

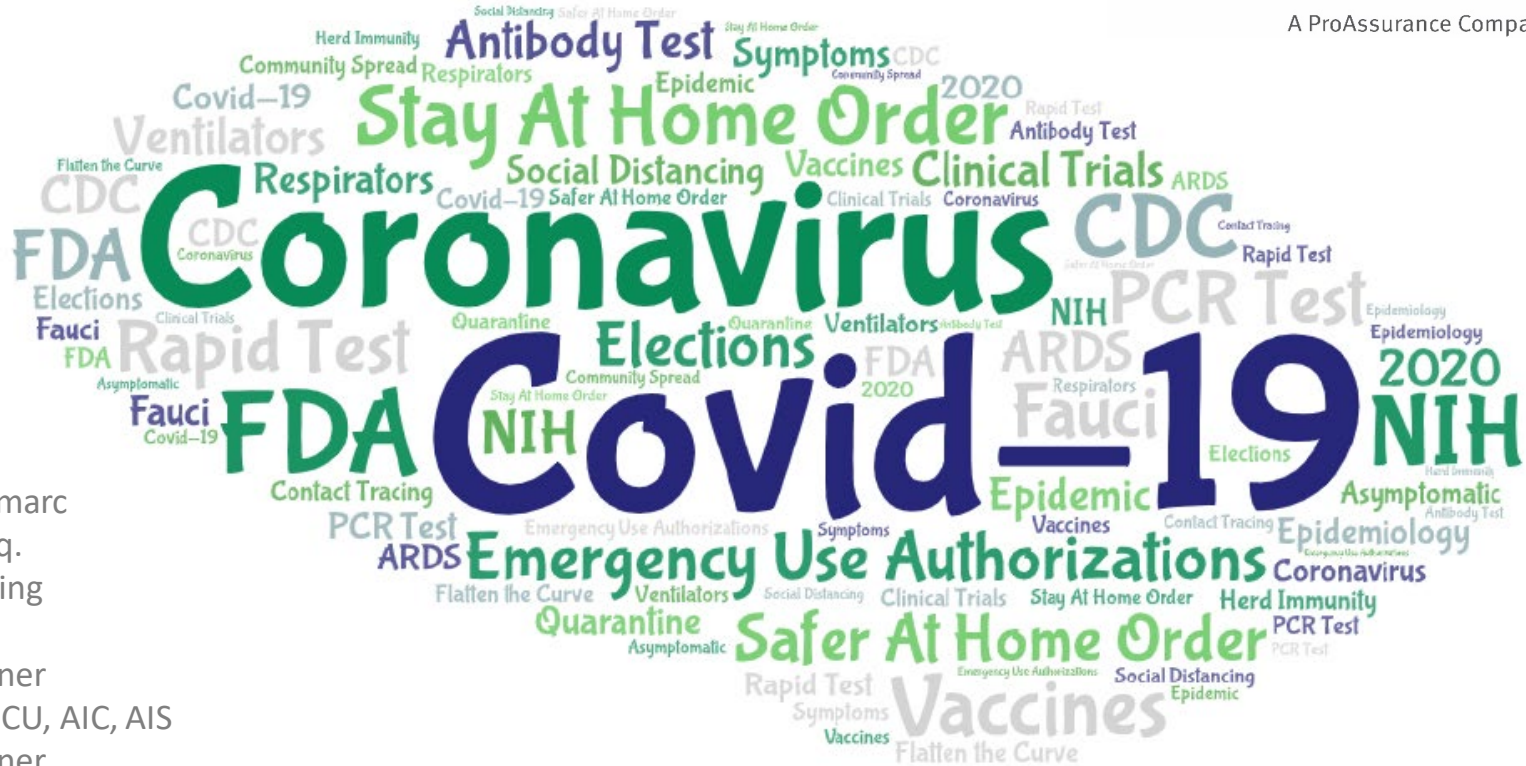
# 2020: A Year Unlike Any Other



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# Agenda

- ▶ Welcome
- ▶ Setting the Stage: 2020
- ▶ Life Sciences Litigation
  - ▶ Significant decisions
  - ▶ Verdicts and Settlements
- ▶ Opioid litigation
- ▶ Prep Act and Covid-19 Products
- ▶ Virtual Jury Selection and Trials
- ▶ President-Elect Biden's FDA Priorities



# *Life Sciences Products Liability Overview*

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- ▶ Products liability filings continue to increase.
- ▶ Medical Device and Pharma cases composed 38% of these new filings.
- ▶ Largest Federal MDL filings were in E.D. of Louisiana.
- ▶ Weitz and Luxemburg (NY) had the most products cases filed.

## ▶ ALBRECHT (US SC 2019)

### ▶ Clear Evidence Standard

- FDA fully informed of warning required by state law
- FDA informed manufacturer it would not approve a change to label which includes the warning

### ▶ To be determined by the Court, not the Jury

# *ALBRECHT IN LOWER COURTS (2020)*

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- ▶ Courts following their obligation to rule on Preemption
- ▶ Decisions go both ways—most recently:
  - ▶ Silverstein (SD FL) preemption
  - ▶ Lyons (ND GA) preemption—appealed to 11th Circ.
  - ▶ Duncan (CD CA) no preemption

# *Jurisdiction—Background*

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## ▶ Why it Matters

- ▶ Key Case--BMS (US SC 2017)

## ▶ General Jurisdiction

- ▶ Principal Place of Business
- ▶ Place of Incorporation

## ▶ Specific Jurisdiction

- ▶ Factual analysis of relationship of case to forum
- ▶ Injured resident plaintiff

# Recent Case—Rios (IL SC 2020)

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- Essure
- Illinois plaintiffs can proceed based on state civil code
- Nonresident plaintiffs with identical claims attempted to join action
- Claimed that clinical trials and MD training occurred in IL
- No injuries caused by activity in IL
- IL SC rules against OOS Plaintiffs



## ▶ Concurring Opinion

- ▶ Follows Sotomayor dissent in BMS
- ▶ Would find jurisdiction wherever product ends up in stream of commerce

## ▶ Election Result

## ▶ FORD (US SC 2021?)

- ▶ Car accident occurs in MN
- ▶ Car not designed, made, or originally sold in MN
- ▶ MN citizen injured
- ▶ Ford challenges jurisdiction since it did not conduct relevant activity in MN

# *Notable Verdicts*

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## ▶ Pre-pandemic

- ▶ Pelvic Mesh
- ▶ Talc

## ▶ More recently:

- ▶ Allergan breast implant
- ▶ Boehringer Ingelheim's Pradaxa
- ▶ Biomet Magnum MOM hips

# Settlements of Mass Torts

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## ▶ Bayer

- ▶ RoundUp
- ▶ Essure

## ▶ Boehringer Ingelheim

- ▶ Pradaxa

## ▶ Johnson and Johnson

- ▶ Talc



# *Opioids*

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# *Opioid Litigation—An Overview*

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## ▶ Federal Court MDL:

- ▶ Trials delayed;
- ▶ Key rulings from trial and appellate courts;
- ▶ Bellwether cases remanded to local federal courts.

## ▶ State Court MDLs:

- ▶ NY AG's trial delayed;
- ▶ Appeal of 2019 Oklahoma verdict.

## ▶ Other developments.

# Federal Court MDL—Trial Delays

## COVID-19 delays trials:

- ▶ Trial in Ohio against pharmacy defendants brought by Summit and Cuyahoga Counties, OH indefinitely delayed;
- ▶ Second pharmacy bellwether set for trial in Ohio delayed until October 2021;
- ▶ Non-jury bellwether trial in West Virginia against three distributors continued indefinitely (may have virtual elements).



*Cleveland*<sup>™</sup>

Photos:  
<https://www.ohnd.uscourts.gov/content/cleveland> ;  
<http://city.cleveland.oh.us/CityofCleveland/Home/Visitors>

# Significant Federal Court MDL Decisions

- ▶ Judge Polster's important 2020 rulings:
  - ▶ Denied motion to dismiss union benefit plan lawsuit;
  - ▶ Trimmed some claims from likely bellwether hospital lawsuit;
  - ▶ Won't set up \$3B common benefit fund for plaintiff attorneys at this time;
  - ▶ Won't reject public nuisance claims against pharmacies for improper dispensing and distribution of opioids.



Photo: [https://www.Cleveland.com/court-justice/2016/06/cleveland\\_federal\\_judge\\_orders.html](https://www.Cleveland.com/court-justice/2016/06/cleveland_federal_judge_orders.html)



# Important Appellate Court Rulings (Federal Court MDL)

- ▶ Two important rulings from the Sixth Circuit:
  - ▶ Negotiating class struck down. Judge Polster improperly used class action rule to create negotiating class of local governments.
  - ▶ Dispensing allegations in first pharmacy bellwether were added too late. Leaves only improper distribution claims.
- ▶ Efforts to remove Judge Polster as trial judge.

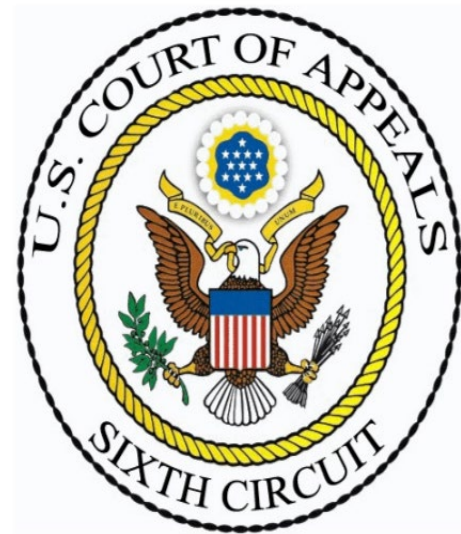


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# *Status of Remanded Bellwether Cases*

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- ▶ **City of Huntington, WV and Cabell County, WV:**
  - ▶ Case set to proceed to trial, but now indefinitely delayed due to COVID-19.
- ▶ **City of Chicago:**
  - ▶ Pre-pandemic, judge rejected Chicago's schedule that would have set an August 2020 trial date. No trial date set.
- ▶ **City of San Francisco:**
  - ▶ Hearing held in August on whether destruction of city property by opioid abusers is independent act breaking causal chain. No ruling on motion. No trial date set.
- ▶ **Cherokee Nation:**
  - ▶ Motion to dismiss pending before court. No trial date.

# Important Developments in State Cases

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## ➤ New York:

- ▶ March jury trial postponed due to COVID-19 and rescheduled for February or March 2021. Jury selection in January 2021. Trial to be livestreamed;
- ▶ Trial for claims brought by New York and two Long Island counties against manufacturers, distributors, and pharmacies.

## ➤ Oklahoma:

- ▶ \$465M verdict against J&J in 2019;
- ▶ J&J appealed to Oklahoma Supreme Court;
- ▶ Key question is whether opioid claims fall within state's public nuisance law.

# Other Notable Events

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## ▶ Notable settlements/negotiations:

- ▶ Mallinckrodt reached \$1.6B settlement to exit federal court MDL;
- ▶ J&J has offered \$5B to settle all opioid claims against it.

## ▶ Purdue Pharma:

- ▶ Reached deal with federal government that includes guilty pleas to 3 felonies, \$8B in financial penalties, and dissolution of company. Some members of Sackler family will pay \$225M in penalties.

## ▶ Insys:

- ▶ Several executives received prison sentences related to their marketing/sale of opioids. Insys founder convicted on racketeering charges and sentenced to 5 1/2 years in jail.

# Notable Coverage Decisions

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- ▶ *Acuity v. Masters Pharm., Inc.*, (Ohio App. Ct. June 24, 2020).
  - ▶ Acuity filed suit against Masters related to coverage for opioid lawsuits pending against Masters.
  - ▶ Trial court found no duty to defend because opioid plaintiffs sought economic damages, not “bodily injury” to specific individuals.
  - ▶ Appellate court reversed finding that at least some damages could be “because of `bodily injury.’”
  - ▶ Ohio Supreme Court hasn’t decided whether to accept appeal.

# Notable Coverage Decisions, Cont'd

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- ▶ *Cincinnati Ins. Co. v. Discount Drug Mart* (Ct. Comm. Pl. Ohio Sept. 8, 2020).
  - ▶ Cincinnati filed suit seeking ruling it didn't owe coverage to Discount for 27 governmental opioid lawsuits.
  - ▶ Trial court ruled Cincinnati had duty to defend because:
    - Due to procedural technicality, negligence claims had not been dismissed;
    - The public nuisance claims alleged an "occurrence;" and
    - Plaintiffs' economic damages may be "because of 'bodily injury.'"

# Notable Coverage Decisions, Cont'd

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- ▶ *Rite Aid v. ACE Am.* (Super. Ct. Del., Sept. 22, 2020):
  - ▶ Rite Aid sought coverage for over 1,100 opioid suits filed against it;
  - ▶ Trial court found duty to defend primarily because at least some damages could be “because of ‘bodily injury.’”
  - ▶ Petition for appeal pending with Delaware Supreme Court.
- ▶ *Giant Eagle v. Am. Guarantee and Liability Ins. Co.* (W.D. Pa., Nov. 9, 2020)
  - ▶ Two excess insurers must defend Giant Eagle in four federal court MDL lawsuits.
  - ▶ Decision hinged on “because of ‘bodily injury’” analysis.



# *Covid-19 Products, 3D Printing and the Prep Act*

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# *Public Readiness Emergency Preparedness Act- ("Prep Act")*

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- Background
- What does it do? Provides immunity.
- Covered Persons/Covered Countermeasures
- Emergency Use Authorization
- Requires plaintiffs to produce a higher standard of negligence and establishes forum.
- Defense Production Act

# *3D Products Covered Under Prep Act?*

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- What is 3D Printing?
- Can 3D Products assist in the Pandemic?
- Are 3D Products covered under the Prep Act?
- Liability issues with 3D Products.

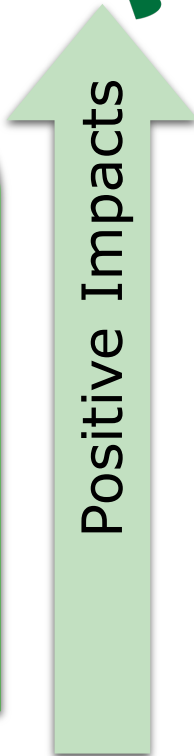
# COVID Effects on the Industry



## Negative Impacts

- Expected overall decrease in Medical Device Market as compared to 2019
- Lockdowns that affect supply chains in manufacturing
- Decreased need for certain products
- Decreased participation in Clinical Trials

- COVID R&D Alliance
- COMMUNITY – CT Platform
- Operational Adaptations
- Increase manufacturing of Needed Medical Equipment and Devices
- Increase of lesser publicized products



## Positive Impacts

## ▶ PPE (gowns, gloves, face masks, respirators, etc.)

- ▶ According to the FDA: 3D-printed PPE may provide a physical barrier, but 3D-printed PPE is unlikely to provide the same fluid barrier and air filtration protection as FDA-cleared surgical masks and N95 respirators.

## ▶ Parts & Components of existing medical devices

- ▶ The FDA specified that the Emergency Use Authorization (EUA) for ventilators, ventilator tubing connectors, and ventilator accessories, could include items such as 3D-printed tubing connectors for multiplexing ventilator use. The FDA encourages original parts where available and cautions that fit and function must be verified before 3D printed parts or components are used.

## ▶ Entire Medical Devices

- ▶ FDA is open to discussing the use of 3D printing for entire medical devices but presently merely invites manufacturers to contact them for more information.

## Home COVID-19 test kits

- ▶ FDA EUA authorized COVID-19 at-home test kit meant to provide a single-use test available by Rx.

## TeleHealth/Broader Access to care

- ▶ Department of Health and Human Services authorized greater use of Telehealth during the COVID-19 emergency for non-emergency situations including: wellness visits; medication consultation; dermatology; eye exams; nutrition counseling; mental health counseling. CMS has also enhanced their services temporarily to provide easier access for those enrolled in Medicare, Medicaid, and CHIP.

# *The Future of COVID-19 Claims/Immunity*

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## ➤ PREP Act:

- ▶ Immunity is only for a limited period of time;
- ▶ Potential extensions/federal COVID-19 liability immunity provision?
- ▶ What happens when immunity expires?

## ➤ State COVID-19 liability immunity provisions:

- ▶ Approximately 12 states have enacted COVID-19 liability immunity provisions;
- ▶ Do these provisions apply to products liability/medical devices?

## ➤ Future for claims:

- ▶ Gray market product claims?
- ▶ Willingness of courts to apply liability immunity provisions.



# *Virtual Jury Selection and Trials*

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# *Virtual Jury Selection and Trials*

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- Utilization of this feature by different courts
- Jury selection
- Civil Trials v. Criminal Trials
- Results of the First Fully Remote Civil Trial
- Will this option survive the pandemic?





# *President-Elect Biden's Priorities at FDA*

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# *Priorities for President-Elect Biden's FDA*

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- ▶ Continued Focus on Covid-19 Medical Countermeasures
- ▶ Leadership and Personnel Changes
- ▶ Medical Product User Fee Negotiations
- ▶ Increased Inspections and Enforcement Activity for Medical Products
- ▶ Generics and Biosimilar Competition
- ▶ Supply Chain and Buy America Policies

**Thank you!**



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