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A ProAssurance Company

December 2, 2020

**RIPPED FROM THE HEADLINES:
A(N EVENTFUL) YEAR IN REVIEW**

REMEMBER JANUARY?

NEITHER DID I...



JANUARY 2020: LIFE BEFORE COVID



AUSTRALIAN BUSHFIRES



BREXIT



THE IMPEACHMENT OF DONALD TRUMP

FDA NEWS RELEASE

FDA informs health care providers, facilities and patients about potential cybersecurity vulnerabilities for certain GE Healthcare Clinical Information Central Stations and Telemetry Servers

FDA NEWS RELEASE

FDA Approves Three Drugs for Nonprescription Use Through Rx-to-OTC Switch Process

FDA NEWS RELEASE

FDA Continues Strong Support of Innovation in Development of Gene Therapy Products

Guidances issued today provide regulatory clarity for product developers

FDA NEWS RELEASE

FDA Takes Action with Indian Government to Protect Consumers From Illicit Medical Products

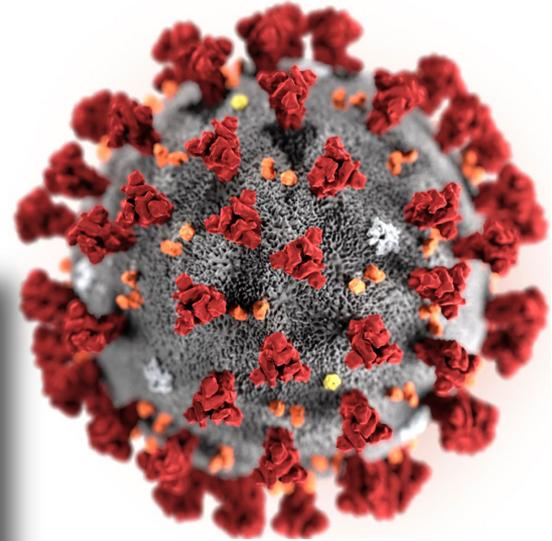
First Bilateral Enforcement Operation with India Stopped Approximately 500 Shipments Through International Mail

FDA NEWS RELEASE

FDA approves first drug for treatment of peanut allergy for children

JANUARY 21, 2020

First confirmed case of coronavirus in Washington State



COVID-19 PANDEMIC



RAPID CHANGE OF FOCUS

- By the end of January, there were nearly 10,000 confirmed cases worldwide, but only 8 in the U.S.



New coronavirus 'not spreading' in the US, CDC says

No new coronavirus cases were diagnosed in the U.S. Monday.

By [Erin Schumaker](#)

January 27, 2020, 10:18 PM • 8

[HEALTH](#)

Coronavirus: 110 people in 26 states 'under investigation' for disease; 5 U.S. cases so far

[John Bacon](#) USA TODAY

Published 8:03 a.m. ET Jan. 27, 2020



RAPID CHANGE OF FOCUS

By the end of March, the world had changed completely

March jobs one-month net change



Bloomberg
Law

ONE MILLION INFECTIONS

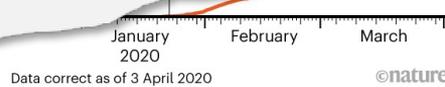
There have now been more than one million confirmed cases of the coronavirus worldwide.



Pharmaceutical & Life Sciences News

FDA Suspends Domestic Routine Surveillance Facility Inspections

March 18, 2020, 4:23 PM



There are multiple immediate, end-to-end supply-chain actions to consider in response to COVID-19.

Supply-chain actions

Create transparency on multitier supply chain

- Determine critical components and determine origin of supply
- Assess interruption risk and identify likely tier-2 and onward risk
- Look to alternative sources if suppliers are in severely affected regions

Optimize production and distribution capacity

- Assess impact on operations and available resource capacity (main: workforce)
- Ensure employee safety and clear communicate with employees
- Conduct scenario planning and assess impact on operations, based on available capacity
- Optimize limited production, according to human-health impact, margin, and opportunity cost/penalty



Estimate available inventory

- Estimate inventory along the value chain, including spare parts/remanufactured stock
- Use after-sales stock as bridge to keep production running

Identify and secure logistics capacity

- Estimate available logistics
- Accelerate customs clearance
- Change mode of transport (e.g. prebook air/rail capacity, given current exposure)
- Collaborate with all parties to leverage freight capacity jointly

McKinsey
& Company



World Health Organization

Shortage of personal protective equipment endangering health workers worldwide

3 March 2020 | News release | Geneva | Reading time: 2 min (471 words)

Harvard Business Review

Coronavirus Is a Wake-Up Call for Supply Chain Management

by Jeffrey Pfeffer, Roger W. Rogers, and Bindiya Vakili

MEDICAL EQUIPMENT SUPPLY CHAINS

Global

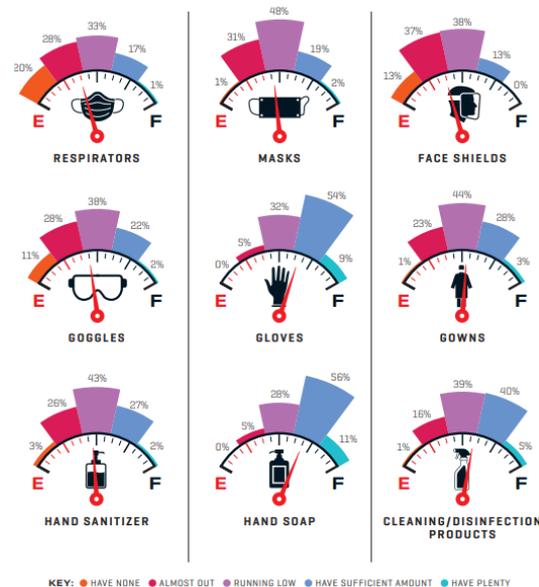
- ▶ Reliance on outsourcing PPE manufacturing to China
- ▶ Unpredictable demand

Financial

- ▶ Hospital budget shortfalls
 - Cancellation of non-emergent surgical procedures
 - Massive increase in critical care/inpatient services
 - Surge in uninsured visits

Running on Empty

Healthcare professionals, including infection preventionists, are being asked to risk their own health and their families' health to care for us. The federal government must act **NOW** to secure more personal protective equipment and coordinate distribution where it's needed most. Every minute matters. Every minute wasted puts more lives at risk.



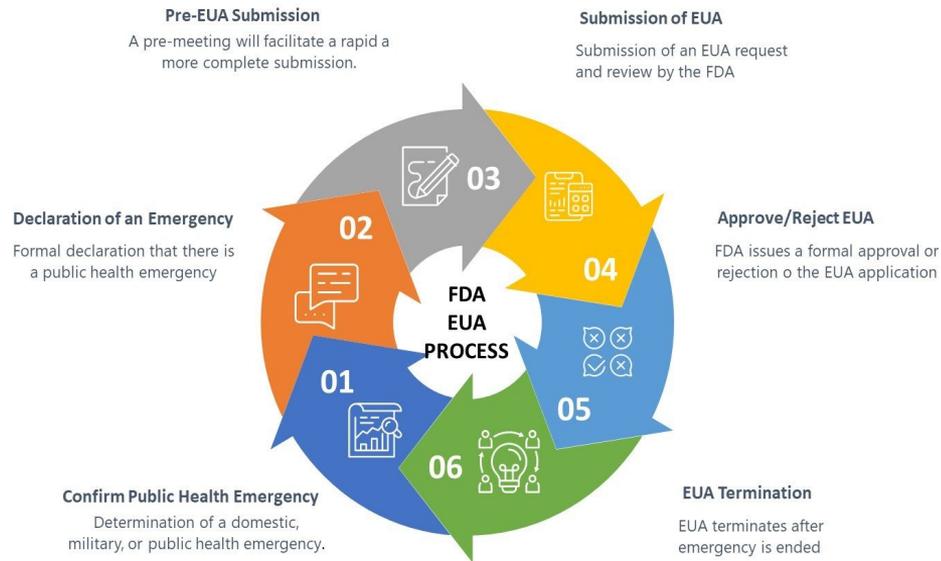
ABOUT THE SURVEY: APIC conducted an online survey of its 11,922 U.S.-based infection preventionist members March 23-25, 2020. Results shown are based on responses from 1,140 infection preventionists located throughout the United States.

STOPGAP MEASURES

▶ The Secretary of Health and Human Services issued a PREP Act declaration for COVID-19, effective February 4th.

▶ FDA Emergency Use Authorizations

- ▶ Diagnostic Tests
- ▶ PPE
- ▶ Ventilators
- ▶ Drugs and Biologics



DIAGNOSTIC TESTS

- ▶ Initial limitation on entities authorized to develop tests
 - ▶ CLIA-certified labs added later
- ▶ Molecular-base lab-developed tests are limited to the labs that created test
 - ▶ Demand outstripped capacity



May 11, 2020 02:55 PM

COVID-19 testing problems started early, U.S. still playing from behind

DIAGNOSTIC TESTS

Antigen tests

- ▶ Rapid results
- ▶ High rate of reported false negatives
 - As high as **50%**
- ▶ Abbott BinaxNOW
 - EUA granted in August
 - Comparison with PCR-based tests since EUA shows increased accuracy over early antigen test kits
 - Potential for home-based testing

SCIENCE TECH HEALTH

FDA authorizes Abbott's fast \$5 COVID-19 test

Abbott's BinaxNOW uses the same technology as a pregnancy test

By Nicole Wetsman | Aug 26, 2020, 8:18pm EDT



PERSONAL PROTECTIVE EQUIPMENT

Umbrella EUAs

- ▶ Surgical masks
- ▶ Non-NIOSH-approved filtering facepiece respirators
- ▶ Imported, non-NIOSH-approved filtering facepiece respirators

Respiratory Protective Devices

- Unlike surgical masks, respirators are specifically designed to provide respiratory protection by forming a tight seal against the wearer's skin and efficiently filtering out airborne particles including pathogens.
- The N95 designation indicates that the respirator filters at least 95% of airborne particles.



N95 Filtering Facepiece Respirator – Tight-fitting. Tested and approved by the NIOSH.



Surgical Mask – Loose fit creates gaps where particles can enter. Cleared by the FDA



Surgical N95 Filtering Facepiece Respirator – Tight-fitting and fluid-resistant. Tested and approved by the NIOSH, cleared by the FDA.

VENTILATORS

THE SLATEST
**How Difficult Is It to Switch a
Factory From Cars to Ventilators?**
By CHLOE HADAVAS
APRIL 01, 2020 • 5:49 PM



THE
NATIONAL LAW REVIEW
**What If Your Automaker-Manufactured Ventilator Is a
Lemon?**
Thursday, May 7, 2020

May 29, 2020
RELEASE 20-058

Eight US Manufacturers Selected to Make NASA COVID-19 Ventilator



DRUGS AND BIOLOGICS

- Off-label use of existing drugs
- Compassionate use
- EUA for limited use
- Convalescent plasma



72 HOURS TO REMDESIVIR COVID-19 COMPASSIONATE USE

Submit request to Gilead (email): <https://drugs.gilead.com> [no confirmation email]

Gilead requires: date, each prescriber agreement, source form completion & drug info [to prescriber, pharmacologist, pharmacist]

Complete requested clinical data entry for Gilead (online)

Secure prescriber agreement to Gilead (email)

Request sIND from FDA (phone)

Be patient or family member

Gilead needs: letter of agreement (email)

FDA issues sIND (email)

Send sIND to Gilead (email)

Receive Form 350L, CV medical license, Clinical letter of authorization or FDA (email & mail)

T3

T+1 hour

T+25 hours

T+30 hours

T+48 hours

T+72 hours

Gilead approves request (email)

Inform local IRB (email)

FDA sends Form 350L (email)

Drug arrives (zip)

Prescribe drug, order safety kits

*Note that Form 350L, CV medical license usually returned to FDA first before sIND granted but not in this case. IND@FDA.DHQPAC

Have you recovered from COVID-19?

You may be able to help others recover by donating plasma.

If you are interested, please contact South Texas Blood & Tissue Center COVID19@southtexasblood.org or call us at 210-731-2719

SouthTexasBlood.org



▶ Trial modifications

- ▶ Ongoing assessment of safety risks
- ▶ Expanded use of telehealth
 - Relaxed enforcement of HIPAA for teleconferencing
- ▶ Focus on patient safety

▶ Communication is key

- ▶ Communication of protocol deviations or modifications to IRB and participants

THE LANCET

WORLD REPORT | [VOLUME 396, ISSUE 10250, P523-524, AUGUST 22, 2020](#)

COVID-19 and readjusting clinical trials

[Aaron van Dorn](#)

Published: August 22, 2020

APPLIED CLINICAL TRIALS

COVID-19 and Its Impact on the Future of Clinical Trial Execution

October 22, 2020

[Stephen Le Breton](#), [Mary Jo Lamberti, PhD](#), [Adam Dion](#), [Kenneth A. Getz](#)

[Comment](#) | [Published: 05 August 2020](#)

Impact of the COVID-19 pandemic on clinical research

[Katherine R. Tuttle](#) 

[Nature Reviews Nephrology](#) **16**, 562–564(2020) | [Cite this article](#)

6588 Accesses | **1** Citations | **10** Altmetric | [Metrics](#)



COVID AND PRODUCTS LIABILITY

COVID AND PRODUCTS LIABILITY

▶ PREP Act Liability Shield

- ▶ Nearly blanket immunity
- ▶ Applies to:
 - Drugs, biologics, devices meant to counteract an epidemic or pandemic, and
 - Manufacturers, distributors, and healthcare providers who produce and/or administer the products
- ▶ Encourage industry to respond to public health crises

▶ HHS Secretary Declaration of a Public Health Emergency

- ▶ FDA Emergency Use Authorizations (EUAs)
- ▶ Products may be marketed under the EUA until:
 - Approved/cleared via traditional pathway,
 - Public health emergency ends, or
 - EUA revoked by FDA

PREP ACT IN PRACTICE

- ▶ PREP Act liability shield is *broad*
 - ▶ Sole explicit exception is for willful misconduct

- ▶ PREP Act liability shield is largely untested because it is intended for these rare circumstances
 - ▶ Little case law, but the act itself is drafted to be a high bar

THE
NATIONAL LAW REVIEW

What Product Liability Claims Can We Expect to See as a Result of COVID-19?

Thursday, June 25, 2020

 LexisNexis

22 Apr 2020

Product Liability: A Growing Practice Area Amidst the COVID-19 Pandemic

**MedTech
Intelligence**

November 12, 2020

Soapbox

Liability Risks and Litigation Defenses for COVID-19 Tests: Provider and Laboratory Liability

By Jordan Lipp, Sierra Ward

PLAINTIFFS' BAR

- ▶ Well-organized
- ▶ Trolling for plaintiffs
- ▶ Television

Defective Medical Device
Pelvic Mesh & Bladder Sling Injury

D. MILLER & ASSOCIATES, PLLC
Houston, Texas

444-8757
D.MILLERLAW.COM

Our firm may be a serious matter and should not be based solely upon future results. While we retain joint responsibility of these cases, we do not accept any responsibility for principal responsibility. In the absence of recovery, client is responsible for attorney fees or case expenses.

D. Miller, Attorney at Law, Principal Office: Houston, TX.

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800-417-9951

Antidepressants
Linked To
Birth Defects

child has suffered a birth defect because their mother took an antidepressant seizure drug while pregnant...

Wellbutrin® • Lexapro® • Topamax® • Depakote®

Water Law Firm
55-1212

Talcum Powder linked to OVARIAN CANCER

If you or a loved one was diagnosed with **OVARIAN CANCER** after using talcum powder products

Paid Non-Attorney Spokesperson

1-800-398-3563
Call Avram Blair & Associates Right Now!

...of a potential
...of action because
...FDA enforcement
...action.

LOOKING AHEAD



WHAT IS AHEAD?

VACCINES

- ▶ Pfizer, Moderna completed clinical trials and submitted applications for EUA
- ▶ CDC determination of priority for access to vaccines
 - Residential nursing facility staff and residents
 - Healthcare providers
 - Over 65
 - Compromised health
 - General population



- ▶ Impact of a new administration at the helm of HHS and FDA

THANK YOU!