Ask a Patient® Health News

Ask a Patient Health News November 27,2022

Health News: November 27, 2022

- The FDA added safety label updates for some amoxicillin-containing drugs, including Augmentin, to warn of the risk of Severe Cutaneous Adverse Reactions (SCAR) such as Stevens-Johnson Syndrome and skin rashes.

Amoxicillin Label Change

Augmentin XR Label Change

- At a recent American College of Allergy, Asthma & Immunology (ACAAI) meeting, Aquestive announced that its new **sublingual** product (a film-like medication that dissolves under the tongue) may be as effective at delivering **epinephrine** for **allergic anaphylaxis** as intramuscular injections (such as the "Epi-pen"). The product is currently under review by the FDA.

Another product by Aquestive is a unique formulation of **diazepam** called **Libervant**, which received **FDA** <u>tentative approval</u> as an oral rescue therapy for epilepsy patients with **breakthrough seizures or seizure clusters**. Libervant is administered buccally (inside of the cheek) and will be available in strengths ranging from 7.5 mg to 20 MG per dose.

https://www.medpagetoday.com/meetingcoverage/acaai/101753

Libervant: https://aquestive.com/pipeline/diazepam/#Standard/orphan

Health Research

- A study by the National Institutes of Health's (NIH) Heart Blood and Lung Institute found that while low levels of HDL cholesterol predicted an increased risk of heart attacks or related deaths for white adults – a long-accepted association – the same was not true for black adults. Adults with increased levels of low-density lipoprotein (LDL) cholesterol and triglycerides had modestly increased risks for cardiovascular disease, which aligned with findings from previous research. Surprisingly, **higher HDL cholesterol levels** were **not associated with reduced cardiovascular disease risk** for either group. The authors suggest that it may be **quality**, not **quantity** of HDL that can reduce cardiovascular disease risk. The study was published in the *Journal of the American College of Cardiology*.

https://scitechdaily.com/heart-disease-good-cholesterol-may-not-be-good-for-everyone/

- A study led by UCLA researchers and funded by National Institutes of Health suggests that older **type 2 diabetes drugs** called glitazones (or **TZDs**) such as rosiglitazone (Avandia) or pioglitazone (Actos), may help **reduce dementia risk** in older patients. In the 8-year observational study of patients age 60 and up, the use of a TZD alone was associated with a 22% lower risk of dementia from any cause, compared with the use of metformin alone. According to the researchers, these drugs may effectively prevent dementia in high-risk individuals with mild to moderate type 2 diabetes. Those younger than 75 benefited more from giltazones than older patients, highlighting the importance of early prevention for dementia. The study was published in *BMJ Open Diabetes Research & Care*.

https://scitechdaily.com/diabetes-drug-linked-to-a-decreased-risk-of-dementia/

- Expressing **gratitude** might be not only a nice thing to do, but a healthy one, too. *American Heart Association News* interviewed Emiliana Simon-Thomas, science director of the Greater Good Science Center at the University of California on the topic. She says that simply waking up and saying a prayer of gratitude, or thinking about something you're grateful for, can be "really, really powerful." Cultivating gratitude takes some work, and Simon-Thomas provides tips on how people can give thanks to others in a structured way.

https://www.heart.org/en/news/2022/11/21/feast-on-gratitude-this-season-it-could-be-good-for-you-mentally-and-physically

Largest Medical Device Recall in a Decade:

Philips Respironics Ventilators, BiPAP, and CPAP machines

- The FDA announced that it has received more than 90,000 medical device reports (MDRs), including 260 reports of death, associated with **Philips Respironics ventilators**, **BiPAP machines**, and **CPAP** machines since April 2021. The reports

https://www.askapatient.com/news/newsletter-archive/

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- Ask a Patient® Health News were due to breakdown or suspected breakdown of the **polyester-based polyurethane** (PE-PUR) **foam** used in the devices included in the recall announced in June 2021. Some devices were recalled that were not associated with the PE-PUR foam issue.
- *The New York Times* reports that back in 2015, Philips Respironics knew its breathing devices had a problem, but did nothing at the time. **Foam** inside the CPAP machines, which help people with sleep apnea breathe at night, was breaking off into **black flecks** and blowing into the **mouths and noses** of users. Years went by as complaints mounted, with **little action** by the company, according to an investigation conducted later by the FDA.

Now, hundreds of people are suing Philips Respironics, including retired tech executive Doug Shiffler, whose wife began using the device in 2018. She developed a persistent cough. By mid-2020, she was diagnosed with an aggressive lung cancer and died within the year. The company has claimed that it was not until April 2021 that it realized the flaking foam contained potentially cancer-causing particles, setting off the **largest and most disruptive medical device recall in more than a decade**. https://www.sltrib.com/news/nation-world/2022/11/19/family-says-recalled-breathing/

RECALLED SLEEP APNEA DEVICES



Above: Examples of some of the recalled devices. Image source: Cpapstoreusa

- **Dupuytren's contracture** is a progressive disease that affects the tendons in the hands, starting with lumps underneath the skin that over time can pull the fingers into a curve over the palm. Often, people with Dupuytren's contracture mistakenly assume they have arthritis or tendinitis, or don't notice a problem until their fingers start to bend. It is the "most common crippling hand condition' you've never heard of" but is often treatable if diagnosed early. https://www.washingtonpost.com/wellness/2022/11/20/dupuytrens-crippling-hand-disease-treatments/
- After contracting strep in September 2017, 14-year old Erin from Lincoln, Nebraska was irritable, her pupils looked dilated, and much of what she said made no sense. Even more alarming, according to her mother, Erin would sleep **for up to 20 hours at a time**. This happened 11 more times over the next 2 ½ years, with each episode lasting an average of 10 days. Between episodes, Erin's behavior was normal. She visited pediatric neurologists, a neurosurgeon, an obstetrician-gynecologist and other specialists in a largely fruitless search to identify the condition that drastically alters her personality and **temporarily shuts down her life** two or three times a year. Check out Sandra Boodman's latest **medical mystery**. https://www.washingtonpost.com/wellness/2022/11/19/medical-mystery-teen-sleep/?itid=sf_article_list

Covid-19 and Influenza News

- Patients and prescribers need to know about potential interactions between the Covid drug **Paxlovid** (**nirmatrelvir and ritonavir**) and a variety of **heart medications**. Researchers at several Massachussetts hospitals conducted a review of them in "Cardiovascular Drug Interactions With Nirmatrelvir/Ritonavir in Patients With COVID-19," which was published in the *Journal of the American College of Cardiology*.

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3 Ask a Patient® Health News https://scitechdaily.com/warning-popular-covid-19-drug-may-interact-with-common-heart-medications/

The CDC did not publish its weekly Covid-19 data due to the Thanksgiving holiday.

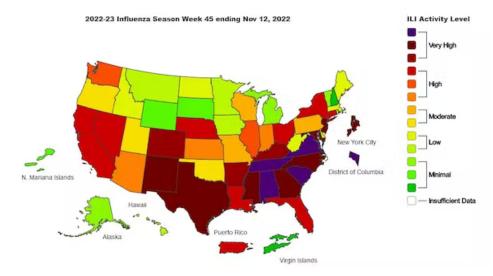
As of November 17, 2022, there are 90 (2.8%) counties, districts, or territories with a high COVID-19 Community Level, 537 (16.7%) counties with a medium Community Level, and **2,590 (80.4%) counties with a low** Community Level. Hospital admission rates are used to determine "Community Level" so the metric is lower than "transmission" levels. Check your county's community level:

CDC Community Level

Under the CDC's "**Transmission**" level metric, which is based on number of new cases in a community, transmission is **high or substantial in 71% of the country**, down from 74% two weeks ago. Check your community's transmission level:

CDC Covid Transmission Level

Much of the country reported very high or high incidence of **flu-like illness** for the week ending November 12, 2022 (the most recent available).



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