

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

- Researchers assess the effects of deprescribing anticholinergic drugs to reduce risk of dementia. [MedPage Today](#) (June 24, 2019)
- A novel diagnostic procedure can detect liver disease decades before it can become fatal. [GenEngNews](#) (June 25, 2019)
- Sandra Boodman's latest "medical mystery" tells the story of a patient who suffered from intense and excruciating itching. After visits to multiple doctors, it was finally linked to her gallbladder surgery a decade prior. [Washington Post](#) (June 25, 2019)
- Strong opioid pain medicine like tramadol does not appear to work as effectively in patients who are also taking certain kinds of antidepressants, based on study at University Hospitals Medical Center. Patients taking Prozac, Paxil, or Wellbutrin required three times the pain medication per day compared with patients not taking the antidepressants. [Science Daily](#) (June 25, 2019)
- Growing opioid addiction problem in Africa is fueled by tramadol. Opioid drug overdose deaths in U.S. continue to rise, but fueled by fentanyl, according to United Nations. [Reuters](#) (June 26, 2019)
- The FDA is soliciting public comment about its pilot program to make clinical trials data summaries, which are a crucial part of new drug applications, publicly available for the first time. [FDA release](#) (June 26, 2019)
- Related to the FDA transparency initiative for clinical trials data, prostate cancer drug Erleada (apalutamide) was a "pilot" drug application that included trials information. [Erleada Documents](#) (June 26, 2019)
- The FDA provided an update about its investigation into the link between cardiac events experienced by dogs and certain types of dry pet food, mainly of the grain-free variety. [FDA Release](#) (June 27, 2019)
- Too many seniors are dying from falls, with more than 25,000 people over the age of 75 dying from falls in 2016 compared with 8,600 in 2000. Experts suggest that patients are not receiving adequate fall risk assessments during their medical visits. [KHN Report](#) (June 27, 2019)
- The federal government, which funds more than \$3 billion of Oklahoma's \$5.2 billion Medicaid program, says it is entitled to a portion of a \$270 million settlement the state of Oklahoma reached with Purdue Pharma to end an opioid lawsuit. [Tulsa World](#) (June 28, 2019)
- Twenty former female soccer players over the age of 40 have signed up to participate in a study on the degenerative brain disease chronic traumatic encephalopathy (CTE), to be conducted by Boston University. In 2016, BU conducted a similar study on brain trauma in former football players. [Boston Globe](#) (June 28, 2019)
- This week, the FDA approved a new use for Dupixent (dupilumab): the injectable drug treats adults with nasal polyps that are accompanied by chronic rhinosinusitis. Dupixent is also approved to treat a certain type of eczema and asthma. [FDA Release](#) (June 26, 2019)
- Yet another losartan recall was issued this week for NMBA impurities found in some lots of the blood pressure drug from MacLeods Pharma product manufactured by Hetero Labs in India. [Recall notice](#) (June 26, 2019) (see *AskaPatient's related article on the [valsartan debacle](#)*)
- The FDA announced that certain insulin pumps (Medtronic MiniMed) are being recalled due to potential cybersecurity risks. Unauthorized wireless connections can change the pump's settings, resulting in over-delivering insulin to a patient or stopping insulin delivery. [Announcement and list of products](#) (June 27, 2019)

FDA Ends Alternative Summary Reporting Program for Medical Devices

This month, the FDA formally ended its Alternative Summary Reporting (ASR) program for medical device manufacturers, and will replace it with the Voluntary Malfunction Summary Reporting (VMSR) program. The ASR was a "hidden" alternative method for reporting device malfunction and injury reports from 1999 - June 2019. The program collected summary reports of medical device malfunctions not required to be reported individually into the MAUDE (Manufacturer and User Device Experience) system.

The MAUDE database is similar to the FAERS (FDA Adverse Event Reporting System) database for adverse effects of prescription drugs reports. It contains ten years' worth of individual medical device incident reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) along with voluntary reports from health care professionals, patients and consumers that are submitted through the MedWatch program.

Kaiser Health News examined some of the newly publicly available data from the Alternative Summary Reporting database and reported on its findings. For example, "blood glucose meters for patients with diabetes had more unique incidents than any other device in the database, logging 2.4 million reports over the past 20 years."

Sources and More Reading:

- KHN's report: "[Five Things We Found in the FDA's Hidden Device Database](#)" (June 27, 2019)
- [MedWatch Program](#): Consumers and health care providers report serious problems with drugs, devices, food, supplements, and cosmetics using FDA's MedWatch forms.
- [MAUDE database](#) of device malfunctions. Searchable by brand name, manufacturer, date, and more.

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