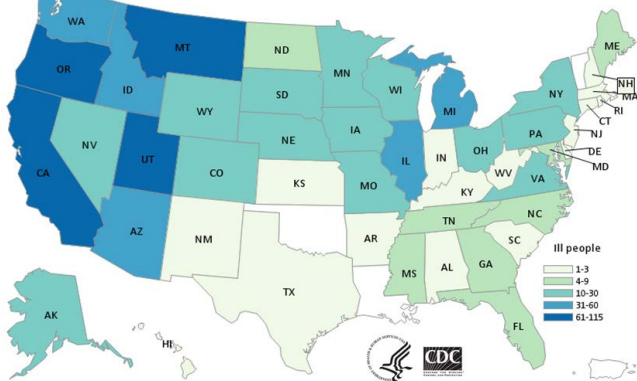


Health News

- A new **salmonella outbreak** has caused widespread recalls, this time for **bagged peaches** sold at Aldi, Wegmans, Kroger, and elsewhere. So far, nine states have been affected.

<https://www.cdc.gov/salmonella/enteritidis-08-20/index.html>

The CDC says that **contaminated onions** have now caused more than 600 cases of salmonella illness in these states:



<https://www.cdc.gov/salmonella/newport-07-20/map.html>

Symptoms of salmonella poisoning can start between 6 hours to 6 days after infection and last 4-7 days.

Diarrhea, fever, stomach cramps, nausea, vomiting, and headache are common symptoms. Certain medicines, like stomach acid reducers, increase the risk of infection.

- A major data leak left **medical and insurance records** related to **car accident claims** and referrals for neck and spine injuries exposed on the internet. The majority of the personal information is thought to be for individuals located in **New York**, with a total of 2,594,261 records exposed.

<https://www.pcmag.com/news/report-ai-company-leaks-over-25m-medical-records>

- Bayshore Pharmaceuticals is recalling two lots of **Metformin Hydrochloride** extended release tablets. Check the **complete recall list for diabetes drug metformin** at the FDA.

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

Highlights of Drug Safety Labeling Updates for June - August 2020

Since June, safety-related labeling changes were issued for a number of drugs. Here are descriptions of the label changes for some of the more common drugs.

Colonoscopy preparation drugs:

Superbowel Prep Kit has new warnings for patients with gag reflex, patients with renal impairment, and warnings about reduced level of absorption of co-administered drugs.

<https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=2299>

Patient reviews:

<https://www.askapatient.com/viewrating.asp?drug=22372&name=SUPREP+BOWEL+PREP+KIT>

Golytely has new warnings about risk of anaphylaxis. Golytely may cause serious hypersensitivity reactions

including anaphylaxis, angioedema, rash, urticaria, and pruritus.

<https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=2272>

Patient reviews:

<https://www.askapatient.com/viewrating.asp?drug=19011&name=GOLYTELY>

Drug used for interstitial cystitis / bladder disease

Elmiron, which is already is linked to vision problems, has new warnings for the possibility of pigmentary changes in the retina associated mainly with long-term use (3 years or longer). Visual symptoms in reported cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision.

<https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=2277>

Patient reviews:

<https://www.askapatient.com/viewrating.asp?drug=20193&name=ELMIRON>

Drug used for quitting smoking

Contrive's label was changed to warn that it could potentially pose risk to fetus and be present in breast milk.

<https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=1045>

The active ingredient, **bupropion hydrochloride**, is the same that is used in many antidepressants (like Wellbutrin) and another quit smoking drug called **Zyban**.

No patient reviews have been received yet for Contrive.

Patient reviews for Zyban:

<https://www.askapatient.com/viewrating.asp?drug=20711&name=ZYBAN>

Drug used for migraine, epilepsy, anticonvulsant

Topamax's label was changed to add a warning about the risk of serious skin reactions.

<https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=1063>

Patient reviews:

<https://www.askapatient.com/viewrating.asp?drug=20505&name=TOPAMAX>

Drug for dry eye

Xiidra had its label changed to warn of the potential for allergic conjunctivitis.

<https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=1402>

Patient reviews:

<https://www.askapatient.com/viewrating.asp?drug=208073&name=XIIDRA>

Cancer drug

Opdivo, which has been approved for treating ten different kinds of cancers, was given expedited approval for some of the indications in advance of completion of some of the clinical trials. The label was recently changed to report its clinical trial results for testing the drug for Esophageal Squamous Cell Carcinoma. Unfortunately, serious adverse reactions occurred in 38% of patients receiving Opdivo. The label provides details on the adverse reactions.

<https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?>

[event=searchdetail.page&DrugNameID=233](#)

(No patient reviews have been received yet for Opdivo.)

First aid for anaphylaxis

Epipen and **Epipen Jr** labels have been updated to provide additional information on how to use the devices safely. [https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?](https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=227)

[event=searchdetail.page&DrugNameID=227](#)

Patient review:

<https://www.askapatient.com/viewrating.asp?drug=19430&name=EPIPEN>

Coronavirus News

- Last year, an estimated 5% of U.S retail prescriptions (about 100 million prescriptions) were delivered by mail, with the U.S. Postal Service handling half the volume. Since March of this year, because of lock downs, the **use of mail order for prescriptions rose by 20%**. With heavy demands for mail delivery, along with problems at the USPS, many patients are experiencing **delay in the delivery of their medications**.

<https://www.nytimes.com/2020/08/20/health/Covid-us-mail-prescription-drugs.html>

- Researchers in Germany studied **how COVID-19 affects the heart in the weeks after recovery** or asymptomatic infection, and made some alarming discoveries. Nearly 80 percent of the 100 patients (median age 49) that received an MRI scan of their heart had persistent abnormalities and 60 percent had evidence of **myocarditis**. A cardiologist discusses Covid-19-associated myocarditis in this *New York Times* opinion piece.

<https://www.nytimes.com/2020/08/17/opinion/covid-19-heart-disease.html>

- **Children** may play a larger role in community spread of COVID-19 than previously thought, according to a study by Massachusetts General Hospital (MGH) and Mass General Hospital for Children (MGHfC).

https://www.eurekalert.org/pub_releases/2020-08/mgh-rsc081720.php

- Scientists at Washington University School of Medicine in St. Louis have developed the first **intranasally administered vaccine** that targets the SARS-CoV-2 virus. Only tested in mice so far, the nasal delivery route created a strong immune response throughout the body and was particularly effective in the nose and respiratory tract, preventing the infection from taking hold in the body. Researchers plan to begin human trials soon.

https://www.eurekalert.org/pub_releases/2020-08/wuso-nva082120.php

- The U.S. FDA announced that it is **revoking** umbrella emergency use authorization (EUA) for “**passive protective barrier enclosures without negative pressure**” used in hospitals because they may not be effective in decreasing health care providers’ exposure to airborne particles. However, FDA has authorized the use of several negative pressure barrier enclosures, which can be found on FDA’s Emergency Use Authorization website. An example of a protective barrier is the COVID-19 Airway Management Isolation Chamber1 (“CAMIC”) developed by the U.S. army:

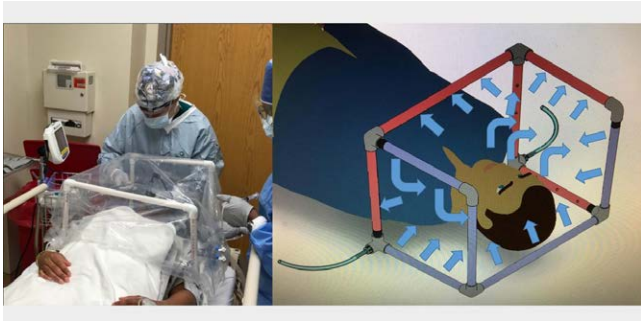


Image of COVID-19 Airway Management Isolation Chamber1 ("CAMIC"): rtmagazine.com

<https://www.fda.gov/medical-devices/letters-health-care-providers/protective-barrier-enclosures-without-negative-pressure-used-during-covid-19-pandemic-may-increase>

FDA's list of EUA personal protective equipment:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas>

Updated Covid-19 stats for Sunday, August 16, 2020: Worldwide totals: 23.31 million cases and over 806,000 deaths. **United States totals:** 5.69 million cases and more than 176,000 deaths. Brazil has the second-highest number of cases globally with over 3.5 million cases. India has 3 million cases.

Source: Johns Hopkins University Coronavirus Dashboard

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

Ask a Patient Weekly Healthcare Newsletter: August 23, 2020

The *Ask a Patient Newsletter* will be on vacation next week; check back for feature on generics safety on September 6.

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