

Health News

- The U.S. Food and Drug Administration (FDA) sent warning letters to 17 websites for illegally selling **unapproved and misbranded opioids**, including tramadol and oxycodone.

<https://www.fda.gov/news-events/press-announcements/fda-warns-website-operators-illegally-selling-opioids-consumers>

- In November, **medical marijuana** ballot measures will be considered by voters in **Mississippi** and **Nebraska**. **South Dakota** will be the first state to vote on legalizing both recreational and medical marijuana on the same ballot.

<https://khn.org/news/altered-mindsets-marijuana-making-its-mark-on-ballots-in-re>

- An FDA safety alert warned physicians not to use a combination of atezolizumab (**Tecentriq**) and **paclitaxel** (also known as **Taxol**) in patients with previously untreated inoperable locally advanced or metastatic triple negative **breast cancer** (mTNBC) because a recent clinical trial showed the combination did not work to treat the disease.

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-professionals-and-oncology-clinical-investigators-about-efficacy-and>

- **Pharmacists** in all 50 states are now authorized to administer **childhood vaccines**. This step, directed by the Health and Human Services Department (HHS), preempts restrictions in 22 states and is designed to help prevent vaccination rates from falling during the pandemic. In 2018, only about 7 percent of childhood flu shots and even less of other kinds of pediatric shots were administered at pharmacies.

<https://www.nbcnews.com/health/health-news/pharmacists-can-give-childhood-vaccines-u-s-officials-say-n1237326>

- The number of U.S. **youth using e-cigarettes** has declined from 5.4 million in 2019 to 3.6 million in 2020, according to recent survey.

<https://www.cdc.gov/media/releases/2020/p0909-youth-e-cigarette-use-down.html>

- The FDA issued guidance for industry for resuming pre-pandemic levels of **drug manufacturing**. They recommend giving high priority to drugs that are in shortage or at risk of shortage and provide guidelines for risk-based assessment of practices.

<https://www.fda.gov/media/142051/download-states/>

- Abbvie agreed to pay \$24 million to settle a California lawsuit charging that it used "**nurse ambassadors**" to boost sales for R.A. drug **Humira**.

<https://www.sacbee.com/news/local/health-and-medicine/article244772252.html>

- University of Arizona researchers found that **levodopa** (Sinemet), a drug commonly used to treat **Parkinson's** disease, may help treat an advanced form of **age-related macular degeneration** (AMD).

<https://www.elsevier.com/about/press-releases/research-and-journals/levodopa-may-improve-vision-in-patients-with-macular-degeneration>

- University of Mainz researchers found that **color-emotion associations** are surprisingly similar around the world, based on a survey of participants from 30 nations over six continents. "For example, throughout the world the color of red is the only color that is strongly associated with both a positive feeling -- love -- and a negative feeling -- anger. Brown, on the other hand, triggers the fewest emotions globally." Several anomalies specific to some nations were noted.

<https://www.sciencedaily.com/releases/2020/09/200910150247.htm>

- A recent University of British Columbia study published in *Clinical Journal of Pain* examining pain among **cannabis users** suggests that -- unlike long-term opioid use, regular cannabis use does not appear to increase **pain sensitivity**.

<https://news.ok.ubc.ca/2020/09/10/new-ubco-study-examines-pain-tolerance-among-cannabis-users/>

- The Max Planck Institute reports that based on their study, the risk of suffering from **cognitive impairment** and **dementia** has increased in the U.S. over the past 20 years.

<https://www.sciencedaily.com/releases/2020/08/200827105945.htm>

Coronavirus News

- A study by an interdisciplinary team of scientists from 13 research institutions in the U.S., Belgium, Canada and the U.K. implicates a **direct-from-China source of the U.S. coronavirus outbreak**, right around the time the U.S. administration implemented a travel ban for travelers from China in early February.

<https://www.sciencedaily.com/releases/2020/09/200910150245.htm>

- An Ohio State University survey says that about 70% of Americans would definitely or probably get a **coronavirus vaccine** when it is ready.

<https://www.sciencedaily.com/releases/2020/09/200910150346.htm>

- People have differing opinions about the safety of **opening gyms**, which most states now allow on a limited basis. One infectious disease expert says that "a gym where you can adequately social distance and you can limit the number of people there and force mask-wearing, that's one of the safer activities." But Saskia Popescu, an infectious disease epidemiologist in Phoenix is less optimistic: "Interventions such as increasing the distance between cardio machines might help, but tiny infectious airborne particles can travel farther than 6 feet."

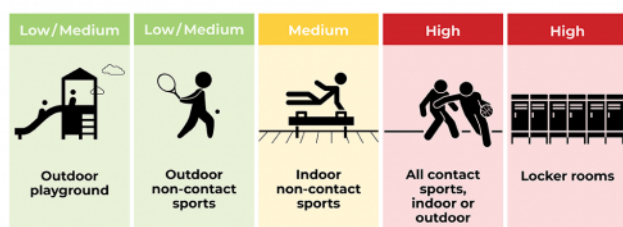
<https://khn.org/news/making-gyms-safer-why-the-virus-is-less-likely-to-spread-there-than-in-a-bar/>

- Popescu and other health policy colleagues developed a series of infographics portraying the **relative COVID-19 risk of various activities** based on a number of factors, including 1) Enclosed space 2) Duration of interaction 3) Crowds 4) Forceful exhalation.

<http://www.ezekielemanuel.com/writing/all-articles/2020/06/30/covid-19-activity-risk-levels>

Sample charts for **school-related** activity risk levels:

Recess & Athletics



- What is the **risk of catching coronavirus** on a **plane**? There are a number of risk factors, including seat assignment, ventilation, boarding, and even which airline you use.

<https://khn.org/news/what-is-the-risk-of-getting-coronavirus-on-a-plane/>

- Separating Covid patients into **separate units** is considered best practice in hospitals and nursing homes, but not all facilities are doing this. Patient mixing has been a scattered concern at **nursing homes**, which Medicare officials discovered when they reviewed infection control practices at more than 15,000 facilities.

<https://khn.org/news/hospitals-nursing-homes-fail-to-separate-covid-patients-putting-others-at-risk/>

- Adults with confirmed COVID-19 are about twice as likely to have **dined at a restaurant** within a two-week period prior to becoming sick, according to a small study reported in the CDC's Morbidity and Mortality Weekly Report.

<https://www.wabe.org/adults-with-covid-19-twice-as-likely-to-have-eaten-at-restaurants-cdc-study/>

- Are you wearing your **mask** properly? If you have one of the blue-white disposable surgical masks, wear it **blue-side out** and put the **flexible wire edge** of the mask at the top, over your nose bridge so that it makes a gap-free connection. Following these simple steps will ensure your mask is fitted properly:

HOW TO WEAR A MASK?

Use surgical masks instead of N95 masks.



Updated Covid-19 stats for Sunday, September 13, 2020: **Worldwide totals:** 28.8 million cases and over 921,000 deaths. **United States totals:** 6.5 million cases and more than 193,000 deaths. India has recorded over 4.7 million cases. Brazil has the third-highest number of cases globally with over 4.3 million cases.

Source: Johns Hopkins University Coronavirus Dashboard

<https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>

Factors Affecting the Performance and Safety of Generic Drugs Part 2: Manufacturing

(view last week's [Part 1 - Ingredients Variations](#))

According to the U.S. FDA, generic drugs now account for nine out of ten prescriptions filled. Competition among generic makers can lead to lower prices and better availability, but consumers need to be aware that **medication quality issues**, which include **ingredient variations and manufacturing procedures**, can affect drug performance and safety.

Around 80% of active pharmaceutical ingredients (APIs) used to make generic drugs are now sourced from overseas, and the vast majority of those APIs now come from China. Starting about 20 years ago, extraordinarily low prices for APIs were made possible by cheaper labor, lack of pollution regulations, and other factors unique to China. As a consequence, many U.S. companies found it impossible to compete with the prices for Chinese suppliers' ingredients and closed, sold, or repurposed their facilities. The last U.S. penicillin plant closed in 2004.



A 2010 image of the penicillin plant at Bristol-Myers Squibb in East Syracuse, New York (Syracuse.com)

With competition driven out, API prices have risen and oligopoly and "cartel" situations have evolved. The so-called "penicillin cartel" makes the entire world dependent on China for this essential antibiotic. (See Rosemary Gibson's book [China Rx](#) for more on this topic.)

How has the change in the sourcing and manufacturing of drugs affected drug safety? Although the FDA has stepped-up its efforts to inspect overseas manufacturing plants in recent years, many experts say that the quality inspections are inadequate. Amid the pandemic, inspections were halted completely between March and July, and are very limited now. And because inspections are announced in advance, the "surprise" element that can help identify quality issues more easily is removed.

Recent drug quality control problems include 2018-2019 recalls of all generic versions of **valsartan**, one of the most commonly used hypertension drugs. A contaminant formed during the manufacturing process for the API for valsartan and other **Angiotensin II Receptor Blockers (ARBs)** led to massive recalls that are still ongoing. The contaminant, N-nitrosodimethylamine (**NDMA**), is linked to increased risk of cancer when taken over long periods of time and in large enough concentrations. The ARBs recall was followed by similar recalls for all lots of popular heartburn treatment **ranitidine** (Zantac) and most recently, for similar contaminants found in diabetes drug **metformin**.

Acknowledging that the manufacturing problem could involve far more than just three drugs recalled so far, the FDA issued guidance for industry, entitled "[Control of N-Nitrosamine Impurities in Human Drugs](#)." It recommends steps manufacturers of active pharmaceutical ingredients and drug products should take to detect and prevent objectionable levels of nitrosamine impurities in pharmaceutical products.

Concerns about drug quality and lack of inspections led to a recent Senate hearing on the topic. Some panel experts called for **more and better inspections, more testing of drugs** and **more U.S.-based manufacturing**. Bright spots have emerged in this regard: an HHS-nonprofit project is underway for manufacturing essential generics in the U.S. and a proposed California-funded project are examples of recent steps towards decreasing reliance on overseas manufacturing.

Sources and Additional Reading:

- Senate hearing on oversight of foreign drug manufacturing inspection process (June 2, 2020)
<https://www.finance.senate.gov/hearings/covid-19-and-beyond-oversight-of-the-fdas-foreign-drug-manufacturing-inspection-process>
- *China Rx: Exposing the Risks of America's Dependence on China for Medicine* by Rosemary Gibson and Janardan Prasad Singh, Prometheus Books, 2018.
ChinaRxBook.com
- The U.S. Health and Human Services Department (HHS) has contracted with several companies, including Richmond, Virginia startup and non-profit Civica RX (formed by more than 1,000 hospitals and Mayo Clinic), to cooperatively manufacture essential generic drugs at a new facility in Virginia.
<https://www.ajmc.com/focus-of-the-week/hhs-contracts-with-pharma-companies-further-insulating-us-from-global-covid19-response>
- California is poised to become the first state to develop its own line of generic drugs, starting with diabetes drugs. Gov. Gavin Newsom will have until Sept. 30 to sign or veto the measure.
<https://khn.org/news/california-rx-state-may-dive-into-generic-drug-market/>
- FDA Guidance for Industry issued September 1, 2020.
<https://www.fda.gov/news-events/press-announcements/fda-provides-guidance-industry-detecting-and-preventing-nitrosamines-drugs>
- A University of Connecticut pharmacist and researcher says that because the FDA relies heavily on the honor system with foreign manufacturers, U.S. consumers get burned.
<https://www.phillyvoice.com/are-generic-drugs-safe-fda-lax-uconn-pharmacist/>

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Health and Drug News Feeds

New! 2020-2021 Flu Vaccine Options

2020-2021 Flu Vaccine Choices				
FLU VACCINE	AGE RANGE	TYPE	PRODUCTION	COMPANY
AFLURIA QUADRIVALENT*	6 months and up	shot	egg-based	Seqirus
FLUAD QUADRIVALENT (adjuvanted)	65 and up	shot	egg-based	Seqirus
FLUAD TRIVALENT (adjuvanted)	65 and up	shot	egg-based	Seqirus
FLUARIX QUADRIVALENT*	6 months and up	shot	egg-based	Glaxo
FLUBLOK QUADRIVALENT	18 and up	shot	genetic recombining process	Sanofi
FLUCELVAX QUADRIVALENT*	4 and up	shot	cell-based	Seqirus
FLULAVAL QUADRIVALENT*	6 months and up	shot	egg-based	Glaxo
FLUMIST QUADRIVALENT	2 and 49	nasal spray	egg-based with live weakened vaccine	AstraZeneca
FLUZONE QUADRIVALENT (High Dose)	65 and up	shot	egg-based	Sanofi
FLUZONE QUADRIVALENT*	6 months and up	shot	egg-based	Sanofi

New! [Patient Guide to Coronavirus Websites](#)

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