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BY ELECTRONIC MAIL

Jon Stevens
Vice President of Quality and Regulatory
20001 North Creek Pkwy.
Verathon, Inc.
Bothell, WA 98011
jon.stevens@verathon.com

Re: Cease and Desist: Misleading Representations Regarding FDA-Regulated Reprocessing of
GlideScope® and GlideRite® Single-Use Devices

Dear Mr. Stevens,

I write you 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, Verathon, Inc. (“Verathon”), immediately and permanently cease and desist from making false and misleading claims and comparative superiority claims about its single-use devices (SUDs), including but not limited to claims comparing such products to reprocessed versions of the same devices, as well as other similarly reprocessed devices.

¹ 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* lists 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

As detailed below, AMDR has become aware that Verathon is distributing a letter, LTR-0254 Rev-00, to healthcare provider customers and potential customers concerning the reprocessing of GlideScope® and GlideRite® single-use devices (“SUDs”). The letter is misleading and includes unsupported representations concerning the regulatory status, safety, and permissible use of FDA-regulated reprocessed versions of Verathon’s single-use devices. Such claims and marketing practices are 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 Verathon’s actions in response to this letter, we will discuss suitable legal remedies with our client.

I. VERATHON’S ILLEGAL PROMOTIONAL ACTIVITIES

Verathon’s advertisement is a calculated effort to mislead and frighten consumers away from safe, reprocessed SUD catheters. Reprocessed catheters are subject to the same quality system requirements as the original device, and reprocessors are regulated by FDA as medical device manufacturers.² Your letter includes several false and misleading statements that ignore this regulatory framework, including the following:

A. Assertions that reprocessed devices are used “off label” is false and misleading

Significantly, reprocessed devices must have the same intended use as the original device, yet Verathon’s letter asserts categorically that use of reprocessed GlideScope® and GlideRite® devices constitutes “off-label use.” That assertion is false because reprocessed versions of these devices are FDA-regulated reprocessed devices and are permitted to be used for one use before being further reprocessed.

Under the federal regulatory framework established for reprocessed SUDs, a third-party reprocessor is regulated by FDA as a manufacturer, the same way the OEM is regulated. Reprocessed SUDs are separately manufactured, labeled, and marketed products intended for an additional single use. They are not simply the original device being “reused” by a hospital. FDA’s regulatory framework subjects qualifying reprocessors to requirements including premarket review (in the case of Class II devices), quality-system requirements, performance testing, post market obligations, and validation of the number of permitted reprocessing cycles. The purpose of that framework is to assure that reprocessed devices meet applicable requirements for safety and effectiveness. Accordingly, the fact that Verathon’s original labeling identifies a device as “single use” does not, standing alone, establish that a separately manufactured and FDA-regulated reprocessed version of that device is being used “off-label.”

Indeed, FDA has expressly recognized that the fact that a single-use device has not been validated by its original manufacturer for reprocessing does not mean that the device is incapable

² See, Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-use Medical Devices, Guidance for Industry and FDA Staff, Center for Devices and Radiological Health, U.S. Food and Drug Administration, June 2004.

of being reprocessed. A representation that the use of an FDA-regulated reprocessed SUD is inherently “off-label” is deceptive, false, and misleading.

B. Reprocessors are not required to be authorized to reprocess Verathon’s devices

Your letter emphasizes that Verathon “has not partnered with, nor authorized, any third party to reprocess its single-use products.” The placement and context of this statement creates the misleading impression that Verathon's authorization is necessary before a third party may lawfully reprocess one of its SUDs. That is false. It is not Verathon that determines whether a third-party reprocessor may lawfully manufacture and market a reprocessed SUD. That determination is governed by the applicable federal regulatory requirements administered by FDA. Verathon should therefore immediately cease representing or implying that the absence of Verathon's authorization, partnership, or participation makes the resulting reprocessed product unlawful. If Verathon contends otherwise, AMDR demands that Verathon provide, in writing, the specific federal statutory, regulatory, or FDA authority upon which it relies.

C. Safety warnings included in the letter are unsupported

At the outset, AMDR does not object to accurate, appropriately qualified communications concerning legitimate patient-safety risks. In fact, AMDR and its members appreciate complaints about devices so safety risks can be investigated, and corrective action can be taken as appropriate in order to ensure patient safety.

Verathon's letter warns customers of “Performance Risk” and “Cross-Contamination Risk,” stating that reprocessing “may compromise” functionality and that inadequately cleaned or sterilized devices “may increase the risk” of cross-contamination. Your letter, however, does not identify any study, adverse-event data, regulatory finding, testing, or other evidence demonstrating that FDA-regulated reprocessed GlideScope® or GlideRite® devices present the generalized risks suggested by the letter. Nor does the letter distinguish between an unregulated attempt by a hospital to reuse a single-use device and a commercially reprocessed device manufactured by an FDA-regulated reprocessor pursuant to FDA requirements.

AMDR therefore demands that Verathon provide the factual and scientific substantiation for each safety representation made in its letter, including:

1. all data supporting the assertion that reprocessing may result in performance degradation or device failure;
2. all data supporting the assertion regarding cross-contamination;
3. identification of any FDA finding, warning, recall, adverse-event determination, or other regulatory action concerning FDA-regulated reprocessed GlideScope® or GlideRite® devices that supports these representations; and
4. identification of any independently generated, peer-reviewed evidence upon which Verathon relies.

Absent such substantiation, Verathon should immediately withdraw these representations.

D. Extorting technical support to Verathon customers

Verathon's statement that it “may not be able to provide technical support or system troubleshooting” where a hospital uses a third-party reprocessed device with Verathon monitors and cables is particularly concerning. A manufacturer should not use access to technical support, system functionality, software, troubleshooting, or other services as a means of discouraging hospitals from purchasing otherwise lawful competing products. Such a written warning creates a reasonable concern that customers could interpret the statement as a threat that their access to Verathon's support or system functionality may be impaired if they purchase reprocessed devices.

Accordingly, we demand that Verathon clarify in writing:

- whether Verathon has ever denied technical support because a customer used a lawfully FDA-regulated reprocessed SUD;
- whether Verathon has any written policy limiting technical support based on a customer's use of reprocessed SUDs;
- whether use of a lawfully reprocessed SUD affects any warranty, service agreement, software access, technical support, troubleshooting, or other customer entitlement; and
- the precise circumstances in which Verathon believes it “may not be able” to provide technical support or troubleshooting.

AMDR further demands that Verathon cease making statements that imply that hospitals will lose support, system access, warranty protection, or other services merely because they choose to purchase lawful, FDA-regulated reprocessed devices.

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 labeling³ 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 renders such device misbranded is a false or misleading representation with

³ 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).

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 Verathon-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)).

As discussed above, the claims made in your letter are false and misleading. Further, the letter is devoid of any supporting evidence and flies in the face of the statutory and regulatory construct for FDA regulation of these products. 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 Verathon Devices.

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.⁴ 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***.⁵ “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.⁶

⁴ See e.g. *In re Dahlberg*, 1995 U.S. Dist. LEXIS 19697, at *1 (D. Minn. Mar. 31, 1995).

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

⁶ See 16 CFR § 255.5.

Verathon's claims do not appear to be supported by competent and reliable scientific evidence.

C. Lanham Act Violations

The claims in the letter 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.⁷ 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.⁸ 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.* Verathon's false and misleading claims also constitute common law disparagement.⁹ Though in the end consumers also benefit from the FDA or FTC's proper enforcement, the Lanham Act's cause of action is for competitors, not consumers.¹⁰ The letter'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 Verathon's SUDs. This could result in patient harm as Verathon's SUDs 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.

III. REQUEST FOR IMMEDIATE ACTION

The misinformation being disseminated by Verathon 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 Verathon immediately remove all illegal promotional and marketing materials that make unsupported safety or superiority claims about its SUDs in comparison to reprocessed alternatives.

⁷ 15 U.S.C § 1125(a)(1)(B).

⁸ *Eli Lilly & Co.*, 23 F. Supp. at 475.

⁹ *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.).

¹⁰ *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014).



Additionally, AMDR requests that Verathon issue a corrective communication to every recipient of the letter, clarifying that the statement regarding “off label use” was not accurate and that Verathon’s authorization is unnecessary, and correct any statements regarding safety that cannot be substantiated pursuant to our demands above.

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,

A handwritten signature in blue ink, appearing to read "J. Mason Weeda".

J. Mason Weeda
Counsel to AMDR

OFW: mw

cc: Dan Vukelich
President
AMDR