Health News

- Despite the need to focus attention on providing regulatory guidance related to the coronavirus pandemic, the U.S. Food and Drug Administration has managed to approve **35 new drugs so far in 2020**. Not many of the new treatments will be utilized by a large number of patients, since most address rare diseases, advanced-stage cancers, are for hospital use, or are for very small cohorts of patients. Here are five new approvals this year that treat fairly common conditions:

Drugs Approved in 2020 for Common Conditions			
Drug	Treats	Route	Company
NURTEC	Migraine	Oral -Tablet,	Biohaven
ÖDT	treatment	Disintegrating	Pharm
ONGENTYS	Parkinson's "off" episodes	Oral - Capsule	Neurocrine
VYEPTI	Migraine prevention	Injection - Infusion Once Every Three Months	Lundbeck Seattle Biopharmaceut icals
XEĞLYZE	Head lice	Topical - lotion	Dr Reddys Labs
ZEPOSIA	Relapsing forms of M.S.	Oral - Capsule	Celgene Intl
Approved by FDA as of August 14, 2020			

Have you taken any of the new drugs listed above? They are all in the Ask a Patient database, so please share your experience! View the **complete list of 35 novel drugs** approved in 2020, including a new treatment approved this week for Duchenne muscular dystrophy:

https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biologicalproducts/novel-drug-approvals-2020

- The U.S. FDA finalized its rule for foods made with **fermented or hydrolyzed ingredients** that make a "**gluten free**" claim. It covers foods like yogurt, sauerkraut, pickles, cheese, green olives, kombucha drinks, kefir, and hydrolyzed plant proteins used in processed foods. With this new rule, along with rules that have been in place since 2013 covering other foods, the FDA says consumers can be confident that any food that carries the label "gluten-free," "no gluten," "free of gluten," or "without gluten" contains less than 20 parts per million (ppm) of gluten.

https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-final-rule-gluten-free-labeling-fermented-andhvdrolvzed-foods

More on gluten-free labeling and benefits to patients with celiac disease: <u>https://www.fda.gov/food/food-labeling-nutrition/gluten-free-labeling-foods</u>

- If you feel **tired** on a regular basis, it may be time to examine your **diet**. A recent *Consumer Reports* piece on eating foods that fight fatigue identifies three nutrients that, when lacking, can lead to feelings of tiredness and exhaustion, especially in older adults: **iron**, **magnesium**, and **vitamin B12**. <u>https://www.consumerreports.org/nutrition-healthy-eating/foods-that-fight-fatigue-exhaustion/</u>

- The U.S. Environmental Protection Agency has registered a new insect repellent ingredient that smells better

than DEET and is more effective at repelling mosquitoes and ticks. **Nootkatone** is derived from Alaskan yellow cedar trees (also known as **Nootka cypress**) and **grapefruit skin** and is already used in some foods and perfumes. The Centers for Disease Control led the development of the ingredient and partnered with Swiss biotech company Evolva to make the ingredient synthetically.

https://www.smithsonianmag.com/smart-news/grapefruit-scent-wards-insects-and-safe-enough-eat-180975552/



Alaskan yellow cedar tree - source: <u>American Conifer Society</u> This lyme disease organization provides a short animated video on Nootkatone:

https://www.lymedisease.org/nootkatone-registered-epa-cdc/

- North Carolina State University researchers have created new, simpler, and far cheaper technology for conducting **ultrasounds** that could put the cost of equipment in the \$100 range instead of the \$100,000 range. <u>https://www.sciencedaily.com/releases/2020/08/200813131257.htm</u>

- A **multiple sclerosis drug** approved in 2010 shows promise as a treatment for **HIV**. Researchers at George Washington University found that **Fingolimod** (brand name <u>Gilenya</u>), blocks HIV transmission and infection in human cells, and also reduces "latent resevoirs," which are infected cells that may reactivate at any time. <u>https://www.sciencedaily.com/releases/2020/08/200813142339.htm</u>

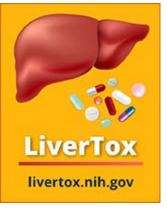
Drug-Induced Liver Injury Patient Resource

Many medicines (including more than 200 in the Ask a Patient database) have been linked to liver problems, ranging from **temporarily elevated liver enzymes** to more severe conditions like **jaundice** and **abdominal pain**. A recent *Worst Pills* article says that "drug-induced liver injury is the most frequent reason cited for the withdrawal from the market of an approved drug, and it also accounts for more than 50 percent of the cases of acute liver failure in the United States today."

Antibiotics are the class of drugs causing the most drug-induced liver injuries, and <u>Amoxicillin-clavulanate</u> (brand name Augmentin) is the most common cause of clinically apparent, drug induced acute liver injury both in the United States and Europe. The analgesic **acetaminophen** (brand name Tylenol) is another common drug that can cause liver injury; its label warns of liver toxicity if you take more than the maximum daily amount or use with other drugs containing acetaminophen.

To learn more about your medicine and whether it has a propensity to cause liver injury, look it up in the **LiverTox database**, produced by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). This online publication is regularly updated and contains more than 1,000 prescription and over-the-counter medications and herbal and dietary supplements. Each drug has a separate article that discusses the potential for liver toxicity, how long it takes for liver injuries to happen, and how soon or how well the condition resolves after

time passes or after the medication is stopped. Many entries also include case studies. While the information is technical, it is written for both patients and physicians. https://www.ncbi.nlm.nih.gov/books/NBK547852/



Coronavirus News

- The **first vaccine** has been approved for preventing COVID-19. "**Sputnik V**" was developed by the Gamaleya Research Institute in Moscow and was approved this week by the Russian Federation's Ministry of Health. However, health experts are questioning the vaccine's safety and efficacy since it has not yet entered phase 3 clinical trials. The institute plans to start phase 3 clinical trials this month. https://www.nytimes.com/2020/08/11/world/europe/russia-coronavirus-vaccine-approval.html

- The FDA granted emergency use authorization for Yale School of Public Health's "Saliva Direct," a COVID-19 diagnostic test that does **not** require a separate nucleic acid extraction step. That step is used in other tests, and requires a kit that has been in short supply, delaying results. The **National Basketball Association** (NBA) partnered with Yale to help validate the test in a program involving asymptomatic players, coaches and staff from various teams

https://news.yale.edu/2020/08/15/yales-rapid-covid-19-saliva-test-receives-fda-emergency-use-authorization

- Rensselaer Polytechnic Institute researchers developed a **model for predicting the spread of COVID-19 based on air travel** rather than on physical distance. "While China and Thailand may be geographically more proximate to one another, if there are significantly more flights between China and the United States, the chance of disease spread may be higher." The team examined the effectiveness of various travel restrictions countries implemented in an effort to slow the transmission of the virus, and found that while some travel bans have helped, better coordination between countries was and is needed. They believe the model (which correctly predicted when the virus arrived in the U.S.) could be applied to future pandemics in addition to alleviating some of the ongoing effects of the current one.

https://news.rpi.edu/content/2020/08/13/new-covid-19-model-reveals-need-better-travel-restriction-implementation

Updated Covid-19 stats for Sunday, August 16, 2020: Worldwide totals: 21.48 million cases and over 771,000 deaths. United States totals: 5.36 million cases and more than 169,000 deaths. Brazil has the second-highest number of cases globally with over 3.3 million cases. India has 2.58 million cases. Source: Johns Hopkins University Coronavirus Dashboard https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6

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