

Board of Pharmacy News



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The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality health care in the field of pharmacy through licensing pharmacy technicians and student interns, issuing permits to pharmacies and distributors, setting pharmacy practice standards and through developing and enforcing regulations and legislation, resolving complaints, and educating the public.

Maryland Board of Pharmacy 4201 Patterson Avenue Baltimore, Maryland 21215 Tel: 410-764-4755 Fax: 410-358-6207 Toll Free: 800-542-4964 TTYL BALTO-383-7555

Maryland Board of Pharmacy--A Look Back at Fiscal Year 2019

Deena Speights-Napata, Executive Director

As the end of the current State of Maryland 2019 fiscal year approaches, the Board of Pharmacy takes time to reflect on the issues we have faced and contributions we have made to the field of pharmacy in Maryland.

One of the Board's proudest accomplishments has been the implementation of pharmacist contraception prescribing guidelines in Maryland. The Board, to date, has validated for use in Maryland three contraception training programs from MPhA, Wegmans, and Oregon State University. By so doing, Maryland has not only contributed to the expansion of the scope of pharmacy practice, but also increased access to much-needed healthcare services for Maryland residents.

The Board has also created a committee and released a survey on the feasibility of implementing tech-check-tech programs in Maryland pharmacies. The committee will be meeting soon to discuss next steps. The Board has also discussed the possibility of adding a technician seat on the Board, which will require a change in Maryland statutes.

Internal administration has focused on building a more robust IT system that can provide more easily accessible information in licensee electronic profiles. This will enable our staff to easily access more detailed information in response to licensee inquiries. The Board has also added additional call center staff to ensure queries are responded to and applications entered within 48 hours. Board inspectors have additional features now available in the mobile application system that will enable faster inspection application upload and review. We are also focusing on additional training for the Board's investigation and licensing units that will include sessions on legal training and the NABP system e-profile connect.

Finally, an enhanced communication system will allow the board to communicate critical updates in a more effective manner. The newsletter will also present a new look to licensees.

The Board of Pharmacy would like to hear from you if you have additional suggestions for program initiatives.

Please contact us at 410-764-4755, or email us at <u>mdh.mdbop@maryland.gov</u>



UMES Attendees

Board of Pharmacy Public Board Meeting at University of Maryland, Eastern Shore

The Maryland Board of Pharmacy staff and commissioners convened at the University of Maryland Eastern Shore (UMES) on April 17, 2019. There were over 100 students, faculty, and staff in attendance from UMES.

The meeting began at 9:35 AM, when Board President, Kevin Morgan, introduced himself and welcomed guests. Following his introduction, commissioners were invited to share a brief overview of their professional backgrounds, individual

accomplishments, and experiences with the Board.

Next, the Acting Dean from UMES, Tim Gladwell, welcomed attendees from the Board, students, and staff on behalf of the UMES community. He told the first year students, who had their first law class later that day, of the

unique relationship that pharmacists and pharmacy interns have with the Board. Recalling the varied experiences mentioned by each commissioner, he explained to students that they can never know where their career is going to end up. Tim shared a personal story regarding his experience with a Board inspection and the first time an inspector walked into his retail pharmacy. He explained that the role of the Board was one of protecting the public and encouraged students to understand their role of protecting the public as well.



L to R: Timothy Gladwell, Deena Speights-Napata, Kevin Morgan

Following Acting Dean Gladwell, the Executive Director of the Maryland Board of Pharmacy, Deena Speights-Napata, began the Executive Director report by informing attendees about the successful meeting she and her staff

had with students from UMES the previous afternoon, April 16th, 2019. At the meeting, there was a short presentation and staff was available to share information and answer questions about the licensing process with the Maryland BOP.

Finally, Joy Strand, the Executive Director of the Maryland Medical Cannabis Commission (MMCC), joined the meeting to provide an overview of the cannabis program in the State of Maryland. She explained that the MMCC is the regulatory body for the State, engaging in inspecting, licensing, and providing regulatory guidance for the program. She stated that there were currently over 62,000 certified patients as well as 1,375 certified providers. She shared that one of the difficulties that the MMCC faces is of encouraging more physicians to register as Certifying Providers.



L to R: Jennifer Hardesty, Linda Bethman, Kevin Morgan, Deena Speights-Napata, Rhonda Toney

As a reminder, if you are a pharmacist administering vaccines, please be advised that Md. Code Ann., Health Occ. § 12-508(a)(4) states that "A pharmacist shall (i) Report all vaccinations administered by the pharmacist to the ImmuNet Program established under § 18-109 of the Health--General Article."

> **For more information please contact Maryland ImmuNet at:** <u>https://phpa.health.maryland.gov/OIDEOR/IMMUN/Pages/Pharmacists.aspx</u>



2018 New Regulations

COMAR 10.34.40 – Pharmacists Prescribing Contraceptives. On July 1, 2017, a new statute, Md. Code Ann., Health Occ. § 12-511 became effective. This law allows pharmacists to prescribe and dispense contraceptives pursuant to the requirements of regulations adopted by the Board. The Board's regulations, COMAR 10.34.40.01-06, became effective on July 2, 2018. As required by the statute, the Board's regulations establish standard procedures to be used by pharmacists to either select the appropriate contraceptive to prescribe for patients or refer the patient to a primary care provider or reproductive healthcare practitioner. The regulations establish the requirements for a pharmacist to become eligible to prescribe and dispense contraceptives, establish record-keeping requirements, and require one hour of annual continuing education related to contraception for participating pharmacists.

COMAR 10.34.32.03D – Requirements to Administer Vaccinations. Added provision to existing regulations requiring pharmacists to have proof of active CPR certification readily available in order to administer vaccinations. The new provision became effective on December 31, 2018.

PENDING:

COMAR 10.34.05.05 – Pharmacy Security. The Board amended this regulation to require pharmacists to report significant losses of controlled substances, in addition to the existing requirement of reporting theft. Under the amended regulation, pharmacies must report thefts of non-controlled prescription drugs to the Board, and must report thefts or significant losses of controlled substances to 1) the Board, 2) local police, 3) the Office of Controlled Substances Administration, and 4) the U.S. Drug Enforcement Administration. The comment period for this regulation ended on January 22, 2019. The Board has not received notification of an effective date for the amendments as of April 12, 2019.

COMAR 10.34.09.02 – Fees. This regulation amended an existing regulation to waive fees for pharmacy technician training programs submitted to the Board when the didactic portion of the program is comprised entirely of a didactic program that has been previously approved by the Board. The comment period for this regulation ended on January 22, 2019. The Board has not received notification of an effective date for the amendments as of April 12, 2019.

COMAR 10.34.30 – Changes to Permits. This amendment to COMAR 10.34.30 codifies the Board of Pharmacy's policies and procedures regarding name change, ownership change, location change, and other changes made by a licensee to information contained in a previously submitted application. The amendment also codifies the Board's policy of requiring applicants to re-submit all application materials and fees if an incomplete application has not been completed within one year after submission. The comment period for this amendment ended on February 19, 2019. The Board has not received notification of an effective date for the amendments as of April 12, 2019.

Time to Renew Your Maryland Distributor Permit

Dear Permit Holder:

Your Distributor Permit will expire on <u>May 31, 2019.</u> To renew your distributor permit, visit the Maryland Board of Pharmacy website by clicking <u>here</u>. The renewal period began on March 13, 2019.

<u>Wholesale Distributors</u>: You may renew online using only Visa or MasterCard as forms of payment. You may also renew by downloading and submitting a renewal application.

<u>Manufacturers and Virtual Manufacturers Distributing Their Own Prescription Drugs or Devices:</u> Online renewal is not available. You may renew by downloading and submitting a renewal application.

A completed application postmarked or received by the Board on or before May 31, 2019, must be accompanied by a <u>\$1,750.00</u> renewal fee. Applications postmarked after May 31, 2019, are subject to a <u>\$3,250.00</u> fee (\$1,750 renewal fee plus \$1,500 reinstatement fee). PLEASE NOTE: You must submit a substantially completed application at least 14 days before May 31, 2019, to guarantee an uninterrupted period of licensure. If you submit your application between May 18 and May 31, 2019, your permit may lapse before processing is complete, and you may be subject to an additional reinstatement fee.

For more information and instructions on the online renewal process, please visit this page: <u>https://health.maryland.gov/pharmacy/Pages/Establishments.aspx</u>, contact the Board via phone at 410-764-4755 or 1-800-542-4964 (Maryland residents only), or email: <u>mdh.mdbop@maryland.gov</u>.

Maryland Society of Health-System Pharmacy Awards

Each year, the Maryland Society of Health-System Pharmacy (MSHP) honors the achievements of its members through the presentation of seven different annual awards. This past fall, members of MSHP celebrated the awardees at an event held at Camden Yards. The recipients of the 2018 annual awards are listed below. Congratulations and thank you for your dedication to health-system pharmacy practice!

- The W. Arthur Purdum Award: Meghan Swarthout, Pharm.D., MBA, BCPS, Johns Hopkins Health System
- The Jeffery E. Ensor Award: Zachary R. Noel, Pharm.D., BCPS, University of Maryland School of Pharmacy
- Pharmacist of The Year: John T. Jordan Jr., Pharm.D., Peninsula Regional Medical Center/University of Maryland Eastern Shore School of Pharmacy
- Pharmacy Technician of the Year: William Lee III, CPhT, Carroll Hospital Center
- Preceptor of the Year: **Omayma A. Kishk**, Pharm.D., BCPPS, University of Maryland Medical Center
- MSHP Excellence Award: Sujin Lee Weinstein, Pharm.D., BCPP, The Johns Hopkins Hospital
- Medication Safety Award: Elle Sadler, Pharm.D., Children's National Medical Center; Edina Avdic, Pharm.D., MBA, BCPS, AQ-ID Kate Dzintars, Pharm.D., MBA, BCPS, AQ-ID The Johns Hopkins Hospital; Michael Grimes, Pharm.D., Meghan Swarthout, Pharm.D., MBA, BCPS, Johns Hopkins Homecare Group

If your organization is interested in the possibility of having its awards published in the next edition of the newsletter, please send an email to <u>mdh.mdbop@maryland.gov</u> detailing the event, awards, and recipients

Inspection Issues First Quarter 2019

The Maryland Board of Pharmacy requires all Maryland pharmacies to be inspected annually; these inspections can reveal a number of different issues, some of which result in complaints that the Board investigates.

The following graph represents the inspection issues that resulted in complaints in the first quarter of 2019:



New Commissioner Announcement



George Garmer

The Maryland Board of Pharmacy would like to introduce **George Garmer, R.Ph., B.S.P.**, as our new Independent Board Commissioner. George graduated from the University of Maryland, School of Pharmacy in 1991. George was appointed by Governor Hogan to serve as a commissioner, March 2019. George is an avid genealogy and Maryland history buff, the sixth generation of his family to live in the Canton neighborhood of Baltimore. During his appointment, he hopes to be a positive voice in protecting the public in the pharmacy setting.

We welcome you, George, to the Maryland Board of Pharmacy.

Board of Pharmacy is currently accepting submissions from readers for upcoming newsletter articles. Desired subjects covered may include public health or general educational topics. Submissions should be 500 words or less, in Microsoft Word document format.

Send any submissions to mdh.mdbop@maryland.gov by July 1st.

The Board does not guarantee that articles submitted will be published. Authors will be contacted as to whether the submission will be used.



Changes in Maryland PDMP Dispenser Reporting Requirements

Please take note of changes impacting most pharmacies and practitioner dispensers of controlled dangerous substance (CDS) prescriptions who report data to the Maryland Prescription Drug Monitoring Program (PDMP). The PDMP is an important clinical tool for practitioners across Maryland to make informed treatment decisions; this tool is most effective when all applicable data are reported. Your timely response to these changes helps ensure that the PDMP can deliver comprehensive prescription information!

Dispensers must begin reporting data to a new data collection software product, RxGov, no later than June 1st, 2019. Dispensers are required to report data every 24 hours, including zero reports, effective July 1st, 2019. A summary of the changes is below, and **detailed instructions for compliance are available in the 'Dispenser Reporting' section of the Maryland PDMP website**: <u>https://bha.health.maryland.gov/pdmp/Pages/Home.aspx</u>

Data Collection Vendor Change: Maryland PDMP has contracted with a new data collection software, RxGov, which has begun accepting data submissions. Dispensers, or their authorized data submitter, must begin reporting data to RxGov by June 1st, 2019. Every data submitter account currently registered with the existing RxSentry platform will be migrated to the new software, RxGov.

Daily Reporting Change: Maryland statute governing the PDMP was amended (HB437/Chapter 147, 2016) to change the dispenser reporting frequency in line with national PDMP best practices. All nonexempt dispensers of CDS medications are required to report applicable dispenses every 24 hours to the Maryland PDMP, including submission of zero reports if no dispensing occurs. "Zero reports" will be required on any day that the dispenser does not dispense a CDS prescription, regardless of whether or not the dispensing facility is open for business that day. Monitoring for compliance with the daily reporting requirement will begin July 1st, 2019.

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Dispensers who submit data themselves: Dispensers who serve as a data submitter will have their accounts migrated to the new RxGov product; you will "claim" your account by setting a new password and can begin uploading data to the new site using your existing method.
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Dispensers who rely on a 3rd party vendor to report data: Pharmacy and practitioner dispensers often rely on software vendors to submit dispensed CDS prescription data to the PDMP on their behalf. All data submitters currently registered with the Maryland PDMP have been notified of these two changes and provided instructions to comply. However, dispensers remain responsible for ensuring their data are submitted to the Maryland PDMP. You should contact your vendor to confirm their plans so you are not found out of compliance.

Policy questions should be directed to the Maryland PDMP at <u>mdh.pdmp@maryland.gov</u> or 410-402-8686, directly to PDMP Data Quality Specialist Katherine Johnson at <u>Katherine.johnson@maryland.gov</u>, or visit our website: <u>www.MarylandPDMP.org</u>

Gabapentin as a drug of abuse: A Growing Epidemic

by Heather Hurley Wade, Pharm.D., BCPS

Gabapentin is a GABA analog, initially approved by the FDA in 1993 as an adjunctive treatment for epilepsy, with later label expansion to include Postherpetic neuralgia (shingles) in $1996.^{1}$ Its off-label use in recent years has soared for a wide range of uses, including fibromyalgia, migraines, generalized neuropathies, and other chronic pain conditions. It garnered the attention of many state legislatures and the mainstream news with an NBC news story dated April 1, 2018: "Health Officials are sounding an alarm on the drug gabapentin. And it's not even an opioid."²

Initially thought to be a safer alternative to opioids, like tramadol before it, Gabapentin has become a common drug of abuse. Drug abusers often use it to heighten the effects of substances such as heroin, marijuana and cocaine, and have nicknamed the pills "Johnnies." Gabapentin has become the 7th most prescribed drug in the United States.³ The non-controlled federal DEA classification makes getting prescriptions relatively easy and it is now available generically and low cost to users. It is a substance not often included in drug screens.

A 2016 report published in *Addiction* found that about 40 to 65% of individuals who were prescribed gabapentin misused it, and that 15 to 22% of persons with an opioid abuse problem also abuse Gabapentin. Abuse usually was attributed to recreational use, self-medication or intentional self-harm, and the drug often was used in combination with opioids, benzodiazepines and/or alcohol. $\frac{3}{2}$

A Canadian study published in 2016 found that Gabapentin use alongside prescription opioid use resulted in a "substantial increase" in the risk of opioid-related death. The case control study found that opioid-related deaths were 49% higher in individuals recently exposed to a combination of opioids and Gabapentin than in those

To Taper off Gabapentin therapy, consider the following guide:

Days	Total Daily Dose (Mg)	Direction
1-3	2400 mg	Take 1200 mg (2-600 mg tablets) by mouth twice daily for 3 days.
4-6	1800 mg	Take 900 mg (3-300 mg tablets) by mouth twice daily for 3 days.
7-9	1200 mg	Take 600 mg by mouth twice daily for 3 days
9-12	800 mg	Take 400 mg by mouth twice daily for 3 days
12-15	400 mg	Take 200 mg by mouth twice daily for 3 days.
16-18	200 mg	Take 100 mg by mouth twice daily for 3 days.
19-21	100 mg	Take 100 mg by mouth in the evening for 3 days then STOP!

taking opioids alone. The risk was further increased with higher doses of gabapentin were used (\geq 900 mg daily) it was associated with a 60% increase in the odds of opioid-related death.⁴

Individual states are collecting data and debating the medication's status ahead of any federal decisions. In December 2016, Ohio found that it was the most prescribed medication in the state. Kentucky became the first in the nation to make Gabapentin a scheduled V controlled substance July 1, 2017. Ohio, West Virginia, Tennessee, Texas, and Michigan are all actively debating this very change in their respective legislatures to limit unnecessary prescribing and better track its dispensing.

Alternatives with less abuse potential have been added to many formularies to aid in the management of patients with neuropathy. Also focusing on diabetic patients in particular, optimizing blood sugar control to prevent the progression or development of peripheral neuropathy.

In light of the actual or potential change in the controlled substance status, facilities should be aware of the clinical risk factors for abuse and workflow implications. As a potential drug of abuse, it may be advisable to institute increased security measures ahead of any state/federal requirements to do so. In addition to the handling of gabapentin within your medical units and medication storage areas, assessment of patient level diversion should be assessed and "crush and float" practices considered.

QA Corner: A Refresher on Universal Precautions

by Valerie Barnes, Pharm.D., MS, BCPS

Universal precautions are safety guidelines in which all blood and other potentially infectious materials are handled as if they were contaminated. These include: blood, semen, vaginal secretions, saliva that may contain blood, cerebrospinal fluid, synovial fluid, pleural fluid, any body fluid where blood is visible, and any body fluid that cannot be identified. The revised recommendations by the Occupational Safety and Health Administration (OSHA) includes body fluids such as nasal secretions, sweat, tears, urine and feces. This update was made because it's difficult to determine whether these fluids contain traces of blood. Following universal precautions means using personal protective equipment and following safe work practice controls.

Special care with Sharps

The handling of sharps may increase risk of exposure to blood borne pathogens despite use of protective gloves. Proper care must be taken to prevent unintentional needle stick or sharps injury that would lead to occupational exposure to potentially infectious materials. Follow these rules of thumb when handling sharps.

- 1. Do not recap, bend, break or otherwise manipulate used sharps by hand.
- 2. Do not remove used needles from disposable syringes.
- 3. Place used sharps in labeled, leak proof, closable sharps containers for disposal.
- 4. Do not overfill sharps containers.
- 5. Consider the use of non-sharps equipment whenever possible.

Emergency procedures for an unexpected exposure incident.

- If blood or other potentially infectious material splashes in your eyes or other mucous membranes, flush area with running water for 20 minutes if possible.
- Wash any exposed area well, preferably with antibacterial soap.
- Treat any scabs and sores gently when cleaning your skin.
- Report the exposure to your supervisor as soon as possible.
- Save any potentially contaminated objects for testing purposes.
- Seek medical care as soon as possible.

Airborne Pathogens

There are three types of airborne pathogens: viral, bacterial and fungal. Meningitis, influenza, pneumonia and tuberculosis are all examples of diseases transmitted through the air.

An infectious person's cough or sneeze can send tiny droplets of moisture into the air that contain the pathogen. These contaminants can remain airborne for several hours.

Exposure does not always result in infection. The likelihood of transmission depends on the following: how contagious the infectious person is, where the exposure occurs, how long the exposure lasts, and how healthy you are at the time of exposure.

According to the Centers for Disease Control and Prevention, employees in certain workplaces face a greater risk of exposure. These work places include: correctional facilities, drug and treatment centers, homeless shelters and long-term care facilities. Transmission of airborne pathogens may be prevented by isolating patients with confirmed or suspected diagnosis of TB and meningitis, installing special air filters, and wearing fitted face masks and respirators when around people known to have meningitis, influenza, pneumonia or TB.

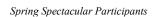
DISCIPLINARY ACTIONS

PHARMACIST	LIC. #	SANCTION	DATE
James Greenwald	08846	Fine	1/22/2019
John DeMary	18473	Suspension	2/21/2019
Stefany Overbeck	13193	Summary Suspension 3/12/2019	
Charles Presley	13538	Fine 1/25/2019	
Walter Ramirez	21705	Probation 2/21/2019	
Radhika Utturkar	19987	Fine	2/19/2019
PHARMACY TECHNICIANS	REG. #	SANCTION I	DATE
Janean Shaw	T08363	Revocation	1/16/2019
Patrice Shelton	T17157	Revocation 1/16/2019	
Kameara Tynes	T18182	Revocation 3/20/2019	
Tyrone Watkins	T12012	Summary Suspension 4/11/2019	
Kathleen Belfar	T01546	Summary Suspension 5/10/201	
ESTABLISHMENTS	PERMIT #	SANCTION I	DATE
Cantrell Drug Company, Inc.	D05438	Reprimand	1/9/2019
Drug Depot Inc dba APS Pharmacy	P07142	Fine	1/28/2019
TW Wellness Compounding Pharmacy	Unlicensed	Fine	2/21/2019
Complete Pharmacy and Medical Solutions	P07479	Fine	3/22/2019





Jered Pasav



Events Corner



Nakia Jordan

The Maryland Chapter of the American Society of Consulting Pharmacists held an all-day "Spring Spectacular" on Saturday, March 9th, 2019. The Board of Pharmacy was in attendance, with Nakia Jordan, Board staff, an informational table and handouts. MD Board of Pharmacy Laboratory Scientist, Jered Pasay, gave a presentation entitled "Changes USP-NF Compounding in Guidelines: Upcoming Changes to USP-797 and Implementation of USP-800."

Pharmacists and Pharmacy Technicians attending the talk received 1.5 hours towards their Continuing Education credits. Attendees earned 6 Continuing Education credits for verified participation in the day's programming.

One guest speaker of interest was Wanda D. Binns, LCSW-C, from Pharmacy Rehabilitation Service (PRS). She answered questions and distributed literature. PRS is a program that provides assistance to pharmacists who may be experiencing personal problems, including stress, drug dependence, medical problems, etc.

The event was an overall success. There were plenty of attendees and excitement for each talk, with a crowd staying to hear about immunization at the end of the day. The Board staff enjoys the opportunity to interact with and educate the public, and will continue, as always, to participate in the pharmaceutical community.

National Association of Boards of Pharmacy National Pharmacy Compliance News

Reprinted from the National Association of Boards of Pharmacy FOUNDATION

FDA Launches Pilot Program to Improve Security of Drug Supply Chain with an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an <u>FDA press</u> <u>release</u>. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-andtrace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the Federal Register.

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary

supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements.

These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at

https://www.fda.gov/newsevents/newsroom/pressannoun cements/ucm631065.htm

Seven Pharmacists among 60 Individuals Arrested for Conduct Related to Opioid Diversion

Sixty people, including seven pharmacists, 31 doctors, and eight nurse practitioners, have been arrested and charged for their alleged participation in the illegal prescribing and distributing of opioids and other dangerous narcotics, in addition to their participation in health care fraud schemes. These arrests were the result of investigations by the

Appalachian Regional Prescription Opioid (ARPO) Strike Force, which is made up of prosecutors and data analysts with the Health Care Fraud Unit, prosecutors with the 10 United States Attorneys' Offices in the region, and special agents with Federal Bureau of Investigation, The Department of Health and Human Services Office of the Inspector General, and Drug Enforcement Administration (DEA). The charges involve multiple schemes, over 350,000 prescriptions for controlled substances (CS), and over 32 million pills.

Among the schemes detailed in a Department of Justice press release was a Dayton, OH pill mill involving a doctor who is alleged to have at one time been the highest prescriber of CS in the state, and several pharmacists. Between October 2015 and October 2017, the pill mill allegedly dispensed over 1.75 million pills. Other schemes included a Kentucky doctor leaving blank, pre-signed prescriptions for office staff, who then used them to prescribe CS when he was out of the office, and a group of 15 providers in Tennessee who were charged for inappropriately prescribing powerful and dangerous combinations opioids of and benzodiazepines for approximately three years.

DEA Warns of Increase in 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 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 Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing Valsartan, Losartan, and Irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at <u>https://www.fda.gov/newsevents/newsroom/%20pressan</u> nouncements/ucm629796.htm.

BOARD COMMISSIONERS

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Daniel Ashby Efstratios (Steve) Bouyoukas Karla Evans Alford Laws Neil Leikach Kristopher Rusinko Brenda Oliver George Garmer Ellen H. Yankellow Chain Drug Store Representative At-Large Representative Long Term Care Representative

Acute Care Hospital Representative Chain Drug Store Representative Acute Care Hospital Representative Consumer Representative Independent Pharmacist Representative Home Infusion Representative Consumer Representative Independent Pharmacist Representative At-Large Representative

BOARD MEETINGS

Public Pharmacy Board meetings begin at 9:30am on the third Wednesday of each month and are open to the public. The Board encourages all interested parties to attend the monthly Board Meetings and awards 2 LIVE CEs to all licensees.

2019 PUBLIC BOARD MEETINGS

Third Wednesday of each month June 19th, 2019 July 17th, 2019 August 21st, 2019 September 18th, 2019 **Location**: 4201 Patterson Avenue Baltimore, MD 21215

CONTACT DIRECTORY Customer Service Center 410-764-4755 • mdh.mdbop@maryland.gov • health.maryland.gov/pharmacy • 1-800-542-4964							
Executive Director Deena Speights-Napata							
Deputy Director & Operations Manager	Director of Compliance	Manager of Program Intake, Assessment & Evaluation	Acting Licensing Manager				
Edward Fields	Trina Leak	Nakia Jordan	Doris James				

Maryland Board of Pharmacy



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