

Commentary

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Regulatory measures when implementing a new medical device into the cosmetic surgery industry. A case example: Macrolane

Gennaro Selvaggi, Anna Elander

Department of Plastic Surgery, Sahlgrenska University Hospital, Gothenburg 40332, Sweden.

Correspondence to: Prof. Gennaro Selvaggi, MD, PhD, Department of Plastic Surgery, Sahlgrenska University Hospital, Gröna Stråket 8, Gothenburg 40332, Sweden. E-mail: selvaggiennaro@yahoo.it

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Abstract

Over the past two decades, the cosmetic surgery industry has experienced significant global growth. This expansion has piqued the interest of healthcare professionals and product manufacturers, both aiming to enhance accessibility to surgery for a broader demographic. This manuscript presents the case example of “macrolane” hyaluronic acid. This product was introduced into the cosmetic surgery industry in 2007 and then removed from the market in 2012 by the manufacturer. The manuscript also presents and discusses the regulatory measures that were enacted following the introduction of macrolane into the European market. Specifically, these regulatory measures involved: insurance, professional qualifications and training, clinician representatives, sanitation, safety, cooling-off periods, informed consent, and advertising. Within the manuscript, it is also highlighted that interests from different stakeholders can create tension in the cosmetic industry, specifically: 1. clients might ask for a product, and they need to be protected; 2. healthcare providers are seeking a profit, and are subject to liability; 3. product’s manufacturers, who are seeking to expand their market, need to pass through regulatory processes. In conclusion, we wish to raise awareness of the ethical issues related to the regulatory measures implemented by European regulatory agencies responsible for public health, especially during the launch of a new product. These ethical considerations encompass several aspects: establishing accountability for validating research authenticity, delineating the functions of compensatory systems, overseeing educational processes, and supervising advertising and marketing practices. It should be noted that the comprehensive exploration of these ethical matters falls outside the scope of this manuscript, as they pertain more to public affairs rather than the realm of cosmetic surgery itself. Therefore, the discourse on these matters is better suited for engagement by experts in political and



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social ethics. Level of Evidence: Level V, analysis of current regulatory practices.

Keywords: Cosmetic surgery, cosmetic medicine, regulation, ethics, macrolane

INTRODUCTION

The “cosmetic surgery industry” has experienced global growth over the past two decades. This term encompasses not only cosmetic surgical procedures but also cosmetic medical interventions, including the injections of fillers and botulin toxin. As to the data provided by the British Association of Aesthetic Plastic Surgeons, 50,122 cosmetic procedures were performed in the UK in 2013; this represented an increase of 17% from 2012^[1]. Also in the UK, the cosmetic surgery industry accumulated £750 million in 2005, £2.3 billion in 2010, and it was forecast to reach £3.6 billion by 2015^[2]. According to the 2013 Keogh Report from the UK Department of Health, socio-economic and technological factors have caused a change in society, with normalization of “serious and potentially harmful cosmetic interventions”; as a consequence, the demand for cosmetic enhancement increased^[3].

In 2017, Griffiths and Mullock^[4] highlighted the risks of poorly regulated cosmetic surgery, especially in countries where the market can offer cheaper surgery, thus becoming accessible to a larger population. Specifically, they were referring to “cosmetic tourism”, emphasizing that many stakeholders are motivated to make surgery accessible to a larger population. Examples of these stakeholders are: manufacturers of products used for cosmetic surgery procedures, organizations that offer cosmetic procedures (such as private clinics), and healthcare professionals (such as physicians and nurse practitioners who perform these procedures). The authors conclude that patients demanding these procedures need to be protected^[4].

This manuscript presents the case example of “macrolane” hyaluronic acid, which was utilized in the cosmetic surgery industry during the period of 2007 to 2012. Additionally, the manuscript discusses and analyzes the regulatory measures that were implemented subsequent to the introduction of macrolane into the European market. Specifically, these regulatory measures involved: insurance, professional qualifications and training, clinician representatives, sanitation, safety, cooling-off periods, informed consent, and advertising.

The interests of different stakeholders can create tension in the cosmetic industry, specifically: clients might ask for a product, and they need to be protected; healthcare providers are seeking a profit and are subject to liability; finally, product manufacturers, who are seeking to expand their market, need to pass through regulatory processes.

In this manuscript, our focus is on regulations. We not only shed light on the interests held by various stakeholders but also delve into the tensions that can arise among them; thus, we pinpoint ethical concerns that hold significance for policy makers as they formulate new policies and regulations.

The scope of this manuscript does not encompass a discussion of these ethical issues. In fact, delving into these matters would venture into the realm of public affairs, rather than focusing solely on cosmetic surgery itself. Therefore, the responsibility of addressing these ethical concerns rests with political and social ethicists.

History of macrolane

The press often reports the introduction of a new cosmetic surgery procedure, especially when a famous person associated with the idea of beauty undergoes it. In the case of macrolane, the award-winning journalist Alice Hart-Davis wrote in *The Guardian* how she received a “ten-minute boob job” in a private clinic in London in 2008^[5]. One year later, the same journalist wrote in the *Daily Mail* how her “30-min boob job” turned into a nightmare. According to her description, she first experienced a complication called capsular contracture and, 1-year later, noticed a lump in her breast. Nevertheless, she admitted having been informed of the risk of complications prior to surgery and was also aware that the use of this product for breast enhancement was new. Despite her original confidence in both the product manufacturer and the physician, the latter article described her as having been treated as a guinea pig, and some of the information received from London clinics was misleading and not supported by adequate scientific evidence^[6].

In 2012, the magazine *Marie Claire* presented an article concerning a ban on the “lunchtime boob job”^[7]. Additionally, Haaron Siddique from *The Guardian* summarized the history of macrolane in order to highlight new approaches by regulatory agencies and government authorities to prevent doctors and clinics from irresponsible advertising and to emphasize the patient consent process following the uncontrolled increase in its use in the cosmetics industry^[8].

Macrolane Volume Restoration Factor (Q-Med AB, Uppsala, Sweden) was a relatively new formulation of injectable - stabilized - hyaluronic acid gel based on non-animal stabilized hyaluronic acid (NASHA) technology. This substance results in the formation of a molecular network that stays biocompatible with the endogenous hyaluronic acid for a long time^[9]. The use of NASHA-based gel for facial aesthetics is an established procedure with no associated safety concerns^[10]. To date, the use of NASHA-based gel is diffused worldwide, with more than 10 million in the fields of aesthetics, osteoarthritis, and urology.

Macrolane Volume Restoration Factor was authorized first in France in 2007^[11]; one year later, despite the lack of available studies and the low level of scientific evidence, the European agency authorized its use for breast augmentation as well^[12]. At that time, only pilot studies^[10,13,14] with a low grade of evidence, and thus with minimal or no scientific validity, were available; these studies were conducted internally by the manufacturer, involving only a small number of patients and having short-term follow-ups; notably, there were no clinical trials evaluating the safety of the product for breast enhancement^[15].

Despite the absence of clinical evidence, in the period 2008 - 2012, the manufacturer’s website promoted the use of macrolane in 17 countries in Europe and Asia. Although the indication to use this product was limited to scar reduction and correction of contour deformities following liposuction, it was also marketed for other purposes, such as buttock and breast augmentations and calf shaping. In the case of breast enhancement, macrolane manufacturers targeted a new market population: women seeking “minor” breast size increases, thus refusing conventional surgical augmentation with breast implants.

Due to the nature of the substance being classified as a medical product necessitating minor surgery for its insertion into the body, its purchase and usage were restricted only to physicians. Although being used by healthcare professionals, this product gave rise to many complications, such as (hard) scar formation and pain in the injected area, localized infection, and displacement of the substance. Moreover, radiologists highlighted that it is more difficult to make a diagnosis of breast cancer in those patients who had the breast injected with macrolane^[16-18]. Thus, following the concerns associated with mammographies and the alerts from Health Departments and national professional associations in several European countries, in 2012, the

manufacturer removed macrolane from the market.

The company manufacturing macrolane

Q-Med AB was founded in 1987 in Uppsala, Sweden, by Bengt Ågerup in order to commercialize his research associated with hyaluronic acid. In 2011, Q-Med AB was purchased by Galderma UK & Ireland, and in 2014, Nestlé Skin Health was founded, and ownership of Galderma UK & Ireland transferred to Nestlé S.A. (Vevey, Switzerland).

Review of the scientific literature concerning macrolane

The first article evaluating the role of macrolane in breast surgery was published by Inami *et al.* in the *Japanese Journal of Plastic and Reconstructive Surgery* (2006)^[19]; unfortunately, this article and journal are not currently accessible, and their findings were not available outside of Japan^[15]. Five years later (2011), macrolane use for breast enhancement was described by Heden *et al.*^[10]; these same authors were also employed by Q-Med as consultants. In their trials on 24 patients, 69% experienced complications, such as capsular contracture, breast tenderness, and filler visibility and displacement. Soon after this report, another study^[20] noted the high rate of complications following macrolane injections, and difficulty in detecting malignancies at mammogram examinations^[15,20,21]. More specifically, Grippaudo *et al.* described lump formations within the breast tissue following the use of macrolane; they also emphasized the role of different imaging systems^[21].

In 2015, Trignano *et al.* published the results of trials involving 20 women presenting for augmentation mammoplasty and diagnosed with intramammary and intramuscular cysts of hyaluronic acid following previous macrolane treatment^[11]. All these patients underwent surgical evacuation of the hyaluronic acid-based cysts at the time of the breast augmentation with conventional implants.

The largest report was presented by Ishii and Sakata^[19]: in their study, macrolane was used for breast enhancement in about 4,000 women with breast asymmetry. Despite the small amounts (30-40 mL) of the injected substance, patients reported complications such as infection, migration, and nodule formation^[18,21]. No long-term follow-up has been reported.

Macrolane has also been used for increasing volume and for contouring other body parts, such as the buttocks area (for cosmetic enhancement)^[22], different body areas following human immunodeficiency virus treatment^[23], for correction of contour defects following liposuction^[24], penis enlargement^[25], pectus excavatum^[26], and hand augmentation^[27]. Other studies also reported complications^[16], such as infection, capsular contraction, skin necrosis, pain, swelling, and cellulitis, following calf injections^[28]. Immediate and 6-month follow-up results after macrolane use in these areas appear to be mostly positive; however, there are no long-term follow-up studies, and there is no evidence regarding the outcomes of repeated injections over multiple years. Therefore, the quality of the evidence associated with these articles is considered low.

MEASURES TAKEN BY REGULATORY AGENCIES

This section presents the measures taken by the regulatory agencies to stop the use of macrolane in the UK and Europe.

The difference between the approaches adopted by the US Food and Drug Administration (FDA) and the European regulatory agencies, specifically for products used in breast augmentation, are highlighted. Finally, the different domains that are pertinent to the cosmetic surgery industry and that require regulations are discussed.

Measures by regulatory agencies to stop the use of macrolane in the UK and Europe

Chaput *et al.* summarized the history of macrolane in France. On August 26, 2011, by applying the precautionary principle associated with article 14b of European Directive 93/42/EEC, the “Agence Française de Sécurité Sanitaire des Produits de Santé” (AFSSAPS) banned macrolane for breast augmentation^[29]. This decision followed four main arguments against the “fat grafting” into the breast tissue^[30]: (1) the repetition of an invasive procedure into the breast tissue might cause inflammation, with increased risk for breast cancer; (2) macrolane injection might cause the formation of nodules which could interfere with clinical examinations; (3) these nodules might interfere with the interpretation of imaging exams, thus delaying the diagnosis of breast disease; and (4) screening and early diagnosis of breast cancer, in many countries, is a public health priority^[29-33].

In the UK, the use of macrolane was forbidden with a Medical Device Alert released by the Medicine and Healthcare Products Regulatory Agency, an executive agency of the UK Department of Health, in April 2012. The reason for this alert was related to the impossibility of differentiating between cancer and scar-tissue formation around the macrolane at mammography examination^[16].

National professional associations of plastic surgeons from Italy and Sweden (personal knowledge of the GS, author of the manuscript and member of both SICPRE - Italian Society of Plastic Surgery, and SPKF-Svenska Plastik Kirurgi Förening) soon followed France and the UK in alerting members to stop using macrolane. Since that same year, the manufacturer removed macrolane from the market, and no additional action was required by other regulatory agencies from other countries.

Products for breast augmentation: FDA vs. European regulatory agencies

McCleave^[34] summarized the regulation of products for breast augmentation and emphasized differences between the FDA and other European regulatory agencies. In 2006, macrolane was approved for use in Europe as a soft-tissue filler, based on the research data available, which were limited to the use of hyaluronic acids in facial aesthetic surgery. In Europe, approval of a new implantable medical device is under the competence of the Conformité Européenne (CE) mark, whereas in the UK, approvals are under the competence of the Medicines and Healthcare Products Regulatory Agency (MHRA). However, if a device had already been approved by the CE, it could still be introduced into the UK market^[34].

On the opposite, the American FDA never approved the use of macrolane for the US market. In fact, FDA can authorize a new implantable medical product only after clinical trials^[35].

Macrolane is not the only product of its kind authorized in this way; in fact, there are examples of other breast augmentation products that were authorized for use, despite the limited amount of clinical data supporting the specific product safety. These include Trilucent (soybean-oil-filled) breast implants and hydrogel breast implants. Between 1995 and 1999, 9,000 Trilucent implants were implanted in almost 5,000 women in the UK (mhra.gov.uk); following concerns that the soybean-oil filler could degrade into a genotoxic carcinogen, thus causing severe inflammation upon implant rupture, the MHRA banned Trilucent implants in the UK and recommended its explantation^[36]. Similar to macrolane, Trilucent implants were also never approved by the FDA. In 1994, hydrogel breast implants were introduced to the UK market. The implants consisted of a silicone shell that contained a hydrogel filler with the ability to swell and retain water within its structures. In the period 1996 - 2000, approximately 4,000 women received hydrogel breast implants in the UK; in 2000, MHRA reviewed that the biological safety assessment of this product by the manufacturer was inadequate (lack of long-term toxicity data, lack of clinical follow-up, methodological flaws in some of the preclinical tests); thus, MHRA published a device alert [2000 (07) and DA 2000 (08)]; devices were immediately withdrawn, and the CE marking for these implants was

later (2002) deleted (mhra.gov.uk).

The fact that the macrolane authorization came after the other two events shows that the European regulatory standard did not improve since previous negative experiences with implants^[34].

Following analysis of product licensing for entry to the European market, McCleave^[34] concluded, 2 years before macrolane was banned, that clinicians should seriously assess the scientific literature behind this product and then decide whether to use it in clinical practice.

Domains pertinent to the cosmetic surgery industry that are requiring regulations

1. Insurance: In order to maintain privileges to practice in private hospitals, most European surgeons must hold professional indemnity insurance for practicing plastic and reconstructive surgery. Keogh^[3] argued that professional indemnity coverage should cover not only surgical complications but also product failures^[3]; according to Latham^[37], this insurance should cover the care provided by the National Health Service, if required.

2. Professional qualifications and training: It remains controversial who should qualify to perform cosmetic surgical and medical treatments. Traditionally, cosmetic surgeries are performed by plastic surgeons; nevertheless, many other specialists (otolaryngologists, maxillofacial surgeons, ophthalmologists, general and breast surgeons, and dermatologists) might perform cosmetic surgeries, regardless whether they took, or not, specific courses in cosmetic surgery. Similarly, in countries such as the UK and Sweden, nurses and dentists are allowed to perform cosmetic fillers, whereas in Italy and France, nurses are not.

As said, physicians and practitioners might perform cosmetic surgery and medicine without hands-on training. Teaching programs should include hands-on, supervised training, and continuous medical education should be required; it is an open question whether this should be monitored by the regulation authority. A special case is when a new procedure or a new product enters the market, the regulation authority is not aware of its properties and use and, therefore, might not require the practitioners to undergo specific training prior to using the product. On the other hand, clinics might require practitioners to provide proof of specific training before granting them the privilege to perform specific procedures; however, this might not be the case for all clinics.

3. Clinician representatives: Patients often meet clinician representatives before the surgical practitioner. In some clinics, these representatives might be nurses, whereas in others, they might not be medically qualified, but rather simply have a background in sales. In any case, the role of such representatives can be extended to discussing the procedure, recommending an operation (e.g., implant size for breast augmentation), providing logistical information, offering discounts, and booking surgery. These representatives affect the decision-making process in terms of both economic and medical decisions. It is an open question whether the role of the clinician representative should be regulated or whether their responsibilities fall under the clinic or the physician with whom they work.

4. Sanitation, safety, and registration: Sanitation is required to avoid infections; therefore, any cosmetic surgery must take place in surgical facilities appropriately equipped with technological instruments, including provisions for data collection for patient status, treatment, and satisfaction. Moreover, licenses associated with these aspects must be renewable^[37]. These are currently considered minor issues in higher-income countries, given that several authorities from relevant health departments are specifically tasked with this type of oversight. However, concerns remain for patients traveling for medical tourism^[4] and

mostly to countries in economic transition, where sanitation and safety standards are not monitored and, therefore, might not be commensurate with those in higher-income countries. Procedure- and product-specific registries can also be used. In Western countries, many registries currently exist for many diseases and procedures (e.g., diabetes), with most European nations and the United States maintaining a breast implant registry. This also represents an issue for patients traveling and undergoing procedures in countries in transition.

5. Cooling-off period and informed consent: In France, the Kouchner law obliges the use of informed consent: “Under Article L 6322-2 of the Public Health Code, each patient seeking cosmetic surgery must be informed by the surgeon on the risks, future consequences, and complications, no matter how unlikely or insignificant”; this should include both medical and social inconveniences associated with cosmetic surgery^[37]. Also in France, a 15-day cooling-off period before surgery or cosmetic medicine is mandatory. This allows patients additional time to comprehend and contemplate the information received, such as risks and costs involved, and eventually to consult with the surgeon again, if required^[37]. In the UK, written informed consent is also an essential and compulsory element of the discussion between surgeons and patients; it aims to guarantee that both patient and practitioner understand and agree on the desired outcomes, as well as the risks and limitations of the procedure^[3]. Along with the informed consent, standardized patient information needs to be developed and provided.

6. Advertising: In France, the Kouchner law regulates advertising to the point that, in specific situations, a practitioner’s license could be revoked^[37]. In the UK, the Advertising Standards Authority requires advertisements to be prepared responsibly, and not be misleading, harmful, or offensive^[37]. Similarly, Keogh^[3] recommends forbidding financial inducements and time-limited deals, in order to protect vulnerable patients.

7. Prescription-only medical devices: It is a matter of discussion whether a specific medical device, such as a filler, should be reclassified as “prescription-only”. In the UK, Keogh^[3] argued for the need for extensive regulations on cosmetic medicine: the EU Medical Devices Directive should include dermal fillers within their regulations, and fillers should be reclassified as prescription-only medical devices.

TENSIONS WITHIN THE COSMETIC SURGERY INDUSTRY: PATIENT REQUESTS, MEDICAL TOURISM, AND PRODUCT QUALITY

According to Griffiths and Mullock^[4], the accessibility of cosmetic surgery to a larger population contributes to the normalization of surgical enhancement; as a consequence, this creates a cultural pressure that is pushing a larger part of the population to take risks for beauty enhancement purposes. Latham^[37] highlights that (social) media, advertising, and celebrity endorsement contributed to this normalization. Keogh^[3] emphasized that cosmetic surgery “once was undertaken discreetly now is celebrated, [but] now many more people will admit to it and even celebrate it”.

The cosmetic surgery industry is then driven by demands for cheaper surgeries and accessibility to a larger population^[4]. Examples include medical tourism and the utilization of cheaper products. These above are related: in fact, a specific product or procedure, which might not be allowed or might be more expensive in one country, can be found (cheaper) abroad. Regulations need to address both of these issues.

Griffiths and Mullock^[4] would primarily advise global regulation; however, since this is unlikely to happen, they suggest reinforcing domestic ones.

Introducing new products for cosmetic surgery (such as macrolane) into the market is a representative case example of the tension among different stakeholders within the cosmetic surgery industry. These stakeholders include manufacturers, healthcare providers, and clients/patients. This tension is currently recognized by government authorities and regulatory agencies, which are obliged to protect citizens as potential clients of this market.

RAISING AWARENESS OF ETHICAL ISSUES

Although government authorities and regulatory agencies evaluate such market and health issues, a number of ethical issues must also be considered and are presented here with regard to health issues and the associated regulations already enforced by some government authorities. The intention of this manuscript is not to provide answers to these ethical issues; instead, it serves as an informational foundation and an articulation of these ethical issues, which can be submitted to political and societal ethicists for their thoughtful deliberation.

Responsibility to verify the validity of scientific research

For a given medical product, appropriate scientific research is required; this should span from pre- to post-clinical trials and sometimes also involve animal studies. Who is responsible for ensuring that a specific product has passed all screening tests, which are required before the product can be sold and used by healthcare professionals? In the event of adverse outcomes, are manufacturers, regulatory agencies, and healthcare professionals equally responsible? Or does the responsibility specifically lie with one of them?

Insurance and compensation

Keogh^[3] suggests insurance as one method for regulating the cosmetic surgery industry. However, it remains unclear how professional indemnity insurance could represent a regulatory method. On what ethical ground would a healthcare professional be obliged to pay for insurance? In Scandinavian countries, physicians are not obligated to hold professional indemnity insurance, and, typically, physicians are not sued in a court of law; instead, cases involving physicians can be brought to the attention of the IVO (The Health and Social Care Inspectorate), a specific agency under the Swedish Department of Health; thus, when a patient suffering from damage due to suspected malpractice, they can directly seek compensation from the government authority, which will be responsible for its disbursement. Differently, in most Western countries, patients can sue physicians or clinics and directly ask them for compensation.

Some patients might hold their own private health insurance. What is its role? Who should compensate for the unforeseen economic loss incurred by the patient?

A comparison could be made between someone experiencing damage following cosmetic surgery and someone experiencing adverse side effects following other (risky) actions and behaviors, such as travel, sports activities, or substance abuse (including alcohol and an unhealthy diet). The question arises: should private insurance cover or not cover the aftermath of a sports-related injury sustained during travel, while simultaneously refusing coverage for the adverse effects following cosmetic surgery during (or not) travel?

Finally, to what extent does the existence of professional insurance contribute to the growth of a more litigious culture in the healthcare field^[38]? Does the existence of professional insurance create a defensive type of medicine? Moreover, how does a defensive type of medicine affect healthcare costs? Indeed, further discussions extending to politics, society, and healthcare are required to answer these questions, and several theories of justice concerning healthcare distribution could be introduced.

Education

Do healthcare professionals have access to up-to-date, hands-on training during their education, and later, is their continuous medical education facilitated and monitored? Do healthcare professionals have easy access to appropriate scientific information associated with highly accurate evidence-based data? How should healthcare professionals act in cases where there is only limited evidence on a specific procedure or product? Finally, how often are healthcare professionals misinformed by manufacturers, and how can such misinformation be regulated and monitored?

Cooling-off period

A cooling-off period of 2 weeks prior to a cosmetic surgical procedure is frequently suggested; however, on what evidence is this suggestion based? Is this period necessary for all patients (i.e., those having already spent extended time considering the possible outcomes and either unwilling or unable to wait)?

Informed consent

What risks need to be addressed as part of the informed consent? More specifically, should the informed consent include those complications that are more common but not life-threatening? Should it (also) include those complications that are less frequent but life-threatening? What should the minimum age of consent for cosmetic procedures be, and why^[39]?

Advertising

What regulatory procedures are necessary for the (aggressive) advertisement of medical devices or other potentially harmful products, such as high-sugar drinks, high-cholesterol foods, and alcohol? Is there coordination between agencies regulating advertisements and agencies regulating healthcare? Are the agencies regulating advertisements controlling the different platforms for advertisements, such as social media like (old) Facebook, Instagram, TikTok applications, etc.?

Market

Prices for healthcare services are not always fixed, and cosmetic surgery patients often request discounts; thus, they might base their decision on differences in cost between providers. Should financial inducement be restricted? Should the price for a specific procedure be regulated?

LIMITATIONS

In this commentary manuscript, we review the history of Macrolane as a case example to elucidate some of the regulatory measures required for implementing a new medical product into the cosmetic surgery industry. We highlight the tension created by the interests of the different stakeholders involved, and, finally, we formulate ethical issues related to the regulatory measures that have been initiated by the European regulatory agencies.

The first limitation of this manuscript could be represented by the manuscript's references, which are often older than 10 years; this is because these references are related to the period when macrolane was used. Nevertheless, the regulatory issues are still contemporary for any new device introduced to the healthcare market, and no scientific paper, to date, has ever raised awareness of the ethical issues following the new regulatory measures.

A second limitation is that the illustrated regulatory measures are related to the European regulatory agency, following the approval of the product into the same European market, thus not consistent with other worldwide markets, for example, the American one; in fact, macrolane (and Trilucent implants) was never approved by the FDA, which required more extended clinical trials.

A third limitation is that ethical issues are related to the context in which these are raised. This dependence on local regulations and culture means that ethical issues can vary significantly. Nevertheless, this manuscript offers a robust array of ethical topics for political and social scientists worldwide to engage in discussions.

The strength of this manuscript lies in its broad appeal, capturing the interest of not only plastic surgeons and healthcare professionals engaged in the cosmetic surgery industry, but also healthcare product manufacturers, as well as political and social scientists. Thus, the manuscript is written in the format of a Commentary -in accordance with the Editor's guidelines, which aligns well with the subject matter and the target audience.

CONCLUSION

This manuscript presents a case example of "macrolane" hyaluronic acid, which was used by the cosmetic surgery industry from 2007 to 2012.

Interests from different stakeholders can create tension in the cosmetic industry. Government authorities and their agencies, which oversee public health, as well as marketing regulations, are facing the difficult task of regulating processes that span from the manufacturing of such products, their delivery, and the quality of the surgical results, in order to ensure the best outcomes for clients or patients.

By building upon the existing regulations, we have heightened awareness of the ethical issues associated with regulatory measures initiated by some of the European regulatory agencies overseeing public health during the launch of a new product. These ethical issues comprise: establishing clear accountability for validating research validity, delineating the functions of compensatory systems, overseeing the requisite educational processes for providers, setting guidelines for the timing of surgical and medical interventions, outlining protocols for obtaining informed consent, and ultimately, governing advertising and marketing practices.

The ethical issues presented herein constitute topics that political and societal ethicists can deliberate on to provide guidance to policy makers aiming to enhance healthcare regulations.

DECLARATIONS

Authors' contributions

Contributed via the conception and design of the study, and manuscript writing: Selvaggi G, Elander A

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Conflicts of interest

All authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

Not applicable.

Consent for publication

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