

What's Inside...

Rx News.....	1
Law Review.....	2
Focus On:	2
<i>Feature Article:</i>	
COVID-19: An Update for Pharmacists.....	3
Ask PRN.....	4
Did You Know?.....	4
Pharmacy Fun.....	4

FDA NEWS

New Warning Required on Montelukast Label

The Food and Drug Administration (FDA) has ordered that a **black-box warning** be added to the label of all Montelukast products. This action is being taken in response to continued reports of mental health side effects with montelukast use. Neuropsychiatric symptoms reported have included suicidal thoughts and actions. In addition to the label warning, the agency recommends:

- Montelukast should only be used for allergic rhinitis in patients who do not respond to, or can not tolerate, alternative therapies.
- Ask patients about any history of psychiatric illness prior to initiating treatment.
- Advise patients and parents/caregivers to stop taking montelukast and contact a health care professional immediately if changes in behavior or new psychiatric symptoms, suicidal thoughts or behavior occur.

.....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....

NURTEC ODT (Rimegepant).

Category: Calcitonin gene-related peptide receptor (CGRP) antagonist for the acute treatment of migraine.

Initial Dose: 75 mg as needed.

MDD: 75 mg in 24-hour period.

Biohaven has announced FDA approval of Nurtec ODT, an orally disintegrating tablet for the acute treatment of migraine with or without aura. Nurtec ODT is the second CGRP antagonist to be marketed in an oral formulation (Ubrovelvy was the first). This class of drugs is believed to work by blocking the effects of CGRP, which include cerebral vasodilation, release of inflammatory mediators, and transmission of pain signals. Clinical trials demonstrated pain relief within 2 hours of dosing, which was sustained for up to 48 hours. The recommended dose of Nurtec ODT is 75 mg, placed on or under the tongue, as needed for acute migraine. The maximum dose in a 24-hour period is 75 mg. The safety of treating more than 15 migraines in a 30-day period has not been established. Nurtec ODT is not indicated for the preventive treatment of migraine.

NEXLETOL (Bempedoic acid).

Category: Adenosine triphosphate-citrate lyase (ACL) inhibitor for lowering LDL-C.

Initial Dose: 180 mg orally once daily with or without food.

MDD: 180 mg.

Esperion has been granted approval to market Nexletol, a first-in-class ATP citrate lyase (ACL) inhibitor indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults who require additional lowering of LDL-C. ACL inhibition lowers LDL-C by decreasing cholesterol synthesis in the liver and through upregulation of low-density lipoprotein receptors. The recommended dose of Nexletol is 180 mg once daily with or without food. Nexletol can cause elevations in serum uric acid; monitor patients for signs and symptoms of hyperuricemia. Tendon rupture has occurred. Discontinue Nexletol at the first sign of tendon rupture. Avoid Nexletol in patients who have a history of tendon disorders or tendon rupture. Avoid concomitant use with simvastatin doses greater than 20 mg and pravastatin doses greater than 40mg. Nexletol should not be used in pregnant women.

New York Responds to the Coronavirus Pandemic

The world has changed since we last spoke. As I sit in the office, high above the streets of Queens, New York, the epicenter of the epicenter, the startling and eerie silence which has descended upon our city is broken only by the ever-increasing wail of ambulance sirens heard passing by on their way to the next emergency. Once again New York, and New Yorkers, are on the front line as our nation confronts an unprecedented crisis, and pharmacists and pharmacy technicians are an integral part of the army of dedicated workers fighting the pandemic. New York State and the Office of the Professions (which includes the Board of Pharmacy) have already taken action to amend or suspend regulations to assist pharmacists in practicing during the crisis (see page 2 for details). Here are a list of some of the additional resources being offered by New York State and New York City which may be of assistance to our community:

New York City Regional Enrichment Centers: New York City has opened about 100 Regional Enrichment Centers (RECs) across all 5 boroughs, which are open Monday through Friday from 7:30 AM to 6:00 PM, for the children of essential workers, including pharmacists and pharmacy employees, who need daycare. RECs will supply 3 meals a day, as well as remote learning. To apply for a REC near you, go to:

<https://www.schools.nyc.gov/enrollment/enrollment-help/regional-enrichment-centers>

New York State Coronavirus information: New York State has opened both a hotline and a website for the latest information on the pandemic:

Call: [1-888-364-3065](tel:1-888-364-3065) or go to:

<https://coronavirus.health.ny.gov/home>

New York State Free Mental Health Counseling: The State has created a COVID-19 Emotional Support Hotline for mental health counseling.

Call: [1-844-863-9314](tel:1-844-863-9314)



LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State



New York State Executive Orders Relating to the Coronavirus Pandemic

In response to the coronavirus pandemic, which has already hit hard in New York, Governor Andrew Cuomo has issued Executive Order 202.10, which temporarily suspends or modifies a number of laws relating to the disaster emergency previously declared in the state. These modifications were announced on March 23, and will remain in force until at least April 22, 2020. The actions taken in the order which are directly related to the practice of pharmacy are listed below.

- ♦ **No pharmacist shall dispense hydroxychloroquine or chloroquine except when written as prescribed for an FDA-approved indication; or as part of a state approved clinical trial related to COVID-19 for a patient who has tested positive for COVID-19, with such test result documented as part of the prescription. No other experimental or prophylactic use shall be permitted, and any permitted prescription is limited to one fourteen day prescription with no refills.**
- ♦ **Notwithstanding any law or regulation to the contrary, healthcare providers are relieved of recordkeeping requirements to the extent necessary for health care providers to perform tasks as may be necessary to respond to the COVID-19 outbreak, including, but not limited to, requirements to maintain records that accurately reflect the evaluation and treatment of patients, or requirements to assign diagnostic codes or to create or maintain other records for billing purposes. Any person acting reasonably and in good faith under this provision shall be afforded absolute immunity from liability for any failure to comply with any record-keeping requirement.**
- ♦ **Subdivision (1) of Section 6801 of the Education Law, Section 6832 of the Education Law and Section 29.7(a)(21)(ii)(b)(4) of Title 8 of the NYCRR [is amended], to the extent necessary to permit a certified or registered pharmacy technician, under the direct personal supervision of a licensed pharmacist, to assist such licensed pharmacist, as directed, in compounding, preparing, labeling, or dispensing of drugs used to fill valid prescriptions or medication orders for a home infusion provider licensed as a pharmacy in New York, compliant with the United States Pharmacopeia General Chapter 797 standards for Pharmaceutical Compounding — sterile preparations, and providing home infusion services through a home care agency licensed under Article 36 of the Public Health Law.**

FOCUS ON: NEW YORK STATE OFFICE OF THE PROFESSIONS REACTS TO CORONAVIRUS PANDEMIC

The New York State Office of the Professions (OP) has issued guidance for pharmacists regarding changes to regulations during the current emergency situation:

Q: During the COVID-19 outbreak are pharmacists still required to document when a patient declines medication counseling?

A: Pursuant to Executive Order 202.10 (see above), which among other things, relieves recordkeeping requirements to the extent necessary for health care providers to perform tasks as may be necessary to respond to the COVID-19 outbreak, pharmacists are not required to document when a patient declines medication counseling.

Q: Are CE requirements being waived?

A: Not at this time. However, for those licensees whose registrations are due to renew March 1 to June 1, 2020, the Department of Health will grant an adjustment to all licensees to complete up to 100% of the continuing education as self study, thus waiving the requirement for pharmacists to complete 23 of their 45 credits through live CE courses.

Q: Will the live CPR or BLS course requirement for pharmacist immunization certification be temporarily suspended to permit pharmacists to take CPR or BLS courses online or virtually to satisfy their required CPR or BLS certification for their immunization privilege?

A: Yes, the live CPR or BLS course requirement for pharmacist immunization certification is temporarily suspended to permit pharmacists to take CPR or BLS courses online or virtually to satisfy their required CPR or BLS certification for their immunization privilege. The temporary suspension of this live course requirement will be in effect until 30 days after the expiration of Executive Order 202. All other pharmacist immunization certification requirements remain in effect.

Q: Are pharmacists still permitted to dispense clozapine if a patient is unable to get a current ANC test due to the epidemic?

A: The New York State Office of Mental Health has confirmed with the FDA that pharmacies have discretion to order and dispense clozapine without an absolute neutrophil count reported within the specified timeframes.

COVID-19: AN UPDATE FOR PHARMACISTS

The public health emergency caused by the emergence of a novel coronavirus, SARS-CoV-2, is a fast-moving and constantly evolving story. We have endeavored here to provide pharmacists with the latest information available at the time of publication. While much has been learned about both the virus and the disease, there is still a long way to go before a full understanding emerges. We will continue to monitor the science and keep our readers informed.

The Virus

The virus, which seems to have first appeared in humans in Wuhan, China, in December, 2019, has been named SARS-CoV-2, which stands for severe acute respiratory syndrome coronavirus 2. It is closely related to other coronaviruses, such as SARS and MERS. The virus appears to be nearly identical to a coronavirus found in the horseshoe bat, and may have jumped to humans through an intermediate host, such as the pangolin, a scaly anteater-like mammal. It has been demonstrated the virus enters human cells by binding to the angiotensin converting enzyme 2 (ACE2) receptor, which is found in the lungs, heart, kidneys, and intestines.

The Disease

The disease caused by SARS-CoV-2 has been named COVID-19 (coronavirus disease 2019). COVID-19 is primarily a respiratory disease, although some patients have exhibited gastrointestinal or cardiac symptoms. The most common presentation is that of patients exhibiting fever, fatigue, and dry cough. Other symptoms which have been commonly reported include diarrhea and the loss of the senses of smell and taste. The most serious symptom of COVID-19 is shortness of breath, which in some cases may progress to acute respiratory distress syndrome (ARDS), which can lead to the need for ventilation and may result in death.

The Treatment

Currently there is no proven pharmacological treatment for COVID-19. Treatment, both at home and in the medical setting, is supportive. Rest, hydration, and OTC medications to treat symptoms are recommended. There has been some controversy over the use of ibuprofen to treat fever in COVID-19 patients since the French Health Ministry advised against it (NSAIDs could theoretically increase ACE2 expression). However, lacking any hard evidence of harm, the World Health Organization is not currently advising patients to avoid the use of ibuprofen. There are many drugs currently under investigation as possible treatments for COVID-19.

Clinical Trials

Researchers are currently investigating dozens of drugs, both marketed and investigational, for use in the treatment of COVID-19. Some of the clinical trial currently underway include the following:

Remdesivir: Gilead Sciences developed this antiviral for the treatment of the Ebola virus, but it has been shown to be effective, in vitro, against coronaviruses, including SARS, MERS, and SARS-CoV-2. It has been used in a small number of patients with reported success, and is now in clinical trials in both China and the U.S.

Hydroxychloroquine/ Chloroquine: These decades-old antimalarial drugs have shown promise, again, in vitro, in SARS and SARS-CoV-2. There have also been anecdotal reports of success in COVID-19 patients. One small study in France, which added the antibiotic azithromycin to hydroxychloroquine, demonstrated a decrease in viral shedding. Clinical trials are underway in the U.S., but enthusiasm over the promise of a treatment for COVID-19 has led to a nationwide shortage of hydroxychloroquine, which is an important therapy in the treatment of rheumatoid arthritis, lupus, and other autoimmune diseases.

Avigan: Also known as favipiravir, this Japanese-developed antiviral was originally used for influenza, but has shown effect against SARS-CoV-2 in Chinese studies.

Best Practices for Pharmacies

Community pharmacy is an essential service, and as such is exempt from the order, in New York and many other states, for all businesses to shut down in an attempt to slow the spread of the coronavirus pandemic. As such, pharmacists and their staffs need to be considered first responders, and should be afforded all the protections that we expect for our front line workers. Below are some suggestions, gathered from our colleagues, for keeping safe while serving our patients.

- **Wherever possible, all staff should be supplied with gloves and masks at the start of each shift. Gloves should be replaced as needed.**
- **Surfaces which are touched by customers or staff should be disinfected as often as possible, and staff should wash hands whenever feasible.**
- **Consider waiving the requirement for patients to sign for prescriptions to minimize contact with surfaces (New York State is relaxing recordkeeping requirements. See Law Review on page 2.).**
- **Ask all staff members to submit to having their temperature taken at the beginning and end of each shift. Colleagues who have a fever should not be allowed to work. It is likely that infection among co-workers is a major source of the spread of the virus.**
- **Enforce social distancing by placing markers on the floor in the pick-up and drop-off areas which would keep people on line at least 6 feet apart if at all possible. Also, to whatever extent possible, keep staff at workstations as far apart as space limitations allow.**
- **Consider limiting the number of customers allowed in the store at any one time, especially in pharmacies that are smaller in size and would not allow for social distancing when busy.**
- **Consider reducing store hours to reduce exposure and allow for cleaning the store after closing each day.**

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Founder and Editor:
James Murphy, RPh

Contributors
Sasha Budhram, PharmD

Medical Liaison:
Deborah Blenner, MD

Marketing:
Michelle Ye

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Or, if you prefer, write us at:
PRN Publishing
7636 113th Street
Suite 6C
Forest Hills, New York 11375



ASK PRN...

Is it permissible under FDA regulations for pharmacists to contemporaneously prepare hand sanitizer for their staff and patients?

Yes. The FDA recently issued guidance permitting pharmacists in licensed pharmacies to compound alcohol-based hand sanitizers. This guidance will remain in effect for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020. The agency has published specific parameters regarding *ingredients* and *concentrations* which must be adhered to when compounding hand sanitizer.

Ingredients: the hand sanitizer must be compounded using only the following ingredients:

- Ethanol ($\geq 94.9\%$) OR Isopropyl Alcohol
- Glycerin, USP or food grade
- Hydrogen peroxide
- Sterile water

Concentrations: the hand sanitizer must be compounded according to the following formula:

- Ethanol 80% (v/v) OR Isopropyl Alcohol 75% (v/v) in aqueous solution
- Glycerin 1.45% (v/v)
- Hydrogen peroxide 1.25% (v/v)
- Sterile distilled water or boiled cold water

The compounder must not add other active or inactive ingredients, such as ingredients to improve the smell or taste due to the risk of accidental ingestion in children. Different or additional ingredients may impact the quality or potency of the product. The hand sanitizer must be labeled consistent with templates provided by the agency here: [hand sanitizer label templates](#).

GOT QUESTIONS? WE HAVE ANSWERS!

Send your questions to us at:
askprn@prnnewsletter.com

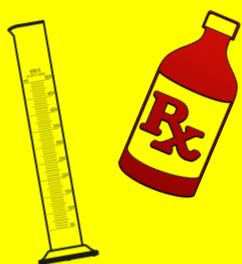
PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW that the surgical face mask, so ubiquitous these days, was first used in 1897 by French surgeon Paul Berger? Berger was influenced by the work of German bacteriologist Carl Flügge, who showed that ordinary conversation could spread infectious droplets¹, and Polish surgeon Jan Mikulicz-Radecki, who designed an early version of the mask. The surgical mask was put to the test during the Manchurian plague of 1910. Malaysian-born Chinese physician Wu Lien-teh pioneered the widespread use of the masks during the outbreak, and managed to protect himself and his staff from an airborne disease with an estimated mortality rate between 95 and 99%.

PHARMACY FUN

This month's puzzle puts a pharmaceutical twist on an a classic riddle. You find yourself in an old, broken-down pharmacy and are asked to prepare a compound which requires **exactly 400 ml** of water. You have a working sink, but the only equipment available to measure out the H₂O is a 500 ml graduated cylinder and a 300 mL amber rx bottle. Unfortunately, only the 500 mL mark on the graduate is still visible; all the other gradations have been worn away over time. And the amber bottle has only one volume demarcation at the 300 mL level. Your mission, should you choose to accept it, is to figure out how to measure out exactly 400 ml of water using only the 500 mL graduated cylinder and the 300 ml rx bottle. The first reader to submit the correct answer to puzzle@prnnewsletter.com will win a \$10 gift card from Amazon, which will be sent electronically to the winner's Amazon account.



Answers to last month's **PHARMACY FUN**:

1. Warfarin 2. Invokana 3. Eliquis 4. Trulicity 5. Metoprolol 6. Xarelto

References:

1. Spooner, John L. "History of surgical face masks." *AORN Journal*, vol 5 no. 1, (1967): 76-80.