STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
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"Bath Salts": Report on Department's Findings
July 21, 2011

Multiple national reports document increasing abuse of a variety of synthetic compounds that produce stimulant effects when ingested. These synthetic stimulants, which are based on a variety of known compounds, such as "MDPV" (3, 4-methylenedioxypyrovalerone), mephedrone (4-methylmethcathinone), methylone (3,4-methylenedioxymethcathinone), 4 – Fluoromethcathinone (Flephedrone, 4-FMC), 3 – Fluoromethcathinone (3-FMC), 4 – Methoxymethcathinone (Methedrone, bk-PMMA, PMMC) are sold under the guise of "bath salts" or "plant food" in retail outlets and over the internet. They are marketed under names such as "Ivory Wave," "Purple Wave," "Vanilla Sky," and "Bliss." In addition to their psychoactive effects, they also have potentially harmful side effects when ingested. These products are not approved by the FDA for human consumption, and are not currently listed by the federal government on any schedule under the Controlled Substances Act (CSA).

Maryland's Department of Health and Mental Hygiene (DHMH) has monitored national data regarding "bath salts" abuse to identify trends and anticipate a possible emerging public health concern in Maryland. The following summarizes some recent national reports. Poison centers in the U.S. received 302 calls on "bath salts" and related products/drugs in all of 2010, but answered 1782 calls in the first four months of 2011. Many of the initial cases were concentrated in a few states such as Louisiana, Florida and Kentucky, but poison centers in 33 states, including Maryland, have seen and increasing number of calls. Users have developed tachycardia, hypertension, agitation, delirium, paranoia and psychosis. There have been several cases in which users have attempted to inflict injury on themselves or others. The agitation and delirium may persist for days. In Maryland, there has been one confirmed death associated with the ingestion of "bath salts" as of July 20, 2011. As a result, Maryland's Office of the Chief Medical Examiner has amended protocols with increased surveillance and testing for the ingestion of "bath salts" as appropriate, in determining cause of death. Maryland's Poison Center issued professional guidance to hospital emergency department staff alerting them to signs, symptoms, and management of individuals with intoxication from "bath salts."

Public Comment and Retail Assessment

In order to more fully assess the extent of abuse of "bath salts" and associated health consequences in Maryland, DHMH issued a notice on June 9, 2011, inviting public comment on "bath salts." The comment period, between June 10, 2011 and July 11, 2011, yielded 18 comments from family members, elected officials, physicians, and citizens. Most comments expressed strongly worded and very serious anecdotal reports of severe observed consequences resulting from the use of "bath salts". With the exception of the one comment which recommended a focus on obesity and alcohol instead of "bath salts," every other comment recommended that "bath salts" should not be legal in Maryland.

DHMH also contacted all of the State's 24 local health departments to conduct onsite surveys of various types of retail establishments to determine the availability of "bath salts" in Maryland. Over 400 locations were visited throughout Maryland, with three locations were found to sell "bath salts." "Bath salts" are available for sale on the internet.

Assessment

Section 5-202(b) of the Criminal Law Article provides authority for the Department of Health and Mental Hygiene (the "Department") to add substances to the schedules of controlled dangerous substance "[i]n accordance with the Administrative Procedure Act." Section 5-202(c) requires the Department to consider the following factors in determining whether to add a substance to one of the schedules:

1. **the actual or relative potential for abuse of the substance;**
2. **if known, scientific evidence of the pharmacological effect of the substance;**
3. **the state of current scientific knowledge regarding the substance;**
4. **the history and current pattern of abuse of the substance;**
5. **the scope, duration, and significance of abuse of the substance;**
6. **any risk that the substance poses to the public health;**
7. **the ability of the substance to cause psychological or physiological dependence;**
8. **and whether the substance is an immediate precursor of a controlled dangerous substance.**

The Department finds, for each factor, cause to issue an order to control these substances.

(1) **<u>The actual or relative potential for abuse of the substance</u>**

1) Michigan: 35 persons who had ingested, inhaled, or injected "bath salts" and visited a Michigan ED during November 13, 2010--March 31, 2011. Among the 35 patients, the most common signs and symptoms of toxicity were agitation (23 patients [66%]), tachycardia (22 [63%]), and delusions/hallucinations (14 [40%]). Seventeen patients were hospitalized, and one was dead upon arrival at the ED.[1]
2) "Mephedrone is of particular concern because, according to the United Kingdom experience, it presents a high risk for overdose. They can also confer a high risk for other medical adverse effects. Some of these may be linked to the fact that, beyond their known psychoactive ingredients, the contents of "bath salts" are largely unknown, which makes the practice of abusing them, by any route, that much more dangerous."[2]
3) Anecdotal reports from users state the presence of cravings.[3]

(2) **Scientific evidence of the pharmacological effect of the substance**

a) These substances are norepinephrine and dopamine reuptake inhibitors that produce amphetamine-like effects.[4]
b) "Doctors and clinicians at U.S. poison centers have indicated that ingesting or snorting "bath salts" containing synthetic stimulants can cause chest pains, increased blood pressure, increased heart rate, agitation, hallucinations, extreme paranoia, and delusions"[4] and delirium. "There have been several cases in which users have attempted to inflict injury on themselves or others. The agitation and delirium may persist for days and could require large doses of benzodiazepines.[2]
c) Higher doses of MDPV have caused intense, prolonged panic attacks in stimulant-intolerant users.[3]
d) The duration of the subjective effects is about 3 to 4 hours and the side effects continuing a total of 6 to 8 hours after administration.[3]
e) It has been demonstrated that MDPV administered to mice increased the extracellular levels of dopamine levels 60 min after administration of MDPV. Though MDPV increased dopamine levels, the effect was not as marked as the increases induced by methamphetamine or MDMA.[3]

(3) **The state of current scientific knowledge regarding the substance**

a) These products often contain various chemicals, such as methylenedioxypyrovalerone (MPDV), mephedrone and pyrovalerone, and cathinone.[4]
b) Methylenedioxypyrovalerone, or MDPV, is also not approved for medical use in the United States.
c) Methylenedioxypyrovalerone (MDPV) is a designer drug of the phenethylamine class. MDPV is structurally related to cathinone, an active alkaloid found in the khat plant, methamphetamine, and methylenedioxymethamphetamine (MDMA).[3]

(4) **The history and current pattern of abuse of the substance**

a) The use of "bath salts" first came to the attention of clinicians and the public in the USA in 2010.
b) Most of the cases presenting to emergency departments involve snorting the powder, but the drug can also be ingested, smoked or injected.[4]

c) It was first seized in Germany in 2007. The abuse of MDPV is increasing, particularly in Europe and Australia.[3]

d) MDPV and/or mephedrone have been banned in the following countries as of April 28, 2011: Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.[5]

e) On April 27, 2011, the Order of the Acting Director lists the following chemicals as Schedule I Controlled Dangerous Substances in New Jersey, supported by clinical and public health justifications for this order[5]:

   a. 3,4 – Methylenedioxypyrovalerone (MDPV)
   b. 4 – Methylmethcathinone (Mephedrone, 4-MMC)
   c. 3,4 – Methylenedioxymethcathinone (Methylone, MDMC)
   d. 4 – Fluoromethcathinone (Flephedrone, 4-FMC)
   e. 3 – Fluoromethcathinone (3-FMC)
   f. 4 – Methoxymethcathinone (Methedrone, bk-PMMA, PMMC)

f) In addition to New Jersey, 23 other states have banned "bath salts." Those states are: Alabama, Alaska, Florida, Idaho, Indiana, Kentucky, Louisiana, Michigan, Mississippi, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Texas, Utah, Virginia, Washington, West Virginia, and Wyoming.

(5) **<u>The scope, duration, and significance of abuse of the substance</u>**

- The Maryland Poison Control Center has reported 15 cases of "bath salts" ingestion with minor to major effects, treated by emergency rooms from January through June 2011.[6]
- The American Association of Poison Control Centers reports 303 calls to poison control centers about "bath salts" and related products/drugs in all of 2010. From January 1 to July 30, 2011, there were 3740 answered calls.[7]
- There has been one confirmed death in 2011 reported by the Maryland Office of the Chief Medical Examiner as an accidental death due to Methylenedioxypyrovalerone intoxication.

(6) **<u>Any risk that the substance poses to the public health</u>**

These substances are being misleadingly labeled and sold for household and garden uses, avoiding the intended effect of causing euphoria and other illicit drug-like effects. For example, "bath salts" are being sold over the internet and in convenience stores, gas stations, gift shops, tobacco stores and other local establishments under such brand names as

"Ivory Wave", "Vanilla Sky", "Red Dove", "Zoom", "Bloom", "Cloud Nine", "Blue Silk", "Ocean Snow", "White Lightening", "Scarface" and "Hurricane Charlie". The packages are labeled "bath salts" and "not for human consumption" but are being promoted and used as cocaine substitutes.

(7) **The ability of the substance to cause psychological or physiological dependence**

These agents "trigger intense cravings not unlike those experienced by methamphetamine users, and clinical reports from other countries appear to corroborate their addictiveness." [4]

(8) **Whether the substance is an immediate precursor of a controlled dangerous substance.**

a) MDPV is structurally related to cathinone, an active alkaloid found in the khat plant, methamphetamine, and methylenedioxymethamphetamine (MDMA).[3]
b) It is not an immediate precursor of a CDS.

Conclusion

Based on facts and data set forth in current literature, Maryland-specific surveillance data, input from health care professionals and the public, the Department makes the finding that "bath salts" pose a significant potential for abuse and immediate risk to public health in Maryland.

The Department therefore concludes that the following substances must be controlled as a controlled dangerous substances in Maryland:

A. 3,4 – Methylenedioxypyrovalerone (MDPV);
B. 4 – Methylmethcathinone (Mephedrone, 4-MMC);
C. 3,4 – Methylenedioxymethcathinone (Methylone, MDMC);
D. 4 – Fluoromethcathinone (Flephedrone, 4-FMC);
E. 3 – Fluoromethcathinone (3-FMC); and
F. 4 – Methoxymethcathinone (Methedrone, bk-PMMA, PMMC).

Footnotes:

1. Maryland Poison Control Center Reports sent directly to the ADAA, 2011.

2. "bath salts" (MDPV) from Toxic Tidbits, Maryland Poison Control Center, February 2011, http://www.mdpoison.com/publications/toxtidbit_pdf/2011/February%202011%20Toxtidbits.pdf

3. MMWR Morb Mortal Wkly Rep. 2011 May 20;60(19):624-7. Emergency department visits after use of a drug sold as "bath salts" --- michigan, november 13, 2010--march 31, 2011. Centers for Disease Control and Prevention (CDC)

4. Volkow, Nora. Message from the NIDA Director on "bath salts" - Emerging and Dangerous Products. http://www.nida.nih.gov/about/welcome/MessageBathSalts211.html, February 2011.

5. American Association of Poison Control Centers, "bath salts" Data Updated July 7, 2011 http://www.aapcc.org/dnn/Portals/0/Bath%20Salts%20Data%20for%20Website%207.07.2011.pdf

6. Methylenedioxypyrovalerone (MDPV) (Street Names: "bath salts", Ivory Wave, plant fertilizer, plant food, Vanilla Sky, Energy-1), US Department of Justice, Office of Diversion Control, Drug and Chemical Evaluation Section, March, 2011, http://www.deadiversion.usdoj.gov/drugs_concern/mdpv.pdf

7. Order of the Acting Director, Controlled Dangerous Substances, State of New Jersey, Department of Law and Safety, division of Consumer Affairs, April 27, 2011, http://www.njconsumeraffairs.gov/bathsalts/