovations and selections in healthy, fresh foods as well as other regional and diverse products. The added convenience of fuel price savings would be an added value for local residents.

The 7-Eleven planned for this site will be even more aesthetically pleasing than the modern 7-Eleven located at 609 Rancho Conejo Blvd. in Thousand Oaks, CA 91320. Elliot Megdal & Associates has agreed to proactively deed restrict beer & wine sales at

Rob McCoy, Mayor, et al  
Page 2  
September 5, 2019

the site. It is my understanding that the City of Moorpark will net approximately \$300,000 annually in sales tax revenue from this location.

The gas station, convenience store, and auto repair facility was faithfully operated at this site for several decades. The new, modern design now proposed will be in keeping with its historical use. Should the community or City Council desire any further architectural changes, it is my understanding that the developer is willing to go out of his way to make any reasonable or appropriate architectural modifications.

Our family has incurred significant holding costs over the past years in addition to having to deal with the ever-present displaced persons population. In its current idle state, this commercially desirable location is not in keeping with the thriving and dynamic business and residential community.

Your approval of this proposed modern fuel station with a fresh fare themed market would dovetail nicely for this commercial zoned and desirous corner parcel location.

Sincerely Yours,



Alvin Cox

## Stephen Kearns

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**From:** Taylor Megdal <tmegdal@elliottmegdal.com>  
**Sent:** Tuesday, September 10, 2019 11:39 AM  
**To:** Rob McCoy; Al Adam; claudia4slowgrowth@roadrunner.com; Bob Engler; Ed Jones  
**Cc:** Stephen Kearns  
**Subject:** 7-Eleven Applicant: Hope you can skim this before council (we think its important!)  
**Attachments:** Thousand Oaks Political Analysis.docx; Scan0023.jpg; Scan0024.jpg; Scan0025.jpg; Scan0026.jpg

Council-members - I look forward to presenting in front of you this evening. I wanted to make you aware of the attached neighborhood analysis (pardon the dreadful timing; I just received this from our weekend's neighborhood efforts).

It perfectly explains what we have gone through for the last two years in as many pages.

I would be so thankful if you could make time to just even skim it - I think it offers objective insight into the politics behind this drama we have unwittingly become.

Thank you

Taylor Megdal

PS Steve: can you kindly include in the record...



**Winning strategies from the ground up**

300 West Valley Blvd. #50, Alhambra, CA 91803

September 6, 2019

Mr. Taylor Megdal

Megdal and Associates

252 S. Beverly Drive, Suite #C

Beverly Hills, CA 90212

Dear Taylor,

A four-person crew canvassed for (1) of the (3) proposed days we initially discussed. I personally spent the day along with my very experienced team of canvassers who have worked on numerous local, statewide campaigns, propositions and community outreach efforts.

It became very evident to me; the proposed Thousand Oaks nearby residents voiced a number of incorrect beliefs on the 7-11 project. There has definitely been a sustained misinformation campaign against the proposed 7-11 in the surrounding neighborhood by the proposed project. After hearing many of the same (misinformed) comments in the first hour, we adjusted our approach and I directed our team to begin asking residents "what have you heard about the 7-11" to whom we spoke to and where did they hear it? The following issues came up:

- 1.) Many residents expressed they heard this information through Social Media and neighborhood chatter, and as one gentleman put it "The loud mouths that live around here". He specifically said he wanted to support the project but did not want to have his name on it because he didn't want to deal with these people. That comment was echoed by other residents when I debriefed with staff at the end of the day. Combined we spoke to 131 residents.
- 2.) Many were not aware of the No Beer, Wine, Alcohol, e-cigarettes and limited hours proposed. Many also expressed their fear that alcohol would lead to vagrants hanging out before we informed them of the truth. In some cases, we could persuade them with the truth, but most of

those did not want to sign up to support because of fear of reprisal from as one woman put it “the bully neighborhood activists”.

- 3.) One woman (a senior citizen) was told and therefore scared, it would lead to the homeless hanging out. There are existing homeless issues behind the adjacent office building so it is fair concern. However, they didn't know about 7-Eleven's state of the art technology surveillance apparatus and the local and regional security teams that monitor and respond to store security escalations.
- 4.) If you look at the surnames of our support signatures (attached), **Latinos** signed in great proportion and felt the need for the convenience of having a place nearby to grab quick items like milk, coffee, gas and yes even “Slurpee's” for example. They appreciated the willingness of you as a developer to limit hours and types of sales in consideration of the school and neighborhood. “Oh that's good”, was heard again and again.

If we had a couple of additional field days, we could have had over a hundred additional Latino support signatures.

Caucasians were the most fearful and misinformed on the belief that there were going to be Alcohol sales, e-cigarettes and 24-hour store hours. They were almost universally unwilling to sign the support petition. When we tried to explain their mistaken attributes, we heard comments such as “we were told to expect that the Developer would lie to them.”

It was noteworthy when you mentioned that all 19 opposition speakers during Planning Commission were unrecognizable to you, having not attended even one of your four community outreach meetings over two years. From review of the transcript, all the speakers seemed to be from mostly five or six families.

In sum, there seems to be a mobilized and effective effort to smear the project amongst this demographic. It's what we call a **FEAR and WHISPER CAMPAIGN**.

- 5.) What was consistent of this group as we explained to them none of those things are proposed with the location and then even after showing them the architectural renderings, the commented “that looks nice” (to their surprise), but would still rather not sign, but possibly would support if these things were true. The hostility posture”, left the conversation and most people were actually nice to talk to.
- 6.) After talking with our staff, many commented on how the location used to be a gas station many years ago. My team and I were not aware of this. I adjusted and quickly told staff to begin asking those that opposed the project if they remembered the gas station? Then told them to ask if they remember if there were any problems with the gas station that was there before? Not a single person recalled any problems before.

7.) **As a side note:** We ate lunch at the Subway in the Trader Joe's and Rite Aid shopping center prior to going door to door. While at Subway for a half hour, I asked the sandwich maker and (5) customers who came through to eat if they would support the proposed project. (3) said they drive by the location daily and that would be good for them (without me having to explain no beer, e-cigarettes, etc). One said that would be great for gas price competition. The other said his kids would love it and it's too hot in Thousand Oaks. The sandwich maker asked if we were hiring.

I usually see city councils look beyond these dirty fear tactics (most of them have been through one or many of themselves) but it's important to remind them when they are this blatant.

Darrell Allatore



WE SUPPORT THE PROPOSED 7-ELEVEN GAS STATION SO LONG AS:

- NO VAPE OR E-CIGARETTE SALES!!!
- NO BEER OR WINE OR ALCOHOL SALES!!!
- STORE HOURS REDUCED TO 5 AM - MIDNIGHT

NAME	ADDRESS	EMAIL
Todd Ogden	139 Teasdale St. T.O.	Marie set. 2010 at h... dippp22@gmail
DECK DIPPO	161 Teasdale St. T.O.	7-15mole@gmail
DECK CLARKE	320 Banton St. T.O.	

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NAME	ADDRESS	EMAIL
Penney Jimmy	786 Calle Pensamiento	<del>Penney50@gmail.com</del>
Davina Hernandez	680 Calle Pensamiento	
Hilda Tapia	650 calle pensamiento	
Reina Hernandez	"	
Liz Ortega	"	
Alyn Gamba	636 Calle Pensamiento	alana.skate@gmail.com
ELAZA ZUNIGA	636 Calle Pensamiento	alana505-405-4149
<del>Samuel Lopez</del>	240 Calle Jazmin	
Marcos Lopez	280 Calle Jazmin	
Samuel Lopez	280 Calle Jazmin	
Leticia Reyes	316 Calle Jazmin	
Soledad Anula	330 Calle Jazmin	
Oscar Espinosa	330 Calle Jazmin	
Nael grande	330 Calle Jazmin	
Jorge Pacheco	330 Calle Jazmin	
Mike Perez	400 Calle Jazmin	
Walter Perez	400 Calle Jazmin	
Francisco Perez	400 Calle Jazmin	



**From:** Paul Castillo <[paul.castillo@rimonlaw.com](mailto:paul.castillo@rimonlaw.com)>  
**Sent:** Tuesday, September 10, 2019 1:30 PM  
**To:** City Clerk's Office <[cityclerk@toaks.org](mailto:cityclerk@toaks.org)>  
**Subject:** Documents to be Entered Into the Public Record for Tonight's City Council Meeting

Laura,

It was a pleasure speaking with you this afternoon and thank you for your assistance. Attached are the documents that my client Ventura Seed Company, LLC would like to have entered into the public record for tonight's City Council meeting. In addition to the documents, I prepared a cover page, I am not sure if it needs to be submitted into the public record. Please let me know if any further information or documentation is needed.

Thanks again,

---

**Paul Castillo** | Associate

**RIMÓN** LAW

| [paul.castillo@rimonlaw.com](mailto:paul.castillo@rimonlaw.com)

Office: 800.930.7271 ext. 413

Direct: 213.457.7479

2029 Century Park East Suite 400N, Los Angeles, CA 90067

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**TO COUNCIL: 9/10/19**  
**AGENDA ITEM NO.: 9A**  
**MEETING DATE: 9/10/19**

September 10, 2019

*Sent Via Electronic-Mail*

Thousand Oaks City Council Administrative Staff  
2100 Thousand Oaks Blvd.  
Thousand Oaks, CA 91362  
cityclerk@toaks.org

Dear Thousand Oaks City Council Administrative Staff and Esteemed Councilmembers,

Recently, Ventura Seed Company, LLC (“VSC”), a local agricultural company very active in the Ventura County industrial hemp space, submitted a Summary of Business Operations for an Industrial Hemp Processing Facility Located at 1415 Lawrence Drive, Thousand Oaks, CA 91320, to the City of Thousand Oaks Economic Development Department.

VSC respectfully requests that the Summary of Business Operations document be allowed to enter the public record for the City Council’s upcoming September 10, 2019 meeting. This request is being made so that the Summary may help inform the City Council’s discussion during the City’s Cannabis Program Update, as hemp is an agenda item. In addition, VSC also requests that recent statements issued by the United States Department of Agriculture and the Federal Drug Administration, regarding the legality of hemp and hemp derived cannabidiol (“CBD”) products, be allowed to enter the public record as well.

Thank you for your time and consideration of this important issue.

Sincerely,  
Paul Andrew Castillo  
Counsel for Ventura Seed Company, LLC

**Ventura Seed Company, LLC**  
**Summary of Business Operations for an Industrial Hemp Processing Facility Located at 1415**  
**Lawrence Drive, Thousand Oaks, CA 91320**

The following is a summary of the proposed business operations for the industrial hemp processing facility, located 1415 Lawrence Drive, Thousand Oaks, CA 91320, which will be owned and operated by Ventura Seed Company, LLC (“VSC”). In addition to the summary, there is also a brief overview on the legal distinction between industrial hemp and cannabis and the current industrial hemp regulations at both the state and federal level.

**Summary of Business Operations**

**A. Operations and Capacity**

With the equipment and industrial hemp biomass that VSC has procured, it anticipates drying and extracting a minimum of One Million Pounds (1,000,000 lbs) of hemp biomass and processing it into stable high quality cannabidiol (“CBD”) oil.

The drying will be conducted through the utilization of a design system, which is the only industrial hemp drying system currently on the market which allows for “under the floor” access for CBD collection. The drying system includes, the dryer, a blower, a heater, specialized flooring, and a hand rail. The drying system will enable VSC to reduce the moisture of the wet industrial hemp biomass from Seventy Percent (70%) to a range of Eight to Ten Percent (8% to 10%). This drying system will allow VSC and those who utilize its drying services to maximize the yields received on their crops.

VSC currently has several hundred acres of industrial hemp being cultivated under its ownership and/or management, within Ventura County. All VSC’s current industrial hemp cultivation activities have been registered and licensed with the Ventura County Department of Agriculture.

Based on the current number of acres under its management, VSC anticipates drying approximately Forty-Thousand Pounds (40,000 lbs) of industrial hemp every Twenty-Four Hours (24 hrs). This translates to processing roughly Twenty (20) acres of harvested industrial hemp per day. During the harvest season, which runs from approximately mid-October to mid-November, VSC anticipates that approximately One Hundred Twenty Thousand Pounds (120,000 lbs) of wet industrial hemp biomass will be delivered to the proposed drying facility daily.

In addition to its own cultivation efforts, VSC also has strong connections to various hemp farming groups and individuals throughout California. VSC will market and promote its drying and extraction services to these outside farming entities, as production capacity allows. VSC will also implement compliance protocols to ensure that all industrial hemp biomass received from third-parties has been registered and tested in compliance with California law.

**B. Buyers of Products Produced**

VSC anticipates selling the majority of its finished products to wholesalers who specialize in hemp derived CBD oil. Through their various contacts in the industrial hemp industry, the VSC management group has been able to establish connections with several wholesalers throughout the county. Some end-product manufactures have also expressed an interest in utilizing VSC produced CBD oil for

implementation into their nutraceutical products, as well as other consumer products such as hemp oil infused consumables.

In addition, VSC is also working to develop a VSC branded product line. These products will include the hemp derived CBD oil which will be produced at the proposed facility but may also include finished products such as topical creams and lotions.

### **C. Security and Waste Management**

For security purposes, VSC will install a video surveillance system which will operate Twenty-Four Hours (24hrs) a day. In addition to video surveillance, a private security firm will be retained to conduct Twenty-Four hour (24hr) in person monitoring of the facility. VSC personnel will also undergo security training in order to ensure that the facilities are properly secured and monitored while in use.

For waste management, VSC has entered into an arrangement with the Rodale Institute to develop and implement industrial hemp cultivation and production protocols which will utilize principles of regenerative agriculture. These protocols will be implemented in order to ensure that all plant-based waste is disposed in a manner which is environmentally safe. All non-plant-based waste will be disposed of per state and local law.

### **Legal Background on Cannabis v. Industrial Hemp**

Cannabis and industrial hemp are two separate and distinct plants, as defined by federal, state, and local law. The distinctive element of the two plant types is the naturally occurring cannabinoid, tetrahydrocannabinol (“THC”). THC is the psychoactive compound which produces the “high” in cannabis use. Industrial hemp only contains trace amounts of THC (0.3% as prescribed by both state and federal law) and is non-psychoactive.

Under the Agriculture Improvement Act of 2018 (“2018 Farm Bill”), hemp was removed from the purview of the federal Controlled Substances Act and is to be regulated as an agricultural commodity by the United States Department of Agriculture (“USDA”). Similarly in California, hemp is governed by Cal. Food and Ag. Code § 81000 *et al.*, which establishes that industrial hemp and cannabis are two separate and distinct plant types and that industrial hemp shall be regulated by the Department of Food and Agriculture (“CDFA”) and not the Bureau of Cannabis Control.

Currently the USDA is developing a regulatory regime for the oversight of hemp, which is expected to be rolled out this fall and implemented for next year’s growing cycle. California recently implemented its hemp regulatory regime and this year is the first year that full-scale commercial cultivation has been allowed to take place.

Similarly, the City of Thousand Oaks Municipal Code also defines industrial hemp and cannabis separately, “[f]or the purpose of this division, “cannabis” does not mean “industrial hemp” as defined by Section 11018.5 of the [California] Health and Safety Code.” (See Thousand Oaks Municipal Code, Chapter 29, Section 5-29.05. Definitions).

### **Concluding Remarks**

VSC and its management team have been working diligently for months, to secure the equipment and industrial hemp biomass needed to implement a processing regime of this size and scale. The equipment

which will be utilized is state of art and the industrial hemp which is currently being cultivated for production is some of the finest certified organic hemp being produced in California today.

VSC is committed to working with the City of Thousand Oaks, to ensure that its processing facility is maintained and operated in compliance with all applicable local regulations.



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May 28, 2019

## MEMORANDUM

SUBJECT: EXECUTIVE SUMMARY OF NEW HEMP AUTHORITIES

On December 20, 2018, President Trump signed into law the Agriculture Improvement Act of 2018, Pub. L. 115-334 (2018 Farm Bill). The 2018 Farm Bill legalized hemp production for all purposes within the parameters laid out in the statute.

The Office of the General Counsel (OGC) has issued the attached legal opinion to address questions regarding several of the hemp-related provisions of the 2018 Farm Bill, including: a phase-out of the industrial hemp pilot authority in the Agricultural Act of 2014 (2014 Farm Bill) (**Section 7605**); an amendment to the Agricultural Marketing Act of 1946 to allow States and Indian tribes to regulate hemp production or follow a Department of Agriculture (USDA) plan regulating hemp production (**Section 10113**); a provision ensuring the free flow of hemp in interstate commerce (**Section 10114**); and the removal of hemp from the Controlled Substances Act (**Section 12619**).

The key conclusions of the OGC legal opinion are the following:

1. As of the enactment of the 2018 Farm Bill on December 20, 2018, hemp has been removed from schedule I of the Controlled Substances Act and is no longer a controlled substance.
2. After USDA publishes regulations implementing the new hemp production provisions of the 2018 Farm Bill contained in the Agricultural Marketing Act of 1946, States and Indian tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under a State or Tribal plan or under a license issued under the USDA plan.
3. States and Indian tribes also may not prohibit the interstate transportation or shipment of hemp lawfully produced under the 2014 Farm Bill.
4. A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on producing hemp under the Agricultural Marketing Act of 1946. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill **before December 20, 2018**, and whose conviction also occurred before that date.

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With the enactment of the 2018 Farm Bill, hemp may be grown only (1) with a valid USDA-issued license, (2) under a USDA-approved State or Tribal plan, or (3) under the 2014 Farm Bill industrial hemp pilot authority. That pilot authority will expire one year after USDA establishes a plan for issuing USDA licenses under the provisions of the 2018 Farm Bill.

It is important for the public to recognize that the 2018 Farm Bill preserves the authority of States and Indian tribes to enact and enforce laws regulating the **production** of hemp that are more stringent than Federal law. Thus, while a State or an Indian tribe cannot block the shipment of hemp through that State or Tribal territory, it may continue to enforce State or Tribal laws prohibiting the growing of hemp in that State or Tribal territory.

It is also important to emphasize that the 2018 Farm Bill does not affect or modify the authority of the Secretary of Health and Human Services or Commissioner of Food and Drugs to regulate hemp under applicable U.S. Food and Drug Administration (FDA) laws.

USDA expects to issue regulations implementing the new hemp production authorities in 2019.

Attachment



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May 28, 2019

MEMORANDUM FOR SONNY PERDUE  
SECRETARY OF AGRICULTURE

SUBJECT: LEGAL OPINION ON CERTAIN PROVISIONS OF THE  
AGRICULTURE IMPROVEMENT ACT OF 2018 RELATING TO  
HEMP

This memorandum provides my legal opinion on certain provisions of the Agriculture Improvement Act of 2018 ("2018 Farm Bill"), Pub. L. No. 115-334, relating to hemp.

As explained below, this memorandum concludes the following:

1. As of the enactment of the 2018 Farm Bill on December 20, 2018, hemp has been removed from schedule I of the Controlled Substances Act ("CSA") and is no longer a controlled substance. Hemp is defined under the 2018 Farm Bill to include any cannabis plant, or derivative thereof, that contains not more than 0.3 percent delta-9 tetrahydrocannabinol ("THC") on a dry-weight basis.
2. After the Department of Agriculture ("USDA" or "Department") publishes regulations implementing the hemp production provisions of the 2018 Farm Bill contained in subtitle G of the Agricultural Marketing Act of 1946 ("AMA"), States and Indian tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under a State or Tribal plan or under a license issued under the Departmental plan.
3. States and Indian tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under the Agricultural Act of 2014 ("2014 Farm Bill").
4. A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on producing hemp under subtitle G of the AMA. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

This memorandum also emphasizes two important aspects of the 2018 Farm Bill provisions relating to hemp. First, the 2018 Farm Bill preserves the authority of States and Indian tribes to enact and enforce laws regulating the **production** (but not the interstate transportation or shipment) of hemp that are more stringent than Federal law. For example, a State law prohibiting the growth or cultivation of hemp may continue to be enforced by that State. Second, the 2018 Farm Bill does not affect or modify the authority of the Secretary of Health and Human Services or Commissioner of Food and Drugs under applicable U.S. Food and Drug Administration laws.

## I. BACKGROUND

The 2018 Farm Bill, Pub. L. No. 115-334, enacted on December 20, 2018, includes several provisions relating to hemp.<sup>1</sup> This legal opinion focuses on sections 7605, 10113, 10114, and 12619, summarized below.

- **Section 7605** amends section 7606 of the 2014 Farm Bill (7 U.S.C. § 5940), which authorizes institutions of higher education or State departments of agriculture to grow or cultivate industrial hemp under certain conditions — namely, if the hemp is grown or cultivated for research purposes in a State that allows hemp production. Among other things, section 7605 amends 2014 Farm Bill § 7606 to require the Secretary of Agriculture (“Secretary”) to conduct a study of these hemp research programs and submit a report to Congress. Section 7605 also repeals 2014 Farm Bill § 7606, effective one year after the date on which the Secretary establishes a plan under section 297C of the AMA.<sup>2</sup>
- **Section 10113** amends the AMA by adding a new subtitle G (sections 297A through 297E) (7 U.S.C. §§ 1639o – 1639s) relating to hemp production. Under this new authority, a State or Indian tribe that wishes to have primary regulatory authority over the production of hemp in that State or territory of that Indian tribe may submit, for the approval of the Secretary, a plan concerning the monitoring and regulation of such hemp production. *See* AMA § 297B. For States or Indian tribes that do not have approved plans, the Secretary is directed to establish a Departmental plan concerning the monitoring and regulation of hemp production in those areas. *See* AMA § 297C. The

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<sup>1</sup> The 2014 Farm Bill defines “**industrial hemp**” as “the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” 7 U.S.C. § 5940(a)(2). The 2018 Farm Bill added a new, slightly different definition of “**hemp**” in section 297A of the AMA, defined as “the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” 7 U.S.C. § 1639o(1). Both definitions require a THC concentration of not more than 0.3 percent for a *Cannabis sativa* L. plant to be considered hemp versus marijuana. For purposes of this legal opinion, I use the terms “**hemp**” and “**industrial hemp**” interchangeably.

<sup>2</sup> The Conference Report accompanying the 2018 Farm Bill explains the effect of the repeal as follows: “The provision also repeals the hemp research pilot programs one year after the Secretary publishes a final regulation allowing for full-scale commercial production of hemp as provided in section 297C of the [AMA].” H.R. REP. NO. 115-1072, at 699 (2018).

Secretary is also required to promulgate regulations and guidelines implementing subtitle G. *See* AMA § 297D. The new authority also provides definitions (*see* AMA § 297A) and an authorization of appropriations (*see* AMA § 297E).

- **Section 10114** (7 U.S.C. § 1639o note) is a freestanding provision stating that nothing in title X of the 2018 Farm Bill prohibits the interstate commerce of hemp or hemp products. Section 10114 also provides that States and Indian tribes shall not prohibit the interstate transportation or shipment of hemp or hemp products produced in accordance with subtitle G through the State or territory of the Indian tribe.
- **Section 12619** amends the CSA to exclude hemp from the CSA definition of marijuana. Section 12619 also amends the CSA to exclude THC in hemp from Schedule I.<sup>3</sup>

In passing the 2018 Farm Bill, Congress legalized hemp production for all purposes within the parameters of the statute but reserved to the States and Indian tribes authority to enact and enforce more stringent laws regulating production of hemp.

## II. ANALYSIS

### A. As of the Enactment of the 2018 Farm Bill on December 20, 2018, Hemp Has Been Removed from Schedule I of the Controlled Substances Act and Is No Longer a Controlled Substance.

CSA § 102(6) defines “controlled substance” to mean “a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this title. . . .” 21 U.S.C. § 802(6). Marijuana<sup>4</sup> is a controlled substance listed in schedule I of the CSA. *See* CSA § 202(c)(10), schedule I (21 U.S.C. § 812(c), Schedule I (c)(10)); 21 C.F.R. § 1308.11(d)(23).

The 2018 Farm Bill amended the CSA in two ways.

- First, 2018 Farm Bill § 12619(a) amended the CSA definition of marijuana to exclude hemp. Before enactment of the 2018 Farm Bill, CSA § 102(16) (21 U.S.C. § 802(16)) defined marijuana as follows:

(16) The term ‘marihuana’ means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake,

<sup>3</sup> For additional background on hemp production prior to enactment of the 2018 Farm Bill, *see* Congressional Research Service, “Hemp as an Agricultural Commodity” (RL32725) (updated July 9, 2018), *available at* <https://crsreports.congress.gov/product/pdf/RL/RL32725>.

<sup>4</sup> This opinion uses the common spelling of “marijuana” except when quoting the CSA, which uses the “marihuana” spelling.

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or the sterilized seed of such plant which is incapable of germination.

As amended by the 2018 Farm Bill, the CSA definition of marijuana now reads:

(A) Subject to subparagraph (B), the term ‘marihuana’ means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.

(B) The term ‘marihuana’ does not include—

(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946; or

(ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

- Second, 2018 Farm Bill § 12619(b) amended the CSA to exclude THC in hemp from the term “tetrahydrocannabinols” in schedule I. As amended by the 2018 Farm Bill, CSA § 202(c)(17), schedule I (21 U.S.C. § 812(c)(17), schedule I) now reads:

Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946).

By amending the definition of marijuana to exclude hemp as defined in AMA § 297A, Congress has removed hemp from schedule I and removed it entirely from the CSA. In other words, hemp is no longer a controlled substance. Also, by amending schedule I to exclude THC in hemp, Congress has likewise removed THC in hemp from the CSA.

It is important to note that this decontrolling of hemp (and THC in hemp) is self-executing. Although the CSA implementing regulations must be updated to reflect the 2018 Farm Bill amendments to the CSA, neither the publication of those updated regulations nor any other action is necessary to execute this removal.

I address here two principal objections to the view that the decontrolling of hemp is self-executing. The first objection is that, because regulations have not been published under CSA § 201, the legislative changes to schedule I regarding hemp are not effective. This objection is not valid.

The typical process for amending the CSA schedules is through rulemaking. Under CSA § 201(a), the Attorney General “may by rule” add to, remove from, or transfer between the schedules, any drugs or other substances upon the making of certain findings. 21 U.S.C. § 811(a). However, the schedules also can be amended directly by Congress through changes to the statute; and Congress has done so several times.<sup>5</sup>

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<sup>5</sup> See, e.g., Pub. L. 112-144, § 1152 (amending schedule I to add cannabimimetic agents); Pub. L. 101-647, § 1902(a) (amending schedule III to add anabolic steroids).

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The second objection is that, because the legislative changes to schedule I regarding hemp are not yet reflected in 21 C.F.R. § 1308.11, the removal is not yet effective. This objection also is not valid.

It is axiomatic that statutes trump regulations. *See Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Gonzales*, 468 F.3d 826, 829 (D.C. Cir. 2006) (“[A] valid statute always prevails over a conflicting regulation[.]”). Congress established the five CSA schedules in statute, providing that “[s]uch schedules shall initially consist of the substances listed in this section.” 21 U.S.C. § 812(a).<sup>6</sup> Congress further provided that “[t]he schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.” 21 U.S.C. § 812(a). The requirement to update and republish the schedules, however, is not a prerequisite to the effectiveness of the schedules “established by [the statute].” *Id.* In other words, where Congress itself amends the schedules to add or remove a controlled substance, the addition or removal of that controlled substance is effective immediately on enactment (absent some other effective date in the legislation); its addition to or removal from a schedule is not dependent on rulemaking.<sup>7</sup>

To illustrate, Congress amended the CSA in 2012 to add “cannabimimetic agents” to schedule I. That amendment was enacted as part of the Synthetic Drug Abuse Prevention Act of 2012 (Pub. L. 112-144, title XI, subtitle D), which was signed into law on July 9, 2012. Almost six months later, the Drug Enforcement Administration (“DEA”) published a final rule establishing the drug codes for the cannabimimetic agents added to schedule I by Congress and making other conforming changes to schedule I as codified in 21 C.F.R. § 1308.11. *See* 78 Fed. Reg. 664 (Jan. 4, 2013). In explaining why notice-and-comment rulemaking was unnecessary, DEA noted that “the placement of these 26 substances in Schedule I **has already been in effect since July 9, 2012.**” *Id.* at 665 (emphasis added). In other words, the legislative changes to schedule I were effective immediately upon enactment. The reflection of those changes in 21 C.F.R. § 1308.11, although required by 21 U.S.C. § 812(a), was not necessary for the execution of those changes to schedule I.

Accordingly, enactment of the 2018 Farm Bill accomplished the removal of hemp (and THC in hemp<sup>8</sup>) from the CSA. Conforming amendments to 21 C.F.R. § 1308.11, while required as part

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<sup>6</sup> “Marihuana” and “Tetrahydrocannabinols” were both included in the initial schedule I established by Congress in 1970.

<sup>7</sup> *Cf. United States v. Huerta*, 547 F.2d 545, 547 (10th Cir. 1977) (“[F]ailure to publish the ‘updated’ schedules as required by Section 812(a) had no effect upon the validity of those substances initially listed in the five schedules.”); *United States v. Monroe*, 408 F. Supp. 270, 274 (N.D. Cal. 1976) (“Thus, while section 812(a) clearly orders the controlled substance schedules to be republished, it is clear that Congress did not intend republication to serve as a reissuance of the schedules, which if done improperly would cause those schedules to lapse and expire. . . . [T]he requirement that the schedules, once ‘updated,’ be ‘republished’ was solely for the purpose of establishing one list which would reflect all substances which were currently subject to the Act’s provisions. . . .”).

<sup>8</sup> Schedule I, as published in 21 C.F.R. § 1308.11, includes a definition of “tetrahydrocannabinols” in paragraph (d)(31) that does not appear in the CSA. Notwithstanding the presence of that definition in the current regulations, I

of DEA's continuing obligation to publish updated schedules, are not necessary to execute the 2018 Farm Bill changes to schedule I.<sup>9</sup>

**B. After the Department of Agriculture Publishes Regulations Implementing the Hemp Production Provisions of the 2018 Farm Bill Contained in Subtitle G of the Agricultural Marketing Act of 1946, States and Indian Tribes May Not Prohibit the Interstate Transportation or Shipment of Hemp Lawfully Produced Under a State or Tribal Plan or Under a License Issued Under the Departmental Plan.**

AMA § 297D(a)(1)(A) directs the Secretary to issue regulations and guidelines "as expeditiously as possible" to implement subtitle G of the AMA. 7 U.S.C. § 1639r(a)(1)(A). These regulations will address the approval of State and Tribal plans under AMA § 297B and the issuance of licenses under the Departmental plan under AMA § 297C. As explained below, once these regulations are published, States and Indian tribes may not prohibit the transportation or shipment of hemp (including hemp products) produced in accordance with an approved State or Tribal plan or produced under a license issued under the Departmental plan.

Transportation of hemp is addressed in 2018 Farm Bill § 10114.<sup>10</sup> Subsection (a) provides:

(a) RULE OF CONSTRUCTION.—Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp (as defined in section 297A of the Agricultural Marketing Act of 1946 (as added by section 10113)) or hemp products.

7 U.S.C. § 1639o note. This provision states that nothing in title X of the 2018 Farm Bill

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am of the opinion that THC in hemp is excluded from THC as a schedule I controlled substance under the CSA by virtue of the 2018 Farm Bill amendments.

<sup>9</sup> Schedule I, as reflected in 21 C.F.R. § 1308.11, includes a separate listing of "marihuana extract" in paragraph (d)(58). Marijuana extract is not reflected in schedule I in the statute because it was added after 1970 by regulation under CSA § 201. The term "marihuana extract" is defined in regulation as "an extract containing one or more cannabinoids that has been derived from any plant of the genus *Cannabis*, other than the separated resin (whether crude or purified) obtained from the plant." The 2018 Farm Bill amended the definition of "marihuana" to exclude hemp, but because the regulatory definition of "marihuana extract" in schedule I does not use the words "marihuana" or "tetrahydrocannabinols" to define the term, a question arises whether **hemp extract** is still considered to be listed as a schedule I controlled substance. While the issue is not further addressed in this opinion, I think that the revised statutory definition of "marihuana" has effectively removed hemp extract from schedule I, and that reflecting such in 21 C.F.R. § 1308.11(d)(58) would be merely a conforming amendment.

<sup>10</sup> Hemp transportation is also addressed in annual appropriations acts, which restrict Federal appropriated funds from being used to prohibit the transportation of hemp. However, those provisions are limited in scope because they address only hemp produced under the 2014 Farm Bill authority, and they address only Federal government actions. That is, while the provisions prohibit Federal actors from blocking the transportation of so-called "2014 Farm Bill hemp," they do not restrict State action in that regard. See Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2019, Pub. L. 116-6, div. B, § 728 (prohibiting funds made available by that Act or any other Act from being used in contravention of 2014 Farm Bill § 7606 or "to prohibit the transportation, processing, sale, or use of industrial hemp, or seeds of such plant, that is grown or cultivated in accordance with [2014 Farm Bill § 7606], within or outside the State in which the industrial hemp is grown or cultivated"). See also Commerce, Justice, Science, and Related Agencies Appropriations Act, 2019, Pub. L. 116-6, div. C, § 536 ("None of the funds made available by this Act may be used in contravention of [2014 Farm Bill § 7606] by the Department of Justice or the Drug Enforcement Administration.").

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prohibits the interstate commerce of hemp. However, this provision, standing alone, does not have the effect of sanctioning the transportation of hemp in States or Tribal areas where such transportation is prohibited under State or Tribal law.

Subsection (b), however, specifically prohibits States and Indian tribes from prohibiting the transportation of hemp through that State or Tribal territory. Subsection (b) provides:

(b) TRANSPORTATION OF HEMP AND HEMP PRODUCTS.—No State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the Agricultural Marketing Act of 1946 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable.

7 U.S.C. § 1639o note. In effect, this provision preempts State law to the extent such State law prohibits the interstate transportation or shipment of hemp that has been produced in accordance with subtitle G of the AMA.

As a matter of constitutional law, “[t]he Supremacy Clause provides a clear rule that federal law ‘shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any [S]tate to the Contrary notwithstanding. . . .’ Under this principle, Congress has the power to preempt [S]tate law.” *Arizona v. United States*, 567 U.S. 387, 398-99 (2012) (citing U.S. Const. art. VI, cl. 2). “Under the doctrine of federal preemption, a federal law supersedes or supplants an inconsistent [S]tate law or regulation.” *United States v. Zadeh*, 820 F.3d 746, 751 (5th Cir. 2016).

Federal courts generally recognize three categories of preemption: (1) express preemption (where Congress “withdraw[s]” powers from the State through an “express preemption provision”);<sup>11</sup> (2) field preemption (where States are “precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance”);<sup>12</sup> and conflict preemption (where State laws are preempted when they conflict with Federal law, which includes situations “where ‘compliance with both federal and [S]tate regulations is a physical impossibility’” or situations “where the challenged [S]tate law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress’”).<sup>13</sup> *Arizona*, 567 U.S. at 399-400 (citations omitted); *see also Zadeh*, 820 F.3d at 751.

<sup>11</sup> *See, e.g.*, 7 U.S.C. § 1639i(b) (“(b) Federal preemption.—No State or a political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered (which shall include such other similar terms as determined by the Secretary of Agriculture) or was developed or produced using genetic engineering, including any requirement for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering.”).

<sup>12</sup> *See, e.g., Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm’n*, 461 U.S. 190, 212 (“[T]he federal government has occupied the entire field of nuclear safety concerns, except the limited powers expressly ceded to the [S]tates.”).

<sup>13</sup> *See, e.g.*, 21 U.S.C. § 903 (“No provision of this subchapter shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is

Section 10114(b) of the 2018 Farm Bill satisfies the definition of conflict preemption because a State law prohibiting the interstate transportation or shipment of hemp or hemp products that have been produced in accordance with subtitle G of the AMA would be in direct conflict with section 10114(b), which provides that no State may prohibit such activity.<sup>14</sup> Therefore, any such State law has been preempted by Congress. The same result applies to Indian tribes.<sup>15</sup>

In sum, once the implementing regulations are published, States and Indian tribes may not prohibit the shipment of hemp lawfully produced under an approved State or Tribal plan or under a license issued under the Departmental plan.

**C. States and Indian Tribes May Not Prohibit the Interstate Transportation or Shipment of Hemp Lawfully Produced Under the Agricultural Act of 2014.**

Because the 2018 Farm Bill does not immediately repeal the hemp pilot authority in 2014 Farm Bill § 7606 — and because the publication of regulations implementing the hemp production provisions of the 2018 Farm Bill will likely not occur until later in 2019 — the question arises whether States and Indian tribes are prohibited from blocking the interstate transportation or shipment of hemp (including hemp products) lawfully produced under the 2014 Farm Bill. The answer depends on the meaning of the phrase “in accordance with subtitle G of the Agricultural Marketing Act of 1946” in 2018 Farm Bill § 10114(b) (7 U.S.C. § 1639o note). Only hemp produced in accordance with subtitle G is covered by the preemption provision discussed above. As explained below, it is my opinion that the answer to this question is yes, by operation of AMA § 297B(f).

AMA § 297B(f) states the legal effect of the provisions authorizing States and Indian tribes to develop plans for exercising primary regulatory authority over the production of hemp within that State or territory of the Indian tribe. Specifically, section 297B(f) provides:

(f) EFFECT.—Nothing in this section prohibits the production of hemp in a State or the territory of an Indian tribe—

(1) for which a State or Tribal plan is not approved under this section, if the production of hemp is in accordance with section 297C or other Federal laws (including regulations); and

(2) if the production of hemp is not otherwise prohibited by the State or Indian tribe.

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a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.”).

<sup>14</sup> Alternatively, section 10114(b) might be considered an express preemption provision because the statute expressly withdraws the power of a State to prohibit the transportation or shipment of hemp or hemp products through the State.

<sup>15</sup> AMA § 297B(a)(3) contains an anti-preemption provision stating that nothing in § 297B(a) “preempts or limits any law of a State or Indian tribe” that “regulates the production of hemp” and “is more stringent than [subtitle G].” 7 U.S.C. § 1639p(a)(3). However, that anti-preemption provision is limited to the production of hemp — not the transportation or shipment of hemp — and thus does not conflict with 2018 Farm Bill § 10114(b).

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7 U.S.C. § 1639p(f) (emphasis added).

This provision addresses the production of hemp in a State or Tribal territory for which the State or tribe does not have an approved plan under AMA § 297B. This provision acknowledges that, in such a scenario, the production of hemp in that State or Tribal territory is still permissible if it is produced **either** in accordance with the Departmental plan under AMA § 297C **or** in accordance with other Federal laws, and the State or tribe does not otherwise prohibit its production.

The plain language of subtitle G of the AMA, as added by the 2018 Farm Bill, thus clearly contemplates a scenario in which hemp is neither produced under an approved 297B plan nor under a license issued under the Department's 297C plan, but is still legally produced under "other Federal laws." It is my opinion that "other Federal laws" encompasses 2014 Farm Bill § 7606.<sup>16</sup>

To my knowledge, before enactment of 2014 Farm Bill § 7606, the CSA was the only Federal law that authorized the production of hemp. Indeed, the production of hemp — as the "manufacture" of a schedule I controlled substance — was generally prohibited under the CSA except to the extent authorized under a registration or waiver under the CSA. *See* 21 U.S.C. §§ 802(15), 802(22), 822, and 823; 21 C.F.R. part 1301. Given (1) the removal of hemp as a controlled substance under the CSA, (2) the delayed repeal of the 2014 Farm Bill § 7606 authority, and (3) the enactment of the new hemp production authorities in subtitle G of the AMA, it is my opinion that "other Federal laws" refers to the provisions of 2014 Farm Bill § 7606, which are still in effect. Such an interpretation gives immediate effect to the phrase "other Federal laws." It is a "cardinal principle of interpretation that courts must give effect, if possible, to every clause and word of a statute." *See, e.g., Loughrin v. United States*, 573 U.S. 351, 358 (2014) (internal quotations and citations omitted).

Therefore, reading AMA § 297B(f) in harmony with 2018 Farm Bill § 10114(b), if the hemp is legally produced in accordance with 2014 Farm Bill § 7606 ("other Federal law"), then, by virtue of AMA § 297B(f), its production is not prohibited. Such hemp would have been produced "in accordance with subtitle G," which specifically addresses just such a scenario, as AMA § 297B(f) is part of subtitle G. Accordingly, under 2018 Farm Bill § 10114(b), a State or Indian

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<sup>16</sup> That Congress envisioned such a scenario is apparent given the language in 2018 Farm Bill § 7605(b) delaying the repeal of 2014 Farm Bill § 7606 until 12 months after the Secretary establishes the 297C plan. Accordingly, this interpretation is not precluded by AMA § 297C(c)(1), which provides: "[i]n the case of a State or Indian tribe for which a State or Tribal plan is not approved under section 297B, it shall be unlawful to produce hemp in that State or the territory of that Indian tribe without a license issued by the Secretary under subsection (b)." Given the reference to "or other Federal laws" in AMA § 297B(f)(1) — and the fact that 2014 Farm Bill § 7606 is still in effect — it would be an absurd reading of AMA § 297C(c)(1) to conclude that hemp produced in accordance with Federal law (2014 Farm Bill § 7606) is, at the same time, unlawful without a separate license issued by the Secretary under the 297C plan. As courts have long recognized, statutory interpretations that "produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available." *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982).

tribe may not prohibit the transportation or shipment of so-called “2014 Farm Bill hemp” through that State or Tribal territory.<sup>17</sup>

#### Recent Developments

I acknowledge that this conclusion is in tension with a recent decision in a case in the District of Idaho, but it also is consistent with a recent decision in a case in the Southern District of West Virginia. Neither court addressed the “other Federal laws” language in AMA § 297B(f)(1), which I find conclusive.

In *Big Sky Scientific LLC v. Idaho State Police*, Case No. 19-CV-00040 (D. Idaho), a magistrate judge found that a shipment of Oregon hemp bound for Colorado and interdicted by Idaho State Police could not have been produced “in accordance with subtitle G” because the State of origin does not yet have an approved plan under AMA § 297B and the Secretary has not yet established a plan under AMA § 297C.<sup>18</sup> The magistrate acknowledged Oregon law authorizing the cultivation of hemp, noting the plaintiff’s assertion that the hemp was produced by a grower licensed by the Oregon Department of Agriculture (and, thus, presumably in compliance with 2014 Farm Bill § 7606 requirements).<sup>19</sup> However, in denying the plaintiff’s motion for a preliminary injunction, the magistrate concluded that, in enacting the 2018 Farm Bill, Congress intended to “create a regulatory framework around the production and interstate transportation of hemp for purposes of federal law, and that framework is to be contained in the federal (or compliant [S]tate or [T]ribal) plan for production of hemp found in the 2018 Farm Bill.”<sup>20</sup> Although the 2018 Farm Bill allows hemp to be transported across State lines, the magistrate found those interstate commerce protections apply only to hemp produced under regulations promulgated under the authority of the 2018 Farm Bill.<sup>21</sup> Therefore, because those regulations do not yet exist, the interdicted hemp is subject to Idaho law prohibiting its transportation.

USDA is not a party in the *Big Sky* case, and this office does not concur with the reasoning of the magistrate regarding the shipment of hemp lawfully produced under the 2014 Farm Bill. In

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<sup>17</sup> This conclusion seems to be supported in the legislative history as well. In explaining the effect of the preemption provision, the Conference Report states: “While [S]tates and Indian tribes may limit the production and sale of hemp and hemp products within their borders, the Managers, in Sec. 10112 [sic], agreed to not allow [S]tates and Indian tribes to limit the transportation or shipment of hemp or hemp products through the [S]tate or Indian territory.” H.R. REP. NO. 115-1072, at 738 (2018). Notably, the Managers referred to hemp generally, not merely hemp produced under a plan developed under subtitle G of the AMA.

<sup>18</sup> See *Big Sky*, ECF Doc. #32, Memorandum Decision and Order Re: Plaintiff’s Motion for Preliminary Injunction; see also ECF Doc. #6, Memorandum Decision and Order Re: Plaintiff’s Emergency Motion for Temporary Restraining Order and Preliminary Injunction and Plaintiff’s Motion to File Overlength Brief (*available at* 2019 WL 438336 (Feb. 2, 2019)).

<sup>19</sup> *Big Sky*, ECF Doc. #32, at 5, 7-8.

<sup>20</sup> *Id.* at 3.

<sup>21</sup> *Id.* at 19-26.

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interpreting the statutory language, the magistrate correctly noted the well-recognized principle of statutory construction that statutes should not be interpreted “in a manner that renders other provisions of the same statute inconsistent, meaningless, or superfluous.”<sup>22</sup> However, seemingly ignoring that guiding principle of interpretation, the magistrate did not address the effect of the “other Federal laws” language in AMA § 297B(f) or attempt to give that language any meaning. The Idaho court failed to read the statute as a whole and did not consider the “other Federal laws” clause that I find conclusive. Given the preliminary nature of the magistrate’s ruling, I find his opinion denying a preliminary injunction unpersuasive.<sup>23</sup>

Conversely, the interpretation of 2018 Farm Bill § 10114 advanced by this legal opinion is consistent with a decision issued in the Southern District of West Virginia. In *United States v. Mallory*, Case No. 18-CV-1289 (S.D. W. Va.), the Department of Justice filed a civil action to seize hemp allegedly grown in violation of the CSA and also outside the scope of the 2014 Farm Bill. At issue in that case was hemp purportedly grown by a producer licensed by the State of West Virginia under a 2014 Farm Bill § 7606 pilot program, where the hemp seeds were shipped from a Kentucky supplier licensed by the Commonwealth of Kentucky under a 2014 Farm Bill § 7606 pilot program. The court relied on a combination of laws — the 2014 Farm Bill, the appropriations acts provisions,<sup>24</sup> and the 2018 Farm Bill — to dissolve a preliminary injunction against the defendant<sup>25</sup> and to dismiss entirely the government’s case.<sup>26</sup> In dissolving the preliminary injunction, the court permitted the defendants to transport the hemp product across State lines to Pennsylvania for processing and sale.<sup>27</sup>

Although the *Mallory* court did not have occasion to address any State attempts to block the transportation of hemp, the court did reference 2018 Farm Bill § 10114, noting that it “expressly allows hemp, its seeds, and hemp-derived products to be transported across State lines.”<sup>28</sup> The district judge’s opinion addressed hemp produced under 2014 Farm Bill § 7606 and not hemp produced under State, Tribal, or Departmental plans. The conclusion reached by the *Mallory* court is consistent with my interpretation that States cannot block the shipment of hemp, whether

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<sup>22</sup> *Id.* at 21-22 (citing *Padash v. I.N.S.*, 258 F.3d 1161, 1170-71 (9th Cir. 2004)). The magistrate continued:

It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant. . . . It is our duty to give effect, if possible, to every clause and word of a statute.

*Id.* at 23 (internal quotations and citations omitted).

<sup>23</sup> Indeed, the magistrate’s ruling is under appeal. See *Big Sky Sci. LLC v. Bennetts*, Case No. 19-35138 (9th Cir.).

<sup>24</sup> See *supra* footnote 10.

<sup>25</sup> *Mallory*, ECF Doc. #60, Memorandum Opinion and Order, 2019 WL 252530 (S.D. W. Va. Jan. 17, 2019).

<sup>26</sup> *Mallory*, ECF Doc. #72, Memorandum Opinion and Order, 2019 WL 1061677 (S.D. W. Va. Mar. 6, 2019).

<sup>27</sup> *Mallory*, ECF Doc. #60, 2019 WL 252530, at \*3.

<sup>28</sup> *Mallory*, ECF Doc. #72, 2019 WL 1061677, at \*6.

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that hemp is produced under the 2014 Farm Bill or under a State, Tribal, or Departmental plan under the 2018 Farm Bill. It is also a final judgment of the Southern District of West Virginia court, and not a preliminary ruling as with the District of Idaho magistrate's opinion.<sup>29</sup>

In matters of statutory interpretation, the text of the statute governs. One must read that text in its entirety and give every word meaning. The reference to "other Federal laws" must be given meaning, and that language clearly refers to the Federal law that currently authorizes the production of hemp — 2014 Farm Bill § 7606. Therefore, hemp produced under that pilot authority is hemp produced in accordance with subtitle G of the AMA. States and Indian tribes may not prohibit the transportation or shipment of such hemp through that State or Tribal territory.

**D. The 2018 Farm Bill Places Restrictions on the Production of Hemp by Certain Felons.**

The 2018 Farm Bill added a new provision addressing the ability of convicted felons to produce hemp. The 2014 Farm Bill is silent on the issue. AMA § 297B(e)(3)(B) (hereafter, "Felony provision"), as added by the 2018 Farm Bill, provides:

(B) FELONY.—

(i) IN GENERAL.—Except as provided in clause (ii), any person convicted of a felony relating to a controlled substance under State or Federal law before, on, or after the date of enactment of this subtitle shall be ineligible, during the 10-year period following the date of the conviction—

(I) to participate in the program established under this section or section 297C; and

(II) to produce hemp under any regulations or guidelines issued under section 297D(a).

(ii) EXCEPTION.—Clause (i) shall not apply to any person growing hemp lawfully with a license, registration, or authorization under a pilot program authorized by section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940) before the date of enactment of this subtitle.

7 U.S.C. § 1639p(e)(3)(B) (emphasis added). The references to "the date of enactment of this subtitle" are to subtitle G of the AMA, as added by section 10113 of 2018 Farm Bill. Therefore, the "date of enactment of this subtitle" is the date of enactment of the 2018 Farm Bill — December 20, 2018.

In explaining the Felony provision, the Conference Report notes:

Any person convicted of a felony relating to a controlled substance shall be ineligible to participate under the [S]tate or [T]ribal plan for a 10-year period following the date of the conviction. However, this prohibition shall not apply to producers who have been lawfully participating in a [S]tate hemp pilot program as authorized by the Agricultural Act of 2014, prior to enactment of this subtitle. Subsequent felony convictions after the date of enactment of this subtitle will trigger a 10-year

<sup>29</sup> *Mallory*, ECF Doc. #72, 2019 WL 1061677, at \*9 (denying the United States' motion to amend and granting the defendants' motion to dismiss). *Big Sky*, ECF Doc. #32, at 28 (denying the plaintiff's motion for preliminary injunction and noting that the court will separately issue an order setting a scheduling conference to govern the case going forward).

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nonparticipation period regardless of whether the producer participated in the pilot program authorized in 2014.

H.R. REP. NO. 115-1072, at 737 (2018).

In sum, a person convicted of a State or Federal felony relating to a controlled substance — regardless of when that conviction occurred — is ineligible to produce hemp under subtitle G of the AMA for a period of 10 years following the date of the conviction. An exception exists in clause (ii) of the Felony provision that applies to a person who was lawfully producing hemp under the 2014 Farm Bill **before December 20, 2018**, and who had been convicted of a felony relating to a controlled substance before that date. States and Indian tribes now have a responsibility to determine whether a person wishing to produce hemp in that State or Tribal territory has any Federal or State felony convictions relating to controlled substances that would make that person ineligible to produce hemp.

### III. OTHER ISSUES

There are two additional important aspects of this issue that should be emphasized.

First, the 2018 Farm Bill preserves the authority of States and Indian tribes to enact and enforce laws regulating the production of hemp that are more stringent than Federal law. *See* AMA § 297B(a)(3) (7 U.S.C. § 1639p(a)(3)) (“Nothing in this subsection preempts or limits any law of a State or Indian tribe that . . . (i) regulates the production of hemp; and (ii) is more stringent than this subtitle.”). For example, a State may continue to prohibit the growth or cultivation of hemp in that State.<sup>30</sup> As discussed above, however, while a State or Indian tribe may prohibit the production of hemp, it may not prohibit the interstate shipment of hemp that has been produced in accordance with Federal law.

Second, the 2018 Farm Bill does not affect or modify the authority of the Secretary of Health and Human Services (“HHS Secretary”) or Commissioner of Food and Drugs (“FDA Commissioner”) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) and section 351 of the Public Health Service Act (42 U.S.C. § 262). *See* AMA § 297D(c) (7 U.S.C. § 1639r(c)). While AMA § 297D(b) provides that the Secretary of Agriculture shall have “sole authority” to issue Federal regulations and guidelines that relate to the production of hemp, this authority is subject to the authority of the HHS Secretary and FDA Commissioner to promulgate Federal regulations and guidelines under those FDA laws. 7 U.S.C. § 1639r(b).

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<sup>30</sup> Certain states continue to prohibit the cultivation of hemp. *See* National Conference of State Legislatures, “State Industrial Hemp Statutes,” available at <http://www.ncsl.org/research/agriculture-and-rural-development/state-industrial-hemp-statutes.aspx#state> (updated Feb. 1, 2019).

#### IV. CONCLUSION

I have analyzed the hemp provisions enacted as part of the 2018 Farm Bill and reach the following conclusions:

1. As of the enactment of the 2018 Farm Bill on December 20, 2018, hemp has been removed from schedule I of the CSA and is no longer a controlled substance.
2. After USDA publishes regulations implementing the hemp production provisions of the 2018 Farm Bill contained in subtitle G of the AMA, States and Indian tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under a State or Tribal plan or under a license issued under the Departmental plan.
3. States and Indian tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under the 2014 Farm Bill.
4. A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on producing hemp under subtitle G of the AMA. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

The 2018 Farm Bill preserves the authority of States and Indian tribes to enact and enforce laws regulating the production of hemp that are more stringent than Federal law. Additionally, the 2018 Farm Bill does not affect or modify the authority of the HHS Secretary or FDA Commissioner to regulate hemp under applicable FDA laws.

# FDA is Committed to Sound, Science-based Policy on CBD

*By: Amy Abernethy, M.D., Ph.D., Principal Deputy Commissioner, and Lowell Schiller, J.D., Principal Associate Commissioner for Policy*



*Amy Abernethy, M.D., Ph.D.*

Science forms the basis for decisions at the U.S. Food and Drug Administration (FDA) and is paramount when it comes to making decisions that will impact the health and safety of the American public. We apply this rigorous, science-based approach to matters large and small that come before the Agency — including with respect to products containing cannabis or cannabis-derived compounds, including cannabidiol (CBD).

We recognize that there is significant public interest in these products, for therapeutic purposes and otherwise. At the same time, there are many unanswered questions about the science, safety, and quality of many of these products. As we approach these questions, we do so as a science-based regulatory agency committed to our mission of protecting and promoting public health.

The FDA's approach to cannabis and cannabis-derived compounds has been consistent. We treat substances derived from cannabis just like we do any other substances, and they are subject to the same authorities as any other substance. That said, some other relevant laws have changed, and so has the market.

On the state level, some jurisdictions have eliminated certain prohibitions on cannabis or cannabis-derived compounds. On the federal level, the Agriculture Improvement Act of 2018 (Farm Bill) removed cannabis and cannabis derivatives that are very low in THC from the definition of marijuana in the Controlled Substances Act (CSA). At the same time, that legislation specifically preserved the FDA's responsibility over such products.

As these other laws have changed, and as more cannabis products come to the market (whether lawfully or otherwise), the FDA's role is becoming more practically relevant to many affected stakeholders. We recognize the need to be clear and open about where things stand, and about the efficient and science-based way in which we are moving forward. This includes being transparent and up-front with the public and all of our stakeholders ([/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis](#)) as we continue to collect information and data to deepen our understanding of CBD.



*Lowell Schiller, J.D.*

## Where things stand

Under the statutory authorities that the FDA has the responsibility to administer, the relevant legal requirements vary depending on which type of product we're talking about. For example, if a product is being marketed as a drug — meaning, for example, that it's intended to have a therapeutic effect such as treating a disease — then it's regulated as a drug, and it generally cannot be sold without FDA approval (or, in the case of an over-the-counter drug, an FDA monograph). Drugs have important therapeutic value, and it is critical that we continue to do what we can to support the science needed to develop new drugs from cannabis.

Food, including dietary supplements, is regulated differently, but with the same overarching goal of protecting consumers. Among other things, it is currently illegal to put into interstate commerce a food to which CBD has been added, or to market CBD as, or in, a dietary supplement. Essentially, the relevant statutory provisions prohibit these uses of CBD because CBD was the subject of substantial clinical investigations into its potential medical uses before it was added to foods (including dietary supplements), and, separately, because CBD is the active ingredient in Epidiolex, an FDA-approved prescription drug product to treat rare, severe forms of epilepsy.

At the same time, we recognize that there is substantial public interest in marketing and accessing CBD in food, including dietary supplements. The statutory provisions that currently prohibit marketing CBD in these forms also allow the FDA to issue a regulation creating an exception, and some stakeholders have asked that the FDA consider issuing such a regulation to allow for the marketing of CBD in conventional foods or as a dietary supplement, or both. This raises important and challenging questions of regulatory policy and public health.

When dealing with complex questions like those posed by CBD, the FDA's top priority is always our mission of protecting and promoting public health. The Agency is committed to science-based decision making when it comes to CBD, while also taking steps to consider if there are appropriate regulatory pathways for the lawful marketing of CBD, outside of the drug setting.

While we recognize the potential benefits of CBD, questions remain regarding its safety. During our review of the marketing application for Epidiolex, we identified certain safety risks, including the potential for liver injury. Furthermore, unsubstantiated therapeutic claims — such as claims that CBD products can treat serious diseases — can lead consumers to put off getting important medical care. Over the past several years, the Agency has issued several warning letters to firms that were marketing unapproved new drugs claiming to contain CBD, including for uses such as treating cancer or Alzheimer's disease. These products were not approved by the FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease. Consumers should beware of purchasing and using any such products. The FDA also tested the chemical content of cannabinoid compounds in some of the products, and many were found not to contain the levels of CBD they claimed to contain.

The Agency understands the importance of communicating clearly with the public about our approach to CBD (</news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>) and is taking an Agency-wide, integrated, and collaborative approach to addressing the regulation of products made from CBD that fall under our jurisdiction. Through this work, the FDA is exploring potential pathways for various types of CBD products to be lawfully marketed. An important component of this work is obtaining and evaluating information to address outstanding questions related to the safety of CBD products that will inform the Agency's consideration of potential regulatory frameworks for CBD while maintaining the FDA's rigorous public health standards.

## Listening to and learning from stakeholders

The magnitude of the issue was center stage at the FDA's recent public hearing ([/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds](#)), on May 31st, where the Agency provided stakeholders a platform to share feedback and experiences and to provide the Agency with scientific data and other information related to cannabis and cannabis-derived compounds, including CBD. Perspectives were shared from supporters of cannabis and cannabis-derived products, as well as commenters who are concerned about potentially harmful products being widely available.

In addition to the overall uncertainty about the safety of CBD, there were several significant takeaways from the hearing. Several commenters expressed a desire for a regulatory pathway to enable lawful marketing of cannabis-derived products (especially CBD) in food and dietary supplements, with appropriate regulatory oversight that includes: clear safety standards and strong enforcement; the need to support research evaluating the therapeutic effects of CBD; the need for consistent terminology related to these products; and, the need for industry standards to address the potentially dangerous manufacturing quality issues with some cannabis-derived products on the market today.

The Agency benefitted from the myriad of viewpoints expressed and information shared during the recent public hearing, including new scientific data, and we look forward to reviewing written comments submitted to the public docket ([/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds](#)), including comments on safety (including whether there is a threshold level that could appropriately be considered safe for foods and dietary supplements), manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds.

Information collected through the public docket will assist our ongoing work in this area. Together, this will allow us to articulate what we reliably know and where new research is needed. Where data gaps are identified, we will be examining how additional research can be performed quickly and efficiently to address critical questions about the safety and effectiveness of CBD.

There are many unanswered questions about CBD products outside the approved drug context. For example, there are open questions such as:

- How much CBD is safe to consume in a day? How does it vary depending on what form it's taken?
- Are there drug interactions that need to be monitored?

- What are the impacts to special populations, like children, the elderly, and pregnant or lactating women?
- What are the risks of long-term exposure?

These and other questions need to be considered if there is interest in exploring a framework under which CBD might be available more widely.

## **Preserving incentives for research and drug development**

We take to heart concerns from stakeholders about the challenges in conducting research with cannabis and CBD. The FDA is committed to doing what we can to facilitate and preserve incentives for clinical research. We are also concerned that widespread availability in products like foods or dietary supplements could reduce commercial incentives to study CBD for potential drug uses, which would be a loss for patients.

To conduct clinical research that could potentially lead to an approved new drug, researchers need to submit an Investigational New Drug application to the FDA's Center for Drug Evaluation and Research (</news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>). For use as an animal drug product, researchers would establish an Investigational New Animal Drug (INAD) file with the FDA's Center for Veterinary Medicine.

Because the 2018 Farm Bill removed hemp from the definition of marijuana in the CSA, this change may streamline the process for researchers to study hemp and certain cannabis derivatives, including CBD, which could speed the development of new drugs from those substances.

## **Paving the way for regulatory clarity**

While the Agency continues to believe that the drug approval process is the best way to ensure the safety of new drugs, including those made with CBD, the Agency is committed to evaluating the regulatory frameworks for non-drug uses, including products marketed as foods and dietary supplements. We remain steadfast in our effort to obtain research, data, and other safety and public health input to inform our approach and to address consumer access in a way that protects public health, maintains incentives for cannabis drug development, and creates a robust administrative record needed to support the initiation of any rulemaking. As we learn more, we will continue to update the public about our path forward and provide information that is based on sound science and data.