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#### STATEMENT FOR IMMEDIATE RELEASE

# AMDR Applauds Federal Court Decision to Bar Johnson & Johnson's Biosense Webster Unit from Further Violation of Anti-Trust Laws in a Win for Hospitals, Patients, and the Environment

Yesterday Court Issued Final Injunction After Jury Finds that Biosense Webster's Unlawful, Anti-Competitive Practices Forced Hospitals to Purchase More Costly, Wasteful Products

[Washington, D.C. — August 28, 2025] — The Association of Medical Device Reprocessors (AMDR) announced that Judge James Selna of the U.S. District Court for the Central District of California has issued a permanent injunction against Johnson & Johnson's (NYSE: NI) Biosense Webster (BSW) medical device unit for unlawful, anti-competitive conduct. The ruling prohibits BSW from blocking hospitals' access to safe, lower-cost, FDA-regulated reprocessed cardiac catheters. The decision follows a jury verdict ordering BSW to pay plaintiff Innovative Health, LLC \$147 million in damages which has automatically tripled to \$442 million—for violating federal and state antitrust laws.

## The permanent injunction:

- prohibits BSW from tying clinical support for its cardiac mapping machines to buying compatible devices from BSW instead of a competing reprocessor;
- prevents BSW from discriminating in how it provides clinical support or cardiac mapping machines based on a care provider's use of BSW devices reprocessed by another company;
- bans new anti-reprocessing "kill switches" and other blocking technologies intentionally designed to prevent BSW devices from functioning when reprocessed by another company; and,
- blocks BSW from hoarding used catheters that it does not reprocess to prevent reprocessors from lawfully obtaining source materials.

The injunction will remain in effect for an initial term of five years, though the Court reserved the power to "shorten or lengthen" it to reflect "market conditions."

AMDR agrees with the testimony offered during the trial from Eric Forister, PhD, an expert economist specializing in antitrust, market power, market definition, and damages analysis.

"[None of BSW's activities] – the blocking technology, the collection and withholding, and the Case Coverage Policy - none of those things made Biosense's products better," said Dr. Forister. "They just eliminated or restricted the choice of customers to buy their preferred catheters, which happened to be offered by other companies."



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AMDR celebrates the major legal victory for hospitals, patients, the environment, and the medical device reprocessing industry.

"Hospitals and patients have long paid the price for BSW's anticompetitive behavior," said Daniel J. Vukelich, President & CEO of AMDR. "This ruling reaffirms that dominant device manufacturers cannot abuse their market power to prevent hospitals from delivering the best possible care at the lowest possible price to the most patients in need at the least cost to the environment. The verdict from the jury and the injunction from the judge both send strong signals to the MedTech industry that the courts are on alert and will not tolerate monopolistic conduct."

"The court's decision affirms AMDR members' rightful place in the healthcare system as guardians of sustainable practices," said Vukelich. "We thank Innovative Health for its leadership in this six-year process."

## The Case: Unlawful Tying, Chipping and Monopolization

In the verdict, the jury found that BSW:

- Unlawfully tied clinical support services to the purchase of its own catheters in violation of Section I of the Sherman Act and Section 16720 of California's Cartwright Act; and
- engaged in unlawful monopolization under Section 2 of the Sherman Act by, among other acts, installing "kill chips" in its devices to unlawfully delay reprocessors from competing in the market.

Evidence presented at the trial showed that BSW:

- Poached mapping technicians from hospitals that used reprocessed devices;
- enforced non-compete clauses against former BSW personnel that sought to provide clinical support to hospitals;
- withheld training from non-BSW personnel on the BSW cardiac mapping machine (and software updates to the machine) to prevent non-BSW personnel from providing clinical support to hospitals;
- inserted "kill" switches in certain devices that served no other purpose except to prevent devices from being reprocessed by an AMDR member reprocessor and reused; and
- hoarded used devices that had FDA clearance for reprocessing by AMDR members, with the
  stated intent of running these companies out of business. Biosense even collected devices that it
  could not reprocess through Johnson & Johnson's Sterilmed medical device unit, to restrict
  supply for AMDR members that did have FDA approval to reprocess those devices.



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AMDR member reprocessors are required to follow a strict code of conduct as well as the association's bylaws that prohibit interference with a hospital's right to conduct reprocessing programs. J&J Medtech's Sterilmed reprocessing unit is not a member of AMDR.

## **Impact on Hospitals and Patients**

Court testimony showed that reprocessed catheters like those offered by *Innovative Health LLC*—the plaintiff in the case—are just as effective, and as safe or safer, than new devices from BSW, while costing up to 50% less.

Hospitals reported that BSW's tactics directly interfered with their ability to lower costs and increase access to care. Mary Roberts, Corporate Director of Supply Chain for Providence St. Joseph's Hospital, testified that BSW's policy "stops us from being able to meet our goal of making healthcare affordable to everyone."

Portia Tranguch, Director of the Cardiac Catheter Lab at Allegheny Health network testified that BSW's clinical account specialists "refused to use [reprocessed catheters] and in fact pulled them off [the hospital's] shelves."

Underscoring BSW's intentions, one email presented at the trial shows a J&J sustainability staff member using an image of "Dr. Evil" when discussing how BSW and Sterilmed "could cut off [Stryker's Sustainability Solutions] supply" of reprocessable catheters "and crush them."

AMDR has made available a complete summary of the case and select testimony with references.

#### A Verdict with Far Reaching Impact

Hospitals that partner with AMDR members realize numerous benefits:

- Reduced cost: reprocessed devices are 30 to 50% less expensive than original devices;
- Reduced waste: reprocessing diverts tons of medical waste from landfills and incinerators;
- Reduced emissions: reprocessing reduces raw material use. Numerous peer reviewed studies find that reprocessed devices reduce CO<sub>2</sub> emissions by 30 to 60%, shrinking the carbon footprint of surgical and procedure care;
- <u>Strengthened supply chain and increased hospital and patient access</u>: reprocessed devices, sourced from used devices *already within the United States*, fortify the medical device supply chain and effectively help shield healthcare systems from global disruptions thus making safe and effective therapies readily available without needing to purchase new devices abroad.



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#### Hospital Staff Encouraged to Report Anticompetitive Behavior

AMDR has released an Action Alert outlining the precise terms of the permanent injunction with action steps hospitals can take to facilitate the changes. AMDR urges hospitals to contractually forbid vendors from engaging in the practices outlined in the case—including tying clinical support to the use of their own devices, preventing reprocessing through chipping, or hoarding devices to cut off reprocessor supply—and report incidences of such behaviors using our reprocessing interference reporting form (click here to download). Please see our website for more information, guidance, and media coverage of the case.

#### **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 Arjo ReNu Medical, Innovative Health, Medline ReNewal, Stryker's Sustainability Solutions, Sustainable Technologies (a Cardinal Health Business), Vanguard AG, and Vein360. 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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