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Synthetic Cannabinoids

By Amber Covey, PharmD Candidate

Recently many states have been taking legal action to add a drug called K2, and the chemicals it contains, to their lists of controlled substances. K2 is sold commercially as incense under many names including Spice, Red Dragon Smoke, Genie, and Yukatan Fire. While the exact mixture of herbs contained in these types of incense varies, the herbs are sprayed with synthetic cannabinoids, and have become a popular legal alternative to marijuana; the incense is smoked the same as marijuana in order for the person to achieve his or her high. Currently K2 and its components are considered a "drug of concern" by Drug Enforcement Administration (DEA).

The synthetic cannabinoids used are similar to tetrahydrocannabinol (THC), which is the active ingredient in marijuana. Common synthetic cannabinoids that are used to lace the incense are JWH-018, JWH-073, CP 47,497, HU-211, and HU-210. Of these synthetic compounds, currently only HU-210 is classified federally and in Wyoming as a Schedule I substance. While JWH-018, JWH-073, and CP 47,497 are structurally different than THC, all five synthetic cannabinoids display a similar pharmacological action to THC by acting on the Cannabinoids$_1$/Cannabinoids$_2$ receptor (CB_1/CB_2) but with greater affinity than THC. The synthetic cannabinoids are reported to have three to 100 times more potency than THC, which is sometimes attributed to it functioning as complete agonists of the CB receptors versus THC, which is only a partial agonist. While the synthetic cannabinoids have similar psychomotor effects as THC, other effects that have been reported after consumption are seizures, tremors, acute anxiety, elevated heart rate and blood pressure, vomiting, and loss of consciousness.

Many states and cities are taking action and banning the substances. Starting in March 2010, Kansas became the first state to ban the drug. Many states then followed, banning or introducing legislation with the intent to classify the substances as Schedule I. Substances that are classified as Schedule I are deemed to have a high potential for abuse and no accepted medical use in the United States. Although initially these substances were developed in laboratories as alternatives for pain management, there currently are no approved medical uses. Instead, they have found their way into the commercial market and are available for sale in convenience stores, smoke shops, headshops, and from Internet retailers.

Cases are starting to be reported in literature to attest to the addictive and abusive nature of these drugs. Also, the compounds currently cannot be screened by urine sample which makes diagnosing difficult. As countries and states start to regulate or ban the sale of these substances, the manufacturers have adapted by changing the variation of synthetic cannabinoids sprayed onto the herbs by adding high amounts of vitamin E to mask the active ingredients. This makes regulation difficult. Another challenge faced when trying to regulate these chemicals is that there are hundreds of synthetic cannabinoids that can be used to make K2, and while DEA has acknowledged the five listed in this article, there are many more that have been reportedly used in K2 and Spice.

It is anticipated that legislation regulating the sale of these compounds will be introduced in the 2011 Wyoming legislative session. It is important for health care providers to be aware of these substances and the side effects of their abuse and to strive to stay up to date on the legal status of these compounds as more states recognize their abuse potential and negative health side effects.

Self-Inspection of Pharmacies

At its 2010 September Wyoming State Board of Pharmacy meeting, the Board approved the use of "self-inspection" processes for pharmacies in Wyoming. Forms were mailed to each pharmacist-in-charge in November. The Board is asking that each pharmacy complete a self-inspection using the entire check-off list. The forms have references to the specific regulation to facilitate learning what the requirement means. Parts of the list can be delegated to different pharmacy staff so that everyone knows such items such as where licenses are posted or Board *Newsletters* are kept, etc. The results should be discussed and deficiencies corrected before the 2011 inspections. The compliance officers will be asking to review the self-inspection forms and they should be stored with other documents such as the annual May controlled substance physical inventories. The Board's goal is to keep all staff informed of the regulations and facilitate process improvement in pharmacies.

Posting of Disciplinary Actions

Beginning in 2011, disciplinary actions approved by the Wyoming State Board of Pharmacy may be posted on the Board Web site at *http://pharmacyboard.state.wy.us* or listed in the Board *Newsletter*. This would include the person's name, type of license and number, what rules or statutes were involved, and a summary of the type of discipline.

Sterile Compounding Chapter 17

The requirements in the new Wyoming Pharmacy Act, Rules Chapter 17, are to be implemented by January 1, 2012. The compliance officers have been asking this year (2010) for a discussion of

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FDA Alert Regarding Administration of Oral Nimodipine Capsules

Food and Drug Administration (FDA) reminds health care providers that oral nimodipine capsules should be given only by mouth or through a feeding or nasogastric tube and should never be given by intravenous administration. FDA continues to receive reports of intravenous nimodipine use, with serious, sometimes fatal, consequences. Intravenous injection of nimodipine can result in death, cardiac arrest, severe falls in blood pressure, and other heart-related complications.

Nimodipine is a medication intended to be given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage and is only available as a capsule. Prescribing information warns against intravenous use of nimodipine and also provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients who are unable to swallow. The instructions recommend that the syringe used for withdrawal of capsule contents be labeled with "Not for IV Use." FDA will continue working with the manufacturers of nimodipine and with outside groups to evaluate and implement additional ways to prevent medication errors with this product.

An FDA Drug Safety Communication providing additional information for health care providers and patients is available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm.*

FDA Approves Vaccines for the 2010-2011 Influenza Season

FDA approved vaccines for the 2010-2011 influenza season in the United States on July 30, 2010, and some manufacturers began shipping as early as mid-August. The seasonal influenza vaccine protects against three strains of influenza, including the 2009 H1N1 influenza virus, which caused the 2009 pandemic. Last year, two separate vaccines were needed to protect against seasonal flu and the 2009 H1N1 pandemic flu virus because the 2009 H1N1 virus emerged after production began on the seasonal vaccine, but this year, only one vaccine is necessary. The Centers for Disease Control and Prevention has published recommendations for annual influenza vaccination to include all people aged six months and older. The expanded recommendation is to take effect in the 2010-2011 influenza season. More information on the approved vaccine is available in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220718.htm.*

FDA Alert Regarding Adverse Effects in Children After Unintentional Exposure to Evamist

FDA advises patients and health care providers of reports regarding adverse effects from Evamist® in children who may have been unintentionally exposed to the drug through skin contact with women using this product. Evamist contains estradiol, an estrogen hormone, and is a topical product, sprayed on the skin on the inside of the forearm between the elbow and the wrist. Children unintentionally exposed to Evamist may experience premature puberty. FDA is currently reviewing these reported adverse events and is working with the company to identify any factors that may contribute to unintended exposure and to evaluate ways to minimize the risk. FDA advises that patients should make sure that children are not exposed to Evamist and that children do not come into contact with any skin area where the drug was applied, and for those who cannot avoid contact with children to wear a garment with long sleeves to cover the application site. Additional information for patients is provided in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm.*

Safeguards to Implement with 'High Alert' Medications

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

While most medications have a large margin of safety, a small number of drugs have a high risk of causing injury when they are misused. ISMP calls these "high-alert medications" to draw attention to this characteristic so that all involved in their use will treat them with the care and respect that they require. Errors may or may not be more common with these drugs than with the use of any others; however, the consequences of the errors are more devastating. For this reason, special considerations are required. These medications often need to be packaged differently, stored differently, prescribed differently, and administered differently than others. Examples of high-alert medications in community pharmacy include warfarin, insulin, methotrexate, and fentanyl patches. Whenever possible, "forcing functions" – methods that make it impossible for the drug to be given in a potentially lethal manner – should be developed and instituted. Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (eg, patient-specific indication must be entered if high-alert medication selected) is a forcing function.

An independent double-check of a high-alert medication is a procedure in which two pharmacists, alone and apart from each other, separately check each component of dispensing and verifying the high-alert medication, then compare results before giving it to the patient to self-administer. While technological solutions such as bar coding systems have great potential to detect human error, manual redundancies such as independent double checks still play an important role in error detection. Studies show that manual redundancies detect about 95% of errors. Independent double checks serve two purposes: to prevent a serious error from reaching a patient; and just as important, to bring attention to the systems that allow the introduction of human error. In retail pharmacies, with only one pharmacist per shift, the independent double check can be performed via a "will call" bag

check or by another pharmacist at the beginning of the next shift. If the medication has been dispensed, serious harm can be avoided or mitigated if the error is discovered within one or two doses.

The following information must be verified during the double-check process:

Comparison to prescriber's order:

- Is this the prescribed drug?
- Is this the prescribed dose/strength/rate and route of administration?
- Is this the right patient (use two patient identifiers)?
- Is this the prescribed frequency?

Additional cognitive checks:

- Does the drug's indication correspond to the patient's diagnosis?
- Is this the right drug formulation?
- Are dose calculations correct?
- Is the dosing formula (eg, mg/kg) used to derive the final dose correct?
- Is the prescribed dose/frequency/timing appropriate for this patient?
- Is the route of administration safe and proper for this patient?
- Has patient been educated on appropriate monitoring?

ASCO/FDA Program Provides Information on Expanded Access for IND Applications

Developed in partnership with FDA, the American Society of Clinical Oncology (ASCO) offers an online interactive educational program to help providers understand FDA regulations regarding expanded access programs for individual-patient investigational new drug (IND) applications. The program provides an introduction from the viewpoint of various involved stakeholders, including physicians, FDA, industry, and patients and may assist pharmacists in providing patient counsel regarding expanded access.

This interactive module consists of:

- A thorough explanation of all expanded access programs available
- Links to key references and resources that are relevant to the slide content
- Selected virtual meeting presentations from ASCO Annual Meetings
- Helpful resources to use with patients

The program is available at *http://university.asco.org/Expanded Access* and participants may earn a certificate of participation or completion.

Rise in Prescription Pain Pill Abuse Documented in Latest SAMHSA Data

Abuse of prescription pain medications continues to rise, according to the latest data from the Substance Abuse and Mental Health Services Administration (SAMHSA). The agency's Treatment Episode Data Set showed that the proportion of substance abuse treatment admissions for individuals aged 12 and older rose 400% from 1998 to 2008. SAMHSA data also showed an increase in emergency room visits involving the non-medical use of a prescription narcotic pain reliever, which have tripled in proportion since 1998. SAMHSA Administrator Pamela S. Hyde, JD, stressed that the non-medical use of prescription pain relievers is now the second most prevalent form of illicit drug use. Hyde emphasized the importance of raising awareness about this public health threat and educating the public on the "critical importance of properly using, storing, and disposing of these powerful drugs" as reported in a SAMHSA press release available at *www.samhsa.gov/newsroom/advisories/1007140544.aspx*.

USP Recommends Patient-Centered Standards for Prescription Labels

To address the problem of patient misinterpretation of medication instructions, the United States Pharmacopeial Convention (USP) Health Literacy and Prescription Container Labeling Advisory Panel developed and recently released recommendations for standardizing the format, appearance, content, and language of prescription labels. The panel, on which the National Association of Boards of Pharmacy® (NABP®) participated, developed the patient-centered recommendations in response to a call for such standards from the Institute of Medicine. More details about the panel's recommendations are available in a USP press release at *http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=2WSh2u7neSpIu2bXW1HJ5VQ48HGFAOGH1NdNBeuPwJE%3d*.

Seven Pharmacy Organizations Respond to AMA Scope of Pharmacy Practice Document

Seven national pharmacy organizations, including NABP, collaborated on the analysis and responded to the AMA Scope of Practice Data Series: Pharmacists, a document published by the American Medical Association (AMA) that describes the scope of the practice of pharmacy as viewed by the AMA authors. The pharmacy organizations identified significant opportunities for enhanced understanding by the AMA of contemporary pharmacy practice and urged the AMA to correct the identified issues noted in the document. AMA responded that meaningful dialogue will be pursued to examine ways pharmacists and physicians can collaboratively address the health care needs of patients. Collaborating on the pharmacy organizations' review and response were the American Pharmacists Association (APhA), American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, Accreditation Council for Pharmacy Education, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and NABP. The letter and materials sent to AMA are available at the following links from the APhA Web site:

- Recommendations: AMA Scope of Practice Data Series: Pharmacists, *www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=23148&TEMPLATE=/CM/ContentDisplay.cfm*.
- Response Letter: AMA Scope of Practice Data Series: Pharmacists, *www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23149*.
- Scope of Contemporary Pharmacy Practice, *www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23150*.

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plans to comply with the new Rules, Chapter 17, Wyoming Pharmacy Act by the implementation date. In 2011 the inspections will include where the sterile compounding pharmacy is in respect to the requirements, with a reminder that the effective date for compliance is coming soon. Recent inspections of Memorial Hospital of Sweetwater County, Memorial Hospital of Sheridan County, and Cheyenne Regional Medical Center have shown places that have completed remodeling in order to comply.

Updated Pharmacist's Manual

DEA has revised the Pharmacist's Manual in 2010 and it can be found at the following site: *www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf*.

Early Refills

The Wyoming Pharmacy Act, Rules Chapter 9 Section 4 states

> A pharmacist shall review the patient record and each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness by identifying: (i) Overutilization or underutilization; (ii) Therapeutic duplication; (iii) Drug-disease contraindication; (v) Incorrect drug dosage or duration of drug treatment; (vi) Drug-allergy interactions; and (vii) Clinical abuse/misuse. (b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber. The pharmacist shall **document those steps taken.**

The Board has held pharmacists accountable for dispensing early refills without the prescriber's permission.

The pharmacist must decide how to proceed if an alert appears on the computer. A review of the patient profile can reveal possible compliance problems. Too many alerts can cause "warning fatigue" and the alerts may not be reviewed. Patients who are possible "doctor shoppers" keep track of people and places where they may have refills of controlled substances in order to avoid being noticed. Double counting controlled substances in front of the patient or initialing a note on the filled prescription may avoid questions. Quarterly reconciliation of controlled substance inventories is required and can point to possible trends or problems.

Transfer of Prescriptions

Wyoming Pharmacy Act, Rules Chapter 2 was revised in 2009 to state "A pharmacist will transfer prescription order information upon request of a patient." The safest way to do the transfer is to send a **fax** rather than to give information over the telephone. The practice of recording the pharmacy's DEA number when transferring a controlled substance is a federal requirement as laid out in the Code of Federal Regulations (21 CFR 1306.25). The pharmacist receiving the transferred prescription information shall reduce to writing the information including the pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred. Communication between pharmacists needs to occur if there are any questions about the transfer and documentation must be completed. The Board has investigated several prescription errors that involved transfers so caution is advised with this vulnerable process.

Board of Pharmacy Meeting Schedule

At the September Board meeting it was decided to schedule four Board meetings in 2011. Due to budget concerns the meetings will be held alternating between Casper, WY, and Cheyenne, WY, rather than around the state. Attendance around the state has been low. The schedule is:

- December 10, 2010, in Casper at the Holiday Inn, McMurry Park from 8 AM to 2 PM
- March 23-24, 2011, in Cheyenne
- June 23-24, 2011, in Casper
- September 7-8, 2011, in Cheyenne
- December 7-8, 2011, in Casper

(Locations to be determined.)

The *Wyoming State Board of Pharmacy News* is published by the Wyoming State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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