News Highlights:

- Another **ranitidine recall** was issued because of **NDMA** (a carcinogen) contamination. Ranitidine (brand name Zantac) is a histamine-2 blocker used to treat stomach acid. The recall by American Health Packaging was for 150 mg. 100 count blister packs. The most recent **valsartan** (including losartan and irbesartan) recall for NDMA contamination was on September 20, 2019 .The FDA continues to list 43 **valsartan-related drugs** that have been tested and not under recall and 386 products that are still under review.

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-health-packaging-issues-voluntary-nationwide-recall-ranitidine-tablets-usp-150-mg-100-count

AskaPatient article on Angiotensin II Receptor Blocker (ARB) blood pressure drug (valsartan) recall: https://www.askapatient.com/news/generic-api-valsartan-worldwide-recall.asp

- Biohaven won approval for Nurtec for treating migraine headaches. The company says the tablet Nurtec can return migraine sufferers to normal function within an hour and will work for up 48 hours. https://www.stamfordadvocate.com/business/article/New-Haven-drug-maker-s-first-FDA-approval-is-15092044.php
- Researchers analyzed **brain scans** of more than 300 patients with **schizophrenia** and found two distinct neuroanatomical sub-types based on the amount of gray matter in one part of the brain. The discovery could lead to more personalized treatments.

https://www.eurekalert.org/pub_releases/2020-02/uops-rds022520.php

- A new study provides more evidence that a **calorie-restricted diet can have beneficial cellular effects** that protect against aging. In the study, many of the changes that occurred in the cells of experimental rats on a normal diet didn't occur in rats on a restricted diet. Even in old age, many of the tissues and cells of animals on the restricted diet closely resembled those of young rats.

https://www.sciencedaily.com/releases/2020/02/200227144259.htm

- A Johns Hopkins University lab has developed a method that could be used in lieu of or in addition to more expensive animal-based drug testing. Pearl-sized **stem-cell-derived "mini-brains,"** which the researchers call "BrainSpheres," were used to detect harmful side effects of a drug on a developing brain. Researchers found that **paroxetine** (a common antidepressant) suppressed the growth of the mini-brain's nerve synapses, suggesting that the drug can interfere with brain development. The paroxetine label currently has a warning that is should not be taken during the first few months of pregnancy because of the risk of heart and lung defects.

https://www.jhsph.edu/news/news-releases/2020/antidepressant-harms-baby-neurons-in-lab-grown-mini-brains.html

- A new study has found a connection between drinking **dairy milk** and increased incidence of **breast cancer**. The researcher suggested that this could be caused by the presence of sex hormone content in dairy milk; often about 75% of the dairy herd is pregnant.

https://www.sciencedaily.com/releases/2020/02/200225101323.htm

- Doctors wanted to find out why some **ulcerative colitis (UC)** patients have **inflammatory attacks** in their lower digestive systems even after undergoing operations to remove the colon and rectum. Patients ("pouch patients")

who undergo the same procedure for reasons other than UC, such as because of a high risk for colon cancer, don't get these inflammatory attacks. Researchers compared substances in the intestine such as bile acids and microbial diversity between the two patient groups, and found marked differences. In phase 2 of the trial, currently underway, UC pouch patients are testing an orally administered treatment that may help restore microbial diversity.

https://www.sciencedaily.com/releases/2020/02/200225114412.htm

- Researchers from Concordia University in the journal *Obesity Reviews* make the argument that **obesity** should be considered **premature aging**, since it has similar effects on the body, including DNA damage and effects on cognition and the immune system.

https://www.sciencedaily.com/releases/2020/02/200225122954.htm

-The U.S. FDA is investigating the safety of products that use **ozone gas or ultraviolet light** to clean Continuous Positive Airway Pressure (**CPAP**) machines or accessories. CPAP machines are used to help people with sleep apnea breathe better during sleep. The FDA warns that ozone levels inside the CPAP equipment could be above safe limits even a few hours after the ozone gas method of cleaning is completed. Concerns about UV light cleaning method are that the devices cannot properly disinfect the inside surface of CPAP hoses and that UV light may damage CPAP machines. Until the FDA receives evidence of the effectiveness and safety of the cleaning devices, they recommend that consumers follow manufacturers' recommendations for cleaning, which usually involve use of regular soap and water. *This release includes a video*:

https://www.fda.gov/consumers/consumer-updates/continuous-positive-airway-pressure-cpap-machine-cleaning

Worldwide Coronivirus (COVID-19) Outbreak News

- In response to travel restrictions due to the COVID-19 outbreak, the U.S. Food and Drug Administration has stopped on-site inspections of **manufacturing facilities in China**. Instead, they will rely on paper records "in advance or in lieu of" the inspections. In addition, the FDA says it will continue work with Customs and Border Protection to target violating products.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update

- At this week's congressional hearing on the COVID-19 outbreak, questions were asked about active pharmaceutical ingredient (API) manufacturers in China. Our analysis in November showed there were **376 FDA-registered API manufacturing establishments in China**, representing 19% of all such facilities supplying the U.S. with active pharmaceutical ingredients. As of 2018, only 22 FDA inspectors were located in China. https://www.askapatient.com/news/generic-api-valsartan-worldwide-recall.asp
- In order to expedite testing capacity for identifying new cases of novel coronavirus, the U.S. FDA is **relaxing approval requirements for tests** and will allow some laboratories to immediately use tests they have developed and validated.

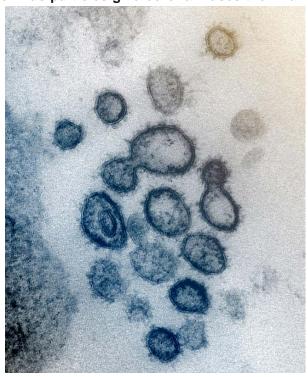
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics

- Check out this interactive tool from **Johns Hopkins University**. It reports that the countries outside of China with the most cases are Korea (3,526 cases) and Italy (1,128 cases) as of March 1, 2020. Total cases worldwide are reported as 87,472. The **World Health Organization** reports that the number of confirmed cases in Hubei province, China, has increased for two successive days after a period of decline. 84% of China's 79,968 confirmed cases and 96% of China's 2,761 deaths have been in the Hubei province. The <u>Worldometer</u> web site

has slightly higher numbers for most countries, and reports 88,346 cases worldwide as of March 01, 2020, 20:35 GMT.

Johns Hopkins Coronavirus tool
World Health Organization Situation Report

- The transmission electron microscope image below shows the SARS-CoV-2 virus (which causes COVID-19) from a patient in the U.S. Virus particles are shown emerging from the surface of cells cultured in the lab. **The spikes on the outer edge of the virus particles give coronaviruses their name, crown-like**.



Source: National Institute for Allergies and Infectious Diseases https://www.niaid.nih.gov/news-events/covid-19-reminder-challenge-emerging-infectious-diseases

A good source for questions and answers on the Centers for Disease Control (CDC) web site is intended for health care professionals but is also interesting for consumers to read. It answers questions such as what treatments are available, whether you have immunity once you recover from the disease, and if your pet is vulnerable: https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html

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