

## News Highlights:

- The U.S. FDA approved Neurocrine Bioscience's **Ongentys** for treating "**off episodes**" of **Parkinson's disease**. It is approved for use in combination with levodopa and carbidopa to extend time before a patient's symptoms return. Because of the COVID-19 pandemic, Neurocrine will delay the launch of the drug until later this year.

<https://www.fiercepharma.com/pharma/neurocrine-scores-fda-nod-for-parkinson-s-drug-ongentys-but-won-t-launch-amid-pandemic>

- The FDA sent warning letters this week to 10 companies that make **vaping-related products aimed at young people**. The products include sweatshirts and backpacks designed to hide vaping cartridges and vaping devices that look like toys, candy, or smart watches.

<https://www.msn.com/en-us/news/us/fda-takes-aim-at-vaping-products-meant-to-look-like-candy-toys/ar-BB13hinw>

<https://www.fda.gov/news-events/press-announcements/fda-warns-manufacturers-and-retailers-remove-certain-e-cigarette-products-targeted-youth-market>

- The U.S. FDA approved Eli Lilly's anxiety and depression drug **Cymbalta (duloxetine)** for treating **fibromyalgia in teenagers**. Fibromyalgia is characterized by widespread muscle pain and fatigue. Cymbalta's only other approved **pediatric use** is for treating **generalized anxiety disorder**. The drug has a boxed warning for increased risk of suicidal thinking and behavior in children, teens, and young adults.

**Cymbalta** is approved for these additional indications in adults: **major depression, diabetic neuropathy, and chronic muscular-skeletal pain**. A revised label was posted this week. The approval was based on a small clinical trial involving 184 pediatric patients, with 149 finishing the trial; while the study showed no improvement for primary (pain) outcomes, improvements were demonstrated for drug vs. placebo for secondary outcomes.

Updated drug label:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/021427s052lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021427s052lbl.pdf)

Patient reviews (adults) of **Cymbalta for fibromyalgia**:

<https://www.askapatient.com/viewrating.asp?drug=21427&name=CYMBALTA&Reason=fibromyalgia>

- The U.S. FDA authorized **emergency use** of Gilead's investigational drug **remdesivir** for treating severe cases (where oxygen therapy is needed) of COVID-19. The drug is authorized to be administered by **intravenous infusion in hospitals only**. The approval was based on a government-sponsored clinical trial involving about 1,000 patients. There have been some questions raised as to why the primary clinical trial outcome measurement was changed while the trial was ongoing-- from how many patients were kept alive using the drug to how long it took surviving patients to recover. Remdesivir was found to **reduce an average hospital stay from 15 days to 11 days**.

<https://www.washingtonpost.com/business/2020/05/01/government-researchers-changed-metric-measure-coronavirus-drug-remdesivir-during-clinical-trial/>

FDA press release on remdesivir: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment>

- Results from a 10-hospital study of **remdesivir** between February 6 and March 12, 2020 involving 237 patients with COVID-19 were published in **The Lancet** this week. Researchers reported that the drug was "**not**

**associated with statistically significant clinical benefits.**" The study, conducted in Hubei China, was terminated on March 29 because of lack of new patient enrollment.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31022-9/fulltext?mod=article\\_inline#seccesstitle70](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31022-9/fulltext?mod=article_inline#seccesstitle70)

- While global demand for novel coronavirus tests soar, concerns are mounting that companies are **shifting production away from tests for HIV, malaria, and tuberculosis**. The coronavirus tests are more lucrative for manufacturers; a COVID-19 test can fetch \$10 compared with about 19 cents per test for a rapid malaria test.

<https://www.theguardian.com/world/2020/may/01/demand-for-coronavirus-tests-raises-concerns-over-hiv-and-malaria>

## COVID-19 and Nursing Homes

- In response to the devastating impact of COVID-19 on residents and staff of long-term care facilities, the **Center for Medicare Services (CMS)** announced a new independent commission that will conduct a comprehensive **assessment of the nursing home response** to the 2019 Novel Coronavirus pandemic.

<https://www.cms.gov/newsroom/press-releases/cms-announces-independent-commission-address-safety-and-quality-nursing-homes>

- **California** reported that **40% of the state's COVID-19 deaths were residents or staff at long-term care facilities**. The *Los Angeles Times* reports that the percentage is likely higher. Similarly, **New Jersey** reported that while 1% of their population is in nursing homes, 40% of COVID-19 deaths are from nursing homes. In **Europe**, the share of COVID-19 deaths from long-term care facilities is also in this range, according to the World Health Organization.

California: <https://www.latimes.com/california/story/2020-04-29/california-coronavirus-related-deaths-nursing-homes>

New Jersey:

<https://www.northjersey.com/story/news/coronavirus/2020/04/17/coronavirus-nj-nursing-home-deaths-account-40-percent-njs-fatalities/5155332002/>

This chart with data from the California Department of Health, while from April 17, gives infection rates for more than 1,000 nursing homes in California. It shows a significant number of staff testing positive for COVID-19, which is leading to infections of residents of nursing homes: <https://flo.uri.sh/visualisation/2014317/embed>

The reported deaths may not include those that occurred after a resident was transferred to a hospital, a private home or other location, according to the *Los Angeles Times*.

- In **Maryland**, Governor Larry Hogan announced mandatory COVID-19 testing of all residents and staff at all nursing homes. Some other states and cities are doing the same, including **West Virginia, San Francisco, Los Angeles**, and **Oklahoma**. About 19% of infections and 48% of fatalities in Maryland are linked to nursing homes or long-term care facilities.

<https://www.foxnews.com/us/maryland-coronavirus-universal-testing-nursing-home-residents-staff>

- Confirmed cases of COVID-19 globally as of 3 May, 2020, 5 pm: **3,485,948**, with 1,149,197 of those cases reported in the United States. Fatalities number **246,475** with 67,447 of those in the U.S.

Johns Hopkins University Coronavirus dashboard:

<https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>

The newsletter will be in brief format for the next few weeks as we work on web site enhancements. You may always check out the real-time news feeds on general, mental health, seniors health, FDA news, and more on the web site:

<https://www.askapatient.com/news/pharmnews.asp>

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