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

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Article

Abstract

This nursing informed policy brief: (1) presents a policy issue concerning to patient safety and informed consent of false, deceptive, and misleading marketing of nonsurgical medical aesthetic devices, (2) overviews a focused background, context, and the current regulatory scheme relevant to marketing medical devices and of informed consent in the United States, (3) offers a balanced critique of viable policy alternatives for addressing the issue, and (4) advances a recommendation for a policy solution of increased formal education for health care professionals on recognizing and responding to false, deceptive, and misleading marketing of medical devices through adaptation of an existing awareness and outreach program. The nursing perspective is applied and implications for nursing education, practice, and research are discussed. Importantly, the present political climate is favorable for addressing this pressing policy issue.

Key Words: nursing, medical device, safety, marketing, recognize and report, deceptive and misleading advertising, aesthetic medicine, plastic surgery, informed consent, nonsurgical, policy brief, advocacy, policy, nursing education

False, deceptive, and misleading marketing of nonsurgical medical aesthetic devices is a policy issue relevant to patient safety...

False, deceptive, and misleading marketing of nonsurgical medical aesthetic devices is an insidious policy issue relevant to patient safety and informed consent. These medical devices are being used at increasing rates (American Society for Aesthetic Plastic Surgery [ASAPS], 2018; CoolSculpting, 2020; The Aesthetic Society, 2022) for a variety of aesthetic concerns, by a variety of practitioners (Camp et al., 2010)— both those with and without formal training in a healthcare discipline (e.g., nursing, medicine), and in a variety of settings. These devices are not without risk of physical, psychological, and financial harm. While arguments around medical marketing practices have been well and increasingly described in the scientific literature and regulatory space, study has focused on the pharmaceutical and tobacco industries (Conko, 2011; Park et al., 2021; Schwartz & Woloshin, 2019). What is missing is explicit consideration of medical device marketing. The dearth of literature and lack of attention in policy decision-making to medical device marketing limits available data for robust evaluation of its true impact. A reasonable first step in reconciling this gap is sought with this brief. The purpose of this nursing-informed policy brief is to (1) provide an overview of the policy issue and context of false, deceptive, and misleading marketing of nonsurgical medical aesthetic devices, (2) present a balanced critique of viable policy alternatives, and (3) advance a recommended policy solution. The nursing lens is applied to assist in framing the issue and the desired outcome from a policy solution. Implications for nursing education, practice, and research are considered.

Policy Issue Identification

The policy issue of focus in this brief is false, deceptive, and misleading marketing practices and media of nonsurgical medical aesthetic devices classified and defined by the FDA as restricted Class II (moderate risk) medical devices.

History and Relevant Background

Relevant background includes a focused review of informed consent in the context of industry-prepared materials (labeling), medical device regulation, and medical device marketing in the United States (U.S.). As the focus is narrowly on medical devices, discussion of relevant spaces such as pharmaceutical and tobacco regulatory activities is excluded here.

Informed Consent

Consent to a medical treatment or procedure is a legal requirement defined by the state and implemented in practice according to organizational policy. Healthcare professionals generally have an affirmative duty of disclosure, including the nature, purpose, risks, and benefits of, and alternatives to the proposed intervention. States follow one of two disclosure standards: malpractice and material risk (Pope, 2017), except Washington state, which updated its state informed consent law in 2016 to reflect a shared decision-making standard following a successful demonstration project. Other states have also made some progress with shared decision-making.

From a clinical practice perspective, any practice that has at some point adopted a nonsurgical medical aesthetic device is likely familiar with the entire industry fanfare of "preparing your practice for [insert latest device here]" materials. Such materials include traditional educational (read: promotional) brochures, scripts for staff to discuss the new device with prospective and existing patients, web copy for use on the practice website, consultation guides, and consent documents. The key point here is these materials are written by the device manufacturer. This matters because if such industry-prepared materials contain false, deceptive, or misleading information about the nature and use of the medical device—or its safety and effectiveness, and these materials are used in the course of clinical practice, there is potential for negatively impacting a person's decision-making and whether or not their consent to treatment is adequately informed so to protect against deception and coercion. Nurses, physicians, and other healthcare team members may or may not question these materials before using them in clinical practice (Grundy et al., 2013).

Legal Authority and Purpose for Medical Device Regulation

The FDA is the official policymaking body with jurisdiction over medical device regulation. Legal authority is primarily granted under the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act ([FFDCA]; Public Law 94-295, 1976). The general purpose of the FDA in regulating medical devices is to protect the public by ensuring the safety and effectiveness of medical devices and communicating related activities and findings with the general public, healthcare consumers, and healthcare professionals. This is accomplished through a variety of administrative and regulatory functions.

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Structure

The Center for Devices and Radiological Health (CDRH) is the branch of the FDA specifically dealing with medical devices. The Medical Devices Advisory Committee supports medical device regulatory activities by making recommendations relating to device classification, possible health risks associated with device use, subject-specific concerns, device exemptions and bans, and clinical study designs pertaining to device safety and effectiveness; the Committee also reviews premarket approval applications, guidelines, and guidance documents (Center for Devices and Radiological Health [CDRH], 2019). The Committee consists of 18 panels; nonsurgical medical aesthetic devices generally fall under the purview of the General and Plastic Surgery Advisory Panel. However, there is no clear guidance or requirements for panel approval or involvement in regulatory decision-making.

Regulatory Requirements for Marketing Medical Devices

The Federal Trade Commission (FTC) and the FDA share regulatory authority for consumer protection to enforce truthful advertising in marketing practices of medical devices and to take action for violations. Legal authority is granted to the FTC through the FTC Act (FTCA) and to the FDA through the FFDCA. Shared activities are described through a memorandum of understanding. To simplify, the general division of oversight activities between the FDA and FTC—specifically with respect to medical device marketing—is such that the FTC is primary over advertising *other than labeling,* and the FDA is primary over labeling and preventing misbranding of medical devices (*Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration*, 1971). The challenge presented by this guidance is the lack of clarity regarding what advertising, if any, is *not* considered device labeling as, "According to an appellate court decision: 'Most if not all advertising is considered labeling….'" (CDRH, 2020, Advertising section). Whether a device is restricted or not *appears* to also play a role in guiding whether the FDA (restricted devices) or FTC (nonrestricted devices) is primary.

State consumer protection acts offer some additional oversight and method for persons seeking legal redress for alleged harms by device manufacturers but are limited by federal preemption clauses in the FFDCA (Byrd, 2019; Congressional Research Service, 2013). Also relevant are nongovernmental—organizational or practice-specific policies for use and review of

materials and marketing activities by medical device manufacturers, healthcare professional codes of ethics (professional self-regulation), and industry self-regulation with oversight activities by the National Advertising Division (NAD).

Key Definitions

See Table 1 for key terms defined for the purpose of this paper.

Table 1. *Key definitions*

Term	Definition

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"; FDA, 2018).
	  • See Supplement 1 for the statutory definition of a "medical device" per section 201(h) of the FFDCA.
	• Medical devices are classified according to risk, which informs the relevant regulatory requirements for the device (CDRH, 2023a, Step 1 section).
	  • See Supplement 2 for an overview of medical device classification and common premarket regulatory pathways in the U.S.

Nonsurgical medical aesthetic devices	• are "noninvasive or minimally invasive medical devices that intend to enhance or improve upon aesthetic concerns and include body contouring, skin tightening, and laser technologies" (Hagopian, 2019, p. 5). • The focus of this brief is on nonsurgical medical aesthetic devices classified and defined by the FDA as restricted Class II (moderate risk) medical devices, subject to general and special controls. • Note "[a] restricted device can only be sold on oral or written authorization by a licensed practitioner or under conditions specified by regulation" (CDRH, 2023b, Restricted devices section).
Labeling	• of a medical device is defined by 21 CFR Part 801 and "includes labels on the device as well as descriptive and informational literature that accompanies the device" (Center for Devices and Radiological Health, 2024, Labeling requirements section). • Labeling requirements of medical devices marketed in the U.S. fall under the regulatory scheme of the FDA, and FDA action around labeling of medical devices is directed by Section 201 of the FFDCA (CDRH, 2020). • Labeling is commonly thought of as the actual physical label that is affixed to the drug or device container or device itself along with its instructions for use; however, advertising material also falls under the umbrella term "labeling" and subject to FDA oversight.
Direct-to-consumer advertising (DTCA)	• refers to industry prepared general public and healthcare consumer (patient)[1]-facing materials and marketing activities.
Healthcare professional (HCP) directed marketing	• includes all healthcare professional-facing marketing materials and activities, such as scripted messaging of advertising, promotional, and patient education and consultation materials, directions or instructions for use of the device as defined above and "detailing visits" and similar activities, including promotional or sponsored meals and office visits by industry representatives ("device reps").
Media	• broadly defined as inclusive of any and all the "leave-behind" or products of communication. • All other activities related to marketing other than media are described in this paper as "practices," which includes, for example, detailing visits by industry representatives, speaker presentations delivered during industry sponsored meals or professional conferences.
Misbranding	• "[a] device is misbranded when all or part of the labeling (i.e., the FDA-approved printed material providing information about the device) is false, misleading, or missing" (Johnson, 2016, p. 8). • "A restricted device offered for sale in any State uses false or misleading advertising, or is sold, distributed, or used in violation of restricted device regulations under Section 820(e) of the FD&C Act" (CDRH, 2023b, Misbranding section).
Paradoxical adipose hyperplasia (PAH)	• a reported complication of cryolipolysis with an estimated incidence "between 0.05% and 0.39%" (Cox et al., 2022, para. 2); and, • is "a condition characterized by gradual, paradoxical adipose tissue enlargement in the treated area months after the procedure" (Cox et al., 2022, para. 2) which requires[2] surgical intervention with liposuction or direct excision to treat (Nikolis & Enright, 2021).

Note:[1] Defined key terms needed for a clear, shared understanding of the policy issue for the purpose of this policy brief. [1]The terms "patient" and "health care consumer" are used interchangeably in this paper for describing all persons considering, seeking, and receiving care and counseling by a healthcare professional on the use of a nonsurgical medical aesthetic device. [2]No reports of spontaneous resolution or effective nonsurgical treatment were identified in preparing this paper.

Context

Political and Legal Factors

The political context to consider is the powerful lobbying presence of the medical device industry (Lenzer, 2012). Legal context includes litigation faced by medical device manufacturers related to marketing activities regarding direct-to-consumer advertising (DTCA) and healthcare professional-directed marketing and promotion (Marks, 2022). For example, Thompson (2017) reports on a False Advertisement Class Action Lawsuit,

"In its motion, Zeltiq argues that 'Zeltiq had no duty to educate consumers on parameters of the 510(k) process or clarify that FDA Cleared is not the same as FDA Approved.' Zeltiq also notes that '...their attempt to impose an additional, novel duty of disclosure on Zeltiq is contrary to California law, which rejects a broad obligation to disclose. Instead, the law imposes liability on manufacturers for omissions only where the undisclosed information relates to a known defect in a product that creates an unreasonable safety hazard,' the motion states (para. 6-7).

The substantive difference in regulatory oversight regarding the safety and effectiveness of medical devices between the premarket notification [510(k)] and premarket approval (PMA) pathways and in the context of limited, if any, formal education on medical device regulation for healthcare professionals, prompts considering if the nondisclosure described in the above case in fact *does* present an unreasonable safety hazard in misleading healthcare professionals. Examples abound of prudent healthcare professionals mistaking the terms as interchangeable.

A second relevant legal case is a personal injury-product liability action filed by a well-known professional model against the manufacturer of a nonsurgical medical aesthetic device, which has prompted increased attention in the news and pop-culture media of nonsurgical medical aesthetic devices (*Evangelista v. Zeltiq Aesthetics, Inc.*, 2022). In 2015, Evangelista, a professional model, presented to her dermatologist requesting nonsurgical body contouring with CoolSculpting (*Evangelista v. Zeltiq Aesthetics, Inc.*, 2022), a nonsurgical medical aesthetic device that applies targeted cooling "intended for the disruption or induction of adipocyte cells indicated for body contouring or reduction in circumference of body areas" through a process termed cryolipolysis (U.S. Food and Drug Administration [FDA], 2024, Definition section). Following treatment, Evangelista experienced a rare but known complication of CoolSculpting – paradoxical adipose hyperplasia (PAH) (*Evangelista v. Zeltiq Aesthetics, Inc.*, 2022). The materialized risk of PAH is a clear undesirable clinical outcome, but cues to possible policy failure are revealed in subsequent legal action: On September 21, 2021, Evangelista filed a personal injury – product liability lawsuit against Zeltiq Aesthetics, Inc., citing, "unlawful, false, misleading, and deceptive marketing practices and with a willful, wanton, and reckless disregard for her safety" resulting in physical, psychological, and financial harm (*Evangelista v. Zeltiq Aesthetics, Inc.*, 2022, Document 1, p. 2). Media buzz has focused on the clinical issue of PAH—what it is and how it happens. Largely overlooked in the conversation is the policy issue around medical device marketing, highlighted by this legal action as, "The fight isn't over what happened to the supermodel's body, but whether or not the company gave her—and others—sufficient warning about the risk of adverse effects" (Marks, 2022, Drop Head Section).

Economic Factors

Healthcare consumer spending on nonsurgical aesthetic procedures is increasing (The Aesthetic Society, 2022). Practitioners - healthcare professionals and otherwise, counseling and performing procedures with nonsurgical medical aesthetic devices have an inherent financial conflict of interest to increase the volume of these procedures, which is often compounded by employment compensation structures and industry-prepared marketing materials designed to "upsell" nonsurgical procedures. Further, there is concern among healthcare professionals about the commercialization of plastic surgery (Nahai, 2013; Swanson, 2013). The cost of regulatory oversight in reviewing and responding to advertising and promotion of medical devices, including field work, e.g., sponsored dinners, detailing visits, and conferences, is also necessary to consider.

Social Factors

A large body of evidence in the decision science and behavioral economics literature demonstrates the important role of cognitive biases on decision-making. There is explicit relevance to informed consent in that, "[d]efining risk is...an exercise in power" (Slovic, 1999, p. 699). When thinking about decision-making and consent processes for whether or not to proceed with a cosmetic procedure involving the use of a nonsurgical medical aesthetic device, it is instructive to consider the consequences of four cognitive biases in particular—the availability, authority, confirmation, and framing biases. Marketing tactics often employ such biases in practice, for example, with a celebrity or "influencer" campaign or endorsement by a healthcare professional (Hagopian, 2019; Smith & George, 2018).

Technological Factors

Socioeconomic and environmental factors comprise the largest percentage of the determinants of population health (Booske et al., 2010). Collectively referred to as the social determinants of health, these factors are upstream to clinical encounters and include, among other factors, the media and information environment (Stiefel & Nolan, 2012). Technological advancements and the availability of nonsurgical medical aesthetic devices are notable here. DTCA has evolved with social media marketing, which plays a substantive role in setting the social acceptability of cosmetic procedures as well as the presence of "influencers" (Hagopian, 2019; Smith & George, 2018). Healthcare consumers often present to clinicians asking for treatment with specific devices. Adoption of new technologies in practice is largely driven by consumer demand rather than evidence, a concern discussed in the plastic surgery literature (Nahai, 2013; Swanson, 2013).

Interested and Concerned Parties

Interested and concerned parties include persons considering, seeking, and receiving treatment with a nonsurgical medical aesthetic device, healthcare professionals counseling and treating persons with a nonsurgical medical aesthetic device, the federal government (FDA, FTC), state attorneys general, the medical device industry, industry self-regulatory bodies (e.g., NAD), and healthcare professional associations, such as, the International Society of Plastic and Aesthetic Nurses (ISPAN), the American Society for Aesthetic Plastic Surgery (The Aesthetic Society), American Society of Plastic Surgeons (ASPS), the American Nurses Association (ANA), and the American Medical Association (AMA).

Nursing Perspective

Professional nursing values and obligations provide frameworks to consider the policy issue and the nursing response. The ANA *Code of Ethics for Nurses with Interpretive Statements* (2015) (the *Code*) guides the nursing profession in describing the *nonnegotiable* obligations of all nurses across all roles and settings practicing in the U.S. (ANA, 2015, Preface) and is explicitly noted as "both normative and aspirational" (p. viii). With nursing ethics fundamentally grounded as a social ethic, the *Code* serves as a useful tool in aiding nurses to see the world as it is ***and*** as it could be in our (nursing) serving humanity. The *Code* informs the actions and behavior of nurses during informed consent, for example, in discussing the duty of nurses to minimize unwanted medical treatment related to a failure of informed consent (ANA, 2015, Provision 1, Interpretive Statement 1.3 The Nature of Health) and in describing persons right to necessary support in decision making for medical treatments, which attends to the context, or manner, of disclosure in addition to the content, or material, of disclosure in informed consent (ANA, 2015, Provision 1, Interpretive Statement 1.4 The Right to Self-Determination). The core nursing value of human dignity is relevant here. Nursing's whole person view locates autonomy and self-determination in the context of respect for human dignity and informs a nurse's role, professional scope of responsibility, and approach to supporting persons decision-making and their consent or refusal to a treatment or procedure.

"[N]ursing bases its commitment to respect for autonomy in human dignity. Nurses offer information and advice to patients in ways that exercise compassion, affirm patient dignity, and recognize the uniqueness of the patient as a person" (Fowler, 2015, p. 18). In doing so, nurses consider actual and potential external and internal factors influencing decision-making. For example, the nurse critically appraises oneself for any biases or conflicts of interest at the intrapersonal level, and, at the interpersonal level, the nurse acknowledges the power differential inherent in the nurse-healthcare consumer relationship and authentically engages with healthcare consumers in decision-making (Crigger, 2009). Further considerations at the meso- and macrosystem levels include the social and structural determinants of health, such as access to care, access to internet, financial constraints, and power differentials beyond the nurse-patient dyad—to include information asymmetry among, for example, healthcare consumers, clinicians, and the medical device industry. Rather than a misplaced emphasis on the theoretical, detached, or acontextual individual choice, respect for human dignity appreciates the complexity of reality in that care, decision-making about care, and a person's health and wellness do not exist in a vacuum (Hagopian, 2024).

Explicit phenomena of concern to nursing as described in *Nursing's Social Policy Statement* (2010) include "health literacy [and] decision making and the ability to make choices" (p. 14). Clarifying the role of the nurse and the context of care delivery related to advertising and promotion of medical devices lends further consideration of nursing expertise in the environment of care and nursing's primary focus on human responses to actual or potential changing states of health and wellbeing. Here, the meaning of human responses concentrates on the human response to false, deceptive, or misleading advertising; collective human response can be drawn from decision science (The Decision Lab, n.d.) and behavioral economics literature. Relevant nursing diagnoses prompting a nursing response are associated with information behavior challenges, to include decisional conflict, readiness for enhanced emancipated decision making, and readiness for enhanced health literacy (Herdman et al., 2021). Decision quality is the desired outcome of consent and occurs when a person seeking and receiving care is informed, meaningfully involved, and where the resulting decision is concordant with their values and preferences (Sepucha et al., 2013, 2016).

Issue Statement

Labeling of medical devices should be monitored to ensure DTCA and healthcare professional-directed marketing and promotion is truthful, balanced, and not misleading.

The policy analysis…applied three criteria for evaluation: (1) Impact on the Decision Quality of Persons Considering, Seeking, and Receiving Treatment with a Nonsurgical Medical Aesthetic Device, (2) Feasibility, and (3) Cost…

Policy Goals and Objectives

The goal of federal regulation of medical device labeling is to ensure the safe and effective use of medical devices to protect and promote the health of the public. Policy objectives include the following:

1. Support healthcare consumers and professionals in their ability to make informed decisions about the adoption and use of medical devices;
2. Ensure public-facing and professional-facing information about the safety and effectiveness of medical devices is truthful, balanced, and not misleading;
3. Educate the general public, healthcare consumers, and healthcare professionals on how to recognize and appropriately respond to medical device labeling that is false, deceptive, or misleading (or otherwise considered "misbranded");
4. Facilitate engagement and vigilance of interested and concerned parties with reviewing industry-prepared materials and activities; and,
5. Take action against adulterated or misbranded (inclusive of labeling that is false, deceptive, or misleading) medical devices.

Policy Options

Policy options to address false, deceptive, and misleading marketing practices and media of nonsurgical medical aesthetic devices classified and defined by the FDA as restricted Class II (moderate risk) medical devices include:

1. *Do nothing option: Continue current methods of regulatory oversight and public and healthcare professional education.* This includes (1) Passive oversight with no requirement for approval of final labeling by the FDA for medical device manufacturers submitting an application through the 510(k) pathway; (2) A reactive approach to compliance and enforcement through (a) direct regulation at the federal level with shared authority between the FDA (per labeling requirements as prescribed by the FFDCA) and the FTC (truthful advertising as prescribed by the FTCA); (b) tort liability at the state level (State consumer protection acts); (c) industry and healthcare professional self-regulation (NAD; healthcare professional associations); and, (3) No formal outreach and awareness program to educate the general public, healthcare consumers, or healthcare professionals on how to recognize and respond to false, deceptive, and misleading advertising and promotion of restricted medical devices, and absent or variable organizational or practice-specific policies for use and review of industry-prepared materials.
2. *Incremental change option: Increase formal awareness and outreach programs to healthcare professionals.* This includes adapting the Office of Prescription Drug Promotion (OPDP), FDA, and FTC Bad Ad Program (focused on prescription drug promotion) (Abrams, 2020) for restricted medical devices to educate healthcare professionals on device labeling—including both direct-to-consumer and healthcare professional directed marketing that present a regulatory concern, and how to recognize and report false, deceptive, and misleading advertising and promotion of restricted medical devices. The Bad Ad program helps healthcare professionals learn to recognize and respond to common regulatory issues in prescription drug promotion, including minimization of risk, exaggeration of effectiveness, and unsubstantiated claims (Abrams, 2020). Potential policy levers include indirect regulation at the federal level through funding (e.g., if led by the FDA CDRH), direct regulation at the state level through professional licensing boards, or self-regulation through development of professional education standards on medical device regulation.
3. *Major change option: Active oversight of healthcare professional-directed marketing.* This would include a requirement for manufacturers of all restricted (FDA Class II-III) medical devices to submit all healthcare professional-directed marketing and promotional materials for final approval by the FDA prior to use. Potential policy levers include direct regulation at the federal level through strengthening and expanding the regulatory authority of the FDA over healthcare professional-directed marketing and indirect regulation at the federal level through funding necessary to accomplish active oversight as described.

4. *Major change option: Ban DTCA of restricted (FDA Class II-III) medical devices.* This alternative was discarded and not included in the critique, with the rationale of it not being a viable policy solution in the U.S., given the constitutional arguments related to protected commercial speech. It is listed here, however, because review of recent history reveals strong, but ultimately unsuccessful, attempts to advance this alternative. Leading proponents calling for a ban of DTCA for prescription drugs and medical devices include the American Medical Association (2015).

Policy Analysis

Criteria for Evaluation

The policy analysis presented below applied three criteria for evaluation: (1) Impact on the Decision Quality of Persons Considering, Seeking, and Receiving Treatment with a Nonsurgical Medical Aesthetic Device, (2) Feasibility, and (3) Cost, in critiquing each policy alternative. See Table 2 for the full description of each criterion as used for the purpose of this analysis.

Table 2. ***Criteria for evaluation***

Criterion	Description
1. Impact on the decision quality of persons considering, seeking, and receiving treatment with a nonsurgical medical aesthetic device	This criterion focuses on the potential of the policy option to meaningfully impact decision quality, which looks at persons informedness, meaningful engagement in decision-making (shared decision making), and decision concordance with informed preferences and values (Sepucha et al., 2013, 2016), reflective of best available evidence and persons unique circumstances.
2. Feasibility	This criterion looks at the realistic potential of the option to succeed with consideration of political will, engagement of interested and concerned parties, and operational considerations—including around implementation, fitness with local context, and potential for unintended consequences. This criterion also assesses the reasonable likelihood for improving the recognition of and appropriate response to medical device labeling (and other medical device advertising and promotional material and activities) that is false, deceptive, or misleading.
3. Cost	This criterion evaluates cost, including sustainability considerations, around potential sources and size of available funding.

Note: Described criteria for evaluation used to critique the policy alternatives presented in this brief.

Critique of Policy Options

Critique of Option 1

Do nothing option.

Criterion 1: Impact on the Decision Quality of Persons Considering, Seeking, and Receiving Treatment with a Nonsurgical Medical Aesthetic Device

Pro. Current marketing methods promote awareness of availability of nonsurgical options and access to clinicians—which could support an argument of decision quality related to informedness, as persons may not otherwise know about such devices and clinicians sans marketing activities.

Con. The fundamental purpose of marketing is to increase the use of marketed medical devices toward increased profit. There is reasonable concern with persons learning about nonsurgical medical aesthetic devices outside the context of counseling with a qualified healthcare professional, given the potential for anchoring bias, inherent financial conflict of interests, and the market presence of bad actors (including unqualified persons) performing aesthetic procedures—the presence of all of which may contribute to misleading healthcare consumers (Smith & George, 2018). Subjective arguments for and against DTCA and other forms of marketing and promotion by the medical device industry are notably limited by the paucity of evidence and research on the subject matter.

Criterion 2: Feasibility

Pro. Continuing current oversight methods requires no change so is assumed to be feasible.

Con. Current methods of oversight are vague. The usability and usefulness of current methods for reporting false, deceptive, and misleading advertising are limited by unclear and inconsistent communication to interested and concerned parties—namely healthcare consumers and professionals. Burdensome voluntary reporting with vague guidance for healthcare consumers and professionals presents concern for meaningful participation in reporting activities.

Criterion 3: Cost

Pro. Continuing current practice requires no additional cost.

Con. There is cautious concern for the potential of financial harm to persons in receiving unwanted or unwarranted treatments with a nonsurgical medical aesthetic device as a consequence of being misled by marketing media and practices. The potential loss of trust in the healthcare consumer-professional relationship related to marketing activities is of further reasonable concern. A call for further research on "[e]xamining the effect of advertising and the level of patient wariness of physicians who accept industry-based payments, for example, could prove useful" (Ortiz & Rosenthal, 2019, p. 41).

Critique of Option 2

Incremental change option.

Criterion 1: Impact on the Decision Quality of Persons Considering, Seeking, and Receiving Treatment with a Nonsurgical Medical Aesthetic Device

Pro. Awareness and outreach efforts support ongoing initiatives at the FDA OPDP related to increasing healthcare professionals' education in learning to recognize and respond to common tactics used in *pharmaceutical* marketing (Abrams, 2020) and of Healthy People 2030 related to health literacy (Healthy People 2030, n.d.).

Con. Increased formal awareness and outreach efforts may not produce the desired result—careful attention to and planning of methods and measures of evaluation to accurately assess impact is critical. Another relevant factor to consider is whether participation and completion of any educational program is made voluntary or mandatory for healthcare professionals, such as for continuing education credit submitted with licensing or certification renewal.

Criterion 2: Feasibility

Pro. The Bad Ad program for prescription drug promotion offers an existing model for educational programming with demonstrated effectiveness (Abrams, 2020).

Con. Initial engagement of interested and concerned parties is required, which may be difficult to inspire. Further, the action of reporting (i.e., where and to whom) and the need to ensure the responsiveness of any implemented reporting system may not be feasible in the current regulatory structure (e.g., there is not an "Office of Medical Device Promotion" equivalent of the OPDP at the FDA). If a similar increase in reports by healthcare professionals is seen with devices as with drugs without having the infrastructure in place to support the review and response to submitted reports may negatively impact the effectiveness of the program.

Criterion 3: Cost

Pro. Adopting the Bad Ad program design of an online, self-directed tutorial limits the cost burden of human resources needing to serve as instructors. If well received, the program is very likely sustainable through several potential funding streams: For example, if led by the FDA CDRH, one option for funding is to apply user fees for device manufacturers submitting an application to market their device in the U.S. as appropriate per the Medical Device User Fee Act (MDUFA). There is further opportunity for relevant healthcare professional associations with a relevant interest or concern to lead the development, implementation, and maintenance of the educational program, thus expanding the potential options for funding.

Con. There is an upfront cost to adapt the Bad Ad program for medical devices, as well as ongoing costs associated with maintaining a website to house the program, its usability, and updating the learning content as appropriate.

Critique of Option 3

Major change option.

Criterion 1: Impact on the Decision Quality of Persons Considering, Seeking, and Receiving Treatment with a Nonsurgical Medical Aesthetic Device

Pro. The role of healthcare professional-directed marketing is substantial: Most promotional spending by the pharmaceutical industry is on marketing to healthcare professionals, for example, marketing to healthcare professionals outspent DTCA by 3:1 with more than $18.5 billion allotted for healthcare professionals marketing efforts of $24 billion spent in 2017 (Abrams, 2020). A 2021 study exploring Open Payments data found that "relative to drug firm payments, device firm payments [to physicians] as a percentage of industry revenue were seven times as large" (Bergman et al., 2021, Abstract). News reports further describe such concerns relevant to the medical device industry (Schulte & Lucas, 2021).

Con. The limited evidence around the impact of industry payments to healthcare professionals is important and potentially limits the strength of support for action. There is also a paucity of data available for study of industry payments to healthcare professionals related to nonsurgical medical aesthetic devices, given these payments are not subject to the same reporting requirements for manufacturers of devices for which the use of their device is eligible for payment under Medicare or Medicaid (U.S. Centers for Medicare & Medicaid Services, n.d.).

Criterion 2: Feasibility

Pro. Focusing narrowly on healthcare professional-directed marketing (labeling) for active regulatory oversight, as opposed to more broadly on all industry-prepared marketing, may be more palatable and met with less opposition by the device industry. Given the potential under this regulatory scheme for rejection of a device application based on reasons related to marketing, this option may also prompt improved and strengthened industry self-regulation so to avoid preventable time delay in moving the device to market.

Con. There is a need for collaboration of interested and concerned parties because the issue extends beyond the scope of healthcare professionals (Dyer, 2001). Similar concerns as described in the critique of option 2 are present around resources needed to support an increase in review and response to marketing practices and media given the limitations of the current regulatory structure. A potential unintended consequence is that this option may only give the illusion of active oversight if the structure and support to do so are insufficient, which may undermine or decrease vigilance in review of industry-prepared materials by end-users (i.e., healthcare consumers and healthcare professionals).

Criterion 3: Cost

Pro. One potential source of funding is through increased fees required of device manufacturers submitting a device application (PMA or 510(k) pathway) to market a device in the U.S.

Con. If the aforementioned funding stream is adopted, anticipating pushback from industry is prudent. Further prudent to consider is the possibility of decreasing the number of devices brought to market with the potential to advance the health and wellness of people in the U.S. as a possible unintended consequence of increasing fees required to do so.

Comparison of Policy Options

Analysis of proposed policy alternatives using a scorecard approach (Table 3) shows option 2, incremental change by increasing formal awareness and outreach programs to healthcare professionals on how to recognize and respond to false, deceptive, and misleading advertising and promotion of restricted medical devices, as the clear lead for recommendation. Reasons for failure of option 1 (do nothing) center on the fundamental lack of regulatory attention to marketing practices of the device industry as being no longer acceptable. The current political and social climate is also favorable for a policy response, particularly one that concentrates on education. Reasons for failure of option 3 (major change) largely focus on the limitations of the current structure and resources of the FDA CDRH to realistically accommodate the active review of all healthcare professional-directed marketing.

Table 3. ***Policy analysis scorecard***

	Alternatives		
Criteria	Continue current oversight	HCP education and outreach programs	Active regulatory oversight of HCP-directed marketing
Impact on decision quality	-	+	+
Feasibility	+	+	+/-
Cost	+	+	-
	2+/1-	3+	2+/2-
Score for each alternative	1	3	0

Note: Scorecard comparison of policy alternatives for regulatory oversight of marketing medical devices classified and defined by the FDA as restricted devices to address the policy issue of false, deceptive, and misleading marketing of nonsurgical medical aesthetic devices. HCP, healthcare professional.

Noted Limitations of Data Quality and Availability

There is limited data in the literature on the marketing of medical devices. Where available, the presented context is focused on nonsurgical medical aesthetic devices. Where gaps are present, context more broadly considers the pharmaceutical and tobacco industries, as these labeling regulatory requirements for these industries also falls under FDA purview.

Summary and Recommended Policy Solution

Labeling (inclusive of DTCA and professional-directed marketing and promotion) of restricted medical devices should be monitored to ensure industry-prepared materials and communications are truthful, balanced, and not misleading. Increasing formal awareness and outreach programs to healthcare professionals by adapting the FDA OPDP Bad Ad Program (focused on prescription drug promotion) for restricted medical devices to educate healthcare professionals is recommended for policy action. Educational programming should include medical device regulation, device labeling, and how to recognize and appropriately respond to false, deceptive, and misleading advertising and promotion of restricted medical devices. Case studies could highlight the focused issue presented in this brief with nonsurgical medical aesthetic devices classified and defined by the FDA as restricted Class II (moderate risk).

The reality of the FDA or otherwise (e.g., healthcare professional associations) developing (adapting) and implementing such medical device-specific programming may prove challenging and take a considerable amount of time to effectuate—at least in the short term. Regardless, there are lessons and recommendations that can be readily implemented in nursing education, practice, and research. The key call-to-action is prompting an educational response for healthcare professionals on how to recognize and appropriately respond to false, deceptive, and misleading advertising. Educators can ensure core curricula covers the basics of medical device regulation including labeling, information and media literacy, and risk communication skills. As such, discussed below are implications for nursing education, practice, and research. Note the focus of discussion here is nursing education but also holds relevance for other healthcare professionals. Considerations for monitoring and evaluation ought to attend to the noted data and evidence gaps.

Implications for Nursing Education

Implications for nursing education include preparing nurses with skills in recognizing and responding to false, deceptive, and misleading claims if and where present in industry-prepared patient education and consent materials. Educators in the health professions ought to ensure educational content covering the media and information environment is included when discussing the social determinants of health. Further prudent to cover is the safe use of social media and the importance of qualified healthcare professional presence in this informational space.

Medical Device Regulation

Content on medical devices in core nursing curricula is limited and variable. While pharmacology is a core nursing course that students place a high degree of importance with respect to studying and engagement, there is no core medical device equivalent course that focuses only on medical devices. Rather, learning about medical devices is variably placed in professional development courses such as quality and safety, informatics, and, perhaps, policy and professional leadership. The point here is not necessarily to argue that a device-specific course is necessary, but rather to call attention to an important gap in learning that may be present. Medical devices range from everyday exam gloves and other personal protective equipment to implanted devices such as artificial hips, breast implants, mechanical heart valves—and everything in between. Without foundational education on how medical devices are regulated, nurses may likely make false assumptions or be otherwise misled in matters regarding medical device safety, effectiveness, and appropriate use (including scope of practice considerations and professional liability coverage around off-label use of devices). As such, foundational learning about medical device regulation ought to include an overview of device classification, the most common premarket regulatory pathways for legally marketing a device in the U.S., and how to report adverse events involving a medical device (Swayze & Rich, 2011). See Table 4 for select resources and readings on medical devices, medical marketing, and reporting adverse events and Supplement 2 for an overview of how the FDA classifies medical devices and the common premarket regulatory pathways

Information and Media Literacy

Information literacy is naturally threaded throughout nursing education and most heavily concentrated in research and evidence based practice courses. The key consideration here is ensuring content is inclusive of all types of media used and encountered during everyday nursing practice and beyond—such as industry-prepared materials (e.g., brochures) frequently used to support patient education, in addition to traditional learning focused on finding and appraising research articles. Attention to media literacy here is needed to educate nurses and other healthcare professionals on how recognize common regulatory concerns with promotional and other healthcare consumer and healthcare professional-directed media and practices. To readily identify false and misleading claims, such as overstating effectiveness, healthcare professionals need knowledge and skills to read and critically appraise effectiveness studies. Curricular content preparing nurses to perform

patient education should include assessing for common information behavior challenges (e.g., uninformed, mis- or disinformed, information overload) and how to appropriately respond (e.g., educational response, fact-fallacy-fact messaging, evidence-based shared decision making).

Table 4. ***Additional resources to support education and practice***

Topic	Resources
Medical device regulation	• Center for Devices and Radiological Health. (2024, January 31). Overview of device regulation. U.S. Department of Health and Human Services, U.S. Food and Drug Administration. Retrieved May 12 2024, from https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation • Johnson, J.A. (2016). FDA regulation of medical devices (No. R42130). *Congressional Research Service*, 53, https://sgp.fas.org/crs/misc/R42130.pdf
Medical marketing	• The FDA OPDP Bad Ad Program: https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program • Schwartz, L.M., & Woloshin, S. (2019). Medical marketing in the United States, 1997-2016. *JAMA, 321*(1), 80-96. https://doi.org/10.1001/jama.2018.19320 • Hagopian, C. O. (2019). Ethical challenges with nonsurgical medical aesthetic devices. *Plastic Surgical Nursing, 39*(1), 5. https://doi.org/10.1097/PSN.0000000000000253 • Smith, C. P., & George, D. (2018). When is advertising a plastic surgeon's individual "brand" unethical? *AMA Journal of Ethics, 20*(4), 372–378. https://doi.org/10.1001/journalofethics.2018.20.4.msoc2-1804
Reporting adverse events	• Swayze, S. C., & Rich, S. E. (2011). Promoting safe use of medical devices. *Online Journal of Issues in Nursing, 17*(1), 9. • U.S. Food and Drug Administration. (2024, April 30). MAUDE—Manufacturer and User Facility Device Experience [Database record]. U.S. Department of Health and Human Services. Retrieved May 12, 2024, from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

Note: Select resources and readings on medical devices, medical marketing, and reporting adverse events.

Implications for Nursing Practice

Concrete recommendations for nursing practice include intrapersonal factors, interpersonal factors, and environment of care considerations. At the intrapersonal level, nurses ought to have an understanding of the mechanism of action of the medical device or devices they use. Just as there is an expectation to have an understanding of the mechanism of action of drugs when passing or prescribing medications, so too is there an expectation of nurses having this knowledge of medical devices they are using, preparing, or prescribing.

In the environment of care, take an inventory of all media, defined as the "leave-behind" or products of communication, used by you, the practice, and the persons and people seeking and receiving care and counseling at your practice; including, web copy, educational or promotional brochures and handouts, phone scripts, consent documents, and other industry-prepared materials. The updated definition of health literacy for Healthy People 2030 offers policy guidance with its inclusion of a new definition of organizational health literacy in recognizing the responsibility of producers and disseminators of health information (Healthy People 2030, n.d.). Importantly there is a need to review and critically appraise all media used in practice: Does your practice or organization have a policy and procedure for use and review of industry-prepared materials? If not, work to develop one (see Supplement 3 for a practical three question action-oriented appraisal along with a few examples).

The medical device industry and its representatives hold differing values and priorities than healthcare professionals—the former is generally understood as considering values of safety and quality care—including education and consent, as means to an end of profit, and the latter considering such values as ends in themselves. There is a responsibility to continue a dialogue with patients and the public to question false and misleading claims and to push back against the use of deceptive tactics (Nahai, 2013; Solomon et al., 2016). If healthcare professionals refused to use deceptive marketing materials (Nahai, 2013), would the device companies not have to change to improve their education and promotional activities? This question is based on the assumption that in the context of restricted devices, the medical device industry—despite its considerable market power—is to some degree ultimately bound by the need of a qualified healthcare professional to prescribe and administer their manufactured device. There is a parallel here to the role of physician-directed marking efforts by the pharmaceutical industry in contributing to the harm of the opioid epidemic (Keefe, 2021). Healthcare professionals ought to learn from the danger of medical marketing tactics employed, for example, around detailing visits by pharmaceutical sales representatives ("drug reps") (Keefe, 2021) and must be vigilant in recognizing the same patterns with the medical device industry. Specifically, it is prudent to review any industry-prepared materials prior to use in clinical practice (See Supplement

3). Healthcare professionals have a responsibility to recognize and remove, revise (correct), and report (as appropriate) false, deceptive, and misleading advertising. A few specific circumstances of where and how healthcare professionals and healthcare consumers may be misled are offered in Supplement 3 for salience. Similar work thoughtfully prepared by other healthcare professionals offers useful added guidance for teaching and learning about acceptable DTCA (American Medical Association, 2023).

Implications for Research

Implications for research include expanding current research methods to consider evolving designs such as digital ethnography being developed by those involved in studying media manipulation and other critical internet studies (*Media Manipulation Casebook*, 2020). For example, applied to the *Evangelista v. Zeltiq Aesthetics, Inc.* (2022) lawsuit, the internet archive is a useful tool in that it allows for viewing the language used on the device manufacturer website related to the safety and effectiveness of the device, including information specifically about PAH, at the time Evangelista was actually making decisions about and receiving CoolSculpting procedures. Further implications for research include identifying and reconciling gaps in data toward improved practice and learning of the impact and relationship of marketing practices and media to the health outcomes of actual people.

Conclusion

This nursing informed policy brief overviews the insidious policy issue of false, deceptive, and misleading marketing of nonsurgical medical aesthetic devices along with focused background, context, and current regulatory scheme relevant to marketing medical devices and of informed consent in the U.S., critiques viable policy alternatives for addressing the issue, and advances a recommended policy solution of increased formal education for healthcare professionals on recognizing and responding to false, deceptive, and misleading marketing of medical devices through adaptation of an existing awareness and outreach program. The appropriateness of an educational response is further appreciated given the current limited and variable preparation in core nursing curricula—as well as other healthcare professional training programs, in learning about medical device regulation and common regulatory concerns with marketing practices and media encountered and used in everyday clinical practice and beyond. Implications for nursing education, practice, and research are discussed. Notably, the present political climate is favorable for addressing this policy issue: Nurses should leverage this window of opportunity for policy advocacy.

Supplemental Materials

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