Here are this week's health care news highlights from AskaPatient:

- An ingredient in many antidepressants may be contributing to antibiotic resistance. http://ow.lv/opvF30lKjp8 (09-10-18)
- Skyrocketing insulin prices are driving patients to ration their doses, a potentially deadly solution. http://ow.ly/yNwT30lKjwO (09-10-18)
- Jet-air hand dryers should not be used in hospital bathrooms because they spread much more bacteria than paper towels. http://ow.ly/Xnik30lKjlT (09-10-18)
- Scientists block a liver protein to prevent obesity, diabetes, and fatty liver disease in mice. http://ow.ly/T9qx30lLtoh (09-11-18)
- Binge drinking affects male and female brains differently, underscoring the importance of gender in effective alcohol abuse treatment. http://ow.lv/aDqU30lLtol (09-11-18)
- Hospital sinks are an ideal environment for pathogens to spread, but special drain covers could offer one solution to reduce splatter. http://ow.lv/OXhX30lLtUa (09-11-18)
- One percent of people infected with HIV have antibodies that neutralize almost all known strains of the virus. http://ow.ly/OIPu30IMscG (09-12-18)
- Lack of sleep in college has at least as much of an impact on GPA as drinking and drug use, survey finds. http://ow.ly/Tror30lMsk8 (09-12-18)
- A simple blood test can measure our internal biological clocks and guide more personalized treatment. http://ow.ly/zquT30lMsBB (09-12-18)
- It is not too late to reverse muscle and strength loss from old age; strength programs still work for 90 year-olds. http://ow.ly/L9wi30lNsKr (09-13-18)
- Medical experts advise against using sleeping pills for extended periods of time, as they can cause serious side effects. http://ow.ly/lbkw30lNsPt (09-13-18)
- Vaping has reached "epidemic" status, according to head of FDA, which is considering banning flavored e-cigarettes. http://ow.ly/af3U30INt2A (09-13-18)
- Sugar pills relieve chronic pain as well as any pain medication for some patients, depending on their brain anatomy and psychology. http://ow.ly/jC1N30INt9N (09-14-18)
- High blood pressure during pregnancy increases likelihood of obesity and diabetes in offspring over a decade later. http://ow.ly/2np830IOrQm (09-14-18)
- Wearable patch can monitor blood pressure in arteries deep under the skin, introducing new possibilities during procedures. http://ow.ly/t9vX30lOrWd (09-14-18)
- Discovery of a critical difference between stroke-causing clots could accelerate treatment times. http://ow.ly/UWkT30lOs6s (09-15-18)

From AskaPatient: Muscle relaxants flagged by FDA for possible connection with serotonin syndrome; list of drugs under scrutiny for safety concerns

In the U.S., the Food and Drug Administration is respons ble for continuously monitoring the safety of approved drug products. The FDA Adverse Events Reporting System (FAERS) enables the FDA to conduct post-market surveillance by requiring pharmaceutical companies to submit "adverse event reports" for patient safety incidents related to their products. In July, we reported on the exponential increase in these reports in recent years, along with an explanation of what the FDA does with the data.

Each quarter, the FDA releases a list of drugs that have been flagged for exhibiting new (not already listed on the product label) potential signals of serious safety risks. The "Potential Signals of Serious Risks" list also includes a description of the action that the FDA is taking or has taken. In some cases, the FDA decides not to take any action based on available information. In other cases, they require a change on a product label to bring attention to a new product risk.

Muscle relaxants and serotonin syndrome connection

In the most recent 2018 quarterly report, a new potential risk of **serotonin syndrome** is associated with the **use of muscle relaxants**. Serotonin syndrome (SS) is an uncommon but serious drug reaction characterized by such symptoms as agitation, confusion, tremors, twitches, high blood pressure, shivering, and fever. It usually happens when a combination of two drugs or an increase in a dosage level of one drug leads to a toxic level of the chemical serotonin. Symptoms occur rapidly, and hospitalization is often required. The majority of drugs associated with SS in the FAERS database are antidepressants. More than 9,400 adverse event reports have been filed with the FDA since 2006 for serotonin syndrome, with 663 cases received in 2018 as of June 30. At least 22 drugs in the AskaPatient database have mentions of serotonin syndrome.

Examples:

Zoloft serotonin syndrome (antidepressant)

Effexor serotonin syndrome (antidepressant)

Cymbalta serotonin syndrome (antidepressant)

Maxalt serotonin syndrome (migraine headache drug)

It has been noted for years that "triptans," such as migraine drugs Imitrex, Zomig, and Maxalt, may trigger serotonin syndrome in patients who are also taking an antidepressant. What is especially unfortunate about the newly recognized possible connection between muscle relaxants and serotonin syndrome is that when a patient is hospitalized for SS, they are often given muscle relaxants as a **treatment** – to control muscle spasms. The FDA does not provide explanations about what led them to put these drugs on the serious safety risk evaluation list, and the publicly available FAERS database does not contain a large number of reports for SS associated with these drugs. Nevertheless, metaxalone (Skelaxin) has 44 FAERS reports and Amrix (cyclobenzaprine hydrochloride) has 60 reports associated with serotonin syndrome, with most received within the last three years. In addition, case studies in the medical literature support the serotonin syndrome/muscle relaxant link.

More drugs being evaluated for safety risks

The following table lists additional prescription drugs that have been identified for potential risks in the two most recent quarterly reports by the FDA. Links go to reviews for the drug. The list is not complete. Click the FDA links below to view complete report, and also check out last month's August 12 newsletter for a recap of other common drugs under review or with new warnings, including **fluoroquinolone antibiotics** drugs causing low blood sugar, acid reflux PPI drug warnings, and Singulair potential risks for neuropsychiatric effects.

Drugs Under FDA Evaluation for Possible Regulatory Action

Report Date

Antifungal drugs causing mineralocorticoid excess

2018 Q1

(high concentrations of cortisol causing high blood pressure and hypokalemialow potassium)

Sporonox

Noxafil

Cancer nausea drugs causing infusion site and hypersensitivity reactions

<u>Varubi</u> <u>2018 Q1</u> Emend 2017 Q4

Insulin-injection products not being

used correctly – failure to remove inner needle cover	2018 Q1
Examples (see FDA report for complete	list):
<u>Lantus</u>	
<u>Toujeo</u>	
Novolog	
<u>Humalog</u>	
Muscle relaxants causing serotonin syndrome	2017 Q4
<u>Amrix</u>	
Equagesic	
Maolate	
<u>Metaxalone</u>	
Norflex	
Norgesic	
Parafon Forte DSC	
Robaxin	
Skelaxin	
<u>Soma</u>	
Rheumatoid arthritis drugs linked to hypertension and lung disease	2018 Q1
<u>Actemra</u>	
Kevzara	
Kineret	
Rheumatoid arthritis drug linked to pancreatitis and liver toxicity	2017 Q4
<u>Actemra</u>	
Thyroid drug linked to fatal cases of vasculitis (inflammation of blood vessels)	2018 Q1

<u>Propylthiouracil</u>

Sources and more reading:

FAERS public dashboard. Use this tool to research adverse events reported to FDA. Search by product name, reaction type, and more.

"Fluoroquinolone antibiotics low blood sugar warning and FDA drug safety list." August 12, 2018 AskaPatient Newsletter.

Diabetes Site Blog: Insulin pen watchlist. "13 different insulin pens added to FDA watch list due to users missing this important step."

NMS vs. Serotonin Syndrome. Emergency Medicine News. Compares characteristics of neuroleptic malignant syndrome (often triggered by antipsychotic drugs or

serotonin-affecting drugs like L-dopa) with serotonin syndrome. These two conditions have similar symptoms so can be confused.



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