Supplemental Material
Supplements 1-3 with References

False, Deceptive, and Misleading Marketing of Nonsurgical Medical Aesthetic Devices: A Nursing Informed Policy Brief

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Supplement 1

Medical device "means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for use in humans" (21 CFR 1.71 "Medical device").
"Per Section 201(h)(1) of the Food, Drug, and Cosmetic Act, a device is: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o)"

(Center for Devices and Radiological Health, 2022, Step 1 section).

References for Supplement 1

Center for Devices and Radiological Health. (2022, September 29). *How to determine if your product is a medical device*. US Department of Health and Human Services, US Food and Drug Administration (U.S. FDA). Retrieved from: https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device

Supplement 2

Overview of medical device classification and common premarket regulatory pathways (U.S.)

Devices are classified "according to risk and the level of regulatory controls needed to provide a reasonable assurance of the safety and effectiveness of the devices" (U.S. FDA, 2022, The FDA uses a risk-based, tiered approach for regulating medical devices for people section). All devices are subject to general controls defined in the 1976 Medical Device Amendments to the FFDCA. Class I devices, such as exam gloves, present the lowest risk of harm to the user and require only general controls. Class II devices present moderate risk of harm to the user and generally require additional regulatory controls (termed "special controls") beyond general controls for reasonable assurance of safety and effectiveness. Special controls may include, for example, specific labeling requirements or post market surveillance, and are typically specific to the device. Most Class II devices require premarket notification [510(k)] for FDA-clearance before marketing the device, although some Class II devices are determined exempt. Class III devices present the highest risk of harm to the user and usually require premarket approval (PMA) before the device can be legally marketed in the U.S.

The most common premarket regulatory pathways for legally marketing a device in the U.S. are the Premarket Notification (commonly referred to as 510(k) notification), Premarket Approval (PMA), De Novo Classification Request, and the Humanitarian Device Exemption (HDE). Importantly, misunderstanding device clearance and approval as being synonymous is common but is of serious concern as the terms refer to substantively different levels of regulatory controls. FDA-cleared devices enter the market through the 510(k) pathway, which only requires demonstrating the device is substantially equivalent to another legally marketed device (which is termed the "predicate" device). The designation of FDA-clearance refers only to the determination of substantial equivalence, not of safety or effectiveness. FDA-approved devices enter the market through the PMA pathway, which "must provide valid scientific evidence demonstrating reasonable assurances of safety and effectiveness for the device's intended use" (Center for Devices and Radiological Health, 2023, Step 2, PMA section).

Note: The content in this Supplement is primarily drawn from the following reference, Center for Devices and Radiological Health. (2023, October 12).

References for Supplement 2

Center for Devices and Radiological Health. (2023b, October 12). *How to study and market your device*. U.S. Department of Health and Human Services, U.S. Food and Drug Administration. Retrieved from https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device

U.S. Food and Drug Administration. (2022, May 10). Is it really "FDA approved"? U.S. Department of Health and Human Services. Retrieved May 12, 2024, from https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved

Supplement 3

Action-oriented appraisal for media used in the course of everyday nursing practice and beyond
Consider applying an action-oriented appraisal by asking three practical questions:

1. What is the **purpose**?
   - *Promotion*, such as, we have [x] service, price, provider, or similar type language?
   - *Inform, educate, or make a decision*, about a condition, diagnosis, medication, medical device, or otherwise?
   - Entertain?

To determine the purpose, consider the author, including and their actual or appearance of conflict of interest. In reviewing, consider the validity (trustworthiness, the credibility of the author and source), applicability or relevance, and importance. Ensure that materials do not contain common regulatory concerns such as exaggerated claims, for example, in overstating effectiveness; omitted or minimized risks; or include misleading comparisons, for example with differing clinical study designs, methods, patient populations in whatever is being presented. Information should be truthful, balanced, and not misleading.

2. What **prompts** review?
   - *New materials*, or there is a *change* in guidelines, evidence, personnel, or resources.

3. Who is the **person or people-in-context**?
   - *Who is using the media*, when are they using it and why (for what purpose)? What are their unique circumstances, internal factors (e.g., personal health literacy, attention and information processing capacity), and external factors such as time, context (e.g., illness, grave diagnosis, stress), and if the materials are readily available when needed.

A few circumstances of where and how healthcare professionals and healthcare consumers may be misled are offered here for salience.

When considering adopting a nonsurgical medical aesthetic device in clinical practice, healthcare professionals ought to review the cited literature in presentations given by device reps during detailing visits. Detailing visits from device reps (that is, an office visit from an industry representative) are common. During such visits, the device rep often brings food for the office staff and reviews a presentation or other materials on the device they represent for the express purpose of getting the healthcare professional(s) to adopt the device in their clinical practice. Healthcare professionals ought to be prepared to critically evaluate the materials the device rep presents and to ask relevant questions. Such materials may contain false or deceptive claims, for example, by presenting a slide with a before-and-after photo and reference to the peer-reviewed article the image is pulled from to support their verbal claim of effective device performance. Navigating to the cited literature may reveal the study was conducted with a different device.[1]

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[1] This is a recent example from the author's experience in clinical practice meeting with a device rep for a skin tightening nonsurgical medical aesthetic device.

There are further implications for clinical practice in using nonsurgical medical aesthetic devices related to professional liability coverage around which healthcare professionals may be otherwise misled: Know whether or not a medical device being used in your clinical practice is actually a legally-marketed device—if it is not a legally-marketed device, do not use it. For example, the FDA has cleared only a limited number of microneedling devices for aesthetic indications, but a variety of such devices beyond those cleared by the FDA are still used in clinical practice (Center for Devices and Radiological Health, 2020).

Healthcare professionals are trusted to counsel and treat persons with nonsurgical medical aesthetic devices and so should take care to not accept industry claims at face value. Other concerns to look for in evaluating claims include if safety and effectiveness data are presented, healthcare professionals should ask about the source and quality of the data. Data may be deceptive or misleading, for example, by presenting risk data with an inappropriately inflated denominator (e.g., based on total number of treatments sold rather than number of patients treated) resulting in the incidence of the materialized risk being presented as the numerator appearing lower than it actually is (Allergan Aesthetics, n.d.; Kodé, 2023). One additional consideration applies more broadly to all healthcare professionals in maintaining knowledge of current practice relevant to their specialty area in that even peer-reviewed literature may also contain misleading claims, for example, in before-and-after images (Swanson, 2023, 2019).

Healthcare consumers are potentially misled by false, deceptive, or misleading claims when actively seeking, considering, and receiving treatment with a nonsurgical medical aesthetic device. DTCA reaches healthcare consumers before they present for consultation with a healthcare professional, and during a clinical encounter, industry-prepared brochures, consultation guides, and "informed" consent documents containing false, deceptive, or misleading claims may be used without prior critical review by the health care professional. For example, the U.S. FDA (2018) published a warning noting concerns with deceptive marketing of "vaginal rejuvenation" devices, an indication for which the FDA had not cleared or approved any device, listing seven device manufacturers as receiving a notification letter from the FDA describing concerns of "inappropriate marketing of their devices" (U.S. FDA, 2018, para. 10). As such, healthcare professionals should be aware of, and ask healthcare consumers during consultation, about information sources used in their decision making as doing so supports a collaborative approach to care in reviewing for potentially misleading language (as another example, in a nonsurgical medical aesthetic device website using terminology in naming a device risk [e.g., "paradoxical hyperplasia"] that differs from what is properly medically recognized [e.g., "paradoxical adipose hyperplasia, PAH"] [Allergan Aesthetics, 2021, p. 2]).

The general public is also impacted by passive viewing of DTCA of nonsurgical medical aesthetic devices laden with anti-aging messaging by and large adding to the collective narrative of ageism in society and is fundamentally false and misleading because said medical devices do not stop or reverse aging but rather are intended to address one or more physical characteristics commonly associated with aging, such as skin laxity (Hagopian, 2023).

References for Supplement 3

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U.S. Food and Drug Administration, Office of the Commissioner. (2018, August 2). *Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to safeguard women's health from deceptive health claims and significant risks related to devices marketed for use in medical procedures for "vaginal rejuvenation"* [FDA News Release]. U.S. Department of Health and Human Services. https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-safeguard-womens-health-deceptive-health-claimshttps://www.fda.gov/news-