Olsson Frank Weeda
Terman Matz PC

2000 Pennsylvania Avenue NW
Suite 4003
Washington, DC 20006
www.ofwlaw.com

Phone: (202)789-1212 • Fax (202)234-3550

J. Mason Weeda
Principal
Direct (202) 518-6362
mweeda@ofwlaw.com

Michael R. Goodman
Principal
Direct (608) 215-0016
mgoodman@ofwlaw.com

October 21, 2025

BY ELECTRONIC MAIL

Geoff Martha
Chairman & CEO
710 Medtronic Parkway
Minneapolis, MN 55432-5604
Phone: 673-514-4000

geoffrey.martha@medtronic.com

Re: Cease and Desist: Medtronic Illegal Online Anti-Reprocessing Video Advertisement On Reprocessed SUD Catheters

Dear Mr. Martha and Team,

We write again on behalf of our client, the Association of Medical Device Reprocessors (AMDR)[1]. AMDR is the global non-profit trade organization representing the interests of FDA-regulated reprocessors that collect, clean, repair, disinfect and/or sterilize (among other steps) medical devices marketed by the original equipment manufacturer ("OEM") for "single use." AMDR members offer safe, effective alternatives to OEM devices, helping hospitals save valuable financial resources, reduce waste and emissions, lower disposal costs, and build more resilient supply chains.

AMDR demands that your company, Medtronic USA, Inc., immediately and permanently cease and desist from making false and misleading comparative superiority claims about

[1] AMDR is the non-profit trade association representing the global "single-use" device reprocessing industry. AMDR members serve over 9,400 hospitals and surgical centers in the U.S., Canada, and 17 other countries. All *U.S. News & World Report* list of America's "honor roll" hospitals are reprocessing with one of AMDR's members. AMDR's core mission is to promote regulated, commercially reprocessed SUDs. In Europe, reprocessing is referred to as remanufacturing. For more information visit www.amdr.org

Medtronic's single-use devices (SUDs), including but not limited to claims comparing such products to 510(k)-cleared, substantially equivalent reprocessed versions of the same devices, as well as other similarly reprocessed devices.

On June 4, 2025, AMDR issued a Cease and Desist letter to Medtronic concerning false and misleading statements made with respect to Medtronic's Remanufactured Pulse Oximeters, Nellcor™ single-use devices, specifically as compared to 510(k)-cleared reprocessed single use pulse oximeters. In response, we believe that Medtronic removed the relevant advertisements.

Despite this, it has come to AMDR's attention that Medtronic continues dissemination of substantially similar false and misleading claims, now pertaining to its ClosureFast™ SUD catheters. These claims, including those published in online marketing and in particular in Medtronic's online anti-reprocessing video advertisement[2], misrepresents ClosureFast™ catheters in comparison to 510(k)-cleared, substantially equivalent reprocessed versions of the same device, as well as other reprocessed catheters. Although AMDR has not yet conducted a comprehensive review of Medtronic's entire marketing program for ClosureFast™ catheters, we hereby formally notify Medtronic of our objection to any further dissemination of such claims.

As detailed below, Medtronic's advertisement is rife with false and misleading statements effectively running roughshod over at least three federal statutes—the federal Food, Drug & Cosmetic Act ("FD&C Act"), Sections 5 & 12 of the FTC Act, the Lanham Act—and state laws concerning unfair and deceptive business practices. Depending on the appropriateness of Medtronic's actions in response to this letter, we will discuss suitable legal remedies with our client.

I. MEDTRONIC'S ILLEGAL PROMOTIONAL ACTIVITIES

Medtronic's advertisement is a calculated effort to mislead and frighten consumers away from safe, FDA-cleared reprocessed SUD catheters. These catheters are required to undergo rigorous 510(k) premarket notification review, including cleaning and sterilization validations to restore them to their original condition.[3] Yet Medtronic tells consumers the opposite. Medtronic loudly attacks the safety of reprocessed catheters—branding them as dangerous—yet the company can only rely on a secretive, internal study to contradict years of peer-reviewed data proving these devices are safe.

For starters, Medtronic's advertisement is almost totally composed of false statements and negative innuendos about the "dangers" of reprocessed catheters; comparing reprocessed catheters—all with 510(k)-clearance—to used cars with "NO GUARANTEE(s)[4]". Predictably, Medtronic states that "nobody can guarantee that a used car will perform like new"—apparently,

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[2] Medtronic's anti-reprocessing video advertisement can be found at: medtronic.com/content/dam/medtronic-com/products/cardiovascular/superficial-vein/closurefast/videos/closurefast-reprocessing-video.mp4.

[3] *See,* Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprcessed Single-se Medical Devices, Guidance for Industry and FDA Staff, Center for Devices and Radiological Health, U.S. Food and Drug Administration, June 2004.

[4] At 32 seconds, Medtronic depicts a used car with dents and scrapes in the background and a hand holding a sales contract with the words in big bold letters "NO GUARANTEE!" and two big red arrows pointing directly at the warning.

not even the FDA. Medtronic also tacitly encourages consumers to think of reprocessed SUD catheters as fringe, dangerous, or broken devices by recommending that they ask "questions like, how much wear and tear is present, or is it like new? Can you be sure it works? Does it come with a warranty?" It also claims that its catheters are "designed to be used *only one time on one patient*" implying that SUD catheters cannot be reprocessed and used again—which is blatantly false. Medtronic claims to have a mysterious evaluation report that it funded through its subsidiary Covidien which supposedly supports its disparaging remarks on reprocessed SUD catheters.

Medtronic's establishment claims rest on a self-funded, unpublished, and thus unreliable "study" designed to serve its commercial interests. Advertising based on such research fails the FTC's standard for ***competent and reliable scientific evidence***[5]. It also botches its obligations to clearly and conspicuously disclose that it—or its affiliate Covidien—paid for the mysterious study.[6] Burying the financial relationship disclosure at the very end of a video makes it difficult for consumers to understand that there is a financial relationship between the advertiser and the author of the study.

Medtronic dismisses competent and reliable scientific evidence by papering over a peer reviewed study published in the Journal of Vascular Surgery that concludes reprocessed ClosureFast™ catheter "performed equivalent to new ClosureFast™ catheters" and instead parading out a mysterious internal "study" essentially stating that the reprocessed catheters are dirty and then plastering the advertisement with inflammatory images and captions like: "RE-PROCESSED CATHETERS WERE NOT **100%** CLEAN!" and "OTHERS TESTED POSITIVE FOR UNIDENTIFIED LIQUIDS!" Such visual dramatics, combined with selective omission of adverse but credible facts to slander a competitor's product as worse and dangerous, while in the same breath morphing biased and unreliable research as gospel violates Lanham, the FTC Act, and the FD&C Act[7]. Visual emphasis and minimized disclosure of credible evidence—that a competitor's product is worse and disguises the bias of its own research is actionable under the Lanham Act.[8]

Finally, Medtronic's alarmism collapses under its own record. Its subsidiary, Covidien, secured 510(k) clearance for a reprocessed ClosureFast catheter in 2013[9]. Medtronic therefore knows firsthand that reprocessed catheters pass stringent FDA review. Yet it now questions

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[5] *See FTC v. Clark*, 2008 FTC LEXIS 97, *5.

[6] *See* 16 CFR § 255.5; *See also Eli Lilly & Co. v. Roussel Corp*., 23 F. Supp. 2d 460, 475 (D.N.J. 1998) (a statement is actionable under § 43(a) of the Lanham Act if it is affirmatively misleading, partially incorrect, or untrue as a result of failure to disclose a material fact.).

[7] U.S. Food and Drug Administration. *Medical Product Communications That Are Consistent With the FDA-Required Labeling: Questions and Answers — Guidance for Industry*. U.S. Department of Health and Human Services, June 2018. https://www.fda.gov/media/102575/download, p. 12 (claims are more susceptible to being false and misleading when based on studies which lack independence, have conflicts of interest, fail to disclose material limitations, overstate conclusions, or not peer-reviewed.).

[8] *See e.g., Procter & Gamble Co. v. Chesebrough-Pond's, Inc*., 588 F. Supp. 1082, 1093 (S.D.N.Y. 1984) (depictions of consumer test results or methodology that deceive consumers about the competitor's product's inherent quality or characteristics are an action under § 43(a).).

[9] Covidien, *Reprocessed ClosureFast Radiofrequency Catheter 60cm, Reprocessed ClosureFast Radiofrequency Catheter 100cm*. Aug. 29, 2013. K131614.

whether they are "like new" and whether consumers "can [] be sure it works." Such rhetorical sleight of hand is not science—it's sophistry.

II. STATUTORY VIOLATIONS

A. Violations of Federal Food, Drug and Cosmetic Act (FDCA)

Under Section 502(a) of the FD&C Act (21 U.S.C. § 352(a)), a medical device is misbranded if its labeling[10] is in any way false or misleading. FDA's medical device labeling requirements prohibit comparative claims that are false and misleading:

> Among representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic.

21 C.F.R. § 801.6. Permissible comparative superiority claims must be rooted in reliable and unbiased data. FDA has used warning letters to cudgel companies making Medtronic-like claims in the past:

- Comparative superiority claims are "false or misleading because data do not demonstrate that the [device] is superior to [a competing device]." (FDA Warning Letter to Lexion Medical LLC (Jul. 26, 2021));
- "[T]he agency has determined that before a manufacturer may make a direct comparison of their orthopedic device with that of another manufacturer, randomized, controlled, head-to-head clinical trials would be required." (FDA Warning Letter to Sulzer Spine-Tech (2000)); and
- A device is misbranded in the absence of "adequate and well-controlled studies comparing the [device] to others in studies designed to support comparative statements of superiority." (FDA Warning Letter to ELA Medical Inc. (1992)).

Most of the claims made in Medtronic's advertisement are false and misleading. Further, Medtronic's supporting evidence for the claims is from a biased and unreliable mystery study. And its financial relationship to the study is buried at the end of the video. These actions, including giving a false impression of independence and objectivity, violate Section 502(a) of the FD&C Act and 21 C.F.R. § 801.6 and thus misbrands the ClosureFast™ catheter line of products and must remove the advertisement immediately and cease making any more statements that misrepresent the safety and efficacy of reprocessed SUD catheters.

[10] Section 201(m) of the FDCA defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Under long-standing court decisions, the term accompanying does not require that the material physically accompany the device to be considered labeling. If it is otherwise part of an integrated sales transaction or offered in conjunction with the product to explain or supplement it, it is considered labeling. *Kordel v. United States*, 335 U.S. 345, 346–47 (1948) and *U.S. v. Paddock*, 67 F. Supp. 819 (W.D. Mo. 1946).

B. Violations Of Sections 5 & 12 Of The FTC Act

While the FDA is the primary regulator of legend medical devices, the FTC has the authority to enforce the FTC Act over claims that constitute purely commercial advertising.[11] Section 5 of the FTC Act (15 U.S.C.S. § 45) prohibits unfair or deceptive acts or practices in commerce. Similarly, Section 12 of the FTC Act (15 U.S.C.S. § 52)—with significant overlap of Section 5—prohibits false or misleading statements made in advertisements such as online ads and other direct promotional content. Claims made in advertisements must all be supported by ***competent and reliable scientific evidence***.[12] Competent and reliable scientific evidence" is defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.*

Moreover, to ensure transparency and prevent misleading endorsements, the FTC requires clear and conspicuous disclosure of any material connection between the speaker and the "*advertised product*" being promoted. If there is a material connection, disclosure must be presented in a way that is noticeable and unavoidable—a mere mention in the closing credits does not satisfy FTC requirements.[13]

Most of Medtronic's claims are not supported by competent and reliable scientific evidence. In fact, Medtronic downplayed competent and reliable scientific evidence in favor of a mysterious study that was bought and paid for by Covidien, a Medtronic subsidiary.

C. Lanham Act Violations

The anti-reprocessing video's claims are also false, misleading, and unlawful under the Lanham Act and common law. The Lanham Act provides a judicial cause of action to any company aggrieved by a competitor's promotional misrepresentations.[14] The Lanham Act creates a cause of action for unfair competition through misleading statements in advertising or labeling. A statement is actionable under § 43(a) if it is affirmatively misleading, partially incorrect, or untrue as a result of failure to disclose a material fact.[15] The Lanham Act encompasses more than blatant falsehoods; it embraces "innuendo, indirect intimations, and ambiguous suggestions" evidenced by the consuming public's misapprehension of the hard facts underlying an advertisement. *Id.* Medtronic's false and misleading claims also constitute common law disparagement.[16] Though in the end consumers also benefit from the FDA or FTC's proper enforcement, the Lanham Act's

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[11] *See e.g. In re Dahlberg,* 1995 U.S. Dist. LEXIS 19697, at *1 (D. Minn. Mar. 31, 1995).
[12] *See FTC v. Clark*, 2008 FTC LEXIS 97, *5.
[13] *See* 16 CFR § 255.5.
[14] 15 U.S.C § 1125(a)(1)(B).
[15] *Eli Lilly & Co.,* 23 F. Supp. at 475.
[16] *See, e.g., Brass Metal Prods. v. E-J Enters.,* 189 Md. App. 310, 351, 984 A.2d 361, 385 (2009) (Injurious falsehood, or disparagement, consists of the publication of matter derogatory to the plaintiff's quality or to the plaintiff's business in general in a manner calculated to prevent others from dealing with the plaintiff or otherwise interfere with the plaintiff's relations with others to the plaintiff's disadvantage.).

cause of action is for competitors, not consumers.[17] The video's claims create a strong basis for a Lanham Act false advertising case.

In addition to the abovementioned violations, these inaccurate claims and marketing definitions you are disseminating could result in safety risks. Inaccurate claims are also often considered unsubstantiated safety superiority claims, which may cause a clinician to potentially minimize the importance of other risk mitigation steps when using Medtronic's SUD ClosureFast™ catheters. This could result in patient harm as SUD ClosureFast™ catheters would be erroneously prioritized over what could be a better option for the patient.

Moreover, these claims are intended to instill fear in hospitals and physicians and could result in hospitals not purchasing safe reprocessed devices and having less inventory, when devices today can suddenly become unavailable due to supply chain vulnerabilities that pose risks to patients.

In the interest of patient safety and product availability, Medtronic's tactics must be ceased altogether. Their unlawful promotion, part of an ongoing pattern of misconduct, demands immediate regulatory scrutiny and corrective action. FDA must, simply put, prohibit Medtronic's deceptive marketing from influencing providers' decisions on patients' health and safety.

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The misinformation being disseminated by Medtronic is false and misleading under the FD&C Act, Sections 5&12 of the FTC Act, Lanham Act, and common law. AMDR respectfully demands that Medtronic immediately remove all illegal promotional and marketing materials that make unsupported safety or superiority claims about its ClosureFast™ catheters in comparison to FDA 510(k)-cleared, substantially equivalent reprocessed alternatives

Additionally, AMDR requests that Medtronic:

- Issue a press release through all appropriate media and its website, publicly acknowledging the inappropriate promotional activities and marketing tactics, and providing truthful, accurate information about the equivalency and safety of 510(k)-cleared reprocessed catheters;
- Disclose any financial relationships or conflicts of interest related to proprietary research or studies cited in Medtronic's marketing, in accordance with FTC requirements for clear and conspicuous disclosure;
- Furnish evidence of immediate corrective actions taken to discontinue and remove deceptive statements and materials on reprocessed SUD catheters from all Medtronic platforms, and outline steps to prevent recurrence of such practices in the future; and

[17] *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014).

- Commit to supporting claims made in promotional materials only with competent, reliable, and peer-reviewed scientific evidence going forward, in strict conformity with FDA and FTC standards.

Please advise the undersigned within ***ten (10)*** business days of receipt of this letter of the measures that you have taken and intend to take to comply with this demand. Absent adequate assurances, we reserve all available recourse toward ensuring a level playing field in the medical device market. We look forward to your response.

Sincerely,

Michael R. Goodman
Counsel for AMDR

OFW: mw

cc: Dan Vukelich
President
AMDR