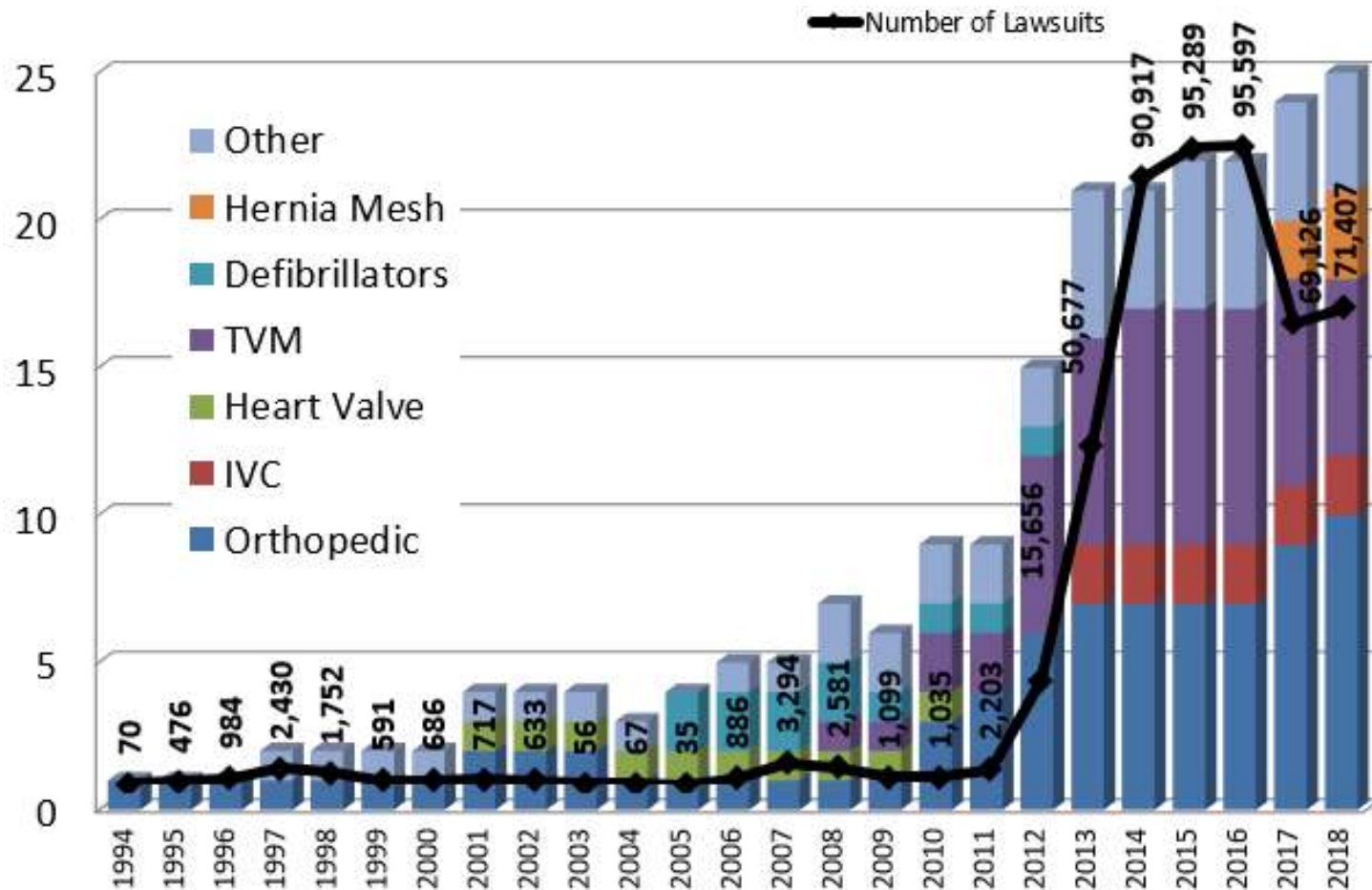


Areas of Cybersecurity Vulnerability for AM

- Internet connected devices
- Security of Digital CAD files and printers
- Protection of patient information for customized printing



The Risk: Medical Device Federal Lawsuits Pending



The Risk: Significant Verdicts

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Hips, Talc Lead Billion Dollar List of Top Verdicts in 2017

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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



Joe Johnson. Photo: Melanie Bell

West Palm Beach personal injury attorney Joseph R. Johnson of Babbitt & Johnson helped cinch a \$3.6 million verdict in bellwether multidistrict litigation involving vascular filters.


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U.S. LEGAL NEWS NOVEMBER 16, 2017 / 1:05 PM / 7 MONTHS AGO

Johnson & Johnson hit with \$247 million verdict in hip implant trial

Tina Bellon 3 MIN READ

NEW YORK (Reuters) - A federal jury in Dallas on Thursday ordered Johnson & Johnson and its DePuy Orthopaedics unit to pay \$247 million to six patients who said they were injured by defective Pinnacle hip implants.



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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 Celect 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 Celect 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 ...

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
- Increased availability of consolidation in MDLs and Data Breach Class Actions – lots of \$\$\$ for little work
- Massive rise in litigation funding and Plaintiffs' advertising



Cybersecurity Vulnerabilities in the News



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The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

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SEP 09, 2020 | MORE ON MEDICAL DEVICES

Personal information of 348,000 people potentially exposed in NorthShore data breach

The exposed information included patients' full name, date of birth, contact information, and admission and discharge dates.

Jeff Lagasse, Associate Editor



Abbott releases firmware patch to fix cybersecurity flaws in 350,000 medical devices

The device manufacturer acquired St. Jude Medical last year and has since been working to fix severe vulnerabilities found in its pacemakers.

By Jessica Davis | April 19, 2018 | 12:39 PM



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NATIONAL CARDIAC DEVICE ATTORNEYS FOR RECALLED **ST. JUDE/ABBOTT CARDIAC DEVICE LAWSUITS**

Certain implantable cardiac devices could be at risk for cyber-attacks, leaving patients vulnerable to serious injury. The attorneys at Parker Waichman LLP are managing cases on behalf of injured

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HOME Legal news View of Lawsuits Filed Over Recalled Healthcare Data Devices

Posted By HIPAA Journal on Sep 25, 2020

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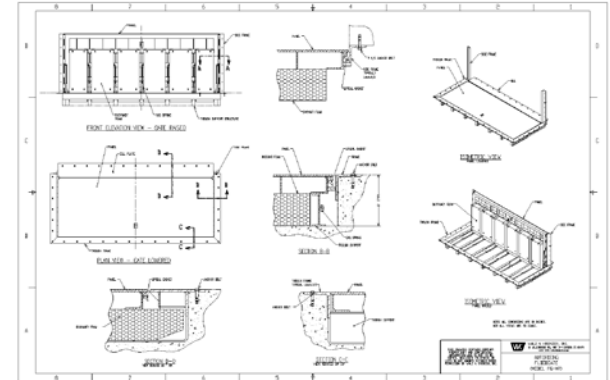
Types of Cybersecurity Related Claims

- Products Liability
 - Design Defect
 - Manufacturing Defect
 - Failure to Warn
- Data Breach
 - HITECH/HIPAA
 - Negligence
 - State Statutes



AM Cybersecurity Issues

- Design Claims
 - Testing worst case scenario
 - Innovation ahead of regulations
- Manufacturing Defect
 - Reverse engineering
 - Malicious attacks on CAD files and AM printers
- Warnings
 - Warning against the unknown
 - Post Market Surveillance obligations
- Negligence
 - Foreseeability



Mitigating Risks and Vulnerabilities

- The importance of census standards
- Open dialogue with the FDA
- Insurance coverage
- Retaining cybersecurity specialists
- Indemnification agreements

