2nd Agenda

CONTROLLED SUBSTANCES ADVISORY COMMITTEE MEETING

November 12, 2013 - 4:00 p.m.

Room 474 (Fourth Floor)
Heber M. Wells Building
160 E. 300 S. Salt Lake City, Utah
This agenda is subject to change up to 24 hours prior to the meeting.

ADMINISTRATIVE BUSINESS:

1. Call Meeting to Order/Sign Per Diem
2. Review and approval of September 9, 2013 minutes

DISCUSSION ITEMS:

4:00 p.m. – Presentation and discussion regarding THC for medical use:

- Representative Froerer
- Laura Warburton

4:50 p.m. – Review Draft Legislation

5:10 p.m. – Reports:

- Law enforcement
- State crime lab
- Health departments and hospitals
- Utah Poison Control
- Medical Examiner
- National trends and policies

2014 MEETING SCHEDULE – Tentatively set for:

- January 14, 2014, 4:00 p.m.
- March 22, 2014, 4:00 p.m.
- May 20, 2014, 4:00 p.m.
- September 2, 2014, 4:00 p.m.
- October 7, 2014, 4:00 p.m.

Note: In compliance with the Americans with Disabilities Act, individuals needing special accommodations (including auxiliary communicative aids and services) during this meeting should notify, Dave Taylor, ADA Coordinator, at least three working days prior to the meeting. Division of Occupational & Professional Licensing, 160 East 300 South, Salt Lake City, Utah 84115, 801-530-6628 or toll-free in Utah only 866-275-3675.

Guests - Please sign

Date: 11-12-13

Controlled Substance Advisory Committee

NAME: (Please Print)	REPRESENTING
Patrice Grossman	Self
Natassja Grossman	Self
Keri Beardall	self
Samantha Beardall	self
Justina Tanner	self
Rebecca Hyer	Self
Kris HANSEN	Epilepsy Assoc. of Utah
Candi Huff	Self
Jason Huff	Self
Rep Brian Greene	House of Reps
Rep C. Froerer	"
Jayme Richards	self
Eric & Barbara Kohler	self
Grant Adams	self
Chris Stock	self
Cassandra Clement	Self
Jaycee Anderson	self
Kim Phillips	self
Brandi Lacey	self
Jennifer Macfarlane	self
April McClellan	Self
[illegible]	self
[illegible]	"
Libby Milne	Utah Council for Crime Prevention & Utah DOC
Emilie Campbell	Hope 4 Children with Epilepsy
April Sintz	

Guests - Please sign

Date: ___________

Controlled Substance Advisory Committee

NAME: (Please Print)	REPRESENTING
Season Atwater	Self
Clinton Atwater	Hope 4 Children with
Julie Christensen	Hope 4 Children Epilepsy
Daina Swapp	Hope 4 Children w/epilepsy
Kylie Swapp	Hope 4 Children w/epilepsy
Jason Swapp	Hope 4 Children w/epilepsy
Mandi Cromar	" H4CE
David Cromar	"
Amie Larsen	"
Bryan Larsen	"
Lindsey Addams	"
Holly Ferrin	Epilepsy Association of Utah
[illegible] Maughan	EAU / H4CE
Kwang Park	Self.
Connor Boyack	Libertas Institute
Brad Nelson	Hope 4 Children w/epilepsy
Katie Nelson	" " "
Ron Gordon	CCJJ
Lela Weinert	Hope 4 Children
Jennifer McNair	DPS - Crime Lab
Kyle Sintz	Hope 4 Children w/ epilepsy
Cameron May	Hope 4 Children with Epilepsy
Laura & Mark Ulrich	"
Rob Timmerman	Utah Prevention Coalition Asso.
Susan Wiet, MD	[illegible]
[illegible] SLC	Mary Lou Emerson USAAV Council

CHECKLIST FOR PUBLIC MEETINGS

(Fill in the blanks to correspond to each respective board, commission, or committee.)

✓ I am David N. Sundwall, MD, Chairperson of the **Utah Controlled Substances Advisory Committee.**

✓ I would like to call this meeting of the **Utah Controlled Substances Advisory Committee** to order.

✓ It is now (time) 4:05 P.M. on **Date**

✓ This meeting is being held in the **Room Number** of the Heber M. Wells Building in Salt Lake City, Utah.

✓ In compliance with Utah's Open Meetings laws, this meeting is being recorded in its entirety.

✓ This recording is classified as a Public Record.

✓ The following Committee Members are in attendance:

	YES	NO
David N. Sundwall, MD, Chairperson	✓	
Todd C. Grey, MD		✓
Jeff Carr	✓	
~~Kristen Ries, MD~~	✓	
Glen R. Hanson, PhD, DDS phone	✓	
Jeffrey Wright, ND		✓
Alexander B. Larsen, DDS		✓
David C. Young, R.Ph	✓	
Elizabeth F. Howell, MD	✓	
Scott Reed	~~✓~~	✓
Darin M. Vercillo, MD	✓	
Blaine Winters, APRN		✓
~~Vacant~~ Dr Paul Clark	✓	

___ The following Committee Members are absent: (Refer to the above list.)

___ The following individuals representing DOPL and the Department of Commerce are in attendance:

	YES	NO
Mark B. Steinagel, Division Director		✓
Rich Oborn, Bureau Manager		✓
Lee Avery, Board Secretary		

___ If present: We welcome all visitors and interested persons at this time. Please be sure to sign the attendance report for the meeting and identify yourself before speaking.

___ As a courtesy to everyone participating in this meeting, at this time we ask for all cell phones, pagers and other electronic devices to be turned off or changed to silent mode.

___ Committee motions and votes will be recorded in the minutes.

___ Let us now proceed with the agenda.

___ End of the Meeting, It is now (time) _____ (am / pm), and this meeting is adjourned.

UNIVERSITY OF UTAH
HEALTH CARE | Pediatric Neurology

November 11, 2013

To whom it may concern

RE: "Alepsia" or Cannibidiol Oil for Utah children with severe epilepsy

Dear Colleague:

I am writing to express my strong support for Utah families seeking to make a specialized cannabis-oil product available to their children here in Utah. I am a pediatric neurologist who has cared for children with epilepsy in Utah for more than 25 years. I am the Division Director of Pediatric Neurology at the University of Utah and a member of the Child Neurology Society. Every day of my professional life I care for numerous children with uncontrolled epilepsy and specifically I care for several children with Dravet syndrome, a type of severe childhood epilepsy that has been in the news in Utah recently relevant to the medical use of cannabidiol. Therefore, I believe I am well qualified to provide an objective medical and neurological opinion on this matter.

Cannibidiol (CBD) is one of the "cannabinoids" or naturally occurring chemical elements found in the natural product Cannabis, or Marijuana. There is extensive "pre-clinical"data (meaning experimental data in animals and laboratory studies) that indicates that CBD as a chemical is effective in reducing epileptic activity, electrophysiologic disturbances analogous to epilepsy or in blocking molecular pathways that are involved in the generation of seizures or epilepsy. Thus, there is extensive and reproducible data demonstrating that, from an experimental point of view, CBD holds great promise as an antiepileptic agent.

In addition to this, there have been recently publicized cases of children with severe epilepsy who have experienced extraordinary seizure control and improvement in their quality of life from natural substances that contain high content of CBD. These substances are purposefully manufactured with high content of CBD (a non-psychoactive component of cannabis) and very low or nearly undetectable levels of tetrahydrocannabinol (THC) which is the "psychoactive" ingredient of cannabis or marijuana. However, due to the manner in which existing regulation regarding availability of cannabis products is interpreted in the United States and Utah, these non-psychoactive products

100 N. Mario Capecchi Dr.
Salt Lake City, Utah 84113
Phone (801) 587-7575
Fax (801) 587-7539

are not currently available to our Utah patients with severe epilepsy.
As a pediatric neurologist who cares for many children with severe epilepsy, I believe any product that is actually legally available in the United States and is legally taken by some of our citizens should be available to United States citizens whether they be residents of Colorado (where the CBD product is legally available) or of Utah (where currently it is not available). In this discussion, the following key points should be considered:

- **CBD oil is a natural product that is not regulated as a medication by the FDA**
- **CDB oil ("Alepsia" or "Realm Oil" and similar preparations) is very high in CBD but has THC content that is as low as or lower than other natural substances** such as hemp-based creams that currently can be legally purchased in Utah
- **CBD oil is not a psychoactive substance**; it does not "produce a high" and is not "mind-altering" in its effect.
- **CBD may be extremely effective in some cases:** The anecdotal experience of many patients and families is that CBD oil results in remarkable seizure control with improvement in quality of life. (This is despite the fact that all these children have previously been on numerous antiseizure medications with minimal benefit).
- **CBD appears to be safe:** So far, experience with CBD oil and related products containing CBD indicates that side effects are very limited or non-existent. This alone is a very unusual property for a substance that may produce remarkable seizure control.
- **CBD is not available currently in the US as a pharmaceutical product.** Thus, our patients in Utah currently cannot access this potentially extremely helpful treatment with CBD without physically moving to a state where they can be legally treated with CBD oil or where they can participate in one of two limited medium sized IND trials (which are only available currently at UCSF [California] or NYU [New York])
- **Pediatric neurologists and physicians routinely recommend substances to their patients that are not FDA-approved medications. There is no logical reason that CBD oil should not be similarly available.**

In summary, I would like to express my strong belief that CBD-based oils (referred to here in Utah as "Alepsia") should be available as soon as possible to Utah children with severe epilepsy. The substance is not psychoactive or hallucinogenic, it contains less THC than do other materials that can be legally purchased in Utah, and it has absolutely no abuse potential. In Utah its use would be supervised by careful and knowledgeable physicians for the benefit of their patients. It is critical that safe and reasonable options for the treatment

of children with severe epilepsy be available in Utah as they are in other states. Otherwise, as a community we would be making the decision to limit access of our children to a potentially life-improving therapy.

Please feel free to contact me if I can provide additional information.

Sincerely yours,

Francis M. Filloux, M.D.
Chief, Division of Pediatric Neurology
The Glenn and Ben Schmidt/Edgar Chair of
Pediatric Neurology
Professor of Pediatrics, Neurology
University of Utah School of Medicine
e-mail: francis.filloux@hsc.utah.edu

Otherwise, as a community we would be making the decision to limit access of our children to a potentially life-improving therapy.

Please feel free to contact me if I can provide additional information.

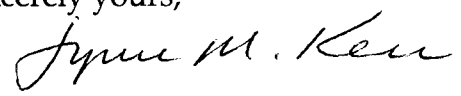
Sincerely yours,

Helen Barkan, MD, PhD
Division of Pediatric Neurology
University of Utah School of Medicine
e-mail: helen.barkan@hsc.utah.edu

Otherwise, as a community we would be making the decision to limit access of our children to a potentially life-improving therapy.

Please feel free to contact me if I can provide additional information.

Sincerely yours,



Lynne Kerr, MD, PhD
Division of Pediatric Neurology
Professor of Pediatrics, Neurology
University of Utah School of Medicine
e-mail: lynne.kerr@hsc.utah.edu

Otherwise, as a community we would be making the decision to limit access of our children to a potentially life-improving therapy.

Please feel free to contact me if I can provide additional information.

Sincerely yours,

Matthew Sweney, MD
Division of Pediatric Neurology
University of Utah School of Medicine
e-mail: helen.barkan@hsc.utah.edu

The Salt Lake Tribune

Editorial: Time for Utah to rethink medicinal cannabis.

Time to rethink medicinal cannabis

PUBLISHED: NOVEMBER 11, 2013 05:32PM
UPDATED: NOVEMBER 11, 2013 05:32PM

Leah Hogsten | The Salt Lake Tribune Piper Koozer tries rolling onto her stomach on the floor of her new Colorado apartment. Her parents, Tennesseans Annie and Justin Koozer relocated in order to obtain a cannabis oil that has proven effective at calming intractable seizures.

It is obvious that Utahns should be allowed access to a marijuana-derived medicine to limit epileptic seizures. One need only hear the stories about heroic parents to know this is not about dodging drug laws.

That is not to say the science has been proven. It's simply that the science should be allowed to go forward, including in Utah. While some of the medical marijuana industry may indeed be a smokescreen for access to recreational pot, it is impossible to dismiss the real research that has produced promising results. This past weekend Salt Lake Tribune reporter Kirsten Stewart detailed results on children in Colorado whose seizures have not been controlled by more widely prescribed pharmaceuticals. And while there is evidence of success in many young patients, there has been no evidence of harm.

The research focuses on cannabis-derived products that are higher in cannabidiol, which helps control seizures and pain, and lower in tetrahydrocannabinol (THC), which produces marijuana's high. We're talking about THC levels around the level of hemp rope. This research has been limited by the U.S. government's classification of marijuana as a Schedule 1 narcotic with no medicinal value. And access to the medicine has been limited by the fact that only 20 states have passed laws to allow medicinal marijuana use.

This has produced medical "refugees," people who move their families in search of cannabis-derived medicine. For a handful of Utah families, it raises the prospect of moving to Colorado. Some already have done it.

But there is a panel of Utah experts — the state Controlled Substance Advisory Group — that could help keep those families in Utah. The group is made up of doctors, police and prosecutors who advise lawmakers on what drugs should be legally kept from Utahns. Some of those Utah families will make their pitch to the group at its meeting Tuesday.

There is a growing body of disciplined, peer-reviewed medicinal marijuana research with double-blind studies that meet the standards of the U.S. Food and Drug Administration for evaluating drug efficacy. Indeed, this research is of a higher quality than much of the science used to justify products coming out of the nutritional supplement industry, which has resisted more FDA oversight.

The debate over full marijuana legalization is complex. Questions abound about whether consumption by minors would increase and whether alcohol abuse would decrease, among other possible outcomes. The legal and social experiments that referendums in Colorado and Washington will provide are well worth watching.

But this isn't about letting the kids have their pot. It's about letting sick kids have cannabis-derived medicine in a controlled, clinical setting. Don't let reefer madness cloud the thinking.

RCC LABS
An SBC Company

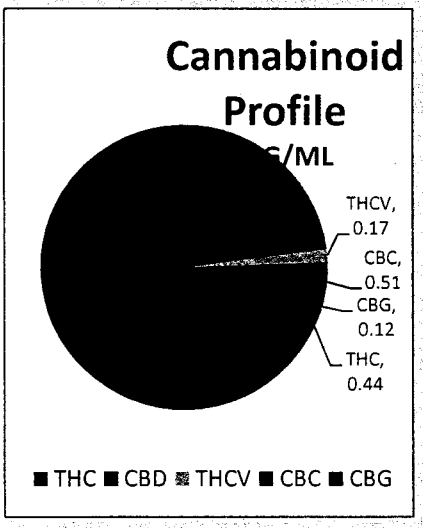
Certificate of Analysis

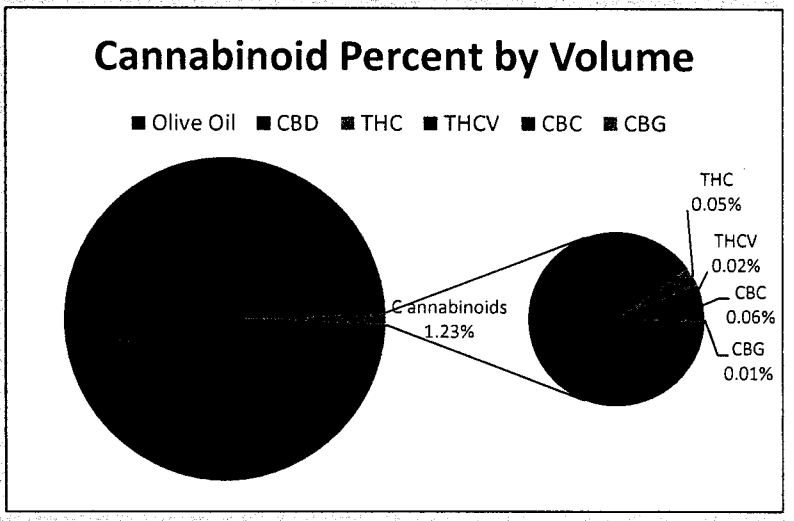
Report By: B. Rast

Analysis Date:	Product: **Alepsia**	Test ID #
9/29/2013	Sample: Olive Oil Infusion	9.29.13.f

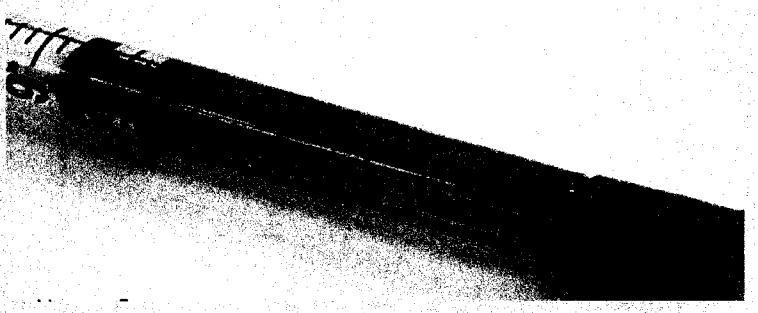
Cannabinoid Profile Assay-HPLC		
	% vol.	mg/ml
CBD	1.10%	10.12
THC	0.05%	0.42
THCV	0.02%	0.17
CBN	0.00%	0
CBC	0.06%	0.51
CBC	0.01%	0.12

Inspections:	Method:	Results:
Molds and Fungus	60x mag. Visual	Pass
Pesticides	HPLC-DAD	Pass
Residual Solvents	GC-FIL	<.01mg/g, Pass
Cannabinoid Analysis	HPLC-DAD	N/A
Terpene Analysis	HPLC-DAD	N/A





Terpene Assay	
	mg/ml
Terpinolene	<.01
Linalool	<.01
Phytol	<.01
Alpha Pinene	<.01
Caryophyllene Ox.	<.01
Beta-Caryophyllene	4.04
Myrcene	<.01
Limonene	7



United States Court of Appeals,Ninth Circuit.

HEMP INDUSTRIES ASSOCIATION USA LLC v. DRUG ENFORCEMENT ADMINISTRATION

HEMP INDUSTRIES ASSOCIATION; All-One-God-Faith, Inc., dba Dr. Bronner's Magic Soaps; Atlas Corporation; Nature's Path Foods USA Inc.; Hemp Oil Canada, Inc.; Hempzels, Inc.; Kenex Ltd.; Tierra Madre, LLC; Ruth's Hemp Foods, Inc.; Organic Consumers Association, Petitioners, v. DRUG ENFORCEMENT ADMINISTRATION, Respondent.

Hemp Industries Association; All-One-God-Faith, Inc., dba Dr. Bronner's Magic Soaps; Atlas Corporation; Nature's Path Foods USA Inc.; Hemp Oil Canada, Inc.; Hempzels, Inc.; Kenex Ltd.; Tierra Madre, LLC; Ruth's Hemp Foods, Inc.; Organic Consumers Association, Petitioners, v. Drug Enforcement Administration, Respondent.

Nos. 03-71366, 03-71693.

Argued and Submitted Sept. 17, 2003. -- February 06, 2004

Before SCHROEDER, Chief Judge, B. FLETCHER, and KOZINSKI, Circuit Judges.

Joseph E. Sandler, Sandler Reiff & Young, Washington, D.C. and Patrick Goggin, San Francisco, CA, for the petitioners-appellants.Daniel Dormont, Senior Attorney, Drug Enforcement Administration, Washington, D.C., for the respondent-appellee.

OPINION

Appellants manufacture, distribute, or sell comestible items containing oil or sterilized seeds from "hemp"-a species of plant within the genus Cannabis. They challenge two Drug Enforcement Administration ("DEA") regulations that, taken together, would ban the sale or possession of such items even if they contain only non-psychoactive trace amounts of tetrahydrocannabinols ("THC"). The DEA asserts that natural, as well as synthetic, THC is included in Schedule I of the Controlled Substances Act ("CSA"). We have previously held that the definition of "THC" in Schedule I refers only to synthetic THC, and that any THC occurring naturally within Cannabis is banned only if it falls within the Schedule I definition of "marijuana."[1] We reiterate that ruling here: in accordance with Schedule I, the DEA's relevant rules and regulations may be enforced only insofar as they ban the presence of marijuana or synthetic THC.

I. BACKGROUND

Appellants' business activities include importing and distributing sterilized hemp seed and oil and cake derived from hemp seed, and manufacturing and selling food and cosmetic products made from hemp seed and oil.[2] On October 9, 2001, the DEA published what it labeled an "Interpretive Rule" stating that "any product that contains any amount of THC is a schedule I controlled substance." Interpretation of Listing of THC in Schedule I, 66 Fed.Reg. 51530, 51533 (Oct. 9, 2001). This rule would have banned the possession and sale of Appellants' products. On the same day, the DEA proposed two rules that subsequently became final on publication in the Federal Register on March 21, 2003. Clarification of Listing of THC in Schedule I, 68 Fed.Reg. 14114 (March 21, 2003). These rules ("Final Rules") are the subject of the instant appeal. DEA-205F amends the DEA's regulations at 21 C.F.R. § 1308.11(d)(27) so that the listing of THC in Schedule I includes natural as well as synthetic THC. DEA-206F exempts from control non-psychoactive hemp products that contain trace amounts of THC not intended to enter the human body. We stayed enforcement of the Final Rules pending disposition of this appeal.

Appellants challenged the putative Interpretive Rule in Hemp Industries Assoc. v. DEA, 333 F.3d 1082 (9th Cir.2003) ("Hemp I"). During our consideration of that case, the DEA notified us that it would soon issue the Final Rules. We set aside considering the merits of Hemp I to await them.

After their publication, we solicited briefing from both parties as to whether Hemp I was rendered moot by the publication of the Final Rules. Appellants in Hemp I argued that the case was not moot. A majority of the panel agreed. Hemp I was filed on June 30, 2003.

Hemp I addressed whether the putative Interpretive Rule was an interpretive rule or a legislative rule under the Administrative Procedure Act. That question turned primarily on whether the putative Interpretive Rule would "amend the DEA's own regulation on the coverage of naturally-occurring THC in Schedule I." Hemp I, 333 F.3d at 1088. In that context, we held that the listing of "marijuana" in Schedule I excludes

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.

Id. (quoting 21 U.S.C. § 802(16)). We held further that the listing of THC in Schedule I, as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, applied only to synthetically-created THC. We reasoned that "if naturally-occurring THC were covered under THC, there would be no need to have a separate category for marijuana, which obviously contains naturally-occurring THC. Yet Congress maintained marijuana as a separate category." Hemp I, 333 F.3d at 1089. We concluded that THC naturally-occurring within non-psychoactive hemp products did not fall under the DEA's regulation, which provided:

The Director has investigated and designates all drugs, unless exempted by regulations in this part, containing any amount of the following substances as having a potential for abuse because of their:

(3) Hallucinogenic effect:

Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity.

21 C.F.R. § 320.3(c) (1970).[3] We held that the imposition of a ban on THC occurring naturally within non-psychoactive hemp products amended the DEA's own regulations, and that doing so could be accomplished, if at all, only by a legislative rule. Hemp I, 333 F.3d at 1091. We explicitly reserved the question of the validity of the DEA's proposed legislative rules, which have become the Final Rules, until the instant case was before us. Id.

II. JURISDICTION

We have jurisdiction to review Appellants' claims that the DEA's Final Rules are invalid under 21 U.S.C. § 877, and the claim of a violation of the Regulatory Flexibility Act under 5 U.S.C. § 611.

III. ANALYSIS

Appellants offer three arguments why the Final Rules may not be enforced with respect to THC naturally-occurring in non-psychoactive hemp products. First, they argue that DEA-205F is a scheduling action-placing non-psychoactive hemp in Schedule I for the first time-that fails to follow the procedures for such actions required by the Controlled Substances Act ("CSA"). Second, they argue that the adoption of DEA 206F is arbitrary and capricious in exempting non-psychoactive hemp products intended to be eaten by animals but not those intended to be eaten by humans, when humans seeking (in vain) any psychoactive effect from these substances could easily eat either. Third, they argue that in issuing DEA-205F, the DEA violated the Regulatory Flexibility Act ("RFA"). We need not reach the latter two arguments because we agree with appellants that the DEA scheduled non-psychoactive hemp without following the required procedures.

We review federal rules and regulations under Chevron U.S.A, Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). Under Chevron's two-part test, "we must decide (1) whether the statute unambiguously forbids the Agency's interpretation, and, if not, (2) whether the interpretation, for other reasons, exceeds the bounds of the permissible." Barnhart v. Walton, 535 U.S. 212, 218, 122 S.Ct. 1265, 152 L.Ed.2d 330 (2002) (citing Chevron, 467 U.S. at 843, 104 S.Ct. 2778). While at step one we "must give effect to the unambiguously expressed intent of Congress," if "the statute is silent or ambiguous with respect to the specific issue," at step two we will "sustain the Agency's interpretation if it is based on a permissible construction" of a statute. Id. at 217-18, 122 S.Ct. 1265 (internal quotation marks omitted).

A. Procedures for Scheduling a Controlled Substance

Since under the Chevron standard we conclude that Congress did not regulate non-psychoactive hemp in Schedule I, we must consider whether the DEA followed the appropriate procedures to schedule it as a controlled substance. The DEA concedes that it did not use the following procedures spelled out in the CSA to adopt the Final Rules.

Under 21 U.S.C. § 811(a):

the Attorney General may by rule-

(1) add to such a schedule or transfer between such schedules any drug or other substance if he-

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5[5 U.S.C. §§ 551 et seq.].

21 U.S.C. § 811(a) calls for formal rulemaking procedures, as described in 5 U.S.C. §§ 556 and 557. Formal rulemaking requires hearings on the record, and section 557(c) invites parties to submit proposed findings and oppose the stated bases of tentative agency decisions, and requires the agency to issue formal rulings on each finding, conclusion, or exception on the record. We will not reproduce the entirety of the Administrative Procedure Act here; it suffices to say that the DEA did not and does not claim to have followed formal rulemaking procedures.

In addition, the DEA did not comply with § 811(a)(1)(B), because the findings required by § 812(b) were not made. Section 812(b) states:

(b) Placement on schedules; findings required. Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance.

The findings required for each of the schedules are as follows:

(1) SCHEDULE I.

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

The DEA does not purport to have met the requirements for placement of non-psychoactive hemp on Schedule I, and indeed disclaims any need to show that non-psychoactive hemp "has a high potential for abuse." Instead, the DEA argues that naturally-occurring THC in those parts of the hemp plant excluded from the definition of "marijuana" have always been included under the listing for "THC," and that it had no previous need to clarify this because the intentional use of such products in foodstuffs is relatively new within the United States. The DEA urges that under Chevron its definition of the meaning of "THC" in the CSA should be given deference. However, no deference is required because this issue is resolved at Chevron step one: the statutory language on point unambiguously precludes an interpretation of the THC definition that includes non-psychoactive hemp.

B. CSA Definitions of THC and Marijuana

Two CSA provisions are relevant to determining whether Appellants' hemp products were banned before the passage of the Final Rules: the definition of THC and the definition of marijuana. Both are unambiguous under Chevron step one: Appellants' products do not contain the "synthetic" "substances or derivatives" that are covered by the definition of THC, and non-psychoactive hemp is explicitly excluded from the definition of marijuana.

1. Statutory Definition of THC

The DEA contends that Appellants' food products may be banned as "any material compound, mixture or preparation" that "contains any quantity of" THC. See 21 C.F.R. § 1308.11(d). However, the definition of THC under the CSA includes only synthetic THC. 21 C.F.R. § 1308.11(d)(27) (defining banned THC as "[s]ynthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers.").[4] As we noted in Hemp I, with a more elaborate explanation than we will provide here:

Notably, if naturally-occurring THC were covered under THC, there would be no need to have a separate category for marijuana, which obviously contains naturally-occurring THC. Yet Congress maintained marijuana as a separate category.

Hemp I, 333 F.3d at 1089. The controlled substances listing of THC is different from the listings for DMT, mescaline, psilocybin, and psilocyn, the definitions for which are not limited to synthetic forms of the drugs. See 21 C.F.R. § 1308.11(d).

Therefore, DEA-205F may ban products that "contain[] any quantity" of THC only insofar as it does not improperly expand the definition of THC as it is used in the CSA. For the same reason, 21 U.S.C. §§ 823(f) and 841(a)(1), which disallow human consumption of Schedule I controlled substances

outside of FDA-approved, DEA-registered research, do not apply to non-psychoactive hemp products: such products do not contain a "Schedule I controlled substance" as the CSA defines it.

As we did in Hemp I, we reject the DEA's contention that the Final Rules merely "clarify that the longstanding placement of THC in schedule I includes both natural and synthetic THC." 68 Fed.Reg. 14116 (Mar. 21, 2003). The DEA's action is not a mere clarification of its THC regulations; it improperly renders naturally-occurring non-psychoactive hemp illegal for the first time.

2. Statutory Definition of Marijuana

Under 21 U.S.C. § 802(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.

The non-psychoactive hemp in Appellants' products is derived from the "mature stalks" or is "oil and cake made from the seeds" of the Cannabis plant, and therefore fits within the plainly stated exception to the CSA definition of marijuana.

Congress was aware of the presence of trace amounts of psychoactive agents (later identified as THC) in the resin of non-psychoactive hemp when it passed the 1937 "Marihuana Tax Act," and when it adopted the Tax Act marijuana definition in the CSA. As a result, when Congress excluded from the definition of marijuana "mature stalks of such plant, fiber ., [and] oil or cake made from the seeds," it also made an exception to the exception, and included "resin extracted from" the excepted parts of the plant in the definition of marijuana, despite the stalks and seeds exception.[5] 21 U.S.C. § 802(16). Congress knew what it was doing, and its intent to exclude non-psychoactive hemp from regulation is entirely clear. The DEA's Final Rules are inconsistent with the unambiguous meaning of the CSA definitions of marijuana and THC, and the DEA did not use the appropriate scheduling procedures to add non-psychoactive hemp to the list of controlled substances.

Although we have determined that non-psychoactive hemp is not banned under Schedule I, we need not determine in this proceeding whether under the current statute it could be listed if the agency were to undertake appropriate rulemaking. We hold only that the DEA did not follow the requisite proceedings for scheduling under 21 U.S.C. §§ 811(a) and 812(b). The Final Rules therefore may not be enforced with respect to THC that is found within the parts of Cannabis plants that are excluded from the CSA's definition of "marijuana" or that is not synthetic.

We find unambiguous Congress' intent with regard to the regulation of non-psychoactive hemp. Therefore, we reject the Final Rules at step one of the Chevron test and need not reach Chevron step two.[6]

IV. CONCLUSION

The DEA's Final Rules purport to regulate foodstuffs containing "natural and synthetic THC." And so they can: in keeping with the definitions of drugs controlled under Schedule I of the CSA, the Final Rules can regulate foodstuffs containing natural THC if it is contained within marijuana, and can regulate synthetic THC of any kind. But they cannot regulate naturally-occurring THC not contained within or derived from marijuana-i.e., non-psychoactive hemp products-because non-psychoactive hemp is not included in Schedule I. The DEA has no authority to regulate drugs that are not scheduled, and it has not followed procedures required to schedule a substance.

The DEA's definition of "THC" contravenes the unambiguously expressed intent of Congress in the CSA and cannot be upheld. DEA-205F and DEA-206F are thus scheduling actions that would place non-psychoactive hemp in Schedule I for the first time. In promulgating the Final Rules, the DEA did not follow the procedures in §§ 811(a) and 812(b) of the CSA required for scheduling. The amendments to 21 C.F.R. § 1308.11(d)(27) that make THC applicable to all parts of the Cannabis plant are therefore void. We grant Appellants' petition and permanently enjoin enforcement of the Final Rules with respect to non-psychoactive hemp or products containing it.

PETITION GRANTED.

FOOTNOTES

1. The Act spells this as "marihuana." We employ the modern spelling here.

2. We refer to hemp stalks, fiber, oil and cake made from hemp seed, and sterilized hemp seed itself-i.e., those substances excluded from the definition of marijuana under 21 U.S.C. § 802(16)-as "non-psychoactive hemp." A "psychoactive" substance is one "affecting the mind or behavior." Merriam-Webster Dictionary.The non-psychoactive hemp used in Appellants' products is derived from industrial hemp plants grown in Canada and in Europe, the flowers of which contain only a trace amount of the THC contained in marijuana varieties grown for psychoactive use. The hemp seed used in food products is an "achene," or small nut, that is either hulled for direct consumption or crushed for oil. It "contains 20 percent high-quality, digestible protein, which can be consumed by humans." U.S. Dept. of Agriculture, Industrial Hemp in the United States: Status and Market Potential 15 (Jan.2000), available at http://ers.usda.gov/publications/ages001e/ages001e.pdf. Hemp seed oil "has a better profile of key nutrients, such as essential fatty acids and gamma-linolenic acid, than other oils . and a similar profile of other nutrients, such as sterols and tocopherols." Thompson, Berger & Allen, Univ. of Kentucky Center for Business and Economic Research, Economic Impact of Industrial Hemp in Kentucky 7-8 (July 1998),

available at www.industrialhemp.net/pdf/hempstudy.pdf. Appellants list a wide range of current and planned commercial products that use hemp oil or seed, including roasted hulled seed, nutrition bars, tortilla chips, pretzels, beer, candy bars, margarine, sauces, dressings, and non-dairy versions of milk and cheese.

3. In 1971 the title "Tetrahydrocannabinols" and a code number were added. The regulations were later transferred from 21 C.F.R. § 320.3(c) to 21 C.F.R. § 1308.11(d)(27). The Final Rules amended 21 C.F.R. § 1308.11(d)(27) to insert the words "Meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis plant), as well as" immediately before "[s]ynthetic equivalents of the substances contained in the cannabis plant" in the section quoted above. In considering the propriety of the Final Rules, we necessarily consider the propriety of this amendment to § 1308.11(d)(27).

4. The Final Rules at issue here amend the definition of THC to include naturally-occurring THC. Because we consider here the propriety of those amendments, we quote the previous definition, which had been in effect since 1970. See supra note 3.

5. The DEA argues that because hemp seeds contain some THC, we should allow it to include hemp seeds and its derivatives as within the "exception to the exception" for the extraction of resin. Neither we nor the DEA are in any position to ignore the express exception for hemp seeds in the CSA, nor can we construe "resin" broadly to mean "seeds" as well. As the DEA informs us, the "exception to the exception" for resin was apparently included out of concern that the "active principle" in marijuana, later understood to be THC, might be derived from nonpsychoactive hemp and so be used for psychoactive purposes. We note that Congress' policy decision is still effective in prohibiting psychoactive drugs: the DEA makes no showing that extracts from parts of hemp seeds or stalks other than resin are used or could be used for psychoactive purposes.

6. Because our conclusion with respect to Chevron deference suffices to invalidate DEA-205F as applied to non-psychoactive hemp products, we need not address Appellants' Regulatory Flexibility Act arguments.

BETTY B. FLETCHER, Circuit Judge.

ROC LABS
An SBC Company

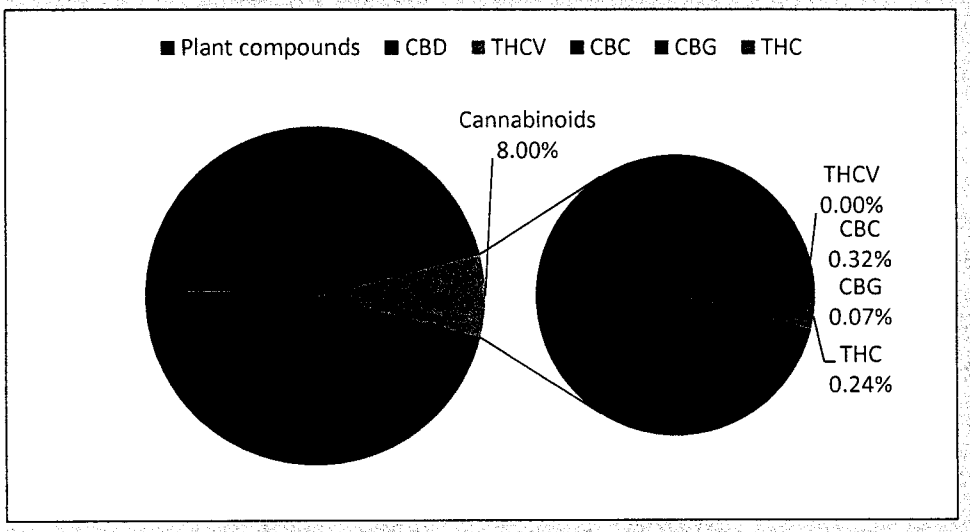
Certificate of Analysis

Report By: B. Rast

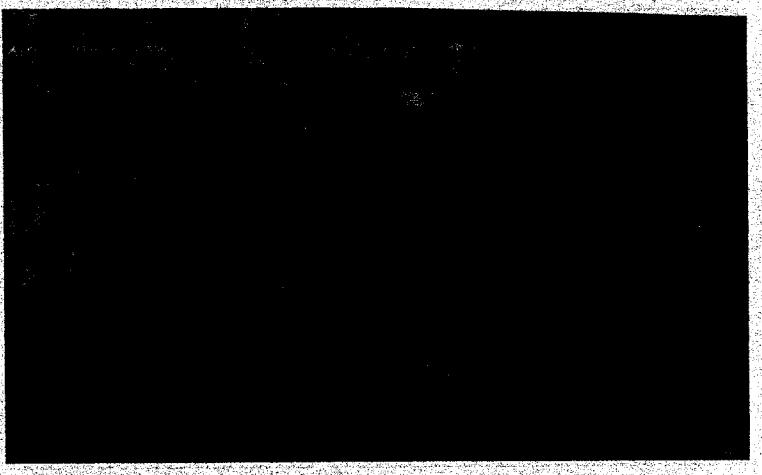
Analysis Date:	Product: Charlotte's Web	Test ID #
10/16/2013	Sample: Whole Plant	10.16.13.a

Cannabinoid Profile Assay-HPLC		
	% wt.	mg/gr
CBD	7.28%	72.8
THC	0.24%	2.41
THCV	0.09%	0.9
CBN	0.00%	0
CBC	0.32%	3.2
CBC	0.07%	0.73

Inspections:	Method:	Results:
Molds and Fungus	60x mag. Visual	Pass
Pesticides	HPLC-DAD	Pass
Cannabinoid Analysis	HPLC-DAD	N/A
Terpene Analysis	HPLC-DAD	N/A



Terpene Assay	
	mg/ml
Terpinolene	<.01
Linalool	<.01
Phytol	<.01
Alpha Pinene	<.01
Caryophyllene Ox.	<.01
Beta-Caryophyllene	28
Myrcene	<.01
Limonene	51



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CONTROL ID: 1866676

PRESENTATION TYPE: Late Breaking Submission

TITLE: WHOLE CANNABIS EXTRACT OF HIGH CONCENTRATION CANNABIDIOL MAY CALM SEIZURES IN HIGHLY REFRACTORY PEDIATRIC EPILEPSIES

AUTHORS (LAST NAME, FIRST NAME): Gedde, Margaret M.[1, 2]; Maa, Edward[3]

INSTITUTIONS (ALL): 1. Gedde Whole Health, Littleton, CO, United States.
2. Realm of Caring Foundation, Colorado Springs, CO, United States.
3. Neurology, University of Colorado School of Medicine, Aurora, CO, United States.

PRESENTER: Margaret Gedde

ABSTRACT BODY:

Rationale: Despite constant but interval advances in antiepileptic drug (AED) pipeline development, a large unmet need still exists for therapies to address medically refractory epilepsies. This is particularly challenging in some forms of devastating pediatric epilepsy syndromes (Dravet, Doose, Lennox-Gastaut). Evolving pre-clinical and early clinical research suggests that cannabidiol (CBD), a nonpsychoactive compound found in the cannabis plant, may be a potent antiepileptic agent. A botanical extract from a strain of cannabis known as Charlotte's Web (CW Realm Oil, or Realm Oil), which contains CBD at a ratio of >16:1 relative to other cannabinoids, has recently become available in Colorado for medical use.

Methods: Realm Oil is available for medical use under supervision by a Colorado treating physician in patients with appropriate state licensure for the use and possession of medical marijuana. Parents of children with severe, medically refractory epilepsy and who had received Realm Oil for at least three months were invited to participate in a survey of the effects of Realm Oil. Thirteen patients were identified that met criteria. Data regarding epilepsy diagnosis, general epidemiological information, baseline and post treatment seizure frequency, side effects, and average dose, were collected in a deidentified manner. Simple statistics were used for data analysis.

Results: 11 of 13 patients (parents) completed interviews. 4 were diagnosed with Doose syndrome, 2 with Dravet syndrome, 1 with Lennox-Gastaut syndrome, 1 with metachromatic leukodystrophy, 1 with cortical dysplasia and 2 with idiopathic epilepsy. Patients had received an average of 10 AEDs in their lifetime.

11 of 11 patients (100%) reported reduction in weekly frequency of motor type seizures (generalized tonic-clonics plus tonic, myoclonic and atonic seizures). Of the 11, 8 reported 98-100% reduction, 1 reported 75%

reduction, and 2 reported 20-45% reduction in weekly seizures at the end of three months. Seven of 11 patients achieved this reduction within the first month of treatment. At three months, 5 of the 11 patients (50%) were seizure-free. Of the 2 patients who have received Realm Oil for more than one year, both have continued to enjoy the seizure reduction attained after 3 months of Realm Oil treatment.

Average therapeutic dose of CBD (as administered in Realm Oil) ranged from 4 to 12 mg/kg/day, in 2 or 3 divided doses.

Realm Oil was remarkably well tolerated. Side effects included sedation and unsteadiness, similar to the profile of existing medications.

Conclusions: While this sample size is small, high concentration CBD extract (Realm Oil) appears to reduce seizures in a highly refractory pediatric epilepsy population. Despite its being a whole plant extract, no psychotropic effects were reported, in keeping with previous clinical studies involving CBD. We propose that the results of this survey can inform the design of a large, randomized, double blinded, placebo-controlled efficacy trial to investigate Realm Oil as an adjunctive therapy in highly refractory pediatric epilepsies.

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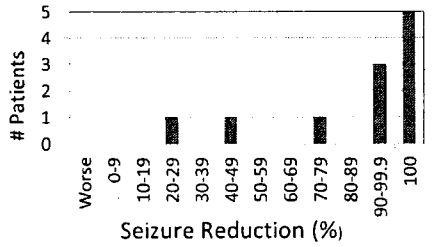

Reduction in Weekly Seizures at Three Months of
High Concentration Cannabidiol Extract (Realm Oil) Therapy

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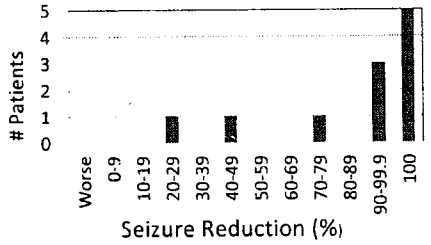


Reduction in Weekly Seizures at Three Months of
High Concentration Cannabidiol Extract (Realm Oil) Therapy

Presenters:

E. Jason Broome, B.Sc. (Hon), M.Sc.

10 years in pharmaceutical industry serving in a variety of roles including sales, marketing, business development, business unit management, government affairs and global advisory teams. Jason left the pharma business in 2008 to establish Kian Consulting Inc., an investment firm focused on partnering with key stakeholders in the healthcare sector to broaden the delivery of medical products and services. In the 4 years that followed Jason established three additional companies: Co-founder, Secretary and Director of Operations of the Kelowna Regional Fertility Centre Inc. a specialized Ob/Gyn Centre of Fertility Excellence in the Interior of British Columbia. Founder, President and Chief Operating Officer of Invaron Pharmaceuticals Inc., a specialty pharmaceutical company focusing on the importation and distribution of niche drugs and medical devices. Co-founder, Chief Executive Officer the Canadian Fertility Institute Inc., a company focused on broadening the delivery of fertility care. Jason now is the acting Chief Operational Officer for the Stanley Brothers Group of Companies.

Josh Stanley

Key player in the legislative efforts that brought the first true regulation in the medical marijuana industry to Colorado and set the standard for true medicinal cannabis by starting Colorado's first true political action committee and 501c4; the Medical Marijuana Industry Group. He led the break-through discovery leading to a cannabis plant with the lowest content of THC and the highest content of CBD in the world. Josh is also the founder of the *Realm of Caring*, a 501c3 non-profit organization committed to providing observational research studies through non-smoke able forms of cannabis treatment for many variations of approved medical conditions in the State of Colorado with a very high rate of success. Josh works with National Geographic on his own television series called American Weed that follows him through his observational research studies and patient successes, and conducts a weekly radio show that airs the world over to promote the responsible uses of cannabis as an alternative form of treatment.

Mark J. Rosenfeld, M.S., Ph.D.
CEO, Science, Member of the Board Isa Scientific - strategic partner for the Stanley Brothers Group of Companies.

- Founder & CEO, Seroctin Research & Technology, Inc.
- Founder & CEO, Impact Diagnostics, Inc. – Grant Life Sciences, Inc.
- Chief Science Officer. DxNA
- Advisor, China Health Ministry
- US Delegate, Joint United Nations FAO/IAEA Committee on Transboundary Diseases (Bird Flu)
- Associate, Katan Associates
- 1 IPO & 1 acquisition

Joel Stanley

Co founder at Realm of Caring Foundation and CEO of ROC Labs, has been instrumental in the development of Alepsia and quality control mechanisms for all Realm of Caring patient medicine in Colorado. He currently oversees the production of CBD medicine from start to finish. Joel's Colorado based companies are sole supplier for more than 100 pediatric epilepsy patients, with almost 200 more to start by the end of 2013. Joel also works closely with Realm of Caring physician and scientist affiliates to move forward important research and development of Cannabidiol medications.

Utah Controlled Substance Advisory Committee Meeting

Alepsia

Hemp Based Supplement

Realm of Caring

RealmOfCaringFoundation.org

Hemp

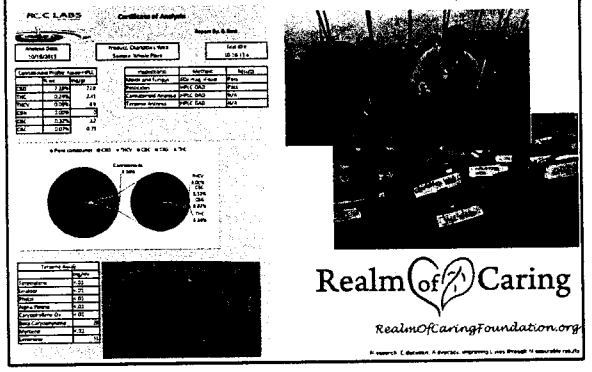
- Three genetic strains

- Ultra low THC level
  - Less than 0.3%
    - *US Department of Agriculture standards for hemp*
  - Used worldwide as human food

Realm of Caring

RealmOfCaringFoundation.org

Charlotte's Web is Hemp



Realm of Caring

RealmOfCaringFoundation.org

Alepsia is Hemp Oil

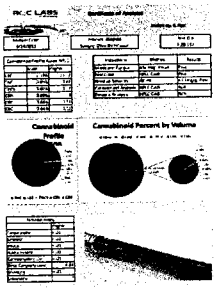
- Ethanol extraction
- Suspension in Olive Oil

- 10mg/mL CBD (1% solution) & 0.5mg/mL THC (<0.3% solution)

Realm of Caring

RealmOfCaringFoundation.org

Alepsia is Hemp Oil

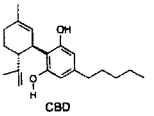


Realm of Caring

RealmOfCaringFoundation.org

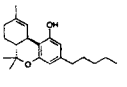
Main Cannabinoids

- CBD
  - Non – Psychoactive
  - Established safety profile*
  - Apparent medicinal benefits



CBD

- THC
  - minute Non-Psychoactive levels in Alepsia™



THC

Realm of Caring

RealmOfCaringFoundation.org

Gloss D, Vickrey B. Cannabinoids for epilepsy. Cochrane Database of Systematic Reviews 2012; Issue 8. Art. No.: CD009270. DOI: 10.1002/14651858.CD009270.pub2

Good Manufacturing Practices

- Compliant with Colorado Regulations
- Tested
- Released as per CoA

Realm of Caring
RealmOfCaringFoundation.org

Realm of Caring

- Not for Profit
- Client support
- Client information (dosing)
- Data collection on different disease states
- Discounted/free Alepsia™
- http://realmofcaringfoundation.org

Realm of Caring
RealmOfCaringFoundation.org

DEPARTMENT OF THE ATTORNEY GENERAL
Legislation Brief

2013 H5325 - S0454
An Act Relating to Food and Drugs – Uniform Controlled Substances Act
Representative McNamara - Senator Archambault

Current Law

- Currently, only eight chemical compounds relating to synthetic drugs are listed in Schedule I (five synthetic marijuana and three synthetic cathinones).

Legislation

- Amends §§21-28-1.02 ("Definitions") and 21-28-2.08 ("Contents of Schedules") to add chemical compound classes of synthetic cannabinoids and synthetic cathinones to Schedule I.
    - Synthetic cannabinoids are structurally different from THC, but act in similar ways to affect the cannabinoid system in the brain. They are usually sold combined with dried herbs intended for smoking and can be purchased in a range of quantities at local stores throughout our neighborhoods. Synthetic cannabinoids are commonly known as "Spice," "Kronic," "Northern Lights," "K2," "Zeus," "Puff," "Tai High," "Aroma" and "Magic Dragon".
        - Known compound classes:
            - Benzylpiperazine (BZP);
            - Trifluoromethylphenylpiperazine (TFMPP);
            - 1,1-Dimethylheptyl-11-hydroxytetrahydrocannabinol (HU-210);
            - 1-Butyl-3-(1-naphthoyl)indole;
            - 1-Pentyl-3-(1-naphthoyl)indole; dexanabinol (HU-211).
            - naphthoylindoles,
            - phenylacetylindoles,
            - benzoylindoles,
            - cyclohexylphenols,
            - naphthylmethylindoles,

- naphthoylpyrroles,
- or naphthylmethylindenes.

- Synthetic cathinones are similar to ephedrine and amphetamines and induce the release of dopamine from striatal preparations that are relabeled either with dopamine or its precursors. Synthetic cathinones is commonly known as "bath salts."

  - Synthetic cathinones are any chemical compound, not including bupropion, structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in one (1) or more of the following ways:

    - 1) by substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one (1) or more other univalent substituents;

    - by substitution at the 3-position with an acyclic alkyl substituent;

    - by substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups, or by inclusion of the 2-amino nitrogen atom in a cyclic structure.

The act also includes into Schedule I any synthetic cannabinoids or synthetic cathinones that are not approved by the U.S. FDA or, if they are approved, are not dispensed or possessed in accordance with state or federal law.

Policy

- Synthetic drugs are an emerging and dangerous trend of drug use, literally the new frontier, and little is known about there ever changing chemical makeup.

- Many synthetic drug chemicals and compounds are not included in Schedule I, therefore individuals can possess, sell, distribute or manufacture these drugs without criminal consequence.

  - Manufacturers of these drugs continually alter, ever so slightly, the chemical composition used to make these products, so once one chemical compound is made illegal, the manufacturer alters the compound slightly and lawfully places the drug back in the marketplace.

- Synthetic drug use by our youth and how to get these drugs off convenience store shelves has been a top priority for my office and fellow Attorneys General across the country.

- After a thorough review of statutes and proposed legislation across the country, I am confident that this legislation will help protect our youth from the dangers synthetic drugs.

- There are hundreds of cannabinoids and cathinones compounds and more are being produced all the time.

- Manufacturers are constantly changing the chemical compositions of these drugs to produce new "legal" products due to the fact that Schedule I currently lists only individual chemical compounds.

- This act adds the known chemical compound classes of synthetic cannabinoids and synthetic cathinones to Schedule I that will capture any alterations made by the manufacturer.

- This is the approach of banning synthetic drugs taken by Kentucky and New Jersey.

- What is known about synthetic drugs is that it provides its users with a cocaine or methamphetamine like high that has been unseen in any other drug and has no real warnings as to its potential effects on its user.

    - The medical effects on its users are extreme and include both psychological and physical side effects including, but not limited to, suicidal tendencies, extreme anxiety, paranoia, hallucinations, increased blood pressure, increased heart rates and chest pain.

    - Even more troubling is that there are currently no tests to see if a person has used synthetic drugs, so the only way we know of its use is by self reporting.

Due to the undetectable nature of synthetic drugs, its emergence has been unprecedented and the effects on its users have been devastating. Adding these chemical compound classes to Schedule I will ensure this dangerous and deadly product remains an illegal substance and will give law enforcement the proper tools to address deal the possession, sale and manufacture of synthetic drugs.

Synthetic Drugs
Legislative Update

Rhode Island Department of Attorney General
Peter F. Kilmartin, Attorney General

Synthetic Drugs

- Generally, they are man-made substances that are created entirely in a laboratory.

Synthetic Drugs

- Natural products distorted by chemistry.
  - Cathinones, amphetamine like stimulant found in the Khat plant.
- Analogs of Scheduled compounds.
- Legitimate products that are misused
  - Piperazines are cattle de-wormers that have psychotropic effects.

Analogs

- A primary chemical compound may be illegal, but the analog is not necessarily illegal.
- There can be many different analogs of the primary chemical compound.
- An analog is similar in structure to the primary chemical compound and has similar effects.

Synthetic Drugs

- Synthetic Drugs are marketed in a way to deceive and evade authorities.
  - I.e., Not for Human Consumption.
- Available via the Internet, convenience stores, gas stations and head shops.

Classes of Synthetic Drugs

- Cannabinoids
- Cathinones

Synthetic Cannabinoids (i.e. Synthetic Marijuana)

- Structurally different from THC, but act in similar ways to affect the cannabinoid system in the brain.
- Common Names: "Spice," "Potpourri," "Incense," "Kronic," "Northern Lights," "K2," "Zeus," "Puff," "Tai High," "Aroma" and "Magic Dragon".

Synthetic Cannabinoids (i.e. Synthetic Marijuana)

- Liquid in its original form.
- Usually sold combined with dried herbs intended for smoking.

Synthetic Cathinones

- A powerful stimulant much like meth, but it is hallucinogenic (unlike meth).
- Chemicals related to cathinone that is an amphetamine-like stimulant found naturally in the Khat plant.

Synthetic Cathinones

- Powder in form; Can be smoked, Injected or inhaled.
- Marketed as "Bath Salts", "Plant Food," or "Jewelry Cleaner."
- Common Names: "Ivory Wave," "Bloom," "Cloud Nine," "Lunar Wave," "Vanilla Sky," "White Lightning," and "Scarface."

Legislative Attention

- General Assembly started considering Synthetic Drug legislation in 2011.

- Bills were filed in both the House and the Senate adding the following compounds to Schedule I classified as stimulants:
  - Methylenedioxymethcathinone (Methylone)
  - Methylenedioxypyrovalerone (MDPV)
  - Methylmethcathinone (Mephedrone)
  - Methoxymethcathinone
  - Fluoromethcathinone

2011 – Compounds Added

- In 2011, DEA used emergency rulemaking powers to add 8 known synthetic drug compounds to Schedule I.
  - 3 Cathinone compounds and 5 Cannabinoid compounds.
- In response, General Kilmartin and Dr. Fine began the State emergency rule making process to add those compounds to Rhode Island's Schedule I.

Cathinones Added

- 4-methyl-N-methylcathinone (Other name: mephedrone)
- 3,4-methylenedioxy-N-methlycathinone (Other name: methylone)
- 3,4-methylenedioxypyrovalerone (Other name: MDPV)

Cannabinoids Added

- 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497)
- 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanoland CP-47,497 c8 homologue
- 1-Butyl-3-(1 naphthoyl)indole, (JWH-073)
- 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)
- 1-Pentyl-3-(1-napthoyl)indole, (JWH-018 and AM678)

- Emergency rules took effect in January of 2012.
- The General Assembly codified these changes in 2012 H7496. R.I. Gen. Laws §21-28-2.08(f)(3)-(5) and (g).

Legislative Challenges

- There are hundreds of cannabinoids and cathinones compounds and more are being produced rapidly.
- Manufacturers constantly alter the chemical compositions of these drugs to produce new "legal" products due to the fact that Schedule I contained only individual chemical compounds.

- General Kilmartin reviewed statutes and proposed legislation across the country.
- Final decision was to add compound classes to Schedule I, rather than going back the General Assembly each year to add new compounds.
- This is the approach of banning synthetic drugs taken by Kentucky and New Jersey.

2013 H5325/S0454

- The act added "synthetic drug" to the definition of a "controlled substance." §§21-28-1.02 ("Definitions").
- A definition of "synthetic drug" was added to the law.
- "Synthetic drug" is defined as any synthetic cannabionoid or piperazines or any synthetic cathinone as provided for in Schedule I. 21-28-2.08 ("Contents of Schedules")

Legislative Effect

- The known chemical compound classes of synthetic cannabinoids and synthetic cathinones are included in Schedule I.
- These compound classes will capture any alterations made by the manufacturer.

Legislative Effect

- If a drug is seized and the chemical compound that it tests positive for is included in a Scheduled chemical compound class, it is illegal.
- Possessing, manufacturing or delivering such a compound, will be charged and prosecuted as a Schedule I offense.

Synthetic Cannabinoids Compounds

- Unless specifically excepted, any chemical compound which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law, that contain:

Known Cannabinoid Compounds

- Benzylpiperazine (BZP);
- Trifluoromethylphenylpiperazine (TFMPP);
- 1,1-Dimethylheptyl-11-hydroxytetrahydrocannabinol (HU-210);
- 1-Butyl-3-(1-naphthoyl)indole;
- 1-Pentyl-3-(1-naphthoyl)indole;
- Dexanabinol (HU-211).

Or any compound in the following structural classes:

- Naphthoylindoles
- Phenylacetylindoles
- Benzoylindoles
- Cyclohexylphenols
- Naphthylmethylindoles
- Naphthoylpyrroles
- Naphthylmethylindenes

Cathinone Compounds

- Any compound, not including bupropion, structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in one (1) or more of the following ways:

- By substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one (1) or more other univalent substituents;
- By substitution at the 3-position with an acyclic alkyl substituent; or
- By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups, or by inclusion of the 2-amino nitrogen atom in a cyclic structure.

CATCHALL

- Any synthetic cannabinoid or synthetic cathinone is a Schedule I drug if it is not approved by the U.S. FDA or, if it is approved, it is not dispensed or possessed in accordance with state or federal law.

Takeaways

- By definition, these are Schedule I drugs.
- Charge whatever you would for any other Schedule I drug.
- No matter what they are named, it is not marijuana and not epsom salt. These are very dangerous chemicals named to evade the law.

Questions?

Joee Lindbeck
jlindbeck@riag.ri.gov
274-4400 x 2424

Thank You!!!

Chapter 326
2013 -- H 5325 SUBSTITUTE A
Enacted 07/15/13

AN ACT
RELATING TO FOOD AND DRUGS - UNIFORM CONTROLLED SUBSTANCES ACT

Introduced By: Representatives McNamara, Corvese, Cimini, Bennett, and Silva
Date Introduced: February 07, 2013

It is enacted by the General Assembly as follows:

SECTION 1. Sections 21-28-1.02 and 21-28-2.08 of the General Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" are hereby amended to read as follows:

21-28-1.02. Definitions. -- Unless the context otherwise requires, the words and phrases as defined in this section are used in this chapter in the sense given them in the following definitions:

(1) "Administer" refers to the direct application of controlled substances to the body of a patient or research subject by:

(i) A practitioner, or in his or her presence by his or her authorized agent; or

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

(2) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, wholesaler, distributor, or dispenser; except that these terms do not include a common or contract carrier or warehouse operator, when acting in the usual and lawful course of the carrier's or warehouse operator's business.

(3) "Apothecary" means a registered pharmacist as defined by the laws of this state and, where the context requires, the owner of a licensed pharmacy or other place of business where controlled substances are compounded or dispensed by a registered pharmacist; and includes registered assistant pharmacists as defined by existing law, but nothing in this chapter shall be construed as conferring on a person who is not registered as a pharmacist any authority, right, or privilege that is not granted to him or her by the pharmacy laws of the state.

(4) "Automated data processing system" means a system utilizing computer software and hardware for the purposes of record keeping.

(5) "Computer" means programmable electronic device capable of multi-functions, including, but not limited to, storage, retrieval, and processing of information.

(6) "Control" means to add a drug or other substance or immediate precursor to a schedule under this chapter, whether by transfer from another schedule or otherwise.

(7) "Controlled substance" means a drug, substance, ~~or~~ immediate precursor, or synthetic drug in schedules I -- V of this chapter. The term shall not include distilled spirits, wine, or malt beverages, as those terms are defined or used in chapter 1 of title 3, nor tobacco.

(8) "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 of them, of a manufacturer, distributor, or dispenser, other than the person or persons who in fact manufactured, distributed, or dispensed the substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, the other manufacturer, distributor, or dispenser, or which substance is falsely purported to be or represented to be one of the controlled substances by a manufacturer, distributor, or dispenser.

(9) "CRT" means cathode ray tube used to impose visual information on a screen.

(10) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a controlled substance or imitation controlled substance, whether or not there exists an agency relationship.

(11) "Department" means the department of health of this state.

(12) "Depressant or stimulant drug" means:

(i) A drug which contains any quantity of:

(A) Barbituric acid or derivatives, compounds, mixtures, or preparations of barbituric acid; and

(B) "Barbiturate" or "barbiturates" includes all hypnotic and/or somnifacient drugs, whether or not derivatives of barbituric acid, except that this definition shall not include bromides and narcotics.

(ii) A drug which contains any quantity of:

(A) Amphetamine or any of its optical isomers;

(B) Any salt of amphetamine and/or desoxyephedrine or any salt of an optical isomer of amphetamine and/or desoxyephedrine, or any compound, mixture, or preparation of them.

(iii) A drug which contains any quantity of coca leaves. "Coca leaves" includes cocaine, or any compound, manufacture, salt, derivative, mixture, or preparation of coca leaves, except derivatives of coca leaves, which do not contain cocaine, ecgonine, or substance from which cocaine or ecgonine may be synthesized or made.

(iv) Any other drug or substance which contains any quantity of a substance which the attorney general of the United States, or the director of health, after investigation, has found to have, or by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system.

(13) "Director" means the director of health.

(14) "Dispense" means to deliver, distribute, leave with, give away, or dispose of a controlled substance to the ultimate user or human research subject by or pursuant to the lawful order of a practitioner, including the packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(15) "Dispenser" is a practitioner who delivers a controlled substance to the ultimate user or human research subject.

(16) "Distribute" means to deliver (other than by administering or dispensing) a controlled substance or an imitation controlled substance and includes actual constructive, or attempted transfer. "Distributor" means a person who so delivers a controlled substance or an imitation controlled substance.

(17) "Downtime" means that period of time when a computer is not operable.

(18) "Drug addicted person" means a person who exhibits a maladaptive pattern of behavior resulting from drug use, including one or more of the following: impaired control over drug use; compulsive use; and/or continued use despite harm, and craving.

(19) "Drug Enforcement Administration" means the Drug Enforcement Administration United States Department of Justice or its successor.

(20) "Federal law" means the Comprehensive Drug Abuse Prevention and Control Act of 1970, (84 stat. 1236)(see generally 21 U.S.C. section 801 et seq.), and all regulations pertaining to that federal act.

(21) "Hardware" means the fixed component parts of a computer.

(22) "Hospital" means an institution as defined in chapter 17 of title 23.

(23) "Imitation controlled substance" means a substance that is not a controlled substance, which by dosage unit, appearance (including color, shape, size, and markings), or by representations made, would lead a reasonable person to believe that the substance is a controlled substance and, which imitation controlled substances contain substances which if ingested, could be injurious to the health of a person. In those cases when the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance" (for example in the case of powder or liquid), the court or authority concerned should consider, in addition to all other logically relevant factors, the following factors as related to "representations made" in determining whether the substance is an "imitation controlled substance":

(i) Statement made by an owner, possessor, transferor, recipient, or by anyone else in control of the substance concerning the nature of the substance, or its use or effect.

(ii) Statements made by the owner, possessor, or transferor, to the recipient that the substance may be resold for substantial profit.

(iii) Whether the substance is packaged in a manner reasonably similar to packaging of

illicit controlled substances.

(iv) Whether the distribution or attempted distribution included an exchange of or demand for money or other property as consideration, and whether the amount of the consideration was substantially greater than the reasonable value of the non-controlled substance.

(24) "Immediate precursor" means a substance:

(i) Which the director of health 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;

(ii) Which is an immediate chemical intermediary used or likely to be used in the manufacture of those controlled substances; and

(iii) The control of which is necessary to prevent, curtail, or limit the manufacture of that controlled substance.

(25) "Laboratory" means a laboratory approved by the department of health as proper to be entrusted with controlled substances and the use of controlled substances for scientific and medical purposes and for the purposes of instruction.

(26) "Marijuana" means all parts of the plant cannabis sativa L., whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin, but shall not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of mature stalks, (except the resin extracted from it), fiber, oil or cake, or the sterilized seed from the plant which is incapable of germination.

(27) "Manufacture" means the production, preparation, propagation, cultivation, compounding, or processing of a drug or other substance, including an imitation controlled 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 the substance or labeling or relabeling of its container in conformity with the general laws of this state except by a practitioner as an incident to his or her administration or dispensing of the drug or substance in the course of his or her professional practice.

(28) "Manufacturer" means a person who manufactures but does not include an apothecary who compounds controlled substances to be sold or dispensed on prescriptions.

(29) "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:

(i) Opium and opiates.

(ii) A compound, manufacture, salt, derivative, or preparation of opium or opiates.

(iii) A substance (and any compound, manufacture, salt, derivative, or preparation of it) which is chemically identical with any of the substances referred to in paragraphs (i) and (ii) of this subdivision.

(iv) Any other substance which the attorney general of the United States, or his or her successor, or the director of health, after investigation, has found to have, and by regulation designates as having, a potential for abuse similar to opium and opiates.

(30) "Official written order" means an order written on a form provided for that purpose by the Drug Enforcement Administration under any laws of the United States making provision for an official form, if order forms are authorized and required by federal law, and if no order form is provided then on an official form provided for that purpose by the director of health.

(31) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability.

(32) "Opium poppy" means the plant of the species papaver somniferum L., except the seeds of the plant.

(33) "Ounce" means an avoirdupois ounce as applied to solids and semi-solids, and a fluid ounce as applied to liquids.

(34) "Person" means any corporation, association, partnership, or one or more individuals.

(35) "Physical dependence" means a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

(36) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(37) "Practitioner" means:

(i) A physician, osteopath, dentist, chiropodist, veterinarian, scientific investigator, or other person licensed, registered or permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

(ii) A pharmacy, hospital, or other institution licensed, registered or permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

(38) "Printout" means a hard copy produced by computer that is readable without the aid of any special device.

(39) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(40) "Researcher" means a person authorized by the director of health to conduct a laboratory as defined in this chapter.

(41) "Sell" includes sale, barter, gift, transfer, or delivery in any manner to another, or to offer or agree to do the same.

(42) "Software" means programs, procedures and storage of required information data.

(43) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any synthetic cathinones as provided for in schedule I;

(44)~~(43)~~ "Ultimate user" means a person who lawfully possesses a controlled substance for his or her own use or for the use of a member of his or her household, or for administering to an animal owned by him or her or by a member of his or her household.

(45)~~(44)~~ "Wholesaler" means a person who sells, vends, or distributes at wholesale, or as a jobber, broker agent, or distributor, or for resale in any manner in this state any controlled substance.

21-28-2.08. Contents of schedules. -- Schedule I

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Opiates. - Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol
(2) Allylprodine
(3) Alphacetylmethadol
(4) Alphameprodine
(5) Alphamethadol
(6) Benzethidine
(7) Betacetylmethadol
(8) Betameprodine
(9) Betamethadol
(10) Betaprodine
(11) Clonitazene
(12) Dextromoramide
(13) Difenoxin
(14) Diampromide
(15) Diethylthiambutene
(16) Dimenoxadol
(17) Dimepheptanol
(18) Dimethylthiambutene
(19) Dioxaphetyl butyrate

(20) Dipipanone
(21) Ethylmethylthiambutene
(22) Etonitazene
(23) Extoxerdine
(24) Furethidine
(25) Hydroxypethidine
(26) Ketobemidone
(27) Levomoramide
(28) Levophenacylmorphan
(29) Morpheridine
(30) Noracymethadol
(31) Norlevorphanol
(32) Normethadone
(33) Norpipanone
(34) Phenadoxone
(35) Phenampromide
(36) Phenomorphan
(37) Phenoperidine
(38) Piritramide
(39) Proheptazine
(40) Properidine
(41) Propiram
(42) Racemoramide
(43) Trimeperidone
(44) Tilidine
(45) Alpha-methylfentanyl
(46) Beta-hydroxy-3-methylfentanyl other names:
N-[1-(2hydroxy-2-phenethyl)-3-methyl-4piperidingyl] Nphenylpropanamide
(c) Opium Derivatives. - Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:
(1) Acetorphine
(2) Acetyldihydrocodeine
(3) Benzylmorphine
(4) Codeine methylbromide
(5) Codeine-N-Oxide
(6) Cyprenorphine
(7) Desomorphine
(8) Dihydromorphine
(9) Etorphine (Except hydrochloride salt)
(10) Heroin
(11) Hydromorphinol
(12) Methyldesorphine
(13) Methylihydromorphine
(14) Morphine methylbromide
(15) Morphine methylsulfonate
(16) Morphine-N-Oxide
(17) Myrophine
(18) Nococodeine
(19) Nicomorphine
(20) Normorphine
(21) Pholcodine
(22) Thebacon
(23) Drotebanol
(d) Hallucinogenic Substances. - Unless specifically excepted or unless listed in another

schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this subsection only, the term "isomer" includes the optical, position, and geometric isomers):

(1) 3, 4-methylenedioxy amphetamine

(2) 5-methoxy-3, 4-methylenedioxy amphetamine

(3) 3, 4, 5-trimethoxy amphetamine

(4) Bufotenine

(5) Diethyltryptamine

(6) Dimethyltryptamine

(7) 4-methyl 2, 5-dimethoxyamphetamine

(8) Ibogaine

(9) Lysergic acid diethylamide

(10) Marihuana

(11) Mescaline

(12) Peyote. Meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lemair whether growing or not; the seeds of the plant; any extract from any part of the plant; and any compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or extracts.

(13) N-ethyl-3-piperidyl benzilate

(14) N-methyl-3-piperidyl benzilate

(15) Psilocybin

(16) Psilocyn

(17) Tetrahydrocannabinols. Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following: delta 1 cis or trans tetrahydrocannabinol, and their optical isomers. Delta 6 cis or trans tetrahydrocannabinol and their optical isomers. Delta 3, 4 cis or trans tetrahydrocannabinol and its optical isomer. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

(18) Thiophene analog of phencyclidine. 1-(1-(2 thienyl) cyclo-hexyl) pipiridine: 2-Thienyl analog of phencyclidine: TPCP

(19) 2,5 dimethoxyamphetamine

(20) 4-bromo-2,5-dimethoxyamphetamine, 4-bromo-2,5-dimethoxy-alpha-methylphenethyamine: 4-bromo-2,5-DMA

(21) 4-methoxyamphetamine-4-methoxy-alpha-methylphenethylaimine: paramethoxyamphetamine: PMA

(22) Ethylamine analog of phencyclidine. N-ethyl-1- phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclophexyl) ethylamine, cyclohexamine, PCE

(23) Pyrrolidine analog of phencyclidine. 1-(1-phencyclohexyl)- pyrrolidine PCPy, PHP

(24) Parahexyl; some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenz o (b,d) pyran: Synhexyl.

(e) Depressants. - Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Mecloqualone.

(2) Methaqualone.

(3) 3-methyl fentanyl (n-(ethyl-1(2-phenylethyl)-4-piperidyl)-N-phenylpropanamide.

(4) 3,4-methyl-enedioxymethamphetamine (MDMA), its optical, positional and geometric isomers, salts, and salts of isomers.

(5) 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP), its optical isomers, salts and salts of isomers.

(6) 1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (PEPAP), its optical isomers, salts

and salts of isomers.

(7) N-(1-(1-methyl-2-phenyl)ethyl-4-piperidyl)-N-phenyl-acetamide (acetyl-alpha-methylfentanyl), its optical isomers, salts and salts of isomers.

(8) N-(1-(1-methyl-2(2-thienyl)ethyl-4-piperidyl)-N-phenylpropanami de (alpha-methylthiofentanyl), its optical isomers, salts and salts of isomers.

(9) N-(1-benzyl-piperidyl)-N-phenylpropanamide (benzyl-fentanyl), its optical isomers, salts and salts of isomers.

(10) N-(1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl)-N-phenyl-propanamid e (beta-hydroxyfentanyl), its optical isomers, salts and salts of isomers.

(11) N-(3-methyl-1(2-hydroxy-2-phenyl)ethyl-4-piperidyl)-N-phenylpro panamide (beta-hydroxy-3-methylfentanyl), its optical and geometric isomers, salts and salts of isomers.

(12) N-(3-methyl)-1-(2-(2-thienyl)ethyl-4-piperidyl)-N-phenylpro- panamide (3-methylthiofentanyl), its optical and geometric isomers, salts and salts of isomers.

(13) N-(1-2-thienyl)methyl-4-piperidyl)-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers.

(14) N-(1-(2(2-thienyl)ethyl-4-piperidyl-N-phenylpropanamide (thiofentanyl), its optical isomers, salts and salts of isomers.

(15) N-[1-(2-phenylethyl)-4-piperidyl]N-(4-fluorophenyl)-propanamid e (para-fluorofentanyl), its optical isomers, salts and salts of isomers.

(16) Gamma hydroxybutyrate, HOOC-CH2-CH2-CH2OH, its optical, position, or geometric isomers, salts and salts of isomers.

(f) Stimulants. - Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Fenethylline

(2) N-ethylamphetamine

(3) 4-methyl-N-methylcathinone (Other name: mephedrone)

(4) 3,4-methylenedioxy-N-methlycathinone (Other name: methylone)

(5) 3,4-methylenedioxypyrovalerone (Other name: MDPV)

(g) Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]phenol (CP-47,497)

(2) 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]phenol (cannabicyclohexanol and CP-47,497 c8 homologue)

(3) 1-Butyl-3-(1 naphthoyl)indole, (JWH-073)

(4) 1-[2-(4-Morpholinyl)ethyl]3-(1-naphthoyl)indole (JWH-200)

(5) 1-Pentyl-3-(1-napthoyl)indole, (JWH-018 and AM678)

(h) Synthetic cannabinoids or piperazines. Unless specifically excepted, any chemical compound which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law, that contains Benzylpiperazine (BZP); Trifluoromethylphenylpiperazine (TFMPP); 1,1-Dimethylheptyl-11-hydroxytetrahydrocannabinol (HU-210); 1-Butyl-3-(1-naphthoyl)indole; 1-Pentyl-3-(1-naphthoyl)indole; dexanabinol (HU-211); or any compound in the following structural classes:

(1) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include, but are not limited, to JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, and AM-2201;

(2) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not

substituted in the phenyl ring to any extent. Examples of this structural class include, but are not limited to, JWH-167, JWH-250, JWH-251, and RCS-8;

(3) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include, but are not limited, to AM-630, AM-2233, AM-694, Pravadoline (WIN 48,098), and RCS-4;

(4) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include, but are not limited to, CP 47,497 and its C8 homologue (cannabicyclohexanol);

(5) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include, but are not limited to, JWH-175, JWH-184, and JWH-185;

(6) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include, but are not limited, to JWH-030, JWH-145, JWH-146, JWH-307, and JWH-368;

(7) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl)indene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include, but are not limited to, JWH-176; or

(8) Any other synthetic cannabinoid or piperazine which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law;

(i) Synthetic cathinones. Unless specifically excepted, any chemical compound which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law, not including bupropion, structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in one or more of the following ways:

(1) By substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituents. Examples of this class include, but are not limited to, 3,4-Methylenedioxycathinone (bk-MDA);

(2) By substitution at the 3-position with an acyclic alkyl substituent. Examples of this class include, but are not limited to, 2-methylamino-1-phenylbutan-1-one (buphedrone);

(3) By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups, or by inclusion of the 2-amino nitrogen atom in a cyclic structure. Examples of this class include, but are not limited to, Dimethylcathinone, Ethcathinone, and α -Pyrrolidinopropiophenone (α -PPP); or

(4) Any other synthetic cathinone which is not approved by the United States Food and Drug Administration or, if approved, is not dispensed or possessed in accordance with state or federal law;

Schedule II

(a) Schedule II shall consist of the drugs and other substances, by whatever official

name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Substances, vegetable origin or chemical synthesis. - Unless specifically excepted or unless listed in another schedule, any of the following substances 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:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding naloxone and its salts, and excluding naltrexone and its salts, but including the following:

(i) Raw opium
(ii) Opium extracts
(iii) Opium fluid extracts
(iv) Powdered opium
(v) Granulated opium
(vi) Tincture of opium
(vii) Etorphine hydrochloride
(viii) Codeine
(ix) Ethylmorphine
(x) Hydrocodone
(xi) Hydromorphone
(xii) Metopon
(xiii) Morphine
(xiv) Oxycodone
(xv) Oxymorphone
(xvi) Thebaine

(2) Any salt, compound, derivative, or preparation which is chemically equivalent or identical with any of the substances referred to in subdivision (1) of this subsection, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in liquid, solid, or powder form which contains the phenanthrine alkaloids of the opium poppy).

(c) Opiates. - Unless specifically excepted or unless listed in another schedule any of the following opiates, including its isomers, esters, ethers, salts; and salts of isomers, esters and, ethers whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine
(2) Anileridine
(3) Bezitramide
(4) Dihydrocodeine
(5) Diphenoxylate
(6) Fentanyl
(7) Isomethadone
(8) Levomethorphan
(9) Levorphanol
(10) Metazocine
(11) Methadone
(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid
(14) Pethidine
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid

(18) Phenaxocine
(19) Piminodine
(20) Racemethorphan
(21) Racemorphan
(22) Bulk Dextropropoxyphene (non-dosage forms)
(23) Suffentanil
(24) Alfentanil
(25) Levoalphacetylmethadol

(d) Stimulants. - Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
(2) Methamphetamine, its salts and salts of its isomers.
(3) Phenmetrazine and its salts.
(4) Methylphenidate.

(e) Depressants. - Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital
(2) Glutethimide
(3) Methyprylon
(4) Pentobarbital
(5) Phencyclidine
(6) Secobarbital
(7) Phencyclidine immediate precursors:
(i) 1-phencyclohexylamine
(ii) 1-piperidinocyclohexane-carbonitrile (PCC)
(8) Immediate precursor to amphetamine and methamphetamine: Phenylacetone. Some other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzone ketone.

Schedule III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.
(2) Chlorhexadol
(3) Lysergic acid
(4) Lysergic acid amide
(5) Sulfondiethylmethane
(6) Sulfonethylmethane
(7) Sylfonmethane
(8) Any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital, or any salt of them and one or more other active medicinal ingredients which are not listed in any schedule.
(9) Any suppository dosage form containing amobarbital, secobarbital, pentobarbital or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.
(10) Ketamine, its salts, isomers and salts of isomers. (Some other names for ketamine: (+)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone).

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts of them:

(1) Not more than one and eight tenths grams (1.8 gms.) of codeine per one hundred milliliters (100 mls.) or not more than ninety milligrams (90 mgs.) per dosage unit, with an equal

or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than one and eight tenths grams (1.8 gms.) of codeine per one hundred milliliters (100 mls.) or not more than ninety milligrams (90 mgs.) per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Not more than three hundred milligrams (300 mgs.) of dihydrocodeinone per one hundred milliliters (100 mls.) or not more than fifteen milligrams (15 mgs.) per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than three hundred milligrams (300 mgs.) of dihydrocodeinone per one hundred milliliters (100 mls.) or not more than fifteen milligrams (15 mgs.) per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than one and eight tenths grams (1.8 gms.) of dihydrocodeine per one hundred milliliters (100 mls.) or not more than ninety milligrams (90 mgs.) per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than three hundred milligrams (300 mgs.) of ethylmorphine per one hundred milliliters (100 mls.) or not more than fifteen milligrams (15 mgs.) per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than five hundred milligrams (500 mgs.) of opium per one hundred milliliters (100 mls.) or per one hundred grams (100 gms.) or not more than twenty-five milligrams (25 mgs.) per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than fifty milligrams (50 mgs.) of morphine per one hundred milliliters (100 mls.) per one hundred grams (100 gms.) with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(c) Stimulants. - Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of the isomers whenever the existence of the salts of isomers is possible within the specific chemical designation:

(1) Benzphetamine
(2) Chlorphentermine
(3) Clortermine
(4) Mazindol
(5) Phendimetrazine

(d) Steroids and hormones. - Anabolic steroids (AS) or human growth hormone (HGH), excluding those compounds, mixtures, or preparations containing an anabolic steroid that because of its concentration, preparation, mixture or delivery system, has no significant potential for abuse, as published in 21 CFR 1308.34, including, but not limited to, the following:

(1) Chlorionic gonadotropin
(2) Clostebol
(3) Dehydrochlormethyltestosterone
(4) Ethylestrenol
(5) Fluoxymesterone
(6) Mesterolone
(7) Metenolone
(8) Methandienone
(9) Methandrostenolone
(10) Methyltestosterone
(11) Nandrolone decanoate
(12) Nandrolone phenpropionate
(13) Norethandrolone
(14) Oxandrolone
(15) Oxymesterone
(16) Oxymetholone
(17) Stanozolol
(18) Testosterone propionate
(19) Testosterone-like related compounds

(20) Human Growth Hormone (HGH)

(e) Hallucinogenic substances.

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in U.S. Food and Drug Administration approved drug product. (Some other names for dronabinol: (6aR-trans)-6a, 7, 8, 10a- tetrahydro-6, 6, 9- trimethyl-3-pentyl-6H- dibenzo[b,d]yra n-1-ol,or(-)-delta-9(trans)-tetrahydrocannabinol.)

Schedule IV

(1) Barbital.

(2) Chloral betaine

(3) Chloral hydrate

(4) Ethchrovynol

(5) Ethinamate

(6) Methohexital

(7) Meprobamate

(8) Methylphenobarbital

(9) Paraldehyde

(10) Petrichloral

(11) Phenobarbital

(12) Fenfluramine

(13) Diethylpropion

(14) Phentermine

(15) Pemoline (including organometallic complexes and chelates thereof).

(16) Chlordiazepoxide

(17) Clonazepam

(18) Clorazepate

(19) Diazepam

(20) Flurazepam

(21) Mebutamate

(22) Oxazepam

(23) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts:

Dextropropoxyphene(alpha-(+)-4-dimethylamino-1,2-diphenyl-3- methyl-2-propronoxybutane).

(24) Prazepam

(25) Lorazepam

(26) Not more than one milligram (1 mg.) of difenoxin and not less than twenty-five (25) micrograms of atropine sulfate per dosage unit.

(27) Pentazocine

(28) Pipradrol

(29) SPA (-)-1-dimethylamino-1, 2-diphenylethane

(30) Temazepam

(31) Halazepam

(32) Alprazolam

(33) Bromazepam

(34) Camazepam

(35) Clobazam

(36) Clotiazepam

(37) Cloxazolam

(38) Delorazepam

(39) Estazolam

(40) Ethyl Ioflazepate

(41) Fludizaepam

(42) Flunitrazepam

(43) Haloxazolam

(44) Ketazolam

(45) Loprazolam
(46) Lormetazepam
(47) Medazepam
(48) Nimetazepam
(49) Nitrazepam
(50) Nordiazepam
(51) Oxazolam
(52) Pinazepam
(53) Tetrazepam
(54) Mazindol
(55) Triazolam
(56) Midazolam
(57) Quazepam
(58) Butorphanol
(59) Sibutramine

Schedule V

(a) Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than two hundred milligrams (200 mgs.) of codeine per 100 milliliters (100 mls.) or per one hundred grams (100 gms.).

(2) Not more than one hundred milligrams (100 mgs.) of dihydrocodeine per 100 milliliters (100 mls.) or per one hundred grams (100 gms.).

(3) Not more than one hundred milligrams (100 mgs.) of ethylmorphine per 100 milliliters (100 mls.) or per one hundred grams (100 gms.).

(4) Not more than two and five tenths milligrams (2.5 mgs.) of diphenixylate and not less than twenty-five (25) micrograms of atropine sulfate per dosage unit.

(5) Not more than one hundred milligrams (100 mgs.) of opium per one hundred milliliters (100 mls.) or per one hundred grams (100 gms.).

(b) Not more than five tenths milligrams (0.5 mgs.) of difenoxin and not less than twenty-five (25) micrograms of atropine sulfate per dosage unit.

(c) Buprenorphine

(d) Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Propylhexedrine (except as benzedrex inhaler)
(2) Pyrovalerone.

SECTION 2. This act shall take effect upon passage.

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LC00952/SUB A
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Chapter 404
2013 -- S 0454 SUBSTITUTE A
Enacted 07/15/13

A N A C T
RELATING TO FOOD AND DRUGS - UNIFORM CONTROLLED SUBSTANCES ACT

Introduced By: Senators Archambault, Cote, Lombardi, Conley, and Doyle
Date Introduced: February 28, 2013

It is enacted by the General Assembly as follows:

SECTION 1. Sections 21-28-1.02 and 21-28-2.08 of the General Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" are hereby amended to read as follows:

21-28-1.02. Definitions. -- Unless the context otherwise requires, the words and phrases as defined in this section are used in this chapter in the sense given them in the following definitions:

(1) "Administer" refers to the direct application of controlled substances to the body of a patient or research subject by:

(i) A practitioner, or, in his or her presence by his or her authorized agent; or

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

(2) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, wholesaler, distributor, or dispenser; except that these terms do not include a common or contract carrier or warehouse operator, when acting in the usual and lawful course of the carrier's or warehouse operator's business.

(3) "Apothecary" means a registered pharmacist as defined by the laws of this state and, where the context requires, the owner of a licensed pharmacy or other place of business where controlled substances are compounded or dispensed by a registered pharmacist; and includes registered assistant pharmacists as defined by existing law, but nothing in this chapter shall be construed as conferring on a person who is not registered as a pharmacist any authority, right, or privilege that is not granted to him or her by the pharmacy laws of the state.

(4) "Automated data processing system" means a system utilizing computer software and hardware for the purposes of record keeping.

(5) "Computer" means programmable electronic device capable of multi-functions, including, but not limited to, storage, retrieval, and processing of information.

(6) "Control" means to add a drug or other substance or immediate precursor to a schedule under this chapter, whether by transfer from another schedule or otherwise.

(7) "Controlled substance" means a drug, substance, ~~or~~ immediate precursor, or synthetic drug in schedules I -- V of this chapter. The term shall not include distilled spirits, wine, or malt beverages, as those terms are defined or used in chapter 1 of title 3, nor tobacco.

(8) "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 of them, of a manufacturer, distributor, or dispenser, other than the person or persons who in fact manufactured, distributed, or dispensed the substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, the other manufacturer, distributor, or dispenser, or which substance is falsely purported to be or represented to be one of the controlled substances by a manufacturer, distributor, or dispenser.

(9) "CRT" means cathode ray tube used to impose visual information on a screen.

(10) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a controlled substance or imitation controlled substance, whether or not there exists an agency relationship.

(11) "Department" means the department of health of this state.

(12) "Depressant or stimulant drug" means:

(i) A drug which contains any quantity of:

(A) Barbituric acid or derivatives, compounds, mixtures, or preparations of barbituric acid; and

(B) "Barbiturate" or "barbiturates" includes all hypnotic and/or somnifacient drugs, whether or not derivatives of barbituric acid, except that this definition shall not include bromides and narcotics.

(ii) A drug which contains any quantity of:

(A) Amphetamine or any of its optical isomers;

(B) Any salt of amphetamine and/or desoxyephedrine or any salt of an optical isomer of amphetamine and/or desoxyephedrine, or any compound, mixture, or preparation of them.

(iii) A drug which contains any quantity of coca leaves. "Coca leaves" includes cocaine, or any compound, manufacture, salt, derivative, mixture, or preparation of coca leaves, except derivatives of coca leaves, which do not contain cocaine, ecgonine, or substance from which cocaine or ecgonine may be synthesized or made.

(iv) Any other drug or substance which contains any quantity of a substance which the attorney general of the United States, or the director of health, after investigation, has found to have, or by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system.

(13) "Director" means the director of health.

(14) "Dispense" means to deliver, distribute, leave with, give away, or dispose of a controlled substance to the ultimate user or human research subject by or pursuant to the lawful order of a practitioner, including the packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(15) "Dispenser" is a practitioner who delivers a controlled substance to the ultimate user or human research subject.

(16) "Distribute" means to deliver (other than by administering or dispensing) a controlled substance or an imitation controlled substance and includes actual constructive, or attempted transfer. "Distributor" means a person who so delivers a controlled substance or an imitation controlled substance.

(17) "Downtime" means that period of time when a computer is not operable.

(18) "Drug addicted person" means a person who exhibits a maladaptive pattern of behavior resulting from drug use, including one or more of the following: impaired control over drug use; compulsive use; and/or continued use despite harm, and craving.

(19) "Drug Enforcement Administration" means the Drug Enforcement Administration United States Department of Justice or its successor.

(20) "Federal law" means the Comprehensive Drug Abuse Prevention and Control Act of 1970, (84 stat. 1236)(see generally 21 U.S.C. section 801 et seq.), and all regulations pertaining to that federal act.

(21) "Hardware" means the fixed component parts of a computer.

(22) "Hospital" means an institution as defined in chapter 17 of title 23.

(23) "Imitation controlled substance" means a substance that is not a controlled substance, which by dosage unit, appearance (including color, shape, size, and markings), or by representations made, would lead a reasonable person to believe that the substance is a controlled substance and, which imitation controlled substances contain substances which if ingested, could be injurious to the health of a person. In those cases when the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance" (for example in the case of powder or liquid), the court or authority concerned should consider, in addition to all other logically relevant factors, the following factors as related to "representations made" in determining whether the substance is an "imitation controlled substance":

(i) Statement made by an owner, possessor, transferor, recipient, or by anyone else in control of the substance concerning the nature of the substance, or its use or effect.

(ii) Statements made by the owner, possessor, or transferor, to the recipient that the substance may be resold for substantial profit.

(iii) Whether the substance is packaged in a manner reasonably similar to packaging of

illicit controlled substances.

(iv) Whether the distribution or attempted distribution included an exchange of or demand for money or other property as consideration, and whether the amount of the consideration was substantially greater than the reasonable value of the non-controlled substance.

(24) "Immediate precursor" means a substance:

(i) Which the director of health 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;

(ii) Which is an immediate chemical intermediary used or likely to be used in the manufacture of those controlled substances; and

(iii) The control of which is necessary to prevent, curtail, or limit the manufacture of that controlled substance.

(25) "Laboratory" means a laboratory approved by the department of health as proper to be entrusted with controlled substances and the use of controlled substances for scientific and medical purposes and for the purposes of instruction.

(26) "Marijuana" means all parts of the plant cannabis sativa L., whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin, but shall not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of mature stalks, (except the resin extracted from it), fiber, oil or cake, or the sterilized seed from the plant which is incapable of germination.

(27) "Manufacture" means the production, preparation, propagation, cultivation, compounding, or processing of a drug or other substance, including an imitation controlled 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 the substance or labeling or relabeling of its container in conformity with the general laws of this state except by a practitioner as an incident to his or her administration or dispensing of the drug or substance in the course of his or her professional practice.

(28) "Manufacturer" means a person who manufactures but does not include an apothecary who compounds controlled substances to be sold or dispensed on prescriptions.

(29) "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:

(i) Opium and opiates.

(ii) A compound, manufacture, salt, derivative, or preparation of opium or opiates.

(iii) A substance (and any compound, manufacture, salt, derivative, or preparation of it) which is chemically identical with any of the substances referred to in paragraphs (i) and (ii) of this subdivision.

(iv) Any other substance which the attorney general of the United States, or his or her successor, or the director of health, after investigation, has found to have, and by regulation designates as having, a potential for abuse similar to opium and opiates.

(30) "Official written order" means an order written on a form provided for that purpose by the Drug Enforcement Administration under any laws of the United States making provision for an official form, if order forms are authorized and required by federal law, and if no order form is provided then on an official form provided for that purpose by the director of health.

(31) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability.

(32) "Opium poppy" means the plant of the species papaver somniferum L., except the seeds of the plant.

(33) "Ounce" means an avoirdupois ounce as applied to solids and semi-solids, and a fluid ounce as applied to liquids.

(34) "Person" means any corporation, association, partnership, or one or more individuals.

(35) "Physical dependence" means a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

(36) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(37) "Practitioner" means:

(i) A physician, osteopath, dentist, chiropodist, veterinarian, scientific investigator, or other person licensed, registered or permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

(ii) A pharmacy, hospital, or other institution licensed, registered or permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

(38) "Printout" means a hard copy produced by computer that is readable without the aid of any special device.

(39) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(40) "Researcher" means a person authorized by the director of health to conduct a laboratory as defined in this chapter.

(41) "Sell" includes sale, barter, gift, transfer, or delivery in any manner to another, or to offer or agree to do the same.

(42) "Software" means programs, procedures and storage of required information data.

(43) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any synthetic cathinones as provided for in schedule I;

(44)~~(43)~~ "Ultimate user" means a person who lawfully possesses a controlled substance for his or her own use or for the use of a member of his or her household, or for administering to an animal owned by him or her or by a member of his or her household.

(45)~~(44)~~ "Wholesaler" means a person who sells, vends, or distributes at wholesale, or as a jobber, broker agent, or distributor, or for resale in any manner in this state any controlled substance.

21-28-2.08. Contents of schedules. -- Schedule I

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Opiates. - Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol
(2) Allylprodine
(3) Alphacetylmethadol
(4) Alphameprodine
(5) Alphamethadol
(6) Benzethidine
(7) Betacetylmethadol
(8) Betameprodine
(9) Betamethadol
(10) Betaprodine
(11) Clonitazene
(12) Dextromoramide
(13) Difenoxin
(14) Diampromide
(15) Diethylthiambutene
(16) Dimenoxadol
(17) Dimepheptanol
(18) Dimethylthiambutene
(19) Dioxaphetyl butyrate

(20) Dipipanone
(21) Ethylmethylthiambutene
(22) Etonitazene
(23) Extoxerdine
(24) Furethidine
(25) Hydroxypethidine
(26) Ketobemidone
(27) Levomoramide
(28) Levophenacylmorphan
(29) Morpheridine
(30) Noracymethadol
(31) Norlevorphanol
(32) Normethadone
(33) Norpipanone
(34) Phenadoxone
(35) Phenampromide
(36) Phenomorphan
(37) Phenoperidine
(38) Piritramide
(39) Proheptazine
(40) Properidine
(41) Propiram
(42) Racemoramide
(43) Trimeperidone
(44) Tilidine
(45) Alpha-methylfentanyl
(46) Beta-hydroxy-3-methylfentanyl other names:
N-[1-(2hydroxy-2-phenethyl)-3-methyl-4piperidingyl] Nphenylpropanamide

(c) Opium Derivatives. - Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine
(2) Acetyldihydrocodeine
(3) Benzylmorphine
(4) Codeine methylbromide
(5) Codeine-N-Oxide
(6) Cyprenorphine
(7) Desomorphine
(8) Dihydromorphine
(9) Etorphine (Except hydrochloride salt)
(10) Heroin
(11) Hydromorphinol
(12) Methyldesorphine
(13) Methylihydromorphine
(14) Morphine methylbromide
(15) Morphine methylsulfonate
(16) Morphine-N-Oxide
(17) Myrophine
(18) Nococodeine
(19) Nicomorphine
(20) Normorphine
(21) Pholcodine
(22) Thebacon
(23) Drotebanol

(d) Hallucinogenic Substances. - Unless specifically excepted or unless listed in another

schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this subsection only, the term "isomer" includes the optical, position, and geometric isomers):

(1) 3, 4-methylenedioxy amphetamine

(2) 5-methoxy-3, 4-methylenedioxy amphetamine

(3) 3, 4, 5-trimethoxy amphetamine

(4) Bufotenine

(5) Diethyltryptamine

(6) Dimethyltryptamine

(7) 4-methyl 2, 5-dimethoxyamphetamine

(8) Ibogaine

(9) Lysergic acid diethylamide

(10) Marihuana

(11) Mescaline

(12) Peyote. Meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lemair whether growing or not; the seeds of the plant; any extract from any part of the plant; and any compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or extracts.

(13) N-ethyl-3-piperidyl benzilate

(14) N-methyl-3-piperidyl benzilate

(15) Psilocybin

(16) Psilocyn

(17) Tetrahydrocannabinols. Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following: delta 1 cis or trans tetrahydrocannabinol, and their optical isomers. Delta 6 cis or trans tetrahydrocannabinol and their optical isomers. Delta 3, 4 cis or trans tetrahydrocannabinol and its optical isomer. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

(18) Thiophene analog of phencyclidine. 1-(1-(2 thienyl) cyclo-hexyl) pipiridine: 2-Thienyl analog of phencyclidine: TPCP

(19) 2,5 dimethoxyamphetamine

(20) 4-bromo-2,5-dimethoxyamphetamine, 4-bromo-2,5-dimethoxy-alpha-methylphenethyamine: 4-bromo-2,5-DMA

(21) 4-methoxyamphetamine-4-methoxy-alpha-methylphenethylaimine: paramethoxyamphetamine: PMA

(22) Ethylamine analog of phencyclidine. N-ethyl-1- phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclophexyl) ethylamine, cyclohexamine, PCE

(23) Pyrrolidine analog of phencyclidine. 1-(1-phencyclohexyl)- pyrrolidine PCPy, PHP

(24) Parahexyl; some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenz o (b,d) pyran: Synhexyl.

(e) Depressants. - Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Mecloqualone.

(2) Methaqualone.

(3) 3-methyl fentanyl (n-(ethyl-1(2-phenylethyl)-4-piperidyl)-N-phenylpropanamide.

(4) 3,4-methyl-enedioxymethamphetamine (MDMA), its optical, positional and geometric isomers, salts, and salts of isomers.

(5) 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP), its optical isomers, salts and salts of isomers.

(6) 1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (PEPAP), its optical isomers, salts

and salts of isomers.

(7) N-(1-(1-methyl-2-phenyl)ethyl-4-piperidyl)-N-phenyl-acetamide (acetyl-alpha-methylfentanyl), its optical isomers, salts and salts of isomers.

(8) N-(1-(1-methyl-2(2-thienyl)ethyl-4-piperidyl)-N-phenylpropanami de (alpha-methylthiofentanyl), its optical isomers, salts and salts of isomers.

(9) N-(1-benzyl-piperidyl)-N-phenylpropanamide (benzyl-fentanyl), its optical isomers, salts and salts of isomers.

(10) N-(1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl)-N-phenyl-propanamid e (beta-hydroxyfentanyl), its optical isomers, salts and salts of isomers.

(11) N-(3-methyl-1(2-hydroxy-2-phenyl)ethyl-4-piperidyl)-N-phenylpro panamide (beta-hydroxy-3-methylfentanyl), its optical and geometric isomers, salts and salts of isomers.

(12) N-(3-methyl)-1-(2-(2-thienyl)ethyl-4-piperidyl)-N-phenylpro- panamide (3-methylthiofentanyl), its optical and geometric isomers, salts and salts of isomers.

(13) N-(1-2-thienyl)methyl-4-piperidyl)-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers.

(14) N-(1-(2(2-thienyl)ethyl-4-piperidyl-N-phenylpropanamide (thiofentanyl), its optical isomers, salts and salts of isomers.

(15) N-[1-(2-phenylethyl)-4-piperidyl]N-(4-fluorophenyl)-propanamid e (para-fluorofentanyl), its optical isomers, salts and salts of isomers.

(16) Gamma hydroxybutyrate, HOOC-CH2-CH2-CH2OH, its optical, position, or geometric isomers, salts and salts of isomers.

(f) Stimulants. - Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Fenethylline

(2) N-ethylamphetamine

(3) 4-methyl-N-methylcathinone (Other name: mephedrone)

(4) 3,4-methylenedioxy-N-methlycathinone (Other name: methylone)

(5) 3,4-methylenedioxypyrovalerone (Other name: MDPV)

(g) Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]phenol (CP-47,497)

(2) 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]phenol (cannabicyclohexanol and CP-47,497 c8 homologue)

(3) 1-Butyl-3-(1 naphthoyl)indole, (JWH-073)

(4) 1-[2-(4-Morpholinyl)ethyl]3-(1-naphthoyl)indole (JWH-200)

(5) 1-Pentyl-3-(1-napthoyl)indole, (JWH-018 and AM678)

(h) Synthetic cannabinoids or piperazines. Unless specifically excepted, any chemical compound which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law, that contains Benzylpiperazine (BZP); Trifluoromethylphenylpiperazine (TFMPP); 1,1-Dimethylheptyl-11-hydroxytetrahydrocannabinol (HU-210); 1-Butyl-3-(1-naphthoyl)indole; 1-Pentyl-3-(1-naphthoyl)indole; dexanabinol (HU-211); or any compound in the following structural classes:

(1) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include, but are not limited, to JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, and AM-2201;

(2) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not

substituted in the phenyl ring to any extent. Examples of this structural class include, but are not limited to, JWH-167, JWH-250, JWH-251, and RCS-8;

(3) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include, but are not limited, to AM-630, AM-2233, AM-694, Pravadoline (WIN 48,098), and RCS-4;

(4) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include, but are not limited to, CP 47,497 and its C8 homologue (cannabicyclohexanol);

(5) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include, but are not limited to, JWH-175, JWH-184, and JWH-185;

(6) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include, but are not limited, to JWH-030, JWH-145, JWH-146, JWH-307, and JWH-368;

(7) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl)indene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include, but are not limited to, JWH-176; or

(8) Any other synthetic cannabinoid or piperazine which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law;

(i) Synthetic cathinones. Unless specifically excepted, any chemical compound which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law, not including bupropion, structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in one or more of the following ways:

(1) By substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituents. Examples of this class include, but are not limited to, 3,4-Methylenedioxycathinone (bk-MDA);

(2) By substitution at the 3-position with an acyclic alkyl substituent. Examples of this class include, but are not limited to, 2-methylamino-1-phenylbutan-1-one (buphedrone);

(3) By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups, or by inclusion of the 2-amino nitrogen atom in a cyclic structure. Examples of this class include, but are not limited to, Dimethylcathinone, Ethcathinone, and ?-Pyrrolidinopropiophenone (?-PPP); or

(4) Any other synthetic cathinone which is not approved by the United States Food and Drug Administration or, if approved, is not dispensed or possessed in accordance with state or federal law;

Schedule II

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Substances, vegetable origin or chemical synthesis. - Unless specifically excepted or unless listed in another schedule, any of the following substances 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:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding naloxone and its salts, and excluding naltrexone and its salts, but including the following:

(i) Raw opium
(ii) Opium extracts
(iii) Opium fluid extracts
(iv) Powdered opium
(v) Granulated opium
(vi) Tincture of opium
(vii) Etorphine hydrochloride
(viii) Codeine
(ix) Ethylmorphine
(x) Hydrocodone
(xi) Hydromorphone
(xii) Metopon
(xiii) Morphine
(xiv) Oxycodone
(xv) Oxymorphone
(xvi) Thebaine

(2) Any salt, compound, derivative, or preparation which is chemically equivalent or identical with any of the substances referred to in subdivision (1) of this subsection, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in liquid, solid, or powder form which contains the phenanthrine alkaloids of the opium poppy).

(c) Opiates. - Unless specifically excepted or unless listed in another schedule any of the following opiates, including its isomers, esters, ethers, salts; and salts of isomers, esters and, ethers whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine
(2) Anileridine
(3) Bezitramide
(4) Dihydrocodeine
(5) Diphenoxylate
(6) Fentanyl
(7) Isomethadone
(8) Levomethorphan
(9) Levorphanol
(10) Metazocine
(11) Methadone
(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid
(14) Pethidine
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid
(18) Phenaxocine

(19) Piminodine
(20) Racemethorphan
(21) Racemorphan
(22) Bulk Dextropropoxyphene (non-dosage forms)
(23) Suffentanil
(24) Alfentanil
(25) Levoalphacetylmethadol

(d) Stimulants. - Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
(2) Methamphetamine, its salts and salts of its isomers.
(3) Phenmetrazine and its salts.
(4) Methylphenidate.

(e) Depressants. - Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital
(2) Glutethimide
(3) Methyprylon
(4) Pentobarbital
(5) Phencyclidine
(6) Secobarbital
(7) Phencyclidine immediate precursors:
(i) 1-phencyclohexylamine
(ii) 1-piperidinocyclohexane-carbonitrile (PCC)
(8) Immediate precursor to amphetamine and methamphetamine: Phenylacetone. Some other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzone ketone.

Schedule III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.
(2) Chlorhexadol
(3) Lysergic acid
(4) Lysergic acid amide
(5) Sulfondiethylmethane
(6) Sulfonethylmethane
(7) Sylfonmethane
(8) Any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital, or any salt of them and one or more other active medicinal ingredients which are not listed in any schedule.
(9) Any suppository dosage form containing amobarbital, secobarbital, pentobarbital or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.
(10) Ketamine, its salts, isomers and salts of isomers. (Some other names for ketamine: (+)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone).

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts of them:

(1) Not more than one and eight tenths grams (1.8 gms.) of codeine per one hundred milliliters (100 mls.) or not more than ninety milligrams (90 mgs.) per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than one and eight tenths grams (1.8 gms.) of codeine per one hundred milliliters (100 mls.) or not more than ninety milligrams (90 mgs.) per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Not more than three hundred milligrams (300 mgs.) of dihydrocodeinone per one hundred milliliters (100 mls.) or not more than fifteen milligrams (15 mgs.) per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than three hundred milligrams (300 mgs.) of dihydrocodeinone per one hundred milliliters (100 mls.) or not more than fifteen milligrams (15 mgs.) per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than one and eight tenths grams (1.8 gms.) of dihydrocodeine per one hundred milliliters (100 mls.) or not more than ninety milligrams (90 mgs.) per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than three hundred milligrams (300 mgs.) of ethylmorphine per one hundred milliliters (100 mls.) or not more than fifteen milligrams (15 mgs.) per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than five hundred milligrams (500 mgs.) of opium per one hundred milliliters (100 mls.) or per one hundred grams (100 gms.) or not more than twenty-five milligrams (25 mgs.) per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than fifty milligrams (50 mgs.) of morphine per one hundred milliliters (100 mls.) per one hundred grams (100 gms.) with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(c) Stimulants. - Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of the isomers whenever the existence of the salts of isomers is possible within the specific chemical designation:

(1) Benzphetamine
(2) Chlorphentermine
(3) Clortermine
(4) Mazindol
(5) Phendimetrazine

(d) Steroids and hormones. - Anabolic steroids (AS) or human growth hormone (HGH), excluding those compounds, mixtures, or preparations containing an anabolic steroid that because of its concentration, preparation, mixture or delivery system, has no significant potential for abuse, as published in 21 CFR 1308.34, including, but not limited to, the following:

(1) Chlorionic gonadotropin
(2) Clostebol
(3) Dehydrochlormethyltestosterone
(4) Ethylestrenol
(5) Fluoxymesterone
(6) Mesterolone
(7) Metenolone
(8) Methandienone
(9) Methandrostenolone
(10) Methyltestosterone
(11) Nandrolone decanoate
(12) Nandrolone phenpropionate
(13) Norethandrolone
(14) Oxandrolone
(15) Oxymesterone
(16) Oxymetholone
(17) Stanozolol
(18) Testosterone propionate
(19) Testosterone-like related compounds
(20) Human Growth Hormone (HGH)

(e) Hallucinogenic substances.

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in U.S. Food and Drug Administration approved drug product. (Some other names for dronabinol: (6aR-trans)-6a, 7, 8, 10a- tetrahydro-6, 6, 9- trimethyl-3-pentyl-6H- dibenzo[b,d]yra n-1-ol,or(-)-delta-9(trans)-tetrahydrocannabinol.)

Schedule IV

(1) Barbital.

(2) Chloral betaine

(3) Chloral hydrate

(4) Ethchrovynol

(5) Ethinamate

(6) Methohexital

(7) Meprobamate

(8) Methylphenobarbital

(9) Paraldehyde

(10) Petrichloral

(11) Phenobarbital

(12) Fenfluramine

(13) Diethylpropion

(14) Phentermine

(15) Pemoline (including organometallic complexes and chelates thereof).

(16) Chlordiazepoxide

(17) Clonazepam

(18) Clorazepate

(19) Diazepam

(20) Flurazepam

(21) Mebutamate

(22) Oxazepam

(23) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts:

Dextropropoxyphene(alpha-(+)-4-dimethylamino-1,2-diphenyl-3- methyl-2-propronoxybutane).

(24) Prazepam

(25) Lorazepam

(26) Not more than one milligram (1 mg.) of difenoxin and not less than twenty-five (25) micrograms of atropine sulfate per dosage unit.

(27) Pentazocine

(28) Pipradrol

(29) SPA (-)-1-dimethylamino-1, 2-diphenylethane

(30) Temazepam

(31) Halazepam

(32) Alprazolam

(33) Bromazepam

(34) Camazepam

(35) Clobazam

(36) Clotiazepam

(37) Cloxazolam

(38) Delorazepam

(39) Estazolam

(40) Ethyl loflazepate

(41) Fludizaepam

(42) Flunitrazepam

(43) Haloxazolam

(44) Ketazolam

(45) Loprazolam

(46) Lormetazepam
(47) Medazepam
(48) Nimetazepam
(49) Nitrazepam
(50) Nordiazepam
(51) Oxazolam
(52) Pinazepam
(53) Tetrazepam
(54) Mazindol
(55) Triazolam
(56) Midazolam
(57) Quazepam
(58) Butorphanol
(59) Sibutramine

Schedule V

(a) Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than two hundred milligrams (200 mgs.) of codeine per 100 milliliters (100 mls.) or per one hundred grams (100 gms.).

(2) Not more than one hundred milligrams (100 mgs.) of dihydrocodeine per 100 milliliters (100 mls.) or per one hundred grams (100 gms.).

(3) Not more than one hundred milligrams (100 mgs.) of ethylmorphine per 100 milliliters (100 mls.) or per one hundred grams (100 gms.).

(4) Not more than two and five tenths milligrams (2.5 mgs.) of diphenixylate and not less than twenty-five (25) micrograms of atropine sulfate per dosage unit.

(5) Not more than one hundred milligrams (100 mgs.) of opium per one hundred milliliters (100 mls.) or per one hundred grams (100 gms.).

(b) Not more than five tenths milligrams (0.5 mgs.) of difenoxin and not less than twenty-five (25) micrograms of atropine sulfate per dosage unit.

(c) Buprenorphine

(d) Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Propylhexedrine (except as benzedrex inhaler)
(2) Pyrovalerone.

SECTION 2. This act shall take effect upon passage.

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LC01023/SUB A
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CSDB Real-Time Pilot

Lessons Learned

1. Pharmacists are interested in improving the timeliness of the CSD system. In the initial call to explain the real time program, most of the pharmacists were interested in participating and readily supplied contact information for regional managers or IT managers to continue the discussion. The decision-makers were more apprehensive then the pharmacists.
2. Medium and small chains use a third party software. This makes it easier for them to participate in the real-time program.
3. Larger pharmacies do not tolerate a 10 second delay anywhere in their process.
4. Large Chains would prefer to use centralized service – exchanges they already use to minimize their integration concerns. The region manager from target was very interested. However, their national IT director was not interested in creating this service that would talk to the state's system from each location. It would have caused changes to their firewalls and custom development of their software.
5. Large Chains custom develop their pharmacy software.
6. Changing to a daily batch would be less intrusive for the large chains.
7. Changes to a daily batch would be more intrusive for the small chains – it is a manual process
8. Anecdotal evidence – DOPL employee/prescriber checked the system in the morning, her patient did not have any recent controlled substance prescribed. The pharmacy that afternoon called the prescriber to let her know that multiple prescriptions had been filled for that same patient that day.

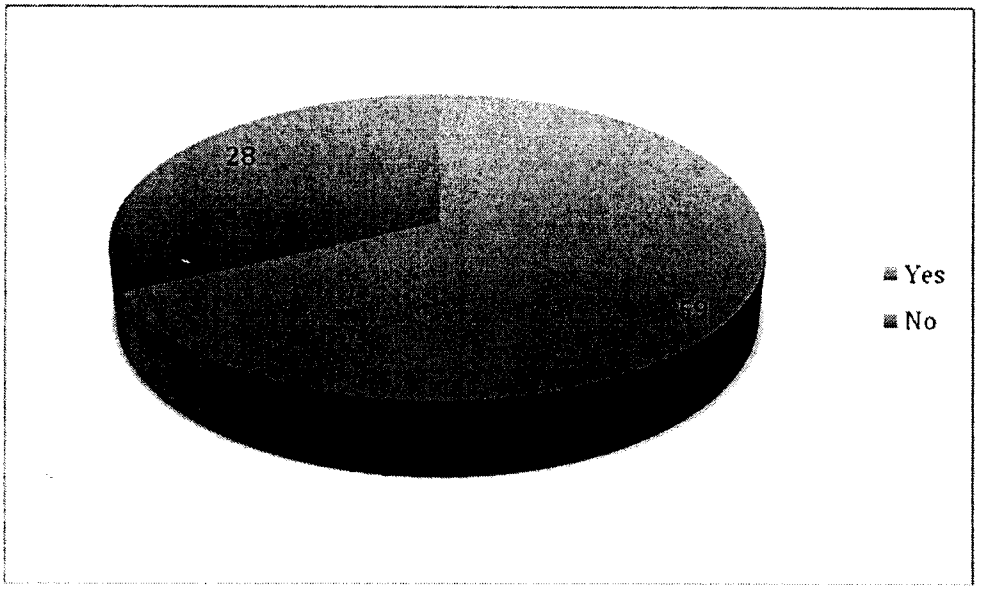
Survey Summary

Survey results go here...

Pharmacy responses to initial invitation

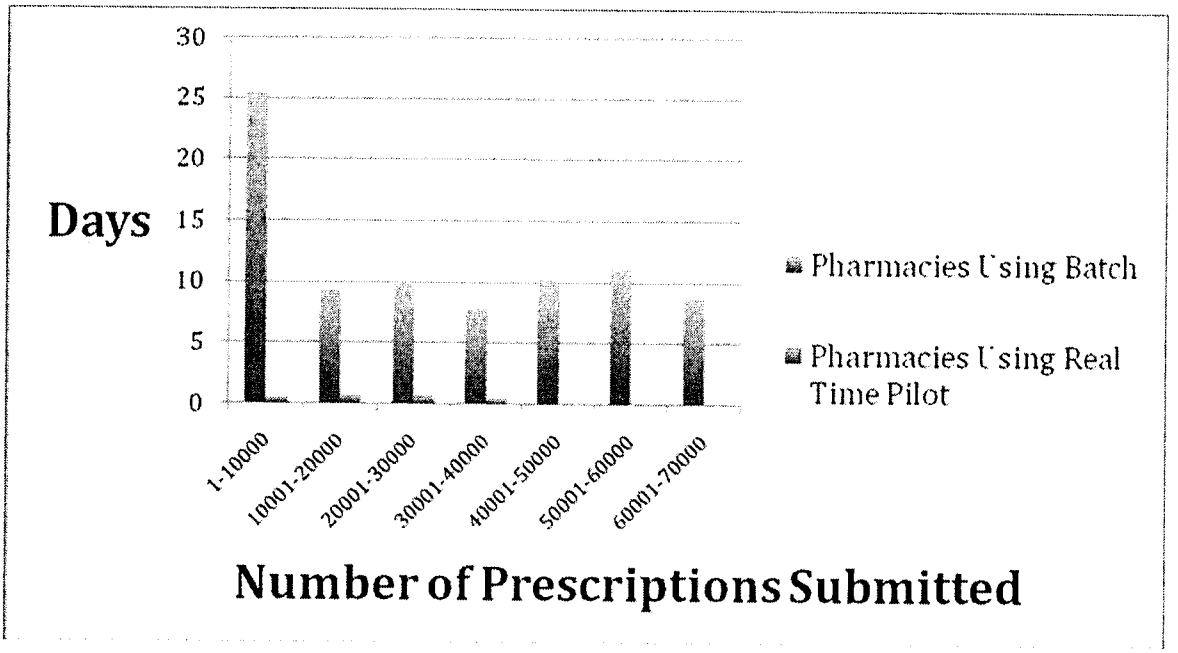
Out of 87 invitations, 32% were interested in participating. 68% were not interested. Listed below are the main reasons for opting out of the pilot program.

- We don't have a point of sale device
- Don't want to rock the boat
- Since this is an optional program, the Corporate office is not interested in developing a custom solution for their Utah branches.



Graphs

Average delay between RX Filled and Recorded in CSD
(Oct 1, 2012 – Sept 30, 2013)



Average Prescriptions per pharmacy

[Graph goes here]