

## News Highlights:

- Amneal, Teva (Activis), and Marksans Pharma Limited, India recalled some lots of **extended release metformin** because of detection of **NDMA (a carcinogen)**. Apotex expanded its recall from last week.

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>

- For more information on **nitrosamine impurities**, like NDMA, check out the FDA's information page: "What patients should know about nitrosamine impurities."

<https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications>

- A **Kobe University** study provided insights about **where sugar goes when it is removed from the blood** by **diabetes** drug **metformin**. A new imaging apparatus, the "**PET-MRI**" allowed scientists to look at where sugar is accumulating in the bodies of patients taking metformin. They discovered that **sugar is excreted into the intestines and into the stool**. A similar imaging technology "FDG-PET" with CT is used to find hard-to-find cancers in the body, since cancers consume more sugar than normal tissue. Comparison images show the locations of sugar accumulation in the metformin-taking patients.

<https://www.sciencedaily.com/releases/2020/06/200603100503.htm>

- The FDA approved expanding the use of AstraZeneca's **blood thinner drug Brilinta** for reducing the risk of a first heart attack or stroke in high-risk patients with coronary artery disease. Brilinta, approved in 2014, has a **boxed warning** for bleeding risk and for reduced effectiveness when used with more than 100mg of aspirin. Patients commonly take it when getting a stent placement.

<https://www.reuters.com/article/us-astrazeneca-fda-idUSKBN2381FJ>

Read patient reviews for [Brilinta](#) and its rival [Plavix](#).

## COVID-19 News

### *Drug and Vaccine Production*

- A bipartisan senate finance committee heard testimony on the **FDA's foreign drug manufacturing inspection process**. Because of the novel coronavirus pandemic, no foreign inspections of facilities are taking place, and more than 70% of the U.S. active pharmaceutical ingredients are made overseas. Concern about drug quality is also heightened because of **impurities** recently found in generics like valsartan, ranitidine, and metformin. Some panel experts called for more testing of drugs and more U.S.-based manufacturing.

<https://www.finance.senate.gov/hearings/covid-19-and-beyond-oversight-of-the-fdas-foreign-drug-manufacturing-inspection-process>

Related story:

<https://www.fiercepharma.com/manufacturing/are-metformin-recalls-just-start-valisure-ceo-calls-for-independent-testing-foreign>

- The Health and Human Services Department (HHS) contracted with several companies, including Richmond, Virginia startup [Phlow Corporation](#) and non-profit **Civica RX**, to cooperatively manufacture **essential generic drugs** at a new facility in Virginia.

<https://www.ajmc.com/focus-of-the-week/hhs-contracts-with-pharma-companies-further-insulating-us-from-global-covid19-response>

- A public-private international partnership called **Gavi** aims to make a future novel coronavirus vaccine available to people throughout the world. With an "advance market commitment" goal of **\$2 billion**, it makes the process of developing a vaccine less financially risky for vaccine makers.

<https://www.reuters.com/article/us-health-coronavirus-vaccines-advance/gavi-raises-567-million-of-2-billion-goal-to-buy-covid-19-vaccines-for-poor-idUSKBN23B2IR>

- In response to Gavi's announcement, the non-profit **Doctors without Borders** issued a plea for government leaders to demand pharmaceutical corporations commit to selling any potential future COVID-19 vaccines **at cost**. "To date, governments and philanthropic organisations have given over **US\$4.4 billion to pharmaceutical corporations** for research and development for COVID-19 vaccines. However, by and large, **no conditions for access or affordability** have been included as a precondition to any of that funding."

<https://www.msf.org/any-future-covid-19-vaccines-must-be-sold-cost>

- A whopping **2 billion doses of the novel coronavirus vaccine** being developed by Oxford University and AstraZeneca have now been pre-funded with collaboration partners including Britain, the United States, the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi the Vaccine Alliance, as well as the Serum Institute of India.

<https://www.reuters.com/article/us-health-coronavirus-astrazeneca-partne/astrazeneca-says-open-for-more-vaccine-production-deals-idUSKBN23B2TP>

### **COVID-19 Transmission**

- A study by the Netherlands' National Institute for Health (RIVM) concluded that **children under the age of 12 play little role in transmitting the new coronavirus**; they suggest that transmission occurs primarily **between adults** and from **adults to children**. Transmission between children or from children to adults is less common.

<https://www.reuters.com/article/us-health-coronavirus-netherlands-study/dutch-coronavirus-study-children-are-not-big-spreaders-idUSKBN23A361>

- A new study suggests that just **20% of coronavirus cases are responsible for 80% of all coronavirus transmissions** and that indoor "**superspreader events**," in which one person infects a disproportionately large number of others, are the primary means by which the coronavirus spreads.

<https://www.businessinsider.com/super-spreader-events-account-for-most-coronavirus-transmission-2020-6?op=1>

### **Statistics**

- On June 4, Centers for Medicare Services released its first set of data on the **number of cases of COVID-19 for nursing homes and long-term care facilities**. As of May 31, 88% of the 15,000 facilities in the U.S. had reported data.

<https://www.cms.gov/newsroom/press-releases/nursing-home-covid-19-data-and-inspections-results-available-nursing-home-compare>

Nursing home data **infographic**:

<https://www.cms.gov/files/document/covid-nursing-home-reporting-numbers-5-31-20.pdf>

- In a related story, **discrepancies** have been identified in the just-released nursing home data.

<https://www.newschannel6now.com/2020/06/05/new-federal-covid-nursing-home-data-fraught-with-inaccuracies-overcounts-undercounts/>

**Updated stats for Sunday, June 7, 2020: Worldwide:** 6.9 million cases and over 401,000 deaths. **United**

**States:** 1.9 million cases and more than 110,000 deaths. **Brazil** has the second-highest number of cases globally with over 672,000 cases.

Source: Johns Hopkins Coronavirus Dashboard:

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

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