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What's Inside…

FDA NEWS

FDA Issues Warning on Hydroxychloroquine Use in COVID-19

On April 24, 2020, the Food and Drug Administration (FDA) released a Drug Safety Communication regarding the use of hydroxychloroquine in patients suffering from COVID-19. The agency, which approved the temporary use of the drug in hospitalized COVID-19 patients under an Emergency Use Authorization (EUA), stressed the following points in the warning:

- **Hydroxychloroquine can cause abnormal heart rhythms such as QT interval prolongation and can lead to a dangerously rapid heart rate called ventricular tachycardia, and the risk of these outcomes may be increased when the drug is combined with azithromycin.**
- **Hydroxychloroquine should be used for COVID-19 only when patients can be appropriately monitored in the hospital as required by the EUA or are enrolled in in a clinical trial with appropriate screening and monitoring.**

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ONGENTYS (Opicapone).
Category: COMT inhibitor for Parkinson's.
Initial Dose: 50 mg orally once daily at bedtime. Patients should not eat for 1 hour before and for at least 1 hour after dose.
MDD: 50 mg orally once daily.

Neurocrine Biosciences has received FDA approval for Ongentys, a novel, once-daily catechol-O-methyltransferase (COMT) inhibitor. Ongentys is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing OFF episodes. Symptoms of OFF episodes may include tremor, stiffness, slowed movement, and difficulty walking. Ongentys should be administered once daily at bedtime, at least 1 hour after any food, and is contraindicated in patients taking non-selective monoamine oxidase (MAO) inhibitors. Ongentys is also contraindicated in patients with a history of pheochromocytoma, paraganglioma, or other catecholamine-secreting neoplasms.

KYNMOBI (Apomorphine HCl).
Category: Non-ergoline dopamine agonist.
Initial Dose: 10 mg to 30 mg administered sublingually, as needed.
MDD: Maximum of 5 doses per day; maximum single dose is 30 mg.

Sunovion Pharmaceuticals has announced FDA approval of Kynmobi, a sublingual film containing apomorphine, a non-ergoline dopamine agonist. Kynmobi is indicated for the acute, intermittent treatment of OFF episodes in patients wit Parkinson's disease. Apomorphine is a well-known and powerful emetic, and as such it is recommended that an antiemetic (e.g., trimethobenzamide 300 mg TID) be started 3 days prior to the initial dose of Kynmobi. Dosing is 10 to 30 mg, sublingually, as needed, up to 5 times per day. Kynmobi doses should be separated by at least 2 hours. Based on reports of profound hypotension when administered with ondansetron, Kynmobi is contraindicated for use with 5HT3 antagonists.

NYC Reaches Another Grim Milestone: Most Deaths Per Capita on the Planet

Even as the coronavirus pandemic finally appears to be ebbing in New York, the city has posted yet another world-leading statistic: the number of deaths per capita now far exceeds that of any other city, or country, for that matter, in the world. This adds to the area's other horrific statistics—more confirmed cases and deaths than any city in the U.S., and more cases in New York State than in any country, beside the U.S. (although it is likely the New York will soon be overtaken by Brazil and Russia, countries with populations many times greater than that of the state). To get an idea of just how outsized the disease has become in the five boroughs, we have put together a chart comparing New York City to the U.S., the United Kingdom (U.K.) and the area previously thought to be the hardest hit by coronavirus, the Lombardy region of Italy:

Country/City	Total Cases	Cases per 100,000	Deaths per 100,000
United States	1,608,289	492	29
United Kingdom	254,195	382	55
Lombardy, Italy	86,384	859	157
New York City	201,298	**2384**	**244**

Unlike the infection fatality rate, which will decrease as more cases are discovered, deaths per 100,000 is a measure than can only increase over time, since the denominator is a fixed number — the population of the city. For example, the case fatality rate (deaths ÷ confirmed cases) in NYC is about 8%, but since most experts believe there are about 10 times more cases in the city than have been confirmed, the infection fatality rate is actually closer to 0.8% (much better, but still 8 times deadlier than the average seasonal influenza). Currently about 2% of New Yorkers have tested positive for the virus, but antibody testing has revealed a 20% infection rate, bearing out the idea that actual infections are about 10 times greater than confirmed infections. Meanwhile, the deaths per 100,000 figure, which can not decrease, inches ever closer to that of the 1918 influenza pandemic, which reached 470 deaths per 100,000 in New York City[1].

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Prior Authorization Waived for Certain Backordered Drugs

The New York State Medicaid Program has announced that it will remove prior authorization (PA) requirements for certain drug classes which are currently unavailable due to market shortages or allocation restraints. This policy change is intended to ensure access to necessary medications during the Declared Disaster Emergency in New York. The following agents are affected:

- **Asmanex HFA** will be covered without PA if the preferred product, Flovent HFA, is unavailable. *Effective 5/6/20.*
- **Zithromax** brand-name products will be covered without PA if generic azithromycin products are unavailable. *Effective 4/1/20.*
- **Keppra** and **Keppra XR** brand-name products will be covered without PA if generic levetiracetam IR/ER are unavailable. *Effective 5/8/20.*
- **Azulfidine** and **Azulfidine Entab** brand-name products will be covered without PA if generic sulfasalazine IR/DR/EC are unavailable. *Effective 5/8/20.*
- **Hiprex** brand-name will be covered without PA if generic methenamine is unavailable. *Effective 5/8/20.*
- **Albuterol HFA**, **Levalbuterol HFA**, **ProAir Digihaler** and **RespiClick**, **Proventil HFA**, **Ventolin HFA**, and **Xopenex HFA** will be covered without PA if the preferred product, ProAir HFA, is unavailable. *Effective 3/19/20.*
- **Effexor XR** will be covered without PA if generic venlafaxine ER capsules are unavailable. (Clinical criteria may still apply). *Effective 5/22/20*

This information has been communicated to the Medicaid Managed Care plans as well.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Pharmacists Authorized to Order and Administer COVID-19 Tests

An executive order issued by New York Governor Andrew Cuomo on April 25, 2020 authorizes pharmacists in the state to order and administer COVID-19 tests, approved by the FDA, to detect SARS-CoV-2 or its antibodies, subject to completion of appropriate training developed by the Department of Health (a link to the training is provided here). The order also allows for pharmacists to be designated as a qualified healthcare professional for the purpose of directing a limited service laboratory to test patients suspected of a COVID-19 infection or its antibodies, provided that such test is FDA-approved and waived for use in a limited service laboratory. Information on obtaining a limited service laboratory registration certificate is available from the Department of Health via this link.

Overview of Requirements for Pharmacist-Ordered COVID-19 Test:

New York State licensed pharmacists may order a COVID-19 test when:

- The pharmacist/pharmacy has notified the State that they will be ordering COVID-19 tests, providing the name and address of the laboratory that will be performing the test; AND
- The test is ordered in accordance with NYS Protocol for COVID-19 Testing, set forth in the following link; AND
- Specimens are either:
  - ♦ Sent to a clinical laboratory permitted by NYS and the result, reported back to the pharmacist by the laboratory, as well as to DOH, is provided directly to:
    - ♦ The patient, with appropriate education and counseling about the result; AND
    - ♦ The patient's primary care health provider; OR
  - ♦ Tested within a limited service laboratory and results reported to:
    - ♦ The patient, with appropriate education and counseling about the result; AND
    - ♦ The patient's primary care health provider; AND
    - ♦ The Department of Health, through ECLRS, within 24 hours of test completion.

Executive Order on Hydroxychloroquine Amended

Executive Order 202.10, which set forth regulations on the dispensing of hydroxychloroquine by pharmacists, has been amended as follows:

> *"No pharmacist shall dispense hydroxychloroquine of chloroquine except when written: as prescribed for an FDA-approved indication; for an indication supported by one or more citations included or approved for inclusion in the compendia specified in* 42 U.S.C. 1396r-8(g)(1)(B)(i*); for patients in inpatient settings; for residents in a subacute part of a skilled nursing facility; or as part of a study approved by an Institutional Review Board. Any person authorized to prescribe such medications shall denote on the prescription the condition for which the prescription has been issued.*

Note that the original order included a limitation on the days supply of hydroxychloroquine and chloroquine prescriptions to no more than a 14-day supply. This provision has been eliminated. Days supply must match the quantity required by the prescription order, as long as the prescription is compliant with these guidelines and the amount requested falls within the normal treatment guidelines of the FDA-approved indication

FEATURE ARTICLE...

UPDATE ON THE CORONAVIRUS PANDEMIC

It has been 124 days, as of this writing, since the first known case of COVID-19 was detected in the United States. In the four months following this discovery, life has been altered in ways unimaginable before the advent of the novel coronavirus known as SARS-CoV-2. While a great deal has been learned over these tumultuous days, there is still a near continuous flow of new information about the disease, its treatment, and the multitudinous effects it can have on the human body. We present here but a small selection of the latest developments, and take a brief interlude to look back at how New York dealt with the last devastating respiratory disease to ravage the planet, the 1918 influenza pandemic.

Crucial Remdesivir Study Data Released

In late April, Federal officials announced that clear evidence had emerged for the effectiveness of the antiviral agent remdesivir in the treatment of COVID-19. Almost a month later now, a preliminary report on the study has been published in the New England Journal of Medicine. The treatment trial, known as ACTT-1, was a double-blind, randomized, placebo-controlled evaluation of 1,063 patients in 10 countries. Treatment of COVID-19 patients with remdesivir resulted in a shorter time to recovery in hospitalized patients. **Patients treated with the drug averaged 11 days to recovery vs. 15 days for patients given the placebo**. The effect was most pronounced in hospitalized patients requiring supplemental oxygen. There was a reduction in mortality seen in the treated group, but the difference was not statistically significant ($p = 0.059$). Remdesivir was administered intravenously as a 200 mg loading dose on day 1, followed by a 100 mg maintenance dose given daily on days 2 through 10, or until hospital discharge or death.

Largest Study to Date of Hydroxychloroquine Use in COVID-19 Patients

The Lancet, a leading British medical journal, has just published the results of a large observational study on the use of hydroxychloroquine for the treatment of COVID-19. The multinational analysis looked at 96,032 hospitalized patients with the disease; of that number 14,888 were in the treatment group and 81,144 were in the control group. Patients received either chloroquine or hydroxychloroquine, with or without the addition of a macrolide (azithromycin or clarithromycin). **The death rate in the control group was found to be 9.3%.** Death rates in the treated groups were as follows:

- **Chloroquine: 16.4%**
- **Chloroquine + macrolide: 22.2%**
- **Hydroxychloroquine: 18%**
- **Hydroxychloroquine + macrolide: 23.8%**

After adjusting to account for other clinical factors, the researchers state that the use of hydroxychloroquine for COVID-19 increased the risk of death by 34 to 45%.

Multisystem Inflammatory Syndrome in Children (MIS-C)

In late April and early May, just weeks after cases of COVID-19 exploded in New York, making the city the epicenter of infection, the city's Health Department started receiving reports of children presenting with a Kawasaki-like syndrome. Symptoms included fever, rash, red or pink eyes, abdominal pain, swollen hands or feet, and red, cracked lips or red, bumpy "strawberry' tongue. About 70% of patients hospitalized with this syndrome required ICU care, and almost all tested positive for coronavirus or its antibodies, indicating previous infection. Complications have include inflammation of the heart or brain and there have been 3 deaths (ages 5, 7, and 18) among the 160 or so cases in New York. Cases have now been found in many states and in Europe as well. The CDC has named the disorder Multisystem Inflammatory Syndrome in Children (MIS-C) and established the following diagnostic criteria:

- **Individuals aged < 21 years with fever, inflammation, and evidence of clinically severe illness requiring hospitalization, with multisystem (≥ 2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic, or neurological); AND**
- **No alternative plausible diagnoses; AND**
- **Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test, or COVID-19 exposure within 4 weeks prior to the onset of symptoms**

How Does New York City Respond to a Pandemic: Spanish Flu vs. Coronavirus

March, 2020: a highly contagious and deadly respiratory virus suddenly descends upon New York, the largest and most densely populated city in the United States. Hospital emergency wards are pushed to their limit, and beyond. More than one public official proclaims, "this has never happened before." Well, actually...it had. In the Fall of 1918, an influenza virus, misnamed the "Spanish Flu," devastated the city, costing nearly 30,000 residents their lives. Here is a comparison of the city's response to the two pandemics:

Schools: Then, as now, the decision as to whether to close schools was a controversial one. In 1918, the city's new health commissioner, Royal S. Copeland, chose not to close schools, reasoning that schools were actually a safer and healthier place for children, many of whom, at that time, lived in overcrowded and unsanitary tenements. In 2020, once the mayor and governor settled their turf dispute, schools were closed. In light of MIS-C (see above), this now seems a reasonable choice.

Businesses: In 2020, all non-essential businesses were closed at the peak of the outbreak. In 1918, they took a different approach, opting to order businesses to stagger their work hours in order to avoid crowded rush hours on the public transit system.

Masks: "Americans don't wear masks!" some insist. Not true! Though they lacked the styles and colors available today, face coverings were worn in 1918 by citizens and municipal workers alike.

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Founder and Editor:
James Murphy, RPh

Medical Liaison:
Deborah Blenner, MD

Marketing:
Michelle Ye

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PRN Publishing
7636 113th Street
Suite 6C
Forest Hills, New York 11375

ASK PRN...

Is it true that pharmacists licensed in New York, but not currently registered to practice, are being permitted to work as pharmacists in the State during the pandemic emergency?

Yes, with one qualification: their license must currently be in good standing in New York State. On April 16, 2020, Governor Andrew Cuomo issued Executive Order 202.18, which states:

"*I hereby temporarily suspend or modify Section 6502 of the Education Law and 8 NYCRR 59.8 to the extent necessary to allow...pharmacists...who have an unencumbered license and are currently in good standing in New York State but not registered in New York State to practice in New York State without civil or criminal penalty related to lack of registration.*"

This executive order was originally designated to expire on May 16, 2020, but was extended to June 7, 2020 by Executive Order 202.29.

Under New York State regulations, would it be permitted for pharmacists to work at home during the declared disaster emergency in the State?

Yes. As part of Executive Order 202.18, issued on April 16, 2020, the Governor stated:

"I hereby temporarily suspend or modify Sections 6802, 6808, and 6841 of the Education Law and Part 29.7 (10) and 63.6 of Title 8 of the NYCRR, to the extent necessary to permit pharmacy technicians and pharmacists to practice at an alternative location, including their home, as long as there is adequate security to prevent any Personal Health Information from being compromised."

This executive order was originally designated to expire on May 16, 2020, but was extended to June 7, 2020 by Executive Order 202.29.

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 ibuprofen was discovered by a pharmacist working at the largest drug store chain in the United Kingdom? Stewart Adams earned his Bachelor of Pharmacy degree in 1945 and went to work at Boots— then, as now, the largest pharmacy chain in the UK. By 1953 the young chemist was working at the company's pharmaceutical division, searching for a safer alternative to aspirin for the treatment of rheumatoid arthritis. By 1961 he and his team had synthesized ibuprofen, and Adams took the first dose himself. The blockbuster drug hit the market in 1969 in the UK and 1974 in the US. The name ibuprofen comes from the three functional groups on the molecule: isobutyl (IBU), propionic acid (PRO), and phenyl (FEN).

PHARMACY FUN

Here's another classic riddle, dressed up in pharmaceutical garb. After many years on the "bench," you decide to make a career move. You open up your own pharmaceutical supply company and are ready to ship your first order of weights out to expectant customers. Suddenly, just as you are about to hand the precious cargo over to the UPS driver, your production manager appears in an apoplectic state— he has just learned that one of the 10 sets of 500 one gram weights you are about to deliver is defective! For in just one of those 10 sets, each of the 500 weights is actually 10 mg short of the stated 1 gram weight. Your employee suggests you carefully weigh each box to determine which is the imposter, but there simply isn't time—the UPS guy is giving you the evil eye. In fact you only have time for one single weighing on your handy pharmaceutical scale. With just one chance to use the scale one time, how do you determine, beyond doubt, which is the faulty box of weights? The first reader to submit the correct answer to *puzzle@prnnesletter.com* will win a $25 gift card from Amazon, which will be sent electronically to the winner's Amazon account.

Answers to last month's ***PHARMACY FUN***:
Fill the 500 mL cylinder and pour out into the 300 mL bottle, then discard this 300 mL and pour the 200 mL remaining in the graduate into the bottle. Refill the 500 mL graduate and pour into the 300 mL bottle until it is full again. That will leave exactly 400 ml in the 500 mL container!

References:
1. Aimone, Francesco. The 1918 influenza pandemic in New York City: a review of the public health response. *Public Health Reports*, 2010 Supplement 3, volume 125.