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CBD and 'Farmacy'

Contributed by Anthony B. Gray, JD, General Counsel

By now, everyone has probably seen cannabidiol (CBD) stores or products for sale in your local grocery, gas station, or pharmacy. In Kentucky, CBD products are being sold everywhere. Recently, Kentucky Governor Matt Bevin announced that International Farmaceutical Extracts, LLC, which specializes in CBD oil extraction and distillation, plans for a $6 million-plus manufacturing plant in Boyle County that would create up to 34 full-time jobs over a 10-year period.

Many states are going to have to deal with what a "pharmacy" means under the law. Should these businesses be allowed to represent themselves as a "farmacy" just by substituting an "f" for a "ph"?

Many pharmacists believe that "farmacy" is misleading to the public. Brett Vickey, PharmD, RPh, BCPS, BCCP, stated in a recent Kentucky Board of Pharmacy meeting, "I feel 'farmacy' is very misleading to the public and diminishes public perception to the value of services pharmacies provide as well [as] to the education and licensure of each pharmacist required to staff a proper pharmacy."

"Farmacy" attenuates the strength of the laws and statutes that regulate appropriate pharmacy practice for public welfare. – Brett Vickey

In Kentucky, all pharmacies are required to be licensed by the Board and renew that license annually. In addition, all pharmacists must be licensed and obtain 15 hours of continuing education (CE) each year to maintain that license. Pharmacists are required to have attended an accredited pharmacy school and pass the Multistate Pharmacy Jurisprudence Examination® and the North American Pharmacist Licensure Examination®.

CBD products are being sold in multiple locations across the state and the Board has no jurisdiction over the selling of these products. The manufacturers of these products are not monitored, licensed, or inspected by any state or federal agency to ensure the products' safety and effectiveness. Food and Drug Administration (FDA) can become involved upon a mislabeled product but these are products that are not FDA-approved for any disease state and are not monitored or tested at this time for accuracy in contents, including the tetrahydrocannabinol (THC) percentage.

Recently, FDA announced that it has issued a warning letter to Curaleaf, Inc, of Wakefield, MA, for illegally selling unapproved products containing CBD online with unsubstantiated claims that the products treat cancer, Alzheimer's disease, opioid withdrawal, pain, and pet anxiety, among other conditions or diseases. The agency continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses and have not been approved by FDA. CBD is marketed in a variety of product types, such as oil drops, capsules, syrups, teas, and topical lotions and creams. Often such products are sold online and are therefore available throughout the country. Other than one prescription human drug product to treat rare, severe forms of epilepsy, FDA has not approved any other CBD products and there is very limited information for other marketed CBD products.

As a result of the booming CBD industry, many "farmacies" are appearing everywhere from malls to freestanding stores. Employees of those CBD stores are representing themselves as "farmacists." KY CBD Farmacy is a new business in Nicholasville, KY, that represents itself as a Kentucky Proud CBD oil farmacy. But what does Kentucky law say regarding these representations?

Kentucky Revised Statute (KRS) 315.030(1) states,

> No person shall take, use or exhibit the title of drug, drug store, pharmacy or apothecary, or any combination of such names or titles, or any title, name or description of like import, or any form designed to take the place of such a title, or use any

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National Pharmacy Compliance News

September 2019

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

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> place with respect to which any of those terms are used in any advertisement or telephone directory listing, unless the facility has been issued a permit by the board.

In addition, KRS 315.030(2) states,

> No person shall call himself or hold himself out as or use the title of "pharmacist," "registered pharmacist," "licensed pharmacist," "druggist," or use the initials "R.Ph." or terms which would imply that he is a pharmacist, unless he is duly licensed under the provisions of KRS Chapter 315.

So, as you can see, using an "f" in pharmacies is a creative way to not necessarily be in violation of the law. However, the clear intent is to obtain the esteem and prominence of a pharmacy or pharmacist by merely changing the phonetic spelling of the word. Recently, the Board decided to issue cease and desist orders to any business representing itself as a "farmacy." A statutory amendment could be considered in the future. For now, the public should understand that any business or person representing itself as a "farmacy" or a "farmacist" is not licensed or recognized by the Board.

Compounding in Kentucky – Update

At the July 31, 2019 Board meeting, the Board voted to not adopt United States Pharmacopeia (USP) Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. The Board also discussed the revisions to USP Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations and USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations, both released on June 1, 2019. Board President Craig Martin, MD, RPh, called for motions on USP Chapter <795> and USP Chapter <797>; however, no action was taken. Discussion on USP Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging, released on June 1, 2019, was tabled until the September 25, 2019 Board meeting.

In summary, Kentucky will not update regulation 201 Kentucky Administrative Regulations (KAR) 2:076 Compounding to include USP Chapter <800>. Pharmacies compounding hazardous drugs will continue to follow the January 2014 version of USP Chapter <795> and the June 2008 version of USP Chapter <797>. Pharmacies performing any compounding will continue to follow the January 2014 version of USP Chapter <795> and the June 2008 version of USP Chapter <797> per 201 KAR 2:076.

Other entities, such as pharmacy liability insurance providers, third-party payers, accreditation organizations, and other governmental agencies, may require compliance with USP Chapters <800> and <825> and the June 1, 2019 versions of USP Chapters <795> and <797>.

USP is currently providing complimentary access to the revised USP Chapters <795> and <797>, and the new USP Chapters <800> and <825> on its website, *https://www.usp.org*. USP is also providing summaries of the chapters as well as responses to frequently asked questions. In addition, USP offers live and web-based continuing pharmacy education (CPE) programs on the revised and new chapters.

CBD in Kentucky

Contributed by Katie Busroe, RPh, Pharmacy Inspections and Investigations Supervisor

Both hemp and marijuana are plants in the genus cannabis. CBD and THC are two of the over 100 cannabinoids found in cannabis plants, with CBD found most prominently in hemp and THC found most prominently in marijuana. THC is the cannabinoid most associated with psychoactive effects, including euphoria. CBD has not been found to have these effects.

In December 2018, the 2018 federal Farm Bill was signed into law by President Donald J. Trump. This bill removed industrial hemp, cannabis sativa, and all of its extracts not containing more than 0.3% THC concentration on a dry weight basis from the federal list of controlled substances (CS). It allows states to regulate hemp if there is a state plan in place to monitor and regulate its production. Since 2013, the Kentucky Department of Agriculture has issued licenses, pursuant to KRS 260.858, to persons and/or businesses to grow and process hemp. Two state statutes, KRS 218A.010(27) and KRS 260.850(5), remove CBD from the Kentucky list of CS. These statutes require that the CBD must be hemp-derived and contain no more than 0.3% THC concentration on a dry weight basis.

Hemp-derived CBD products with not more than 0.3% THC are available in multiple forms, including topical, oral, and sublingual products. Kentucky law prohibits the sale of CBD hemp leaf material to be smoked. Although these products are no longer CS, FDA still regulates any claims that may be made by CBD producers. CBD products may not make any medical claims that have not been proven and approved by FDA. FDA has sent warning letters to multiple CBD companies for making non-approved claims that the product prevents, diagnoses, treats, or cures diseases when there has been no FDA approval. There is one FDA-approved CBD product on the market called Epidiolex®. The CBD product was approved in June 2018 as a Schedule V CS medication indicated to treat two forms of epilepsy: Lennox-Gastaut syndrome and Dravet syndrome.

Because CBD products may contain up to 0.3% THC, it is possible for people to test positive for THC during a drug

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screen. Some pain management physicians have discharged patients who tested positive for THC from the use of CBD products. Hospitals are seeing an increase in positive THC drug screens due to the use of CBD products by patients.

Over-the-counter CBD products derived from hemp and not containing more than 0.3% THC are legal as long as no health claims are made. The products do not have to be manufactured in Kentucky; however, if they are, the producers must be licensed by the Kentucky Department of Agriculture. Pharmacists must practice due diligence in deciding which, if any, CBD products to sell, by being aware of the percentage of THC in the product and reviewing the packaging for claims of any health benefits.

CE Highlights

1. Kentucky requires 15 credit hours **every calendar year.**
2. The Board audits **every** CPE Monitor® account **every year.**
3. Check your CPE Monitor account today to ensure that you have 15 CE hours. Please do not procrastinate if you do not have your 15 CE hours yet.
4. Last year, more than 100 pharmacists paid a $500 fine for not having 15 CE hours. Please do not be one of those.
5. Extension waivers are very rare. Please do not count on a waiver.

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