2019 HOUSE JUDICIARY

HB 1113

2019 HOUSE STANDING COMMITTEE MINUTES

Judiciary Committee
Prairie Room, State Capitol

HB 1113
1/7/2019
30483

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Delores D. Shimek

Explanation or reason for introduction of bill/resolution:

A BILL relating to the definition of marijuana and the scheduling of controlled substances; and to declare an emergency.

Minutes: 1,2,3

Chairman Koppelman: Opened the hearing on HB 1113.

Mark Hardy Executive Director, State Department of Pharmacy: (See Attachment 1 & 2) Read his testimony and went through it thoroughly, as well as the bill. 2:00-13:00.

Representative Satrom: Is there any differentiation between standard Hemp, Agricultural VS. Nonagricultural?

Mark Hardy: The Farm Bill clearly created a carve out for the hemp plant. Specifically, the provision is that it's less than .3% THC. There is going to be a state based program to be sure of checks and balances to assure hemp is produced appropriately. Derived products that will be marketed for sale will only come from state based and approved providers of the hemp plant.

Representative Satrom: Are they different between the hemp that's being used for non-medicinal products Vs medicinal components.

Mark Hardy: Hemp will be hemp but it has to contain less than a certain percentage of THC concentration.

Rep. McWilliams: Does this mean the state can have a program that does not have to be an experimental crop run by NDSU?

Mark Hardy: I don't know for sure how the program will be run and it may be a better question for the Agricultural Commissions office. All we know, from my standpoint it created that section that clearly delineates Hemp from marijuana, which is important for the Controlled Substance Act.

Representative McWilliams: On page 24, line 9 of the bill it says "Derived from cannabis and no more than .1% weight for weight residual with amounts of THC. Can you go into more detail regarding the ".1% weight for weight"? I have not heard the term "weight for weight".

Mark Hardy: That is word for word definition that the DEA used specifically for pharmaceutical product, Epidiolex, that was brought to market and how they listed it. They were very distinct in that language as it has to be an approved Cannabidiol drug. This has gone through phased clinical trials and rigorous testing of any pharmaceuticals. They are specific on the weight of dialects so that it wouldn't be lumped into other compounds as well. Epidiolex are derived from the marijuana plant, not the hemp plant, to have a specific exception in the Controlled Substance act.

Representative Vetter: You said there is a separation between hemp type products. Is there anything in this definition that separates CBD or medical type products from recreation use marijuana?

Mark Hardy: That definition on page 1. I have a proposed amendment that I will work to make more clear. Marijuana overall will have different subsets; Medical Marijuana will have its own section of the code but it still will revert back to the definition of marijuana in the controlled substance act.

Representative Vetter: So there is just 1 basic all-encompassing definition regarding everything related to marijuana?

Mark Hardy: Correct. The important component without that clear delineation of hemp, that product will also fall within the definition of marijuana currently.

Chairman K. Koppelman: Would this definition or any of this interfere with the Medical Marijuana at the state level?

Mark Hardy: I will double check with the Department of Health.

Representative Hanson: Would this bill, with the amendments, restrict CBD capsules or oil sold over the counter?

Mark Hardy: This would open up a legal path way for that process. Currently there are different legal interpretations on the CBD marketed. The farm bill did create the legal pathway for that.

Rep. Rick Becker: You indicated that gabapentin is not scheduled by the FEDS but we want to schedule it at a state level because of significant increase of abuse rates in the state. How many states have gone beyond and scheduled it? how do the incidents of gabapentin abuse compare to opioid abuse in North Dakota?

Mark Hardy: Many states that collect info thru the prescription drug monitoring program. There is a number of states that are and have moved it. I can get you more specific information on that. Regarding the second question; It's a difficult question to answer. There

are some parallels in the fact that opioids had a rapid escalation in illicit use. And we see that similar parallel gabapentin. I would parallel it with the drugs of Tramadol, which was scheduled in 2015 based on escalation of illicit usage. When we began collecting that information on the Prescription Drug Monitoring program we saw some troubling patient profiles. Per health professionals, many would agree gabapentin should be scheduled.

Chairman K. Koppelman: The other drugs you said are paralleled in terms of what was moved to schedule 5 a few years ago. What is the impact of that?

Mark Hardy: Better awareness and draw some good highlights to the dangerous aspects of it. Certainly it's becoming more and more familiar with folks. Tramadol is a good example, as veterinarians were often prescribing that drug and once scheduled then it imposes inventory requirements that pharmacies need to keep track of.

Representative Jones: I appreciate the testimony and I guess my question is going to be to you but really for information for the committee. This is an industry that is changing so fast that it's almost impossible to keep up. Farmers are looking for an alternative crop that will generate income. Farmers can plant thousands of acres of this and Canada has developed the harvesting equipment for the hemp plant so they can take off the top seed to produce the CBD/ CBD is going to be plentiful and accessible. And I appreciate what they did in the Farm Bill, ND is recognizing the hemp as a different substance than THC compounds grown for hallucinogen benefits and to some of the questions that have been asked, there is no comparison. With the CBD oil and the CBD grown in hemp, you could smoke it all day long and wouldn't get any effects. It is almost purely for medical purposes and other purposes. I appreciate you coming forward and addressing the scheduling. Are you able to keep up regarding the fast changes?

Mark Hardy: Obviously there has been a lot of attention drawn to the hemp and cannabis but if you look at the other changes in the Schedule 1 compounds, those are very significant. Those are the compounds that are killing folks and causing a lot of issues. A lot of efforts at the Federal level are taking place to crack down on the importing of these compounds.

Chairman K. Koppelman: With respect to hemp; we had passed a law many years ago allowing for the growth of industrial hemp. We ran into a road block with the federal government at the time, because it was too similar to marijuana, they said. Someone could grow a little crop of marijuana in a larger field of hemp and it not be discernable, that was the concern. We and other states have been battling this for many years. Now fast forward to more recent years where states are legalizing marijuana, either medicinal or recreational but it remains illegal on the federal level so you've gone from one extreme of the federal government, not allowing the growth of hemp because of its similarity to states legalizing a substance that the federal government says is not legal. Do you see the day coming when medicinal marijuana be treated like other pharmaceuticals? Where the doctor writes the prescription and the pharmacist fills it?

Mark Hardy: That's a hard question to answer. From a pharmacist perspective, we look to the medical field to provide proper dosage and medication to treat a patient based on a specific condition they may have. Having different companies bring drugs to the market, with cannabidiol, or THC helps from a medicinal standpoint to determine what that is. There is

still going to be a desire and need for CBD from the public. There's less concern about the product when there's no THC in the product.

Chairman Koppelman: I realize a lot of that depends on the Federal Government's action whether they crackdown, which they could, based on current federal law. Or whether they loosen up on that whole thing and do something similar to what other states have done.

Representative Jones: One last comment is to make it clear what they have done on the farm bill and what they have done on the Federal level is now is made hemp legal. Before if you raised hemp in ND, you couldn't ship across state lines due to it being a schedule 1. Now hemp raise in ND can be moved across state lines. The race is on now to determine how to use the entire crop in a beneficial way. There are fibers involved with the stalks that make ropes and clothing, etc. There has been a lot of talk in the past if how people could use this plant it would be great for the nation. It is now time for those people to step up and identify the products that are marketable and good and develop this into a crop. But this is a big step for us now to be able to get the CBD off the top of the hemp for medical purposes and be able to utilize the rest of the plant. Hopefully this will be a beneficial crop agriculturally to aid production in ND and other states.

Chairman K. Koppelman: Are there portions of this bill that deal with what we were calling "Designer Drugs" a few years ago and some of these compounds that are rapidly changing? Background for the committee; There have been issues over the years with particular compounds that were being abused and we would schedule them due to their danger and they had not been tested and were being sold as "bath salts" or other products and then reformulations would occur and our regulations would no longer apply. I know we gave some general authority for a more generalized description of those kinds of items. Is any of that addressed in this bill?

Mark Hardy: Yes. When you get into some of the modifications to the chemical structures of some of those different chemical compounds. That is getting back to the heart of the issue and looking at future modifications to those substances that could be made to skirt the written laws.

Chairman Koppelman: Which part of the bill refers to that?

Mark Hardy: A number of different areas. Pg. 8, is a good example-lines 11,15 and 16. Pg. 12 line 27- Pg. 13 line 1

Representative Vetter: One more question here. Looking at section 1 of the amendment. As defined, Marijuana means all parts of the plant cannabis Sativa L; whether growing or not the seeds thereof. I know you are copying the Federal but federal doesn't have legal marijuana. As I see it, this definition has all encompassing. They are saying there are carve outs for hemp but I do not see any carve outs for the CBD portion of this. It appears everything is grouped under marijuana except for hemp. This amendment is about hemp. Wouldn't CBD as defined all parts of the plant, would you think it would be wise to further define this definition? Do you think it would be wise to further define the definition on Page 1, Section 1? Why are we coping the federal law if the feds don't have it?

Mark Hardy: The amendment has to do savoring out the hemp product. This is not a definition of marijuana. It's not so much about the scheduling of it. As far as the medical marijuana, that made a specific allowance for marijuana through the medical program. It allows access based on those conditions to the marijuana and compounds derived from that. Certainly we can go back to Legislative council to inquire if any provisions need to be made Maybe we need to discuss with Legislative counsel.

Representative Vetter: I see that you are copying the federal law, however marijuana is not legal at the Federal Level. Why would be essentially copying their law when there isn't anything other than it's illegal.

Mark Hardy: I think that is something we can bring back to Legislative Council.

Chairman K. Koppelman: Your intent with the suggested amendment is to clarify that hemp and therefore the CBD as I understand it, could be derived from hemp, is exempt from that marijuana definition in this statute and then that the Medical Marijuana law in ND does not conflict with the two.

Mark Hardy: Yes, you said it better than I.

Representative Simons: Mr. Hardy, on pg. 1 line 13 it states stalks of the plant, fiber produced from the stalks oil or cake. Could you explain to me what cake is?

Mark Hardy: I am uncertain; we can inquire with the Agricultural Department for better references as to what that is. I cannot speak Intelligently about that.

Opposition:

Steven Peterson: Committee with Compassionate Care in ND: Presented opposed testimony, Attachment 3

Representative Jones: How difficult is it to determine the CBD and THC content of a plant or a medicine?

Steven Peterson: The CBD market was developed in the Medical Marijuana market with THC being involved with it, under the cannabis known as Charlotte's Web. If you have watched any of the news documentaries about how they help children with seizures. It's that CBD discovery came from developing that medical cannabis plant and in that oil developed it was a full plant extract, otherwise known as a full spectrum oil. This means it's necessary to have the THC and other terpenes that are available in the cannabis plant to work in the entourage effect to be able to bring upon the beneficial results.

Representative Jones: Yes, I am familiar with that particular plant and it was 99.9% pure cannabidiole content. And so it was very popular and well thought of. I am also familiar with the fact that some treatments using cannabis require THC. A certain amount of THC to make it effective. It can't just use the Charlotte's Web plant because it won't be effective in the treatment that they are getting. You are asking us to differentiate between cannabis and

marijuana. I am 100% in your corner. We have two different things here. Society wants to just recognize marijuana as marijuana. And in case you haven't noticed, marijuana is bad and there is a lot of science coming out saying there is a lot of good stuff in marijuana that involves cannabis and other stuff. I am trying to get it established and figure out how it can be differentiated simply and easily so we may do exactly what you are asking. So we can have a medical product as a cannabis derivative that stands on its own because of its medical properties. I know when you are growing marijuana and a bit of matter is taken and placed into a type of equipment it can determined how much cannabidiole and or THC is in that plant. And they buy their plants based on the type of compound needed as well as pay based on that simple test. And so I know somewhere and this is medical CBD or whatever the test determines. I was hoping you could help us determine that distinction and where we can help you identify the two things and two different substances.

Steven Paterson: I will need to do additional research for you. I have been reaching out to other industry groups that have already addressed that. They have come up with a method of measuring product to where it's CBD/THC so you can see it's a 1:1 ratio or a 1:20 or a 20:1 ratio. I guess my biggest concern is, admittedly we need to have proper measuring of the product. But the demonization of THC as you referenced, is necessary in the treatment of certain things and listing this as an hallucinogenic really may scare a lot of the health professionals already having problems signing applications for medical patients.

Representative Satrom: I'm curious about the third bullet point in your testimony regarding the hallucinogenic properties of cannabis and why it's important to reflect that?

Chairman K. Koppelman: Request for copy of testimony

Steven Peterson: I've been following a lot of clinical trials happening internationally, especially out of Israel and Australia. The Experimentations show 100% CBD and 100% THC-1:1 ratio. I am not seeing any of the results stating it's a hallucinogen. I personally have never had a hallucinogenic reaction. I'm hoping we can look, specifically, at the clinical trial results which use modern science in effort to avoid the admitted hyper baling and fear mongering of the past.

Chairman K. Koppelman: Mr. Peterson, when you talk of the definition of cannabis, Are you referring to page 1 of the bill, the marijuana definition? When I look at the changes it softens the law in keeping with the Federal Farm Bill. With Representative Jones help with the amendments.:

Steven Peterson: I have reached out and am waiting for review The marijuana policy project nationally is reviewing this and I am awaiting their notes. I see many aspects of the definition of cannabis as problematic with how the pharmacy board is looking at it. I am not trying to be unfair to them, understanding the judicial branch needs clear guidelines when we are looking at sentencing guidelines for those stepping outside the "allowed". Hence, why this is the only problematic language I find in the bill. I would like to see this be more reflective of the marijuana program so patients can get fair and reasonable access and that doctors aren't afraid to prescribe as they fear patients will be exposed to its hallucinogenic effects, which is nowhere mentioned in current clinical trials, as mentioned.

Chairman K. Koppelman: I guess when I am looking at the bill Mr. Peterson, I know there is a reference to synthetic cannabis or cannabinoids, which is current law, which is much of this. So when I look at the changes being requested, if anything they soften the definition, based on current law. Specifically, in the area they are trying to separate out the hemp plant and keeping with the Federal Farm bill referenced. I don't believe there is any intent to be problematic with respect to the medical marijuana law in ND, nor the committee.

Representative Jones: Discuss his personal experience in dealing with medical marijuana. I have firsthand experience in Medical marijuana and have watched in horror the way we have dealt with the Medical Marijuana bill in ND. We are creating a white elephant. The people of ND wanted access to Medicinal Marijuana. Rather than giving them access to medical Marijuana by saying, "You can raise 6 or 9 plants in your house if your doctor says it's going to be beneficial for your conditions. Instead we have a different situation. If a person is raising plants in their house, we could have a regulatory agency simply going to visit those permitted people and by sampling their plants they can determine CBD/THC content. Easily determining if the plant contains CBD content primarily or whether it's being raised for THC content. The plants go all the way from the Charlotte's Web which is 99.9% CBD to plants that are 100% THC. People wanting to raise recreational marijuana under the guise of Medical, would be outed. If their plant meets the criteria for their diagnosed condition, they are ok. If you find 6 or 8 in their home for medical purposes, turns out they test high in THC, their permits get taken away and privileges lost.
North Dakota now has created a white elephant, we are going to have grower, dispensaries, state agency control which will cost hundreds of thousands of dollars. When we get done we will have medical marijuana available to our citizens that is going to be so expensive that they are going to drive right past our dispensaries and go to Colorado because, the reality is, you have to be able to provide that at a competitive price to the open market. With this increase in raising hemp and removing the tops of the stalks to make CBD, we are going to have so much CBD the price is going to go down. I've made a personal study to try to figure out what we can do to help ND and citizens.

Chairman K. Koppelman: We are not reopening the debate on medical marijuana, we are looking at the reclassification of various drugs and chemical compounds in this bill, by the board of pharmacy so we want to make sure there aren't some unintended consequences.

Roger Dacsher: Processor of hemp seed. I've been processing since 2016. We do cold press expelling, milling sifting and producing protein powders. We are also working with the seed itself for the oil. Cake is actually what remains after the seed is defatted or expelled from oil. Cake is interchangeable between meal.

Representative Rick Becker: Why is there opposition to this bill? The bill is very extensive and covers a multitude of chemicals. So what specifically are you opposed to?

Roger Dacsher: I have some concerns that some of the local people cannot sell CBD's, I don't want to see them marketed through only pharmacies

Chris Noldon: Concerned citizen. I am in opposition of HB 1113. I want to help educate and fix the issues Senate Bill 23444 created for HB 1113. I believe the definition of marijuana, as it pertains to this bill is a broken definition. Legislature owes it to ND to correct the

definition. With this definition, you do not have a functional Medical Cannabis system. A few other problems with the bill. Pg. 7, line 17 Notice tetrahydrocannabinols are added into this list. It means THC, it does not belong there and I believe it is part of the reason we as patients are having issues getting certified as patients.

Chairman K. Koppelman: This bill doesn't change that

Chris Nolden: I understand that, I just wanted to draw attention to this. I am just a citizen, I am a lawyer or a doctor. I'm finding it hard to believe this isn't a push from GW Pharmaceuticals to push through Epidiolex and Sativexs and make that the only option. There is a study coming out of Israel which shows there is a bit of a honeymoon period with Epidiolex. They are seeing after 5-7 months the drug is becoming ineffective for a lot of people. Increasing the dose may or may not help, more than not the medication is no longer effective, even with increased dosage. The only thing this thing is carving out is the open door to Epidiolex and Sativexs.

Chairman K. Koppelman: Any concerned or opposed to the bill, this is not the vehicle to change the current law on medical marijuana. If you want to do that, that would be a different bill being introduced. We certainly want to hear about any unintended consequences where this may step on the Medical Marijuana world, this bill does not propose to fix or impede the current law.

Renita Brannon: Discussed the classification and need for the definition to change. CBD levelers.

Rep. Rick Becker: What is it about the current definition that is upsetting so many?

Renita Brannon: So it says in the original written words, the word "marijuana". It didn't say the words, "all things from the cannabis family". Ultimately, we do not want hemp included as it doesn't get you high.

Rep. Rick Becker: What the law currently says, "Marijuana means all parts of the plant cannabis. The bill we are discussing at this time adds Sativa L. It is currently cannabis and is now specifically cannabis sativa.

Renita Brannon: There is sativa and indica when you are looking at both of those, they act differently. One is marijuana, one is hemp. I misunderstood the bill.

Chairman K. Koppelman: All this bill is doing is showing the portion of law that currently exists. Again, this is not the vehicle to change that law.

Renita Brannon: So people will still be able to purchase CBD from hemp in our state?

Koppelman: To my understanding, unless Mr. Hardy can define?

Mark Hardy: This amendment will create a clear legal pathway for the use of CBD products derived from the Hemp plant.

Chairman K. Koppelman: Would this allow only to be sold through pharmacies?

Mark Hardy: Certainly that would be true of Sativex and Epidiolex but that's only specific to those products that is created by GW Pharmaceuticals.

Representative Rick Becker: Is Sativa the Marijuana plant and is Hemp the Indica plant?

Mark Hardy: I don't know that I can answer that for certain.

Renita Brannon: They are for different strengths and can contain different proteins. Some have higher some have lower amounts of THC. The real differentiation should be between Hemp and marijuana to word it like that.

Representative Vetter: They want a definition that we should have them separated. Definitions do mean something.

Representative Paur: Why did you add the word Sativa to Cannabis? It appears there are two medical marijuana classifications, Indica and Sativa. Why are we just referencing the one?

Mark Hardy: The Term Marijuana means all part of the plant Cannabis Sativa L. So We just tried to conform the federal definition.

Representative Paur: Any idea why Indica is not included in that?

Mark Hardy: I am uncertain, but can get back to you about it.

Chairman K. Koppelman: Mark Hardy work with legislative counsel and Representative Jones with the amendment.

Renita Brannon: So all industrial hemp being grown is from the Sativa.

Chairman K. Koppelman: Mr. Hardy, when you speak of the legal pathway there is nothing in this amendment that would disallow the products being sold?

Mark Hardy: Probably not no. There are different It is clear hemp drive CBD is going to be a legal reality.

Koppelman: Please be sure that we clarify that this is the case.

Representative Vetter: Can I move to get a subcommittee?

Koppelman: No I believe we are equipped with people to do the legwork and once we know get questions answered if a subcommittee is necessary, I will do that at a later point.

Representative Jones: Tying Sativa L to marijuana is inappropriate. It entangles something that is not or should not be tied to pharmaceuticals. If Sativa L, is the hemp side of things it

shouldn't be listed side by side. If anything the Indica should be if it is the THC side of things. Would not adding Sativa L but possibly adding Indica pose any issues?

Mark Hardy: It's a potential that you have a variation from the Federal definition of marijuana.

Rep. Rick Becker: Please understand, as the law stands now it is Cannabis which is Indica and Sativa. Simply removing Sativa does not protect Sativa, but does the opposite. This may require a rewrite.

Renita Brannon: There needs to be clarity in the definition.

Hearing Closed.

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2019 HOUSE STANDING COMMITTEE MINUTES

Judiciary Committee
Prairie Room, State Capitol

HB 1113
1/9/2019
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☐ Subcommittee
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Committee Clerk: Delores D. Shimek typed by Nicole Klaman

Explanation or reason for introduction of bill/resolution:

A BILL relating to the definition of marijuana and the scheduling of controlled substances; and to declare an emergency.

Minutes: 1,2

Chairman Koppelman: Reopened the meeting on HB 1113.

Representative Jones: Proposed amendment to HB 1113. (Attachment #1). Due to many concerns surrounding the definition of marijuana and why Sativa is listed and not Indica. Research shows many broad and differing explanations. Defined per the Farm Bill 297A 1946. Stopped 5:00)

Chairman K. Koppelman: Page 8 line 1, recommended amendment doesn't indicate where that would go on line 1. Discussed where the proposed amendment would be placed in the bill. Clarifies in that section and the definition of marijuana and THC does not include hemp as defined.

Mark Hardy Executive Director, State Department of Pharmacy: Clarified the definition of hemp. (See attachment 2).

Chairman K. Koppelman: If we reference our Century code; then if we do need to change that definition. Determined if an Amendment were to be made to the suggested amendment it would appear: As defined in, strike the rest of that description and just substituting NDCC 4.1-18-01.

Rep. Paur: You are defining hemp as "Sativa L". Correct? And in line 9, we are defining Marijuana as Sativa L".

Representative Jones: There is nothing wrong with defining it as Sativa L. It's like potatoes, only we have marijuana here, which is actually cannabis. There is a lot of different strains like the potato has Russets, Reds, Whites. It doesn't matter what genesis they are talking about. They can't differentiate between them. One group is telling me Sativa L is hemp because it grows tall. Then another group is telling me "No" it's high in THC. To the contrary

another group says "No" it's low in THC. There is so much confusion, and no scientific basis that I can find that differentiates between Indica and Sativa. My son, who is raising Medical marijuana tells me that Sativa L has got pretty high concentrations of THC. The experts say, they work really hard to get that done because it used to be the strain that had 0% THC. These plants are being manipulated genetically resulting in mixed characteristics of both Sativa and Indica to the point of indistinguishable. Most Important is the THC level. As long as we define the THC level at .3 or less, it's hemp. If defined greater THC level, on a dry matter basis, then it's considered marijuana. It gets really complicated because that's dry matter. Then when you concentrate it and start processing it, somebody comes and tests and you may have it concentrated to ten times that THC. But this is why it has to be measured in its natural form and dry matter basis. At least this gives us a standard to go by.

Representative Rick Becker: My concern isn't Sativa Vs Indica. I think the question of the matter in the definition of hemp is the THC concentration. My concern is a matter of how we are phrasing things. The marijuana definition includes the subset of the hemp definition because the marijuana definition as it stands in this bill includes everything from Sativa L. Hemp definition if we amend it as such includes everything from Sativa L with a THC of less than. It would seem we would have to include in the marijuana definition everything with Sativa L greater than .3 THC, so that they are exclusive subsets of Sativa L. As opposed to the current definition again, hemp is within the definition of marijuana. Am I making that clear?

Chairman K Koppelman: I think it's either or.

Representative Becker: I would ask Mr. Hardy. Is there a definition for Marijuana that includes the Sativa L greater than .3% THC?

Mark Hardy: I have not seen that as far as a distinguisher of marijuana and its definition. When the FEDS passed that they made an exception to the definition, it does not include hemp as defined in their definition.

Representative Jones: Should there be reference in our code where it references Sativa L as greater than .3% THC?

Rep. Vetter: Where does the medical fall under this? Is that under the hemp definition or the marijuana definition? We still do not have a defined definition between hemp and medical marijuana, so Marijuana is just everything?

Representative Jones: That is correct. I do not even know where you would look for a definition of Medical marijuana as it's being developed now for cancer patients, they need to have pretty high THC concentration. These plants for this condition will contain 50 %CBD and 50% THC to make the combination that helps with the ailment. Health professionals will be the one's calling the ratios per condition. The farm bill called out the hemp definition and making it available to any body across the whole nation. So people that want CBD, predominantly CBD hardly any THC. This can be raised by farmers in ND. All they will do is take the top of the plant, the seeds and the pods. That is going to be almost all CBD up to .3% THC. As long as farmers remain in the 0-.3% THC content they can grow and sell that without any special permitting. The farm bill recognizes permission granted, at the federal

level giving us the opportunity to grow, process, develop products, ship and utilize these plants to their fullest. There is still going to be a huge movement and there will be a lot of decisions made regarding how to deal with the plants that need to be higher in THC for medical uses. However, this is not the time we will be delving into that.

Chairman K. Koppelman: The intent of the bill is obviously the federal government authorized that we could grow hemp through the farm bill. The amendment simply clarifies this. (22:44)

Representative Jones: Medical marijuana is completely different, it is regulated. It will be raised in the state of North Dakota by permit. The parameters will be clearly stated and those permitted will know those well, regulated. My son does this in California and he gets the type of seeds, and grows what is for that market and he is checked periodically to see if he is growing the right type. Hemp is unregulated industry they just need to make sure they are under that .3% THC. (26:56 amendment)

Chairman K. Koppelman: The only change to the amendment will be which definition of hemp we are referencing and it is preferable to reference our NDCC 4.1-18-01 versus the 1946 law. After the word "in" on Page1 line 16 and on Page 8 line 1 after the words "defined in", we would insert "the NDCC 4.1-18-01" and strike out "Section 297A of the Agricultural Marketing Act of 1946".

Rep. Rick Vetter: I move the amendments with that change.

Rep. Magrum: Seconded. Voice vote on amendment. Motion Carried.

Rep Becker: If we pass this bill as amended cannabis indica or marijuana would be completely unregulated.

Chairman K. Koppelman: We are adding Sativa L so we are not including the other. We didn't reference either before so I don't think it will make a difference.

Rep. Jones: There are thousands of subsets of marijuana, which is part of the confusion.

Rep. Paur: Motion to delete Sativa L. out of line 9 page 1 of the HB 1113.

Rep Jones: Seconded.

Rep. Jones: I am not sure the reason of why we are taking the Sativa L out of the definition marijuana or hemp? It will make it inconsistent with the Federal Farm bill.

Mark Hardy: The federal code, the farm bill and our definition of hemp is consistently Sativa L, but in other states are listed more broadly as far as Cannabis overall. I can't say if there would be a problem with taking that out.

Chairman K. Koppelman: Marijuana. Out of line 9 page 1 of the bill. Putting it in there may have caused this confusion.

Rep. Jones: I really like Rep. Paur's proposed amendment. If we are taking it out of the definition for Marijuana, the most authentic definition of what Sativa L was supposed to be hemp. It is supposed to be a tall plant and mostly wanted for its fiber and the L references that as I understood it. I like this amendment because it seems to clarify the definition.

Chairman K. Koppelman: We have the motion to further amend the bill to remove the term Sativa L from line 9 page 1.

Roll Call Vote: On the proposed amendment. Yes 3 No 11 Absent 0. Motion fails.

Chairman K. Koppelman: What is the wishes of the committee?

Representative Satrom: Do Pass as amended.

Rep. Magrum: Seconded.

Discussion:

Rep. Bob Paulson: We heard a lot of testimony, I think the concern is over the medical marijuana issue as opposed to the validity of this bill. Is this true?

Chairman K. Koppelman: I would say that is true and I think there is a desire out there in the public that we have medical marijuana less restricted and the other concern was that there is a fear that this was an attempt by the board of pharmacy to restrict cannabis. Mr. Hardy has stated that it is not their intent at all.

Rep. Magrum: I have a lot of people in my area who use CBD oils and I hope we don't make a mistake and affect the medical marijuana bill with this.

Roll Call Vote: Yes 13 No 1 Absent 0. Motion Carried.

Rep. Jones: will carry the bill.

Hearing closed.

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Adopted by the Judiciary Committee

January 9, 2019

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1113

Page 1, line 16, after the period insert "The term marijuana does not include hemp as defined in section 4.1-18-01."

Page 7, line 22, overstrike the comma and insert immediately thereafter "; excluding tetrahydrocannabinols found in hemp as defined by section 4.1-18-01;"

Renumber accordingly

Date: 1/9/2019
Roll Call Vote #: 1

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
HB 1113

House **Judiciary** Committee

☐ Subcommittee

Amendment LC# or Description: 19.8043.01001

Recommendation: ☒ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Rep .Vetter Seconded By R ep. Mag um

Representatives	Yes	No	Representatives	Yes	No
Chairman Koppelman			Rep. Buffalo		
Vice Chairman Karls			Rep. Karla Rose Hanson		
Rep. Becker					
Rep. Terry Jones					
Rep. Magrum					
Rep. McWilliams					
Rep. B. Paulson					
Rep. Paur					
Rep. Roers Jones					
Rep. Satrom					
Rep. Simons					
Rep. Vetter					

Voice Vote

Total (Yes) _____ No _____

Absent _____

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Voice Vote Carried

Date: 1/9/2019
Roll Call Vote #: 2

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
HB 1113

House **Judiciary** Committee

☐ Subcommittee

Amendment LC# or Description: Delete the word sativa L on Line 9 Page 1 of HB1113.

Recommendation: ☒ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Rep .Paur Seconded By Rep .Jones

Representatives	Yes	No	Representatives	Yes	No
Chairman Koppelman	X		Rep. Buffalo		X
Vice Chairman Karls		X	Rep. Karla Rose Hanson		X
Rep. Becker		X			
Rep. Terry Jones	X				
Rep. Magrum		X			
Rep. McWilliams		X			
Rep. B. Paulson		X			
Rep. Paur	X				
Rep. Roers Jones		X			
Rep. Satrom		X			
Rep. Simons		X			
Rep. Vetter		X			

Total (Yes) 3 No 11

Absent 0

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Motion Fails

Date: 1/9/2019
Roll Call Vote #: 3

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
HB 1113

House **Judiciary** Committee

☐ Subcommittee

Amendment LC# or Description: 19.8043.01001

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☒ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Rep. Satrom Seconded By Rep. Magrum

Representatives	Yes	No	Representatives	Yes	No
Chairman Koppelman	X		Rep. Buffalo	X	
Vice Chairman Karls	X		Rep. Karla Rose Hanson	X	
Rep. Becker	X				
Rep. Terry Jones	X				
Rep. Magrum	X				
Rep. McWilliams	X				
Rep. B. Paulson	X				
Rep. Paur	X				
Rep. Roers Jones	X				
Rep. Satrom	X				
Rep. Simons		X			
Rep. Vetter	X				

Total (Yes) 13 No 1

Absent 0

Floor Assignment Rep. Jones

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1113: Judiciary Committee (Rep. K. Koppelman, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (13 YEAS, 1 NAYS, 0 ABSENT AND NOT VOTING). HB 1113 was placed on the Sixth order on the calendar.

Page 1, line 16, after the period insert "The term marijuana does not include hemp as defined in section 4.1-18-01."

Page 7, line 22, overstrike the comma and insert immediately thereafter "; excluding tetrahydrocannabinols found in hemp as defined by section 4.1-18-01;"

Renumber accordingly

2019 SENATE JUDICIARY COMMITTEE

HB 1113

2019 SENATE STANDING COMMITTEE MINUTES

Judiciary Committee
Fort Lincoln Room, State Capitol

HB 1113
2/6/2019
Job #32264 (25:15)

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Meghan Pegel

Explanation or reason for introduction of bill/resolution:

A BILL for an Act to amend and reenact subsection 18 of section 19-03.1-01, section 19-03.1-05, subsection 7 of section 19-03.1-07, subsection 4 of section 19-03.1-09, subsection 7 of section 19-03.1-11, and subsection 5 of section 19-03.1-13 of the North Dakota Century Code, relating to the definition of marijuana and the scheduling of controlled substances; and to declare an emergency.

Minutes: 3 Attachments

Chair Larson opens the hearing on HB 1113.

Mark Hardy, Executive Director of the ND State Board of Pharmacy, testifies in favor (see attachments #1-3)

Hardy: One important consideration for this is that there's a little bit of a competing bill that's working its way through the House as far as changes to the hemp program through the Agricultural department. It's HB 1349 and has come out of committee do pass as amended. Basically it's enacting a new portion of the Century Code in 4.1-18.1 to line up the policy for the state of North Dakota in accordance to what the farm bill changed as far as the hemp production process. What we recommend is that we reference the definition of hemp from the federal side of things. The House made the determination that they wanted to reference the definition of hemp in the State Century Code which is currently in place but that may create a new section. There's no real difference there, it's just a matter of what section of the code that we'll be referencing.

Chair Larson: We have two members in this committee also on the Senate Agriculture; both the Chairman and Vice Chair. This is good information.

(5:05) Mr. Hardy continues testimony

(15:25) Senator Luick: With the sections of these drugs, you have the brackets and sub brackets. Can you explain those?
Hardy: Essentially when you're looking to put together the chemical description of a compound, that's the nomenclature of how that works. We're putting the brackets around a specific area and looking at the core chemical structure and the different areas of that structure that you make substitutions on to make it completely different. If you think of a hexagon ring and the additions that can be made on that, that all gets to be how you name that compound. If you make it on the right side versus the left side, it's totally different as far as how that chemical would work in the body.

Vice Chairman Dwyer: Is section 4.1 in a House bill that is creating that statute?
Hardy: 4.1-18-01 currently exists in the Century Code. The bill that's working its way through the House Agricultural committee, HB 1349, basically strikes that section of the code and makes one that's very similar to it. It would be 4.1-18.01 instead of -01. Obviously it's hard to point towards a chapter that isn't there yet from a legal perspective, and that's why we need to work out how we mesh that considering if that bill will move forward, which we fully anticipate it will.

Senator Myrdal: We usually say "industrial hemp". Can you comment on why you chose to just use "hemp" in your testimony?
Hardy: The word industrial hemp was always kind of used to drive the federal policy to create what we have now with the federal farm bill. The reason we just use hemp is to be consistent with the federal definition of that. I don't see anywhere where they're referencing industrial hemp in any of that law moving forward. Hopefully that creates some clarity.

Senator Luick: Is there a psychoactive reaction with CBD oil or is it just with THC?
Hardy: The answer is mostly going to be tied to a THC from a psychoactive potential and hallucinogen affect. People may disagree with that, but generally from a medical standpoint more research is driven on the CBD component of it and certainly there isn't as much concern with the elicit use of that.

(20:10) Vice Chairman Dwyer: What exactly did the farm bill do with hemp?
Hardy: The federal farm bill basically created two categories: traditional marijuana with medical marijuana programs and then you have hemp. Obviously there are concerns- it looks the same, but it doesn't have nearly the amount of THC, it's less than 3/10ths of 1%. There is an intent to drive policy that will allow the production then the manufacturing of those hemp derived products. The problem is you need to drive a state-based system like the state of North Dakota has done for the production of that product. The federal farm bill states you can control this policy. It needs to be a structured program and processes in place to ensure the integrity so that there's not marijuana being grown at the same time. The bill created a framework to allow states to say this is how you can do it. The agricultural commissioner can go to the USDA and make sure that program is approved and that's what HB 1349 does from my understanding of it. It creates that set of policies then if a state doesn't come up with that, then the feds will develop standards for how they're going to regulate in that area.

Chair Larson: I appreciate this through information.

Chair Larson closes the hearing on HB 1113.

Senator Luick: Moves a Do Pass.
Senator Bakke: Seconds.

A Roll Call Vote was Taken: 6 yeas, 0 nays, 0 absent. Motion passes.

Senator Luick will carry the bill.

2019 SENATE STANDING COMMITTEE MINUTES

Judiciary Committee
Fort Lincoln Room, State Capitol

HB 1113
2/12/2019
#32559 (7:20)

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Meghan Pegel

Explanation or reason for introduction of bill/resolution:

A BILL for an Act to amend and reenact subsection 18 of section 19-03.1-01, section 19-03.1-05, subsection 7 of section 19-03.1-07, subsection 4 of section 19-03.1-09, subsection 7 of section 19-03.1-11, and subsection 5 of section 19-03.1-13 of the North Dakota Century Code, relating to the definition of marijuana and the scheduling of controlled substances; and to declare an emergency.

Minutes: 1 Attachment

Chair Larson begins discussion on HB 1113.

Chair Larson: We had forgotten to do a small amendment on this bill. Since we still have the bill in our possession, we'll bring this back for reconsideration.

Senator Bakke: Moves to Reconsider HB 1113.
Senator Myrdal: Seconds.

A Roll Call Vote was Taken: 6 yeas, 0 nays, 0 absent. Motion passes.

Mark Hardy, Exec. Director of the ND State Board of Pharmacy (see attachment #1)

Hardy: We're working through a potential conflict in the passage of this bill. There is a competing bill, 1349, that is in relation to the agricultural hemp production process that looks to be coming to the Senate; I don't anticipate any negative consequences. That bill looks at the farm bill and makes changes to the agricultural program in relation to that. One of the issues I want to bring forward is that as you look on the legislation and the amendment that was made by the House, they reference that the term "marijuana" does not include hemp as defined in section 4.1-18-01. The potential conflict that may arise at the end of the session is 1349 actually creates a new section which would be 4.1-18.1. Theoretically if this went through and 1349 became law, this piece of legislation, the controlled substance act would point to a section that really doesn't exist. I asked John Bjornson with Legislative Counsel what his recommendation would be and his recommendation would be that we would just

broadly reference the definition in hemp as defined in section 4.1 and remove the "-18-01". That leaves the opportunity that when that new bill potentially becomes law, then that would still reference that definition of hemp. Theoretically if that bill got killed, the definition of hemp would still be in 4.1 as it sits today.

Chair Larson: I remember you bringing that up earlier; sorry we forgot to secure that.

Hardy: It's okay. There's two different places: page 1 line 17 where that would be removed and also under the definition of THC on page 7 line 23. That would make it consistent to the farm bill. As alluded to in my testimony, our recommendation was to reference the definition of hemp in the federal code, but the House wanted to reference the definition of hemp in the state code. I can understand why.

Senator Myrdal Moves adopt the amendment to remove "-18-01" on page 1, line 17 and page 7, line 23.
Vice Chairman Dwyer Seconds.

Vice Chairman Dwyer: We would now be dereferencing 4.1.
Hardy: That's correct.

Vice Chairman Dwyer: Then we would need to change the word "section" as well. We'd be referring to a title instead.

Hardy: Thank you for that catch.

Senator Myrdal: Moves to further amend and replace "section" with "title" on page 1, line 17 and page 7, line 23 to now say "title 4.1" in those two areas of the bill.
Vice Chairman Dwyer: Seconds.

A Roll Call Vote was Taken: 6 yeas, 0 nays, 0 absent. Amendment is adopted.

Senator Luick: Moves for a Do Pass as Amended.
Senator Myrdal: Seconds.

A Roll Call Vote was Taken: 6 yeas, 0 nays, 0 absent. Motion passes.

Senator Luick will carry the bill.

Adopted by the Senate Judiciary Committee

February 12, 2019

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1113

Page 1, line 17, replace "section 4.1-18-01" with "title 4.1"

Page 7, line 23, replace "by section 4.1-18-01" with "in title 4.1"

Renumber accordingly

Date:2/6/2019
Roll Call Vote:1

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1113

Senate **Judiciary** Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Senator Luick Seconded By Senator Bakke

Senators	Yes	No	Senators	Yes	No
Chair Larson	X		Senator Bakke	X	
Vice Chair Dwyer	X				
Senator Luick	X				
Senator Myrdal	X				
Senator Osland	X				

Total (Yes) 6 No 0

Absent 0

Floor Assignment Senator Luick

If the vote is on an amendment, briefly indicate intent:

Date:2/12/2019
Roll Call Vote: 1

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1113

Senate **Judiciary** Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☒ Reconsider ☐ _____

Motion Made By Senator Bakke Seconded By Senator Myrdal

Senators	Yes	No	Senators	Yes	No
Chair Larson	X		Senator Bakke	X	
Vice Chair Dwyer	X				
Senator Luick	X				
Senator Myrdal	X				
Senator Osland	X				

Total (Yes) 6 No 0

Absent 0

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Date:2/12/2019
Roll Call Vote: 2

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1113

Senate **Judiciary** Committee

☐ Subcommittee

Amendment LC# or Description: **(see below)**

Recommendation: ☒ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Senator Myrdal Seconded By Vice Chairman Dwyer

Senators	Yes	No	Senators	Yes	No
Chair Larson	X		Senator Bakke	X	
Vice Chair Dwyer	X				
Senator Luick	X				
Senator Myrdal	X				
Senator Osland	X				

Total (Yes) 6 No 0

Absent 0

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

On page 1, line 17 and page 7, line 23, replace "section 4.1-18-01" with "title 4.1".

Date:2/12/2019
Roll Call Vote: 3

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1113

Senate **Judiciary** Committee

☐ Subcommittee

Amendment LC# or Description:

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☒ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐

Motion Made By Senator Luick Seconded By Senator Myrdal

Senators	Yes	No	Senators	Yes	No
Chair Larson	X		Senator Bakke	X	
Vice Chair Dwyer	X				
Senator Luick	X				
Senator Myrdal	X				
Senator Osland	X				

Total (Yes) 6 No 0

Absent 0

Floor Assignment Senator Luick

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1113, as engrossed: Judiciary Committee (Sen. D. Larson, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1113 was placed on the Sixth order on the calendar.

Page 1, line 17, replace "section 4.1-18-01" with "title 4.1"

Page 7, line 23, replace "by section 4.1-18-01" with "in title 4.1"

Renumber accordingly

2019 TESTIMONY

HB 1113

#1
HB1113
1-7-19
1

OFFICE OF THE EXECUTIVE DIRECTOR
1906 E Broadway Ave
Bismarck ND 58501-4700
Telephone (701) 328-9535
Fax (701) 328-9536
STATE BOARD OF PHARMACY

State of North Dakota
Doug Burgum, Governor

Mhardy@ndboard.pharmacy
www.nodakpharmacy.com

Mark J. Hardy, PharmD, R.Ph.
Executive Director

House Bill No 1113 – Controlled Substances Rescheduling

House Judiciary Committee – Prairie Room
10:50 AM - Monday – January 7th, 2019

Chairman Koppelman, members of the House Judiciary Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you today.

House Bill 1113 is the biennial bill introduced by State Board of Pharmacy to bring the Controlled Substances Act up-to-date with what the Food and Drug Administration [FDA] and Drug Enforcement Administration [DEA] have done over the past two years. This bill also revises the definition of marijuana to be consistent with the Federal Law, adds to the chemical modifications of synthetic schedule I drug to ensure future modifications will be illegal, and adds Gabapentin to be a schedule V drug in the state of North Dakota.

The drafting of this bill, specifically schedule I controlled substances, was done in conjunction with the ND State Crime Lab. A representative of the Crime Lab is here and can explain much of the chemistry and reasons for the chemical changes in Schedule I compounds, if requested. Our intension for these changes in Schedule I compounds is to be proactive to ensure we have future chemical modifications that could be made to the substances identified as controlled substances. This bill is very lengthy and, we feel, as comprehensive as possible with the information that we have at this time.

I would like to highlight each provision of the bill to ensure you have an understanding of the changes we have proposed for your considerations.

On page 1, Section 1 – starting on line 7 is the amendment to make the definition of Marijuana in North Dakota's Century Code consistent with the federal definition. This would ensure that any federal policy changes could be applied to North Dakota. We will also put forward an amendment, for your considerations, that could make further changes to the definition of marijuana. This amendment is derived by the recent signing of the federal Agricultural Improvement Act of 2018 (Farm Bill), which was signed in December 2018. This definition change appears to have opened up a clear legal pathway for production and marketing of hemp derived products to be marketed for sale, including cannabidiol (CBD). Understandably, there is much that needs to be determined on the federal level on how these changes will be implemented for availability of hemp derived products, like CBD, as is explained in the December 20, 2018 statement from the FDA commissioner which is attached to my testimony

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HB1113
1-7-19
2

On page 3, line 20 is simply correcting a typographical error that was made in the last session in 2017.

On page 4, starting on line 29 and continuing to page 5, line 24 are proposed revisions to the specific fentanyl derivatives drafted in conjunction with the Drug Enforcement Administration scheduling during the past year. Of importance, North Dakota was in front of the federal government in scheduling fentanyl compounds during the 2017 Legislative session. These are the compounds that are often derived by rogue chemists in China and are at blame for too many overdose deaths. This change was a critical component to ensure individuals who may sell or distribute these extremely potent compounds will face the appropriate penalties for their actions.

On page 8, lines 11,15 & 16 are additional potential substitutions to the core chemical structure, which were added to ensure that the potential modifications to the Indole Carboxaldehydes can be appropriately included as Schedule I compounds in North Dakota.

On page 10, lines 13 & 17 are similar modifications and substitutions to the core chemical structure of the Indole Carboxamides.

On page 11 and continuing into page 12 are modifications to the specifically listed Indole Carboxamides to be consistent with DEA's listing of these compounds. This listing of the compounds and their other names is meant to assist law enforcement and prosecutorial officials in identifying compounds they may encounter in cases.

On page 12, line 27 through page 13 line 1 are again additional potential substitutions to the core chemical structure, which were added to ensure that the potential modifications to the Indole Carboxylic acids are included as Schedule I compounds in North Dakota.

On page 13, line 18 is the addition of the other known name CBL2201 to be consistent with DEA scheduling.

On page 19, line 20 was the retraction of Flunitrazepam from the Schedule I controlled substances, as it does have a medical use and is currently scheduled in Schedule IV.

On page 21, lines 17-18 is the addition of a compound in the substituted cathinone category to be consistent with DEA's listing of this compound.

On page 22, lines 3-4 is the addition of Dronabinol solution, which is a Schedule II compound which was recently scheduled by the DEA.

On page 23, lines 3-4, we are proposing the addition of a substance called Sativex, which is a drug derived from marijuana which is currently going through clinical trials by GW Pharmaceuticals, which has brought a similar drug to market called Epidiolex. Sativex is indicated in other countries as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medications. We are proposing scheduling this in Schedule III which is consistent with GW Pharmaceutical's request to ensure that it can be brought to market for North Dakota patients prior to the next legislative session.

Also on page 23, lines 23-24 you will notice the striking of the terminology that we added last legislative session regarding Epidiolex.

#1
HB1113
1-7-19
3

On page 24, lines 6-10 is the final language approved to the Federal Controlled Substances Act regarding Epidiolex as approved in 2018 for the treatment of a rare childhood-onset seizure disorder. The DEA scheduled it as a Schedule V Controlled Substance. The language used makes this only applicable for an FDA approved cannabidiol drug. To be clear, this provision has no effect on CBD products derived from the Hemp plant which again we are proposing, with amendment, to add language consistent with the Agricultural Improvement Act of 2018.

Lastly, on page 24, line 11 we are requesting the scheduling of Gabapentin as a Schedule V drug in North Dakota. This is not consistent with the federal scheduling. However, North Dakota has been monitoring the use of Gabapentin usage through the Prescription Drug Monitoring Program (PDMP), which indicated widespread illicit use in patients using multiple pharmacies to obtain Gabapentin. Gabapentin is traditionally used as a medication for neuropathic pain and seizure disorders. The concerns of abuse have been increasing exponentially the past few years. Initially, it had seemed localized to a few counties but since these abuse reports have since spread state wide. The exact mechanism on the illicit effects of Gabapentin is difficult to pinpoint, however it appears to enhance the "high" from other substances and has become a sought-after medication. We encourage your considerations to Schedule this as a Schedule V substance in North Dakota based on the interaction with healthcare professionals and law enforcement findings.

Lastly, consistent with previous years, we respectfully ask for an emergency measure to be attached to this bill that if enacted would make these changes occur as quickly as possible.

Thank you for listening to our testimony and I will be happy to answer any questions.

SUBSTANCE *Scheduled under 21 USC 811(h) **Extension of temporary control	PROPOSAL PUBLICATION DATE	FINAL ORDER PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	CSA SCHEDULE
N-(1-AMINO-3-METHYL-1-OXOBUTAN-2-YL)-1-(4-FLUOROBENZYL)-1H-INDAZOLE-3-CARBOXAMIDE (AB-FUBINACA)		09-06-16	81 FR 61130	9/6/2016	I
QUINOLIN-8-YL 1-(5-FLUOROPENTYL)-1H-INDOLE-3-CARBOXYLATE (5-FLUORO-PB-22; 5F-PB-22)		09-06-16	81 FR 61130	9/6/2016	I
QUINOLIN-8-YL 1-PENTYL-1H-INDOLE-3-CARBOXYLATE (PB-22; QUPIC)		09-06-16	81 FR 61130	9/6/2016	I
3,4-DICHLORO-N-[2-(DIMETHYLAMINO)CYCLOHEXYL]-N-METHYLBENZAMIDE (U-47700)*		11-14-16	81 FR 79389	11/14/2016	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLFURAN-2-CARBOXAMIDE (FURANYL FENTANYL) *		11-29-16	81 FR 85873	11/29/2016	I
PENTEDRONE	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
BUTYLONE	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
ALPHA-PYRROLIDINOBUTIOPHENONE (α-PBP)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
4-METHYL-ALPHAPYRROLIDINOPROPIOPHENONE (4-MePPP)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
4-FLUORO-N-METHYLCATHINONE (4-FMC)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
3-FLUORO-N-METHYLCATHINONE (3-FMC)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
NAPHYRONE	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
4-METHYL-N-ETHYLCATHINONE (4-MEC)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
ALPHA-PYRROLIDINOPENTIOPHENONE (α-PVP)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
PENTYLONE	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
DRONABINOL IN ORAL SOLUTION IN DRUG PRODUCT APPROVED FOR MARKETING BY U.S. FOOD AND DRUG ADMIN.		03-23-17	82 FR 14815	3/23/2017	II
N-(1-AMINO-3,3-DIMETHYL-1-OXOBUTAN-2-YL)-1-(4-FLUOROBENZYL)1H-INDAZOLE-3-CARBOXAMIDE (ADB–FUBINACA)*		04-10-17	82 FR 17119	4/10/2017	I
METHYL 2-(1-(CYCLOHEXYLMETHYL)-1H-INDOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (MDMB-CHMICA)*		04-10-17	82 FR 17119	4/10/2017	I
N-(ADAMANTAN-1-YL)-1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDE (5F–APINACA, 5F–AKB48)*		04-10-17	82 FR 17119	4/10/2017	I
METHYL2-(1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDO)-3-METHYLBUTANOATE (5F-AMB)*		04-10-17	82 FR 17119	4/10/2017	I
METHYL2-(1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (5F-ADB)*		04-10-17	82 FR 17119	4/10/2017	I
METHYL 2-(1-(4-FLUOROBENZYL)-1H-INDAZOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (MDMB–FUBINACA)*		04-10-17	82 FR 17119	4/10/2017	I
N-(4-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)ISOBUTYRAMIDE (4-FLUOROISOBUTYRYL FENTANYL)*		05-03-17	82 FR 20544	5/3/2017	I
ACETYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLACETAMIDE)		06-07-17	82 FR 26349	6/7/2017	I
ACRYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLACRYLAMIDE)*		07-14-17	82 FR 32453	7/14/2017	I

SUBSTANCE *Scheduled under 21 USC 811(h) **Extension of temporary control	PROPOSAL PUBLICATION DATE	FINAL ORDER PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	CSA SCHEDULE
ORTHO-FLUOROFENTANYL OR 2-FLUOROFENTANYL (N-(2-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL))*		10-26-17	82 FR 49504	10/26/2017	I
TETRAHYDROFURANYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLTETRAHYDROFURAN-2-CARBOXAMIDE)*		10-26-17	82 FR 49504	10/26/2017	I
METHOXYACETYL FENTANYL (2-METHOXY-N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLACETAMIDE)*		10-26-17	82 FR 49504	10/26/2017	I
FUB–AMB, MMB– FUBINACA (METHYL 2-(1-(4-FLUOROBENZYL)-1HINDAZOLE-3-CARBOXAMIDO)-3-METHYLBUTANOATE*		11-03-17	82 FR 51154	11/3/2017	I
CYCLOPROPYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLCYCLOPROPANECARBOXAMIDE)*		01-04-18	83 FR 469	1/4/2018	I
MT-45 (1-CYCLOHEXYL-4-(1,2-DIPHENYLETHYL)PIPERAZINE))		12-13-17	82 FR 58557	1/12/2018	I
N-(2-FLUOROPHENYL)-2-METHOXY-N-(1-PHENETHYLPIPERIDIN-4-YL)ACETAMIDE (OCFENTANIL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(4-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)BUTYRAMIDE (PARA-FLUOROBUTYRYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(4-METHOXYPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)BUTYRAMIDE (PARA-METHOXYBUTYRYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(4-CHLOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)ISOBUTYRAMIDE (PARA-CHLOROISOBUTYRYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLCYCLOPENTANECARBOXAMIDE (CYCLOPENTYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLPENTANAMIDE (VALERYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLISOBUTYRAMIDE (ISOBUTYRYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
FENTANYL-RELATED SUBSTANCES, AS DEFINED IN 21 CFR 1308.11(h)*		02-06-18	83 FR 5188	2/6/2018	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLBUTANAMIDE (BUTYRYL FENTANYL)		04-20-18	83 FR 17486	4/20/2018	I
3,4-DICHLORO-N-[2-(DIMETHYLAMINO)CYCLOHEXYL]-N-METHYLBENZAMIDE (U-47700)		04-20-18	83 FR 17486	4/20/2018	I
N-(1-AMINO-3-METHYL-1-OXOBUTAN-2-YL)-1-(5-FLUOROPENTYL)-1 H-INDAZOLE-3-CARBOXAMIDE (5F-AB-PINACA)*		07-10-18	83 FR 31877	7/10/2018	I
1-(5-FLUOROPENTYL)-N-(2-PHENYLPROPAN-2-YL)-1 H-PYRROLO[2,3-B]PYRIDINE-3-CARBOXAMIDE(5FCUMYL-P7AICA)*		07-10-18	83 FR 31877	7/10/2018	I
1-(4-CYANOBUTYL)-N-(2-PHENYLPROPAN-2-YL)-1 H-INDAZOLE-3-CARBOXAMIDE (4-CN-CUMYL-BUTINACA)*		07-10-18	83 FR 31877	7/10/2018	I
NAPHTHALEN-1-YL 1-(5-FLUOROPENTYL)-1 H-INDOLE-3-CARBOXYLATE (NM2201; CBL2201)*		07-10-18	83 FR 31877	7/10/2018	I
METHYL 2-(1-(CYCLOHEXYLMETHYL)-1 H-INDOLE-3-CARBOXAMIDO)-3-METHYLBUTANOATE (MMB-CHMICA, AMB-CHMICA)*		07-10-18	83 FR 31877	7/10/2018	I
1-(1,3-BENZODIOXOL-5-YL)-2-(ETHYLAMINO)-PENTAN-1-ONE (N-ETHYLPENTYLONE, EPHYLONE)*		08-31-18	83 FR 44474	8/31/2018	I

SUBSTANCE *Scheduled under 21 USC 811(h) **Extension of temporary control	PROPOSAL PUBLICATION DATE	FINAL ORDER PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	CSA SCHEDULE
APPROVED CANNABIDIOL DRUGS , AS DEFINED IN 21 CFR 1308.15(f)		09-28-18	83 FR 48953	9/28/2018	V
ACRYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLACRYLAMIDE)		11-29-18	83 FR 61320	11/29/2018	I
N-(4-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)ISOBUTYRAMIDE (4-FLUOROISOBUTYRYL FENTANYL)		11-29-18	83 FR 61320	11/29/2018	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLFURAN-2-CARBOXAMIDE (FURANYL FENTANYL)		11-29-18	83 FR 61320	11/29/2018	I
N-(2-FLUOROPHENYL)-2-METHOXY-N-(1-PHENETHYLPIPERIDIN-4-YL)ACETAMIDE (OCFENTANIL)		11-29-18	83 FR 61320	11/29/2018	I
TETRAHYDROFURANYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLTETRAHYDROFURAN-2-CARBOXAMIDE)		11-29-18	83 FR 61320	11/29/2018	I

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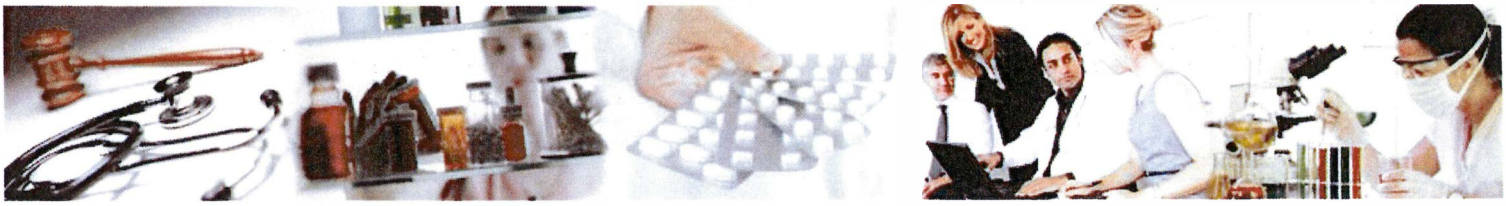

Title 21 United States Code (USC) Controlled Substances Act

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SUBCHAPTER I — CONTROL AND ENFORCEMENT

Part A — Introductory Provisions

§802. Definitions

As used in this subchapter:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Drug Enforcement Administration" means the Drug Enforcement Administration in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means—

(A) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(12) The term "drug" has the meaning given that term by section 321(g)(1) of this title.

(13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term "isomer" means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term "isomer" means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term "isomer" means any optical or geometric isomer.

(15) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation,

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compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

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

(17) The term "narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term "opiate" or "opioid" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term "opium poppy" means the plant of the species Papaver somniferum L., except the seed thereof.

(20) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(22) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term "immediate precursor" means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(24) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health and Human Services.

(25) The term "serious bodily injury" means bodily injury which involves—

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.

(26) The term "State" means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(27) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(28) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(29) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(30) The term "detoxification treatment" means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(31) The term "Convention on Psychotropic Substances" means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.

(32)(A) Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance—

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

(C) Such term does not include—

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 355 of this title to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

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Agriculture Improvement Act of 2018 "Farm Bill"

"(b) REPORT.—Not later than 1 year after the date of enactment of the Agriculture Improvement Act of 2018, the Secretary shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report that includes—

"(1) a summary of the data sets identified under subsection (a);

"(2) a summary of the steps the Secretary would have to take to provide access to such data sets by university researchers, including taking into account any technical, privacy, or administrative considerations;

"(3) a summary of safeguards the Secretary employs when providing access to data to university researchers;

"(4) a summary of appropriate procedures to maximize the potential for research benefits while preventing any violations of privacy or confidentiality; and

"(5) recommendations for any necessary authorizations or clarifications of Federal law to allow access to such data sets to maximize the potential for research benefits.".

SEC. 12619. CONFORMING CHANGES TO CONTROLLED SUBSTANCES ACT.

(a) IN GENERAL.—Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) is amended—

(1) by striking "(16) The" and inserting "(16)(A) Subject to subparagraph (B), the"; and

(2) by striking "Such term does not include the" and inserting the following:

"(B) The term 'marihuana' does not include—

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

"(ii) the".

(b) TETRAHYDROCANNABINOL.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)), is amended in subsection (c)(17) by inserting after "Tetrahydrocannabinols" the following: , except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946)".

Speaker of the House of Representatives.

Vice President of the United States and President of the Senate.

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FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds

For Immediate Release

December 20, 2018

Statement

Today, the Agriculture Improvement Act of 2018 was signed into law. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as cannabis (*Cannabis sativa L.*), and derivatives of cannabis with extremely low (less than 0.3 percent on a dry weight basis) concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC). These changes include removing hemp from the Controlled Substances Act, which means that it will no longer be an illegal substance under federal law.

Just as important for the FDA and our commitment to protect and promote the public health is what the law *didn't* change: Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. In doing so, Congress recognized the agency's important public health role with respect to all the products it regulates. This allows the FDA to continue enforcing the law to protect patients and the public while also providing potential regulatory pathways for products containing cannabis and cannabis-derived compounds.

We're aware of the growing public interest in cannabis and cannabis-derived products, including cannabidiol (CBD). This increasing public interest in these products makes it even more important with the passage of this law for the FDA to clarify its regulatory authority over these products. In short, we treat products containing cannabis or cannabis-derived compounds as we do any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of the source of the substance, including whether the substance is derived from a plant that is classified as hemp under the Agriculture Improvement Act. To help members of the public understand how the FDA's requirements apply to these products, the FDA has maintained a **webpage**

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(/NewsEvents/PublicHealthFocus/ucm421168.htm) with answers to frequently asked questions, which we intend to update moving forward to address questions regarding the Agriculture Improvement Act and regulation of these products generally.

In view of the proliferation of products containing cannabis or cannabis-derived substances, the FDA will advance new steps to better define our public health obligations in this area. We'll also continue to closely scrutinize products that could pose risks to consumers. Where we believe consumers are being put at risk, the FDA will warn consumers and take enforcement actions.

In particular, we continue to be concerned at the number of drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds. Among other things, the FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce. This is the same standard to which we hold any product marketed as a drug for human or animal use. Cannabis and cannabis-derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases (such as cancer, Alzheimer's disease, psychiatric disorders and diabetes) are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns, as it may keep some patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases.

Additionally, it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug.

We'll take enforcement action needed to protect public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and are being marketed in violation of the FDA's authorities. The FDA has sent **warning letters (/NewsEvents/PublicHealthFocus/ucm484109.htm)** in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

While products containing cannabis and cannabis-derived compounds remain subject to the FDA's authorities and requirements, there are pathways available for those who seek to lawfully introduce these products into interstate commerce. The FDA will continue to take steps to make the pathways for the lawful marketing of these products more efficient.

These pathways include ways for companies to seek approval from the FDA to market with therapeutic claims a human or animal drug that is derived from cannabis. For example, in June 2018, the FDA approved a drug, **Epidiolex (/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm)**, that contains cannabis-derived CBD for the treatment of seizures associated with two rare and severe forms of epilepsy. That approval was based on adequate and well-controlled clinical studies, which gives prescribers confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

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In addition, pathways remain available for the FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement. Although such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement. We are taking new steps to evaluate whether we should pursue such a process. However, the FDA would only consider doing so if the agency were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients.

It should also be noted that some foods are derived from parts of the hemp plant that may not contain CBD or THC, meaning that their addition to foods might not raise the same issues as the addition of drug ingredients like CBD and THC. We are able to advance the lawful marketing of three such ingredients today. We are announcing that the agency has completed our evaluation of three **Generally Recognized as Safe (/Food/NewsEvents/ConstituentUpdates/ucm628910.htm)** (GRAS) notices related to hulled hemp seeds, hemp seed protein and hemp seed oil and that the agency had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for these uses without food additive approval, provided they comply with all other requirements and do not make disease treatment claims.

Given the substantial public interest in this topic and the clear interest of Congress in fostering the development of appropriate hemp products, we intend to hold a public meeting in the near future for stakeholders to share their experiences and challenges with these products, including information and views related to the safety of such products.

We'll use this meeting to gather additional input relevant to the lawful pathways by which products containing cannabis or cannabis-derived compounds can be marketed, and how we can make these legal pathways more predictable and efficient. We'll also solicit input relevant to our regulatory strategy related to existing products, while we continue to evaluate and take action against products that are being unlawfully marketed and create risks for consumers.

At the same time, we recognize the potential opportunities that cannabis or cannabis-derived compounds could offer and acknowledge the significant interest in these possibilities. We're committed to pursuing an efficient regulatory framework for allowing product developers that meet the requirements under our authorities to lawfully market these types of products.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

Lyndsay Meyer (mailto:lyndsay.meyer@fda.hhs.gov)
240-402-5345

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Mark J. Hardy

From: Levi Andrist <landrist@gagroup.law>
Sent: Monday, November 12, 2018 2:40 PM
To: Mark J. Hardy
Cc: Amy Lunde; Joel Gilbertson
Subject: Sativex

Hi, Mark,

I hope you had a great Veterans Day weekend!

I'm reaching out on behalf of Greenwich Biosciences, which as you know as of very lately has brought Epidiolex to market. We've already had some patient outreach, so even in our low-population state, there is strong interest, which makes the state's proactive approach that much more impactful!

Greenwich has another drug named Sativex for which it is looking to proactively reschedule out of schedule 1 pending federal action/rescheduling. Here is some background for context:

- *Trade Name*: Sativex
- *Ingredients*: 2.7 mg delta-9-tetrahydrocannabinol (THC) and 2.5 mg cannabidiol (CBD) from Cannabis sativa L
- *Therapeutic Indications*: 4.1
    - Outside the US - Currently not approved my the US FDA
    - Sativex is indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.
- *FDA Process*: Greenwich is meeting with the FDA to determine what additional data the FDA would require before Greenwich can file an NDA. Greenwich is hoping to file a "rolling" NDA submission in 2019.

I'd greatly appreciate your insights as we look to the 2019 session, and, of course, am hopeful you'd consider including similar language from your 2017 CSA update bill relating to Epidiolex in your 2019 CSA update bill.

Many thanks, as always, Mark; I look forward to hearing from you.

Best,
Levi

Levi Andrist
GA Group, PC
1661 Capitol Way
Bismarck, ND 58501
(701) 240-3372
landrist@gagroup.law
www.gagroup.law

LEGAL STATUS

LEGAL STATUS

Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements

A Rule by the Drug Enforcement Administration on 09/28/2018

DOCUMENT DETAILS

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ENHANCED CONTENT

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DEA-2018-0014 (https://www.regulations.gov/docket?D=DEA-2018-0014)

Supporting/Related Materials:

ENHANCED CONTENT

PUBLISHED DOCUMENT

AGENCY:

Drug Enforcement Administration, Department of Justice.

ACTION:

Final order.

SUMMARY:

With the issuance of this final order, the Acting Administrator of the Drug Enforcement Administration places certain drug products that have been approved by the Food and Drug Administration (FDA) and which contain cannabidiol (CBD) in schedule V of the Controlled Substances Act (CSA). Specifically, this order places FDA-approved drugs that contain CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V. This action is required to satisfy the responsibility of the Acting Administrator under the CSA to place a drug in the schedule he deems most appropriate to carry out United States obligations under the Single Convention on Narcotic Drugs, 1961. Also consistent therewith, DEA is adding such drugs to the list of substances that may only be imported or exported pursuant to a permit.

DATES:

Effective September 28, 2018.

FOR FURTHER INFORMATION CONTACT:

Kathy L. Federico, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

The United States is a party to the Single Convention on Narcotic Drugs, 1961 (Single Convention), and other international conventions designed to establish effective control over international and domestic traffic in controlled substances. 21 U.S.C. 801 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=801&type=usc&link-type=html)(7). The Single Convention entered into force for the United States on June 24, 1967, after the Senate gave its advice and

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consent to the United States' accession. *See* Single Convention, 18 U.S.T. 1407. The enactment and enforcement of the Controlled Substances Act (CSA) are the primary means by which the United States carries out its obligations under the Single Convention.[1] Various provisions of the CSA directly reference the Single Convention. One such provision is 21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html)(d)(1), which relates to scheduling of controlled substances.

As stated in subsection 811(d)(1), if control of a substance is required "by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by [subsections 811(a) or 812(b)] and without regard to the procedures prescribed by [subsections 811(a) and (b)]." This provision is consistent with the Supremacy Clause of the U.S. Constitution (art. VI, sec. 2), which provides that all treaties made under the authority of the United States "shall be the supreme Law of the Land." In accordance with this constitutional mandate, under section 811(d)(1), Congress directed the Attorney General (and the Administrator of DEA, by delegation) [2] to ensure that compliance by the United States with our nation's obligations under the Single Convention is given top consideration when it comes to scheduling determinations.

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Section 811(d)(1) is relevant here because, on June 25, 2018, the Food and Drug Administration (FDA) announced that it approved a drug that is subject to control under the Single Convention. Specifically, the FDA announced that it approved the drug Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm)*. Epidiolex is an oral solution that contains cannabidiol (CBD) extracted from the cannabis plant. This is the first FDA-approved drug made from the cannabis plant.[3] Now that Epiodiolex has been approved by the FDA, it has a currently accepted medical use in treatment in the United States for purposes of the CSA. Accordingly, Epidiolex no longer meets the criteria for placement in schedule I of the CSA. *See* 21 U.S.C. 812 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=812&type=usc&link-type=html)(b) (indicating that while substances in schedule I have no currently accepted medical use in treatment in the United States, substances in schedules II-V do); *see also United States* v. *Oakland Cannabis Buyers' Cooperative,* 532 U.S. 483, 491-92 (2001) (same). DEA must therefore take the appropriate scheduling action to remove the drug from schedule I.

In making this scheduling determination, as section 811(d)(1) indicates, it is necessary to assess the relevant requirements of the Single Convention. Under the treaty, cannabis, cannabis resin, and extracts and tinctures of cannabis are listed in Schedule I.[4] The cannabis plant contains more than 100 cannabinoids. Among these are tetrahydrocannabinols (THC) and CBD.[5] Material that contains THC and CBD extracted from the cannabis plant falls within the listing of extracts and tinctures of cannabis for purposes of the Single Convention.[6] Thus, such material, which includes, among other things, a drug product containing CBD extracted from the cannabis plant, is a Schedule I drug under the Single Convention.

Parties to the Single Convention are required to impose a number of control measures with regard to drugs listed in Schedule I of the Convention. These include, but are not limited to, the following:

- Limiting exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of such drugs. Article 4.

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- Furnishing to the International Narcotics Control Board (INCB) annual estimates of, among other things, quantities of such drugs to be consumed for medical and scientific purposes, utilized for the manufacture of other drugs, and held in stock. Article 19.
- Furnishing to the INCB statistical returns on the actual production, utilization, consumption, imports and exports, seizures, and stocks of such drugs during the prior year. Article 20.
- Requiring that licensed manufacturers of such drugs obtain quotas specifying the amounts of such drugs they may manufacture to prevent excessive production and accumulation beyond that necessary to satisfy legitimate needs. Article 29.
- Requiring manufacturers and distributors of such drugs to be licensed. Articles 29 & 30.
- Requiring medical prescriptions for the dispensing of such drugs to patients. Article 30.
- Requiring importers and exporters of such drugs to be licensed and requiring each individual importation or exportation to be predicated on the issuance of a permit. Article 31.
- Prohibiting the possession of such drugs except under legal authority. Article 33.
- Requiring those in the legitimate distribution chain (manufacturers, distributors, scientists, and those who lawfully dispense such drugs) to keep records that show the quantities of such drugs manufactured, distributed, dispensed, acquired, or otherwise disposed of during the prior two years. Article 34.

Because the CSA was enacted in large part to satisfy United States obligations under the Single Convention, many of the CSA's provisions directly implement the foregoing treaty requirements. None of the foregoing obligations of the United States could be satisfied for a given drug if that drug were removed entirely from the CSA schedules. At least one of the foregoing requirements (quotas) can only be satisfied if the drug that is listed in Schedule I of the Single Convention is also listed in schedule I or II of the CSA because, as 21 U.S.C. 826 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=826&type=usc&link-type=html) indicates, the quota requirements generally apply only to schedule I and II controlled substances.

The permit requirement warrants additional explanation. As indicated above, the Single Convention obligates parties to require a permit for the importation and exportation of drugs listed in Schedule I of the Convention. This permit requirement applies to a drug product containing CBD extracted from the cannabis plant because, as further indicated above, such a product is a Schedule I drug under the Single Convention. However, under the CSA [7] and DEA regulations, the import/export permit requirement does not apply to all controlled substances. Rather, a permit is required to import or export any controlled substance in schedule I and II as well as certain controlled substances in schedules III, IV, and V. *See* 21 U.S.C. 952 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=952&type=usc&link-type=html) and 953; 21 CFR 1312.11 (/select-citation/2018/09/28/21-CFR-1312.11), 1312.12, 1312.21, 1312.22. Thus, in deciding what schedule is most appropriate to carry out the United States' obligations under the Single Convention with respect to the importation and exportation of Epidiolex, I conclude there are two options:

(i) Control the drug in schedule II, which will automatically require an import/export permit under existing provisions of the CSA and DEA regulations or

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(ii) control the drug in schedule III, IV, or V, and simultaneously amend the regulations to require a permit to import or export Epidiolex.

It bears emphasis that where, as here, control of a drug is required by the Single Convention, the DEA Administrator "shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, *without regard to the findings required by [21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-*

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type=html) (a) or 812(b)] and without regard to the procedures prescribed by [21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html) (a) or (b)]." 21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html)(d)(1) (emphasis added). Thus, in such circumstances, the Administrator is not obligated to request a medical and scientific evaluation or scheduling recommendation from the Department of Health and Human Services (HHS) (as is normally done pursuant to section 811(b)).[8] Nonetheless, DEA did seek such an evaluation and recommendation from HHS with respect to the Epidiolex formulation. In responding to that request, HHS advised DEA that it found the Epidiolex formulation to have a very low potential for abuse and, therefore, recommended that, if DEA concluded that control of the drug was required under the Single Convention, Epidiolex should be placed in schedule V of the CSA.[9] Although I am not required to consider this HHS recommendation when issuing an order under section 811(d)(1), because I believe there are two legally viable scheduling options (listed above), both of which would satisfy the United States' obligations under the Single Convention, I will exercise my discretion and choose the option that most closely aligns to the HHS recommendation. Namely, I am hereby ordering that the Epidiolex formulation (and any future FDA-approved generic versions of such formulation made from cannabis) be placed in schedule V of the CSA.

As noted, this order placing the Epidiolex formulation in schedule V will only comport with section 811(d)(1) if all importations and exportations of the drug remain subject to the permit requirement. Until now, since the Epidiolex formulation had been a schedule I controlled substance, the importation of the drug from its foreign production facility has always been subject to the permit requirement. To ensure this requirement remains in place (and thus to prevent any lapse in compliance with the requirements of the Single Convention), this order will amend the DEA regulations (21 CFR 1312.30 (/select-citation/2018/09/28/21-CFR-1312.30)) to add the Epidiolex formulation to the list of nonnarcotic schedule III through V controlled substances that are subject to the import and export permit requirement.

Finally, a brief explanation is warranted regarding the quota requirement in connection with the Single Convention. As indicated above, for drugs listed in Schedule I of the Convention, parties are obligated to require that licensed manufacturers of such drugs obtain quotas specifying the amounts of such drugs they may manufacture. The purpose of this treaty requirement is to prevent excessive production and accumulation beyond that necessary to satisfy legitimate needs. Under this scheduling order, the United States will continue to meet this obligation because the bulk cannabis material used to make the Epidiolex formulation (as opposed to the FDA-approved drug product in finished dosage form) will remain in schedule I of the CSA and thus be subject to all applicable quota provisions under 21 U.S.C. 826 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=826&type=usc&link-type=html).[10]

Requirements for Handling FDA-Approved Products Containing CBD

As noted, until now, Epidiolex has been a schedule I controlled substance. By virtue of this order, Epidiolex (and any generic versions of the same formulation that might be approved by the FDA in the future) will be a schedule V controlled substance. Thus, all persons in the distribution chain who handle Epidiolex in the United States (importers, manufacturers, distributors, and practitioners) must comply with the requirements of the CSA and DEA regulations relating to schedule V controlled substances. As further indicated, any material, compound, mixture, or preparation *other than Epidiolex* that falls within the CSA definition of marijuana set forth in 21 U.S.C. 802 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=802&type=usc&link-type=html)(16), including any

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non-FDA-approved CBD extract that falls within such definition, remains a schedule I controlled substance under the CSA.[11] Thus, persons who handle such items will continue to be subject to the requirements of the CSA and DEA regulations relating to schedule I controlled substances.

Regulatory Analyses

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control of a drug is required by the United States' obligations under the Single Convention. 21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html)(d)(1). Under such circumstances, the Attorney General must "issue an *order* controlling such drug under the schedule he deems most appropriate to carry out such obligations," without regard to the findings or procedures otherwise required for scheduling actions. *Id.* (emphasis added). Thus, section 811(d)(1) expressly requires that this type of scheduling action not proceed through the notice-and-comment rulemaking procedures governed by the Administrative Procedure Act (APA), which generally apply to scheduling actions; it instead requires that such scheduling action occur through the issuance of an "order."

Although the text of section 811(d)(1) thus overrides the normal APA considerations, it is notable that the APA itself contains a provision that would have a similar effect. As set forth in 21 U.S.C. 553 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=553&type=usc&link-type=html)(a)(1), the section of the APA governing rulemaking does not apply to a "foreign affairs function of the United States." An order issued under section 811(d)(1) may be considered a foreign affairs function of the United States because it is for the express purpose of ensuring that the United States carries out its obligations under an international treaty.

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Executive Order 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in Executive Order 13563 (/executive-order/13563) (Improving Regulation and Regulatory Review), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This order is not an Executive Order 13771 (/executive-order/13771) regulatory action.

Executive Order 12988, (/executive-order/12988) Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (/executive-order/12988) to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, (/executive-order/13132) Federalism

This action does not have federalism implications warranting the application of Executive Order 13132 (/executive-order/13132). This action does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, (/executive-order/13175) Consultation and Coordination With Indian Tribal Governments

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This action does not have tribal implications warranting the application of Executive Order 13175 (/executive-order/13175). The action does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 (https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=601&type=usc&link-type=html)-612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this order from the APA notice-and-comment rulemaking provisions. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501 (https://api.fdsys.gov/link?collection=uscode&title=44&year=mostrecent&section=3501&type=usc&link-type=html)-3521. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

As noted above, this action is an order, not a rulemaking. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, the DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (CRA), 5 U.S.C. 801 (https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=801&type=usc&link-type=html)-808.

List of Subjects

21 CFR Part 1308 (/select-citation/2018/09/28/21-CFR-1308)

- Administrative practice and procedure
- Drug traffic control
- Reporting and recordkeeping requirements

21 CFR Part 1312 (/select-citation/2018/09/28/21-CFR-1312)

- Administrative practice and procedure
- Drug traffic control
- Exports
- Imports
- Reporting requirements

For the reasons set out above, DEA amends 21 CFR parts 1308 (/select-citation/2018/09/28/21-CFR-1308) and 1312 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

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Authority: 21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html), 812, 871(b), 956(b) unless otherwise noted.

2. In § 1308.15, add paragraph (f) to read as follows:

§ 1308.15 Schedule V.

* * * * *

(f) *Approved cannabidiol drugs.* (1) A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols 7367

(2) [Reserved]

* * * * *

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

3. The authority citation for part 1312 is revised to read as follows:

Authority: 21 U.S.C. 821 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=821&type=usc&link-type=html), 871(b), 952, 953, 954, 957, 958.

4. In § 1312.30, revise the introductory text and add pargraph (b) to read as follows:

§ 1312.30 Schedule III, IV, and V non-narcotic controlled substances requiring an import and export permit.

The following Schedule III, IV, and V non-narcotic controlled substances have been specifically designated by the Administrator of the Drug Enforcement Administration as requiring import and export permits pursuant to sections 201(d)(1), 1002(b)(2), and 1003(e)(3) of the Act (21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html)(d)(1), 952(b)(2), and 953(e)(3)):

* * * * *

(b) A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

Dated: September 21, 2018.

Uttam Dhillon,

Acting Administrator.

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Footnotes

1. *See S. Rep. No. 91-613, at 4 (1969) ("The United States has international commitments to help control the worldwide drug traffic. To honor those commitments, principally those established by the Single Convention on Narcotic Drugs of 1961, is clearly a Federal responsibility."); Control of Papaver Bracteatum, 1 Op. O.L.C. 93, 95 (1977) ("[A] number of the provisions of [the CSA] reflect Congress' intent to comply with the obligations imposed by the Single Convention.").*
Back to Citation

2. *28 CFR 0.100 (/select-citation/2018/09/28/28-CFR-0.100).*
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3. *The drug Marinol was approved by the FDA in 1985. Marinol contains a synthetic form of dronabinol (an isomer of tetrahydrocannabinol) and thus is not made from the cannabis plant.*
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4. *The text of the Single Convention capitalizes schedules (e.g., "Schedule I"). In contrast, the text of the CSA generally refers to schedules in lower case. This document will follow this approach of using capitalization or lower case depending on whether the schedule is under the Single Convention or the CSA.*
It should also be noted that the schedules of the Single Convention operate somewhat differently than the schedules of the CSA. Unlike the CSA, the Single Convention imposes additional restrictions on drugs listed in Schedule IV that go beyond those applicable to drugs listed in Schedule I. All drugs in Schedule IV of the Single Convention are also in Schedule I of the Convention. Cannabis and cannabis resin are among the drugs listed in Schedule IV of the Single Convention.
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5. *There are numerous isomers of cannabidiol, which will be referred to here collectively as "CBD."*
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6. *Although the Single Convention does not define the term "extract," the ordinary meaning of that term would include a product, such as a concentrate of a certain chemical or chemicals, obtained by a physical or chemical process. See, e.g., Webster's Third New International Dictionary 806 (1976). Thus, the term extract of cannabis would include any product that is made by subjecting cannabis material to a physical or chemical process designed to isolate or increase the concentration of one or more of the cannabinoid constituents.*
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7. *The provisions of federal law relating to the import and export of controlled substances—those found in 21 U.S.C. 951 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=951&type=usc&link-type=html) through 971—are more precisely referred to as the Controlled Substances Import and Export Act (CSIEA). However, federal courts and DEA often use the term "CSA" to refer collectively to all provisions from 21 U.S.C. 801 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=801&type=usc&link-type=html) through 971 and, for ease of exposition, this document will do likewise.*
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8. *In the House Report to the bill that would become the CSA (H. Rep. No. 91-1444, at 36 (1970)), this issue is explained as follows:*
Under subsection [811(d)], where control of a drug or other substance by the United States is required by reason of its obligations under [the Single Convention], the bill does not require that the Attorney General seek an evaluation and recommendation by the Secretary of Health, Education, and Welfare, or pursue the procedures for control prescribed by the bill but he may include the drug or other substance under any of the five schedules of the bill which he considers most appropriate to carry out the obligations of the United States under the international instrument, and he may do so without making the specific findings otherwise required for inclusion of a drug or other substance in that schedule.
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9. HHS most recently updated its medical and scientific evaluation and scheduling recommendation for the Epidiolex formulation by letter to DEA dated June 13, 2018.
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10. At present, the cannabis used to make Epidiolex is grown in the United Kingdom and the drug is imported into the United States in finished dosage form.
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11. Nothing in this order alters the requirements of the Federal Food, Drug, and Cosmetic Act that might apply to products containing CBD. In announcing its recent approval of Epidiolex, the FDA Commissioner stated:
[W]e remain concerned about the proliferation and illegal marketing of unapproved CBD-containing products with unproven medical claims. . . . The FDA has taken recent actions against companies distributing unapproved CBD products. These products have been marketed in a variety of formulations, such as oil drops, capsules, syrups, teas, and topical lotions and creams. These companies have claimed that various CBD products could be used to treat or cure serious diseases such as cancer with no scientific evidence to support such claims.
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611047.htm (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611047.htm).
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Gabapentin (Neurontin®)

2-[1-(aminomethyl) cyclohexyl] acetic acid

October 2018
DEA/DC/DP/DPE

Introduction:

Gabapentin is a prescription medication approved by the Food and Drug Administration (FDA) for the treatment of neuropathic pain and epileptic disorders. It is currently marketed in capsule, tablet and oral solution formulations. In recent years however, gabapentin has been increasingly encountered by law enforcement, documented in national crime lab reports, reported to poison control centers and diverted for illicit use.

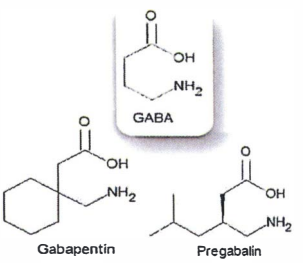
Licit Uses:

According to the FDA-approved product label, gabapentin is used clinically in the management of postherpetic neuralgia in adults and as an adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization in adults and pediatric patients 3 years and older with epilepsy.

From 2011 through 2017, annual total prescriptions for gabapentin steadily increased over two-fold from 2,965,784 in 2011 to 6,722,145 (IMS Health™). Gabapentin is available in various dosage forms and strengths including capsule strengths of 100, 300 and 400 milligrams, tablet strengths of 600 and 800 milligrams and the oral liquid form is typically produced as a 250 milligrams/5 mL solution.

Chemistry:

The chemical structures for gabapentin [1-(aminomethyl) cyclohexaneacetic acid], gamma-aminobutyric acid (GABA) and pregabalin are shown below. Gabapentin closely resembles pregabalin, a Schedule V drug under the Controlled Substances Act in its chemical structure and pharmacological activity.



The chemical structure of gabapentin is derived from the addition of a lipophilic cyclohexyl group to the backbone of GABA. Gabapentin is a crystalline substance and freely soluble in water, alkaline and acidic solutions.

Pharmacology:

The exact mechanisms through which gabapentin exerts its analgesic and antiepileptic actions are unknown, However, according to the information from the FDA approved label for gabapentin drug product, gabapentin has no effect on GABA binding, uptake or degradation. In-vitro studies have shown gabapentin binds to auxiliary α2-δ subunits of voltage-gated Ca^{2+} channels on neurons thereby resulting in a decrease in neuronal excitability.

At clinically therapeutic doses (900-3600 mg/day), gabapentin does not bind to $GABA_A$ or $GABA_B$ receptors, nor does it bind to benzodiazepine sites.

FDA-approved product label for gabapentin mentions adverse reactions such as dizziness, somnolence (drowsiness), peripheral edema (swelling), ataxia (incoordination), fatigue and nystagmus (involuntary rapid eye movement). According to a published study which analyzed online information from 32 websites, gabapentin use, similar to pregabalin, is associated with sedative and/or psychedelic effects.

Illicit Uses:

Gabapentin has been encountered in postmortem toxicology reports as indicated by data from the American Association of Poison Control Centers (AAPCC). According to the 2016 annual report of AAPCC's National Poison Data System (NPDS), gabapentin was detected in a total of 168 fatalities from 2012 to 2016. Of those cases, gabapentin was the primary cause of death in 23 individuals. Total exposure calls as a result of gabapentin increased from 5,889 in 2012 to 20,064 in 2016 for a total of 72,283. The single substance exposure involving gabapentin alone increased from 2,141 in 2012 to 7,024 in 2016. Additionally, according to the Drug Abuse Warning Network (DAWN), emergency department (ED) visit rates (per 100,000 population) for gabapentin rose from 2.7 in 2004 to 4.9 in 2011.

User Population:

In a cohort of 503 adults reporting nonmedical use of pharmaceuticals (and not enrolled in treatment facilities for such illicit use) in Appalachian Kentucky, 15% of respondents reported using gabapentin specifically to "get high". This number represented a 165% increase compared to one year prior and a 2,950% increase from 2008 respondents within the same cohort. In a 2013 online survey distributed to 1,500 respondents from the United Kingdom aged 16 to 59 years, 1.1% self-reported lifetime prevalence of gabapentin misuse.

Illicit Distribution:

STARLiMS, a web-based, commercial laboratory information management system, and the System to Retrieve Information from Drug Evidence (STRIDE), federal databases for seized drugs analyzed by DEA forensic laboratories, and the National Forensic Laboratory Information System (NFLIS), a system that collects drug analysis information from state, local, and other federal forensic laboratories contain 28 (STARLiMS and STRIDE combined data) and 2,219 reports, respectively for gabapentin in 2016. This number represents approximately a 6.75 and 6.5-fold increase respectively from reports in 2007. Additionally, the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) system, a prescription drug abuse/misuse and diversion monitoring system that collects geographically-specific data, indicate that 407 cases of gabapentin diversion were reported in 41 states between 2002 and 2015. The rates of diversion steadily increased from 0.0 in 2002 to 0.027 cases per 100,000 population in 2015. Published evidence also indicates that gabapentin is commonly offered for sale online from numerous websites.

Control Status

Gabapentin is not currently controlled under the Controlled Substances Act of 1970.

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BROOKINGS

FixGov

The Farm Bill, hemp legalization and the status of CBD: An explainer

John Hudak Friday, December 14, 2018

This week, Congress agreed to the final version of the 2018 Farm Bill, and President Trump is expected to sign the legislation within days. But this is not your typical farm bill. While it provides important agricultural and nutritional policy extensions for five years, the most interesting changes involve the cannabis plant. Typically, cannabis is not part of the conversation around farm subsidies, nutritional assistance, and crop insurance. Yet, this year, Senate Majority Leader Mitch McConnell's strong support of and leadership on the issue of hemp has thrust the cannabis plant into the limelight.

For a little bit of background, hemp is defined in the legislation as the cannabis plant (yes, the same one that produces marijuana) with one key difference: hemp cannot contain more than 0.3 percent of THC (the compound in the plant most commonly associated with getting a person high). In short, hemp can't get you high. For decades, federal law did not differentiate hemp from other cannabis plants, all of which were effectively made illegal in 1937 under the Marihuana Tax Act and formally made illegal in 1970 under the Controlled Substances Act—the latter banned cannabis of any kind.

It's true that hemp policy in the United States has been drastically transformed by this new legislation. However, there remain some misconceptions about what, exactly, this policy change does.

Hemp is legal in the United States—with serious restrictions

The allowed pilot programs to study hemp (often labeled "industrial hemp") that were approved by both the U.S. Department of Agriculture (USDA) and state departments of agriculture. This allowed small-scale expansion of hemp cultivation for limited purposes. The 2018 Farm Bill is more expansive. It allows hemp cultivation broadly, not simply pilot programs for studying market interest in hemp-derived products. It explicitly allows the transfer of hemp-derived products across state lines for commercial or other purposes. It also puts no restrictions on the sale, transport, or possession of hemp-derived products, so long as those items are produced in a manner consistent with the law.

However, the new Farm Bill does not create a completely free system in which individuals or businesses can grow hemp whenever and wherever they want. There are numerous restrictions.

First, as noted above, hemp cannot contain more than 0.3 percent THC, per section 10113 of the Farm Bill. Any cannabis plant that contains more than 0.3 percent THC would be considered non-hemp cannabis—or marijuana—under federal law and would thus face no legal protection under this new legislation.

Second, there will be significant, shared state-federal regulatory power over hemp cultivation and production. Under section 10113 of the Farm Bill, state departments of agriculture must consult with the state's governor and chief law enforcement officer to devise a plan that must be submitted to the Secretary of USDA. A state's plan to license and regulate hemp can only commence once the Secretary of USDA approves that state's plan. In states opting not to devise a hemp regulatory program, USDA will construct a regulatory program under which hemp cultivators in those states must apply for licenses and comply with a federally-run program. This system of shared regulatory programming is similar to options states had in other policy areas such as health insurance marketplaces under ACA, or workplace safety plans under OSHA—both of which had federally-run systems for states opting not to set up their own systems.

Third, the law outlines actions that are considered violations of federal hemp law (including such activities as cultivating without a license or producing cannabis with more than 0.3 percent THC). The law details possible punishments for such violations, pathways

for violators to become compliant, and even which activities qualify as felonies under the law, such as repeated offenses.

Ultimately, the Farm Bill legalizes hemp, but it doesn't create a system in which people can grow it as freely as they can grow tomatoes or basil. This will be a highly regulated crop in the United States for both personal and industrial production.

Hemp research remains important

One of the goals of the 2014 Farm Bill was to generate and protect research into hemp. The 2018 Farm Bill continues this effort. Section 7605 re-extends the protections for hemp research and the conditions under which such research can and should be conducted. Further, section 7501 of the Farm Bill extends hemp research by including hemp under the Critical Agricultural Materials Act. This provision recognizes the importance, diversity, and opportunity of the plant and the products that can be derived from it, but also recognizes an important point: there is a still a lot to learn about hemp and its products from commercial and market perspectives. Yes, farmers—legal and illegal—already know a lot about this plant, but more can and should be done to make sure that hemp as an agricultural commodity remains stable.

Hemp farmers are treated like other farmers

Under the 2018 Farm Bill hemp is treated like other agricultural commodities in many ways. This is an important point. While there are provisions that heavily regulate hemp, and concerns exist among law enforcement—rightly or wrongly—that cannabis plants used to derive marijuana will be comingled with hemp plants, this legislation makes hemp a mainstream crop. Several provisions of the Farm Bill include changes to existing provisions of agricultural law to include hemp. One of the most important provisions from the perspective of hemp farmers lies in section 11101. This section includes hemp farmers' protections under the Federal Crop Insurance Act. This will assist farmers who, in the normal course of agricultural production, face crop termination (crop losses). As the climate changes and as farmers get used to growing this "new" product, these protections will be important.

Cannabidiol or CBD is made legal—under specific circumstances

One big myth that exists about the Farm Bill is that cannabidiol (CBD)—a non-intoxicating compound found in cannabis—is legalized. It is true that section 12619 of the Farm Bill removes hemp-derived products from its Schedule I status under the Controlled Substances Act, but the legislation does not legalize CBD generally. As I have noted elsewhere on this blog CBD generally remains a Schedule I substance under federal law. The Farm Bill—and an unrelated, recent action by the Department of Justice—creates exceptions to this Schedule I status in certain situations. The Farm Bill ensures that any cannabinoid—a set of chemical compounds found in the cannabis plant—that is derived from hemp will be legal, *if and only if* that hemp is produced in a manner consistent with the Farm Bill, associated federal regulations, association state regulations, and by a licensed grower. All other cannabinoids, produced in any other setting, remain a Schedule I substance under federal law and are thus illegal. (The one exception is pharmaceutical-grade CBD products that have been approved by FDA, which currently includes one drug: GW Pharmaceutical's Epidiolex.)

There is one additional gray area of research moving forward. Under current law, any cannabis-based research conducted in the United States must use research-grade cannabis from the nation's sole provider of the product: the Marijuana Program at the University of Mississippi School of Pharmacy's National Center for Natural Products Research. That setup exists because of cannabis's Schedule I status.[1] However, if hemp-derived CBD is no longer listed on the federal schedules, it will raise questions among medical and scientific researchers studying CBD products and their effects, as to whether they are required to get their products from Mississippi. This will likely require additional guidance from FDA (the Food and Drug Administration who oversees drug trials), DEA (the Drug Enforcement Administration who mandates that research-grade cannabis be sourced from Mississippi), and NIDA (National Institute on Drug Abuse who administers the contract to cultivate research-grade cannabis) to help ensure researchers do not inadvertently operate out of compliance.

State-legal cannabis programs are still illegal under federal law

The Farm Bill has no effect on state-legal cannabis programs. Over the past 22 years, 33 states have legalized cannabis for medical purposes, and over the past six years, 10 states have legalized cannabis for adult use. Every one of those programs is illegal under federal law, with no exceptions, and the Farm Bill does nothing to change that. That said, many in the advocacy community hope that the reforms to hemp policy under the Farm Bill serve as a first step toward broader cannabis reform. (Although I would argue that a soon-to-be-sworn-in Democratic House majority alongside a president with a record of pro-cannabis reform rhetoric is the more likely foundation for broader cannabis reform.)

Even CBD products produced by state-legal, medical, or adult-use cannabis programs are illegal products under federal law, both within states and across state lines. This legal reality is an important distinction for consumer protection. There are numerous myths about the legality of CBD products and their availability. Under the 2018 Farm Bill, there will be more broadly available, legal, CBD products; however, this does not mean that all CBD products are legal moving forward. Knowing your producer and whether they are legal and legitimate will be an important part of consumer research in a post-2018 Farm Bill world.

Mitch McConnell, cannabis champion?

Many advocates applaud Leader McConnell for his stewardship of these hemp provisions into the Farm Bill and his leadership on the legislation overall. That assessment is accurate. Without Mr. McConnell's efforts, the hemp provisions would never had found their way into the legislation initially. And although his position as Senate leader gave him tremendous institutional influence over the legislation, he went a step further by appointing himself to the conference committee that would bring the House and Senate together to agree on a final version.

McConnell understood much about this issue. First, he knows hemp doesn't get you high and that the drug war debate that swept up hemp was politically motivated, rather than policy-oriented. Second, Kentucky—the leader's home state—is one of the best places to cultivate hemp in the world, and pre-prohibition the state had a robust hemp sector. Third, the grassroots interest in this issue was growing in Kentucky, and McConnell knows that his role as Senate Majority Leader hangs in the balance in 2020, as does his Senate

seat as he faces re-election that same year. McConnell emerges from the Farm Bill as a hemp hero, but advocates should be hesitant to label him a cannabis champion; Leader McConnell remains a staunch opponent of marijuana reform and his role in the Senate could be the roadblock of Democratic-passed legislation in the 116th Congress.

[1] Under the Controlled Substances Act, all controlled drugs fall under five schedules. Schedule I has the highest level of control, designated a substance as having no safe medical use and has a high risk of abuse or misuse. Schedule I substances are illegal under the law.

State of North Dakota
Doug Burgum, Governor

OFFICE OF THE EXECUTIVE DIRECTOR
1906 E Broadway Ave
Bismarck ND 58501-4700
Telephone (701) 328-9535
Fax (701) 328-9536
STATE BOARD OF PHARMACY
Email= Mhardy@ndboard.pharmacy
www.ndboard.pharmacy

Mark J. Hardy, PharmD
Executive Director

F2
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1-7-19

HB1113 Proposed Amendments to mirror Federal Law.

1. Page 1, Line 15 - Consideration of placing parenthesis around **"except the resin extracted therefrom"** to match the Federal definition

From the Federal Controlled Substance Act:
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, or the sterilized seed of such plant which is incapable of germination.

2. Page 1 within definition of marijuana add the following language – **"The term marijuana does not include hemp (as defined in section 297A of the Agricultural Marketing Act of 1946)"**
3. Page 7 within definition of Tetrahydrocannabinols add the following language – **"except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946)"**

From the Agricultural Improvement Act of 2018 (Farm Bill)

(a) IN GENERAL.-Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) is amended-(1) by striking "(16) The" and inserting "(16)(A) Subject to subparagraph (B), the"; and (2) by striking "Such term does not include the" and inserting the following: "(B) The term 'marihuana' does not include- "(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946; or "(ii) the".

(b) TETRAHYDROCANNABINOL.-Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)), is amended in subsection (c)(17) by inserting after "Tetrahydrocannabinols" the following: ", except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946)".

#3
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1-7-19

North Dakota House Judiciary Committee

January 7th 2019

Chairman Koppelman and members of the Committee, my name is Steven James Peterson of The Committee for Compassionate Care of North Dakota.

The Committee for Compassionate Care is a patient advocacy group seeking to enable fair and reasonable access to medical marijuana in the state of North Dakota.

I have four (4) statements about this bill which would express my concerns.

HB 1113

- This definition and description of Cannabis is detrimental to the efforts of the Medical Marijuana program in North Dakota
- I have concerns that without either amendment or complete rewrite that this bill would create problems for hospitals in North Dakota trying to decide how to serve patients with cannabis care plans
- The definition of cannabis should reflect the evidence-based clinical trial results which none of which that I am aware of reflect any hallucinogenic properties of cannabis
- The definition of synthetic cannabis derivatives would effectively prevent new drugs that are being developed nationally and internationally from being able to be used by patients without revisiting this matter which could prevent patients from accessing clinical trials and treatment

I am available for any questions about this bill.

Steven James Peterson

701-936-4362 Steven@ravenrisingllc.com

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DRAFTED AT THE REQUEST OF MARK J. HARDY

STATE BOARD OF PHAMACY

and

Rep. Terry Jones

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1113

Page 1, line 15, immediately following "stalks" replace ", " with " ("

Page 1, line 15, immediately following "therefrom" insert ")"

Page 1, line 16, immediately following "germination. " insert "The term marijuana does not include hemp (as defined in ~~section 297A of the Agricultural Marketing Act of 1946~~)."

Page 8, line 1, insert "The definition of tetrahydrocannabinols does not include tetrahydrocannabinols in hemp (as defined in section 297A of the Agricultural Marketing Act of 1946)."

NBCC 4.1-18-01

Renumber Accordingly

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1/9/2019
p 1.

AGRICULTURE IMPROVEMENT ACT OF 2018

PL 115-334, December 20, 2018, 132 Stat 4490

As part of the federal "Farm Bill" a new definition of hemp will be as follows:

SEC. 10113. HEMP PRODUCTION.

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.) is amended by adding at the end the following:

T. 7 ch. 38 subch. VII prec. § 1639o

"Subtitle G—Hemp Production

<< 7 USCA § 1639o >>

"SEC. 297A. DEFINITIONS.

"In this subtitle:

"(1) HEMP.—The term 'hemp' means 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."

The Agriculture Improvement Act of 2018 (P.L. 115-334), often called the "2018 farm bill," was enacted on December 20, 2018.

Upon conferring with Legislative Council, the committee should be advised although they can deviate from the federal definition of hemp as provided in Sec. 297A it may create constitutional challenges in the future.

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pg 1

OFFICE OF THE EXECUTIVE DIRECTOR
1906 E Broadway Ave
Bismarck ND 58501-4700
Telephone (701) 328-9535
Fax (701) 328-9536
STATE BOARD OF PHARMACY

State of North Dakota
Doug Burgum, Governor

Mhardy@ndboard.pharmacy
www.nodakpharmacy.com

Mark J. Hardy, PharmD, R.Ph.
Executive Director

House Bill No 1113 – Controlled Substances Rescheduling
Senate Judiciary Committee – Fort Lincoln Room
10:00 AM - Wednesday – February 6th 2019

Madam Chair Larson, members of the Senate Judiciary Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you today.

House Bill 1113 is the biennial bill introduced by State Board of Pharmacy to bring the Controlled Substances Act up-to-date with what the Food and Drug Administration [FDA] and Drug Enforcement Administration [DEA] have done over the past two years. This bill also revises the definition of marijuana to be similar to the Federal Law, adds to the chemical modifications of synthetic schedule I drug to ensure future modifications will be illegal, and adds Gabapentin to be a schedule V drug in the state of North Dakota.

The drafting of this bill, specifically schedule I controlled substances, was done in conjunction with the ND State Crime Lab. A representative of the Crime Lab is here and can explain much of the chemistry and reasons for the chemical changes in Schedule I compounds, if requested. Our intension for these changes in Schedule I compounds is to be proactive to ensure we have future chemical modifications that could be made to the substances identified as controlled substances. This bill is very lengthy and, we feel, as comprehensive as possible with the information that we have at this time.

I would like to highlight each provision of the bill to ensure you have an understanding of the changes we have proposed for your considerations.

On page 1, Section 1 – starting on line 7 are changes to make the definition of Marijuana in North Dakota's Century Code consistent with the federal definition. This would ensure that any federal policy changes could be applied to North Dakota. The House adopted an amendment based on our recommendation on lines 16-17 referencing the definition of hemp in the ND Century Code 4.1-18-01. This amendment was derived by the recent passage of the federal Agricultural Improvement Act of 2018 (Farm Bill), which was signed in December 2018. This definition change appears to have opened up a clear legal pathway for production and marketing of hemp derived products to be marketed for sale, including cannabidiol (CBD). Understandably, there is much that needs to be determined on the federal level on how these changes will be implemented for availability of hemp derived products, like CBD, as is explained in the December 20, 2018 statement from the FDA commissioner which is attached to my testimony

On page 3, line 20 is simply correcting a typographical error that was made in the last legislative session in 2017.

On page 4, starting on line 29 and continuing to page 5, line 24 are proposed revisions to the specific fentanyl derivatives drafted in conjunction with the Drug Enforcement Administration scheduling during the past year. Of importance, North Dakota was in front of the federal government in scheduling fentanyl compounds during the 2017 Legislative session. These are the compounds that are often derived by rogue chemists in China and are at blame for too many overdose deaths. This change was a critical component to ensure individuals who may sell or distribute these extremely potent compounds will face the appropriate penalties for their actions.

On page 7, lines 22-23 again is a House amendment made to the original bill based on our recommendations to be consistent with the passage of the Farm Bill, which exempts tetrahydrocannabinols found in hemp, as defined by the Century Code. We specifically recommended language consistent with the Agricultural Improvement Act [Farm Bill].

On page 8, lines 11,15 & 16 are additional potential substitutions to the core chemical structure, which were added to ensure that the potential modifications to the Indole Carboxaldehydes can be appropriately included as Schedule I compounds in North Dakota.

On page 10, lines 13 & 17 are similar modifications and substitutions to the core chemical structure of the Indole Carboxamides.

On page 11 and continuing into page 12 are modifications to the specifically listed Indole Carboxamides to be consistent with DEA's listing of these compounds. This listing of the compounds and their other names is meant to assist law enforcement and prosecutorial officials in identifying compounds they may encounter in cases.

On page 12, line 27 through page 13 line 1 are again additional potential substitutions to the core chemical structure, which were added to ensure that the potential modifications to the Indole Carboxylic Acids are included as Schedule I compounds in North Dakota.

On page 13, line 18 is the addition of the other known name CBL2201 to be consistent with DEA scheduling.

On page 19, line 20 was the retraction of Flunitrazepam from the Schedule I controlled substances, as it does have a medical use and is currently scheduled in Schedule IV.

On page 21, lines 17-18 is the addition of a compound in the substituted cathinone category to be consistent with DEA's listing of this compound.

On page 22, lines 3-4 is the addition of Dronabinol solution, which is a Schedule II compound which was recently scheduled by the DEA.

On page 23, lines 3-4, we are proposing the addition of a substance called Sativex, which is a drug derived from marijuana which is currently going through clinical trials by GW Pharmaceuticals, which has brought a similar drug to market called Epidiolex. Sativex is indicated in other countries as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medications. We are proposing scheduling this in Schedule III which is consistent with GW Pharmaceutical's request to ensure that it can be brought to market for North Dakota patients prior to the next legislative session.

Also on page 23, lines 23-24 you will notice the striking of the terminology that we added last legislative session regarding Epidiolex.

On page 24, lines 6-10 is the final language approved to the Federal Controlled Substances Act regarding Epidiolex as approved in 2018 for the treatment of a rare childhood-onset seizure disorder. The DEA scheduled it as a Schedule V Controlled Substance. The language used makes this only applicable for an FDA approved cannabidiol drug. To be clear, this provision has no effect on CBD products derived from the Hemp plant which again we are proposing, with amendment, to add language consistent with the Agricultural Improvement Act of 2018.

Lastly, on page 24, line 11 we are requesting the scheduling of Gabapentin as a Schedule V drug in North Dakota. This is not consistent with the federal scheduling. However, North Dakota has been monitoring the use of Gabapentin usage through the Prescription Drug Monitoring Program (PDMP), which indicated widespread illicit use in patients using multiple pharmacies to obtain Gabapentin. Gabapentin is traditionally used as a medication for neuropathic pain and seizure disorders. The concerns of abuse have been increasing exponentially the past few years. Initially, it had seemed localized to a few counties but since these abuse reports have since spread state wide. The exact mechanism on the illicit effects of Gabapentin is difficult to pinpoint, however it appears to enhance the "high" from other substances and has become a sought-after medication. We encourage your considerations to Schedule this as a Schedule V substance in North Dakota based on the interaction with healthcare professionals and law enforcement findings.

Lastly, consistent with previous years, we respectfully ask for an emergency measure to be attached to this bill that if enacted would make these changes occur as quickly as possible.

Thank you for listening to our testimony and I will be happy to answer any questions.

SUBSTANCE *Scheduled under 21 USC 811(h) **Extension of temporary control	PROPOSAL PUBLICATION DATE	FINAL ORDER PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	CSA SCHEDULE
N-(1-AMINO-3-METHYL-1-OXOBUTAN-2-YL)-1-(4-FLUOROBENZYL)-1H-INDAZOLE-3-CARBOXAMIDE (AB-FUBINACA)		09-06-16	81 FR 61130	9/6/2016	I
QUINOLIN-8-YL 1-(5-FLUOROPENTYL)-1H-INDOLE-3-CARBOXYLATE (5-FLUORO-PB-22; 5F-PB-22)		09-06-16	81 FR 61130	9/6/2016	I
QUINOLIN-8-YL 1-PENTYL-1H-INDOLE-3-CARBOXYLATE (PB-22; QUPIC)		09-06-16	81 FR 61130	9/6/2016	I
3,4-DICHLORO-N-[2-(DIMETHYLAMINO)CYCLOHEXYL]-N-METHYLBENZAMIDE (U-47700)*		11-14-16	81 FR 79389	11/14/2016	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLFURAN-2-CARBOXAMIDE (FURANYL FENTANYL) *		11-29-16	81 FR 85873	11/29/2016	I
PENTEDRONE	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
BUTYLONE	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
ALPHA-PYRROLIDINOBUTIOPHENONE (α-PBP)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
4-METHYL-ALPHAPYRROLIDINOPROPIOPHENONE (4-MePPP)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
4-FLUORO-N-METHYLCATHINONE (4-FMC)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
3-FLUORO-N-METHYLCATHINONE (3-FMC)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
NAPHYRONE	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
4-METHYL-N-ETHYLCATHINONE (4-MEC)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
ALPHA-PYRROLIDINOPENTIOPHENONE (α-PVP)	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
PENTYLONE	03-04-16	03-01-17	82 FR 12171	3/1/2017	I
DRONABINOL IN ORAL SOLUTION IN DRUG PRODUCT APPROVED FOR MARKETING BY U.S. FOOD AND DRUG ADMIN.		03-23-17	82 FR 14815	3/23/2017	II
N-(1-AMINO-3,3-DIMETHYL-1-OXOBUTAN-2-YL)-1-(4-FLUOROBENZYL)1H-INDAZOLE-3-CARBOXAMIDE (ADB–FUBINACA)*		04-10-17	82 FR 17119	4/10/2017	I
METHYL 2-(1-(CYCLOHEXYLMETHYL)-1H-INDOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (MDMB-CHMICA)*		04-10-17	82 FR 17119	4/10/2017	I
N-(ADAMANTAN-1-YL)-1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDE (5F–APINACA, 5F–AKB48)*		04-10-17	82 FR 17119	4/10/2017	I
METHYL2-(1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDO)-3-METHYLBUTANOATE (5F-AMB)*		04-10-17	82 FR 17119	4/10/2017	I
METHYL2-(1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (5F-ADB)*		04-10-17	82 FR 17119	4/10/2017	I
METHYL 2-(1-(4-FLUOROBENZYL)-1H-INDAZOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (MDMB–FUBINACA)*		04-10-17	82 FR 17119	4/10/2017	I
N-(4-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)ISOBUTYRAMIDE (4-FLUOROISOBUTYRYL FENTANYL)*		05-03-17	82 FR 20544	5/3/2017	I
ACETYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLACETAMIDE)		06-07-17	82 FR 26349	6/7/2017	I
ACRYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLACRYLAMIDE)*		07-14-17	82 FR 32453	7/14/2017	I

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SUBSTANCE *Scheduled under 21 USC 811(h) **Extension of temporary control	PROPOSAL PUBLICATION DATE	FINAL ORDER PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	CSA SCHEDULE
ORTHO-FLUOROFENTANYL OR 2-FLUOROFENTANYL (N-(2-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL))*		10-26-17	82 FR 49504	10/26/2017	I
TETRAHYDROFURANYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLTETRAHYDROFURAN-2-CARBOXAMIDE)*		10-26-17	82 FR 49504	10/26/2017	I
METHOXYACETYL FENTANYL (2-METHOXY-N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLACETAMIDE)*		10-26-17	82 FR 49504	10/26/2017	I
FUB–AMB, MMB– FUBINACA (METHYL 2-(1-(4-FLUOROBENZYL)-1HINDAZOLE-3-CARBOXAMIDO)-3-METHYLBUTANOATE*		11-03-17	82 FR 51154	11/3/2017	I
CYCLOPROPYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLCYCLOPROPANECARBOXAMIDE)*		01-04-18	83 FR 469	1/4/2018	I
MT-45 (1-CYCLOHEXYL-4-(1,2-DIPHENYLETHYL)PIPERAZINE))		12-13-17	82 FR 58557	1/12/2018	I
N-(2-FLUOROPHENYL)-2-METHOXY-N-(1-PHENETHYLPIPERIDIN-4-YL)ACETAMIDE (OCFENTANIL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(4-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)BUTYRAMIDE (PARA-FLUOROBUTYRYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(4-METHOXYPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)BUTYRAMIDE (PARA-METHOXYBUTYRYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(4-CHLOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)ISOBUTYRAMIDE (PARA-CHLOROISOBUTYRYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLCYCLOPENTANECARBOXAMIDE (CYCLOPENTYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLPENTANAMIDE (VALERYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLISOBUTYRAMIDE (ISOBUTYRYL FENTANYL)*		02-01-18	83 FR 4580	2/1/2018	I
FENTANYL-RELATED SUBSTANCES, AS DEFINED IN 21 CFR 1308.11(h)*		02-06-18	83 FR 5188	2/6/2018	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLBUTANAMIDE (BUTYRYL FENTANYL)		04-20-18	83 FR 17486	4/20/2018	I
3,4-DICHLORO-N-[2-(DIMETHYLAMINO)CYCLOHEXYL]-N-METHYLBENZAMIDE (U-47700)		04-20-18	83 FR 17486	4/20/2018	I
N-(1-AMINO-3-METHYL-1-OXOBUTAN-2-YL)-1-(5-FLUOROPENTYL)-1 H-INDAZOLE-3-CARBOXAMIDE (5F-AB-PINACA)*		07-10-18	83 FR 31877	7/10/2018	I
1-(5-FLUOROPENTYL)-N-(2-PHENYLPROPAN-2-YL)-1 H-PYRROLO[2,3-B]PYRIDINE-3-CARBOXAMIDE(5FCUMYL-P7AICA)*		07-10-18	83 FR 31877	7/10/2018	I
1-(4-CYANOBUTYL)-N-(2-PHENYLPROPAN-2-YL)-1 H-INDAZOLE-3-CARBOXAMIDE (4-CN-CUMYL-BUTINACA)*		07-10-18	83 FR 31877	7/10/2018	I
NAPHTHALEN-1-YL 1-(5-FLUOROPENTYL)-1 H-INDOLE-3-CARBOXYLATE (NM2201; CBL2201)*		07-10-18	83 FR 31877	7/10/2018	I
METHYL 2-(1-(CYCLOHEXYLMETHYL)-1 H-INDOLE-3-CARBOXAMIDO)-3-METHYLBUTANOATE (MMB-CHMICA, AMB-CHMICA)*		07-10-18	83 FR 31877	7/10/2018	I
1-(1,3-BENZODIOXOL-5-YL)-2-(ETHYLAMINO)-PENTAN-1-ONE (N-ETHYLPENTYLONE, EPHYLONE)*		08-31-18	83 FR 44474	8/31/2018	I

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SUBSTANCE *Scheduled under 21 USC 811(h) **Extension of temporary control	PROPOSAL PUBLICATION DATE	FINAL ORDER PUBLICATION DATE	FEDERAL REGISTER CITATION	EFFECTIVE DATE	CSA SCHEDULE
APPROVED CANNABIDIOL DRUGS , AS DEFINED IN 21 CFR 1308.15(f)		09-28-18	83 FR 48953	9/28/2018	V
ACRYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLACRYLAMIDE)		11-29-18	83 FR 61320	11/29/2018	I
N-(4-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)ISOBUTYRAMIDE (4-FLUOROISOBUTYRYL FENTANYL)		11-29-18	83 FR 61320	11/29/2018	I
N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLFURAN-2-CARBOXAMIDE (FURANYL FENTANYL)		11-29-18	83 FR 61320	11/29/2018	I
N-(2-FLUOROPHENYL)-2-METHOXY-N-(1-PHENETHYLPIPERIDIN-4-YL)ACETAMIDE (OCFENTANIL)		11-29-18	83 FR 61320	11/29/2018	I
TETRAHYDROFURANYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLTETRAHYDROFURAN-2-CARBOXAMIDE)		11-29-18	83 FR 61320	11/29/2018	I

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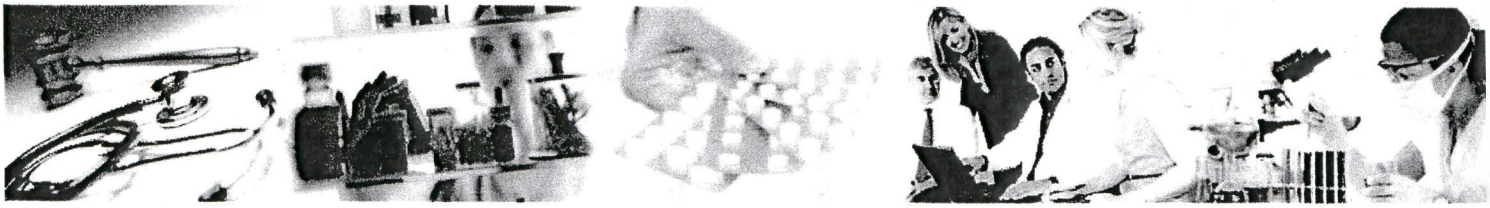

Title 21 United States Code (USC) Controlled Substances Act

SUBCHAPTER I — CONTROL AND ENFORCEMENT

Part A — Introductory Provisions

§802. Definitions

As used in this subchapter:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Drug Enforcement Administration" means the Drug Enforcement Administration in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means—

(A) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(12) The term "drug" has the meaning given that term by section 321(g)(1) of this title.

(13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term "isomer" means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term "isomer" means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term "isomer" means any optical or geometric isomer.

(15) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation,

Cases Against Doctors
Chemical Control Program
CMEA (Combat Meth Epidemic Act)
Controlled Substance Schedules
DATA Waived Physicians
Drug Disposal Information
Drug and Chemical Information
E-commerce Initiatives
Federal Agencies & Related Links
Federal Register Notices
National Prescription Drug Take Back Day
NFLIS
Publications & Manuals
Questions & Answers
Significant Guidance Documents
Synthetic Drugs
Title 21 Code of Federal Regulations
Title 21 USC Codified CSA

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compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

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

(17) The term "narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term "opiate" or "opioid" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term "opium poppy" means the plant of the species Papaver somniferum L., except the seed thereof.

(20) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(22) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term "immediate precursor" means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(24) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health and Human Services.

(25) The term "serious bodily injury" means bodily injury which involves—

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.

(26) The term "State" means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(27) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(28) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(29) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(30) The term "detoxification treatment" means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(31) The term "Convention on Psychotropic Substances" means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.

(32)(A) Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance—

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

(C) Such term does not include—

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 355 of this title to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

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Agriculture Improvement Act of 2018 "Farm Bill"

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"(b) REPORT.—Not later than 1 year after the date of enactment of the Agriculture Improvement Act of 2018, the Secretary shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report that includes—

"(1) a summary of the data sets identified under subsection (a);

"(2) a summary of the steps the Secretary would have to take to provide access to such data sets by university researchers, including taking into account any technical, privacy, or administrative considerations;

"(3) a summary of safeguards the Secretary employs when providing access to data to university researchers;

"(4) a summary of appropriate procedures to maximize the potential for research benefits while preventing any violations of privacy or confidentiality; and

"(5) recommendations for any necessary authorizations or clarifications of Federal law to allow access to such data sets to maximize the potential for research benefits.".

SEC. 12619. CONFORMING CHANGES TO CONTROLLED SUBSTANCES ACT.

(a) IN GENERAL.—Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) is amended—

(1) by striking "(16) The" and inserting "(16)(A) Subject to subparagraph (B), the"; and

(2) by striking "Such term does not include the" and inserting the following:

"(B) The term 'marihuana' does not include—

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

"(ii) the".

(b) TETRAHYDROCANNABINOL.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)), is amended in subsection (c)(17) by inserting after "Tetrahydrocannabinols" the following: ", except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946)".

Speaker of the House of Representatives.

Vice President of the United States and President of the Senate.

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FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds

For Immediate Release

December 20, 2018

Statement

Today, the Agriculture Improvement Act of 2018 was signed into law. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as cannabis (*Cannabis sativa L.*), and derivatives of cannabis with extremely low (less than 0.3 percent on a dry weight basis) concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC). These changes include removing hemp from the Controlled Substances Act, which means that it will no longer be an illegal substance under federal law.

Just as important for the FDA and our commitment to protect and promote the public health is what the law *didn't* change: Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. In doing so, Congress recognized the agency's important public health role with respect to all the products it regulates. This allows the FDA to continue enforcing the law to protect patients and the public while also providing potential regulatory pathways for products containing cannabis and cannabis-derived compounds.

We're aware of the growing public interest in cannabis and cannabis-derived products, including cannabidiol (CBD). This increasing public interest in these products makes it even more important with the passage of this law for the FDA to clarify its regulatory authority over these products. In short, we treat products containing cannabis or cannabis-derived compounds as we do any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of the source of the substance, including whether the substance is derived from a plant that is classified as hemp under the Agriculture Improvement Act. To help members of the public understand how the FDA's requirements apply to these products, the FDA has maintained a **webpage**

(/NewsEvents/PublicHealthFocus/ucm421168.htm) with answers to frequently asked questions, which we intend to update moving forward to address questions regarding the Agriculture Improvement Act and regulation of these products generally.

In view of the proliferation of products containing cannabis or cannabis-derived substances, the FDA will advance new steps to better define our public health obligations in this area. We'll also continue to closely scrutinize products that could pose risks to consumers. Where we believe consumers are being put at risk, the FDA will warn consumers and take enforcement actions.

In particular, we continue to be concerned at the number of drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds. Among other things, the FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce. This is the same standard to which we hold any product marketed as a drug for human or animal use. Cannabis and cannabis-derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases (such as cancer, Alzheimer's disease, psychiatric disorders and diabetes) are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns, as it may keep some patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases.

Additionally, it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug.

We'll take enforcement action needed to protect public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and are being marketed in violation of the FDA's authorities. The FDA has sent **warning letters (/NewsEvents/PublicHealthFocus/ucm484109.htm)** in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

While products containing cannabis and cannabis-derived compounds remain subject to the FDA's authorities and requirements, there are pathways available for those who seek to lawfully introduce these products into interstate commerce. The FDA will continue to take steps to make the pathways for the lawful marketing of these products more efficient.

These pathways include ways for companies to seek approval from the FDA to market with therapeutic claims a human or animal drug that is derived from cannabis. For example, in June 2018, the FDA approved a drug, **Epidiolex (/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm)**, that contains cannabis-derived CBD for the treatment of seizures associated with two rare and severe forms of epilepsy. That approval was based on adequate and well-controlled clinical studies, which gives prescribers confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

In addition, pathways remain available for the FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement. Although such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing use of a pharmaceutical ingredient in a food or dietary supplement. We are taking new steps to evaluate whether we should pursue such a process. However, the FDA would only consider doing so if the agency were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients.

It should also be noted that some foods are derived from parts of the hemp plant that may not contain CBD or THC, meaning that their addition to foods might not raise the same issues as the addition of drug ingredients like CBD and THC. We are able to advance the lawful marketing of three such ingredients today. We are announcing that the agency has completed our evaluation of three **Generally Recognized as Safe (/Food/NewsEvents/ConstituentUpdates/ucm628910.htm)** (GRAS) notices related to hulled hemp seeds, hemp seed protein and hemp seed oil and that the agency had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for these uses without food additive approval, provided they comply with all other requirements and do not make disease treatment claims.

Given the substantial public interest in this topic and the clear interest of Congress in fostering the development of appropriate hemp products, we intend to hold a public meeting in the near future for stakeholders to share their experiences and challenges with these products, including information and views related to the safety of such products.

We'll use this meeting to gather additional input relevant to the lawful pathways by which products containing cannabis or cannabis-derived compounds can be marketed, and how we can make these legal pathways more predictable and efficient. We'll also solicit input relevant to our regulatory strategy related to existing products, while we continue to evaluate and take action against products that are being unlawfully marketed and create risks for consumers.

At the same time, we recognize the potential opportunities that cannabis or cannabis-derived compounds could offer and acknowledge the significant interest in these possibilities. We're committed to pursuing an efficient regulatory framework for allowing product developers that meet the requirements under our authorities to lawfully market these types of products.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

Lyndsay Meyer (mailto:lyndsay.meyer@fda.hhs.gov)
240-402-5345

Mark J. Hardy

From: Levi Andrist <landrist@gagroup.law>
Sent: Monday, November 12, 2018 2:40 PM
To: Mark J. Hardy
Cc: Amy Lunde; Joel Gilbertson
Subject: Sativex

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Hi, Mark,

I hope you had a great Veterans Day weekend!

I'm reaching out on behalf of Greenwich Biosciences, which as you know as of very lately has brought Epidiolex to market. We've already had some patient outreach, so even in our low-population state, there is strong interest, which makes the state's proactive approach that much more impactful!

Greenwich has another drug named Sativex for which it is looking to proactively reschedule out of schedule 1 pending federal action/rescheduling. Here is some background for context:

- *Trade Name*: Sativex
- *Ingredients*: 2.7 mg delta-9-tetrahydrocannabinol (THC) and 2.5 mg cannabidiol (CBD) from Cannabis sativa L
- *Therapeutic Indications*: 4.1
    - Outside the US - Currently not approved my the US FDA
    - Sativex is indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.
- *FDA Process*: Greenwich is meeting with the FDA to determine what additional data the FDA would require before Greenwich can file an NDA. Greenwich is hoping to file a "rolling" NDA submission in 2019.

I'd greatly appreciate your insights as we look to the 2019 session, and, of course, am hopeful you'd consider including similar language from your 2017 CSA update bill relating to Epidiolex in your 2019 CSA update bill.

Many thanks, as always, Mark; I look forward to hearing from you.

Best,
Levi

Levi Andrist
GA Group, PC
1661 Capitol Way
Bismarck, ND 58501
(701) 240-3372
landrist@gagroup.law
www.gagroup.law

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Gabapentin (Neurontin®)

2-[1-(aminomethyl) cyclohexyl] acetic acid

October 2018
DEA/DC/DP/DPE

Introduction:

Gabapentin is a prescription medication approved by the Food and Drug Administration (FDA) for the treatment of neuropathic pain and epileptic disorders. It is currently marketed in capsule, tablet and oral solution formulations. In recent years however, gabapentin has been increasingly encountered by law enforcement, documented in national crime lab reports, reported to poison control centers and diverted for illicit use.

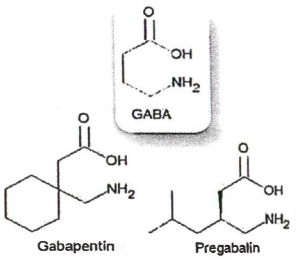
Licit Uses:

According to the FDA-approved product label, gabapentin is used clinically in the management of postherpetic neuralgia in adults and as an adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization in adults and pediatric patients 3 years and older with epilepsy.

From 2011 through 2017, annual total prescriptions for gabapentin steadily increased over two-fold from 2,965,784 in 2011 to 6,722,145 (IMS Health™). Gabapentin is available in various dosage forms and strengths including capsule strengths of 100, 300 and 400 milligrams, tablet strengths of 600 and 800 milligrams and the oral liquid form is typically produced as a 250 milligrams/5 mL solution.

Chemistry:

The chemical structures for gabapentin [1-(aminomethyl) cyclohexaneacetic acid], gamma-aminobutyric acid (GABA) and pregabalin are shown below. Gabapentin closely resembles pregabalin, a Schedule V drug under the Controlled Substances Act in its chemical structure and pharmacological activity.



The chemical structure of gabapentin is derived from the addition of a lipophilic cyclohexyl group to the backbone of GABA. Gabapentin is a crystalline substance and freely soluble in water, alkaline and acidic solutions.

Pharmacology:

The exact mechanisms through which gabapentin exerts its analgesic and antiepileptic actions are unknown, However, according to the information from the FDA approved label for gabapentin drug product, gabapentin has no effect on GABA binding, uptake or degradation. In-vitro studies have shown gabapentin binds to auxiliary α2-δ subunits of voltage-gated Ca^{2+} channels on neurons thereby resulting in a decrease in neuronal excitability.

At clinically therapeutic doses (900-3600 mg/day), gabapentin does not bind to $GABA_A$ or $GABA_B$ receptors, nor does it bind to benzodiazepine sites.

FDA-approved product label for gabapentin mentions adverse reactions such as dizziness, somnolence (drowsiness), peripheral edema (swelling), ataxia (incoordination), fatigue and nystagmus (involuntary rapid eye movement). According to a published study which analyzed online information from 32 websites, gabapentin use, similar to pregabalin, is associated with sedative and/or psychedelic effects.

Illicit Uses:

Gabapentin has been encountered in postmortem toxicology reports as indicated by data from the American Association of Poison Control Centers (AAPCC). According to the 2016 annual report of AAPCC's National Poison Data System (NPDS), gabapentin was detected in a total of 168 fatalities from 2012 to 2016. Of those cases, gabapentin was the primary cause of death in 23 individuals. Total exposure calls as a result of gabapentin increased from 5,889 in 2012 to 20,064 in 2016 for a total of 72,283. The single substance exposure involving gabapentin alone increased from 2,141 in 2012 to 7,024 in 2016. Additionally, according to the Drug Abuse Warning Network (DAWN), emergency department (ED) visit rates (per 100,000 population) for gabapentin rose from 2.7 in 2004 to 4.9 in 2011.

User Population:

In a cohort of 503 adults reporting nonmedical use of pharmaceuticals (and not enrolled in treatment facilities for such illicit use) in Appalachian Kentucky, 15% of respondents reported using gabapentin specifically to "get high". This number represented a 165% increase compared to one year prior and a 2,950% increase from 2008 respondents within the same cohort. In a 2013 online survey distributed to 1,500 respondents from the United Kingdom aged 16 to 59 years, 1.1% self-reported lifetime prevalence of gabapentin misuse.

Illicit Distribution:

STARLiMS, a web-based, commercial laboratory information management system, and the System to Retrieve Information from Drug Evidence (STRIDE), federal databases for seized drugs analyzed by DEA forensic laboratories, and the National Forensic Laboratory Information System (NFLIS), a system that collects drug analysis information from state, local, and other federal forensic laboratories contain 28 (STARLiMS and STRIDE combined data) and 2,219 reports, respectively for gabapentin in 2016. This number represents approximately a 6.75 and 6.5-fold increase respectively from reports in 2007. Additionally, the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) system, a prescription drug abuse/misuse and diversion monitoring system that collects geographically-specific data, indicate that 407 cases of gabapentin diversion were reported in 41 states between 2002 and 2015. The rates of diversion steadily increased from 0.0 in 2002 to 0.027 cases per 100,000 population in 2015. Published evidence also indicates that gabapentin is commonly offered for sale online from numerous websites.

Control Status

Gabapentin is not currently controlled under the Controlled Substances Act of 1970.

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BROOKINGS

FixGov

The Farm Bill, hemp legalization and the status of CBD: An explainer

John Hudak Friday, December 14, 2018

This week, Congress agreed to the final version of the 2018 Farm Bill, and President Trump is expected to sign the legislation within days. But this is not your typical farm bill. While it provides important agricultural and nutritional policy extensions for five years, the most interesting changes involve the cannabis plant. Typically, cannabis is not part of the conversation around farm subsidies, nutritional assistance, and crop insurance. Yet, this year, Senate Majority Leader Mitch McConnell's strong support of and leadership on the issue of hemp has thrust the cannabis plant into the limelight.

For a little bit of background, hemp is defined in the legislation as the cannabis plant (yes, the same one that produces marijuana) with one key difference: hemp cannot contain more than 0.3 percent of THC (the compound in the plant most commonly associated with getting a person high). In short, hemp can't get you high. For decades, federal law did not differentiate hemp from other cannabis plants, all of which were effectively made illegal in 1937 under the Marihuana Tax Act and formally made illegal in 1970 under the Controlled Substances Act—the latter banned cannabis of any kind.

It's true that hemp policy in the United States has been drastically transformed by this new legislation. However, there remain some misconceptions about what, exactly, this policy change does.

Hemp is legal in the United States—with serious restrictions

The allowed pilot programs to study hemp (often labeled "industrial hemp") that were approved by both the U.S. Department of Agriculture (USDA) and state departments of agriculture. This allowed small-scale expansion of hemp cultivation for limited purposes. The 2018 Farm Bill is more expansive. It allows hemp cultivation broadly, not simply pilot programs for studying market interest in hemp-derived products. It explicitly allows the transfer of hemp-derived products across state lines for commercial or other purposes. It also puts no restrictions on the sale, transport, or possession of hemp-derived products, so long as those items are produced in a manner consistent with the law.

However, the new Farm Bill does not create a completely free system in which individuals or businesses can grow hemp whenever and wherever they want. There are numerous restrictions.

First, as noted above, hemp cannot contain more than 0.3 percent THC, per section 10113 of the Farm Bill. Any cannabis plant that contains more than 0.3 percent THC would be considered non-hemp cannabis—or marijuana—under federal law and would thus face no legal protection under this new legislation.

Second, there will be significant, shared state-federal regulatory power over hemp cultivation and production. Under section 10113 of the Farm Bill, state departments of agriculture must consult with the state's governor and chief law enforcement officer to devise a plan that must be submitted to the Secretary of USDA. A state's plan to license and regulate hemp can only commence once the Secretary of USDA approves that state's plan. In states opting not to devise a hemp regulatory program, USDA will construct a regulatory program under which hemp cultivators in those states must apply for licenses and comply with a federally-run program. This system of shared regulatory programming is similar to options states had in other policy areas such as health insurance marketplaces under ACA, or workplace safety plans under OSHA—both of which had federally-run systems for states opting not to set up their own systems.

Third, the law outlines actions that are considered violations of federal hemp law (including such activities as cultivating without a license or producing cannabis with more than 0.3 percent THC). The law details possible punishments for such violations, pathways

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for violators to become compliant, and even which activities qualify as felonies under the law, such as repeated offenses.

Ultimately, the Farm Bill legalizes hemp, but it doesn't create a system in which people can grow it as freely as they can grow tomatoes or basil. This will be a highly regulated crop in the United States for both personal and industrial production.

Hemp research remains important

One of the goals of the 2014 Farm Bill was to generate and protect research into hemp. The 2018 Farm Bill continues this effort. Section 7605 re-extends the protections for hemp research and the conditions under which such research can and should be conducted. Further, section 7501 of the Farm Bill extends hemp research by including hemp under the Critical Agricultural Materials Act. This provision recognizes the importance, diversity, and opportunity of the plant and the products that can be derived from it, but also recognizes an important point: there is a still a lot to learn about hemp and its products from commercial and market perspectives. Yes, farmers—legal and illegal—already know a lot about this plant, but more can and should be done to make sure that hemp as an agricultural commodity remains stable.

Hemp farmers are treated like other farmers

Under the 2018 Farm Bill hemp is treated like other agricultural commodities in many ways. This is an important point. While there are provisions that heavily regulate hemp, and concerns exist among law enforcement—rightly or wrongly—that cannabis plants used to derive marijuana will be comingled with hemp plants, this legislation makes hemp a mainstream crop. Several provisions of the Farm Bill include changes to existing provisions of agricultural law to include hemp. One of the most important provisions from the perspective of hemp farmers lies in section 11101. This section includes hemp farmers' protections under the Federal Crop Insurance Act. This will assist farmers who, in the normal course of agricultural production, face crop termination (crop losses). As the climate changes and as farmers get used to growing this "new" product, these protections will be important.

Cannabidiol or CBD is made legal—under specific circumstances

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One big myth that exists about the Farm Bill is that cannabidiol (CBD)—a non-intoxicating compound found in cannabis—is legalized. It is true that section 12619 of the Farm Bill removes hemp-derived products from its Schedule I status under the Controlled Substances Act, but the legislation does not legalize CBD generally. As I have noted elsewhere on this blog CBD generally remains a Schedule I substance under federal law. The Farm Bill—and an unrelated, recent action by the Department of Justice—creates exceptions to this Schedule I status in certain situations. The Farm Bill ensures that any cannabinoid—a set of chemical compounds found in the cannabis plant—that is derived from hemp will be legal, *if and only if* that hemp is produced in a manner consistent with the Farm Bill, associated federal regulations, association state regulations, and by a licensed grower. All other cannabinoids, produced in any other setting, remain a Schedule I substance under federal law and are thus illegal. (The one exception is pharmaceutical-grade CBD products that have been approved by FDA, which currently includes one drug: GW Pharmaceutical's Epidiolex.)

There is one additional gray area of research moving forward. Under current law, any cannabis-based research conducted in the United States must use research-grade cannabis from the nation's sole provider of the product: the Marijuana Program at the University of Mississippi School of Pharmacy's National Center for Natural Products Research. That setup exists because of cannabis's Schedule I status.[1] However, if hemp-derived CBD is no longer listed on the federal schedules, it will raise questions among medical and scientific researchers studying CBD products and their effects, as to whether they are required to get their products from Mississippi. This will likely require additional guidance from FDA (the Food and Drug Administration who oversees drug trials), DEA (the Drug Enforcement Administration who mandates that research-grade cannabis be sourced from Mississippi), and NIDA (National Institute on Drug Abuse who administers the contract to cultivate research-grade cannabis) to help ensure researchers do not inadvertently operate out of compliance.

State-legal cannabis programs are still illegal under federal law

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The Farm Bill has no effect on state-legal cannabis programs. Over the past 22 years, 33 states have legalized cannabis for medical purposes, and over the past six years, 10 states have legalized cannabis for adult use. Every one of those programs is illegal under federal law, with no exceptions, and the Farm Bill does nothing to change that. That said, many in the advocacy community hope that the reforms to hemp policy under the Farm Bill serve as a first step toward broader cannabis reform. (Although I would argue that a soon-to-be-sworn-in Democratic House majority alongside a president with a record of pro-cannabis reform rhetoric is the more likely foundation for broader cannabis reform.)

Even CBD products produced by state-legal, medical, or adult-use cannabis programs are illegal products under federal law, both within states and across state lines. This legal reality is an important distinction for consumer protection. There are numerous myths about the legality of CBD products and their availability. Under the 2018 Farm Bill, there will be more broadly available, legal, CBD products; however, this does not mean that all CBD products are legal moving forward. Knowing your producer and whether they are legal and legitimate will be an important part of consumer research in a post-2018 Farm Bill world.

Mitch McConnell, cannabis champion?

Many advocates applaud Leader McConnell for his stewardship of these hemp provisions into the Farm Bill and his leadership on the legislation overall. That assessment is accurate. Without Mr. McConnell's efforts, the hemp provisions would never had found their way into the legislation initially. And although his position as Senate leader gave him tremendous institutional influence over the legislation, he went a step further by appointing himself to the conference committee that would bring the House and Senate together to agree on a final version.

McConnell understood much about this issue. First, he knows hemp doesn't get you high and that the drug war debate that swept up hemp was politically motivated, rather than policy-oriented. Second, Kentucky—the leader's home state—is one of the best places to cultivate hemp in the world, and pre-prohibition the state had a robust hemp sector. Third, the grassroots interest in this issue was growing in Kentucky, and McConnell knows that his role as Senate Majority Leader hangs in the balance in 2020, as does his Senate

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seat as he faces re-election that same year. McConnell emerges from the Farm Bill as a hemp hero, but advocates should be hesitant to label him a cannabis champion; Leader McConnell remains a staunch opponent of marijuana reform and his role in the Senate could be the roadblock of Democratic-passed legislation in the 116th Congress.

[1] Under the Controlled Substances Act, all controlled drugs fall under five schedules. Schedule I has the highest level of control, designated a substance as having no safe medical use and has a high risk of abuse or misuse. Schedule I substances are illegal under the law.

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[redacted]AL STATUS

LEGAL STATUS

Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements

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A Rule by the Drug Enforcement Administration on 09/28/2018

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Effective Date:
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21 CFR 1312

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ENHANCED CONTENT

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Docket Number:
DEA-2018-0014 (https://www.regulations.gov/docket?D=DEA-2018-0014)

Supporting/Related Materials:

ENHANCED CONTENT

PUBLISHED DOCUMENT

AGENCY:

Drug Enforcement Administration, Department of Justice.

ACTION:

Final order.

SUMMARY:

With the issuance of this final order, the Acting Administrator of the Drug Enforcement Administration places certain drug products that have been approved by the Food and Drug Administration (FDA) and which contain cannabidiol (CBD) in schedule V of the Controlled Substances Act (CSA). Specifically, this order places FDA-approved drugs that contain CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V. This action is required to satisfy the responsibility of the Acting Administrator under the CSA to place a drug in the schedule he deems most appropriate to carry out United States obligations under the Single Convention on Narcotic Drugs, 1961. Also consistent therewith, DEA is adding such drugs to the list of substances that may only be imported or exported pursuant to a permit.

DATES:

Effective September 28, 2018.

FOR FURTHER INFORMATION CONTACT:

Kathy L. Federico, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

The United States is a party to the Single Convention on Narcotic Drugs, 1961 (Single Convention), and other international conventions designed to establish effective control over international and domestic traffic in controlled substances. 21 U.S.C. 801 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=801&type=usc&link-type=html)(7). The Single Convention entered into force for the United States on June 24, 1967, after the Senate gave its advice and

consent to the United States' accession. *See* Single Convention, 18 U.S.T. 1407. The enactment and enforcement of the Controlled Substances Act (CSA) are the primary means by which the United States carries out its obligations under the Single Convention.[1] Various provisions of the CSA directly reference the Single Convention. One such provision is 21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html)(d)(1), which relates to scheduling of controlled substances.

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As stated in subsection 811(d)(1), if control of a substance is required "by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by [subsections 811(a) or 812(b)] and without regard to the procedures prescribed by [subsections 811(a) and (b)]." This provision is consistent with the Supremacy Clause of the U.S. Constitution (art. VI, sec. 2), which provides that all treaties made under the authority of the United States "shall be the supreme Law of the Land." In accordance with this constitutional mandate, under section 811(d)(1), Congress directed the Attorney General (and the Administrator of DEA, by delegation) [2] to ensure that compliance by the United States with our nation's obligations under the Single Convention is given top consideration when it comes to scheduling determinations.

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Section 811(d)(1) is relevant here because, on June 25, 2018, the Food and Drug Administration (FDA) announced that it approved a drug that is subject to control under the Single Convention. Specifically, the FDA announced that it approved the drug Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm)*. Epidiolex is an oral solution that contains cannabidiol (CBD) extracted from the cannabis plant. This is the first FDA-approved drug made from the cannabis plant.[3] Now that Epiodiolex has been approved by the FDA, it has a currently accepted medical use in treatment in the United States for purposes of the CSA. Accordingly, Epidiolex no longer meets the criteria for placement in schedule I of the CSA. *See* 21 U.S.C. 812 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=812&type=usc&link-type=html)(b) (indicating that while substances in schedule I have no currently accepted medical use in treatment in the United States, substances in schedules II-V do); *see also United States* v. *Oakland Cannabis Buyers' Cooperative,* 532 U.S. 483, 491-92 (2001) (same). DEA must therefore take the appropriate scheduling action to remove the drug from schedule I.

In making this scheduling determination, as section 811(d)(1) indicates, it is necessary to assess the relevant requirements of the Single Convention. Under the treaty, cannabis, cannabis resin, and extracts and tinctures of cannabis are listed in Schedule I.[4] The cannabis plant contains more than 100 cannabinoids. Among these are tetrahydrocannabinols (THC) and CBD.[5] Material that contains THC and CBD extracted from the cannabis plant falls within the listing of extracts and tinctures of cannabis for purposes of the Single Convention.[6] Thus, such material, which includes, among other things, a drug product containing CBD extracted from the cannabis plant, is a Schedule I drug under the Single Convention.

Parties to the Single Convention are required to impose a number of control measures with regard to drugs listed in Schedule I of the Convention. These include, but are not limited to, the following:

- Limiting exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of such drugs. Article 4.

- Furnishing to the International Narcotics Control Board (INCB) annual estimates of, among other things, quantities of such drugs to be consumed for medical and scientific purposes, utilized for the manufacture of other drugs, and held in stock. Article 19.
- Furnishing to the INCB statistical returns on the actual production, utilization, consumption, imports and exports, seizures, and stocks of such drugs during the prior year. Article 20.
- Requiring that licensed manufacturers of such drugs obtain quotas specifying the amounts of such drugs they may manufacture to prevent excessive production and accumulation beyond that necessary to satisfy legitimate needs. Article 29.
- Requiring manufacturers and distributors of such drugs to be licensed. Articles 29 & 30.
- Requiring medical prescriptions for the dispensing of such drugs to patients. Article 30.
- Requiring importers and exporters of such drugs to be licensed and requiring each individual importation or exportation to be predicated on the issuance of a permit. Article 31.
- Prohibiting the possession of such drugs except under legal authority. Article 33.
- Requiring those in the legitimate distribution chain (manufacturers, distributors, scientists, and those who lawfully dispense such drugs) to keep records that show the quantities of such drugs manufactured, distributed, dispensed, acquired, or otherwise disposed of during the prior two years. Article 34.

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Because the CSA was enacted in large part to satisfy United States obligations under the Single Convention, many of the CSA's provisions directly implement the foregoing treaty requirements. None of the foregoing obligations of the United States could be satisfied for a given drug if that drug were removed entirely from the CSA schedules. At least one of the foregoing requirements (quotas) can only be satisfied if the drug that is listed in Schedule I of the Single Convention is also listed in schedule I or II of the CSA because, as 21 U.S.C. 826 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=826&type=usc&link-type=html) indicates, the quota requirements generally apply only to schedule I and II controlled substances.

The permit requirement warrants additional explanation. As indicated above, the Single Convention obligates parties to require a permit for the importation and exportation of drugs listed in Schedule I of the Convention. This permit requirement applies to a drug product containing CBD extracted from the cannabis plant because, as further indicated above, such a product is a Schedule I drug under the Single Convention. However, under the CSA [7] and DEA regulations, the import/export permit requirement does not apply to all controlled substances. Rather, a permit is required to import or export any controlled substance in schedule I and II as well as certain controlled substances in schedules III, IV, and V. *See* 21 U.S.C. 952 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=952&type=usc&link-type=html) and 953; 21 CFR 1312.11 (/select-citation/2018/09/28/21-CFR-1312.11), 1312.12, 1312.21, 1312.22. Thus, in deciding what schedule is most appropriate to carry out the United States' obligations under the Single Convention with respect to the importation and exportation of Epidiolex, I conclude there are two options:

(i) Control the drug in schedule II, which will automatically require an import/export permit under existing provisions of the CSA and DEA regulations or

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(ii) control the drug in schedule III, IV, or V, and simultaneously amend the regulations to require a permit to import or export Epidiolex.

It bears emphasis that where, as here, control of a drug is required by the Single Convention, the DEA Administrator "shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, *without regard to the findings required by [21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-*

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type=html) (a) or 812(b)] and without regard to the procedures prescribed by [21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html) (a) or (b)]." 21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html)(d)(1) (emphasis added). Thus, in such circumstances, the Administrator is not obligated to request a medical and scientific evaluation or scheduling recommendation from the Department of Health and Human Services (HHS) (as is normally done pursuant to section 811(b)).[8] Nonetheless, DEA did seek such an evaluation and recommendation from HHS with respect to the Epidiolex formulation. In responding to that request, HHS advised DEA that it found the Epidiolex formulation to have a very low potential for abuse and, therefore, recommended that, if DEA concluded that control of the drug was required under the Single Convention, Epidiolex should be placed in schedule V of the CSA.[9] Although I am not required to consider this HHS recommendation when issuing an order under section 811(d)(1), because I believe there are two legally viable scheduling options (listed above), both of which would satisfy the United States' obligations under the Single Convention, I will exercise my discretion and choose the option that most closely aligns to the HHS recommendation. Namely, I am hereby ordering that the Epidiolex formulation (and any future FDA-approved generic versions of such formulation made from cannabis) be placed in schedule V of the CSA.

As noted, this order placing the Epidiolex formulation in schedule V will only comport with section 811(d)(1) if all importations and exportations of the drug remain subject to the permit requirement. Until now, since the Epidiolex formulation had been a schedule I controlled substance, the importation of the drug from its foreign production facility has always been subject to the permit requirement. To ensure this requirement remains in place (and thus to prevent any lapse in compliance with the requirements of the Single Convention), this order will amend the DEA regulations (21 CFR 1312.30 (/select-citation/2018/09/28/21-CFR-1312.30)) to add the Epidiolex formulation to the list of nonnarcotic schedule III through V controlled substances that are subject to the import and export permit requirement.

Finally, a brief explanation is warranted regarding the quota requirement in connection with the Single Convention. As indicated above, for drugs listed in Schedule I of the Convention, parties are obligated to require that licensed manufacturers of such drugs obtain quotas specifying the amounts of such drugs they may manufacture. The purpose of this treaty requirement is to prevent excessive production and accumulation beyond that necessary to satisfy legitimate needs. Under this scheduling order, the United States will continue to meet this obligation because the bulk cannabis material used to make the Epidiolex formulation (as opposed to the FDA-approved drug product in finished dosage form) will remain in schedule I of the CSA and thus be subject to all applicable quota provisions under 21 U.S.C. 826 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=826&type=usc&link-type=html).[10]

Requirements for Handling FDA-Approved Products Containing CBD

As noted, until now, Epidiolex has been a schedule I controlled substance. By virtue of this order, Epidiolex (and any generic versions of the same formulation that might be approved by the FDA in the future) will be a schedule V controlled substance. Thus, all persons in the distribution chain who handle Epidiolex in the United States (importers, manufacturers, distributors, and practitioners) must comply with the requirements of the CSA and DEA regulations relating to schedule V controlled substances. As further indicated, any material, compound, mixture, or preparation *other than Epidiolex* that falls within the CSA definition of marijuana set forth in 21 U.S.C. 802 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=802&type=usc&link-type=html)(16), including any

non-FDA-approved CBD extract that falls within such definition, remains a schedule I controlled substance under the CSA.[11] Thus, persons who handle such items will continue to be subject to the requirements of the CSA and DEA regulations relating to schedule I controlled substances.

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Regulatory Analyses

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control of a drug is required by the United States' obligations under the Single Convention. 21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html)(d)(1). Under such circumstances, the Attorney General must "issue an *order* controlling such drug under the schedule he deems most appropriate to carry out such obligations," without regard to the findings or procedures otherwise required for scheduling actions. *Id.* (emphasis added). Thus, section 811(d)(1) expressly requires that this type of scheduling action not proceed through the notice-and-comment rulemaking procedures governed by the Administrative Procedure Act (APA), which generally apply to scheduling actions; it instead requires that such scheduling action occur through the issuance of an "order."

Although the text of section 811(d)(1) thus overrides the normal APA considerations, it is notable that the APA itself contains a provision that would have a similar effect. As set forth in 21 U.S.C. 553 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=553&type=usc&link-type=html)(a)(1), the section of the APA governing rulemaking does not apply to a "foreign affairs function of the United States." An order issued under section 811(d)(1) may be considered a foreign affairs function of the United States because it is for the express purpose of ensuring that the United States carries out its obligations under an international treaty.

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Executive Order 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in Executive Order 13563 (/executive-order/13563) (Improving Regulation and Regulatory Review), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This order is not an Executive Order 13771 (/executive-order/13771) regulatory action.

Executive Order 12988, (/executive-order/12988) Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (/executive-order/12988) to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, (/executive-order/13132) Federalism

This action does not have federalism implications warranting the application of Executive Order 13132 (/executive-order/13132). This action does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, (/executive-order/13175) Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of Executive Order 13175 (/executive-order/13175). The action does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

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Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 (https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=601&type=usc&link-type=html)-612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this order from the APA notice-and-comment rulemaking provisions. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501 (https://api.fdsys.gov/link?collection=uscode&title=44&year=mostrecent&section=3501&type=usc&link-type=html)-3521. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

As noted above, this action is an order, not a rulemaking. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, the DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (CRA), 5 U.S.C. 801 (https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=801&type=usc&link-type=html)-808.

List of Subjects

21 CFR Part 1308 (/select-citation/2018/09/28/21-CFR-1308)

- Administrative practice and procedure
- Drug traffic control
- Reporting and recordkeeping requirements

21 CFR Part 1312 (/select-citation/2018/09/28/21-CFR-1312)

- Administrative practice and procedure
- Drug traffic control
- Exports
- Imports
- Reporting requirements

For the reasons set out above, DEA amends 21 CFR parts 1308 (/select-citation/2018/09/28/21-CFR-1308) and 1312 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html), 812, 871(b), 956(b) unless otherwise noted.

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2. In § 1308.15, add paragraph (f) to read as follows:

§ 1308.15 Schedule V.

* * * * *

(f) *Approved cannabidiol drugs.* (1) A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols 7367

(2) [Reserved]

* * * * *

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

3. The authority citation for part 1312 is revised to read as follows:

Authority: 21 U.S.C. 821 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=821&type=usc&link-type=html), 871(b), 952, 953, 954, 957, 958.

4. In § 1312.30, revise the introductory text and add pargraph (b) to read as follows:

§ 1312.30 Schedule III, IV, and V non-narcotic controlled substances requiring an import and export permit.

The following Schedule III, IV, and V non-narcotic controlled substances have been specifically designated by the Administrator of the Drug Enforcement Administration as requiring import and export permits pursuant to sections 201(d)(1), 1002(b)(2), and 1003(e)(3) of the Act (21 U.S.C. 811 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=811&type=usc&link-type=html)(d)(1), 952(b)(2), and 953(e)(3)):

* * * * *

(b) A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

Dated: September 21, 2018.

Uttam Dhillon,

Acting Administrator.

Footnotes

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1. *See S. Rep. No. 91-613, at 4 (1969) ("The United States has international commitments to help control the worldwide drug traffic. To honor those commitments, principally those established by the Single Convention on Narcotic Drugs of 1961, is clearly a Federal responsibility."); Control of Papaver Bracteatum, 1 Op. O.L.C. 93, 95 (1977) ("[A] number of the provisions of [the CSA] reflect Congress' intent to comply with the obligations imposed by the Single Convention.").*
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2. *28 CFR 0.100 (/select-citation/2018/09/28/28-CFR-0.100).*
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3. *The drug Marinol was approved by the FDA in 1985. Marinol contains a synthetic form of dronabinol (an isomer of tetrahydrocannabinol) and thus is not made from the cannabis plant.*
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4. *The text of the Single Convention capitalizes schedules (e.g., "Schedule I"). In contrast, the text of the CSA generally refers to schedules in lower case. This document will follow this approach of using capitalization or lower case depending on whether the schedule is under the Single Convention or the CSA.*
It should also be noted that the schedules of the Single Convention operate somewhat differently than the schedules of the CSA. Unlike the CSA, the Single Convention imposes additional restrictions on drugs listed in Schedule IV that go beyond those applicable to drugs listed in Schedule I. All drugs in Schedule IV of the Single Convention are also in Schedule I of the Convention. Cannabis and cannabis resin are among the drugs listed in Schedule IV of the Single Convention.
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5. *There are numerous isomers of cannabidiol, which will be referred to here collectively as "CBD."*
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6. *Although the Single Convention does not define the term "extract," the ordinary meaning of that term would include a product, such as a concentrate of a certain chemical or chemicals, obtained by a physical or chemical process. See, e.g., Webster's Third New International Dictionary 806 (1976). Thus, the term extract of cannabis would include any product that is made by subjecting cannabis material to a physical or chemical process designed to isolate or increase the concentration of one or more of the cannabinoid constituents.*
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7. *The provisions of federal law relating to the import and export of controlled substances—those found in 21 U.S.C. 951 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=951&type=usc&link-type=html) through 971—are more precisely referred to as the Controlled Substances Import and Export Act (CSIEA). However, federal courts and DEA often use the term "CSA" to refer collectively to all provisions from 21 U.S.C. 801 (https://api.fdsys.gov/link?collection=uscode&title=21&year=mostrecent&section=801&type=usc&link-type=html) through 971 and, for ease of exposition, this document will do likewise.*
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8. *In the House Report to the bill that would become the CSA (H. Rep. No. 91-1444, at 36 (1970)), this issue is explained as follows:*
Under subsection [811(d)], where control of a drug or other substance by the United States is required by reason of its obligations under [the Single Convention], the bill does not require that the Attorney General seek an evaluation and recommendation by the Secretary of Health, Education, and Welfare, or pursue the procedures for control prescribed by the bill but he may include the drug or other substance under any of the five schedules of the bill which he considers most appropriate to carry out the obligations of the United States under the international instrument, and he may do so without making the specific findings otherwise required for inclusion of a drug or other substance in that schedule.
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9. HHS most recently updated its medical and scientific evaluation and scheduling recommendation for the Epidiolex formulation by letter to DEA dated June 13, 2018.
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10. At present, the cannabis used to make Epidiolex is grown in the United Kingdom and the drug is imported into the United States in finished dosage form.
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11. Nothing in this order alters the requirements of the Federal Food, Drug, and Cosmetic Act that might apply to products containing CBD. In announcing its recent approval of Epidiolex, the FDA Commissioner stated:
[W]e remain concerned about the proliferation and illegal marketing of unapproved CBD-containing products with unproven medical claims. . . . The FDA has taken recent actions against companies distributing unapproved CBD products. These products have been marketed in a variety of formulations, such as oil drops, capsules, syrups, teas, and topical lotions and creams. These companies have claimed that various CBD products could be used to treat or cure serious diseases such as cancer with no scientific evidence to support such claims.
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611047.htm (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611047.htm).
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HB1113 amendments - addressing the potential discrepancy with HB1349 in referencing NDCC Chapter 4.1

Page 1, line 17: remove "-18-01"

Page 7, line 23: remove "-18-01"