

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

- The White House announced that the new FDA Commissioner nominee will be Dr. Stephen Hahn, a radiation oncologist who has been at MD Anderson in Houston since 2015. If confirmed, he will succeed former FDA Commissioner Scott Gottlieb, who stepped down earlier this year.

<https://www.reuters.com/article/us-usa-healthcare-fda/trump-nominates-md-anderson-oncologist-as-u-s-fda-commissioner-idUSKBN1XB4WU>

- Three additional companies issued recalls this week for ranitidine products (brand name Zantac) because of possible contamination with the carcinogen NDMA: Perrigo, Novitium Pharma, and Lannett. The FDA also released lab results for ranitidine testing they have completed so far. They equate the amount of NDMA found in ranitidine to the amount of carcinogen you might receive when eating grilled or smoked meat. Nevertheless, some versions of the over-the-counter medicine had as much as nine times the "acceptable limit" for NDMA.

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine>

- Researchers found that an HIV drug, rilpivirine, also suppresses the Zika virus. The drug targets enzymes that both HIV and Zika viruses depend on for their replication. Potentially, the drug might be used to halt replication of other viruses that have the same enzyme such as dengue, yellow fever, West Nile fever, and hepatitis C.

<https://www.sciencedaily.com/releases/2019/10/191030132700.htm>

- As people with Down syndrome age, they are increasingly likely to develop dementia. An NIH-funded study of Medicaid claims of enrollees with Down syndrome found that more than half of those age 55 and older had filed claims for dementia and almost a third had filed claims related to Alzheimer's disease.

<https://www.nih.gov/news-events/news-releases/high-rates-dementia-alzheimers-observed-among-older-people-down-syndrome>

- If you think you're allergic to penicillin, you are probably wrong, according to research presented at an international infectious disease meeting this week. A penicillin allergy assessment can be done quickly using a one-page questionnaire, and in some cases, a skin test. In the study, 98 out of 100 patients who had a penicillin allergy on their medical record were deemed not to be allergic to it after all.

<https://www.news-medical.net/news/20191029/UGA-researcher-working-to-correct-penicillin-allergy-misconception.aspx>

- Hundreds of hospitals have joined the opioid lawsuit bandwagon, seeking compensation for the expense of treating uninsured overdose and opioid-addicted patients.

<https://khn.org/news/hospitals-lawsuit-opioid-makers-addiction-treatment-uninsured/>

- The FDA is planning to require that new drugs being considered for approval file safety reports electronically using the same system that is used for reporting adverse events after a drug is on the market: the FDA Adverse Reporting System (FAERS). Currently, safety reports for drugs under investigation are filed on paper or electronically as a PDF, making review more labor-intensive.

<https://www.fda.gov/news-events/press-announcements/digital-submission-adverse-event-reports-investigational-new-drug-applications-reflects-fdas-ongoing>

- While medicinal cannabis has been shown to be helpful for treating conditions like nausea and epilepsy, a medical literature review found a lack of high quality evidence supporting its effectiveness for treating mental health disorders.

Researchers analyzed 83 studies involving cannabis as a treatment for anxiety, depression, ADHD, Tourette syndrome, PTSD, and psychosis. The findings highlight an urgent need for high quality trials of medical cannabis, particularly since patients are increasingly requesting this treatment for a variety of conditions.

<https://www.reuters.com/article/us-health-mental-cannabis/medicinal-cannabis-not-proven-in-mental-health-study-finds-idUSKBN1X72AV>

- A University of British Columbia team analyzed more than 9,000 brain scans from previously published studies that compared the brain activity of healthy adults with those diagnosed with depression or anxiety. They found that patients with either type of disorder had abnormally *low* activity in the prefrontal parietal cortex – key brain areas for emotional and cognitive control, along with *hyperactivity* in the parts of the brain that process emotions, including the left amygdala and thalamus. The findings set a path for new research that will identify interventions that target these specific regions of the brain.

<https://www.sciencedaily.com/releases/2019/10/191030120309.htm>

- An experimental drug, MRTX849, that targets a specific genetic mutation that occurs in some lung and colorectal cancers, shows promise for reducing lung cancer tumor size by 30% or more. In the small study of just 12 patients, tumors either shrank or stabilized except in one patient where the cancer worsened. Another similar experimental cancer drug, AMG510, shows promise for lung cancer but not colon cancer. FDA has granted it "fast track" status for lung cancer.

<https://www.reuters.com/article/us-mirati-cancer/mirati-drug-shrinks-tumors-in-some-cancer-patients-in-early-stage-trial-idUSKBN1X7265>

- Ten years ago, a government-run pension benefits and retirement program for the elderly was introduced in rural parts of China. The aim was to reduce poverty in areas where the elderly lacked family supports that traditionally had been available to them. Researchers recently studied the cognitive health of that population and found widespread cognitive decline. This was surprising, since other studies found improvement in health, with residents getting better sleep, drinking less alcohol, and smoking less. Researchers determined that the negative cognitive effects and associated decrease in quality of life outweighed the positive health effects, and that the program needs changes in order to address the lack of social connections and other factors related to cognitive decline in the population.

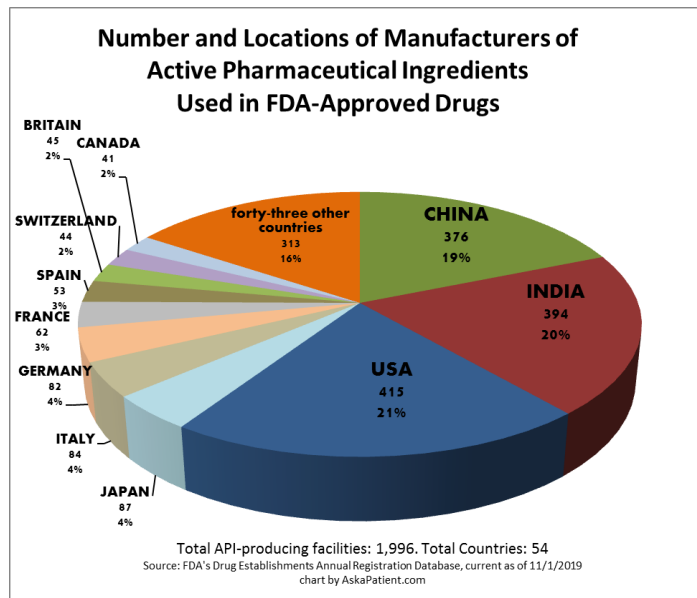
<https://www.sciencedaily.com/releases/2019/10/191029131506.htm>

### **Active Pharmaceutical Ingredients (APIs) - Manufacturing Facilities and Drug Safety**

The recent surge in drug recalls due to manufacturing impurities has put a spotlight on the fact that many of the drugs sold in the U.S. are actually manufactured at plants overseas, particularly in China and India. Even if a drug product is made in the U.S., often its "active pharmaceutical ingredient" (API) is imported.

While about **40%** of registered API manufacturing facilities are located in China or India, the share of total production supply from those facilities is much greater. CNBC reports that about **80%** of the APIs in U.S. drugs come from facilities in China and India. Inspecting the quality of hundreds of overseas manufacturing facilities is not easy. As of 2018, just 22 FDA staff were present in China. The European Medicines Agency, similar to the U.S. FDA, conducts 20-40 facility inspections per year. About ten percent of those inspected are found to be non-compliant with good manufacturing practices.

This chart shows number of firms worldwide that have API manufacturing operations registered with the U.S. FDA:



Sources: <https://www.cnbc.com/2018/08/06/chinas-growing-drug-scandal-is-having-a-ripple-effect-around-the-worl.html> and [FDA Drug Establishment Database](#)

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