

News Highlights:

- The U.S. Food and Drug Administration (FDA) announced that the process of reviewing **new drug applications** may be slowed down because of reallocation of staff to Covid-19 – related work. To expedite the application review process, they will sometimes use collaborative efforts with other countries' **drug regulatory agencies**. Tukysa's approval (described below) is one example.

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-user-fee-related-reviews-through-covid-19>

- Under a joint drug review collaboration involving four other countries' drug regulatory agencies, including **Australian** Therapeutic Goods Administration (TGA), **Health Canada**, Health Sciences Authority (HSA, **Singapore**) and Swissmedic (SMC, **Switzerland**) the U.S. FDA approved a new breast cancer drug. Seattle Genetics, Inc.'s **Tukysa (tucatinib)** in combination with chemotherapy (trastuzumab and capecitabine) was approved for the treatment of advanced forms of **HER2-positive breast cancer**. The application is still under review at the other countries' agencies.

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-new-drug-under-international-collaboration-treatment-option-patients-her2>

- The FDA approved Incyte Corporation's **Pemazyre (pemigatinib)** tablet, the first targeted treatment for **cancer of the bile ducts (cholangiocarcinoma)**, a rare cancer that is usually advanced by the time it is diagnosed. The approval was based on a small clinical trial with 107 patients; 2.8% of the patients had a complete response and 33% had a partial response. Of those with a response, 7 patients (18%) had a response lasting 12 months or longer.

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-targeted-treatment-patients-cholangiocarcinoma-cancer-bile-ducts>

- The FDA approved UroGen Pharma's **Jelmyto (mitomycin gel)**, the first therapy to treat low-grade upper tract **urothelial cancer** (UTUC), a cancer of the lining of the urinary system. Low-grade UTUC is rare, but affects 6,000-8,000 new patients in the United States every year.

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-therapy-treatment-low-grade-upper-tract-urothelial-cancer>

Coronavirus – Announcements and Research

- The American College of Cardiology is urging patients who have symptoms of **heart attack or stroke to call 911** and not to be afraid to go to the emergency room or to seek medical help. Appropriate precautions are being taken at hospitals and clinics to protect all patients from COVID-19. Check out their "**Coronavirus and Your Heart: Don't Ignore Heart Symptoms**," infographic:

<https://www.eurekalert.org/multimedia/pub/229533.php>

- U.S. Cotton plans to produce new **polyester swabs** to be used in a new method of **coronavirus diagnostic testing**. The **smaller swabs**, designed like Q-tips – will allow for self-collection by patients thereby limiting exposure of healthcare providers. Also, it is more comfortable for patients as the sample comes from the front of the nose instead of through the back of the nose or throat. The U.S. FDA, UnitedHealth Group, the Gates Foundation, and Quantigen collaborated on the study of the polyester swabs.

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-gates-foundation-unitedhealth-group-quantigen-and-us-cotton>

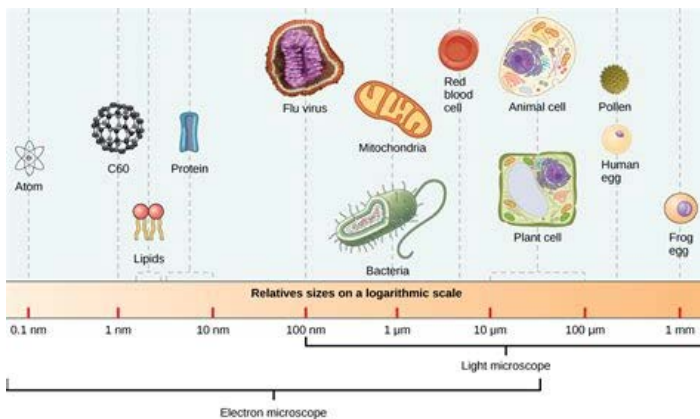
A **USA Today** investigation has found that at least **2,300 long-term care facilities in 37 states have reported positive cases of COVID-19**, and the numbers are probably much higher. Six of the states, including Florida, did not respond to their request for numbers, and other states had incomplete information. About 1.3 million people live in the nation's 15,600 nursing homes, according to the CDC. Managing infections has been a chronic problem for long term care facilities.

<https://www.usatoday.com/story/news/2020/04/13/coronavirus-nursing-homes-2-300-facilities-report-positive-cases/2978662001/>

- Normally, our cells are equipped to fight off infections by viruses or bacteria. After being infected, if you develop a fever and have aches and pains, your body is signaling that your immune system is fighting the **intruding pathogens**. For some people, this immune response gets so amped up that it stops differentiating between infected and healthy cells and attacks everything in its path. COVID-19 is shedding new light on the deadly phenomenon that is known as "**cytokine storm syndrome**".

<https://www.forbes.com/sites/claryestes/2020/04/16/what-is-the-cytokine-storm-and-why-is-it-so-deadly-for-covid-19-patients/#60a3ceef460f>

- Confused about the different microbiology-related nomenclature related to the virus pandemic, including **red blood cells, lymphocytes, white blood cells, bacteria, viruses, and cytokines**? Here is a visual that shows the relative sizes of these and other microscopic parts. While you can view bacteria with a regular light microscope, viruses are ten times smaller and are best viewed with an electron microscope. Cytokines (a kind of protein triggered by immune response and other types of cells) are orders of magnitude smaller than viruses. Not included on the chart below are white blood cells (including lymphocytes), which are about twice as big as red blood cells.



Source: [Concepts of Biology - 1st Canadian Edition](#) by Charles Molnar and Jane Gair

(Creative commons attribution)

- How do **blood pressure medications affect the outcomes of patients with Covid-19**? Some evidence suggests that blood pressure medicines improve organ response and protect against the virus while other evidence suggests that the medications make things worse by enhancing the virus's destructive effects. A new study by **Penn Medicine** is trying to get a definitive answer. The study involves 152 hospitalized patients with COVID-19 taking two categories of blood pressure medications: **ARBs and ACE inhibitors**. Patients will be randomly assigned to either stop or continue taking their already prescribed medications, and progress will be carefully monitored.

https://www.eurekalert.org/pub_releases/2020-04/uops-hdb041520.php

- The variation in how the human body reacts to the novel coronavirus is baffling scientists and **challenging conclusions that can be made about a person's immunity based on antibody tests**. For example, some people with mild symptoms of COVID-19 who test positive using a PCR (respiratory test) and then recover may later on show few or no antibodies in an antibody test. Does that mean they can be reinfected? Scientists don't know. Evidence from a report from South Korea suggests it is possible; health officials documented 91 patients who had recovered from the virus with a negative PCR test but who subsequently tested positive for the virus.

https://www.omaha.com/eedition/sunrise/articles/immunity-remains-question-mark-for-a-country-eager-to-reopen/article_23652b83-cf12-50fc-be2c-8aab150afcb1.html

- A troubling **case study of two elderly twin sisters' experience** in dealing with the COVID-19 pandemic as they socially isolated in their apartments: the **fear of contracting the virus was overwhelming to the point of paranoia**. One of the sister's hands were worn and dry from constant washing and her family worried about her excessive cleaning regimen. She would avoid contact with dishware, and lost weight because she was not getting needed nourishment.

<https://khn.org/news/i-wasnt-eating-senior-twin-sisters-battle-pandemic-anxiety-together/>

Coronavirus: New Cases and Stats

China **raised its coronavirus death toll by 50 percent for Wuhan**, the city where the outbreak first emerged, to 3,869 deaths, an increase of 1,290 from the previous figure. The revised number of confirmed cases increased slightly by 325 to 50,333. With these revisions, China reports its total death toll for the entire country to be 4,632, up from 3,342, and its total number of cases to be 82,692, up from 82,367. Governments around the world have **questioned the accuracy** of China's official numbers.

<https://www.nytimes.com/2020/04/17/world/asia/china-wuhan-coronavirus-death-toll.html>

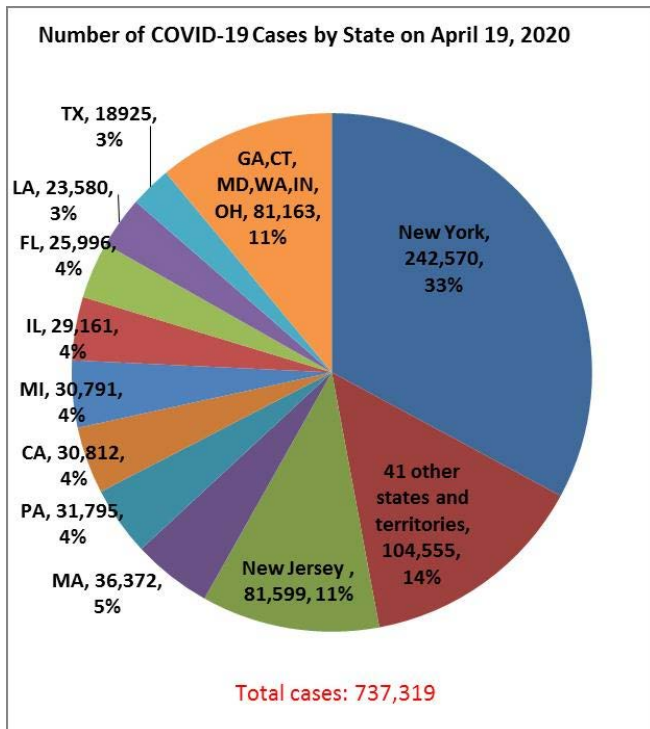
The **total cases of COVID-19 in the U.S. are 737,319 as of Sunday, April 19**, according to the Johns Hopkins Coronavirus dashboard. Total COVID-19-related deaths in the U.S. are reported to be over 39,000. Here are the states with 10,000 or more cases:

Number of COVID-19 Cases in States with 10,000 or More Confirmed Cases on April 19, 2020

| State | April 19 |
|---------------|----------|
| New York | 242,570 |
| New Jersey | 81,599 |
| Massachusetts | 36,372 |
| Pennsylvania | 31,795 |
| California | 30,812 |
| Michigan | 30,791 |
| Illinois | 29,161 |
| Florida | 25,996 |
| Louisiana | 23,580 |
| Texas | 18,925 |
| Georgia | 17,841 |
| Connecticut | 17,550 |
| Maryland | 12,847 |
| Washington | 12,062 |
| Indiana | 10,641 |
| Ohio | 10,222 |

source: Johns Hopkins Coronavirus Dashboard

Recently, **New York** accounted for more than half of U.S. cases. New York now accounts for about **one-third of the cases** as infections increase in other states:



Source of Data: Johns Hopkins University Coronavirus dashboard:

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

Please vote in our latest opinion poll and share the link:

**How would you rate the media coverage of the novel coronavirus in terms of
1)quality and 2)quantity?**

- Good; right amount of coverage
- Good; too much coverage
- Too alarmist; right amount of coverage
- Too alarmist; too much coverage
- Other (list below)

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