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*Life Sciences Claims 2023: Making
Sense of an Evolving Landscape*

Forward Looking Statements

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There are a number of factors which could cause our actual results to vary materially from those projected in this presentation. The principal risk factors that may cause these differences are described in various documents we file with the Securities and Exchange Commission, such as our Current Reports on Form 8-K, and our regular reports on Forms 10-Q and 10-K, particularly in "Item 1A, Risk Factors." Please review this presentation in conjunction with a thorough reading and understanding of these risk factors.

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Agenda

- Litigation updates
- Conspiracy theories and safety-ism
- Litigation funding
- Personal jurisdiction
- What's happening at the FDA?
- Questions





Litigation Updates

Mass Tort Litigation

- ▶ Products Liability Cases Leading the Way in MDLs:
 - ▶ Of the 464,724 pending MDL cases, **90%** consist of products liability cases
- ▶ Largest MDLs include:
 - ▶ Combat Arms Earplug—3M; largest MDL in history (286K plaintiffs)
 - ▶ Talcum Powder—J&J (53K plaintiffs)
 - ▶ Hernia Mesh—C.R. Bard (21K plaintiffs)
 - ▶ Heartburn Medication—Zantac (14K plaintiffs)
 - ▶ Proton Pump Inhibitors—Prilosec/Nexium (13K plaintiffs)
 - ▶ Chemotherapy—Taxotere (Docetaxel) (10K plaintiffs)
- ▶ Fastest growing MDLs include:
 - ▶ Paragard IUDs
 - ▶ CPAP Ventilators



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▶ **Acetaminophen MDL**

- ▶ **Allegations/Injuries:** Tylenol's active ingredient, acetaminophen, causes an increased risk of prenatal exposition to autism and ADHD
- ▶ Created October 5, 2022
- ▶ Judge Denise Cote (S.D.N.Y.)
- ▶ MDL certified against 9 retailers (CVS, Costco, Family Dollar, Rite Aid, Safeway, Sam's Warehouse, Target, Walgreens, and Walmart)
- ▶ *Daubert* hearing December 7, 2023



<https://pipevet.com/tylenol-extra-strength>

▶ **CPAP Ventilators**

- ▶ **Allegations/Injuries:** the polyurethane (PE-PUR) foam used to reduce sound and vibration can break down, which can result in the foam or certain chemicals being swallowed or inhaled. Plaintiffs allege respiratory conditions, lung disease, and cancer as a result
- ▶ In 2021, Phillips issued a recall of almost all its CPAP devices because of potential health risks
- ▶ Created October 8, 2021
- ▶ Judge Joy Flowers Conti (W.D.Pa.)
- ▶ *Daubert* hearings anticipated in early 2025

▶ **Tepezza MDL**

- ▶ **Allegations/Injuries:** Tepezza causes risk of permanent hearing damage and/or tinnitus (ringing in the ears)
- ▶ Created June 2, 2023
- ▶ Judge Thomas Durkin (N.D.Ill.)
- ▶ MDL growing slowly, 59 cases as of mid-November
- ▶ MDL discovery beginning

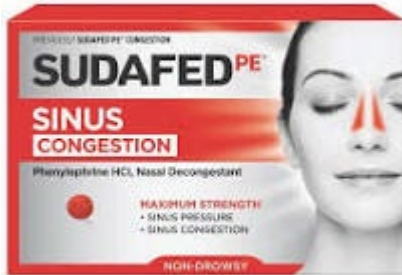
▶ **Suboxone**

- ▶ **Allegations/Injuries:** Suboxone causes risk of severe tooth decay, broken teeth, and other dental injuries
- ▶ Plaintiffs petitioned the JPML for MDL consolidation on November 27, 2023

MDLs to Watch, con't.

➤ **Phenylephrine**

- **Allegations/Injuries:** companies knew that the over-the-counter products containing phenylephrine did not work as advertised
- Lawsuits filed in response to FDA advisory committee agreeing that products containing phenylephrine are ineffective
- JPML hearing held on November 30, 2023



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Conspiracy Theories and Safety-ism



Poll Question

- ▶ Which of these is the best predictor of who will be a plaintiff's juror:
 - ▶ Political affiliation?
 - ▶ Belief in conspiracy theories?
 - ▶ Demographics?

Conspiracy Theories

- ▶ Scenario: plaintiff says migraine medication caused cancer
 - ▶ 258 eligible jurors surveyed online
 - ▶ Biggest predictors of juror behavior:
 - #1—Belief in conspiracy theories (Plaintiff)
 - #2—Extreme sympathy and need to help plaintiff regardless of evidence (Plaintiff)
 - #3—Cognitive reflection, which is ability to override emotion with rational thought (Defendant)



Nick Polavin, PhD, *Who Needs Evidence? The Rise of Conspiracy-Minded Jurors*,
IMS Consulting & Expert Services,
<https://www.expertservices.com/insight/evidence-conspiracy-jurors/> (last
visited 11/22/2023)

<https://www.svgheart.com/product/bigfoot-sasquatch-silhouette-free-svg-file/>

Conspiracy Theories, con't

- ▶ Believing in conspiracy theories is common:
 - ▶ Of 11 conspiracy theories tested:
 - 33.4% believe at least one conspiracy “probably” or “definitely” true
 - On average, 19.4% believed each conspiracy theory was “probably” or “definitely” true
- ▶ Conspiracy theorists cross political and demographic lines



<https://render.fineartamerica.com/images/rendered/default/print/5.5/8/break/images/artworkimages/medium/2/cat-in-a-tin-foil-hat-looking-up-suzanne-tucker.jpg>

Characteristics:

- ▶ Total avoidance of risk or harm
- ▶ Emotional reasoning trumps logic or science
- ▶ Have a good v. evil mindset/tribal mindset

Indicators of safety-ism juror:

- ▶ Higher education
- ▶ Urban resident
- ▶ Strong Democrats



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Safety-ism, con't

- ▶ Indicators of safety-ism juror, con't:
 - ▶ Gets news through electronic means
 - ▶ Strong belief in scientific conclusions not sponsored by corporation
 - ▶ Received COVID vaccine and plan or did get booster

Poll Question

▶ Most jurors believe that a product should be 100% safe if it's on the market:

- ▶ Yes
- ▶ No

What do safety-ism jurors think?

- ▶ Products can't be safe enough:
 - ▶ **Most** respondents said that “companies should take every possible measure to ensure their products are 100% safe . . . ”
 - ▶ Companies should warn about every possible risk or side effect, regardless of size
- ▶ Even potential risks are too much:
 - ▶ **Majority** said they'd stop using a product if possibility it could cause cancer. Some had already done this



<https://thumbs.dreamstime.com/b/bubble-wrap-man-holding-roll-plastic-45824118.jpg>

Why does this matter?

- ▶ The old ways don't work!
 - ▶ FDA approval/clearance isn't the gold star of safety in life sciences
 - ▶ Jurors expect companies to do more than the regulatory or industry standard
 - ▶ Jurors are predisposed to not trust corporations
 - ▶ Think the worst when dealing with gaps in the company's story



<https://media1.giphy.com/media/jTfmBts5vvjK651km0/giphy.gif>

What do we do about it?

► Be prepared!

► Defense attorneys:

- Focus your *voir dire* on finding and striking conspiracy-minded and safety-ism jurors
- Craft litigation themes and strategies with assumption you must appeal to these jurors;
- Deal head-on with problems with the company story;

► Companies:

- Understand that current anti-corporate beliefs mean you start from a negative position with many jurors;



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What do we do about it, con't?

▶ Companies, con't:

- ▶ Meeting FDA, CPSC, industry standards is not enough
- ▶ Be prepared to defend your actions on all aspects of product design, manufacture, and warnings
 - Was the issue considered? If so, what was done about it?
 - Document and be prepared to defend
- ▶ Take adverse events and consumer complaints seriously
 - Did you investigate? Were changes made?
 - Document and be prepared to defend
- ▶ Would you feel comfortable defending your company's actions on the stand at trial?



Third Party Litigation Funding

Sonia M. Valdes

Third Party Litigation Funding (TPLF)

- ▶ What is it?
- ▶ Benefits—increased access to the courts
- ▶ Generally three types of funding arrangements:
 - ▶ Nonrecourse loans made directly to plaintiffs
 - ▶ Loans to lawyers or a law firm
 - ▶ Funding of complex or commercial claims
- ▶ Most attractive cases for TPLF:
 - ▶ Antitrust/Price Fixing
 - ▶ Patent litigation



https://upload.wikimedia.org/wikipedia/commons/4/47/Money_-_Flickr_-_AMagill.jpg

Third Party Litigation Funding (TPLF)

- ▶ Commercial, International or Intellectual Property disputes
- ▶ Ethical Concerns:
 - ▶ Violations of the ancient doctrines of maintenance and champerty
 - ▶ Erosion of the integrity of the lawyer-client relationship
 - ▶ Fear that the lack of proper monitoring of TPLF arrangements could result in abuses perpetrated against lawyers and clients

Third Party Litigation Funding (TPLF)

➤ Curbing TPLF:

- ▶ Registration of TPLF in that state
- ▶ Disclosure of TPLF in discovery

➤ Why is TPLF such a problem?:

- ▶ Class Actions
- ▶ Aggregation of Plaintiffs

➤ 2023 Litigation Finance Survey Report:

- ▶ Results



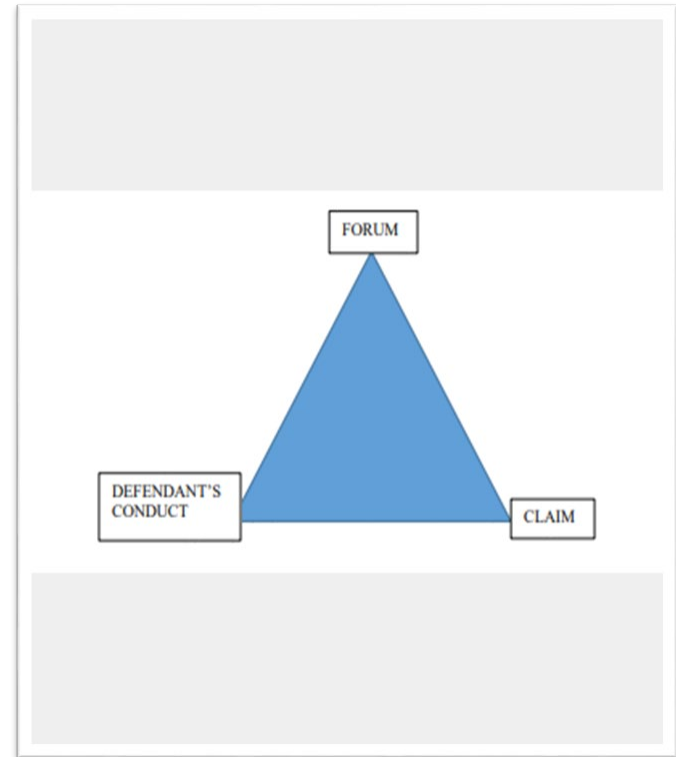
<https://thumbs.dreamstime.com/b/warning-sign-proceed-caution-sign-united-kingdom-white-text-red-background-warning-sign-proceed-caution-sign-united-136287954.jpg>



Personal Jurisdiction

SCOTUS Decisions

- ▶ *BNSF Railway Co. v. Tyrrell* (May 30, 2017)
 - ▶ General jurisdiction: defendant must be at home in the forum
- ▶ *Walden v. Fiore* (Feb. 25, 2014)
 - ▶ Specific jurisdiction: defendant's conduct must form the necessary connection with the forum
- ▶ *Bristol-Myers Squibb v. Superior Court* (June 19, 2017)
 - ▶ Specific jurisdiction: requires a connection between forum and specific claims at issue
- ▶ *Ford Motor Co. v. Montana Eighth Judicial District* (March 25, 2021)
 - ▶ Specific jurisdiction: exists over claims that "arise out of or relate to" defendant's forum conduct provided there is a close connection between the forum conduct and the injury



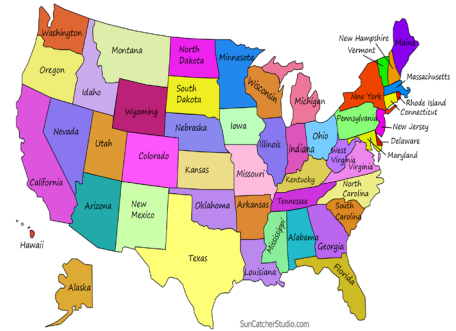
Cases After Ford

▶ Federal:

- ▶ *Yamashita v. LG Chem, Ltd.* (9th Cir. 2023)
- ▶ *Farson v. Coopersurgical, Inc.* (N.D. Ohio 2023)
- ▶ *Rivers v. Nice Recovery Systems LLC, et al.* (D.R.I. 2023)
- ▶ *Greenwood v. Arthrex, Inc.* (W.D.N.Y. 2022)
- ▶ *Brandon v. Wright Medical Technologies, Inc.* (D. Nev. 2021)
- ▶ *Lopez v. Angiodynamics, Inc.* (D. Mass. 2021)

▶ State:

- ▶ *Daimler Trucks North America LLC v. Superior Court* (Cal. Ct. App. 2022)
- ▶ *Bradley v. Globus Medical, Inc.* (Wash. Ct. App. 2022)



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Consent-by-Registration

- ▶ *Mallory v. Norfolk Southern Railway Co.* (June 27, 2023)
 - ▶ *Mallory* addressed a PA statutory scheme that explicitly treats registration to do business by an out-of-state corporation as consent to jurisdiction in the state's courts for all lawsuits, regardless of their connections with the state.
 - ▶ A 4-1-4 plurality of the U.S. Supreme Court held that allowing PA to assert personal jurisdiction in this particular case did not violate the Fourteenth Amendment's Due Process Clause.



[https://www.verywellhealth.com/thmb/sfgL9OUabreAggjJyPq5DRoqaQw=/750x0/filters:no_upscale\(\):max_bytes\(150000\):strip_icc\(\):format\(webp\)/GettyImages-1247144308-d7ef79386af246ec88d332c81f2f00c5.jpg](https://www.verywellhealth.com/thmb/sfgL9OUabreAggjJyPq5DRoqaQw=/750x0/filters:no_upscale():max_bytes(150000):strip_icc():format(webp)/GettyImages-1247144308-d7ef79386af246ec88d332c81f2f00c5.jpg)

Poll Question

- ▶ How many other U.S. states currently have a consent -by- registration requirement similar to PA's?
 - ▶ 0
 - ▶ 13
 - ▶ 22
 - ▶ 34

Potential Effects of Mallory

- ▶ Litigation tourism in PA
- ▶ Changes to other states' business registration regimes
- ▶ Viability of other recent personal jurisdiction decisions





What's happening at the FDA?

- Off-label communication draft guidance:
 - ▶ Draft guidance on when scientific/medical journal articles and clinical reference resources distributed for off-label uses
 - ▶ Expands scope of permissible communications, while setting standards for reliability of materials cited in communications
- Draft 510(k) guidance:
 - ▶ Best practices or “recommendations” for selection of predicate devices
 - ▶ The FDA’s goal is to narrow available predicate devices and modernize devices being used as predicate devices

➤ Mifepristone ruling:

- ▶ Court overruled FDA's approval of the drug, appellate court overturned part of that ruling. Does USSC take the case?
- ▶ What is scope of FDA's authority to regulate?

➤ Cybersecurity guidance:

- ▶ Consolidated Appropriations Act of 2023
 - FDA given increased authority for cybersecurity in medical devices
- ▶ Device should be secure by design, prove compliance with FDA regulations in its submission, and companies should have post-market cybersecurity surveillance measures in place.

Questions?

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