



Protect Your Innovation Product Liability Risks for MedTech Startups

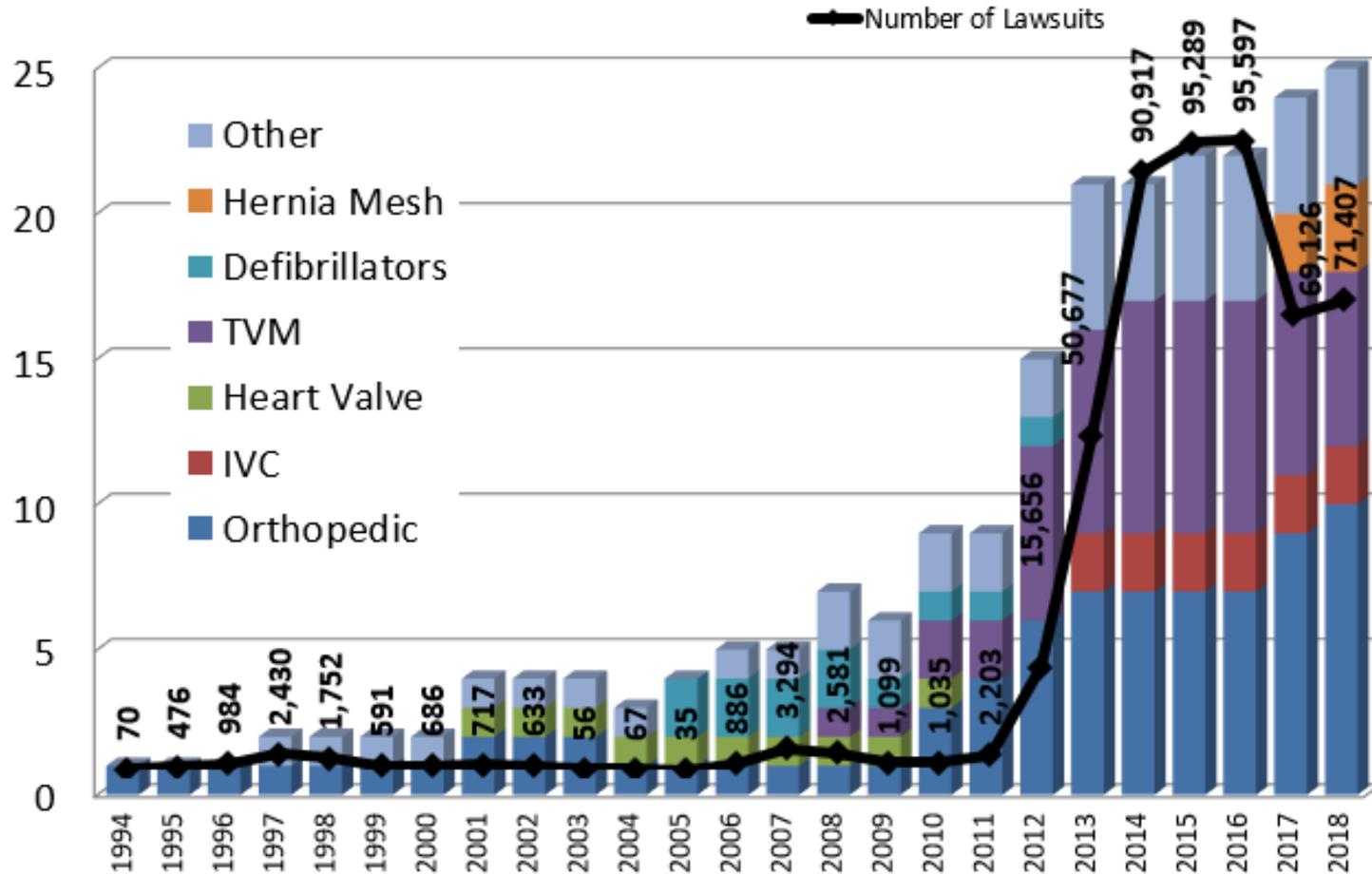
March 18, 2026

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Today's Agenda

- Trends in Medical Device Litigation
- What Drives Litigation?
- Products Liability Law 101
- Use of FDA Evidence
- Best Practices for Preventing Litigation and Minimizing Risk

Medical Device Trends—More Cases



Medical Device Trends — Bigger Verdicts

Nuclear Verdicts Surge to \$14.5 Billion in 2023 – Report

By Ezra Amacher | May 10, 2024



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Nuclear verdicts of at least \$10 million reached a 15-year high in 2023, with "thermonuclear," or more than \$100 million, according to a new report from Harris Martin Publishing.

The report, "Corporate Verdicts Go Thermonuclear," found that nuclear verdicts increased by 27% in 2023 compared to the prior year. In 2022, nuclear verdicts reached a 15-year high of \$14.5 billion.

HARRIS MARTIN PUBLISHING

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STORY FROM: DRUGS & MEDICAL DEVICES

Cook Medical Hit With \$1.2 Million Verdict in Texas IVC Filter Action

May 29, 2018

HOUSTON — A Texas state jury has awarded \$1.24 million to a man who alleged that he was seriously injured when his inferior vena cava was perforated by a Celest IVC filter manufactured by Cook Medical Inc.

The Harris County District Court jury returned the May 24 verdict after determining that Cook Medical failed to adequately warn implanting surgeons about the Celest device. However, the jury of 12 also found there was no design defect in the IVC Filter and, therefore, Cook Medical Inc. was not negligent in designing the device that allegedly caused the plaintiff's injury.

The jury ...

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West Palm Beach Attorney Wins \$3.6 Million Verdict in Blood Filter MDL

"The short story is this was a human experiment that went terribly wrong," plaintiff lawyer Joe Johnson said.

By Samantha Joseph | April 23, 2018 at 04:41 PM

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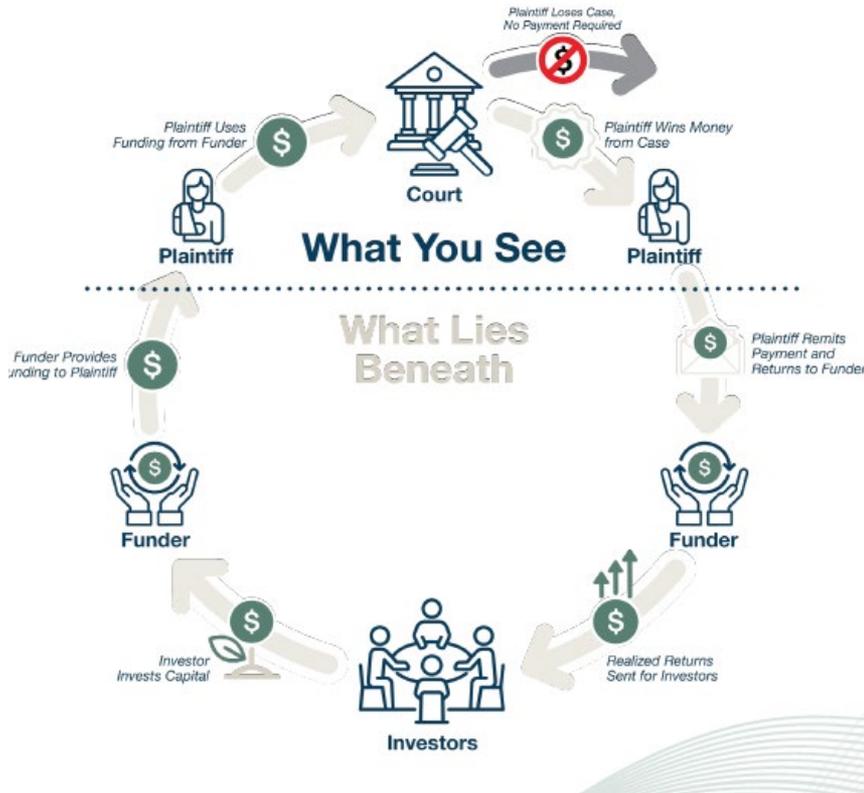
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...h R. Johnson of Babbitt & Johnson helped ...
...strict litigation involving vascular filters.

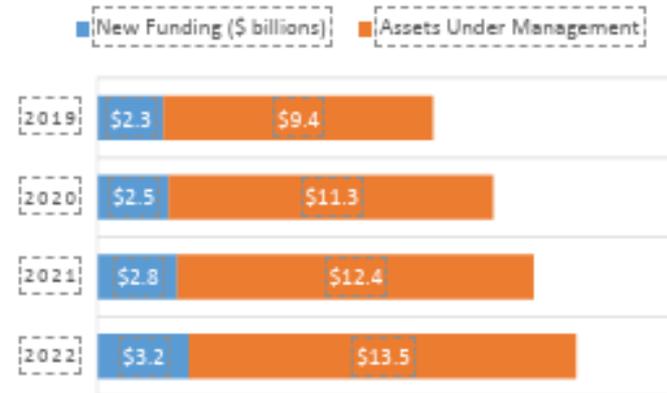
Plaintiff Playbook

- Litigation Funding
- Attorney Advertising
- Multidistrict Litigation
- Company Conduct

Third Party Litigation Funding



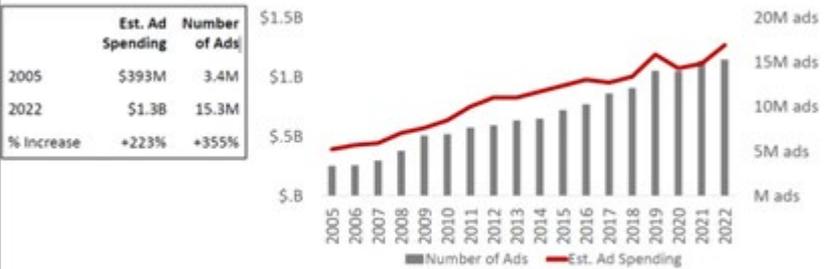
COMMERCIAL LITIGATION FUNDING BY MAJOR DEDICATED LENDERS



Westfleet Advisors, 2021 and 2022 Litigation Finance Market Reports

Legal Advertising

Total Legal Services TV Advertising



Note: TV advertising data covers all airings of television advertisements on local broadcast networks in 210 media markets, nationally syndicated broadcast programming and on 11 national broadcast networks and more than 80 national cable networks. Estimated ad spending is estimated based on publicly available data provided by media sellers and, since January 2019, transaction data from ad agencies and media buyers. Data are estimates and may vary over time. Our system reviews the database over time and edits it to account for duplicates or errors.

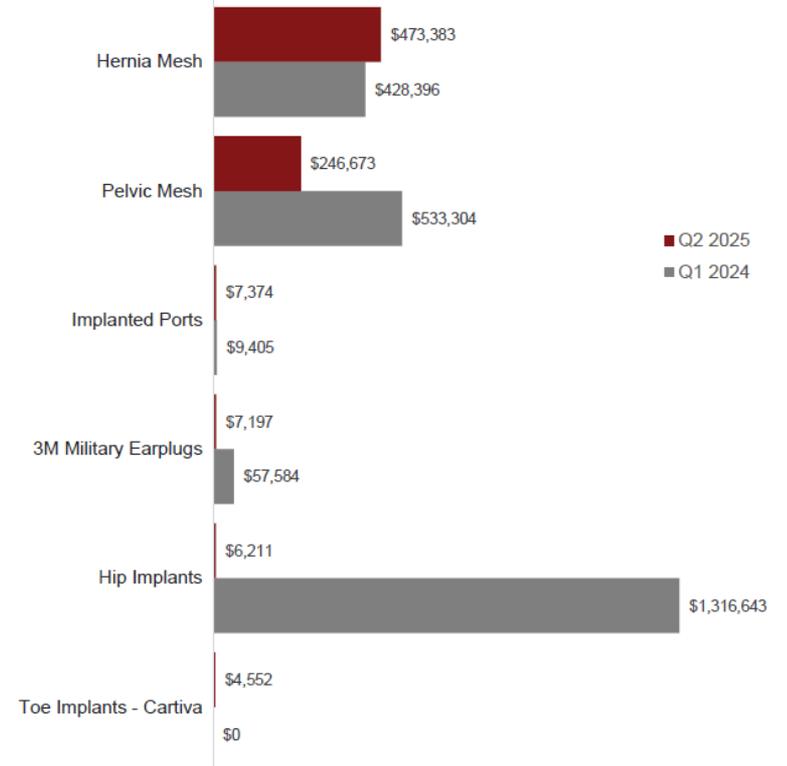
Source: X Ante analysis using data provided by Vivus CMAG.

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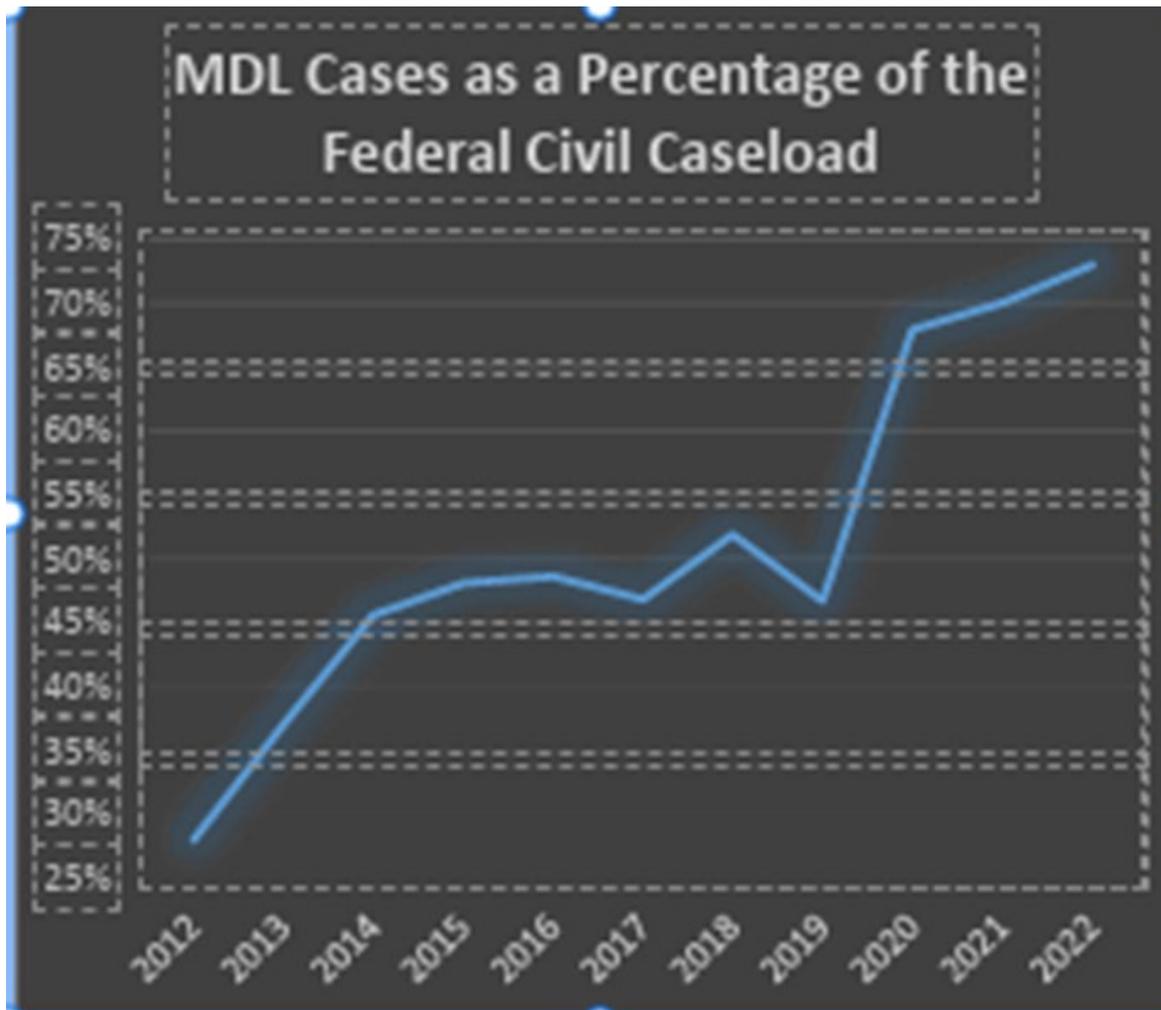
X ANTE



Top Medical Device Mass Tort TV Advertising Targets
Est. Ad Spending, Q2 vs. Q1 2025



Medical Device Trends—Federal MDL's



What Can We Learn?

- The number of claims is increasing
 - MDLs are rapidly growing in number – very few from 1994 – 2006, then a significant number in the last 10 years
- The verdicts and settlements are getting larger
 - Jury verdicts in single cases in the hundreds of millions
 - Settlements for “inventories” of cases well over \$1 billion
- The stakes are getting higher
 - Costs to the company go beyond verdict or settlement
 - Reputational harm
 - Attorneys’ fees
 - Time and resources spent defending litigation



Drivers of Litigation

- How Plaintiffs' Attorneys Find New Lawsuits:
 - Media
 - Pending litigation against competitor products
 - Company field actions / recalls
 - FDA safety communications, labeling changes, and warning letters
 - Scientific and medical literature
 - *Information that is publicly available*
- Increased availability of consolidation in MDLs – lots of \$\$\$ for little work
- Massive rise in litigation funding and Plaintiffs' advertising
 - Driven by rising verdicts



Hip Replacement Lawsuits

People who developed painful complications after hip replacements have filed more than 29,000 lawsuits against hip implant manufacturers. Companies have spent billions of dollars settling more than half of those cases as more people continue to file lawsuits.

Types of Product Liability Claims

- **Strict Liability**
 - Design Defect
 - Manufacturing Defect
 - Failure to Warn
- **Negligence**
- **Fraud, Misrepresentation**
 - May be based on sales representatives' conduct

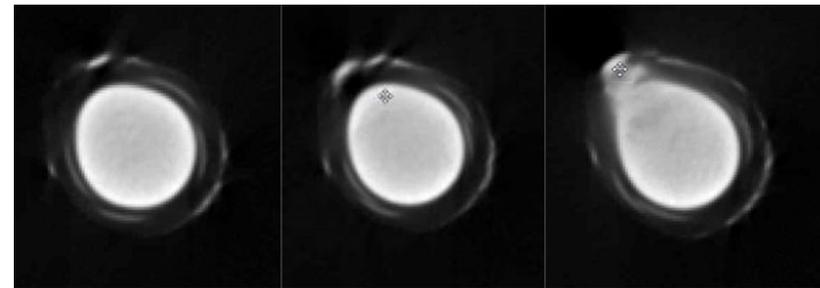
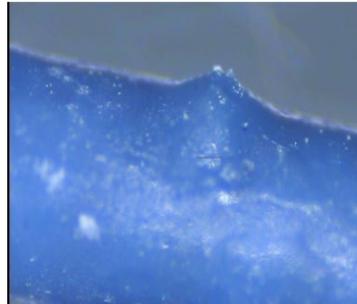


Design Defect Claims

- An alleged defect where the manufacturer could have reduced a foreseeable risk by adopting a reasonable and economically feasible alternative design
 - May be determined by the “**risk-utility test**”
 - Probability of injury X gravity of injury > cost of alternative design plus diminished utility?
 - Plaintiff must typically prove a feasible alternative design exists, often through expert testimony
- Evidence a product is NOT defective:
 - If used in an unusual, unforeseeable manner
- PMA devices: design defect claims generally preempted
 - Preemption does **not** apply to devices cleared through the 510(k) process

Manufacturing Defect Claims

- An imperfection in a specific product that departs from its intended design
- Can be ascertained by
 - Comparing the subject device to a properly manufactured item
 - Review of the manufacturing or “lot history” records
 - Inspection of the device



Failure to Warn Claims



- A manufacturer should provide adequate warnings when it is known or reasonably ought to be known that a product is unsafe for use by its expected and intended users.
- A marked increase in reported adverse events can lead FDA to require a labeling change
 - FDA-mandated labeling changes draw the attention of the plaintiffs' bar and frequently lead to lawsuits alleging failure to warn of the newly labeled risk
- Who do medical device manufacturers have a duty to warn?
 - Prescribing physicians, otherwise known as the **Learned Intermediaries** who must pass on warnings to their patients as they deem appropriate.

FDA Issues at Trial

- Regulatory Pathway
 - 510(k) Clearance
 - Minor Modification
- Compliance
 - Complaint tracking and reporting
 - Warnings and recalls

510(k) “Loophole”

If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis.... The § 510(k) notification process is by no means comparable to the [premarket approval] process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours.... Section 510(k) notification requires

little information, rarely elicits a negative response from the FDA, and gets processed very quickly.²

--United States Supreme Court

The Secret Database

☰ **THL** 🔍 📞

FDA Secret Database

The bigger concern is the realization that a hidden database established by the FDA years ago exists. The database essentially allowed adverse events, including deaths, to go unnoticed by doctors and patients alike for years. Since 2016, 1.1 million adverse events, either injuries, deaths, or malfunctions, have been reported to the hidden, internal database instead of being publicly acknowledged. Even former FDA deputy commissioner, Dr. Robert Califf, was unaware of the existence of such a database.

If only evaluating adverse events reported to the public Manufacturer and User Facility Device Experience (MAUDE), surgical staplers would appear safe to use, even efficient, for external and internal usage. But, the hidden database depicts otherwise. Along with hidden adverse reports related to the surgical stapler, the hidden database includes “about 100” other medical devices with similar reporting exemptions.

According to Larry Kessler, a former FDA official, the database was created to avoid under-reporting and alleviate the time it

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Preventing Litigation

- Design and Development
 - Use of Pre-Submission Meetings
 - Risk assessment — balancing risks and benefits
 - ASTM and ISO standards
 - Understanding state of the art
- Manufacturing
 - Audits
 - Documented procedures



Preventing Litigation — Manufacturing Records

- Can be used to present evidence that a device did not contain any manufacturing defects

Medtronic's investigation also included reviewing the lot history for the lot number of the Marksman used in Plaintiff's procedure. *Id.* at ¶ 10. The device lot history review did not reveal any quality issues or manufacturing discrepancies that would contribute to the detachment of the tip of the Marksman. *Id.* at ¶ 10. No other complaints were reported against the lot number. *Id.* at ¶ 10. The lot history of the marker band used in Plaintiff's procedure was also reviewed and no quality issues were noted. *Id.* at ¶ 10. All Marksman Micro Catheters are inspected for damage and irregularities prior to packaging. *Id.* at ¶ 11.

Preventing Litigation

- Failure to Warn
 - Collaborative effort on drafting/updating warnings
 - Acknowledging unknowns in labeling
 - Post market surveillance and complaint analysis
 - Corrective and Preventive Actions (CAPA)
 - Responsiveness to customers (surgeons, hospitals, etc.)
 - Sales representative training



Preventing Litigation — Sales Field Training

> Hello [REDACTED],

>

> Thank you for the update and information. Please keep us in the loop for any updates on the patient's condition. We would eventually need to know if the patient will recover to normal state or not. Please ship the defective catheter back to:

<



Questions?

Thank you!



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