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Cosm*ethics*: the ethics and law of cosmetics. An interdisciplinary inquiry

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Cosm*ethics*: the ethics and law of cosmetics. An interdisciplinary inquiry

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ABSTRACT: The controversies over the distribution, manufacturing and sale of cosmetics have secured a seat in the worldwide debate with respect to ethical implications concerning such chemical compounds. The cosmetic industry counts multinational corporations devolving the production of their products to smaller businesses, thereby raising the issue of transparency in the supply chain, leaving the consumers with just a packaging and a list of ingredients; for this reason, the essay will expound on the laws regarding information requirements. The legal dimension, in particular consumer protection, will accompany the analysis of the world of cosmetics for the whole discourse. In this regard, the legislative framework is represented by diverse instruments of European Union law, but considerations out of the EU system will be introduced. In assessing the European regulatory framework, an interesting insight on how the Court of Justice of the European Union manages to deliberate on bioethical matters will be provided. An interdisciplinary perspective is crucial to explore the issue in a complete manner, and to spark interest from a variety of standpoints. Subsequently, the inquiry will evolve as to comprehend analysis on: (i) animal testing in the cosmetic factory and correlated alternatives, (ii) the issue of toxic ingredients contained in personal grooming products, and the provocative – open – question as to (iii) whether cosmetics may replace some specific medical treatments.

KEYWORDS: Cosmetics factory; bioethical assessment; consumer protection; toxicity; health safety

SUMMARY: 1. Introduction – 2. EU Legislation: Legal Basis to the Acts or to Bio-Ethical Assessment of Cosmetics? – 3. Cosmetics and Consumer Protection: EU vs. U.S Laws. – 4. Animal Testing and Alternatives – 5. Toxic Ingredients in Cosmetics – 6. May cosmetics replace pharmaceutical products? The cases of second skin and Body Dysmorphic Disorder (BDD) – 7. Concluding Remarks

1. Introduction

Cataloguing cosmetic products, from deodorants or make-up, to toothpastes and sunscreen, makes us reasonably think that they have both an essential function and an emotional impact for consumers' lives, as to encourage one's self-confidence, to improve well-being or for personal care. Notwithstanding, cleansing or beautifying should not harm human health. This paper consists of a personal research in the field and will give insight on the controversies around the world of cosmetics. Our path into this realm will tackle multiple issues and discussions, such as implications on consumer protection and labelling, animal testing and toxic ingredients, and considerations on the possible replacement of pharmaceutical products with cosmetics will be examined too. At the outset of our voyage, a brief economic overview is provided, in order to introduce the European Regulation 1223/2009[1], which will accompany us during the whole discourse. Assumed the fundamental role played by practices of personal grooming, it is not surprise that the European cosmetics

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[1] Regulation (EC) No 1223/2009 of the European Parliament and of the Council (2009) on cosmetic products, OJ L 342, 22.12.2009, p. 59–209, 30 November. Also "The Cosmetic Regulation", to which I will refer as "CR" in some passages.

market is immense, actually the largest in the world, valued at 78.6 billion at final sales price in 2018[2]. Germany placed at the first place, with a consumption valued at approximately 13.80 billion euros, followed by France (11.39 billion euros), the U.K. (10.94 billion euros) and Italy (10.15 billion euros)[3]. With this in mind, it appears appropriate to assert that the cosmetics industry exhibits an ever-growing boost in European markets; as a consequence, intervention from the European Union could not miss.

2. EU Legislation: Legal Basis to the Acts or to Bio-Ethical Assessment of Cosmetics?

On the basis of the functioning of the Single Market, the EU spoke up in the field of cosmetics. Firstly in 1976, with Council Directive 76/768/EEC[4], the European Communities pondered to harmonize domestic cosmetic legislation to enhance free circulation of goods; then, after several amendments to the Directive, the European Union reassessed the legal framework and enacted Regulation 1223/2009, the Cosmetic Regulation (CR), fully effective since 11 July 2013. On the same date, the Commission Common Criteria Regulation 655/2013[5] entered into force, marking the operationalization of Article 20(2)[6] of the CR, therefore fixing common criteria to justify a cosmetic claim.

The legal basis of the Cosmetic Regulation relies on Article 114 of the Treaty on the Functioning of the European Union (TFEU)[7], which confers upon the Union the competence to enact measures for the full harmonization of national rules with respect to the establishing and functioning of the European Single Market[8], in accordance with Article 26(1)[9] of the same treaty. In our case, the legal basis founded on Article 114 of the TFEU is complemented by Article 169 TFEU, on health, safety and safeguard of consumers'

[2] Source: *Cosmetic and Personal Care Industry Overview. Economic Overview*. https://cosmeticseurope.eu/cosmetics-industry/ (last access on 22/04/2020)

[3] Source: *Statista*, available at https://www.statista.com/statistics/382100/european-cosmetics-market-volume-by-country/ (last access on 22/04/2020)

[4] Council Directive 76/768/EEC of (1976) on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, p. 169–200, 27 July.

[5] Commission Regulation (EU) No 655/2013 (2013) laying down common criteria for the justification of claims used in relation to cosmetic products, OJ L 190, 11.7.2013, p. 31–34, 10 July.

[6] Article 20(2) of the Cosmetic Regulation – «*The Commission shall, in cooperation with Member States, establish an action plan regarding claims used and fix priorities for determining common criteria justifying the use of a claim.* »

[7] European Union, *Consolidated Version of the Treaty on the Functioning of the European Union*, O J C-202/1, 2012, pp. 1-390, 26-10-2012.

[8] Article 114(1) TFEU – «*[…]The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.*»

[9] Article 26(1) TFEU – «*The Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties.* »

interest[10], whose purposes are to be achieved precisely through the enactment of full harmonization regulations[11] pursuant to Article 114 TFEU.

What is relevant from a bioethical, as well as juridical, point of view is how the following antithesis is handled: on the one hand, there are the lexicon and grammar of life sciences, which are juxtaposed with EU law on the other hand. Such interaction rests on a synergistic, and officious, relationship, which aims at ultimately abating the frontier between bioethics and law. Accordingly, the question on how Union law manages to regulate the relation between the bioethical dimension and law sparks interest. A primary intuition on what the perfect vehicle for the EU to walk into the discipline of bioethical matters would designate Article 168 of the TFEU on public health as essential, because it precisely states that «*a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*»[12]. Notwithstanding, it is not so, and paradoxically enough, the European Single Market stole the spotlight another time, crowning Article 114 the leading vector for our supranational organization to have a say in the bio-realm. Our two dimensions exist in a paradoxical and intertwined relationship: the protection of human health as enshrined by Article 168 of the TFEU is of direct relevance for disciplining life sciences and biolaw matters, but, with further analysis, the legal efficacy of Article 168 TFEU is seen as a weak tool. On the contrary, the decisions at European Union level based on the harmonization of measures for the efficient functioning of the European Single Market ultimately exert a strong influence in the field. Not surprisingly, the role of the Court of Justice of the European Union (CJEU) is always careful in non-overstretching its competences, in the sense that a pronouncement would never tackle ethical or moral factors. In this respect, a significant example in the context of cosmetics is the reinforcing approach of the Court in defining a cosmetic product: already in 1976, with the Cosmetic Directive, the European legislator made it clear that a cosmetic product be any substance meant to get in contact with external parts of the human body, teeth or mucous membranes, for the sole purpose of cleaning, perfuming, protecting them, change their appearance, or correct body odours[13]. In 1991, the Court faced a preliminary question[14] as to reason on the difference

[10] Article 169(1) TFEU – «*In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests*».

[11] Article 169(2)(a) TFEU – «*The Union shall contribute to the attainment of the objectives referred to in paragraph 1 through: (a) measures adopted pursuant to Article 114 in the context of the completion of the internal market.* »

[12] Article 168(1) TFEU, more precisely mandates the EU to take action which «*shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.*

[13] Article 1(1) of Directive 76/768 (Cosmetic Directive) – «*A "cosmetic product" means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.*

[14] Judgment of the Court of 16 April 1991, Upjohn Company and Upjohn NV v Farzoo Inc. and J. Kortmann (C-112/89) Reference for a preliminary ruling: Hoge Raas – Netherlands, EU:C:1991:147

between a cosmetic product and a medicinal product; and it precisely re-stated the definition laid down in the Directive, proving that it needed no specifications. Moreover, under the guises of guardian of consumers and of the Internal Market, the CJEU nonetheless found it undoubtedly vital to stress the importance of the relevance of such products in relation to public health, asserting that the provisions governing medicinal products are stricter than those regulating cosmetics, and as such, the former may enclose particular risks which may not be displayed by the latter[15]. To stress the coherent development of case law, a more recent judgment[16] refers again to the very same definition, and testifies the Court's reliance on the effectiveness of the definition of cosmetic of 1976, which also survived the repeal of Directive 78/768 and was re-inserted in Article 2(1)(a) of the Cosmetic Regulation. To sum up, the European Union does touch upon bio-juridical matters, insofar as it has competence over a specific sector, on the basis of providing an adequate functioning for the Single Market, which requires a major regulatory work, and this goes hand in hand with the European disclosure as far as bioethics are concerned.

Turning our attention, it has proved to be efficient to propose an interesting dialogical comparison between the regulatory framework in the field of cosmetics provided by the European Union as opposed to the United States' one, which represents a valid contrasting regime.

3. Cosmetics and Consumer Protection: EU vs. U.S. Laws.

This section will concentrate on the illustration of the two different normative frameworks, confronting the Cosmetic Regulation on the one hand, antagonized by the U.S. Federal Food Drug and Cosmetic Act of 1938 and the Fair Packaging and Labelling Act of 1967 on the other side, with a view to jurisprudential development particularly concerning cases on misleading advertising for cosmetic products, including an insight of the Italian framework on the matter[17].

Despite the numerous amendments, the Cosmetic Directive of 1976 proved to be effective, therefore, the Cosmetic Regulation's essential purposes insist on what had been laid down previously. No crucial changes had occurred, with particular respect to the allocation of responsibility along the supply chain. In fact, the Regulation confirms the role of responsibility, making it mandatory for a business to designate a *responsible person*, in charge above all of guaranteeing safety and quality of products, submitting the EU Commission

[15] Paragraph 31 of the Decision *Upjohn Company and Upjohn NY v Farzoo Inc. and J. Kortmann* (Case C-112/89).

[16] Judgment of the Court of 2 September 2015, Colena AG v Karnevalservice Bastian GmbH (C-321/14) – Reference for a Preliminary Ruling: Landgericht Krefeld – EU:C:2015:540.

[17] For the purposes of this paper, the inquiry will concentrate on misleading claims in the field of cosmetics, because it exhibits a new turning point in the development of European jurisprudence.

information about them, and cooperating with national competent authorities to survey the market and assure correct enforcement of Union law[18].

In the United States, the regulatory framework is based on the Federal Food Drug and Cosmetic Act (FFDCA, FDCA or FD&C), bestowing upon the Food and Drug Administration (FDA)[19] the authority to monitor the safety of medical devices, drugs, and cosmetics. The other instrument is represented by the Fair Packaging and Labelling Act (FPLA), which regulates the labelling.

The next paragraph will deal with information, and how the European Union and the United States regulate the issue, broadening the discourse also to safety assessments.

As regards the European regulatory framework, the relevant provisions are Articles 19, 20 and 21 of the Cosmetic Regulation. First of all, information must be provided in an indelible, easily legible and visible lettering, displaying also the name and address of the responsible person. In addition, a cosmetic product shall not harm health or safety of consumers, not in its form, odour, colour, appearance, packaging, labelling, volume or size, pursuant also to EU Directive concerning products which may endanger health by appearing other than they are[20]. As far as cosmetic ingredients are concerned, transparency is vital; thus, the packaging of the final product shall include a list of ingredients; in particular, substances which might cause allergic reactions shall be properly mentioned as to catch consumers' attention. Moreover, the consumer shall be provided with precise indications on the durability of use, that is, information on the date until which the cosmetic will continue to fulfil its initial function and remain safe. Furthermore, customers shall be protected from misleading claims concerning the efficacy or other characteristics of the product, with reference to the European Directive on unfair commercial practices on the part of businesses in relation to consumers[21] and the Common Criteria Regulation (655/2013). In this regard, one may raise the following question: but how can the European Union ensure protection from misleading information, when companies usually avail of hyperbolic claims?

What appears to perfectly suit the answer is the already mentioned Common Criteria Regulation, which lays out criteria to justify a cosmetic claim, namely: (i) legal compliance, (ii) truthfulness, (iii) evidential support, (iv) honesty, (v) fairness, and (vi) informed decision making[22]. Accordingly, claims must be authorized by competent authorities; truth must underlie the statement of properties of products and ingredients, complemented by verifiable evidence, comprising valid, reliable and reproduceable methodologies, while

[18] As laid down in Article 5 of the Cosmetic Regulation: "Obligations of Responsible Persons".

[19] A federal agency responsible for protecting public health, by ensuring safety, efficacy, security of drugs, biological products and medical devices. It also ensures safety with regard to U.S. food supply, cosmetics and tobacco products. Source: official website available at: https://www.fda.gov/ (last access on 17/05/2020).

[20] Council Directive 87/357/EEC (1987) on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers, OJ L 192, 11.7.1987, p. 49–50, 25 June.

[21] Directive 2005/29/EC of the European Parliament and of the Council (2005), Concerning Unfair Business-To-Consumer Commercial Practices in The Internal Market, ('Unfair Commercial Practices Directive') OJ L 129/22, 11.6.2005, pp 22-39, 11 May.

[22] Annex to the Common Criteria Regulation 655/2013.

respecting ethical considerations; claims must be honest and fair, that is, they must be objective, must describe product's efficacy not beyond evidence and must not denigrate competitors; lastly, claims must be clear, precise, and understandable to the average consumer.

On the other side of the ocean, the FPLA's primary aim is to assist consumers to prevent unfair or deceptive packaging and labelling. It directs the Federal Trade Commission[23] and the Food and Drug Administration to require a proper labelling of cosmetics, so that producers must disclose the subsequent basic information: the identity of commodity, net contents and name and place of business of the product's manufacturer, packer, or distributor[24]. Further additional regulations are authorized in case of necessity, for instance, to prevent consumer deception in relation to ingredients, for characterization of package sizes or for non-functional slack fill[25] of packages. The noncompliance with this last point may amount to a violation of the FD&C Act as well, precisely with regard to "misbranded product". In fact, turning our discourse to the other important Cosmetic Act in the U.S., it prohibits interstate commerce of misbranded or adulterated products. Misbranding is the violation concerning misleading labelling or deceptive packaging, as well as failure to provide material facts on safe use and warning[26]. Adulteration instead is the violation involving product composition, thus concerning ingredients, contaminants, processing, packaging, shipping or handling; so, products which contain poisonous, filthy, putrid, decomposed substances, which are prepared, packed or held under insanitary conditions or whose container is composed of substances injurious to health fall within this category[27].

Contrary to EU legislation, as far as safety assessments are concerned, companies or manufacturers in the field of cosmetics have no legal obligation to disclose their safety information with the FDA, nor there are any laws requiring specific tests with respect to products or ingredients; hence, responsibility does not amount to a heavy burden in the United States. As a matter of fact, the FD&C Act confers upon the FDA virtually no authority to assess safety of cosmetics, which, notwithstanding, manages to regulate these products. For instance, it has the duty to examine and approve drugs: this implies an attentive surveillance on products such as sunscreens or anti-ageing serums, because they are contemplated under the umbrella of drugs as determined by Section 201(g)[28] of the FD&C Act. From this perspective, the rhetoric used by the

[23] A federal agency established in 1914 by the Federal Trade Commission Act. Its mission is to protect consumers and competition, thus preventing anticompetitive, deceptive, and unfair business practices. Source: official website available at https://www.ftc.gov/.

[24] Pursuant to Title 16, Chapter I, Subchapter E, Part 500 *Regulations Under Section 4 of the Fair Packaging and Labelling Act.*

[25] Non-functional slack fill: the difference between the capacity of a container and the volume of product inside, that misleads consumers on the actual amount of product in a package.

[26] Pursuant to Section 602 of the FD&C Act [21 U.S.C. 362].

[27] Pursuant to Section 601 of the FD&C Act [21 U.S.C. 361].

[28] Section 201(g) – *(b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body*.

FDA itself catches the attention and puts an accent on the issue: *«How cosmetics are not FDA-approved but FDA-regulated».*[29]

In light of the explanation of the normative frameworks, further differences, but also similarities, may be appreciated through the analysis of caselaw concerning misleading cosmetic claims. On the one side, since the EU jurisprudence in the field is of non-completely settled nature at the present day, additional elements are to be considered. The number of litigations before the CJEU on cosmetic law is exiguous due, among others, to the essence of the contract of sale for cosmetics, which regulates an object whose effectiveness cannot be immediately observed, and this puts the consumer in an unbalanced situation, which however does not display any incentive for the consumer to file a lawsuit against the producer[30]. Moreover, at first glance, cosmetic lawsuits *per se* do not constitute a particular legal *genus*[31]. Under this perspective, the Italian doctrine of *dolus bonus* is relevant. *Dolus bonus*[32] is a legal concept descending from the Roman law, whereby claims exalting products are permitted on the presumption that they are recognizable by the customer, and therefore such claims do not amount to a valid ground for terminating the contract. Consequently, the consumer, through critical thinking, should be already in the position to understand and be aware that cosmetic claims shall not be taken literally. But with this in mind, it is captivating to assess Italian decisions going in the other sense: the Italian Competition Authority[33], in a first issue[34], declared that a claim praising the action of a cosmetic product based on experimental proofs was misleading, because the evidence was not backed by statistic accuracy. Accordingly, on another occasion[35], it held that an advertising claim on a physical and aesthetic treatment on weight loss without any diet or physical activity was deceptive. A further example is the appeal[36] brought before the *Tribunale Amministrativo Regionale del Lazio* (administrative tribunal of Italian region Lazio) concerning a sanction imposed by the Italian Competition Authority, which acknowledged the existence of an unfair commercial practice on the part of Garnier and Vichy, precisely referring to three misleading claims for the following products: “Liftactiv Retinol HA Vichy”, “Cellumetric

[29] Source: FDA website, available at: https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#What_does_the_law (last access on: 02/05/2020).

[30] M. C. PAGLIETTI, *Le controversie e la loro risoluzione. 2. Fattispecie generatrici di responsabilità da prodotto cosmetico*, in V. Zeno-Zencovich, *Cosmetici, Diritto, Regolazione Bioetica*, Roma, 2014, p.134.

[31] M. C. PAGLIETTI, *op. cit.*, p. 133.

[32] Definition of *dolus bonus* by Merriam-Webster, Inc. Dictionary – *simple cunning or sagacity in bargaining or in other transactions that is not actionable or punishable as fraud or misrepresentation or ground for rescinding the transaction induced by it.*

[33] In Italian: *Autorità Garante Della Concorrenza E Del Mercato*. It is an administrative independent Authority established by Law no. 287 of 10 October 1990. It has power to monitor and repress unfair commercial practices, misleading, and unlawful comparative advertising. Source: official website available at https://en.agcm.it/en/about-us/ (last access on 19/05/2020).

[34] In Garante concorr. Mercato, no. 7790, *Rass. Dir. Farmaceutico*, 371, 2 December 1999 in A. CARNABUCI, *Articolo 26, Tutela Amministrativa e Giurisdizionale*, in A. CATELANI ET AL., *Codice Del Consumo, Commento al D.Lgs. 6 Settembre 2005, n. 2006*, Milano, p. 290.

[35] In Garante concorr. Mercato, no. 8123, *Rass. Dir. Farmaceutico*, 890, 9 March 2000 in A. CARNABUCI, *Articolo 26, Tutela Amministrativa e Giurisdizionale*, in A. CATELANI ET AL., *Codice Del Consumo, Commento al D.Lgs. 6 Settembre 2005, n. 2006*, Milano, p. 290.

[36] T.A.R. Roma (Lazio) Sez. I, Sent., 09-02-2011, (ud. 10/11/2010, dep. 09/02/2011) n. 1263 (Source: DeJure, Banche Dati Editoriali GFL – Giuffrè Francis Lefebvre)

Vichy", and "Ultralift Garnier". The tribunal upheld the measure of the Italian Competition Authority, because the claims at issue were not scientifically ascertained, with no statistic accuracy and were therefore deceptive.

The same rationale may be found in the United States' caselaw, specifically in *FTC v. California Pacific Research* case[37], which confirms and permanently imposes a previous preliminary injunction on the defendant, because the advertising of a shampoo, claimed to be scientifically ascertained, was misleading, and the defendant was «*falsely and deceptively advertising that their products were effective in growing hair and preventing hair loss*[38]. But contrary to what has been elucidated so far, in another case[39], the plaintiff claimed that given liquid cosmetics marketed by L'Oréal were deceptively labelled and did not make clear that their dispenser would leave a significant amount of the product unusable. The court dismissed the claim by asserting that «*a reasonable consumer would know that a container that dispenses a viscous cosmetic through a pump will not dispense all of the cosmetic*»[40], thus L'Oréal advertising did not fall under the category of misbranded products, nor it displayed misleading labelling under respectively the Federal Food Drug and Cosmetic Act and the Fair Labelling and Packaging Act.

In last instance, what results from this comparison is a statement of comprehensive and intertwined legislative supervision on the part of the European Union, granting consumers a high level of protection, and a lack of authority as well as vigilant monitoring on the part of the United States. As of today, no major changes had occurred, but the Safe Cosmetics and Personal Care Products Act of 2019 has recently been introduced in the menu of Congress options to renew and amend the normative framework in the country, advancing FDA's competence to a universal protection of Americans' health.

The connecting point between the current discussion and the next one is another dissimilarity between the two regimes, represented by the existence of a ban on animal testing for cosmetics. The United States do not require, nor ban, that cosmetics be tested on animals before their launching into the market, whereas the European Union paved the way to stop them and find alternatives; so, let us turn to it.

4. Animal Testing and Alternatives

At the beginning of the 20th century, revolutions blew up, marking political and economic transformations, but for what concerns us, the aesthetic and societal transitions played a major role in the world of cosmetics.

[37] *FTC v. California Pacific Research, Inc.*, 1991 U.S. Dist. Court for the District of Nevada, August 27 1991. Source: Lexis 12967, LexisNexis (computer-assisted legal research).
[38] Procedural Posture of the case *FTC v. California Pacific Research*.
[39] *Critcher v. L'Oreal USA, Inc.*, 2019 U.S. Dist. LEXIS 116365, 2019 (United States District Court for the Southern District of New York) July 11, 2019, Filed). Source: LexisNexis (computer-assisted legal research).
[40] Memorandum and Opinion, Section III, Part B of case *Critcher v. L'Oreal USA.*

This led to a progressive self-evaluation and emancipation of women, who started embellish themselves more and more. But actually, the springing of the first cosmetic businesses steered women towards health issues: between 1933 and 1934, Lash Lure (a new lash and eyebrow dye) provoked infelicitous effects, and in particular blindness, dermatitis and conjunctivitis rang a bell as to improve consumers' safety in relation to cosmetic components. Not unexpectedly, beginning from the 1940s, animal testing represented the common procedure that manufacturers availed of in order to avoid such unpleasant events. Relatively soon after, Leonard Burch and William Russell delineated guideline principles enclosing an ethical assessment with regard to animal testing, the Three Rs (3Rs)[41]: replacement, reduction and refinement, thus respectively preferring non-animal alternatives over animal methods whenever possible, obtaining comparable levels of information from a reduced number of animals, and alleviate or minimize animals' anguish. Henceforth, various efforts have been made to prohibit animal testing for cosmetics, and in Europe these were crowned by the regulatory system here explained. The Cosmetic Directive initially did not envisage any requirement in this respect, but with its 7th Amendment[42], it mandated EU members states to implement a testing ban on cosmetic products. Starting from 2009, also ingredients could not be tested on animals, and a marketing ban was put in place as well. Now, the provision in force is of course contained in the Cosmetic Regulation, namely Article 18, which enshrines both the marketing ban and the testing ban within the whole Union.

Following, the analysis of some of the proposed alternative methods, validated by the EU Reference Laboratory for Alternatives to Animal Testing[43], is introduced. Approaches implying a minimum involvement of animals count alternatives spacing from computer models to human tissues, enumerating *in-vitro* cell cultures as well as model organisms. Nonetheless, substantial lack of sufficient scientific knowledge makes the alternatives need to be implemented in a more effective manner. An example is the carcinogenicity alternative test, i.e. the *in-vitro*[44] Bhas 42 Cell Transformation Assay, which is a short-term system to predict chemical carcinogenicity, thus unlikely to fully model the actual biological processes as to comprehend all hazards and risks of the real world. Yet, it is a reliable cell-line based method, and displays benefits from the 3Rs perspective. As regards corrosive reactions, such as ulcers, bleeding, discoloration of skin or scars, it must be said that it is not a risk that usually occurs within the realm of cosmetics; however, a cosmetic ingredient displaying such property is not directly excluded: that is why we need to ensure high level of safety protection while fostering innovation. The EpiSkin Skin Corrosion Test (SCT) is a test on reconstructed human epidermis,

[41] W.M.S Russell, R.L Burch, *The Principles of Humane Experimental Technique*, London, (1959).
[42] Directive 2003/15/EC amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (2003), OJ L 66/26, 27 February.
[43] Source of the explanation on the alternative methods: The European Commission's science and knowledge service, available at: https://ec.europa.eu/jrc/en/eurl/ecvam/alternative-methods-toxicity-testing (last access on 21/05/2020).
[44] *In vitro* (from the Latin "within the glass) describes research performed on cells or organism outside their biological context.

meant to replace the *in vivo*[45] Draize skin test[46], thus it is used to identify whether a chemical ingredient may potentially have corrosive effects on skin. It is a 3D human skin model and involves a local application of the product, in order to assess cell viability in a subsequent stage. On the side of computational methods, the EU Reference Laboratory for Alternatives to Animal Testing makes reference to the Quantitative Structure-Activity Relationship modelling (QSAR) and Physiologically Based Kinetic and Dynamic (PBK/D). Such alternative procedures may be used both for data generation as well as interpretation and integration. In fact, the first one, by analysing the psychochemical properties of given compounds, is able to predict biological or toxicological chemicals, whereas the second method is deployed to understand *in vitro* toxicity data, and for simulations of internal concentrations after exposure to the chemical analysed.

In ultimate analysis, as already explained, alternatives need further refinement and more systematic implementation, but despite this, the evidence of progressive research in the field testifies all efforts to contribute to the construction of an efficient system of health protection for consumers at European level. Having approached the history of and alternatives to animal testing, it is reasonable to think of the next topic of our voyage, since, at the very foundation, what lies at the basis for the need of toxicity tests to ensure human health is precisely the deployment of toxic ingredients in personal grooming products.

5. Toxic Ingredients in Cosmetics

Typically, the vast majority of chemical ingredients in cosmetics pose little or even no risk, but the worries are about those which have been connected to significant health issues. Recall the Lash Lure-related tragedy in the 1930s, it was precisely due to paraphenylenediamine, which is an allergen that causes dermatitis of particularly severe form in the area around eyes. In fact, the European Union, while restricting its usage according to Annex III[47] of the Cosmetic Regulation, warned that it must not enter in contact with eyebrows or eyelashes; notwithstanding, it is still widely utilized, especially as hair colorant agent. Referring more to the EU Cosmetic Regulation, Annex I mandates the responsible person to file a toxicological profile of the substances in the context of the Cosmetic Product Safety Report, while Annex II consists of an enumeration of all prohibited substances (almost 400). However, this paper will focus on what is not included under the scope of EU legislation, for instance parabens.

Among the several ingredients of personal grooming products, many of them have health implications, spacing from skin irritation to more serious issues such as cancer, including also developmental overweight

[45] *In vivo* (from Latin "within the alive") relates to research carried out on an entire living organism or cell.
[46] The Draize test is an acute toxicity test put in place in 1944 by John Draize and Jacob Spines within the framework of the FDA, as a method for establishing the potential irritation effects of materials.
[47] Annex III of Regulation 1223/2009: List of Substances Which Cosmetic Products Must Not Contain Except Subject to The Restrictions Laid Down

display (as it will be later described). Parabens have been used as preservatives since the 1950s, due to their antifungal properties, to stop the growth of microbes and bacteria. As of today, the EU has banned just five of them, but the most popular ones, namely methylparaben, propylparaben, and butylparaben are missing. So, undoubtedly a question is posed: *what implications do parabens bring with?* A recent article on *Nature*[48] highlighted that maternal exposure to butylparaben may trigger overweight development in early childhood. As parabens are frequently used in cosmetic products, researchers affirmed that cosmetics are one of the principal sources for human paraben exposure, proving direct link with child's issues, and evidence was established by making participants compile a questionnaire before initiating the study. Moreover, a toxicology study[49] reported that parabens' properties bind to estrogen receptors on cells, thereby assuming a hormone disruptive function, envisaging carcinogenic catastrophic effects. At European level, what gives hope to the public opinion with respect to parabens is embodied by the potential actions of the EU commission. As far as endocrine disruptors (i.e. hormone disruptors) are concerned, the restrictions are based on the assessments carried out by the Scientific Committee on Consumer Safety (SCCS)[50], which attentively examines whether specific substances are safe for consumers or could critically hamper their health. In 2018, the Commission adopted a review of the Cosmetics Regulation concerning substances with endocrine-disruptive properties[51], and maintained that the regulation is comprehensive as it is, providing for adequate tools to regulate potential risks. Nevertheless, it pledged to produce a priority list of hormonal disruptors which were not contemplated by the regulation bans, resulting in 28 substances. Thus, it launched a public call for data for the first 14 elements, on May 15th, 2019, whose results are being analysed by the SCCS; thereafter, the Commission would decide whether to take action as to prohibit those substances.

While waiting for the elaboration of data and a potential formalization of a ban for further toxic substances, the average consumer tries to escape her beliefs by approaching a new kind of philosophy, what I will refer to as "skepticism" and "changing of mind". The last point discussed in this interdisciplinary research represents a provocative question, with no actual answer, and is voluntarily left open, since no systematized or methodical study on the matter has been carried out.

6. May Cosmetics Replace Pharmaceuticals? The Cases of Second Skin and Body Dysmorphic Disorder (BDD)

[48] B. LEPPERT, S. STRUNZ, B. SEIWERT, *et al. Maternal paraben exposure triggers childhood overweight development.* in *Nat Commun* 11**,** (2020).

[49] P.D. DARBRE, P.W. HARVEY, *Paraben esters: review of recent studies of endocrine toxicity, absorption, esterase and human exposure, and discussion of potential human health risks*, in J *Appl Toxicol*., 28(5), 2008, pp. 561-578.

[50] It is an independent scientific committee within the European Union which provides opinion on health and safety risks of non-food consumer products. Source: European Commission https://ec.europa.eu/health/scientific_committees/consumer_safety_it (last access 18/05/2020).

[51] European Commission, *Final Report from the Commission to the European Parliament and The Council. Review of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products with regard to substances with endocrine-disrupting properties*, COM (2018) 739, Brussels 7/11/2018.

Although one side of the coin depicts an element of skepticism concerning the involvement of toxic ingredients in cosmetic products, one may ask: *is there an increasing experience towards a possible change of mindset?* To put it other words, nowadays' suspicious beliefs may give rise to a positive answer to this question, representing a potentially ongoing bioethical debate, not to mention the one on medical interventions aiming at curing diseases as opposed to cosmetic surgery for enhancing personal appearance. Before evaluating the relevant arguments to respond to this question, it is appropriate to briefly specify the concepts of health and illness. According to the definition of the WHO[52], which has not been amended since 1948, health is a *state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*[53]. On the other side, as illustrated by an article on the *Journal of Epidemiology and Community Health*, illness is the *ill health that the person identifies themselves with*[54], and disease refers to *a condition that is diagnosed by a physician or other medical expert*[55].

Two extremely interesting Articles on *Nature Materials* reported, respectively, on the development of a second-skin[56], resulting from the synthesis and application of a polymer layer which emulates the properties of youthful skin, and on restorative synthetic skin[57], tailored to conform to functional properties of human skin, considered for applications in cosmetics. To be more precise, the second article properly refers to the first one. This second skin consists of a mixture of *elastomers*[58], and forms itself directly as applied, i.e. *in situ*. The authors studied both bare skin and "skin with second skin" and their properties, specifically distensibility and elasticity: the incredible results showed that the soft reinforcement provided by the second skin enhanced appearance as to reproduce a faithful approximation of young skin. Furthermore, what appears less obvious to an inexpert is the ability of this polymer layer to remodel skin, with special concern to the notorious herniated "eye-bags", almost equating a result attained with cosmetic surgery only. In addition, this polymeric coat may protect users from sunburns, treat psoriasis or dermatitis, and help hydrating skin. Expectations on possible applications of the second skin in the cosmetic field were actually crowned by one of the leading companies in the arena, the Shiseido Company Limited, acquiring such technology in 2018[59].

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[52] The World Health Organization is an agency of the United Nations which works worldwide to promote health, keep the world safe and serve the vulnerable, whose mission is to ensure universal health coverage. Source: WHO official website, available at https://www.who.int/about/what-we-do (last access 20/05/2020).

[53] *Preamble to the Constitution of WHO* as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of WHO, no. 2, p. 100) and entered into force on 7 April 1948.

[54] A. WIKMAN, S. MARKLUND, K. ALEXANDERSON, *Illness, disease, and sickness absence: an empirical test of differences between concepts of ill health,* in J *Epidemiol Community Health*, 59, 2005, pp. 450–454.

[55] *Ibidem.*

[56] B. YU, S. KANG, A. AKTHAKUL, *et al., An elastic second skin.*, in *Nature Mater.15*, pp. 911–918 (2016).

[57] J. ROGERS, G. BALOOCH, *A restorative synthetic skin.*, in *Nature Mater. 15*, 828–829 (2016).

[58] Elastomer (from "elastic polymer"): any material composed of long chainlike molecules or polymers capable of recovering their original shape after being stretched to great extents. Source: Encyclopaedia Britannica, available at https://www.britannica.com/science/elastomer (last access on 04/05/2020).

[59] Source: Shiseido Press Conference, 2018. Available at: https://corp.shiseido.com/en/newsimg/2349_h9x34_en.pdf.

With this in mind, it is reasonably revealing to consider the figures from the American Society for Aesthetic Plastic Surgery (ASAPS) of 2018[60]: the 4 out of 10 top surgical and nonsurgical procedures are meant to enhance facial appearance, thus rejuvenation, photo-rejuvenation, eyelid surgery or botulinum injections. As a consequence, scientific and technological innovation, as the second skin, may spark interest, but surgical or minimally invasive treatment is still preferred.

To deepen our discussion, it is noteworthy to examine the other relevant element, that is, cosmetic applications for Body Dysmorphic Disorder: in a given number of instances, concerns over physical appearance reach an intolerable intensity, causing subjective distress, which damages people of any age, but mostly teenagers, who are too embarrassed to see their problem in psychological terms and do not seek assistance. The dilemma relies precisely in this final concept, that is, people dodging psychological aid and retrieving a sort of confidence through cosmetic treatment. Although the domain has still to be more systematically explored, what can be stated is that the majority of patients with BDD who underwent surgical treatment experienced no step forward towards their well-being, as elucidated in a study of the *Annals of Plastic Surgery*: *«only 2.3% of surgical/MI* [minimally invasive] *procedures led to longer-term improvement in overall BDD symptoms (i.e., preoccupation and emotional distress or impairment in functioning due to dissatisfaction with the treated body part and with other disliked body parts.)»*[61]

Keeping these considerations in mind, some observations may be appreciated. Whether cosmetic solutions could replace medical treatments is actually hard to believe in strict scientific terms, and what may be suggested is a possible combination of psychological aid and cosmetic collaboration. For instance, in a remote case of an aged patient with BDD, the positive effects of the application of a second skin may offer relief, even for a short-term, but with less expenditure in terms of health and money than a surgical treatment. In addition, the dilemma of young people refusing psychological aid has to be handled, and perhaps an effective duo of therapy plus cosmetics might represent an efficient and incisive compromise by youth's lights. Still, it is to reiterate that this last analysis has been prompted as provocative and intriguing starting point for additional research.

7. Concluding Remarks

By the end of this journey into the realm of cosm*ethics*, one may appreciate the nuances noticed while zooming in the discourse: despite the simplicity of these compounds and their everyday usage, an interdisciplinary exploration is propitious as to grasp their profound nature. A bioethical assessment of the existence of cosmetic products may seem absurd, but it reveals instead to be fascinating because of a hidden

[60] Available at https://www.surgery.org/sites/default/files/ASAPS-Stats2018.pdf

[61] C. E. Crerand PhD; W. Menard, K. A. Phillips MD, *Surgical and Minimally Invasive Cosmetic Procedures Among Persons with Body Dysmorphic Disorder,* in *Annals of Plastic Surgery*, Vol. 62 Issue 1, pp. 11-16, July 2010.

gloom that overflows as the matters are explored, and characterizes every single topic at issue. The inquiry developed from the analysis of the vehicles that the European Union avails of in order to tackle bioethical matters, and this sparked interest from the point of view of the antithesis elucidated between life sciences and the legal discipline. Subsequently, the illustration of the normative frameworks at European and United States' level highlighted the central position of consumers, thus normal human beings like us, who everyday must deal with cosmetic products, unaware of the immense world behind them. In the paper, the dissimilarities emerged from the dialogical comparison between the two normative frameworks prompted also the examination of animal testing in history and in its alternatives, which nowadays display a need for further implementation. The laws are modelled to complete, as much as possible, the mission of guaranteeing health safety, protecting consumers' lives, and economic interests, but they may be either limited with regard to universality and comprehensiveness, as in the case of the United States, or missing legislative commands concerning what the public opinion considers as burning issue, like parabens in the European Union. Such elements account for progressive suspicious thoughts, which lead to distrusting authorities, and in worst cases, scientific knowledge, giving rise to skepticism and problems as illustrated in the last section. This personal research depicted multiple sides of the cosmetic world, assessing its controversies and, in diverse instances, affirming that some questions are not completely settled. But that is precisely why cosmetic law represents a fascinating field, fertile in terms of sources for additional investigation, also under several aspects, from regulatory and legal dimensions, to scientific and ethical perspectives. My last words are an appeal to human's conscience and responsibility, to improve critical thinking and awareness, and that although science is *per se* uncertain, it is there as defender of our safety and well-being, and this paper illustrated the efforts (and achievements) of science to construct an effective system of protection for consumers, complemented by necessary legislation on the matters.