

News Highlights:

- There are mixed reactions to the U.S. Food and Drug Administration's decision to provide **temporary flexibility in food labeling requirements** during the coronavirus pandemic. In cases where substitutions of ingredients can be made safely, the FDA is now allowing food companies to do so without making changes to the ingredient labels. The food manufacturing industry asked for the change in order to keep up with production demand, but some consumer advocacy groups are concerned about food safety. There are also concerns that this could end up being a long-term policy change.

<https://www.washingtonpost.com/business/2020/05/27/fda-rolls-back-food-rules-5th-time-during-pandemic/>

FDA's release: <https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-temporary-flexibility-policy-regarding-certain-labeling-requirements-foods-humans>

- The FDA announced a pending recall of at least five companies' extended-release (ER) generic formulation of **metformin, a prescription drug used to control high blood sugar in patients with type 2 diabetes**. The recalls are due to evidence of **unacceptable NDMA (carcinogen)** levels. Apotex Corp's 500 mg extended release formula was the first product listed. More than 20 companies make generic metformin, and it is one of the most-prescribed drugs in the U.S. [Glucophage](#) is a common brand name version.

<https://www.fda.gov/news-events/press-announcements/fda-alerts-patients-and-health-care-professionals-nitrosamine-impurity-findings-certain-metformin>

Metformin reviews: <https://www.askapatient.com/viewrating.asp?drug=76450&name=METFORMIN+HYDROCHLORIDE>

- The FDA's testing of metformin was triggered by independent pharmacy **Valisure**'s citizen petition filed March 2 alerting the FDA that **11 out of 22 companies** selling metformin had NDMA levels detected above the 96 nanograms (ng) daily acceptable intake limit, based on their testing.

<https://www.valisure.com/blog/valisure-news/valisure-detects-high-levels-of-ndma-in-metformin/>

- Some lots of Acella's **hypothyroid** treatment **NP Thyroid** are being recalled because of "**superpotency**." The product may have up to 115% of the labeled amount of **Liothyronine (T3)**. Superpotency in the drug may cause weight loss, heat intolerance, fatigue, muscle weakness, hypertension, chest pain, rapid heart rate, or heart rhythm disturbances. NP Thyroid is a natural-derived (porcine) treatment. While it requires a prescription, it is not an FDA-approved drug. The drug is similar to [Armour Thyroid](#) (click for reviews).

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/acella-pharmaceuticals-llc-issues-voluntary-nationwide-recall-certain-lots-np-thyroidr-thyroid>

Patient reviews for [Synthroid](#), a synthetic version of **levothyroxine** that many patients take for hypothyroidism and Hashimoto's disease:

<https://www.askapatient.com/viewrating.asp?drug=21402&name=SYNTHROID>

- The U.S. Food and Drug Administration granted approval to Astellas Pharmaceutical's **VESIcare LS** (solifenacin succinate) oral suspension, a liquid taken by mouth, for treatment of neurogenic detrusor overactivity (NDO) in **children 2 and older**. NDO is a form of **bladder dysfunction** (similar to overactive bladder) that results from disease (such as spina bifida) or injury in the nervous system. VESIcare (solifenacin succinate) tablets were initially approved in 2004 for the treatment of overactive bladder in adults 18 years and older.

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-form-bladder-dysfunction->

[pediatric-patients-young-2-years-age](#)

- Additional drugs used to treat **overactive bladder** include antimuscarinic drugs, Beta-3 Agonists, Alpha-blockers, and botulism therapy (Botox). Hormone-related changes related to **menopause in women** and age-related **BPH (enlarged prostate) in men** are considered to be contributing factors to the condition. Check out AskaPatient's article on this topic, along with common side effects for each category and average ratings for each drug, including [VESIcare](#).

<https://www.askapatient.com/news/overactive-bladder-oab-medication-treatments-for-women-and-men.asp>

- **Tauvid**, a new diagnostic drug administered by IV, was approved by the FDA to identify the presence of tau proteins in the brain. Two proteins – tau and amyloid – are recognized as hallmarks of **Alzheimer's disease**. Because Tauvid's ability to detect tau pathology was assessed in patients with severe stages of dementia in the clinical trial, it may have lower detection rates for patients in earlier stages of cognitive decline.

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-image-tau-pathology-patients-being-evaluated-alzheimers-disease>

- Nuro Company's autonomous "**pod cars**" have partnered with CVS to begin making **prescription deliveries in the Houston area** across three ZIP codes starting in June. The company received a waiver that allows it to operate the "R2" on public roads even though it doesn't have a human driver or manual driver controls.

<https://venturebeat.com/2020/05/28/nuro-partners-with-cvs-to-deliver-prescriptions-in-houston/>

COVID-19 Resources:

- **Updated COVID-19 stats for Sunday, May 31, 2020: Worldwide:** 6.1 million cases and over 369,000 deaths. **United States:** 1.77 million cases and more than 103,000 deaths. Use the dashboard to also find data by state and county. Source: Johns Hopkins Coronavirus Dashboard

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

- Getting an **antibody test** to find out if you have been exposed to COVID-19? Check to see if it is on the FDA's authorized lists of antibody tests with **higher accuracy rates**:

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance>

- **Frequently Asked Questions** about COVID-19, including lists of common symptoms and answers to questions like "is it possible to have the flu and COVID-19 at the same time?"

<https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Coronavirus-Disease-2019-Basics>

- **DIY Instructions** for a simple cloth facial mask. Save money by making them yourself from fabric scraps. These instructions include patterns for both sew and no-sew versions:

<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html>

- AARP's "**Tele-Town Hall**" is held each Thursday at 1PM EST on the AARP web site on topics related to the COVID-19 pandemic. Call the 800 number in advance to ask your question. Coming up on **June 4**, the topic is **Coronavirus: Personal Resilience in the New Normal** This week's live Q&A event will address the challenges of staying socially engaged and connected to loved ones while remaining safe. Find out how you can stay sharp, manage anxiety and cope with isolation under the shifting regulations.

<https://www.aarp.org/health/conditions-treatments/info-2020/tele-town-hall-coronavirus.html?intcmp=AE-HP-LL1>

Past program on May 21: **Caring for Loved Ones in Care Facilities**

With special guests Emmy-winning actress and New York Times best-selling author Susan Lucci and AARP CEO Jo Ann Jenkins. View the video or read the transcript:

<https://www.aarp.org/health/conditions-treatments/info-2020/tele-town-hall-coronavirus-05-21.html>

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