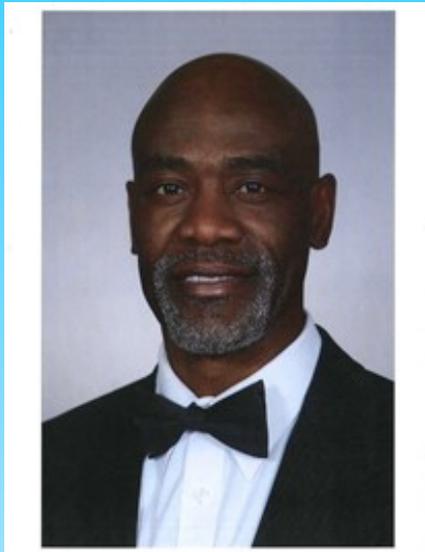


DPICTIONS

Drug & Poison Center Information Center's Newsletter

Holiday Issue 2017



Remembering Alton Chris Nelms

Marsha A. Polk, Manager, Education and Outreach
Alysia Longmire, Prevention Education Specialist

The Drug and Poison Information Center experienced a great loss with the passing of Alton Chris Nelms, who we all remember as "Chris". Chris worked for Cincinnati Children's Hospital – Drug and Poison Information Center (DPIC) as a health educator and Community Outreach Specialist for over 10 years. During his career at DPIC, Chris was lead facilitator of the Maintaining African American Traditions (MAAT) mentoring program, and represented Children's Hospital/DPIC on numerous grassroots and other community committees and boards. The following are little-known facts that contributed to the unique personality and span of expertise that Chris was known for:

*He played on the Reds Farm Team, based in Florida, for 4 years and served as a Chaplain and a member of the Reds Community Fund.

* Chris served in the military for 8 years.

*Chris held a Doctorate and Masters in Education, Licensed Social Worker, Drug Counselor, Certified Sports Counselor, Athletic Administrator, College Professor, and Ordained Minister.

*He was a member of the Cincinnati Federation of Teachers, NAACP, Avondale Community Council, Cincinnati Recreation Commission, UMADAOP, and The People of Color Wellness Alliance (POCWA).

* He directed and managed two branch YMCAs

*Chris served 3 terms with the Cincinnati School Board.

The DPIC family cannot put into words the deep sorrow we feel with the loss of our co-worker and friend. As we continue our community outreach and education mission we are united in saying that Chris is missed, but not forgotten.

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- * The 21st Century CURES Act
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- * Rexulti® (brexipiprazole)
- * Options for Reversing Anticoagulant Effects of New Oral Anticoagulant Drugs
- * Preventing Foodborne Illnesses During the Holidays

Holiday Hazards

Sara Pinkston RN, CSPI



The holidays are certainly a time for fun, merriment, and good cheer. But, they are also a very busy time which can lead to accidental exposures to potentially harmful substances.

One of the scariest things to me as a grandparent are my grandchildren accessing my medication or other relative's medications. Traveling visitors may be careless with their medications leaving them in areas easily accessible to children; for instance, on a nightstand or in their suitcases. **At the Cincinnati Drug and Poison Information Center, 8,992 exposures to prescription and over-the-counter drug products occurred in children under the age of 6 in 2016. So far, we are on course to exceed that number for 2017 with 8,118 exposures already this year.** Many medications look like candies or sweet drinks. It is important that you and/or your visitors lock medications up where children cannot access them.



Foreign body ingestions are yet another source of concern. Batteries are found in many children's toys and in remote controls. Small "button" batteries are easily swallowed by children and can become stuck in the esophagus. Toys, ornaments, and other small decorations can be swallowed by children and pose airway or gastrointestinal obstruction risks. In 2015, poison centers were consulted for approximately 96,000 cases of foreign body and/or button battery ingestions, roughly 6,500 of which involved toys or ornaments (AAPCC, 2016). Parents and caregivers are encouraged to keep small batteries out of the reach of children and to make sure that battery compartments are properly closed on toys.

Nicotine and tobacco products including chewing tobacco, e-cigarette refills and vape devices can be toxic to children. It is important to empty ashtrays promptly and store tobacco products and e-cigarettes and their kits out of the reach of children.

Many homes this time of year are filled with holiday plants. Most plants do not pose a risk to children or pets, but be sure to keep plants such as mistletoe, holly, fruit of Jerusalem cherries, boxwood, yew plants, and poinsettias up and out of reach of children and pets.

Other potentially toxic hazards may not be as easily visible. Lead paint may be present on older decorations and/or toys. Wash your hands after decorating with these products. Closely inspect antique toys and ones that have been made in foreign countries as some of these items pose a higher risk for lead exposure. Do not let children play with older toys with chipping, peeling, or worn paint. Try to read reviews and see if there are toy recall notices before purchasing new toys (AAPCC, 2016).

Household products account for about 10% of poison exposures to kids under the age of 6 years. Common laundry detergent pods, cleansers, soaps, and disinfectants are used to ready the house for guests. Make sure these and all cleaning products are kept out of reach of little ones.

If you or someone you know has come in contact with these or any other potentially poisonous substances call your local poison control center. **Program the Poison Help line by texting "poison" to 797979.** The experts at poison centers are available at **1-800-222-1222** to provide free and confidential information and treatment advice 24 hours per day, seven days a week, year round, including holidays!

Finally, hope your holiday is full of fun, merriment, and good cheer!

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American Association of Poison Control Centers. New Release, December 8, 2016. "American Association of Poison Control Centers Provides Safety Recommendations to Avoid Poison Hazards this Holiday Season". https://aapcc.s3.amazonaws.com/pdfs/releases/2016_AAPCC_Winter_Poison_Safety_Press_Release_FINAL.pdf

Check out our Holiday Hazard Fact sheet on our website:

<https://www.cincinnatichildrens.org/service/d/dpic/community/prevention>

The 21st Century CURES Act

Regina Tarantino RN, CSPI



The 21st Century Cures Act became law on December 13, 2016. This law's intention is to increase medical discovery/development/treatment and make available these advancements to patients and health professionals in a more expedited, inclusive, and efficient manner (US FDA, 2017). The Cures Act is a step in the right direction towards streamlining the current antiquated FDA regulations and paperwork. Most importantly, **the Cures Act increases the individual's state's efforts "to combat opioid abuse**, and [develop] new steps aimed at improving mental health services (Hudson & Collins, 2017, p.111).

SAMHSA indicates the Cures Act "represents the most significant reforms to the mental health system in more than a decade (SAMHSA, 2016). In the next two years, SAMHSA will award up to \$970 million to states beginning in the fiscal year 2017. Ohio's single state agency, the Ohio Department of Mental Health and Addiction Services (OhioMHAS) is eligible to apply for these grants totaling up to \$26 million in FY 2017.

Using feedback from stakeholders and sharing available data, OhioMHAS has designated six areas as priorities for a comprehensive response (21st century CURES Act):

1. Medication-assisted treatment
2. Workforce development
3. Immediate access
4. Primary prevention Screening, Brief Intervention, and Referral to Treatment (SBIRT)
5. Recovery supports, including peer
6. Addressing secondary trauma amongst first responders.

Ohio will focus on integration and congruence of all areas of treatment from beginning to recovery. Although the higher focus placed on areas where the most significant opioid deaths occur and areas where there is the highest level of need, strategies, and activities will be shared and used throughout the state. Hitting Tier One the hardest will have the most significant impact on the opioid epidemic in Ohio.

Current funding tiers from 2010 to 2015 data:

Tier One consists of 61% of the state population living in areas with the highest overdose death counts and fentanyl deaths.

Tier Two consists of 14% of the state population. These areas consist of the next highest overdose death rates.

OhioMHAS will offer statewide continuing education and case review for healthcare professionals. Current evidence-based practices used in primary prevention will receive assistance to expand and build on. Two prime examples are PAX Good Behavior Game and Botvin Life skills. The Ohio Board of Pharmacy together with the Ohio Department of Public Safety and the Ohio Department of Mental Health and Addiction Services will work together in establishing a statewide drug take-back program (21st century CURES Act).

The field of treating opioid addiction is relatively new with more questions than answers. Not all opioid addicted individuals have the opportunity for treatment. Feldman and Frank agree that "closing this treatment gap is a key goal of the Cures Act" (Feldman & Frank, 2017, p.2). Funding of grants should be more available to the evidence-based impact applicants rather than the unsupported promise of effective treatment. We need to find out what treatments work best, how to implement findings to the larger group, what are effective outreach programs, how do we keep opioid users involved in long-term treatment, and how to support the person throughout this journey.

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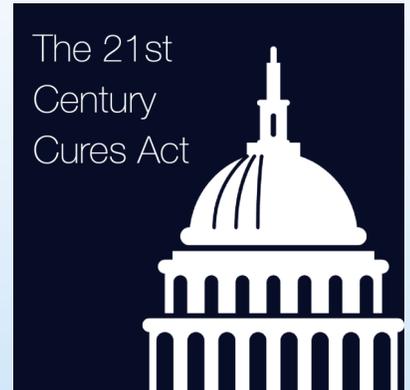
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Legal Consequences for Foreign Fentanyl Manufacturers

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In September 2017, Chinese nationalists Xiaobing Yan and Jian Zhang were indicted by the United States for conspiracy to manufacture and distribute multiple controlled substances, including fentanyl and its derivatives. These medications have high abuse and addiction potential and, depending on the formulation, can have a potency up to 50 times more than heroin. The perpetrators **used websites to illegally sell and distribute these medications through the mail worldwide**. In addition, they were known to operate chemical plants in China that were notorious for producing these drugs. Investigations by the DEA and other U.S. organizations revealed that fentanyl and its analogs manufactured by these labs **were responsible for multiple deaths** in the United States over the past few years. If convicted of the charges, Yan and Zhang could face a maximum statutory penalty of 20 years in prison (US DEA, 2017).



The pair were also designated by the United States as Consolidated Priority Organization Targets. This classification is reserved for criminals who have command and control of international drug trafficking and money laundering organizations. It is known that overseas chemical manufacturers, with the help of illicit domestic distributors, attempt to evade regulatory controls by creating structural derivatives of fentanyl that are not directly listed under the Controlled Substances Act. To prevent exploitation of this legal loophole, the DEA has since published intent for analogs of controlled substances to be temporarily added to the list of highly addictive, abuse-potential drugs (US DEA, 2017).

The Centers for Disease Control estimates that over **20,000 Americans were killed by fentanyl** and its analogues in 2016. The flux of illegal drug imports has been a significant barrier when it comes to managing the potential damage caused by this epidemic (2017).

References:

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U.S. Drug Enforcement Administration (2017). Department of Justice announces significant tool in prosecuting opioid traffickers in emergency scheduling of all fentanyl/s. (Office of Public Affairs Press Release Number 17-1268). Washington, DC: U.S. Department of Justice.

Emergency Preparedness

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Jan Scaglione MT, PharmD, D ABAT

Pharmacists, like other healthcare professions, should be prepared to respond to natural disasters such as wildfires, hurricanes, and earthquakes. **In case of a disaster, a pharmacist should strive to make sure patients have access to needed medications, and will need to consider the impact of state laws, pharmacy policies, and common sense in these situations.** It isn't always possible to stock up on supplies of medications and alternative medications before a disaster occurs, and supplies are often affected by the disaster itself. It is a



great idea to attempt to stock up if advanced notice of disaster has been issued, however. Making sure your patients are taken care of during a disaster helps lessen the stress that naturally comes from life disruption. In the event that a state has declared an emergency, a pharmacist that is helping an existing patient may fill up to a 30-day supply of a maintenance medication if the patient's doctor is unable to be reached. Medications with high abuse potential, those that are labelled as Schedule II controlled substances are not included in the rule that allows pharmacists to dispense during a disaster. A pharmacist may override the computer system to be able to keep track of this type of assistance in a natural disaster.

Pharmacists should encourage patients to make sure that they have adequate supplies to get through a disaster if it is possible to plan ahead for one. Pharmacists may update patients' medication lists to make sure they can get their medications from another pharmacy if necessary. Look into your organizations policy and procedure for handling natural disasters, and consider scheduling extra staff before and after disaster. Also consider reaching out to other pharmacies in case reallocation of stock is needed, and **consider a plan for frozen and refrigerated medications in case of power outage**. Also make sure that there is the ability to back up files, securing controlled substances, and unplugging electronics, notifying personnel, and setting up temporary voicemail messages.

It is also important for a pharmacist to prepare for events after a disaster, which focuses on acute basic health needs. Have a plan ready for patients that come to you without documentation, but have a need to get their medication. This includes helping by calling the pharmacy, prescriber, or insurer. Follow your state board rules concerning any special stipulations available that helps patients gain access to needed medications. Look into any federal assistance programs for patients who do not have insurance following the disaster. And of course, keep accurate records of stock and inventory for losses that may occur.

References:

Pharmacist Letter. (2017, November). Assist Your Patients During a Disaster. Retrieved November 29, 2017, from <https://pharmacist.therapeuticresearch.com/Content/Articles/PL/2017/Nov/Assist-Your-Patients-During-a-Disaster>

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Rexulti® (brexpiprazole)
 Robyn Davis MSN, RN, CSPI



Rexulti® (brexpiprazole) was approved in July of 2015 and is indicated for the **treatment of schizophrenia and as an additional therapy to antidepressants for the treatment of major depressive disorder (MDD).**

Dose: Rexulti® is supplied in tablet form ranging from 0.25mg to 4mg and is taken once daily by mouth. The recommended starting dose is between 0.5-1mg per day with maximum doses of 3-4mg per day, depending on indication. Liver enzymes CYP3A4 and CYP2D6 are primarily responsible for metabolizing Rexulti® so dose adjustments are necessary in patients with renal and liver impairment.

Adverse Reactions: The most common adverse effects reported were weight gain and akathisia (feeling of inner restlessness and need for constant motion).

Rexulti® may cause SERIOUS effects:	Watch for:
Stroke in elderly people	Face drooping, arm weakness, speech difficulty, sudden loss of balance, sudden double vision and/or difficulty seeing
Tardive Dyskinesia	Movements that you can't control in your face, tongue or other body parts. If this develops, it may not go away even if you stop taking Rexulti®.
Low white blood cell count	
Seizures	Convulsions
Problems with Body Temperature control	Avoid getting overheated or dehydrated
Orthostatic hypotension	You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.
High Blood sugar (hyperglycemia)	Excessive thirst, nausea, tiredness, excessive hunger, increased urination,
Neuroleptic Malignant Syndrome (NMS) characterized by high fever, muscle stiffness, confusion, fast heart beat	High fever, stiff muscles, confusion, sweating, changes in pulse, heart rate, and blood pressure. These may be symptoms of a rare and serious condition that can lead to death.

Black Box Warnings: There is a black box warning for Rexulti® for an increased mortality risk in elderly patients with dementia-related psychosis. There is also a warning that antidepressants increase the risk of suicidal thoughts and behaviors in patients 24 years and younger.

Pharmacokinetics: After single therapeutic dose administration of REXULTI® the peak plasma concentration occurred within 4 hours with absolute oral bioavailability being 95%.

Toxicology/ Overdose management: Oral activated charcoal and sorbitol (50 g/240 mL), administered one hour after ingesting oral brexpiprazole, decreased brexpiprazole Cmax and area under the curve (AUC) by approximately 5% to 23% and 31% to 39% respectively; however, there is insufficient information available on the therapeutic potential of activated charcoal in treating an overdose with REXULTI®. There is no information on the effect of hemodialysis in treating an overdose with REXULTI®; hemodialysis is unlikely to be useful because brexpiprazole is highly bound to plasma proteins. At a dose 3-times the maximum recommended human dose (MRHD) for the treatment of schizophrenia and 4-times the MRHD for adjunctive therapy to antidepressants for the treatment of MDD, REXULTI® does not prolong the QTc interval to any clinically relevant extent.

Reference:

Otsuka Pharmaceuticals, Inc. (2017, January). Rexulti® (brexpiprazole) . Retrieved November 15, 2017, from <https://www.Rexulti.com/us/mdd>

Options for Reversing Anticoagulant Effects of New Oral Anticoagulant Drugs

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The new oral anticoagulants (NOACs) are a class of medications used as alternative options to the traditional blood thinner, warfarin. The NOACs were recently approved to prevent and treat deep vein thrombosis (DVT), pulmonary embolism (PE) and stroke in patients with atrial fibrillation and heart failure as well as post-operative orthopedic patients. While warfarin decreases the production of several clotting factors in the blood clotting cascade, the NOACs are designed to directly inhibit one specific clotting factor within the cascade.

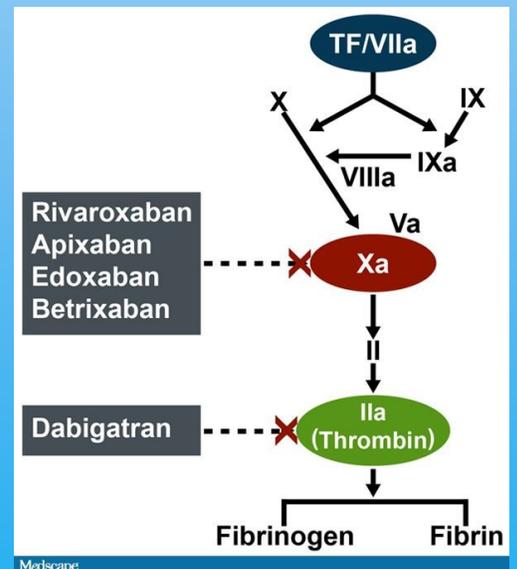
While these drugs may have a more appealing safety profile, there are limited options for reversing the anticoagulant effects of the NOACs. Anticoagulation by warfarin can easily be reversed by administering Vitamin K, but **Pradaxa, a factor IIa inhibitor, is currently the only NOAC with an approved antidote.** **Praxbind** is a humanized monoclonal antibody which binds to Pradaxa and inhibits its anticoagulant effect in situations where emergent surgery is necessary, or in patients with life-threatening or uncontrollable bleeding. **AndexXa, the factor Xa inhibitor reversal agent, is currently under FDA review** and pending approval to reverse the anticoagulant effects of Eliquis, Xarelto, Savaysa, Bevyxxa as well as the low molecular weight heparin drugs Lovenox and Arixtra. AndexXa is a recombinant modified human factor Xa molecule which binds to internal factor Xa inhibitors, allowing endogenous factor Xa to take part in the coagulation cascade (Praxbind, 2017).

Drug	Reversal Agent	Status	Dosing
Pradaxa (dabigatran)	Praxbind (idarucizumab)	Approved	5 g IV (infusion or bolus)
Eliquis (apixiban)	AndexXa (andexanet alfa)	Pending Approval	N/A
Xarelto (rivaroxaban)			
Savaysa (edoxaban)			
Bevyxxa (betrixaban)			

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Preventing Foodborne Illnesses During the Holidays

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As you anticipate consumption of that delicious, tender turkey, and scrumptious mashed potatoes, it is important to take precautions when preparing and consuming holiday meals¹. The Centers for Disease Control and Prevention (CDC) recommends 5 easy steps to prevent food poisoning during the holiday season¹:

1. Thaw your turkey properly in the refrigerator, in the sink filled with cold water that is changed every 30 minutes, or in the microwave on defrost. Never thaw a turkey on the counter. When a turkey is left out at room temperature longer than 2 hours, the turkey reaches a temperature where bacteria are able to grow rapidly. Turkeys should be cooked immediately after the turkey is completely thawed. See the table below recommended by the United States Department of Agriculture for expected thawing time according to the weight of your turkey².
2. The following precautions should be taken to prevent contamination of foods or surfaces while preparing your turkey. Wash your hands for at least 20 seconds with soap and water before, during and after food preparation, as well as before eating. Utensils, cutting boards, and countertops should also be washed with hot soapy water. If the turkey is thawed in the refrigerator overnight, make sure the turkey does not touch other foods. When the turkey is purchased from the grocery store, ensure it is placed in a bag by itself¹.
3. For ideal safety, cook your stuffing outside the turkey in a casserole dish. If you prepare your turkey with stuffing, stuff the turkey right before cooking it. Ensure the stuffing's center reaches a temperature of 165°F. Avoid purchasing pre-stuffed turkey which can provide an opportunity for bacteria to grow¹.
4. When cooking the turkey, set the oven temperature to at least 325°F. Place the thawed turkey breast side up in a roasting pan at least 2-2 ½ inches deep. Cooking times vary depending on the weight of the turkey as listed on the packaging or in the tables below². Regardless of weight, the internal threshold temperature should reach at least 165 °F in the thickest portion of the stuffing, breast, thigh, and wing. After cooking the turkey, let the turkey sit at least 20 minutes¹. How much turkey is enough? Plan for 1 pound of turkey per person².
5. The 5th and last step is ENJOY! Refrigerate any leftovers at 40°C within 2 hours of cooking and discard any unconsumed turkey, stuffing, and gravy within 3-4 days². To guarantee full, happy bellies in the absence of food poisoning, please follow the necessary steps as mentioned above. Happy Holidays!

Weight	Thawing time in fridge	Thawing time in cold water
4-12 pounds	1-3 days	2-6 hours
12-16 pounds	3-4 days	6-8 hours
16-20 pounds	4-5 days	8-10 hours
20-24 pounds	5-6 days	10-12 hours

Turkey Weight	Unstuffed cooking time
4-8 pounds	1 ½ to 3 ¼ hours
8-12 pounds	2 ¾ to 3 hours
12-14 pounds	3 to 3 ¾ hours
14-18 pounds	3 ¾ to 4 ¼ hours
18-20 pounds	4 ¼ to 4 ½ hours
20-24 pounds	4 ½ to 5 hours
Turkey Weight	Stuffed cooking time
4-6 pounds	N/A
6-8 pounds	2 ½ to 3 ½ hours
8-12 pounds	3 to 3 ½ hours
12-14 pounds	3 ½ to 4 hours
14-28 pounds	4 to 4 ¼ hours
18-20 pounds	4 ¼ to 4 ¾ hours
20-24 pounds	4 ¾ to 5 ¼ hours



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Visit our website <https://www.cincinnatichildrens.org/service/d/dpic>

Visit our blog <https://www.cincinnatichildrens.org/service/d/dpic/dpic-blog>

The Cincinnati Drug and Poison Information Center (DPIC) at Cincinnati Children's Hospital Medical Center is a 24-hour emergency and information telephone service for anyone with concerns about poison or drugs.

The center's specially trained staff of pharmacists, pharmacologists and nurses and drug / poison information assistants answer questions about poisonings, drug abuse, product contents, substance identification, interactions and adverse reactions.

The Drug and Poison Information Center also works to provide you with important prevention information, educational materials, first-aid information, common household hazards and references to national helpline organizations and agencies.

The phone number for the Cincinnati Drug and Poison Information Center is **513-636-5111**. You may also call a national hotline, **1-800-222-1222**, and you will be connected to the center that serves your area.

The center also offers contract services to businesses looking for pharmacovigilance and safety surveillance for post-marketing and clinical trials.



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