

John Hoeven, Governor

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

www.nodakpharmacy.com
E-mail= ndboph@btinet.net
Howard C. Anderson, Jr, R.Ph.
Executive Director

APPENDIX J
Rick L. Detwiller, R.Ph.
Bismarck, President
Gary W. Dewhirst, R.Ph.
Hettinger
Laurel Haroldson, Ph.
Jamestown
Bonnie J. Thom, R.Ph.
Granville
Gayle D. Ziegler, R.Ph.
Fargo
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

TUESDAY – SEPTEMBER 14TH, 2010 ADMINISTRATIVE RULES COMMITTEE ROUGHTRIDER ROOM – STATE CAPITOL

Chairman Klein, members of the Administrative Rules Committee, thank you for the opportunity to discuss the following rule change with you.

North Dakota Administrative Code 61-13-01 Controlled Substance Schedules

- 1. This rule did not result from statutory changes made by the Legislative Assembly.
- These rules are not related to any federal statute or regulation, although there are references in the DEA website and printed materials about drugs of concern, and I am enclosing some copies for your reference.
- 3. In January of 2010 the Board of Pharmacy discussed the spice cannabinoids, as we were receiving reports from the North Dakota Transitional Centers about individuals on their way out of incarceration smoking or using some of the products purported to contain spice cannabinoids. We even had one instance where the parolee asked the judge if he could smoke some spice as it was not an illegal drug. We began gathering evidence and information in our office and when reports of adverse health consequences began to appear in newspapers, such as the Bismarck Tribune, I asked my pharmacy intern, at the time Courtney Smith, to do some research relative to Mephedorone. Mephedorone was reported to be in the bath salts which were injected by a local teenage girl who ended up hospitalized. While Ms. Smith was doing research on the chemical entity Mephedorone, Attorney General Wayne Stenehjem called my office concerned that "We", the state of North Dakota, needed to do something before more of our young people hurt themselves using these substances. We met with Attorney General Stenehjem in his office at 11:30 AM on February 25th, 2010 to review the information we had and the options available for protecting the public from these substances.

Keep in mind, many of the products that were being used, such as K-2 or Spice and the bath salts; do not contain labeling which would reveal to the people using them or the physicians trying to care for them in the emergency rooms, what was actually in these products. The chemical nature of these products was revealed by analyses by the North Dakota Crime Laboratory. The Attorney General was considering doing something through the Consumer Protection office, but after discussions it was determined that the authority granted by you to the North Dakota Board of Pharmacy to schedule drugs in the interim between legislative sessions might be the best avenue of approach. This avenue gives teeth to the law enforcement people trying to get these products out of the stores and out of the hands of individuals who might come to harm by their use.

It just so happened that we had a Board of Pharmacy conference call meeting schedule that very night, February 25th, 2010, to handle some routine Board of Pharmacy business. We then went to work with the Governor's Office for authority to move forward with an emergency rule making process. This was granted, the Attorney General's Office worked with the Board of Pharmacy to draft the emergency rule making notice, which was properly disseminated, and the meeting and hearing was held at 9:00 PM that night. The Board of Pharmacy agreed to go ahead with the scheduling as you see it.

A public rule hearing was then set to be held on Saturday April 24th, 2010 in Minot, North Dakota in conjunction with the North Dakota Pharmacist Convention, a copy of that notice is included in this packet as well.

The emergency rule making meeting on February 25th was attended by three individuals representing one of the retail business that sold some of these products. But, after hearing their side of the story the Board of Pharmacy moved ahead with the emergency rule making. At the April 24th, 2010 meeting in Minot there were perhaps 40 individuals in attendance at the hearing and only one of whom raised a question about medical research related to these substances. Of course, there is a process where medical research can be conducted on scheduled products, as long as approval is obtained in advance and the proper protections are in place for any animal or human subjects used for the research.

- 4. I am including the summaries of the rule hearing comments and the answers to the individuals given at that time.
- 5. The approximate cost of this rule hearing was a little more expensive than average since we had to hold both an emergency and a regular rule hearing. This amounted to a total of \$3,303.30.

- 6. These rules, as discussed earlier, were adopted to protect the public from these substances which were imbedded or sprayed upon materials that they might use and unknowingly harm themselves.
- 7. A regulatory analysis was prepared and a copy was enclosed. There are always some questions about how much lost sales could occur when people may no longer sell these products, however it is not in the public interest to foster upon them drugs which might be harmful, either intentionally or unknowingly.
- 8. An economic impact statement and regulatory analysis of impact on small entities was not required, but was prepared to provide this additional information.
- 9. There was no constitutional taking assessment as no property was being seized as a direct result of this rule.
- 10. These rules were adopted as an emergency interim final rule under NDCC 28-32-03, pursuant to authority granted by the Legislature in NDCC 19-03.1-02. A copy of the Governor's letter is enclosed and we have discussed the issues which caused the Board of Pharmacy to take this action, rather than waiting for the legislative session. Protection of the public's health is the main purpose of the Board of Pharmacy, and this rule making authority under the Controlled Substances Act has served to provide this ability while we wait for your legislative session to move these substances from the rule to the statute, should you concur.

Respectfully,

Howard C. Anderson, Jr, R.Ph.

Executive Director



February 25, 2010

Howard C. Anderson, Jr., R.Ph. Executive Director North Dakota Board of Pharmacy P.O. Box 1354 Bismarck, ND 58502-1354

Dear Howard,

On February 25, 2010, I received your request for approval of emergency rulemaking to create a new section 61-13-01-03 of the North Dakota Administrative Code, Article 61-13 "Controlled Substances," which adds addictive, dangerous, and hallucinogenic substances to the Controlled Substances Act (N.D.C.C. § 19-03.1-05).

I have reviewed the request pursuant to N.D.C.C. § 28-32-03(2) and find that emergency rulemaking is necessary to abate an imminent peril that threatens public health and safety.

Sincerely,

ohn/Hoeven

vernor

38:34:58

AMENDED NOTICE & AGENDA

Conference Call Meeting of the North Dakota Board of Pharmacy

9:00 PM - THURSDAY - FEBRUARY 25, 2010

Speakerphone located at: 1906 E. Broadway, Bismarck, ND

or

Call 1-800-423-1988

Under the name of: **Howard** Conference # 1437912

9:00 PM Call to Order - President Gayle Ziegler

- 1. Altru's Collaborative Agreement
- 2. Tara's Thrifty White's request for a subclass K
- 3. Wall's Long Term Care Pharmacy New Class D Pharmacy
- 4. Rob Nelson, PharmD Merit Care Health System request for a variance to NDAC 61-04-08-03, which limits the number of pharmacists an individual physician can have a collaborative agreement with to 3
- 5. Rob Nelson, PharmD Merit Care Health System Collaborative Agreement: Anticoagulation Out-patient Dialysis
- 6. Discussion of rule hearing date
- 7. Hettinger hospital Plans
- 8. Consideration of an emergency rule that creates a new section 61-13-01-03 of the North Dakota Administrative Code, Article 61-13 "Controlled Substances," that adds addictive, dangerous, and hallucinogenic substances to the Controlled Substances Act (N.D.C.C. § 19-03.1-05).

February 25th, 2010 Board of Pharmacy Office Bismarck, ND

Conference call meeting held on Thursday February 25th, 2010. The speaker phone was located at the Board of Pharmacy office at 1906 E Broadway Ave in Bismarck, North Dakota with others on the telephone via conference call.

President Gayle Zieger, R.Ph. called the meeting to order at 9:00 PM. Present at the meeting via conference call were: Board Members Pharmacist Gary W. Dewhirst; Pharmacist Laurel Haroldson; Pharmacist Bonnie J. Thom and Pharmacist Gayle D. Ziegler Absent: Pharmacist Rick L. Detwiller

Also present on the conference call were: Intern PharmD Student Brandi Hagert; Mike Mullen, Assistant Attorney General; Pharmacist Curt Larson District Manager of CVS; Dr Robert Nelson of Merit Care Health Systems and Jenny Michael of <u>The Bismarck Tribune</u>; Dale Wetzel and Julie.

February 25th, 2010 Board of Pharmacy Office Bismarck, ND PAGE 2

Present in the Office with Executive Director Howard Anderson were: ND Attorney General Wayne Stenehjem; Tom Gerhardt, News Director at KXMB-TV; Cassandra Nickel; William J Nickel and Patrina Elagen all representing Big Willies.

After review of the Agenda — it was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to approve the Agenda as presented, except that we would move item #8 to the beginning of the list, as most of the visitors at the meeting were concerned about that particular issue. All Board Members present voted aye and the motion carried. The Agenda was approved with the change of item #8 being moved to item #1.

I am <u>Gayle Ziegler</u> President of the Board of Pharmacy and I will be acting as officer for this public meeting.

It is now <u>9:04 PM</u> on Thursday February 25, 2010 on a conference call or in the conference room of the Board of Pharmacy Office at 1906 East Broadway in Bismarck, North Dakota.

This public meeting has been called for the purpose of allowing all interested individuals an opportunity to submit information concerning: Consideration of an emergency rule that creates a new section 61-13-01-03 of the North Dakota Administrative Code, Article 61-13 "Controlled Substances," that adds addictive, dangerous, and hallucinogenic substances to the Controlled Substances Act (N.D.C.C. § 19-03.1-05).

Information gathered at this meeting will be used by the Board of Pharmacy for it's deliberation and final decision.

The Executive Director of the Board of Pharmacy is taking minutes of this meeting, and this meeting is being recorded, so please identify yourself for the record before you speak.

Everyone present will be given an opportunity to speak. If you have a prepared statement, a written copy of your statement is appreciated and will be helpful.

At this point, I open the meeting for comments:

William J. Nickel of Mandan, North Dakota 58554, expressed concerns that his shop sold some of the products which had been referred to in the public press and in which was eluded might contain some of these chemicals. However, the ingredients on the products he sells does not list any of the chemicals indicated in this rule making. The concern of Mr. Nickel's was primarily that it would be difficult for him to ascertain which of his products actually had the listed chemicals in them and that he felt that he was not responsible for the inappropriate use of his products by the people who purchased them. Mr. Nickel asked what the disposition of suspect products might be, if this rule passed tonight.

It was pointed out that once the rule was published by the Legislative Council, in it's present form, any products containing any of these ingredients would be illegal and would not be able to be sold or possessed.

February 25th, 2010 Board of Pharmacy Office Bismarck, ND PAGE 3

Wayne Stenehjem, North Dakota Attorney General spoke, expressing support for the proposed Emergency Rule. General Stenehjem said that his Bureau of Criminal Investigation Agents, the State Crime Lab and other Law Enforcement Departments have found North Dakota citizens using these products in an inappropriate manner and that in several instances it has been reported that significant harm and hospitalizations have occurred as a result of use of products containing some of these substances. He also indicated that he supported the adoption of this rule and that he felt that those selling products, which the State Lab had identified as containing these dangerous chemicals, either knew or should know, by the high price asked of these products relative to ordinary Incense or Bath Oil Salts, these products were being used inappropriately. General Stenehjem pointed out that the roll of his office and the Board of Pharmacy in supporting and hopefully adopting this rule was for the protection of the public health. Individuals using these products intentionally by inappropriate methods, or by inhaling the smoke or vapors from these products in legitimate fashion, not realizing that they contain dangerous chemicals were a significant risk to the public health. Scheduling these substances and thus making it known that they cannot be added as ingredients to what would otherwise appear to be safe products, will serve to protect the public from these chemicals, whether the individuals using them know they are in the products or if they are using them without knowing that these dangerous chemicals are included in the products.

<u>Cassandra Nickel</u> of Bismarck, ND 58504 pointed out that the selling of these products in their shop, which were purported to contain some of these chemicals, never indicated that these products should be used inappropriately. Most of these products are labeled as Incense or Bath Oil Salts and are labeled not for human consumption.

The <u>State Board of Pharmacy Members</u> offered comments, indicating that they supported their role in the protection of the public health. The scheduling of these substances is necessary to protect those individuals either using them inappropriately or using the products without knowing that these chemicals were contained in the products.

Board Members also pointed out that if legitimate medical uses could be found for these products, they could be moved to an appropriate schedule. But, at this time there is no legitimate medical use for these products. They are used primarily in research for medical purposes. This research can continue under the Schedule I placement of these products until such time as legitimate uses are properly researched and the safety and effectiveness of the products documented.

<u>Mike Mullen</u> Assistant Attorney General pointed out that the rule will affect these products much like a food recall would affect a product that was determined to be adulterated by chemicals not listed on the packaging.

Howard Anderson, Jr, R.Ph., Executive Director of the ND State Board of Pharmacy pointed out some grammatical corrections in the Rule version that was sent out as part of the Notice, where two extra letters had been inserted in the chemical name of HU-211 and a couple of parentheses and brackets had been omitted. Also, Charles Peterson, Dean of NDSU College of Pharmacy had submitted a written comment in which he pointed out that he felt that "or injecting" should be added after ingesting to 61-13-01-01 – Purpose and Scope as how one of the ways users might abuse these substances. This suggestion was included in the final draft.

At the suggestion of Mike Mullen the table under 61-13-01-03 Scheduling was revised slightly to group into group 1 and group 2 the products being scheduled and the history, general authority and law implemented between the two groups eliminated.

A final copy with the above documented corrections was distributed at the meeting and was emailed to the Members of the Board of Pharmacy prior to final action.

CLOSING

61-13-01-03

Thank you all for participating. The Board of Pharmacy will use all of the information gathered at this meeting, in making their decision.

At this point, I will close the discussion on new section 61-13-01-03 of the North Dakota Administrative Code, Article 61-13 "Controlled Substances," that adds addictive, dangerous, and hallucinogenic substances to the Controlled Substances Act (N.D.C.C. § 19-03.1-05).

It was moved by Pharmacist Gary Dewhirst and seconded by Pharmacist Bonnie Thom to adopt this interim final Rule represented by the corrected copy. On a vote by Roll Call: Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – Aye Pharmacist Detwiller – was absent from the Meeting The interim final rule was passed and declared adopted.

Title 61 STATE BOARD OF PHARMACY

SECTION 1. There is hereby created a new Article 61-13 of title 61 of the North Dakota Administrative Rules as follows:

Article 61-13

CONTROLLED SUBSTANCES

Chapter 61-13-01	Controlled Substances Schedules
Section	
61-13-01-01	Purpose and Scope
61-13-01-02	Definitions

Scheduling

NOTICE OF INTENT TO ADOPT, AMEND AND REPEAL ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota Board of Pharmacy will hold a public hearing to address proposed adoption of a New Article to NDAC Title 61 – Article 61-13 Controlled Substances. The hearing will be held at 2:00 p.m. on Saturday, April 24, 2010, in the Executive Room at the Grand International Hotel, 1505 North Broadway, Minot, ND 58703-0777. The purpose of the rule is to schedule substances which have an actual or relative potential for abuse; and which bear risk to the public health by unknown individuals using them by inhaling the smoke, vapors or by ingesting the substance. The proposed rule is not expected to have an impact on the regulated community in excess of \$50,000. No taking of real property is involved in this rulemaking action.

The proposed rule may be reviewed at the office of the North Dakota Board of Pharmacy located at 1906 East Broadway Avenue, Bismarck, ND 58501. A copy of the proposed rule may be requested by writing to the above address, emailing ndboph@btinet.net, or calling 701-328-9535. Written or oral comments on the proposed rule sent to the above address or phone number and received by May 17, 2010 will be fully considered.

If you plan to attend the public hearing and will need specific facilities or assistance relating to a disability, please contact the North Dakota Board of Pharmacy at the above phone number or address at least three days prior to the public hearing.

DATED this 26th day of February 2010.

Howard C. Anderson, Jr, R.Ph, Executive Director

North Dakota Board of Pharmacy

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Less than inches in Total Length

Northern Pike

Less than inches in Total Length

Largemouth Bass Less than Inches in Total Length

e than 1 Channel Catfish than 24 inches in Total Length

listing all regulations is Department, 100 North (701) 328-6300.

ARCHERY AND SPEARFISHING

Archery and spearfishing is legal only from May 1 through September 30 of each fishing year.

Game fish may not be taken with bow/arrows or spears.

Archery and spearfishing is legal only in certain waters.

UNDERWATER SPEARFISHING

Underwater spearfishing is legal only from May 1 through September 30 of each fishing year.

The following fish may not be taken with underwater spearfishing gear: smallmouth bass, muskellunge, paddlefish and sturgeon.

Underwater spearfishing is legal only in certian waters.

DARKHOUSE SPEARFISHING

Darkhouse spearfishing is legal only from December 1 through March 15 of each fishing year. (exception: Spiritwood Lake opens January 1.)

All individuals who participate in darkhouse spear fishing must first register with the Department.

Northern pike and nongame fish are the only legal species for darkhouse spearlishing.

Darkhouse spearfishing is legal only in certain waters.

PADDLEFISH SNAGGING

The snagging of paddlefish is legal May 1 through May 31 of each fishing year, in certain areas of the Missouri and Yellowstone rivers.

Snagging paddlefish shall be legal only from 8:00 a.m. to 10:00 p.m. (Central Time) each day. Snaggers must immediately release all paddlefish on Snag and Release Days and immediately tag their one paddlefish on Harvest Days.

COMMERCIAL FISHING

Non-contract commercial fishing may be allowed in certain waters from May 15 through November 30.

The season for harvesting leeches by licensed balt

The season for harvesting leeches by licensed bait dealers is from April 1 through November 30. The season for harvesting clams or mussels shall be closed.

NEW FOR 2010-2012

(Summary of Changes)

- Harmon Lake and Crown Butte Dam, both in Morton County, were added to the list of "no live baitfish" lakes.
- The State Fair Pond in Ward County is closed to all fishing from November 1 through March 31.
- Added all waters open to public fishing in Ramsey County; Carlson Lakes in Ward County; Gravel Lake in Rolette County; and West Napoleon Lake in Logan County; to the list of open waters for darkhouse spearfishing. Closed Patterson Reservoir in Stark County to darkhouse spearfishing.
- For Lake Metigoshe in Bottineau County the daily and possession limit for bluegill was reduced to 10 and 20 respectively.
- The 14-inch minimum walleye size limit has been eliminated on Spiritwood Lake in Stutsman County, and on Lake Ashtabula in Barnes County.

For additional fishing information visit our website at gf.nd.gov

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In addition to the license fee(s), a service charge will be added. Service charge will vary depending on amount of transaction. specifications are available on the NDDOT website at

http://www.dot.nd.gov and may

inspected at the Construction Services Division, NDDOT, Room 333, 608 East Boulevard Avenue, Bismarck, North Dakota 58505-0700. NDDOT reserves the right to reject any and all proposals, waive technicalities, or to accept such as may be determined in the best interests of the state.

Requested by:

Francis G. Ziegler, P.E., Director North Dakota

Department of Transportation (Publish March 29, 2010)

NOTICE OF INTENT TO ADOPT, AMEND AND REPEAL ADMINISTRATIVE RULES

relating to Controlled Substances. The purpose of the proposed rule is to schedule substances which have an actual or relative potential for abuse; and which bear risk to the public health by unknown individuals using them by inhaling the smoke, vapors or by ingesting the substance.

North Dakota State Board of Pharmacy

will hold a public hearing to address proposed adoption of a New Article to NDAC Title 61 – Article 61-13 Controlled Substances

Executive Room Grand International Hotel 1505 N. Broadway Minot, ND 58703-0777 Sat., April 24, 2010 2:00 p.m. CT

A copy of the proposed rules may be reviewed at the office of the North Dakota Board of Pharmacy located at 1906 East Broadway Ave., Bismarck, ND 58501, A copy of the proposed rule may be requested by writing to the above address, emailing ndboph@btinet.net, or calling 701-328-9535. Written or oral comments on the proposed rule sent to the above address or phone number and received by May 17, 2010 will be fully considered. If you plan to attend the public hearing and will need special facilities or assistance relating to a disability, please contact the ND State Board of Pharmacy at the above telephone number or address at least three days

prior to the public hearing.
Dated this 26th day of Feb. 2010.
Howard C. Anderson, Jr., R.Ph.
Executive Director
North Dakota Board of Pharmacu

3/29 Cavington

At this point, I open the hearing for comments:

- Attorney General Wayne Stenehjem expressed his support for continuing the rule as passed in emergency form and the continued scheduling of these seven substances as Schedule I Controlled Substances. General Stenehjem discussed incidents where Bureau of Criminal Investigation Agents have seized these products and several publicly reported incidents where people had been hospitalized as a result of using either spice cannabinoids or the injectable stimulants listed in the rule. [Full statement in Addendum A- attached to these minutes.]
- Ernie Thurman Security Director at MedCenter One in Bismarck, North Dakota spoke about several incidents where people came into the Emergency room after using these substances, being very combative, hard to control and a danger to themselves and others. Mr. Thurman pointed out that when these products are sold with no active ingredients listed, and yet contain these now controlled substances, it makes it very difficult for the hospital staff to effectively treat them, as the etiology of their problems is unknown.
- An individual expressed his concern that making these controlled substances would make it difficult, if not impossible to conduct medical research as to their effectiveness to treat pain or disease in actual patients.
- Executive Director Anderson pointed out that scheduling these substances does not prevent medical research, but would make sure that if it were to be conducted in North Dakota, it would have to be under a Letter of Authorization from his office, done according to an FDA protocol and approved by an institutional review board, if the research were to be conducted on human or animal subjects. We do this for many other drugs and the process is well known to researchers.
- A Bureau of Criminal Investigation Agent was present with samples of the marketed products, which were demonstrated by analysis by the State Crime Lab to contain one or more of the substances listed in this rule. None of these marketed products listed any of the active ingredients on their labels.

CLOSING

Thank you all for coming. The Board of Pharmacy will use all of the information gathered at this hearing, in making their decision.

The record will be held open for written comment through May 17th, 2010.

At this point, I will close the hearing on: Article 61-13 Controlled Substances

A registration sheet is being circulated; I ask that everyone present please sign this sheet before they leave.

Along with the full Board of Pharmacy and the following individuals were in attendance and signed the sheet at the Meeting:

1	Last Name	First Name	Address	City	State	<u>Zip</u>
	Anstadt	Jill	701 32nd Ave N #204	Fargo	ND	58102
	Behm	Cody	570 4th Ave SW	Dickinson	ND	58601
	Berg-Gibbens	Erin E	4330 47th St S Unit L	Fargo	ND	58104

Boyer Julie 4303 9th Ave Cir #201 Fargo ND 58103 Browne Robert Minot Minot Buck Samantha 1405 25th Ave S #302 Fargo ND 58103 Craham William H 1412 31st Ave SW #2 Minot ND 58702 Hardy Mark 418 Main Street Neche ND 58265 Hendrickson Garrett 107 University Village Fargo ND 58102 Hursman Allison 4963 19th Ave W West Fargo ND 58078 Jacobson Eric 2202 35th Ave S Fargo ND 58104 Lothspeich Taviah 2201 33rd Ave S #206 Fargo ND 58104 Miller Erin E 1541 5th Street N Fargo ND 58102 Ness Jan 7001 Highway 83 N Minot ND 58703 Ness Loren 7001 Highway 83 N Minot ND 58102 Olsen John 3285 Broadway #6 </th <th>Born</th> <th>Megan</th> <th>1704 Dakota Dr #104</th> <th>Fargo</th> <th>ND</th> <th>58102</th>	Born	Megan	1704 Dakota Dr #104	Fargo	ND	58102
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	Wolf	Jordan	1605 N Univeristy Dr B	Fargo	ND	58102

President Ziegler presided over the Rule Hearing protocols at the appointed time of 2:00 PM. After the close of the hearing and a brief period of time where participants were allowed to view the sample products brought by the Attorney General, the Board Members continued with the Agenda for the meeting.

After the pharmacy remodeling plans were reviewed and discussed the following motions were made:

It was moved by Pharmacist Thom and seconded by Pharmacist Detwiller to require a consultation room with the remolding of Paul Bilden Pharmacy located at 10 North Main Street in Northwood, ND. All Board Members voted aye – motion carried.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Dewhirst to approve remodeling plans for Churchill Pharmacy located at 1190 W Turnpike Ave in Bismarck, ND as presented. All Board Members voted aye – motion carried.

It was moved by Pharmacist Detwiller and seconded by Pharmacist Thom to approve the plans for a Class K - Telepharmacy Permit at Drayton Drug located at 104 E HWY 66 in Drayton, ND; with the understanding that this Pharmacy would be operated as a full Class K – Telepharmacy with prescription drug inventory on site and registered pharmacy technicians preparing the prescriptions for dispensing by a pharmacist via the telepharmacy links. The plan drawn by Chuck McGuire of Dakota Drug was acceptable, indicating that the lock box for filled prescriptions would be accessible only from the outside of the prescription drug storage area, should the prescription be dispensed when the technician is out of the pharmacy and a supportive person is needed to connect the patient with the pharmacist for dispensing and counseling via the telepharmacy link.

ND BOARD OF PHARMACY

TESTIMONY OF ATTORNEY GENERAL WAYNE STENEHJEM, April 24, 2010

I am here to encourage the Board to continue the listing of the subject products to the schedule of controlled substances that were addressed by the Board in its emergency rule on Feb. 26, 2010.

Starting late last year, and into this year, my office began hearing reports from law enforcement, school resource officers, probation officers and judges about the use of a new chemical substance among young people. The substance goes by a variety of names, including Spark, K2, Spice, Yucatan Gold, JWH-018, and others. We heard reports of adverse reaction to the use of this item, which was commonly sold in head shops in several North Dakota communities.

Hospital emergency room personnel also were reporting patients presenting with a variety of adverse reactions resulting from the use of the product. Research revealed that the active ingredient in the product was similar to that in marijuana, with indications that its potency greatly exceeded that of THC. And, as far as we could initially determine, the product was legal. The product was being marketed as an incense, an aromatherapy product or other allegedly legal and benign purpose, but it was well known in the drug culture and among its user as a synthetic and legal alternative to marijuana. The product was sold at a price far in excess of anything that would be seen for a traditional incense, more similar in price to the street prices we see for marijuana — as much as \$35 to \$50 per gram.

I instructed a narcotics task force agent to obtain some of the product so we could have it tested at the Crime Lab. Agents bought two one gram packages of a product labeled "Spark." The analysis of the product confirmed it as Methelene dioxy pyro valerone [MDPV].

This product has been banned in a number of European countries, including Austria, Germany, Sweden, and since Dec. 23, 2009, UK. Some US states have likewise taken, or are considering, doing the same.

The sale and use of this product is troubling for a number of reasons:

- Detailed and exhaustive studies of this relatively new substance have yet to be conducted.
- There is certainly no quality control, so intentional use of the product can have unknown consequences. For example, the sample tested at our crime lab indicated that in addition to the MDPV in the substance, there was also an indication of the presence of lidocaine, a pain medication.
- People may inaccurately assume that because these products were legal, that must also mean they are safe.

The product has no known medical use, and as will be seen, a high potential for abuse.

Here to testify today are an emergency room physician, a hospital security provider and a highly experienced agent from BCI.

error was noticed in the designation of the Northland Association of Pharmacy Technicians, this was corrected at the same time as the fee adjustment.

It was moved by Pharmacist Thom and seconded by Pharmacist Haroldson to approve this as a non-substantive rules change, which will be forwarded directly to the Legislative Council for publication. All Board Members voted aye – the motion carried.

Article 61-13 Controlled Substances was discussed. Board Members reviewed the minutes of the Emergency Scheduling Meeting held on February 25, 2010 with it's summary of comments along with the April 24th, 2010 Rule Hearing. All comments received have been in favor of adopting the rule. There was one comment at the April 24th meeting, expressing concern that scheduling may prevent research into the medical uses of these substances. It was explained at that time to the individual expressing the concern that scheduling did not impede research into the medical uses of these substances, but did require that procedures would have to be in place to request authorization from the Board of Pharmacy to do the research and to furnish the research protocols and the institutional review Board before getting authorization from the Board of Pharmacy to do research with these substances.

It was moved by Pharmacist Dewhirst and seconded by Pharmacist Detwiller to approve Article 61-13 Controlled Substances as presented at the Rule Hearing, contingent upon approval from the Attorney General's Office. On a vote by Roll Call: Pharmacist Detwiller – Aye Pharmacist Dewhirst – Aye Pharmacist Haroldson – Aye Pharmacist Thom – Aye Pharmacist Ziegler – A Nays none – the motion carried.



OFFICE OF ATTORNEY GENERAL

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JUL 1 9 2010

OPINION

July 16, 2010

Howard C. Anderson, Jr., R.Ph. Executive Director North Dakota Board of Pharmacy 1906 E Broadway Ave Bismarck, ND 58501-4700

Dear Dr. Anderson:

The Office of Attorney General has examined the proposed new N.D.A.C. art. 61-13 concerning controlled substances, along with the notice of the proposed rules, the publication of that notice, and the filing of that notice with the Legislative Council. This office has also determined that 1) a written record of the agency's consideration of any comments to the proposed rules was made, 2) a regulatory analysis was not issued or requested, 3) a takings assessment was not prepared, 4) a small entity regulatory analysis and an economic impact statement were prepared, and 5) the proposed rules are within the agency's statutory authority.

When reviewing administrative rules, I may not approve any rule as to legality when the rule is written in a manner that is not concise or easily understandable. Proposed new N.D.A.C. § 61-13-01-02 makes references to chapter 19-03.1 and chapter 43-15 without noting that those chapters are to the North Dakota Century Code. While it is my opinion that this omission did not make the rules promulgation process misleading to the public because it would be understood in context that the references are to the North Dakota Century Code, I recommend for clarity that this rule be amended by adding the phrase "of the North Dakota Century Code" at the end of the sentence.

Subject to the above, these administrative rules are in compliance with N.D.C.C. ch. 28-32 and are hereby approved as to their legality. Upon final adoption, these rules may be filed with the Legislative Council.

Sincerely

Wayne Stenehjem Attorney General

cc: John Walstad, Legislative Council

¹ N.D.C.C. § 28-32-14.

Mephedrone

From Wikipedia, the free encyclopedia

Mephedrone (2-methylamino-1-*p*-tolylpropan-1-one).^[3] also known as **4-methylmethcathinone** (**4-MMC**), **4-methylephedrone**, **meow meow**,^[4] **Miaow**,^[5] or **MMCAT**, is a stimulant and entactogen drug of the phenethylamine, amphetamine, and cathinone chemical classes. It is reported to be contained in some legal highs and is sometimes sold mixed with methylone, also known as **Bubbles**.^[7]

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- 2 History
- 3 Effects
 - 3.1 Intended effects
 - 3.2 Side effects
 - 3.3 Long-term effects
- 4 Typical usage and consumption
- 5 Toxicity
 - 5.1 Deaths
- 6 Legal status
- 7 See also
- 8 References
- 9 External links

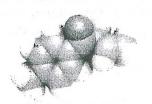
Appearance

Mephedrone is most commonly sold as a white powder or crystal form or capsules containing the powder.^[8] It can also be found in pill form.

History

The Psychonaut Research Project, an EU organisation that searches the internet for information regarding new drugs, first identified mephedrone in 2008. Their research suggests that the drug first became available in 2007. [6] Mephedrone was first seized in France in May 2007 after police sent a tablet that they assumed to be ecstacy to be analysed. [8] The drug was used in early products, such as Neodoves pills, by the legal high company Neorganics, but the range was discontinued in January 2008 after the government of Israel, where the company is based, made mephedrone illegal. It has been reported to be sold as a designer drug, [9] but little is known about its pharmacology or toxicology as of yet. Mephedrone has recently been reported as having been sold as "ecstasy" in the Australian city of Cairns, along with ethylcathinone. [10][11][12] and

Mephedrone



Systematic (IUPAC) name

(RS)-1-(4-methylphenyl)-2-methylaminopropan-1-one

Identifiers

CAS number 1189805-46-6

1189726-22-4 (HCI)

ATC code none

PubChem 29982893

ChemSpider 21485694

Chemical data

Formula C₁₁H₁₅NO

Mol. mass 177.242 g/mol

Synonyms 4-methyl-*N*-methylcathinone

Pharmacokinetic data

Bioavailability ?

Metabolism ?

Half life ?

Excretion ?

Therapeutic considerations

Pregnancy cat. 5

Legal status Illegal in Australia, Germany, Ist

Norway, Estonia and Sweden[1]

Routes Oral, insufflated, intravenous^[2]

Mephedrone

From Wikipedia, the free encyclopedia (Redirected from Mephadrone)

Mephedrone, also known as 4-methylmethcathinone (4-MMC), or 4-methylephedrone, is a synthetic stimulant and entactogen drug of the amphetamine and cathinone classes. Slang names include meph, [4] drone [5] and MCAT. [6] It is reportedly manufactured in China and is chemically based on the cathinone compounds found in the khat plant of eastern Africa. It comes in the form of tablets or a powder, which users can swallow, snort or inject, producing similar effects to MDMA, amphetamines and cocaine.

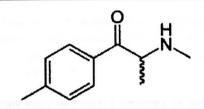
As well as producing the intended stimulant effects, negative side effects occur when mephedrone is used, with teeth grinding being the most common. The metabolism of mephedrone has been studied in rats and humans, with the metabolites being able to be detected in urine after usage. Nothing is known about the potential neurotoxicity of mephedrone, but scientists have suggested possible dangers associated with its use based on its similarity to other drugs. Several people have died after consuming mephedrone, but some deaths that the media attributed to the drug were later determined to have been caused by other factors.

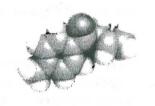
Mephedrone was first synthesised in 1929 but did not become widely known until it was rediscovered in 2003. By 2007 mephedrone was reported to be available for sale on the internet, by 2008 law enforcement agencies had become aware of the compound and by 2010 it had been reported in most of Europe, being particularly prevalent in the United Kingdom. Mephedrone was first made illegal in Israel in 2008, followed by Sweden later that year. In 2010 it was made illegal in many European countries, but remains legal in others. In Australia, New Zealand, the USA and Canada it is considered illegal as an analog of other illegal drugs and is controlled by laws similar to the Federal Analog Act.

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- 4 Pharmacology
 - 4.1 Metabolism
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 - 4.2.1 Deaths
 - 4.2.1.1 Sweden
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 - 4.2.1.3 USA
- 5 Chemistry
 - 5.1 Appearance
 - 5.2 Synthesis

Mephedrone





Systematic (IUPAC) name

(RS)-2-methylamino-1-(4-methylphenyl)propan-1-one^{[1]:5}

Identifiers

CAS number 1189805-46-6

1189726-22-4 (HCl)[1]:5

ATC code None

PubChem CID 29982893

ChemSpider 21485694r

Chemical data

Formula C₁₁H₁₅NO

Mol. mass 177.242 g/mol

Synonyms 4-methyl-N-methylcathinone; 2-

methylamino-1-p-tolylpropan-1-one

[2]

Therapeutic considerations

Pregnancy

cat.

Legal status See legal status section

Routes Oral, Insufflation, IV, rectal^[3]

- 6 Legal status
- 7 See also
- 8 References
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History

According to the European Monitoring Centre for Drugs and Drug Addiction, the synthesis of mephedrone was first reported in 1929 by Saem de Burnaga Sanchez in the Bulletin de la Société Chimique de France, under the name "toluylalpha-monomethylaminoethylcetone". [7][1]:17 but the compound remained an obscure product of academia until 2003, when it was "re-discovered" and publicised by an underground chemist on The Hive website, working under the pseudonym "Kinetic." [8] Kinetic posted on the site, "I've been bored over the last couple of days and had a few fun reagents lying around, so I thought I'd try and make some 1-(4-methylphenyl)-2-methylaminopropanone hydrochloride, or 4methylmethcathinone." before going on to describe that after taking it he had a "fantastic sense of well-being that I haven't got from any drug before except my beloved Ecstasy." [9] A drug similar to mephedrone, containing cathinones was sold in Israel from around 2004, under the name hagigat. When this was made illegal, the chemicals were modified so that they were no longer illegal. [10] The Psychonaut Research Project, an EU organisation that searches the internet for information regarding new drugs, first identified mephedrone in 2008. Their research suggests that the drug first became available to purchase on the internet in 2007.[11] Mephedrone was first seized in France in May 2007 after police sent a tablet that they assumed to be ecstasy to be analysed. [12] The drug was used in early products, such as Neodoves pills, by the legal high company Neorganics, [13][14] but the range was discontinued in January 2008 after the government of Israel, where the company is based, made mephedrone illegal.^[5] Mephedrone was reported as having been sold as ecstasy in the Australian city of Cairns, along with ethylcathinone in 2008. [15][16] Europol noted that they became aware of it in 2008, after it was found in Denmark, Finland and the UK.^[17] The Drug Enforcement Agency noted it was present in the United States in July 2009. [18] By May 2010, mephedrone had been detected in every one of the 22 EU member states that reported to Europol, as well as in Croatia and Norway.^{[1]:21} It was reportedly manufactured in China, but it has since been made illegal there.^[19] In March 2009, *Druglink* magazine reported that it only cost a "couple hundred pounds" to synthesise a kilogram of mephedrone. [10] The Daily Telegraph reported that manufacturers were making "huge amounts of money" from selling the drug. [20] In January 2010 Druglink magazine reported that dealers in Britain spent £2,500 to ship one kilogram from China but could sell it for £10 a gram making a profit of £7,500. [9][21] A later report, in March 2010, stated that the wholesale price of mephedrone was £4000 per kilogram.[22]

In the United Kingdom

Between the summer of 2009 and March 2010 the use of mephedrone grew rapidly in the UK, with it being readily available at music festivals, head shops and on the internet.^[24] A survey of *Mixmag* readers in 2009, found that it was the fourth most popular street drug in the United Kingdom, behind cannabis, cocaine, and ecstasy. [22] The drug is used by a diverse range of social groups. Whilst the evidence is anecdotal, researchers, charity workers, teachers and users have reported widespread and increasing use of the drug. The drug's rapid growth in popularity was believed to be related to both its availability and legality. [24] Fiona Measham, a criminologist at The University of Lancaster, believes that the emergence of mephedrone was also related to the decreasing purity of ecstasy and cocaine on sale in the UK. [24] The average cocaine purity fell from 60% in 1999 to 22% in 2009 and about half of ecstasy pills seized in 2009 contained no MDMA, [25] and by June 2010, almost all pills seized in the UK, contained no MDMA. [26] A similar pattern was observed in the Netherlands, with the number of ecstacy tablets containing no MDMA rising from 10% in mid 2008 to 60% by mid 2009 and with mephedrone being detected in 20% of ecstacy tablets by mid 2009. [27] The decrease of MDMA was thought in part, to be due to the seizure of 33 tonnes of sassafras oil, the precursor to MDMA, in



The number of samples analysed by the Forensic Science Service of seized MDMA, piperazines and cathinones between the third quarter of 2005 and the first quarter of 2010. MDMA seizures in blue, piperazine seizures in orange and cathinone seizures in purple^[23]

Cambodia in June 2008, which could have been used to make 245 million doses of MDMA.^[9] According to John Ramsey, a toxicologist at St George's University London, the emergence of mephedrone was also related to the UK government banning the benzylpiperazine class of drugs.^[10] Mephedrone was available on at least 31 websites based in the UK in

December 2009; by March 2010 there were at least 78 online shops, half of which sold amounts of less than 200 grams and half that also sold bulk quantities. The price per gram varied from £9.50 to £14.^[1]:11 Between July 2009 and February 2010, UK health professionals accessed the National Poisons Information Service's entry on mephedrone 1664 times and made 157 telephone enquiries; the requests increased month on month over this period. In comparison over a similar time period, the entries for cocaine and MDMA were accessed approximately 2400 times. ^[28]

Media organisations including the BBC and *The Guardian*, as well as a news section in the *Annals of Botany*, ^[29] incorrectly reported that mephedrone was commonly used as a plant fertiliser. In fact sellers of the drug described it as "plant food" because it was illegal to sell the compound for human consumption. ^[25] In late 2009, UK newspapers began referring to the drug as **meow** or **miaow** (sometimes doubled as **meow meow** or **miaow** miaow), a name that was almost unknown on the street at the time. ^[30] In November 2009, the tabloid newspaper, *The Sun* published a story stating that a man had ripped off his own scrotum whilst using mephedrone, ^[31] but this story was later shown to be an online hoax. ^[32] The Advisory Council on the Misuse of Drugs (ACMD) have suggested that the media coverage of the drug lead to increased usage of it. ^[33]

A survey of 1000 secondary school pupils and university students in Tayside, conducted in February 2010, found that 20% of them had previously taken mephedrone. Although at the time it was available legally over the internet, only 10% of users reported purchasing it online, with most purchasing it from street dealers. Of those who had used mephedrone, 97% said that it was easy or very easy to obtain. Around 50% of users reported at least one negative effect associated with the use of mephedrone, with teeth grinding being the most common. [34]

On 30 March 2010, Alan Johnson, then the Home Secretary, announced that mephedrone would be made illegal "within weeks" after the ACMD sent him a report on the use of cathinones. [35][36] Prior to the ban being announced, Dr Polly Taylor, a member of the ACMD resigned, saying she "did not have trust" in the way the government would use the advice given by the ACMD. [37] Eric Carlin, a member of the ACMD and former chairman of the English Drug Education Forum, also resigned after the announcement that mephedrone would be made illegal. He said that the decision by the Home Secretary was "unduly based on media and political pressure" and there was "little or no discussion about how our recommendation to classify this drug would be likely to impact on young people's behaviour."[38] Some ex-members of the ACMD, and various charity groups have expressed concern regarding the banning of the drug, arguing it will inevitably criminalise users, particularly young people. [39] Others have expressed concern that the drug will now be left in the hands of black market dealers, who will only compound the problem. [40] The ACMD had run into problems with the UK Government in 2009 regarding drugs policy, after the government did not follow the advice of the ACMD to reclassify MDMA and cannabis, culminating in the dismissal of the ACMD chairman, David Nutt after he reiterated the ACMD's findings in an academic lecture. [41] Eric Carlin's resignation was specifically linked to the criminalisation of mephedrone, and he stated: "We need to review our entire approach to drugs, dumping the idea that legally-sanctioned punishments for drug users should constitute a main part of the armoury in helping to solve our country's drug problems. We need to stop harming people who need help and support". [42] An editorial in the April 2010 edition of The Lancet questioned the decision to ban mephedrone, saying that the ACMD did not have enough evidence to judge the potential harms caused by mephedrone and arguing that policy makers should have sought to understand why young people took it and how they can be influenced to not take it. [33] In Chemistry World, John Mann professor of chemistry at Queen's University Belfast, suggested that the UK create a law similar to the Federal Analog Act of the United States, which would have made mephedrone illegal as an analog of cathinone. [43] In August 2010, James Brokenshire, the Home Office drugs minister, announced plans to create a new category in the Misuse of Drugs Act 1971 that would allow new legal highs to be made temporarily illegal, without the need for a vote in parliament, as was required to categorise mephedrone.^[44]

According to the Independent Scientific Committee on Drugs, since mephedrone was made illegal a street trade in the drug has emerged, with prices around double that of before the ban, at £20-£25 per gram. [45] In September 2010, *Druglink* reported that the ban had had a mixed effect on mephedrone use, with it decreasing in some areas, remaining similar in others and becoming more prevalent in some areas. [46] Other supposedly legal drugs have also filled the gap in the market since mephedrone was made illegal, including naphyrone (NRG-1) (since made illegal)^[47] and Ivory Wave, which has been found to contain MDPV, a compound made illegal at the same time as mephedrone. However it is possible that some products branded as Ivory Wave do not contain MDPV. [48] When tested, some products sold six weeks after mephedrone was banned, advertised as NRG-1, NRG-2 and MDAI were found to be mephedrone. [49]

Effects

There have been no formal published studies into the effects of mephedrone psychological and behavioural effects of

mephedrone on humans, nor on animals from which the potential effects could be extrapolated. As a result the only information available comes from users themselves and clinical reports of acute mephedrone toxicity. [1]:12 Psychologists at Liverpool John Moores University were to conduct research into the effects of mephedrone on up to 50 students already using the drug, when it was still legal in the UK. [50] At the time the study was proposed, Les Iversen, the chair of the Advisory Council on the Misuse of Drugs called the experiments "pretty unethical". [51] The study was discontinued in August 2010, following the change in the legal status of the drug. [52]

Intended effects

Users have reported that mephedrone causes euphoria, stimulation, an enhanced appreciation for music, an elevated mood, decreased hostility, improved mental function and mild sexual stimulation; these effects are similar to the effects of cocaine, amphetamines and MDMA. These effects last different amounts of time, depending on the way the drug is taken. When taken orally, users report they can feel the effects within 15–45 minutes, when snorted the effects are felt within minutes. The effects last for between two and three hours when taken orally or nasally, but only half an hour if taken intravenously. ^[1] Out of 70 Dutch users of mephedrone, 58 described it as an overall pleasant experience and 12 described it as being an unpleasant experience. ^[27] A survey of UK users, who had previously taken cocaine, found that most users found it produced a better quality and longer lasting high, was less addictive and carried the same risk as using cocaine. ^[3]

Side effects

According to drugs counsellors on Teesside, UK, mephedrone can cause hallucinations, nausea, vomiting, blood circulation problems, rashes, anxiety, paranoia, fits and delusions. [53] According to the drugs advice charity, Crew2000, other side effects may include poor concentration, poor short-term memory, increased heart rate, abnormal heart beats, anxiety, depression, increased sweating, dilated pupils, the inability to normally open the mouth, and teeth grinding. [54] When snorted it can also cause nose bleeds and nose burns. [53] A survey conducted by the National Addiction Centre, UK found that 51% of mephedrone users said they suffered from headaches, 43% from heart palpitations, 27% from nausea and 15% from cold or blue fingers, [55] indicative of vasoconstriction occurring. [28] Doctors at Guy's Hospital, London reported that of 15 patients they treated after taking mephedrone in 2009, 53.3% were agitated, 40% tachycardic, 20% had systolic hypertension and 20% had seizures; three required treatment with benzodiazepines, predominantly to control their agitation. They reported that none of their patients suffered from cold or blue peripheries, contrary to other reports. Nine out of the 15 of patients had a Glasgow Coma Scale (GCS) of 15 or above, 4 had a GCS below 8, but these patients all reported using a central nervous system depressant, most commonly GHB, with mephedrone. The patients also reported polydrug use of a variety of compounds. [56]

Long-term effects

Almost nothing is known about the long-term effects of the drug due to the short history of its use. [55] BBC News reported that one person who used the drug for 18 months became dependent on the drug, in the end using it twice a week, had to be admitted to a psychiatric unit after he started experiencing hallucinations, agitation, excitability and mania. [57][1]:13 Because of its similarity to cathinone, John Mann, has posited that mephedrone may cause impotence with long-term use. [58]

Typical use and consumption

Mephedrone can come in the form of capsules, tablets or white powder that users may swallow, snort or inject. [59] It is sometimes sold mixed with methylone in a product called **bubbles** in the UK [60] and also mixed with other cathinones including ethcathinone, butylone, fluoromethcathinone and methedrone. [1]:9 *The Guardian* reported that some users compulsively redose, consuming their whole supply when they are only meant to use a small dose [61] and there have been other similar reports of users craving mephedrone, suggesting that it may be addictive. [27][1]:13 A survey conducted in late 2009 by the National Addiction Centre (UK) found 41.3% of readers of *Mixmag* had used mephedrone in the last month, making it the fourth most popular drug amongst clubbers. Of those, two thirds snorted the drug and the average dosage per session was 0.9g; the length of sessions increased as the dosage increased. Users who snorted the drug reported using more per session than those who took it orally (0.97 g compared to 0.74 g) and also reported using it more often (5 days per month compared to 3 days per month). [3] An Irish study of people on a methadone treatment program for heroin addicts found that 29 out of 209 patients tested positive for mephedrone usage. [62]

Harm reduction

See also: Responsible drug use

The drugs advice charity Lifeline recommends that to reduce the potential harm caused by using mephedrone, users should only use mephedrone occasionally (less than weekly), use less than 0.5g per session, dose orally rather than snorting the drug and avoid mixing it with alcohol and other drugs. Users should also drink plenty of water whilst taking the drug as it causes dehydration.^[4]

Pharmacology

Writing in the *British Medical Journal*, psychiatrists stated that given its chemical structure, "mephedrone is likely to stimulate the release of, and then inhibit the reuptake of monoamine neurotransmitters".^[63] Professor David Nutt, former chair of the Advisory Council on the Misuse of Drugs (ACMD) in the UK has said "people are better off taking ecstasy or amphetamines than those [drugs] we know nothing about" and "Who knows what's in [mephedrone] when you buy it? We don't have a testing system. It could be very dangerous, we just don't know. These chemicals have never been put into animals, let alone humans."^[64] Les King, a former member of the ACMD, has stated that mephedrone appears to be less potent than amphetamine and ecstasy but that any benefit associated with this could be negated by users taking larger amounts. He also told the BBC "all we can say is [mephedrone] is probably as harmful as ecstasy and amphetamines and wait until we have some better scientific evidence to support that."^[65] Molecular modelling of mephedrone suggests it is more hydrophilic than methyl-amphetamines which may account for the higher doses required to achieve a similar effect, because mephedrone is less able to cross the blood-brain barrier.^{[1]:12[66]}

Metabolism

Based on the analysis of rat and human urine by gas chromatography and mass spectrometry, mephedrone is thought to be metabolised by three phase I pathways. It can be demethylated to the primary amine (producing compounds 2, 3 and 4) the ketone group can be reduced (producing 3) or the tolyl group can be oxidised (producing 5 and 6). It is thought that 5 and 6 are further metabolised by conjugation to the glucuronide and sulfate derivatives. Knowledge of the primary routes of metabolism should allow the intake of mephedrone to be confirmed by drug tests, as well as more accurate determination of the cause of side effects and potential for toxicity. [67]

Proposed scheme for the metabolism of mephedrone (1) based on the analysis of rat and human urine. [67]

Toxicity

As of March 2010, there have been no reported studies on the potential neurotoxicity of mephedrone^[63] nor is the median

lethal dose known.^[3] In 2009, one case of sympathomimetic toxicity was reported in the UK after a person took 0.2 g of mephedrone orally and 3.8 g subcutaneously. The patient was treated with 1 mg of lorazepam and the sympathomimetic features decreased within 6 hours of treatment.^[68] The Swedish medical journal *Läkartidningen* reported that mephedrone could theoretically cause the cardiovascular problems associated with the use of cocaine and amphetamines and serotonin syndrome associated with the use of ecstasy and LSD.^[69] Both enantiomers of methcathinone, which differs only in the lack of the methyl group on the aryl ring when compared to mephedrone, have been shown to be toxic to rat dopamine neurons, and the S-enantiomer was also toxic against serotonin neurons. Simon Gibbons and Mire Zloh of The School of Pharmacy, University of London stated that based on the chemical similarities between methcathinone and mephedrone, "it is highly likely that mephedrone will display neurotoxicity".^[66] However, Brunt and colleagues stated that "extreme caution" should be used when inferring the toxicity of mephedrone from methcathinone, noting that some of the toxicity associated with methcathinone is due to managanese impurities related to its synthesis, rather than the compound itself. They concluded that experimental research is needed to investigate the toxicity of mephedrone.^[27]

Deaths

Sweden

In 2008, an 18-year-old Swedish woman died in Stockholm after taking mephedrone allegedly in combination with cannabis. *Svenska Dagbladet* reported that the woman went into convulsions and turned blue in the face. ^[70] Doctors reported that she was comatose and suffering from hyponatremia and severe hypokalemia; the woman died one and a half days after the onset of symptoms. An autopsy showed severe brain swelling. ^[69] Mephedrone was scheduled to be classified as a "dangerous substance" in Sweden even before the girl's death at Karolinska University Hospital on Sunday, 14 December, but the death brought more media attention to the drug. The possession of mephedrone became classified as a criminal offence in Sweden on 15 December 2008. ^[70]

UK

In 2010, there were unconfirmed reports speculating about the role mephedrone has played in the deaths of several young people in the UK. ^[71] By July 2010, mephedrone had been alleged to be involved in 52 fatalities in the UK, but detected in only 38 of these cases. Of the nine that coroners had finished investigating, two were caused directly by mephedrone. ^[72] The first death reported to be caused by mephedrone use was that of 46 year old, Stirling Smith, who had underlying health problems and repeatedly injected the drug. ^[73] A report in *Forensic Science International* in August 2010 stated that mephedrone intoxication has been recorded as the cause of death in two cases in Scotland. Post mortem samples showed the concentration of mephedrone in their blood was 22 mg/L in one case and 3.3 mg/L in the other. ^[74] The death of a teenager in the UK in November 2009 was widely reported as being caused by mephedrone, but a report by the coroner concluded that she died from natural causes. ^[75] Toxicology reports following the deaths of two teenagers (Louis Wainwright, 18, and Nicholas Smith, 19) that were widely reported by the media to be caused by mephedrone, and which led to a ban on the substance in April 2010, showed that the teenagers had in fact not taken any mephedrone. ^[73] According to Fiona Measham, a criminologist who is a member of the ACMD, the reporting of the unconfirmed deaths by newspapers followed "the usual cycle of 'exaggeration, distortion, inaccuracy and sensationalism'" associated with the reporting of recreational drug use. ^[24]

USA

Mephedrone has been implicated in the death of a 22 year old male, who had also injected black tar heroin. Mephedrone was found in his blood at a concentration of 0.50 mg/L and in his urine at a concentration of 198 mg/L. The blood concentration of morphine, a metabolite of heroin, was 0.06 mg/L. [76] For comparison, the average blood morphine concentration resulting from deadly overdoses involving only heroin is around 0.34 mg/L. [77]. In October 2010, police in Raleigh, North Carolina reported that two men found dead on a fire escape appeared to have been taking mephedrone. [78]

Chemistry

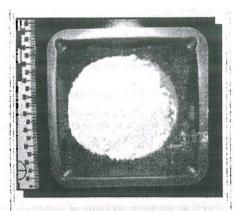
Appearance

Mephedrone is a white substance. It is sold most commonly as crystals or a powder, but also in the form of capsules or pills. [12][65] It can have a distinctive odour, reported to range from a synthetic fishy smell [79] to the smell of vanilla and bleach, stale urine, electric circuit

boards.[80]

Synthesis

Mephedrone can be synthesised in several ways. The simplest method, due to the availability of the compounds, [1]:17 is to add 4-methylpropiophenone dissolved in glacial acetic acid to bromine to create an oil fraction of 4'-methyl-2-bromopropiophenone. This is then dissolved in CH₂Cl₂ and drops of the solution are added to another solution of CH₂Cl₂ containing methylamine hydrochloride and triethylamine. Hydrochloric acid is then added and the aqueous layer is removed and turned alkaline using sodium hydroxide before the amine is extracted using CH₂Cl₂. The CH₂Cl₂ is then evaporated using a vacuum, creating an oil which is then dissolved in a non-aqueous ether. HCl gas is then bubbled through the mixture to produce 4-methylmethcathinone hydrochloride. [13] This method produces a mixture of both enantiomers and requires similar knowledge to that required to synthesise amphetamines and MDMA. [1]:17



A sample of mephedrone that was confiscated in Oregon, USA, 2009

It can also be produced by oxidising the ephedrine analogue (4-methylephedrine) using potassium permanganate dissolved in sulfuric acid. Because 4-methylephedrine can be obtained in a specific enantiomeric form it is possible to produce mephedrone consisting of only one enantiomer. There is a danger associated with this method as it may cause manganese poisoning if the product is not correctly purified. [1]:17

Legal status

When mephedrone was rediscovered in 2003, it was not specifically illegal to possess in any country, as its use has increased many countries have passed legislation making the possession, sale and manufacturing of mephedrone illegal. It was first made illegal in Israel, where it had been found in products such as Neodoves pills, in January 2008. [5] After the death of a young woman in Sweden in December 2008 was linked to the use of mephedrone, it was classified as a hazardous substance a few days later, making it illegal to sell in Sweden. In June 2009, it was classified as a narcotic with the possession of 15 grams or more resulting in a minimum of two years in prison - a longer sentence, gram for gram than given for the possession of cocaine or heroin. [81][82] In December 2008, Denmark also made it illegal [83] and through the Medicines Act of Finland it was made illegal to possess without a prescription. [84] In November 2009, it was classified as a "narcotic or psychotropic" substance and added to the list of controlled substances in Estonia [85] and made illegal to import into Guernsey along with other legal highs, [86] before



Map of Europe showing countries where mephedrone is illegal, correct as of August 2010

being classified as a Class B drug in April 2010.^[87] It was classified as a Class C drug in Jersey in December 2009.^[88]

In 2010, as its use became more prevalent, many countries passed legislation prohibiting mephedrone. It became illegal in Croatia^[89] and Germany^[90] in January, followed by Romania^[91] and the Isle of Man in February.^[92] In March 2010, it was classified as an unregulated medicine in the Netherlands, making the sale and distribution of it illegal.^{[53][93]} On 30 March 2010, the ACMD in the UK published a report on mephedrone and recommended it being classified as a Class B drug. On 7 April 2010 the Misuse of Drugs Act 1971 (Amendment) Order 2010 was passed by parliament, making mephedrone and other substituted cathinones Class B drugs from 16 April 2010.^{[94][95]} Prior to the ban taking effect, mephedrone was not covered by the Misuse of Drugs Act 1971.^[19] It was however an offence under the Medicines Act to sell it for human consumption, so it was often sold as "plant food" or "bath salts" although, as it has no use as such products, this too was

possibly illegal under the Trade Descriptions Act 1968.^{[53][36][55]} The importation of mephedrone into the UK was banned on 29 March 2010.^[96] In May 2010 the Republic of Ireland made it illegal,^{[93][97][98]} followed by Belgium,^[99] France,^[100] Italy,^[101] Lithuania^[102] and Norway^[103] in June. In August 2010, Austria^[104] and Poland^[105] made mephedrone illegal and China announced that it would be illegal as of 1 September 2010.^[106]

In some countries, mephedrone is not specifically listed as illegal but is controlled under legislation that makes compounds illegal if they are analogs of drugs already listed. In Australia it is not specifically listed as prohibited, [13] but Federal Police have stated that it is an analogue to methcathinone and therefore illegal. In February 2010, 22 men were arrested in conjunction with importing mephedrone. [107] Similarly in New Zealand it is not included in the Misuse of Drugs Act 1975, [108] but is illegal as it similar to controlled substances. [109] In Canada, mephedrone is not explicitly listed in any Schedule of the Controlled Drugs and Substances Act, "amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues" are included in Section I of Schedule III of the act. Cathinone and methcathinone are listed in separate sections of Schedule III while diethylpropion and pyrovalerone (also cathinones), are listed in separate sections of Schedule IV, each without language to capture analogues, isomers, etc. [110] According to *The Globe and Mail*, mephedrone is considered a controlled substance by Health Canada. [111] According to the Canadian Medical Association, mephedrone is grouped with other amphetamines as Schedule III controlled substances. [112] There have been several media reports of the Canadian police seizing mephedrone. [113][114][115] Mephedrone is also unscheduled in the United States [116] but has been made illegal in North Dakota. [117] Those selling the drug for human consumption may however, be prosecuted under the Federal Analog Act due to its similarity to methcathinone. [118]

As of April 2010 mephedrone is legal in Singapore, ^[119] in February 2010, 'CNN Go' reported that it was ordered over the internet and exported from the UK. ^[120] In August 2010, a government advisory body in Hungary recommended that mephedrone be made illegal, but it has yet to be controlled by parliament. ^[121] As of August 2010, mephedrone is still legal in Switzerland. ^[122]

See also

- 4-Methylamphetamine
- 4-Methylthioamphetamine
- Methamphetamine
- para-Methoxyamphetamine

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- 30. ^ Private Eye, "Street of Shame", No. 1259, 2-15 April 2010, p. 6: Way back in January 2009, not long after mephedrone first began to be sold online, members of the web forum attached to the now-defunct "headshop" Champagne Legals discussed what brand name they might attach to the new product, which has the chemical identity dimethylmethcathinone or MM-Cat. "What shall we call this drug? It's called MM-CAT, so why not Miaow?" suggested one. The name did not catch on ... But on 1 November 2009, someone did add the name "Meow" to the Wikipedia entry for Mephedrone at the head of a list of "street names." Three weeks later ... the Sun declared the arrival of a "new party favourite called 'meow meow" and the world went cat-call crazy. Among a host of recent headlines the Sunday Times has reported on "the rise of Meow", the Times has heralded "Meow Meow arrests", the Sun shrieked about a "Harman snub for Meow Meow Ban" and the Daily Telegraph took a long hard look at the "Meow Meow Menace in Europe." "No one ever called it Meow seriously till the papers picked up on the Wikipedia entry," one drugs expert tells the Eye.
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External links

- Erowid 4-Methylmethcathinone Vault
- Mephedrone Frequently asked questions www.lifeline.org.uk
- Guardian Daily Podcast: How dangerous is mephedrone?
- Mephedrone: A Musical Movement Or The Latest Fad?

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Categories: Drugs not assigned an ATC code | Dopamine agonists | Serotonin receptor agonists | Cathinones | Drugs acting on the nervous system | Drugs acting on the cardiovascular system | Euphoriants | Phenethylamines | Sympathomimetic amines

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Methylenedioxypyrovalerone

From Wikipedia, the free encyclopedia

Methylenedioxypyrovalerone (MDPV) is a psychoactive drug with stimulant properties which acts as a norepinephrine-dopamine reuptake inhibitor (NDRI). Reportedly, it has four times the potency of methylphenidate (Ritalin, Concerta).^[1] MDPV has no history of FDA approved medical use but has been sold since around 2007 as a research chemical.^[2]

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Appearance

The substance appears as a pure white to light-brown, significantly hydrophilic crumbly powder with a slight odour. It appears to darken slightly in colour and take on a potato-tuber-like odor if exposed to air for any significant length of time. In some of the first batches that appeared on the research chemical market, an impurity was identified and said to consist of pyrrolidine, which could account for its earthy odour when left uncapped. It has also been observed to rapidly degrade and lose potency when in solution.

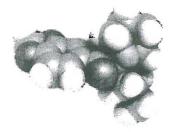
Effects

MDPV acts as a stimulant. The acute effects may include:

- physical: rapid heartbeat, increase in blood pressure, vasoconstriction, sweating
- mental: increases in alertness & awareness, increased wakefulness and arousal, anxiety, agitation, perception of a diminished requirement for food and sleep.

The effects have a duration of roughly 3 to 4 hours, with after effects such as tachycardia, hypertension,

Methylenedioxypyrovalerone



Systematic (IUPAC) name

(RS)-1-(benzo[d][1,3]dioxol-5-yl)-2-(pyrrolidin-1-yl)pentan-1-one

Identifiers

CAS number 687603-66-3

24622-62-6 (HCl)

ATC code

PubChem CID 20111961

Chemical data

Formula $C_{16}H_{21}NO_3$

Mol. mass 275.35 g/mol

Pharmacokinetic data

and mild stimulation lasting from 6 to 8 hours. High doses have been observed to cause intense, prolonged panic attacks in stimulant-intolerant users, and there are anecdotal reports of psychosis from sleep withdrawal and addiction at higher doses or more frequent dosing intervals. MDPV has been remarked about more than once for its powers as an aphrodisiac, which have been said to rival those of methamphetamine when dosed correctly. Users often report to feel compelled to continue redosing but then lose interest in taking it quickly because of the unpleasant side effects caused by higher doses.

Half-life	3 to 5 hours [citation needed]
T	herapeutic considerations
Pregnancy cat.	?
Legal status	Unscheduled (illegal in Denmark and Sweden)
Routes	Oral, Insufflation, Intravenous, Rectal, Vaporization

MDPV is the 3,4-methylenedioxy ring-substituted analogue of the anorectic or appetite suppressant pyrovalerone. However, despite its structural similarity, the effects of MDPV bear little resemblance to other methylenedioxyphenylalkylamine derivatives such as 3,4-methylenedioxy-*N*-methylamphetamine (MDMA), instead producing purely stimulant effects with no entactogenic qualities. Extended binges on MDPV have also been reported to produce severe comedown syndrome similar to that of methamphetamine, characterized by depression, lethargy, headache, anxiety, postural hypotension (lightheadedness and weakness of the muscles), and in some cases severely bloodshot eyes. Time is the solution for these symptoms, which usually subside within 4 to 8 hours. Abdominal pain consistent with kidney pain has also been reported when MDPV is used for extended periods of time.^[3] MDPV may also cause temporary trismus and/or bruxism. Side effects are highly dose-dependant.

Legality

In the UK, following the ACMD's report on cathinone derivatives^[4], MDPV is a Class B drug under the Misuse of Drugs Act 1971, making it illegal to sell, buy, or possess without a license. Penalties include a maximum of five years and/or unlimited fine for possession; Up to 14 years and/or unlimited fine for production or trafficking. See list of drugs illegal in the UK for more information.

MDPV is not specifically listed as a controlled substance in any other countries besides Finland, Denmark and Sweden. In Sweden a 33 year old man has been sentenced to 6 years in prison by an appellate court, Hovrätt, for possession of 250 grams of MDPV that had been acquired prior to criminalization.^[5]

Whilst it is not illegal in Australia(yet), it is currently being seized by Australian Customs and AQIS.

Other drugs with a similar chemical structure include α -pyrrolidinopropiophenone (α -PPP), which has a shorter alkyl chain and no ring substitution, pyrovalerone, which has a 4'-methyl group instead of a methylenedioxy ring, as well as analogues with between 3 and 6 carbons on the alkyl chain. ^[6]

These compounds have been reported as stimulants of abuse mainly in Germany and other European countries since the early 2000s, but they have remained generally vaguely known and rarely used illicitly or encountered by law enforcement.^[7]

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External links

- Pubchem similar compounds
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Inside Diversion Control

Drugs and Chemicals of Concern > 4-methylmethcathinone [Mephedrone, 4-MMC, meow meow, m-CAT, bounce, bubbles, mad cow]

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Drugs and Chemicals of Concern

4-methylmethcathinone
[Mephedrone, 4-MMC, meow meow, m-CAT, bounce, bubbles, mad cow]

July 2010 DEA/OD/ODE

Introduction

4-Methylmethcathinone (mephedrone) is a designer drug of the phenethylamine class and shares substantial structural similarities with methcathinone (Schedule I). Evidence of mephedrone use and associated toxicity has been increasing, in 2009 and 2010, particularly in the United Kingdom and other European countries. To date, one confirmed and several suspected deaths related to mephedrone have been reported by Europol-EMCDDA Joint report on mephedrone 2010. In recent years, law enforcement agencies have documented seizures (Oregon, Illinois and Alabama) associated with mephedrone in the United States.

Licit Uses

Mephedrone is not approved for medical use in the United States.

Chemistry

4-Methylmethcathinone Molecular Formula: C11H15NO

The core chemical structure of mephedrone identifies it as a phenethylamine, and is related in chemical structure to methcathinone differing only by a methyl group (CH3) on the ring. It is a solid at room temperature.

Pharmacology

Structure-activity relationship studies allow to predict that the pharmacology of mephedrone is similar to methcathinone as well as other substances of phenethylamine chemical class. The compounds having similar structure (e.g., methamphetamine, methylone, 3,4-methylenedioxymethamphetamine, cathinone and methcathinone) have been used to assess the pharmacological profile of mephedrone. This class of compounds is known to produce central nervous system stimulation, psychoactivity and hallucinations.

The adverse health effects caused by mephedrone are broadly similar to those seen with other stimulant drugs. Adverse effects produced by phenethylamines are increased heart rate, chest pain, agitation, irritability, dizziness, delusions, nose bleeding, nausea and vomiting. Consistent with the above discussion, mephedrone was reported to produce agitation, dilated pupils, increased heart rate and blood pressure in a 22-year-old man who used it for recreational purpose.

User Population

It is predominantly used by youth population (15-24 years), higher in males than females, from urban areas, who frequent clubs, discos and dance events (Europol-EMCDDA Joint report on Mephedrone, 2010).

Illicit Distribution

Mephedrone is sold over the internet and is promoted as a "research chemical", "bath salts" or "plant food."

Control Status

Mephedrone is not scheduled under Controlled Substance Act (CSA). However, it can be considered an analogue of methcathinone (schedule I substance) under the analogue provision of the CSA (Title 21 United States Code 813). Therefore, law enforcement cases involving mephedrone can be prosecuted under the Federal Analog Act of the CSA.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section, Fax 202-353-1263, Telephone 202-307-7183, or E-mail ODE@usdoj.gov.

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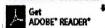




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Drugs and Chemicals of Concern

Spice Cannabinoid

- CP 47,497 and homologues 2-[(1R,3S)-3-hydroxycyclohexyl]-5-(2-methyloctan-2-yl)phenol)
- HU-210 [(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10, 10a-tetrahydrobenzo[c] chromen-1-ol)]
- (dexanabinol, (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl) -6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol)
- JWH-018 1-Pentyl-3-(1-naphthoyl)indole
- JWH-073 1-Butyl-3-(1-naphthoyl)indole

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