Kate Klaus, Esq.
Risk Management Attorney, FDA Specialist

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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's 2020 Agenda

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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

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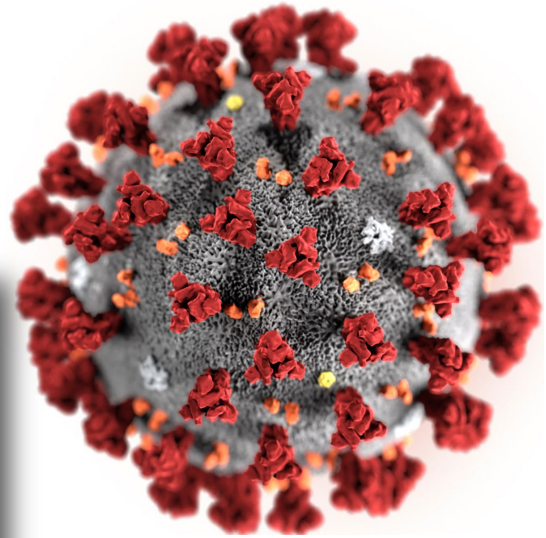
- First confirmed case of coronavirus in Washington State



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.

abc NEWS

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

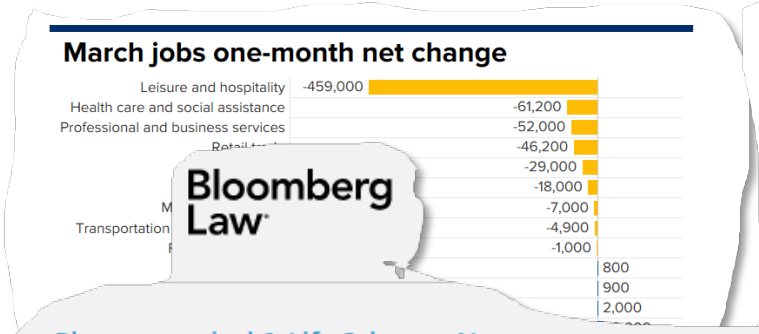
Coronavirus: 110 people in 26 states 'under investigation' for disease; 5 U.S. cases so far

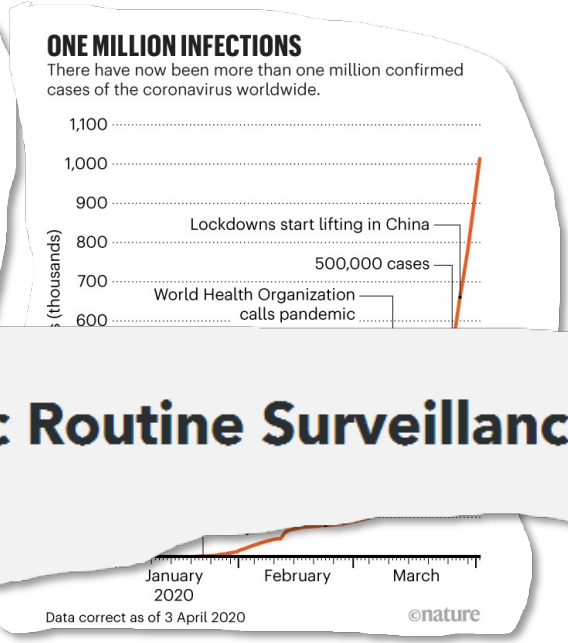
John Bacon USA TODAY

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

Rapid Change of Focus

- By the end of March, the world had changed completely





Pharmaceutical & Life Sciences News

FDA Suspends Domestic Routine Surveillance Facility Inspections

March 18, 2020, 4:23 PM

Supply Chains

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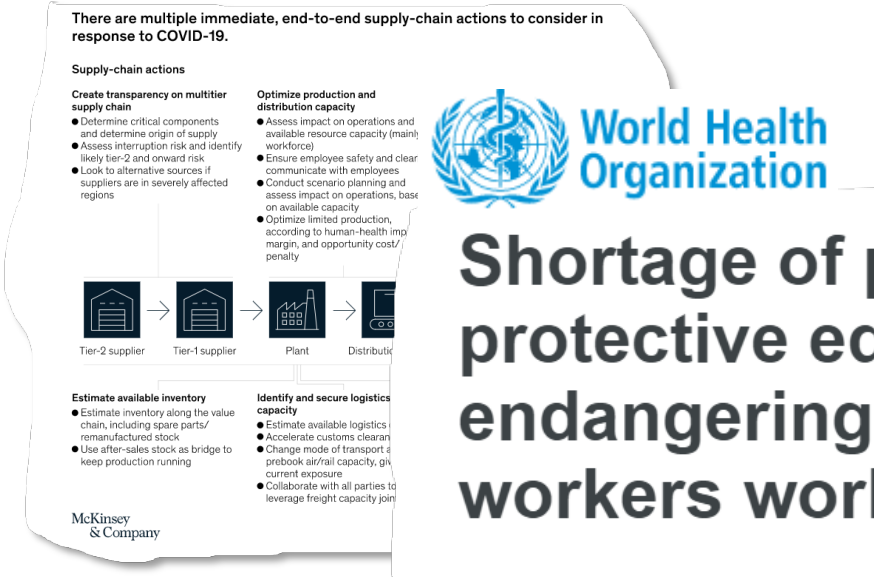

There are multiple immediate, end-to-end supply-chain actions to consider in response to COVID-19.

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 (mainly 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

Tier-2 supplier | Tier-1 supplier | Plant | Distributio

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 clearan
- Change mode of transport a prebook air/rail capacity, giv current exposure
- Collaborate with all parties to leverage freight capacity join

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

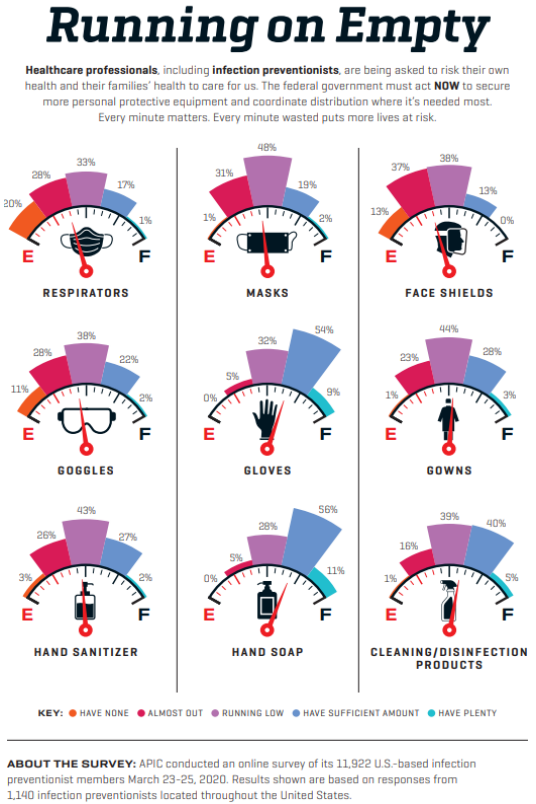
Coronavirus Is a Wake-Up
pply Chain
nt

Rogers, and Bindiya Vakil

Medical Equipment Supply Chains

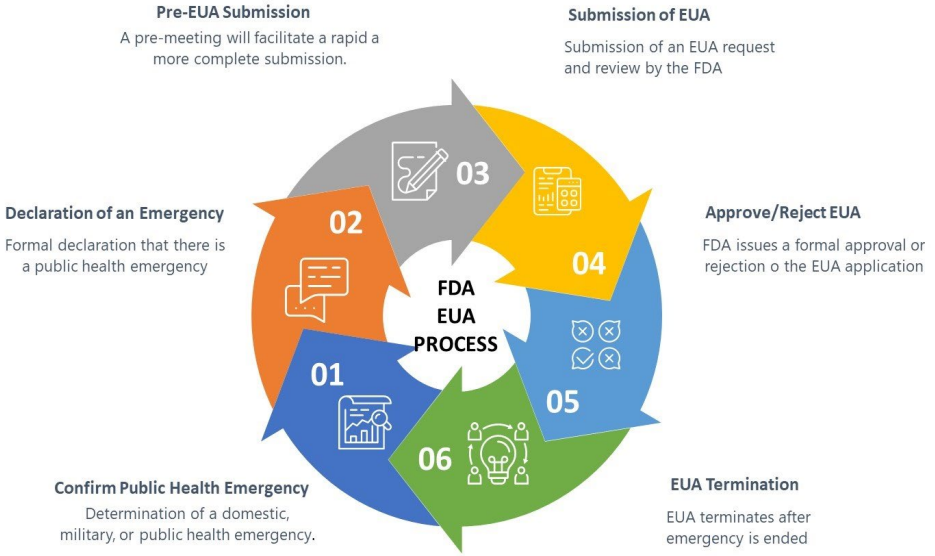
MEDMARC. Treated Fairly

- Global
  - Reliance on outsourcing PPE manufacturing to China
  - Unpredictable demand
- Financial
  - Hospital budget shortfalls
    - Cancelation of non-emergent surgical procedures
    - Massive increase in critical care/inpatient services
    - Surge in uninsured visits



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

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

VENTILATORS

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THE SLATEST

How Difficult Is It to Switch a Factory From Cars to Ventilators?

APRIL 01, 2020 • 5:49 PM

By CHLOE HADAVAS

THE NATIONAL LAW REVIEW

What If Your Automaker-Manufactured Ventilator Is a Lemon?

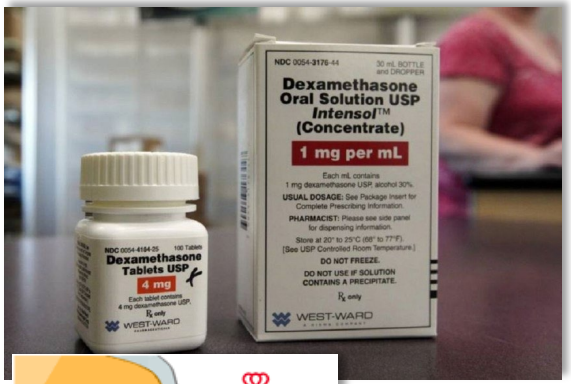
Thursday, May 7, 2020

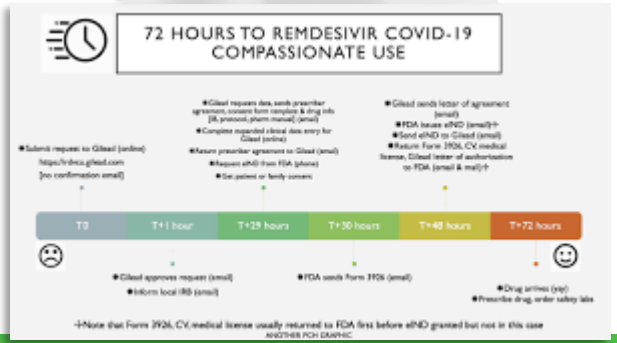
May 29, 2020
RELEASE 20-058

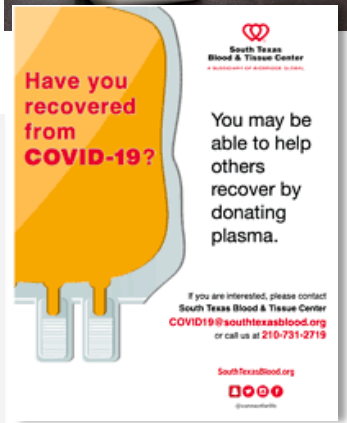
Eight US Manufacturers Selected to Make NASA COVID-19 Ventilator

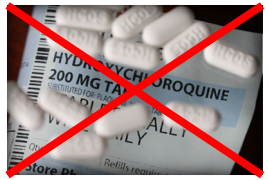
Drugs and Biologics

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









Clinical Trials

- 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

COVID and Products Liability

COVID AND PRODUCTS LIABILITY

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- 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

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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

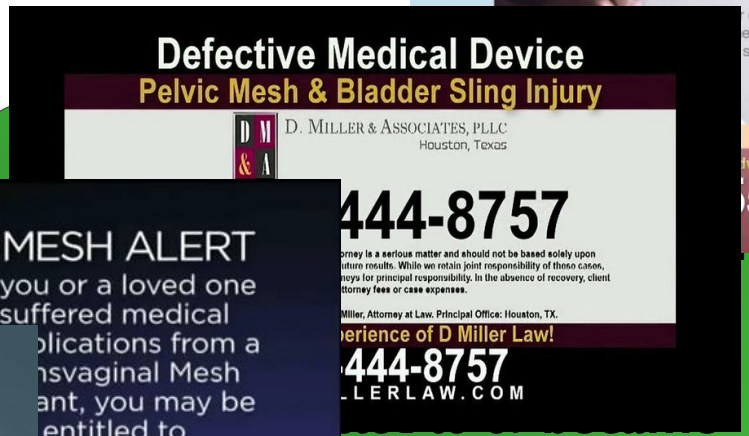
Soapbox

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



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e of action because
FDA enforcement
action.

Looking Ahead

WHAT IS AHEAD?

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- 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!