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NEWS

FOR IMMEDIATE RELEASE

Triple Damages — \$442M — Awarded to AMDR Member Innovative Health in Case Against Johnson & Johnson's Biosense Webster Medical Technology Unit for Withholding Technical Support When Reprocessed Devices Were Used

[Washington, D.C. and Berlin, Germany / 5 June 2025] Today, Judge James V. Selna of the U.S. District Court for the Central District of California entered judgment in Innovative Health LLC v. Biosense Webster, Inc., tripling the jury's May 16 award from \$147 million to \$442 million as required by federal and California antitrust statutes.

The judgment affirms the jury's findings that Johnson & Johnson's (NYSE: NJ) Biosense Webster unit violated Section I and Section 2 of the Sherman Act and California's Cartwright Act by withholding clinical support from hospitals that choose Innovative Health's FDA-regulated, reprocessed electrophysiology catheters. The Court also imposed a post-judgment interest rate and left the door open for injunctive relief and attorneys' fees — meaning the financial and operational consequences for Biosense Webster may grow larger.

"This is a seismic result," said Daniel J. Vukelich, President and CEO of the Association of Medical Device Reprocessors (AMDR). "The court has affirmed what the jury found — that Johnson & Johnson illegally monopolized and tied the market to undermine reprocessed medical devices. This sends an unmistakable message to all device manufacturers: anti-competitive, anti-reprocessing tactics won't be tolerated by the courts or by hospitals committed to cost savings, sustainability, and patient care."

Reprocessed SUDs are domestic devices, and domestic devices make hospitals stronger.

By having the freedom to choose FDA regulated reprocessed SUDs, hospitals reduce costs, waste, and greenhouse gas emissions. Reprocessed SUDs cost 30 to 50% less than their original counterpart. Numerous peer reviewed life cycle assessments have found that reprocessed devices reduce greenhouse gas emissions by 30 to 60%. When using reprocessed SUDs, hospitals also help address supply chain resilience issues that were illuminated by COVID and could be made worse by tariffs.

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How to Stop OEM Anti-Reprocessing Tactics: Proactive Steps for Hospitals

For decades, AMDR and its member companies have reported potentially anticompetitive market manipulation tactics by some OEMs. This case brings these tactics under closer examination. Hospitals, particularly procurement staff, should pay close attention to these activities and take proactive steps to combat them.

1. Threats to void warranties or case support

OEMs cannot lawfully revoke support, void warranties, withdraw service, or otherwise retaliate for using FDA-regulated reprocessed SUDs. Make it policy to document and escalate any such threat and remind sales reps this activity is illegal and will not be tolerated.

2. Unapproved software updates that disable reprocessed devices

Protect your consoles and generators: require written hospital approval before any OEM software upgrade is installed. Explicitly deny updates that "just happen" to block reprocessed devices or force obsolescence, and audit firmware versions after service visits.

3. "Chipping" or ePROMs that brick reprocessed devices

Bar OEMs that use embedded chips or ePROM programming that disable reprocessed devices or shortens their life. Require advance disclosure of any device-identification or authentication features, make chip-based lock-outs a breach of contract, and reject products that rely on forced-obsolescence coding.

4. Contract clauses that restrict reprocessing

When negotiating contracts, particularly those including volume-based discounts, calculate the hidden cost of losing reprocessing savings. Refuse language that conditions "free" equipment or discounts on exclusive use of new SUDs and run all proposals past legal/procurement for anti-competitive red flags.

5. Price gouging on the "reprocessable" model

Track SKU pricing over time and across vendors. If an OEM inflates the price of its reprocessable version to steer you to a non-reprocessable device, document it and consider changing suppliers.

6. Interference with hospital assets

Ban any practice that sabotages your inventory: replacing cables without permission, hiding or discarding reprocessed-device bins, rearranging stock to favor new SUDs, or instructing clinicians to destroy hospital property. Treat such actions as asset tampering and revoke vendor access privileges immediately.



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7. Publication or use of misleading "dirty device" studies

If a rep circulates OEM-funded studies, especially any that have been retracted or flagged for bias, suspend their access pending a formal review, and share the incident with infection-control and value-analysis committees.

Adopt these guardrails as formal policy, train staff to spot violations, and remind OEM partners that the rules of engagement have changed — hospitals will no longer put up with anti-reprocessing sabotage.

AMDR is conferring with its members, and considering legal options, to push back forcefully against behaviors like those described above and identified in *Innovative Health*, *LLC v. Biosense Webster, Inc.*

About AMDR

The Association of Medical Device Reprocessors (AMDR) is the global trade association for the regulated, commercial "single-use" device reprocessing and remanufacturing industry. AMDR members serve over 9,400 hospitals and surgical centers in the U.S., Canada, Europe, Japan and Australia.

Founded in 1997, AMDR advocates for reprocessing and remanufacturing as an important healthcare strategy that helps hospitals and healthcare providers to strengthen the supply chain while simultaneously reducing costs, waste, and emissions. AMDR protects the interests of its members in regulation, legislation, and standard-setting.

AMDR protects the interests of its members in regulation, legislation, and standard-setting. AMDR members include <u>Arjo ReNu Medical</u>, <u>Innovative Health</u>, <u>Medline Renewal</u>, <u>Stryker's Sustainability</u> <u>Solutions</u>, <u>Sustainable Technologies</u> (a Cardinal Health Business), <u>Vanguard AG</u>, and <u>Vein360</u>. Having played a key role in the establishment of the reprocessing industry, AMDR continues to push the global medical technology industry, leading the way for remanufacturing to play a defining role in the evolution of new device technologies.

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