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Ethical Challenges With Nonsurgical Medical Aesthetic Devices

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The medical device industry is an incredibly profitable and rapidly growing sector of health care. In plastic surgery, the nonsurgical medical aesthetic device industry presents ongoing ethical challenges, specifically related to the principles of nonmaleficence and respect for autonomy. The purpose of this article is to increase awareness of the ethical challenges the nonsurgical medical aesthetic device industry presents, including use of deceptive or misleading language in advertising, limited evidence of efficacy, and lack of public and professional understanding of the U.S. Food and Drug Administration regulation of medical devices. Practical application of ethics is presented through the lens of the *Code of Ethics for Nurses With Interpretive Statements* (American Nurses Association, 2015) and the *Code of Ethics of the American Society for Aesthetic Plastic Surgery* (American Society for Aesthetic Plastic Surgery, 2017).

The medical device industry is an incredibly profitable and rapidly growing sector of health care. The recent Netflix documentary, *The Bleeding Edge*, reports on the expansion of this industry as a pervasive patient safety issue (Dick, 2018). The film opens with investigative journalist, Jeanne Lenzer, revealing circumstances behind this growing threat to patient safety: "Technology is running away faster than we are keeping up with the actual science" (Dick, 2018). Plastic surgery has seen a similar demonstration, particularly in the last few years, with the nonsurgical medical aesthetic device industry (American Society for Aesthetic Plastic Surgery [ASAPS], 2018). These 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. With rapidly advancing technology, ethics is where health care must turn to for guidance (Dyer, 2001).

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The purpose of this article is to increase awareness of the ethical challenges the nonsurgical medical aesthetic device industry presents, including use of deceptive or misleading language in advertising, limited evidence of efficacy, and lack of public and professional understanding of the U.S. Food and Drug Administration (FDA) regulation of medical devices. Specifically, the ethical principles of nonmaleficence and respect for autonomy are reviewed in the context of the *Code of Ethics for Nurses With Interpretive Statements* (American Nurses Association [ANA], 2015) and the *Code of Ethics of the American Society for Aesthetic Plastic Surgery* (ASAPS, 2017).

MISLEADING OR DECEPTIVE LANGUAGE

Deceptive or misleading marketing tactics are pervasive and have ethical implications related to the principle of respect for autonomy. Alluring promises, such as noninvasive fat reduction that "achieve results in just one treatment—without surgery or downtime" (Cutera, 2017, "What is truSculpt 3D?") are enticing, but these deceptive claims are often unsubstantiated and cite little or no supporting evidence (Aronson, Cole, Ervin, Miller, & Rowan, 2016, Slides 27–30; Nassab, 2015; Swanson, 2013). Overselling with advertising contributes to the commercialization of plastic surgery and negatively impacts informed decision-making (Swanson, 2013). Montemurro, Porcnik, Hedén, and Otte (2015) found that 95% of patients use easily accessible online information concerning the potential benefits and risks accompanying plastic surgery before scheduling a consultation. Moreover, 85% of plastic surgeons believe that online information, specifically forums and blogs, could contribute to patient harm and unrealistic expectations (Montemurro et al., 2015).

Provision 8 of the ANA (2015) *Code of Ethics for Nurses With Interpretive Statements* speaks to the ethical responsibility of nurses to collaborate with both other health professionals and the public to protect human rights, and "Interpretive Statement 8.3" makes specific reference to facilitating informed choice (p. 32). Nahai (2013) calls for a continued dialogue with patients to question sensational claims and misinformation as can be increasingly seen in corporate direct-to-consumer marketing and reaching the public through a variety of mediums. Furthermore, Nahai (2013) strongly encourages health care providers to

use their voice through deliberate actions, such as "refuse to do business with corporations that market branded surgical procedures … [and] encourage the companies with whom we have relationships to engage in responsible advertising" (p. 1070). Plastic and aesthetic nurses should continue to raise awareness of ethical challenges presented by deceptive or misleading advertising: "Public awareness of plastic surgery advertising, in general, is a focus of plastic surgery nursing education in community campaigns" (ANA & American Society for Plastic Surgical Nurses [ASPSN], 2013, p. 16).

Celebrity Endorsement, Trademarking, or Branding Procedures

A recent article published by Smith and George (2018) in the *American Medical Association Journal of Ethics* reviews ethical concerns related to advertising in cosmetic procedures and uses a case example advertised on social media as "Kim Kardashian's Anti-Aging Secret: The Vampire Facelift®!" (para 2). Although not an explicit ethical violation, the use of celebrity endorsements can influence otherwise prudent consumers of health care (Smith & George, 2018). With the rise of social media, "beauty influencers" have entered the scene as a new type of celebrity. Aesthetic practices have been noted to partner with these beauty influencers to trade complementary or heavily discounted services for social media posts (Fashionista, 2018; Sandler, 2018). More "followers" on social media correlate to greater influence and so the opportunity for the purchasing of followers presents yet another dimension of the ethical challenges with deceptive marketing (Canales, 2018).

Marketing of a procedure, "whether or not trademarked," violates the *Code of Ethics for the American Society for Aesthetic Plastic Surgery* if done so to signify unsubstantiated claims of uniqueness (ASAPS, 2017, Section "3.06 Patents, Trademarks and Trade Secrets"). Health care professionals need to be cognizant of their marketing materials and online presence and continuously review for unintentional complacency with deceptive advertising. Nazarian (2017) urges the plastic surgery community to engage with the public through social media to ensure the true experts stay relevant and advance the quality of information online.

LIMITED EVIDENCE OF EFFICACY

Nonsurgical medical aesthetic devices continue to gain in popularity and serve a useful purpose in filling a gap in practice, but many have significant inherent limitations, including lack of long-term safety data and limited evidence of efficacy (Nassab, 2015). In addition, the utilization of many of these devices is for applications other than the specified FDA-approved or cleared indication(s), referred to as *off-label* (Nahai, 2010). An FDA-approved or -cleared indication means that the device meets the FDA criteria for determining its *reasonable safety and effectiveness* for that specific purpose (Center for Devices and Radiological Health [CDRH] & Center for Biologics Evaluation and Research [CBER], 2014, 2016; Center for Drug Evaluation and Research [CDER], CBER, CDRH, Center for Veterinary Medicine [CVM], & Office of the Commissioner [ONC], 2018). Off-label use may include applying the intended use to a different body area, or it may be using the device for an entirely different purpose—either of which may alter the understood safety and effectiveness profile for the device. For example, using CoolSculpting for cold-assisted lipolysis of the knees or chest would be considered off-label because it applies the intended use to a body area other than for which it was cleared (CDRH, 2018). Likewise, an example of off-label use for an entirely different purpose than that described in the cleared or approved indication would be using an energy-based device for nonsurgical vaginal "rejuvenation," as the FDA has never cleared or approved any device for such purpose (FDA, 2018b). Off-label does not include using a medical device that has not been approved or cleared.

These limitations present a unique challenge when conducting informed consent (Braddock, 2013). As such, it is essential for medical professionals to practice evidence-based medicine when considering new technologies and counseling patients on their risks, benefits, and alternatives (Agha & Orgill, 2016). Similarly, it is imperative to follow published evidence-based guidelines for adopting new devices (Thoma, Kaur, Hong, & Li, 2015). In addition, the importance of using the Manufacturer and User Facility Device Experience (MAUDE) reporting mechanism cannot be overstated to ensure prompt recognition and dissemination of any safety concerns with these technologies (FDA, 2018c). Attention to safety reporting most directly relates to the ethical principle of nonmaleficence.

Informed Patient Choice

It is important to note that a device with limited evidence of efficacy and lack of long-term safety data is not in itself the ethical challenge. Provision 1 of the ANA (2015) *Code of Ethics for Nurses With Interpretive Statements*, explicitly emphasizes the ethical principle of respect for autonomy in decision making in the patient right to self-determination (pp. 2–3). It is the ethical obligation of nurses to protect this patient right by ensuring that informed consent is a shared decision-making process. In collaboration with other health professionals, nurses should explore and affirm the patient's preferred method of decision making, ensure that the information provided is sufficient for making an informed decision, and confirm patient

comprehension of information. The critical application of ethics here is that informed consent must represent an *informed* patient choice. An informed choice is predicated on the patient having relevant, factual, and unbiased information. Although specific standards for information disclosure is subject to debate, the necessity of inclusion of known limited evidence of efficacy and lack of long-term safety data is apparent (Rosen, 2010). Likewise, if providers believe on the basis of their professional judgment that consideration for off-label use of a medical device is warranted, it is imperative to uphold the ethical principles of nonmaleficence and respect for autonomy by having sound reasoning and including any proposed off-label use in informed consent conversations (Nahai, 2010).

FDA REGULATION OF MEDICAL DEVICES

The FDA classifies medical devices on the basis of their risk and degree of invasiveness ranging from Class 1 (*minimal risk*) to Class 3 (*high risk*) (FDA, 2018a; "How Are Medical Devices Classified?"). The classification system aids in systematically determining the degree of regulation required to sufficiently demonstrate the safety and effectiveness of medical devices (CDRH & CBER, 2014, pp. 2–3, 39). In general, nonsurgical aesthetic devices are considered Class 2 devices (*moderate risk*) and enter the market through the 510(k) clearance process (Naghshineh et al., 2014). The premarket approval (PMA) and premarket notification (510(k) clearance) are the two general pathways to market entry (Marcus et al., 2016). The PMA is the most rigorous process for medical devices; however, it is less stringent than the required PMA for drugs (Dick, 2018). The 510(k) clearance process was introduced to increase expediency of innovation and allows for new devices to enter the market if they can demonstrate "substantial equivalence" to an "existing legally marketed device," referred to as a *predicate device*. What this means is that a new medical device needs only to demonstrate that it is "at least as safe and effective" as an existing device on the market [legally] by showing it is similar enough in its intended use, fundamental characteristics, and general performance (CDRH & CBER, 2014, pp. 4, 6–7; FDA, 2018d, "What Is Substantial Equivalence"). This relaxed pathway has been challenged with arguments that "releasing untested devices to the market is not innovative" and "ensuring sufficient regulation for patient safety does not stifle innovation" (Dick, 2018, paraphrased from film). Of concern is that a device used as a predicate may be decades old and use technology that may now be considered obsolete (Gottlieb & Shuren, 2018).

The distinction between *FDA-approved* (via PMA) and *FDA-cleared* (510(k) clearance) is important because FDA approval carries a much higher standard of evidence for independently demonstrating "reasonable assurance of safety and effectiveness" of a device than with the 510(k) clearance pathway that relies on comparatively demonstrating "substantial equivalence" to a predicate (CDRH & CBER, 2016, pp. 5–6, 2014, pp. 6–7). However, the misconception of interchangeability of FDA approved and FDA cleared is frequently seen in online publications, general communications, and advertisements for nonsurgical medical aesthetic devices—including major media outlets, general public and patient forums, and plastic surgery practice Web sites (e.g., Fisher, n.d.; Mackenzie, 2018; Nazarian, n.d.; Wagoner, 2018). This chronic misuse of approval versus clearance suggests a widespread misunderstanding of the substantial difference between the two regulatory approval pathways. Intentionally false advertising campaigns purported by aesthetic medical device companies include the use of claims promoting indications other than what the device was approved or cleared for by the FDA (FDA, 2018b; Scalo, 2018). A recent industry advisory document published by the FDA states, "When these communications lack appropriate evidentiary support, they are likely to be false or misleading and can cause patient harm" (CDER, CBER, CDRH, CVM, & ONC, 2018, p. 11). Furthermore, there is a paucity of education on device regulation in medical training (Naghshineh et al., 2014). Ethical standards for informed decision-making necessitate increasing professional understanding of medical device regulation.

The limited extent of regulatory efforts by government agencies is a patient safety and public health education concern, and increasing transparency is crucial for maintaining ethical integrity (Gandhi et al., 2018). In recognizing the noted concerns and current limitations, a recent communication by FDA Commissioner, Scott Gottlieb, MD, and CDRH Director, Jeff Shuren, MD, discusses current efforts to modernize device regulation, specifically the 510(k) clearance pathway beginning with phasing out use of predicate devices that are more than a decade old (Gottlieb & Shuren, 2018). The communication also announces there will be a forthcoming call for public feedback on the matter. The plastic surgery community ought to stay abreast of, and participate in, such happenings at the FDA CDRH: Subscribing to e-mail alerts is an easy way to start (https://www.fda.gov/AboutFDA/ContactFDA/ucm2005606.htm).

CONCLUSION

The nonsurgical medical aesthetic device industry presents ongoing ethical challenges, specifically related to the principles of nonmaleficence and respect for autonomy. The medical community has a responsibility to pay attention and raise general public and professional awareness of the regulation, adoption, and advertising practices of these devices. Nurses have an ethical duty to become

involved in health policy and the development of professional standards (ANA, 2015; ANA & ASPSN, 2013). When the ethical challenges are beyond the influence of professional self-regulation, collaboration with government agencies to encourage enforced regulation is needed (Dyer, 2001).

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