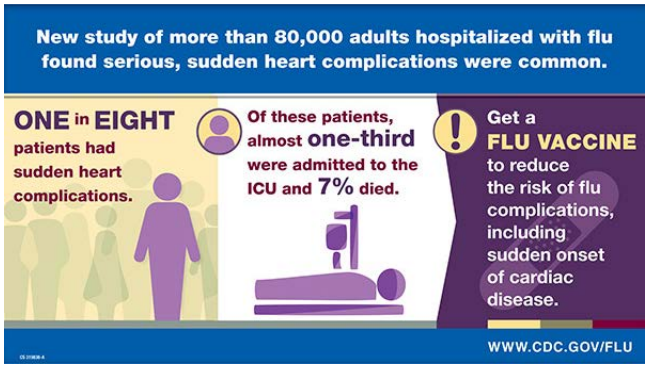
Health News

- A CDC study of more than 80,000 U.S. adults **hospitalized with flu** over eight flu seasons (2010-11 through 2017-18) found that **sudden, serious heart complications** were common and occurred in one out of every eight patients.
https://www.cdc.gov/flu/spotlights/2019-2020/cardiac-events-flu.htm



- **California** is poised to become the first state to develop its **own line of generic drugs**, starting with diabetes drugs. Governor Gavin Newsom will have until September 30 to sign or veto the measure.
https://khn.org/news/california-rx-state-may-dive-into-generic-drug-market/

- Acknowledging that **manufacturing quality problems** may be affecting more products than just the three drugs identified recently and under recall (**valsartan** and other **ARBs**, **ranitidine**, and **metformin**), this week the FDA issued guidance for industry: “Control of N-Nitrosamine Impurities in Human Drugs.” It includes steps manufacturers should take to detect and **prevent unsafe levels of nitrosamine impurities (NDMA)** in pharmaceutical products.
https://www.fda.gov/news-events/press-announcements/fda-provides-guidance-industry-detecting-and-preventing-nitrosamines-drugs

- Novo Nordisk's **Sogroya** (somapacitan) was approved for treating **adults with growth hormone deficiency**. Sogroya is the first human growth hormone (GH) therapy that adult patients only take once a week by injection under the skin; other formulations must be administered daily.
https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-weekly-therapy-adult-growth-hormone-deficiency

- A **tuberculosis vaccine** (called BCG) that is usually only given to children has proven safe for **elderly patients** and appears to make them less susceptible to **respiratory infections**. Researchers from Radboud University Medical Center noted that COVID-19 has not been specifically studied but the vaccine appears to have a broad, stimulating effect on the immune system.
https://www.sciencedaily.com/releases/2020/09/200901094055.htm

- In a bad flu season, such as in 2018, the CDC estimated that **symptomatic influenza** caused 45 million illnesses, 60,000 deaths, and more than 810,000 hospitalizations. This flu season could overwhelm hospitals that are also dealing with COVID-19 cases, so health authorities are leaning hard on getting people to **take the flu shot**.

https://www.wired.com/story/flu-season-and-covid-19-are-about-to-collide-now-what/
CDC data: https://www.cdc.gov/flu/about/burden/index.html

- **People's Pharmacy** co-founder and radio show host **Terry Graedon** answers a question from a reader who wonders whether new diabetes drug **Ozempic** will be safe for her husband to take over the months or years.
https://www.peoplespharmacy.com/articles/will-ozempic-be-safe-over-the-long-term
AskaPatient has 82 reviews for Ozempic, with an average 3.0 (somewhat satisfied) rating:
https://www.askapatient.com/viewrating.asp?drug=209637&name=OZEMPIC

- So far in 2020, **38 first-time generics** have been approved, including generics for Protonix (treats stomach acid or GERD), **Cotempla** (ADHD) **Vascepa** (high triglericides), and **Proventil HFA** (asthma). Complete list:
https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals

Coronavirus News

- The U.S. Centers for Disease Control and Prevention (CDC) asked **states to be ready to distribute a potential coronavirus vaccine** to high-risk groups such as front-line health care providers as early as November 1. Vaccine maker **Pfizer-BioNTech** has already manufactured hundreds of thousands of doses and said it should know by the end of October whether its two-dose COVID-19 vaccine is safe and effective. Third-stage clinical trials are ongoing and involve about 30,000 volunteers. https://www.reuters.com/article/us-health-coronavirus-vaccine-idUSKBN25T3CA

- Russian scientists published the first trial results for their already-approved coronavirus vaccine called "**Sputnik-V**." The report in *The Lancet* says patients involved in early tests developed antibodies with "no serious adverse events."
https://www.rferl.org/a/russian-scientists-say-coronavirus-vaccine-shows-immune-response/30822281.html

- A University of Texas study found that **Multisystem Inflammatory Syndrome in Children** (MIS-C), while rare, can occur even after asymptomatic infection with coronavirus and can severely damage the heart.
https://www.sciencedaily.com/releases/2020/09/200904125111.htm

- **Google** released a database of US search trends for COVID-19 symptoms, hoping it will help public health authorities and researchers track how the virus is spreading.
https://www.businessinsider.com/google-releasing-a-database-of-covid-19-symptom-searches-2020-9

- Dozens of scientists around the world are giving themselves **DIY coronavirus vaccines**. In a controversial situation in Washington State, **North Coast Biologics** is charging patients for administering an unapproved experimental vaccine.
https://www.nytimes.com/2020/09/01/science/covid-19-vaccine-diy.html

- A large **coronavirus antibody study** involving more than 30,000 people in Iceland found that the antibodies last at least four months; other studies had suggested that antibodies might be more fleeting.
https://www.usnews.com/news/health-news/articles/2020-09-01/covid-19-antibodies-last-at-least-4-months-study

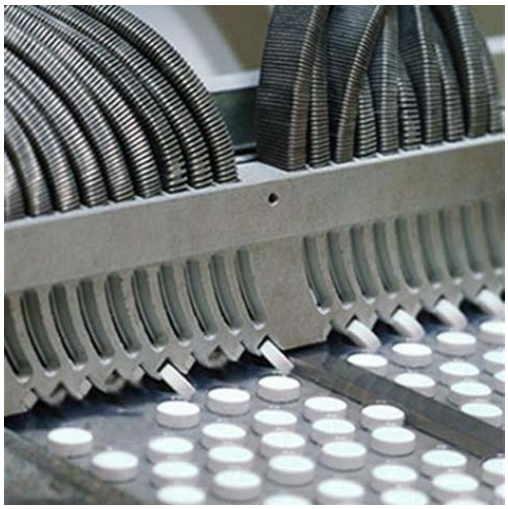
- **Children's National Hospital** researchers have found that the **coronavirus and antibodies can coexist** in young patients. Patients age 6 through 15 years old took a longer time to clear the virus (median of 32 days) compared with patients 16 through 22 years old (median of 18 days). Females in the 6-15 age group took longer

to clear the virus than males (median of 44 days for females compared with a median of 25.5 days for males).
https://www.sciencedaily.com/releases/2020/09/200903075919.htm

Updated Covid-19 stats for Sunday, September 6, 2020: **Worldwide totals**: 26.91 million cases and over 880,000 deaths. **United States totals**: 6.25 million cases and more than 188,000 deaths. Brazil has the second-highest number of cases globally with over 4.1 million cases. India continues to have a surge in cases and now has recorded over 4 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: 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.



Pill Production (Source: U.S. FDA)

Inactive Ingredients

Contrary to what many might think, a generic drug does not contain the exact same ingredients in the same quantities as its associated brand name drug. The colors, flavorings, and other inactive ingredients are often completely different in a generic vs. the associated brand name drug. While unusual, in some cases patients are sensitive to certain inactive ingredients, leading to different effects and a preference for a particular generic.

Active Ingredients

An approved generic drug must have the same amounts of the active pharmaceutical ingredient (API) in the same formulation and show that it has a similar "**bioavailability**," or concentration in the blood as the associated brand name drug. It also must be of the same type (such as pill or injection) and be used for the same indication. Its drug label will have the same dosage instructions, side effects, and warnings as the brand name drug.

Two factors related to active ingredients can be of concern for people who are sensitive to the active ingredients. First, a variance in the **amount of the active ingredient** in a particular drug is allowed by the FDA. For both brands and generics, a drug is allowed to contain **up to 10% more or 10% less** than the labeled amounts of active ingredient (API). Second, allowed **bioavailability variance** in both the U.S. and the European Union can be up to **25% greater or 20% less** than the associated brand name drug, although the way the bioavailability

number is calculated requires that most of the samples be very close to the target amount.

While the variations are not usually a problem for most patients, those who take certain medications for long periods of time and then switch from one generic brand to another, or even from one batch to another batch, may also notice a difference. Sometimes quality control is lacking at the supplier level, and batch-level testing can show that some drugs do not fall even within the allowed variances.

A unique new online pharmacy with its own **laboratory that tests and validates** each batch of drugs it dispenses aims to help reduce medication quality problems for patients. **Valisure**, based in New Haven, Connecticut and licensed to operate throughout the U.S., says that approximately 10% of drugs it tests don't meet the designated quality standards and must be returned to suppliers. Valisure's communications officer Alexandra Jirstrand notes that **high blood pressure medications**, **antidepressants**, and **thyroid treatments** are examples of drugs where patients may notice a difference when switching to generics or between generics. For **epilepsy** drugs, just a slightly different dose could even trigger a seizure.
In such situations, patients need to be careful about which generic they use or request an "authorized" generic (see AskaPatient article on types of generics).

Next week: a look at generic drug safety concerns related to manufacturing and regulation.

Sources and More Reading

- Blog post by Valisure: "Medication quality issues in the U.S. are very real". Valisure has been instrumental in bringing NDMA drug contamination issues to the attention of the FDA in recent months. Check out their site to find out how their pharmacy works. They also sell quality-tested vitamins and supplements. *Please note that AskaPatient is not affiliated with Valisure*.
https://www.valisure.com/blog/valisure-notebook/medication-quality-issues-in-the-u-s-are-very-real/

- U.S. Food and Drug Administration Q&A on generic drugs approval process and how it monitors safety issues and side effects of generics.
https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers

- AskaPatient article explaining regular, authorized, and branded generics, with examples of each type.
https://www.askapatient.com/news/generic-drugs-authorized-branded.asp

- From *Current Drug Metabolism:* Current Regulatory Standpoint on Evaluating the Bioequivalence of Different Classes of Generic Drugs: Is the Evaluation in the Right Direction? Other methods of calculating bioequivalence have been proposed; this literature review examines the limitations of the current approach. (2019).
https://pubmed.ncbi.nlm.nih.gov/31589117/

- Much research has been done on bioequivalence for individual drugs. Check National Library of Medicine's "PubMed" database for your drug (generic name) and the word "bioequivalence."
https://pubmed.ncbi.nlm.nih.gov/?term=+Bioequivalence

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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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