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

- Man who knowingly gave his girlfriend HIV has been sentenced to 30 years in prison. http://ow.ly/QY2z30kDOQT (06-25-18)

- Normalization of 'plus-size' body shapes is undermining efforts to control the growing obesity problem. http://ow.ly/DmSD30kDOSb (06-25-18)

- U.S. House passes massive opioids legislation that would include expanding access to treatment and rehab. http://ow.ly/SWlY30kDOXx (06-25-18)

- U.S. approves first cannabis-derived medication for drug-resistant epilepsy syndromes. http://ow.ly/ZdUm30kF7R2 (06-26-18)

- New drug stops the spread of cancer cells, protecting patients from later stages of cancer. http://ow.ly/jQqf30kF7S4 (06-26-18)

- In an age of instant gratification, is it possible that kids today can delay a reward longer than their 1960's counterparts? http://ow.ly/VUPK30kF7SV (06-26-18)

- Study says men's testosterone levels are largely based on childhood environment, rather than genetics or race. http://ow.ly/Mfer30kG9M0 (06-27-18)

- Researchers develop technique for making an insulin pill which would eliminate painful daily needles. http://ow.ly/Wl4X30kG9Tm (06-27-18)

- Over 1,000 genes associated with intelligence are identified, expanding our understanding of genetic influence on cognitive function. http://ow.ly/YGP930kGa8c (06-27-18)

- Chocolate milk performs as well if not better than sports drinks for post-exercise recovery. http://ow.ly/QVLh30kHhQH (06-28-18)

- Ibuprofen maker shuts down production facility in U.S. due to a technical problem, may not reopen until September. http://ow.ly/OSJD30kHi8B (06-28-18)

- Boosting serotonin improves learning rate, may help people break habits, according to mouse study. http://ow.ly/fOmk30kHikn (06-28-18)

- China turns to AI technology for assistance in a healthcare system stretched too thin. http://ow.ly/aFwo30kIrHl (06-29-18)

- New small-molecule drug therapy opens the door to treating inherited deafness. http://ow.ly/t28L30kIrJ7 (06-29-18)

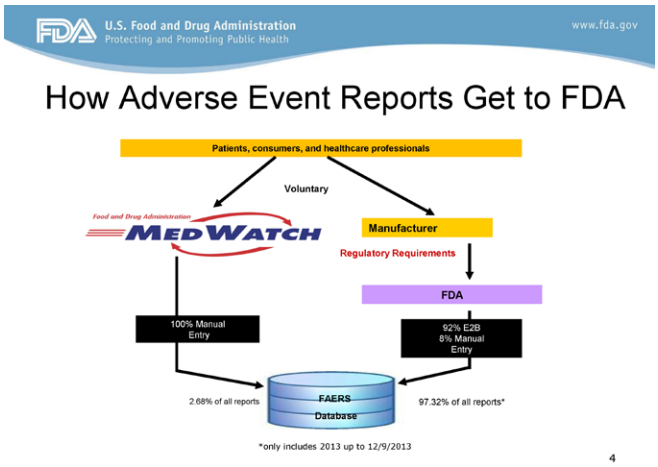
- Jurors order dialysis center company DaVita to pay families $383.5 million for wrongful deaths of family members and concealing information. http://ow.ly/Jdhe30kIrLB (06-29-18)

- FDA approves Demibra's daily topical wipe for excessive armpit sweating as a cheaper alternative to other therapies. http://ow.ly/M7Fm30kJGuw (06-30-18)

- UCLA develops synthetic immune cells, which could expedite cancer treatment development. http://ow.ly/yoVx30kJGvv (06-30-18)

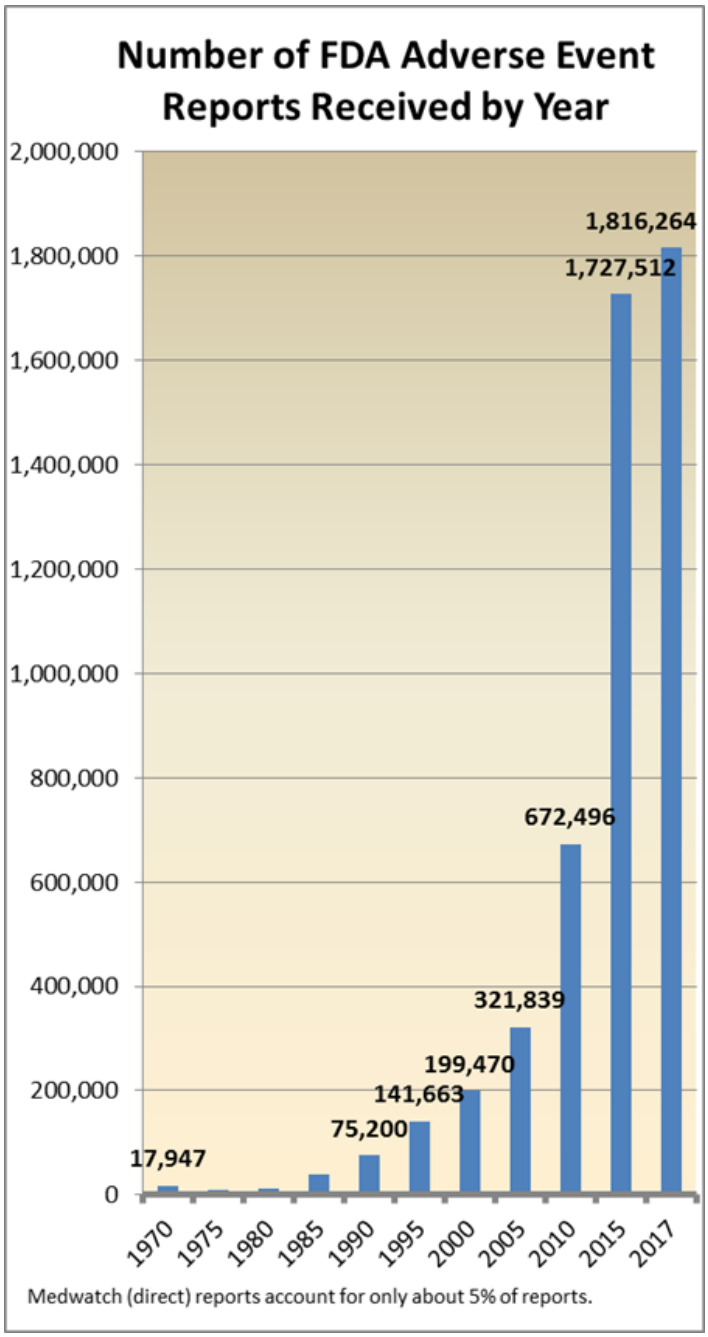
From AskaPatient: Does the FDA's rapidly growing database of adverse events reports improve drug safety?
The FDA has been collecting information about adverse events associated with approved drugs since 1969 as part of its post-approval safety surveillance program. The "Medwatch" initiative was launched in 1993 as a **voluntary** reporting program for consumers, physicians and other healthcare practitioners. In 2013, user-friendly online reporting forms for consumers (Form 3500B) and for healthcare professionals (Form 3500) were launched on the FDA web site.

FDA Adverse Events Reporting System (FAERS)
If healthcare professionals or consumers report drug and biological product adverse events directly to the pharmaceutical company, then the company is required by law to send a report about the event to the FDA. Because this is **mandatory**, it is not part of the "Medwatch" program but is part of the "FDA Adverse Events Reporting System" (FAERS). This chart (see FDA's 50-state meeting in resources listed below for source) shows the data flow from the patient, physician or healthcare practitioner, and pharmaceutical companies to the FAERS database:



How quickly the drug company has to file the report with the FDA depends upon how serious and how unusual the adverse event. According to FDA guidelines, "reports of serious adverse experiences that are **not** listed in the product's current labeling must be reported within 15 calendar days of the initial receipt of the information by the applicant." Other reports may take a long time to make their way to the FDA: non-serious adverse experiences or **serious adverse experiences that are already included in the product's current labeling** must be submitted by the company's regular due date for the reports, which is either quarterly or annually.

The FAERS database contains more than **14 million reports**. In 2015, **1.7 million** reports were received, while just ten years earlier in 2005 only a fraction of that amount were received. The chart below shows the steep increase in the number of adverse event reports filed between 1970 and the present.



About 95% of the drug reports in FAERS come from industry (about 600 companies) and only about 5% come directly from the public (including patients or their family member, and physicians or other healthcare providers).

How do the reports affect drug safety?
The FDA says that if analysis of the reports indicates that there is a new safety issue that is not already listed on the current drug label, it will trigger a warning to the FDA and the pharmaceutical company. Most frequently, the company will have to make a change to the drug label, with FDA sometimes releasing a communications notification about of the new side effect warning or change in dosage or indication recommendations. Sometimes, a "black box" warning will be issued for the drug (this warning also will be printed prominently on the drug label). Less occasionally, the FDA will require the drug company to undertake a study related to the adverse event of concern. Or, the FDA might use its own clinical pharmacologists to analyze the medicine. Very rarely, the drug will be "voluntarily" (at the strong suggestion of the FDA) withdrawn from the market.

On average, the FDA's MedWatch program issues around 180 drug safety alerts annually and between 30 and 60 drug safety labeling changes **each month.** A list of drug safety communications is available on the FDA website : https://www.fda.gov/Drugs/DrugSafety/ucm199082.htm The list include warnings about Biaxin effects that might show up years later in heart patients, rare but dangerous immune reactions associated with epilepsy drug Lamictal, and a warning not to use local anesthetic benzocaine for teething pain in infants.

With so many FDA reports, medical research, clinical trials, as well as buzz on social media and patient forums, one might think it should be easy to quickly recognize and act on emerging safety risks of drugs. But is response time to the alarming reports fast enough? A 2017

JAMA study found that "nearly a third of all drugs cleared by the FDA pose a safety risk." Researchers found that of the 222 drugs approved between 2001 and 2010, **three** drugs were pulled off the market and **61** drugs received **black box warnings** on their labels. On average, it took the FDA about **four years** to take safety-related responsive actions once the drugs were introduced.

Sources and more reading:
- Public dashboard of FAERS database
- Medwatch adverse report online form for consumers (Form 3500B)
- PDF version of Form 3500B for consumers. This PDF version is useful to review before you fill it out online because the online form is broken into separate pages that require you to fill out a section before advancing to the next page.
- *FDA Adverse Event Surveillance Systems and MedWatch: 50 state meeting*, 21 March, 2014. Presentation
- *Postmarket drug safety: the view from the FDA.* Q & A with FDA's Gerald J Dal Pan. Medscape article
- About 20 percent of our poll respondents in 2013 said they had submitted an FDA adverse event report. AskaPatient poll from 2013
- Downing NS, Shah ND, Aminawung JA, et al. *Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010.* JAMA. 2017;317(18):1854–1863
- *20 Drugs approved after 1992 and later withdrawn from the market for safety reasons.* Chart from Public Citizen's Worst Pills web site.

Voice your opinion about drug safety by answering our latest quick poll:
Are there any currently approved prescription drugs that should be removed from the market because of safety reasons?
- No
- Yes, one or two drugs
- Yes, three or more drugs
- Not sure

Click to answer

Contact AskaPatient at admin@askapatient.com
Send newsletter feedback or suggestions to AskaPatientNews@askapatient.com