CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Board of Pharmacy

Regulation/Package Title: Controlled Substance Schedules – Synthetic Drugs

Rule Number(s): 4729-11-01; 4729-11-02

Date: 12/5/13

Rule Type:

- ☐ **New**

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   The two proposed rules, 4729-11-01 and 4729-11-02, would classify the chemical compounds PB-22 and 5F-PB-22 as Schedule I controlled substances (i.e. ban their sale and use). PB-22 and 5F-PB-22 have been found laced on plant material and marketed under the guise of herbal incense products. PB-22 and 5F-PB-22 share effects with two Schedule I substances also encountered laced on plant material, JWH-018 and AM2201. Synthetic marijuana containing these compounds is often sold in legal retail outlets and are labeled "not for human consumption" to mask their intended purpose and avoid Food and Drug Administration (FDA) regulatory oversight of the manufacturing process.

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The rules would also classify compounds that share similar chemical structures (referred to as pharmacophores[1]) of cannabinoids (i.e. synthetic marijuana) and cathinones (i.e. bath salts) as Schedule I controlled substances. This regulation seeks to prevent manufacturers of these dangerous substances from altering the chemical structure of these compounds in an attempt to evade existing bans on synthetic drugs. The prohibition of these dangerous compounds is a necessary action to advance the Ohio State Board of Pharmacy's efforts to protect the health and safety of all Ohioans.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

3719.44 - (A) Pursuant to this section, and by rule adopted in accordance with Chapter 119. of the Revised Code, the state board of pharmacy may do any of the following with respect to schedules I, II, III, IV, and V established in section 3719.41 of the Revised Code:

(1) Add a previously unscheduled compound, mixture, preparation, or substance to any schedule;

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

No this regulation does not implement a federal requirement.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

While Congress has taken steps to ban many of these compounds at the federal level and the Drug Enforcement Agency (DEA) recently used its emergency scheduling authority to schedule three more types of synthetic cannabinoids, they cannot keep pace with the rapidly changing formulas that continue to pose a threat to the health and safety of Ohioans. It has been estimated that at least one new synthetic drug has emerged every month for the past three years. By banning the compounds found in current synthetic drugs as well as compounds with similar chemical structures from manufacture in the future, the Board can reduce access to the supply of these dangerous and potentially lethal substances.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

PB-22 and 5F-PB-22, found in synthetic cannabinoids, are legal in Ohio and thus present a danger to the public's health and safety. Confirmed cases involving PB-22 and 5F-PB-22 began surfacing in Ohio in the first five months of 2013. To date, Ohio has seen at least 51 cases

[1] Pharmacophores are used to define the essential features of one or more molecules with the same biological activity.

involving these substances. According to the DEA, drugs containing these compounds are likely to share effects with two Schedule I substances. Documented symptoms from the use of PB-22 and 5F-PB-22 include, but are not limited to, agitation, paranoia, confusion, violence, convulsions, unconsciousness, lethargy, nervousness, erratic behavior, driving as if intoxicated, inability to stand and slurred speech.

Additionally, potential reformulations of banned cannabinoids (i.e. synthetic marijuana such as K2 or Spice) and cathinones (i.e. stimulants such as bath salts) pose an emerging threat to the health and well-being of Ohio citizens.

Cathinones are known substances of abuse that produce pharmacological effects similar to that of amphetamines. There are hundreds of cathinones reported in the literature, several of which have been listed as Schedule I controlled substances for years. The problem is that not all cathinones with abuse potential are scheduled by the DEA, a loop-hole that is exploited by the illicit drug trade to produce very potent and addictive products that can be legally sold in Ohio. According to the University of Minnesota's College of Pharmacy, "the synthesis and chemical modification of these compounds can be quite simple given the right starting materials".[2] By banning potential reformulations of these dangerous substances, the Board can limit the threat posed by emerging synthetic drugs.

Please note: There is only one synthetic cathinone approved for medical use, bupropion (Wellbutrin®), and it is exempted from this rule.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The agency, in coordination with the Ohio Attorney General's Office, will monitor the success of the regulation using data from Ohio's poison control centers and law enforcement reports that involve the substances banned by this regulation.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
    - Ohio Attorney General's Office
    - Anthony J. Tambasco, Forensic Scientist and Laboratory Director, Mansfield Police Department
    - Dennis M. Mann, PhD, MD, Miami Valley Hospital
    - Dr. Jon E. Sprague, Dean of the Raabe College of Pharmacy and Professor of Pharmacology, Ohio Northern University

[2] http://www.healthtalk.umn.edu/2012/08/01/why-are-synthetic-drugs-so-hard-to-legislate/

- The Ohio State Board of Pharmacy's Rules Review Committee
- The Ohio Council of Retail Merchants

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Anthony J. Tambasco, Forensic Scientist (Sworn Affidavit): *"Having worked with synthetic* substances during the last four years, in my opinion based on my background, training, experience, and knowledge in the forensic science and law enforcement, the risk to the health and safety of the citizens of Ohio associated with the use of PB-22 and 5F-PB-22 is high. PB-22 and 5F-PB-22 pose a significant risk to the public health and safety and should be added to *Schedule I as controlled substances in Ohio."* (Page 12 of Appendix 1)

Dennis M. Mann, PhD, MD (Sworn Affidavit): *"Despite the initial ban on synthetic drugs in* Ohio, more types of synthetic drugs continue to enter the market at an alarming rate. Based on my background, training, knowledge, and experience as a Staff Physician and Senior Research Chemist, it is my opinion to a reasonable degree of medical and scientific certainty that PB-22 and 5F-PB-22 synthetic cannabinoids pose an imminent danger to the citizens of Ohio and should be classified as Schedule I controlled substances. They are structurally to and likely pharmacologically similar to previously banned synthetic cannabinoids such as JWH-018, and likely have been developed for the sole purpose of evading the existing law on synthetic drugs.*"* (Page 48 of Appendix 1)

Dr. Jon E. Sprague (Sworn Affidavit): *"Synthetic cannabinoids have a high potential for* abuse because synthetic cannabinoids have been shown to activate the reward pathways in the *brain…*Based on my knowledge, training, education and experience, it is my opinion to a reasonable degree of pharmacological, toxicological and scientific certainty, that the use of PB-22 and 5F-PB-22 will create the potential for psychic or physiological dependence liability similar to that of individuals who have used other synthetic substances and have become *dependent on them…PB*-22 and 5F-PB-22 pose a significant risk to the public health and safety and should be added to Schedule I as controlled substances in *Ohio."* (Page 55-57 of Appendix 1)

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Three experts (see #8) provided testimony to support the rule. In addition, the following materials were utilized to provide information to develop the rule:

a) Influence of the N-1 alkyl chain length of cannabimimetic indoles upon CB(1) and CB(2) receptor binding. Drug Alcohol Depend. 2000 Aug 1;60(2):133-40. (Page 85 of Appendix 1)

b) Acute toxicity due to the confirmed consumption of synthetic cannabinoids: clinical and laboratory findings. Addiction. 2013 Mar;108(3):534-44. doi: 10.1111/j.1360-0443.2012.04078.x. Epub 2012 Nov 1. (Page 93 of Appendix 1)

c) Drug Enforcement Administration (DEA) Summary of PB-22 and 5F-PB-22 (Page 8 of Appendix 1).

d) Special Report: Synthetic Cannabinoids and Synthetic Cathinones Reported in NFLIS, 2009-2010, September 2011 (Page 112 of Appendix 1).

e) Department of Justice. Statement of Jospeh T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the Senate Caucus on International Narcotics Control, United States Senate, "The Dangers of Synthetic Cannabinoids and Stimulants." April 6, 2011 (Page 116 of Appendix 1).

The data presented in the above materials indicates that synthetic cannabinoids containing PB-22 and 5F-PB-22 elicit serious acute adverse effects such as tachycardia, agitation, hallucination, hypertension, minor elevation of blood glucose, hypokalaemia, vomiting, chest pain, seizures, myoclonia and acute psychosis.

Incident/Investigative Public Narratives for cases documenting adverse effects of PB-22 and 5F-PB-22 were also utilized in the development of the rule (Page 29 of Appendix 1).

Materials referenced above also provide rationale for the ban on compounds that are pharmacologically similar to cathinones (i.e. synthetic stimulants). Adverse effects associated with the ingestion of synthetic cathinones include chest pain, increased blood pressure, increased heart rate, agitation, hallucinations, extreme paranoia and delusions.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

No alternative regulations were considered because adding PB-22 and 5F-PB-22 as Scheduled I controlled substances is the most direct way to reduce the availability of these dangerous drugs. Additionally, adding any of the compounds that are pharmacologically similar, as determined by a forensic laboratory, as Schedule I controlled substances will also reduce the future availability of synthetic drugs.

Per the Ohio Revised Code (3719.44), the Ohio Board of Pharmacy considered the following requirements in its decision to prohibit the compounds:

(1) The actual or relative potential for abuse;

(2) The scientific evidence of the pharmacological effect of the substance, if known;

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

(4) The history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) The risk to the public health;

(7) The potential of the substance to produce psychic or physiological dependence liability;

11. Did the Agency specifically consider a performance-based regulation? Please explain.

No. By classifying PB-22, 5F-PB-22 and compounds that pharmacologically similar to cannabinoids and cathinones as Schedule I controlled substances, the Board has effectively banned the sale and use of synthetic drugs containing these compounds.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

Working with the Ohio Attorney General's Office, the Board of Pharmacy's Director of Legal Affairs reviewed the Ohio Administrative Code to ensure that this regulation does not duplicate an existing Ohio regulation.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The Board will conduct outreach to stakeholders representing retail merchants, law enforcement (including the Ohio Attorney General) and other stakeholders (i.e. Ohio Petroleum Marketers and Convenience Store Association, Ohio Council of Retail Merchants, Ohio Grocers Association, Ohio Manufactures' Association, Ohio Chemistry Technology Council and Ohio Association of Convenience Stores) to inform them of the products that will be banned via the regulation. Information will be provided to these entities so that they may inform their membership of the change. In addition, information will be posted to the Ohio State Board of Pharmacy's web site.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

- The businesses that will be impacted are those currently selling synthetic drugs containing PB-22, 5F-PB-22 and compounds pharmacologically similar to cannabinoids and cathinones, such as convenience stores and gas stations. The DEA reports that PB-22 and 5F-PB-22 were not reported prior to their appearance

on the designer drug market and currently have no industrial purpose (Page 8 Appendix 1).
    - Researchers should not be impacted by this regulation because they are permitted, per DEA and Ohio Board of Pharmacy regulations, to conduct scientific research using Schedule I controlled substances.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

- Businesses that currently sell these dangerous products that contain the prohibited compounds will be required to remove items from their shelves. This will result in minimal employer time to ensure compliance.

c. Quantify the expected adverse impact from the regulation.

- Upon notification, minimal staff time is required to remove the products from the shelves, as the Board of Pharmacy and the Attorney General's Office will provide information for store owners on what products contain the banned compounds.
- A recent news report quoted the price of synthetic cannabinoids at approximately $30 per gram.[3] Assuming an average retail markup of 25%, the average cost of the regulation to a store selling synthetic cannabinoids is estimated at $24 per gram.[4]
- The DEA reports that the average price of synthetic cathinones is $60 - $70 per gram.[5] Assuming an average retail markup of 25%, the average cost of the regulation to a store selling synthetic cathinones is $48 - $56 per gram.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

As stated previously, drugs containing PB-22 and 5F-PB-22 endanger the public's health and safety. These drugs have serious acute adverse effects such as tachycardia, agitation, hallucination, hypertension, minor elevation of blood glucose, hypokalaemia, vomiting, chest pain, seizures, myoclonia and acute psychosis.

A summary of one reported case demonstrates the danger of these compounds:

A homeowner called the police for help because her son's 18-year old friend, who had been smoking a synthetic drug all day long while in her home, began to vomit, went into convulsions, and then became unconscious around mid-afternoon. When the police arrive at the scene, the male was 'comatose one minute and then would become violent the next.' The male was hallucinating and screaming as paramedics attempted to restrain him. Forensic tests showed that the substance he was smoking contained 5F-PB-22.

[3] http://www.wbur.org/2012/05/17/synthetic-marijuana-dangers
[4] http://www.wisebread.com/cheat-sheet-retail-markup-on-common-items
[5] http://www.deadiversion.usdoj.gov/fed_regs/rules/2011/HHS%20PDF/background.pdf

The banning of compounds that share characteristics of existing dangerous cannabinoids and cathinones will deter the widespread availability of emerging synthetics that have no medical purpose and pose a threat to the public's health and safety.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No. The regulation is intended to ban the sale and use of substances that endanger the public's health.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

All attempts will be made by the Ohio State Board of Pharmacy and stakeholders to inform businesses that are impacted by the regulation. Compliance with this regulation does not require paperwork and is not subject to ORC 119.14.

18. What resources are available to assist small businesses with compliance of the regulation?

The Ohio State Board of Pharmacy will work with stakeholder representatives to provide information to small businesses that are impacted by this rule instructing them on the removal of products containing the banned compounds.