AMDR®
amdr.org

North American Office
2000 Pennsylvania Ave. NW Suite 4003
Washington, DC 20006
Phone +1 202.489.7867

European Office
Ebersstraße 63
Berlin, Germany 10827
Phone +49 160 91948402

STATEMENT

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FOR IMMEDIATE RELEASE

Innovative Health Seeks Permanent Injunction Against Johnson & Johnson MedTech's Biosense Webster Following Landmark Antitrust Win

Motion filed includes evidence and testimony presented at trial demonstrating the lengths Johnson & Johnson MedTech's Biosense Webster went to "crush" reprocessor competitors

[Note to Editors: The case information discussed in this statement is publicly accessible on PACER and is summarized from the following documents, which AMDR has highlighted for readability:

- *Innovative Health's Proposed Permanent Injunction*
- *Innovative Health's Notice of Motion and Motion for Permanent Injunction*
- *Declaration of Support of Innovative Health's Motion for Permanent Injunction, which includes evidence in support of a permanent injunction.*

Source: PACER – Case No. 8:19-cv-1984 JVS (KES)]

[Washington, D.C. and Berlin, Germany / 18 June 2025] On June 12, 2025, in "*Innovative Health LLC v. Biosense Webster, Inc.",* the U.S. District Court for the Central District of California published unsealed motions containing previously sealed evidence and testimony as part of Innovative Health's request for permanent injunctive relief. A hearing on the matter is scheduled for July 21, 2025. Innovative Health's request for permanent injunctive relief comes after a $147M jury verdict, trebled to $442M as required by law, awarded to Innovative Health.

Background

On June 5, the Court entered judgment on the verdict as a result of the "jury return[ing] a verdict in favor of Plaintiff Innovative Health LLC and against Defendant Biosense Webster, Inc. on Plaintiff's claims for unlawful tying under Section 1 of the Sherman Act, unlawful monopolization under Section 2 of the Sherman Act, attempted monopolization under Section 2 of the Sherman Act, and unlawful tying under Section 16720 of California's Cartwright Act." The jury awarded Innovative Health $147M in damages. In June, the court issued judgment trebling the damages to $442M, as required by law, and leaving the door open to further permanent injunctive relief.

This statement addresses details revealed from the motion for permanent injunctive relief now filed by Innovative Health.

Why it Matters

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This case is extremely important to the entire medical device reprocessing industry and for healthcare delivery overall. Beyond just protecting Innovative Health, the proposed permanent injunction would prohibit J&J MedTech from using its platform dominance to shut out reprocessors from the market. AMDR has long documented the misconduct highlighted in this case as serious impediments to fairness in hospital procurement. If imposed, this permanent injunction would be among the most consequential legal action in the 25-year history of regulated reprocessing in the U.S.

Our healthcare delivery partners are desperate to lower cost, waste, emissions and now, more than ever, to increase supply chain resilience. FDA regulated medical device reprocessing programs, as the testimony reveals, are crucial in their mission to do so. The anti-competitive misconduct by J&J MedTech exposed in the court transcripts are a pointed slap in the face to hospitals that wish to benefit from the use of reprocessed devices. We urge our healthcare delivery partners and other stakeholders, to take note and resist the blatant misconduct by J&J MedTech and their peers that ultimately drive-up costs, waste, emissions, and obstruct our supply chains.

AMDR urges hospitals to not wait for a formal federal court injunction – hospital resistance to these potentially anti-competitive tactics should begin now.

Key evidence found in the motion:
Innovative Health's filing is filled with clear internal J&J MedTech communications and testimony showing deliberate and systemic anti-competitive—and outright illegal—efforts to maintain its market power and "crush" competition from reprocessors. Below are a few key excerpts from the evidence or testimony filed in support of Innovative Health's motion:

J&J MedTech stifled competition and forced hospitals to spend more money.

"The short summary would be that none of those three things -- the blocking technology, the collection and withholding, and the Case Coverage Policy -- none of those things made Biosense's products better. They just eliminated or restricted the choice of customers to buy their preferred catheters, which happened to be offered by other companies." Testimony, Dr. Eric Forister, expert economist with EconOne (pp. 157-159).

"...cut off their supplies and crush them." How J&J MedTech executed a strategy to destroy reprocessing programs by choking off supplies.

J&J MedTech executives internally discussed how J&J MedTech could collect enough catheters that they "could drive Stryker [Sustainability Solutions] out of the RPO EP [reprocessed electrophysiology] business altogether" (p. 161). From 2015 to 2020, J&J MedTech collected about 156,000 ACUNAV catheters (p. 161-62). After discarding about 42,000 as not fit for reprocessing, they sold 59,000 back into the market and held onto the remaining 54,000 units (p. 162).

J&J MedTech was found to be illegally "tying," and further evidence includes "blocking" chips were used to force hospitals to abandon reprocessing programs.

Biosense Webster told hospitals they would lose case support if they used Innovative Health's FDA-regulated reprocessed catheters (pp. 60-62). In doing so, Biosense Webster was creating an illegal tying arrangement with an unwilling hospital. Engineers also designed "blocking" tech (called "Falcon," an EEPROM) that delayed Innovative Health's market entry; internal emails admit the purpose was to prevent their competitors from reprocessing, "the main driver of implementing the Falcon EEPROM is

preventing our competitors to reprocess the Vizigo Sheath and not as previously understood as to reprocess them ourselves" (p. 66). When Innovative Health secured clearance to reprocess a new device, J&J MedTech immediately added it to the tied bundle (pp. 204-206).

Hospitals did not approve of J&J MedTech's misconduct and saw its egregious action as working against the best interest of the hospital and its patients.

Testimony from HonorHealth, Providence St Joseph and others: without reprocessing savings they "can't support certain procedures," lose millions for community care, and face higher-priced, lower-quality devices (pp. 213-223).

Ten deaths were reported to the FDA's Adverse Event Database that are associated with J&J MedTech's original equipment SoundStar. During the same ten-year period, zero deaths were associated with the Innovative Health reprocessed counterpart.

FDA's MAUDE database includes lower complaint and adverse-event rates for Innovative Health's reprocessed catheters than for J&J MedTech's original devices or reprocessed versions from its affiliate Sterilmed. FDA MAUDE reports from 2013 to 2023 document 116 injuries and 10 patient deaths attributed to Biosense Webster's SoundStar catheters—versus zero deaths attributed to Innovative Health's reprocessed SoundStar. (p.174). This raises serious concerns that, when combined with the company's efforts to catch, shelve, and kill reprocessed products with the intent of putting commercial reprocessors out of business, J&J MedTech knew that it was lowering the safety and quality of care available to patients (pp. 173-174) to boost its profits.

What Innovative Health is asking the court to do:

The proposed injunction (10-year term) would prohibit Biosense Webster from:

- **Conditioning case support on purchases of its own catheters** – ending the "case coverage" tie that Innovative Health argues nearly shut them out of the market entirely.
- **Using chips or software to block reprocessed devices** – banning hardware or firmware "locks" that block or delay reprocessor market entry in the EP space.
- **Hoarding used catheters** – restricting collection of catheters Biosense Webster doesn't have regulatory approval to reprocess, which Innovative Health claims was done to deny inputs to competitors.
- **Rolling out future anti-competitive tactics** – extending protections to new Biosense Webster products and platforms.
- **Keeping quiet** – requiring Biosense Webster to notify hospitals, customers, and its own sales staff about the injunction and a hotline for reporting noncompliance.

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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Contact:

David Sheon
VP External Affairs
202 422-6999
dsheon@amdr.org