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DYING TO BE BEAUTIFUL: AN ASSESSMENT OF HOW A SELF-REGULATING COSMETIC INDUSTRY AND BIOTECHNOLOGY ARE IMPACTING PUBLIC HEALTH

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ABSTRACT

Currently in the United States, the law does not require products that fall under the definition of "cosmetic" as defined by the FDCA, to obtain pre-market approval. It also does not require any specific testing to ensure safety of cosmetic ingredients or final products. With such minimal federal oversight, the industry has fundamentally become self-regulating. Consumers use numerous products on a daily basis, often assuming that ingredients have been tested for safety before being placed on the market, but that is not always the case. Further, the cosmetic industry is rapidly being pulled towards the use of advanced scientific research and innovative biotechnology in the development of cosmetic products. What is the public health effect of the current laws? Have there been any recent updates to the laws? And how does biotechnology fit into all this? These are all questions that this comment will analyze and address.

INTRODUCTION

Typically, when someone hears the word "cosmetic" their first instinct is to think of lipstick, mascara, and other common "makeup" products. While it is true that these products fall into the category, there are a myriad of other products that must be considered as well. The FDA defines cosmetics in a very broad manner, allowing many personal care products to fall under the regulatory definition. That being said, a substantial amount of the population in the United States uses some form of cosmetic product on a daily basis. Consumers mindlessly grab these products from the store shelves, reasonably assuming that they have been tested, and are safe for use. Unfortunately, however, that is not always be the case. Cosmetics are arguably one of the most lightly federally regulated products on the

market – and this may be adversely impacting the population as a whole. Furthermore, as the cosmetic industry continues to rapidly evolve, there has been a shift towards the use of biotechnology to create cosmetics using entirely different methods based on newfound techniques.

The FDA defines a cosmetic as a "product" (excluding purse soap) intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance."[1] Cosmetics as defined by the FDCA are not subject to pre-market approval by the FDA. [2] According to the FDA, "neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients."[3] This comment will focus on the potential health ramifications that may be associated with exposure to the ingredients that are placed in these products, and will analyze whether or not there is sufficient evidence to indicate a causal link between the two, because despite many adverse health reports and lawsuits regarding certain cosmetic products, it is still an extremely lightly-regulated industry.

Though there seem to be many correlations between exposure to certain chemicals and negative health effects, up until this point, it appears that there has been a lack of evidence strong enough to indicate the causal connection that is needed for action. Because of this difficulty, legal battles often fail. This comment will also focus on how biotechnology has affected the cosmetic industry—specifically, it will examine whether the incorporation of biotechnology may pose greater or less health risks for consumers and/or research subjects. As if the cosmetic industry was not complex enough as it currently stands, the rising use of biotechnology has created even more complexities. The incorporation of biotechnology has created blurry lines and uncertainty as to whether a product should be classified as a drug or a cosmetic. It is not unusual for high-end cosmetic brands to make claims promising specific results, including catchy statements on

[1] *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA Approved, but Are FDA-Regulated*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated (Aug. 24, 2020).

[2] *Id.*

[3] *Id.*

packaging such as "based on scientific evidence." These statements lead consumers to believe that the products are tested for efficacy and safety in the same way drugs are. In actuality, cosmetic manufacturers do not want their products going through costly and lengthy, clinical trials. While it is probably not disputed that a goal of biotechnology is to create safe and effective products, it is undeniable that there still remains a significant amount of uncertainty as to whether this comes with increased risk for consumers. Lastly, this comment will address previous and currently proposed legislation, and the obstacles that seem to be hindering a Safe Cosmetics Movement.

A. Evolution of the Regulatory Framework of the Cosmetics Industry

In the United States, the two most important laws regarding cosmetic marketing are the Federal, Food, Drug, and Cosmetics Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA).[4] The Food and Drug Administration (FDA) regulates cosmetics through the authority of these laws.[5] The U.S. FD&C Act was passed by Congress in 1938 and gave the FDA the power to oversee food, drugs, cosmetics and medical devices.[6] This came after the 1906 Food and Drugs Act, which prohibited adulterated food and drugs in interstate commerce.[7] Although this time was "[a]rguably the pinnacle or Progressive Era Legislation," the act still was problematic, as there were gaps in covered products and many products were not covered at all.[8] As a result, many hazardous items legally remained out in the market for consumer purchase.[9] In the early 1930's, consumers sought change, after national outrage arose from cases of consumer products that

[4] *Id.*

[5] *Id.*

[6] *How Did the Federal Food, Drug, and Cosmetic Act Come About?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fda-basics/how-did-federal-food-drug-and-cosmetic-act-come-about (Mar. 28, 2018).

[7] *Id.*

[8] *Id.*

[9] *Id.*

poisoned and killed many people.[10] In 1937, untested pharmaceuticals killed a number of patients as soon as it went on the market, and this event marked the tipping point of the era.[11] In 1938, the FD&C Act was enacted to provide heightened control over drugs and food and also included consumer protection against unlawful cosmetics and medical devices—this is the current law in the United States.[12]

Because Congress enacts federal laws in the United States and authorizes government agencies to create regulations, Congress would have to change the law in order for the FDA's legal authority over cosmetics to change.[13] Currently, the law does not require cosmetic products or their ingredients to be FDA approved before being placed on the market, aside from color additives.[14] There are, however, a few laws which regulate cosmetics that travel through interstate commerce. The FD&C Act prohibits the distribution of cosmetics that are adulterated or misbranded to enter into interstate commerce.[15] It can be tricky to understand who is responsible for the safety of the products in this industry. To clarify, the companies who manufacture the cosmetics bear the legal responsibility of ensuring the safety of their products.[16] Current law does not require cosmetic companies to share any type of safety information or data with the FDA.[17] There are a few ingredients that are prohibited and require warning statements on the labels of certain products.[18] Nonetheless, all cosmetic recalls are voluntary actions that are taken by manufacturers or distributors to remove products from the marketplace that are defective, pose a hazard, or are extremely deceptive to consumers.[19] Although the

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] U.S. FOOD & DRUG ADMIN., *supra* note 1.

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

FD&C Act does not require cosmetics to have premarket approval by the FDA, the FDA does "collect samples for examination and analysis as part of cosmetic facility inspections, import inspections, and follow up complaints of adverse events associated with their use."[20] The FDA may conduct research on cosmetics and their ingredients to address safety concerns if they choose to do so.[21] However, in order to prevent any potential conflict of interest or appearance of one, the FDA does not serve as a testing laboratory.[22]

B. Potential Health Ramifications

According to a 2004 study by the Environmental Working Group (EWG), which is a non-profit environment and health advocacy group, American women use an average of 12 products a day, which equates to approximately 200 chemicals.[23] The EWG is a large proponent of transparency between consumers and the industry and increased regulation of the industry; their hope is to ban many ingredients that have already been banned in other countries.[24] The organization stated in one of their reports that more than 40 countries have banned 1,400 chemicals for use in cosmetic products, while the United States has only banned nine.[25] As a result, the past decade has led to rising concern as to whether chemicals in cosmetics, and the lack of regulatory authority from the FDA, is leading to negative health consequences for consumers. It has been noted by many that cancer, infertility, and various other health issues are on the rise.[26] There has been debate as to whether these health issues are associated with the numerous unknown chemicals that the public is allowing to enter into the skin and bloodstream via the use of these cosmetic products.

[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] Lauren Zanolli, *Pretty Hurts: Are Chemicals in Beauty Products Making Us Ill?*, GUARDIAN (May 23, 2019, 2:00 PM), https://www.theguardian.com/us-news/2019/may/23/are-chemicals-in-beauty-products-making-us-ill.

[24] *Id.*

[25] *Id.*

[26] *Id.*

Though there seems to be correlation between the increasing use of cosmetics and increasing rates of various health issues, it is a known idea in the statistical community that "correlation does not imply causation."[27]

I. CANCER AND OTHER ADVERSE HEALTH CONDITIONS

According to government data, overall cancer rates have declined in recent years.[28] However, the incidence of specific types of cancer, including thyroid, liver, and skin, are increasing.[29] Additionally, though we have seen decreases in the overall rates of cancer diagnoses for males, the rates for women have remained stable since 2008.[30] Whether this may be related to elevated use of personal care products in women, is a disputed question.

Dr. Lorenzo Cohen, MD Anderson professor and director of the Integrative Medicine Department has previously stated that there are concerns that beauty products contain endocrine disrupting chemicals that may interfere with our hormones.[31] He stated, "while a direct link between endocrine disrupting chemicals (EDCs) and cancer is not yet definitive, certain cancers are hormonally-driven.[32] "Even a low dose should cause concern, especially if you use the product every day."[33] A few of the beauty products that scientists have been studying for possible links to cancer include hair dye, hair straightening products,

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[27] Daniel Engber, *The Internet Blowhard's Favorite Phrase*, SLATE (Oct. 2, 2012, 8:33 AM), https://slate.com/technology/2012/10/correlation-does-not-imply-causation-how-the-internet-fell-in-love-with-a-stats-class-cliche.html.

[28] NAT'L INSTS. OF HEALTH, ANNUAL REPORT TO THE NATION: CANCER DEATH RATES CONTINUE TO DECLINE (2020), https://www.nih.gov/news-events/news-releases/annual-report-nation-cancer-death-rates-continue-decline-2020.

[29] Zanolli, *supra* note 23.

[30] *Id.*

[31] Adelina Espat & Brittany Cordeiro, *Beauty Products and Cancer: Are You at Risk?*, UNIV. OF TEX. MD ANDERSON CANCER CTR. (Aug. 2014), https://www.mdanderson.org/publications/focused-on-health/cancer-prevention-cosmetic-beauty-tips.h17-1589046.html.

[32] *Id.*

[33] *Id.*

bath and body care products, and UV nail lamps.[34] Hair dye products contain close to 5,000 chemicals, and there is a possibility that some of those chemicals are linked to cancer.[35] In the 1970's, scientists found that some chemicals contained in hair dyes caused cancer in animals, and upon this finding, these particular chemicals were removed from hair dye.[36] However, scientist are unsure as to whether the remaining thousands of chemicals have any causal connection to cancer; this has been the subject of research for decades but there has been no consensus. The National Cancer Institute has stated that research on cancer and hair dye use is conflicting.[37]

There have also been questions about whether hair smoothing/straightening treatments such as Brazilian Blowouts are linked to cancer because of the fact that many of these products contain formaldehyde which is known to be a cancer causing chemical.[38] According to Cohen, the risk for cancer is increased for people who are regularly exposed to formaldehyde, such as the employees of the salon who are applying the products to customers.[39] However, the risk for individuals who use the products on their hair is apparently lower.[40] Nonetheless, Cohen says, "the long-term health effects of constant exposure are unclear and under investigation." [41] The Environmental Working Group (EWG) found that 28% of all personal care products contain 1,4-dioxane, which is another known carcinogen.[42] Furthermore, a separate organization, the Organic Consumers

[34] Robert Preidt, *Study Ties Hair Straighteners, Dyes to Breast Cancer*, WEBMD (Dec. 4, 2019), https://www.webmd.com/breast-cancer/news/20191204/study-links-hair-straighteners-dyes-to-breast-cancer; Hope Ricciotti & Hye-Chun-Hur, *Safety of LED Nail Lamps*, HARV. HEALTH PUBL'G (May 2018), https://www.health.harvard.edu/staying-healthy/safety-of-led-nail-lamps.

[35] Espat & Cordeiro, *supra* note 31.

[36] *Id.*

[37] *Hair Dyes and Cancer Risk*, NAT'L CANCER INST., https://www.cancer.gov/about-cancer/causes-prevention/risk/myths/hair-dyes-fact-sheet (Aug. 8, 2016).

[38] Espat & Cordeiro, *supra* note 31.

[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] *Id.*

Association (OCA) found the same chemical in 40% of products labeled "natural."[43] This is worrisome from a consumer perspective, because most will see the term "natural" and automatically assume that the product is safe and free from dangerous chemicals, which unfortunately is not the case. The chemical 1,4-dioxane is not listed as an ingredient on product labels; a few chemicals that may contain the chemical include polyethylene, polyethylene glycol, polyoxyethylene, and various other chemicals containing –eth and –oxynol.[44] Although most manufacturers of personal care products have removed chemicals that are known to be carcinogens from baby products, adults may still be at risk.[45]

Another common "beauty tool" that may be posing a cancer risk is a UV nail light; these are used in many salons to speed up the nail drying process. While there is no established causal linkage, Dr. Deborah F. MacFarlane M.D., professor in Dermatology at MD Anderson stated "it appears that exposure to UV nail lights is a risk factor for developing skin cancer."[46] MacFarlane discussed in one of her dermatology articles, the incidents of two women who developed skin cancer on their hands.[47] Both of these women had used UV nail lamps, which may be suggestive of a link or could simply be a coincidence.[48] Although there have been no established causal connections between the above-discussed cosmetic products and adverse health conditions, it is critical that consumers remain cautious of the products that they are using. Dr. Cohen stated, "A good rule of thumb: If you can't pronounce the ingredient and you don't know what it is, you should proceed with caution and seek more information."[49]

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[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.*

[47] *Id.*

[48] *Id.*

[49] Espat & Cordeiro, *supra* note 31.

A. Johnson & Johnson Talc Baby Powder Litigation

Johnson & Johnson is a company that is arguably best known for its baby powder. The company has become the subject of major litigation as a result of their baby powder containing talc, which many claim contains cancer-causing asbestos, and has led to thousands of lawsuits being filed against the company.[50] Approximately 15,000 plaintiffs have come forward alleging that Johnson & Johnson's talc products caused cancer.[51] Johnson & Johnson has continuously denied allegations of carcinogens in their talc powder, and insists that their products have been tested for safety.[52] The company has stated that the principles that plaintiff's expert witnesses are using are insufficient, not based on reliable science.[53] They have successfully defended some lawsuits, and are appealing almost all of the lawsuits they have lost, which includes a judgment for approximately $4.69 billion dollars in 2018.[54] A hearing with Judge Wolfson was scheduled in order to decide whether the expert witness testimony is scientifically reliable and should be allowed as testimony; if it is concluded that the experts methods are not scientifically reliable, thousands of cases are almost sure to fail.[55] In an incredibly significant ruling, Judge Wolfson

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[50] Angelica LaVito, *Johnson & Johnson Faces a Crucial Hearing Monday Over Thousands of Talc Baby Powder Lawsuits*, CNBC (July 22, 2019), https://www.cnbc.com/2019/07/22/jj-faces-crucial-hearing-on-talc-baby-powder-lawsuit-monday.html.

[51] Alyse Shorland, *Johnson & Johnson Lawsuits Raises Fear Over Baby Powder*, N.Y. TIMES: THE WEEKLY, https://www.nytimes.com/2019/10/04/the-weekly/johnson-johnson-baby-powder-cancer-lawsuits.html (Dec. 18, 2019).

[52] Berkeley Lovelace Jr., *Johnson & Johnson Shares Rise After It Says No Signs of Asbestos Found in Baby Powder After Testing*, CNBC (Oct. 29, 2019), https://www.cnbc.com/2019/10/29/johnson-johnson-says-it-found-no-signs-of-asbestos-in-baby-powder-after-testing.html.

[53] Jef Feeley, *J&J Targets the Science Behind Thousands of Baby Powder Cancer Claims*, L.A. TIMES (July 24, 2019), https://www.latimes.com/business/story/2019-07-24/assignment-j-j-targets-science-behind-thousands-of-baby-powder-cancer-cases-new-story.

[54] This judgment was later reduced to $2.12 billion. Johnson & Johnson attempted to appeal this judgment to the Missouri Supreme Court and then later to the Supreme Court of the United States, but both courts refused to hear the appeal. Michelle Llamas, *Supreme Court Won't Hear Johnson & Johnson Appeal of $2 Billion Talc Ovarian Cancer Lawsuit*, DRUGWATCH (June 14, 2021), https://www.drugwatch.com/news/2021/06/14/supreme-court-wont-hear-jj-appeal-talc-ovarian-cancer-lawsuit/.

[55] Feeley, *supra* note 53.

concluded that the general causation experts were qualified to testify—a lawyer for the plainitff's stated, "the decision states, in a nutshell, that plainitffs' general causation experts are going to be able to testify that talcum powder can cause ovarian cancer."[56] In October of 2019, Johnson & Johnson recalled approximately 30,00 bottles of baby powder, after the FDA asserted that they detected "trace amounts" of asbestos in the baby powder.[57] Shortly after this finding, Johnson & Johnson had additional tests conducted by different third-party labs, using the same bottles tested by The FDA labs.[58] They assert that these tests demonstrated that their product was free from asbestos.[59] These types of issues arise because of the current regulatory framework and the lack of pre-market approval of personal care products. A self-regulating industry essentially means no regulation at all, and consumers must suffer before any action is taken by the government. Reuters conducted an investigation which revealed that the company has strategically marketed and advertised their product in geographic regions that are primarily comprised of Hispanic and African American populations.[60] Reuters argues that not only are these populations known for using the product frequently, but these underrepresented populations may also be more vulnerable to these company tactics due to a lack of education and inherent trust in well-known brands.[61]

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[56] Brenda Pierson, *U.S. Judge Rules Talc Lawsuits Against J&J Can Proceed, Testimony Limited*, REUTERS (Apr. 27, 2020), https://www.reuters.com/article/us-johnson-johnson-talc-ruling/u-s-judge-rules-talc-lawsuits-against-jj-can-proceed-testimony-limited-idUSKCN2292QC.

[57] Shanjana Shivdas & Carl O'Donnell, *Johnson & Johnson Says New Tests Show No Asbestos in Johnson's Baby Powder*, REUTERS (Dec. 3, 2019, 5:44 PM), https://www.reuters.com/article/us-johnson-johnson-talc/johnson-johnson-says-new-tests-show-no-asbestos-in-johnsons-baby-powder-idUSKBN1Y72SY.

[58] *Id.*

[59] *Id.*

[60] Kori Hale, *Johnson & Johnson's 100 Million Baby Powder Lawsuit Is Overdue for Hispanic & Black Women*, FORBES (Oct. 14, 2020, 7:57 AM), https://www.forbes.com/sites/korihale/2020/10/14/johnson--johnsons-100-million-baby-powder-lawsuit-settlement-is-overdue-for-black--hispanic-women/?sh=69644f163b3a.

[61] *Id.*

A 2019 documentary titled "Toxic Beauty" focuses much attention on the Johnson & Johnson talc lawsuit and the dangers that may lurk within the chemicals of personal care products.[62] Dr. Daniel Cramer, who is referred to as one of the "grandfathers of epidemiology" has conducted substantial research on the relationship between talc and ovarian cancer, and published his findings of a causal link between the two in 1982.[63] The film alleges that Johnson & Johnson was aware of the health risks of their products way before this, reasoning that reports from 1957 detected asbestos in Johnson & Johnson's products.[64] However, despite all of the evidence that seems to weigh against Johnson & Johnson, the billions of dollars that have been paid out to plaintiffs across the country, and the FDA detections, Johnson & Johnson continues to claim that their products are safe.[65] A striking comparison is made between the Johnson & Johnson trials and the Big Tobacco trials of the 1990's – smoking was "safe" at one point too. In the film, Dr. Rick Smith states, "The best available science points to this cosmetic issue being even bigger than the tobacco industry because we're talking about thousands of chemicals, most of which haven't been accurately safety tested."[66]

B. WEN Hair Products

Another company that has been the subject of much scrutiny in the media is WEN hair products by Chaz Dean. There have been many reports of adverse events from use of WEN Hair products including hair loss, balding, and itching.[67] As a result, a group of approximately 200 people joined together in a class-action lawsuit against the popular hair care brand, which eventually resulted in a preliminary settlement

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[62] Jessica Defino, *The New Toxic Beauty Documentary Asks: Are Skin-Care Products the New Cigarettes?*, VOGUE: BEAUTY (Jan. 29, 2020), https://www.vogue.com/article/toxic-beauty-documentary.

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] *Id*

[67] *Statement on FDA Investigation of WEN by Chaz Dean Cleansing Conditioners*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/cosmetic-products/statement-fda-investigation-wen-chaz-dean-cleansing-conditioners (Nov. 15, 2017).

for approximately 26.25 million dollars.[68] As of November 15, 2016 the FDA had already received 1,386 reports regarding the WEN cleansing conditioner products, which was said to be the largest number of reports known to ever be associated with a cosmetic hair-cleansing product.[69] Even considering this however, the FDA stated "We don't have enough information to determine the cause of these reported reactions."[70] Because of the current regulatory framework of the cosmetic industry, and the fact that the law does not require cosmetic companies to share their safety data or complaints with the FDA, they often do not. A repercussion of this is that when issues do arise, and complaints are directed to the FDA, there is not always enough information to make determinations as to why some users of the products experience adverse reactions, while others do not.[71] Additionally, the FDA has stated that even considering the information that is currently known from their investigation and the substantial number of adverse reports from consumers, there is still not enough to determine that the product does not comply with the law.[72]

[68] Rheana Murray, *FDA Launches WEN by Chaz Dean Hair Loss Investigation*, TODAY (July 22, 2016, 11:54 AM), https://www.today.com/style/wen-chaz-dean-sued-hair-loss-adverse-effects-t61856.

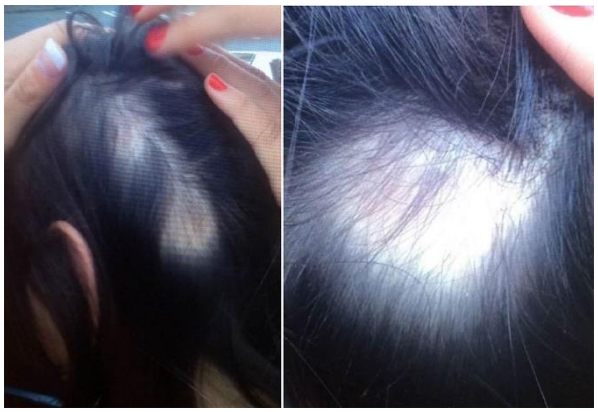
[69] U.S. FOOD & DRUG ADMIN., *supra* note 67.

[70] *FDA Information for Consumers About WEN by Chaz Dean Cleansing Conditioners*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/cosmetic-products/fda-information-consumers-about-wen-chaz-dean-cleansing-conditioners (Nov. 3, 2017).

[71] *Id.*

[72] *Id.*

Figure 1.



Alleged hair loss from using WEN hair products

Images provided by the lawsuit pprovgainst Wen - Murphy Rosen LLP[73]

C. The Honest Company

In the case of *Michael v. Honest Co.*, Jonathan Rubin filed a putative class action against The Honest Company on September 3, 2015.[74] A few days later, on September 7, 2015, Shane Michael filed a parallel action.[75] The complaints were later consolidated and the two plaintiffs' were instructed to file a consolidated, amended complaint.[76] On January 8, 2016, 5 individuals filed a First Amended and Consolidated Class Action (FAC).[77] The FAC alleged that from September 20, 2012 to the present (the "Class Period"), The Honest Company "deceptively and misleadingly labeled, advertised and marketed" various Honest products, including Honest Sunscreen, "as both natural and effective,

[73] Colleen Kratofil, *See the Hair Loss Photos Behind the Wen Haircare Lawsuit Settlement*, PEOPLE (Nov. 7, 2016, 5:57 PM), https://people.com/style/wen-hair-care-lawsuit-hair-loss-photos/.

[74] Michael v. Honest Co., No. LA CV15-7059, 2016 WL 8902574, at *1 (C.D. Cal. Dec. 6, 2016).

[75] *Id.*

[76] *Id.*

[77] *Id.*

when in fact, the Natural Products contain non-natural ingredients, and Honest Sunscreen is ineffective."[78]

The plaintiff's sought to represent two classes: "the first is defined as all U.S. residents who purchased the Natural Products from any retail store or website and who did not register for membership with Honest during a specified time period (the "Natural Products Class")."[79] The second class "is defined as all U.S. residents who have purchased Honest Sunscreen ("Sunscreen") from any retail store or website and who did not register for membership with Honest during specified time period (the "Sunscreen Class")."[80] The main allegations were essentially that the Natural Product Class paid a 10-20% premium for Natural Products based on representations by the Honest Company that the products were natural. [81] However, plaintiffs allege that the products actually contained synthetic and non-natural ingredients.[82] Additionally, the second class of plaintiffs (the "Sunscreen Class") allege that they purchased the Honest Sunscreen based on the representation that it would be "effective" but users of the product suffered severe sunburn.[83] In addition to labeling on the products, and advertisements throughout the media, Jessica Alba, who is a co-founder of the Honest Company stated during a broadcast interview on CNN Money that Honest is "natural, honestly effective, non-toxic."[84]

In regard to the alleged breach of the natural products representation, the FAC alleges that "[n]atural in the context of Defendant' products means each product contains no artificial ingredients."[85] However, plaintiff's alleged and specified, that various products including the Honest dish soap, hand soap, multi-surface

[78] *Id.*

[79] *Id.*

[80] *Id.*

[81] *Id.*

[82] *Id.*

[83] *Id.*

[84] *Id.* at *3.

[85] *Id.* at *4.

cleaner, and diapers contained non-natural ingredients.[86] Plaintiffs asserted that the Honest Company has criticized competitors for using "preservative (and ingredients) with synthetic fragrances" including "methylisothiazolinone" which is a chemical included in the Honest Multi-Surface Cleaner.[87] Further, they alleged that the defendant was "aware of the of the physical and chemical features of its products and of the alleged breach of its implied and express warranties."[88]

In regard to the alleged breach of sunscreen representation, plaintiff's alleged that "defendant falsely represented in advertising and labeling, and continues to so represent, expressly and by necessary implication, that Honest sunscreen is effective, when Defendant knew the only active ingredient in the sunscreen had been reduced by more than half in March 2015."[89] The FAC further alleged that the sunscreen was ineffective, citing online posts by individuals who claim to have suffered severe sunburns after using the Honest Sunscreen.[90]

The FAC alleges that after the defendants received numerous complaints that the sunscreen did not properly provide the protection that was promised, but still marketed the sunscreen as effective.[91] Additionally, the FAC claims that the defendant stated that they had their product tested by a third party to ensure that was in adherence with FDA standards, however, the FDA does not verify this sort of testing nor does it require that manufacturers share the results.[92] One of the issues regarding this lawsuit was whether the claims based on the sunscreen were based on non-actionable representations.[93] The court discusses that another district court has explained that a reasonable consumer standard should be utilized in situations such as

[86] *Id.*

[87] *Id.*

[88] *Id.* at *5.

[89] *Id.*

[90] *Id.*

[91] *Id.*

[92] *Id.*

[93] *Id.* at *13.

this one.[94] Under that standard, a plaintiff must "show that members of the public are likely to be deceived.[95]An important distinction when it comes to marketing representations is that "Advertisements that amount of mere puffery are not actionable because no reasonable consumer relies on puffery."[96] "Factual representations, however, are actionable."[97] Defendant argued that the terms "effective" or "highly effective" on the sunscreen bottles are generalized, vague, unspecific, and unmeasurable, which they claim places the representations into the category of non-actionable puffery.[98] Plaintiff's argument in response to these contentions made by the defendant is that "sun protection is the product's express purpose and thus any consumer would necessarily rely on such representations [regarding the product's sun protection qualities] in deciding to purchase the product."[99] They further contend, that as a result of the misrepresentations, Lung's children suffered severe sunburn.[100] The court concluded that plaintiffs above discussed allegations were sufficient, because they support the claim that defendant's product did not protect users from the sun as it claimed it would, and denied the defendants motion to dismiss.[101]

Another issue the court was tasked with resolving was whether plaintiff's claims regarding the natural products fail because "natural" has no legal meaning; again, the court defers to a "reasonable consumer standard."[102] Defendants argued that the term "natural" is 'vague and ambiguous with no recognized meaning in the law" and that plaintiffs do not plead a basis to their claim that "natural" means that the product contains no synthetic ingredients, and that any

[94] *Id.* at *13 (quoting Freeman v. Time Inc., 68 F.3d 285, 289 (9th Cir. 1995)).

[95] *Id.*

[96] *Id.* (quoting Stickrath v. Globalstar, 527 F.Supp.2d 992, 998 (N.D. Cal. 2007)).

[97] *Id.*

[98] *Id.* at *14.

[99] *Id.* at *15.

[100] *Id.*

[101] *Id.*

[102] *Id.* at *20.

confusion should be clarified by the ingredients list.[103] Courts have addressed similar instances in the past, and in considering those opinions, the court states "even if defendant were correct that a cosmetic product cannot be 'natural,' it does not follow that labeling cosmetic products as natural is per se not misleading."[104] Additionally, plaintiffs essentially argued, and the court agreed, that the FDA did not intend to allow a manufacture to use an ingredient list as a shield from liability from representations made on its label.[105] They reason that "[R]easonable consumers cannot necessarily "be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box."[106] Regarding this issue, the court concluded that whether the term "natural was a misleading statement was a factual issue that could not be decided on this notion; they stated that it was not needed, as the FAC had already stated allegation sufficient to state a claim.[107] As such, the court concluded that the FAC adequately alleged misrepresentation and denied the defendants motion.[108]

II. PREVIOUSLY PROPOSED COSMETIC SAFETY LEGISLATION

As previously mentioned, cosmetic companies have been self-regulated for over a hundred years. However, recently, some lawmakers have pushed for change and have attempted to tighten the regulatory framework for the cosmetic industry after rising concerns relating to the potentially toxic ingredients in many products.[109]

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[103] *Id.*

[104] *Id.* at *21 (quoting Morales v. Unilever U.S. Inc., 2014 WL 1389613, at *7 (E.D. Cal. Apr. 9, 2014)).

[105] *Id.* (quoting Fagan v. Neutrogena Corp., 2014 WL 92255, at *2 (C.D. Cal. Jan. 8, 2014)).

[106] *Id.* (quoting *Fagan*, 2014 WL 92255, at *2).

[107] *Id.* at *22.

[108] *Id.* at *23.

[109] Priyanka Narayan, *The Cosmetic Industry Has Avoided Strict Regulation for Over a Century. Now Rising Health Concerns Has FDA Inquiring*, CNBC (Aug. 2, 2018, 10:08 AM), https://www.cnbc.com/2018/08/01/fda-begins-first-inquiry-of-lightly-regulated-cosmetics-industry.html.

Environmental health advocates have said that scrutiny of the cosmetic industry is long overdue. Scott Faber, who is the senior vice-president for government affairs at the Environmental Watch Group stated "It's hard to think of a category that is less regulated [than cosmetics]. Even pesticides have more."[110]

In October 2017, Senator Hatch introduced S. 2003, titled "FDA Cosmetic Safety and Modernization Act" which is also commonly referred to as the "Hatch Bill."[111] The bill "establishes a series of requirements relating to Cosmetics regulation, including requiring cosmetic manufacturers and distributors to report serious adverse health events to the Food and Drug Administration.[112] Then, on September 26, 2018 Representative Jan Schakowsky introduced a bill in the house that would ban certain chemicals from retail and professional salon products and require full fragrance disclosure.[113] The bill, H.R. 6903, titled the "Safe Cosmetics and Personal Care Products Act of 2018" is the only federal cosmetic safety legislation that would put an end to secret fragrance chemicals.[114] Cosmetic companies can use the term fragrance as a loophole to hide hundreds or thousands of chemicals by simply slapping the term "fragrance" on the ingredients list. A few things that included provisions in the bill would provide for include immediately banning some of the most toxic chemicals that are present in cosmetics, directing the FDA to assess 300 ingredients for safety within 2 years of the bills enactment, providing the FDA with the authority to recall products found to be unsafe or misbranded, and requiring cosmetic companies to register with the FDA and disclose their ingredients to them.[115] Additionally, S. 726, titled "Personal Care Products Safety Act" was introduced in the Senate on March 7, 2019 by Senator Diane Feinstein in attempt to amend the FD&C Act to ensure the safety of cosmetics.[116] The bill

[110] *Id.*

[111] *Id.*

[112] FDA Cosmetic Safety and Modernization Act, S. 2003, 115th Cong. (2017).

[113] Safe Cosmetics and Personal Care Products Act of 2018, H.R. 6903, 115th Cong. (2018).

[114] H.R. 6903.

[115] *Id.* §§ 612, 616, 620.

[116] Personal Care Products Safety Act, S. 726, 116th Cong. (2019).

would require the FDA to test certain ingredients, and would provide them authority to issue recalls and require more complete product labels and warnings from manufacturers.[117] Then, again, in 2019, Representative Jan Schakowsky, showed her commitment to making safe cosmetics a priority by reintroducing the Safe Cosmetics and Personal Care Act of 2019 (H.R. 4296).[118] The bill would be the only federal cosmetic safety legislation to ban 12 of the most toxic chemicals that are still being used in personal care products.[119] The bill would also fund research for safer alternatives to use, address the over exposure of vulnerable populations to toxic chemicals, require cosmetic companies to fully disclose the ingredients in their "fragrance" and ban most animal testing.[120] While there seems to be much interest in tightening up the reigns on the cosmetic industry, the bills simply cannot seem to gain momentum within the legislature. None of these bills have passed yet.

III. BIOTECHNOLOGY IN COSMETICS

In recent years, the term biotechnology has been used in various disciplines – but what exactly is it? Biotechnology is "technology that utilizes biological systems, living organisms, or parts of this to develop or create different products."[121] When genetic engineering was discovered in the 1970's it opened the door for research in biotechnology to flourish because of the newfound ability to alter living organisms' genetic material.[122] As a result, biotechnology made its way into the realm of the cosmetics industry, and took off quite

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[117] *Id.* §§ 607, 611–12.

[118] Erika Wilhelm, *New Federal Bill Will Be the First in the Nation to Ensure That Beauty and Personal Care Products are Safe for All*, BREAST CARE PREVENTION PARTNERS (Sept. 12, 2019), https://www.bcpp.org/resource/new-federal-bill-will-be-the-first-in-the-nation-to-ensure-that-beauty-and-personal-care-products-are-safe-for-all/.

[119] *Id.*

[120] *Id.*

[121] *What is Biotechnology?*, NOR. UNIV. OF SCI. & TECH., https://www.ntnu.edu/ibt/about-us/what-is-biotechnology (last visited Jan. 10, 2021).

[122] *Id.*

rapidly. The cosmetic industry, as with other industries, is incredibly competitive and companies are always trying to create the most new and improved products to place on the market. Biotechnology has made it possible to develop numerous new cosmetic products, both ordinary and extraordinary. It has been said that some of the most modern cosmetics are based off of research in genetic engineering.[123] As a result, cosmetics are comprised of biotechnology-derived ingredients.[124]

Genetic engineering has made it possible to customize cosmetics based on genetics and create individualized skin care, stem cell-based products to help regenerate aging skin tissue, and various other products.[125] The plethora of possibilities that have arisen from genetic engineering and biotechnology in cosmetics has been very beneficial to many consumers. However, cosmetic companies are not always as joyous. This is because as a result of biotechnology crossing into the lane of cosmetics, and the increasing use of science in beauty, the lines have become blurred as to what is truly cosmetic manufacturing/research and what is medical research.[126] This is especially apparent with extremely high-end cosmetic companies who do science-based research on things such as anti-aging processes and antioxidant reactions in order to create new and improved products for consumers.[127] Cosmetics are not required to undergo clinic trials for efficacy as drugs are—this is a huge incentive for biotechnology companies.[128] They often view this lack of regulation or oversight of cosmetic research as a loophole and a way to finance their biotechnology research.[129] This mentality which leads to the blurred line effect can lead to incredibly complex and risky regulatory

[123] Andrea Rinaldi, *Healing Beauty? More Biotechnology Cosmetic Products that Claim Drug-Like Properties Reach the Market*, 9 EMBO REPS. 1073, 1073 (2008).

[124] *Id.*

[125] *Id.*

[126] *Id.*

[127] *Id.*

[128] *Id.*

[129] *Id.*

situations.[130] What further complicates this issue is that high-end cosmetic companies often label their products with claims stating that the product is based on "advanced scientific research."[131] As a result, consumers, reasonably assume that the product is effective, and has gone through the lengthy testing process that drugs go through.[132] The fact of the matter is that cosmetic companies would prefer to avoid having their products being tested as drugs, because this requires costly, lengthy clinical trials.[133] In many instances, the regulatory agency then has to decide whether a product should be classified as a cosmetic or a drug.[134]

A. L'Oréal

The research division of L'Oréal, which is the world's largest cosmetic and beauty companies has taken part in the use of biotechnology for cosmetic products. One particular example of the use of this new tool is the company's involvement in research geared at finding a treatment to restore the natural appearance of an individual's hair.[135] After research findings indicated that damaged hair is deprived of ceramides, L'Oréal developed a synthetic ceramide and now incorporates that ceramide into their products, with a claim that it will "genuinely restore damaged hair."[136] Many believe that the increasing incorporation of scientific research into the development of new cosmetics should lead to benefits for consumers, because it "contributes to the next generation of safer and more efficient beauty products."[137] For many years, L'Oréal has openly accepted the use of science and technology in cosmetics—they have stated "at L'Oréal, we

[130] *Id.*

[131] *Id.*

[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] *Id.*

[136] *Id.*

[137] *Id.*

fully embrace innovations that push the boundaries of science and reinvent beauty and cosmetic rituals."[138]

Another example of this is L'Oréal's active involvement in the production and use of the 3-D printed skin.[139] This product was acquired in 1997, with the intention of using the artificial skin to test new products before they hit the shelves, while also potentially creating a solution to the highly controversial issue of live animal testing.[140] L'Oréal accomplishes this by growing skin in a petri dish.[141] The result is a "gelatinous, dime-sized blob" called "EpiSkin."[142]. Once the "skin" is grown, L'Oréal's researchers utilize it to test their products.[143] Considering the fact that there is no need for pre-market approval for cosmetic products, this is an incredibly innovative way to tackle cosmetic safety issue and consumer protection, while also creating a "cruelty-free" method for testing such products. In 2011, L'Oréal opened a predictive evaluation center in France—the facility is 12,000 square feet and, is staffed with more than 60 scientists, and grows more than 100,000 human skin tissues annually. [144] While L'Oréal has not tested on animals for decades, they technically cannot be labeled a "cruelty free" cosmetic line because their products are sold in China, and those products specifically are required to be tested on animals by government agencies.[145] To be listed as "cruelty free" with People for the Ethical Treatment of Animals (PETA), a company is required to agree that it "does not and will not conduct, commission

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[138] *Innovating Through Science*, L'ORÉAL, https://www.loreal.com/en/beauty-science-and-technology/beauty-research-and-innovation/innovating-through-science (last visited Mar. 4, 2021).

[139] Bob Woods, *Companies are Making Human Skin in Labs to Curb Animal Testing of Products*, CNBC (May 28, 2017, 1:00 PM), https://www.cnbc.com/2017/05/25/loreal-is-making-lab-produced-human-skin-to-curb-animal-testing.html.

[140] *Id.*

[141] *Id.*

[142] *Id.*

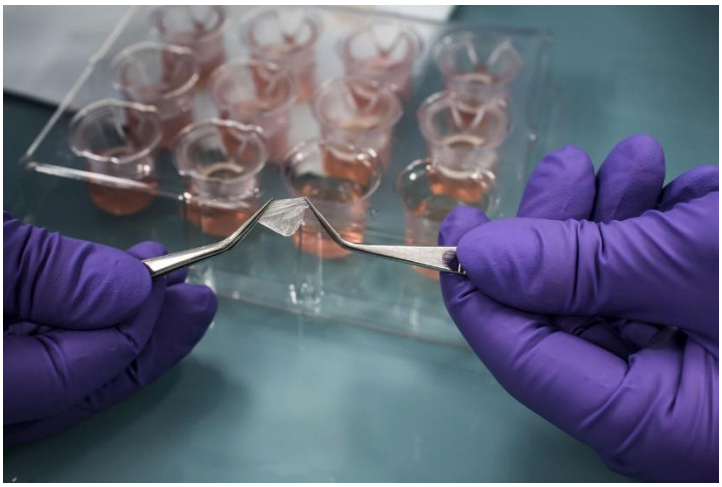
[143] *Id.*

[144] *Id.*

[145] *L'Oréal is Included on PETA's "Do Test" List. What Does that Mean?*, PETA, https://www.peta.org/about-peta/faq/is-loreal-cruelty-free/ (last visited Oct. 11, 2020).

pay for, or allow tests on animals for any of their ingredients, formulations, and products, anywhere in the world."[146]

Figure 2.



Cell cultures to produce human tissue and reconstructed human tissue at the Episkin
Laboratory owned by L'Oreal in Lyon[147]

B. Biossance

Biossance is another well-known cosmetic brand that has taken a full dive into the biotechnology-cosmetic industry crossover. The skincare company markets themselves by claiming that they are "Pioneering Sustainable Beauty Through Biotechnology."[148] Scientists

[146] *Id.*

[147] Susmita Baral, *L'Oréal Uses EpiSkin, Lab-Grown Skin, to Combat Animal Testing*, MIC (May 30, 2017), https://www.mic.com/articles/178406/loreal-just-created-episkin-lab-grown-skin-that-combats-animal-testing.

[148] *Pioneering Sustainable Beauty Through Biotechnology*, BIOSSANCE, https://biossance.com/pages/our-story (last visited Oct. 11, 2020).

from Biossance began a project in 2003 at University of California, Berkeley—from research at Berkeley labs, they were able to develop an accessible cure for malaria.[149] From that research and the incredible discovery that resulted from it, over 120 million royalty-free treatments have been given.[150] After realizing the inventions that could come from the use of biotechnology, they were inspired to continue using biotechnology for good, and decided to pivot towards creating skincare using the technology.[151]

A popular product that Biossance creates is "squalane" which is a shelf stable version of squalene.[152] Squalene is naturally made in the sebaceous glands of the body.[153] Its purpose is to protect the outer layer of the skin by keeping it hydrated and moisturized.[154] However, as we age, our bodies begin to produce less and less squalene.[155] This is where Biossance's product comes in. Utilizing biotechnology, Biossance scientists were able to produce squalane that is marketed as being just as safe and effective as human derived squalene.[156] Though Biossance is not the first or only company to sell squalene based products, the more common practice throughout the industry has been to extract the compound from shark's liver.[157] However, this method raises two issues. First, there is the ethical issue of targeting marine life to extract the compound in the amount that is needed. [158] Second, it is incredibly unsustainable.[159] Therefore, in attempt to transition from extracting from sharks, companies have started

[149] *Id.*

[150] *Id.*

[151] *Id.*

[152] *What is Squalane & What Are the Skincare Benefits*, BIOSSANCE, https://biossance.com/pages/what-is-squalane (last visited Oct. 11, 2020).

[153] Meghan Tahbaz, *Where Beauty and Biotechnology Intersect*, O'REILLY (Aug. 31, 2017), https://www.oreilly.com/ideas/where-beauty-and-biotechnology-intersect.

[154] BIOSSANCE, *supra* note 152.

[155] *Id.*

[156] *Id.*

[157] Tahbaz, *supra* note 153.

[158] *Id.*

[159] *Id.*

obtaining squalene from olives—this has drawbacks of its own.[160] The erratic nature of crops, in conjunction with "naturally occurring impurities" can result in olive-derived squalane that is undependable in regard to quality and availability.[161] This is where bioengineering comes in to create squalane in a much more commercially feasible, sustainable, and ethical manner, by using 100% plant derived, renewable sugarcane.[162]

Furthermore, Biossance stands by the claim that they use ingredients that you can trust. Their website states "we stand for effective, clean skincare , banning 2,000+ ingredients that are toxic to both you and the environment."[163] Unlike most other cosmetic products, Biossance seems to be very transparent about all of the ingredients in their products, and makes their mission of "making clean beauty the new standard" very evident.[164] The "clean academy" section of the website, which is "the destination for clean beauty education" contains information that has been discussed in this paper.[165] This includes the fact that we use about a dozen products every day containing more than 150 ingredients.[166] Additionally, they compare the amount of chemicals that the US bans (30) vs. the amount that the EU has banned (1,300+), remaining very candid about the fact that the United States has not passed major federal legislation governing the cosmetic industry since 1938.[167]

This comment has argued numerous time that cosmetics are the least intensively regulated product that falls under the FDA's jurisdiction. Yet, it has been acknowledged that congressional

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[160] BIOSSANCE, *supra* note 152.

[161] *Id.*

[162] *Id.*

[163] *Clean. Sustainable. Effective Ingredients.*, BIOSSANCE, https://biossance.com/pages/ingredients (last visited Oct. 11, 2020).

[164] *The Biossance Way. The Future Is Clean with Us*, BIOSSANCE, https://biossance.com/pages/no-compromise-beauty (last visited Nov. 15, 2020).

[165] *The Clean Academy*, BIOSSANCE, https://biossance.com/pages/the-clean-academy (last visited Oct. 11, 2020).

[166] *Id.*

[167] *Id.*

legislation was proposed in 2016 in hopes of strengthening the regulatory framework surrounding cosmetics.[168] Unfortunately, no amendments were adopted at the time the committee was writing its report.[169] That being said, there has been discussion as to whether the FDA could effectively regulate the new and innovative biotechnology based cosmetics, with the powers they had in 2017.[170] FDA regularly uses its powers to deem cosmetics as products as drugs or devices.[171] However, simply because a cosmetic may pose a safety risk does not categorize it as a drug or device under the FDA's definitions, and therefore, they cannot regulate it.[172] However, as briefly mentioned earlier in this comment, once a company or product sponsor decides to market their cosmetic with intent to be used for the "cure, mitigation, treatment, or prevention of disease" or if the cosmetic is "intended to affect the structure or any function of the body", the FDA will then have the power to regulate the product.[173]

This boundary, is what may effect many biotechnology cosmetics. By using such advanced technology to create novel products, naturally, companies want to brand them with all types of information and guarantees. However, this is essentially, deeming a cosmetic as a drug, which lets the FDA require pre-market approval for safety and effectiveness and subjects the product to all other pre- and post-market regulatory powers that are vested in the FDA for regulating drugs.[174] This process is lengthy and expensive, and FDA does not bear the costs.[175] Additionally this process is not "risk-stratified."[176] A concern is that the lack of differentiation will de-incentivize the creation of new

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[168] NAT'L ACADS. OF SCIS., ENG'G, & MED., PREPARING FOR FUTURE PRODUCTS OF BIOTECHNOLOGY 79–80 (2017), http://nap.edu/24605.

[169] *Id.*

[170] *Id.*

[171] *Id.*

[172] *Id.*

[173] *Id.*

[174] *Id.* at 80.

[175] *Id.*

[176] *Id.*

and novel cosmetic products that consumers could benefit from.[177] The regulatory framework is based on two polar ends of a spectrum.[178] On one end, you have the FDA's oversight of cosmetics, which is minimal because of the lack of pre-market regulatory review.[179] On the other end, you have the FDA's drug regulation which "subjects all drugs all drugs to the same premarket review process FDA requires for high-risk cancer therapies."[180] An option that has been proposed is to have a strong post-marketing risk detection program that would relieve the pressure of achieving certainty about safety prior to debuting new products, which would facilitate innovation while promoting safety through rapid risk detection and response.[181] Post-market risk analysis is critical even when pre-market risk analysis is required, because not all risks can be determined in the small-scale, short-duration framework that pre-market studies follow, and can only be detected after the product has been placed on the market and has been in widespread commercial use.[182]

Another possibility is for biotechnology based cosmetic products to be classified as medical devices, instead of drugs.[183] A product can be classified as a device as opposed to a drug if it "does not achieve its primary intended purposes through chemical action within or on the body … and is not dependent upon being metabolized."[184] For cosmetics that fall under this FDA definition, a risk-stratified review process is available.[185] This process could both provide safety protection for consumers, while not disincentivizing beneficial innovation.[186] A substantial portion of future biotechnology based

[177] *Id.*

[178] *Id.*

[179] *Id.*

[180] *Id.*

[181] *Id.* at 75.

[182] *Id.*

[183] *Id.* at 80.

[184] *Id.*

[185] *Id.*

[186] *Id.*

cosmetics are going to inevitably be labeled as either a drug or medical device.[187] This is especially true for the products that "achieve their effects at a genomic or microscopic scale where the mode of action could legitimately be characterized as either chemical/metabolic (drug) or mechanical/electrical (device).[188]

The increasing production of cosmetic products that contain biologically active ingredients, has led to a neologism—"cosmeceutical" which is a combination of cosmetic and pharmaceutical.[189] Cosmeceutical is defined as "a substance that is marked as a cosmetic, but contains biologically active ingredients that have an effect on the user."[190] In a different, but relevant example, consider BOTOX® (botulinum toxin type A). The FDA first approved BOTOX® in 1989 for eye muscle disorders, and then in 2000 for treatment of a disorder that causes neck and shoulder spasms.[191] Then, in 2002, the FDA approved the use of BOTOX® for wrinkles.[192] However, because federal law allows physicians to use approved drugs for unapproved purposes ("off-label use"), doctors began injecting BOTOX® into patients to eliminate wrinkles prior to the FDA's approval.[193] Nonetheless, physicians were glad when the FDA made their public statement about BOTOX® use for cosmetic purposes because the approval "provides reassurance to both patients and physicians that it's an OK product in terms of safety and efficacy", said Dr. James Wells, who is a plastic surgeon.[194] However, it should be noted that while the FDA may approve the drug itself, they are not approving the methods of use—consumers should not be deceived into thinking that injection of this toxin into their face to smooth

[187] *Id.*

[188] *Id.*

[189] Andrew Moore, *The Biochemistry of Beauty*, 3 EMBO REPS. 714, 715 (Aug. 2002).

[190] *Id.*

[191] Vicki Kemper, *FDA Smooths the Way for Cosmetic Use of Botox*, L.A. TIMES (Apr. 16, 2002), https://www.latimes.com/archives/la-xpm-2002-apr-16-mn-38123-story.html.

[192] *Id.*

[193] *Id.*

[194] *Id.*

wrinkles has been independently evaluated by the agency for safety and effectiveness, when that is not the case.[195]

Though BOTOX® is a drug, it is also a biotechnological cosmetic. The term "cosmeceutical" has "blurr[ed] the line[s] between drug and cosmetic, doctor and aesthetician, and patient and consumer."[196] There is still much controversy surrounding the use of active ingredients or biological ingredients that are found within cosmeceuticals, "particularly in regards to their mechanisms of action, formulation, optimal concentration, penetration and retention in skin."[197] Although there have been clinical trials done in an attempt to address these concerns, there have not been any concrete answers regarding these cosmeceuticals.[198] However, in vitro tests have shown that many of the ingredients in cosmeceuticals do have a protective, and anti-aging effects on the skin, however, "there has been little translation of this evidence into in vivo testing to determine the possibility of delivering adequate doses to skin that will produce clinical or histologic results."[199] Nonetheless, cosmeceuticals offer both benefits and downside to consumers and physicians. Promoting beauty and anti-aging is a major trend in today's society. And while it is both plausible and realistically achievable in today's modern society, it does not come without risks. As technology continues to advance, and the increasing use of cosmeceuticals becomes even more widespread, it is becoming increasingly important for physicians to familiarize themselves with these products in order to appropriately advise and educate their patients about the risks and benefits of cosmeceuticals.[200]

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[195] *Id.*

[196] Katherine I. Martin & Dee Anna Glaser, *Cosmeceuticals: The New Medicine of Beauty*, 108 MO. MED. 60, 60 (2011).

[197] *Id.*

[198] *Id*

[199] *Id.* at 60–61.

[200] *Id.* at 63.

IV. LOOKING TOWARDS THE FUTURE

In the European Union, cosmetic products must "undergo an expert scientific safety assessment" before they can be sold to customers.[201] This is drastically different from the current laws in the United States. In the United States, the FDA has authority to act on a product that shows evidence of harm *after* it has been placed on the market.[202] The problem with this is easy to recognize—it is not until someone is negatively affected, that the government will intervene. And even when the FDA does identify a safety issue with a product, they still cannot force manufacturers to remove the product from the market because recalls issued by the FDA are voluntary—if the company refuses to comply with the recall, they can simply issue a safety advisory informing about any health concerns associated with the product.[203]

Questions have been proposed as to what Congress can do to best update the FDA's approach to cosmetic safety regulation. Susan Mayne, who is the director of the FDA's center for Food Safety and Applied Nutrition, proposed some basic elements when testifying to the U.S. House subcommittee on Health.[204] First, she stated that Congress needs to make registration and listing of products and their ingredients mandatory, so that the FDA can know who is making regulated products and what those products contain.[205] Second, she stated that Congress needs to give the FDA explicit authority to establish good manufacturing practice regulations.[206] Next, is to make company reporting of adverse events mandatory.[207] Additionally, she stated that she would allow the FDA to have access to the records

[201] Isabella Isaacs-Thomas, *Why Your Cosmetics Don't Have to Be Tested for Safety*, PBS (Dec. 16, 2019, 5:50 PM), https://www.pbs.org/newshour/health/why-your-cosmetics-dont-have-to-be-tested-for-safety.

[202] *Id.*

[203] *Id.*

[204] *Id.*

[205] *Id.*

[206] *Id.*

[207] *Id.*

during routine or for-cause inspections.[208] She stated that she would want Congress to empower the agency to issue mandatory recalls for unsafe cosmetic products and require companies to disclose known cosmetic allergens on a product's label.[209] Her final proposition was that Congress should ensure that the FDA has sufficient resources to implement these public health protections.[210] All of these proposals seem like feasible ways for Congress to step in to ensure that we are protecting the public, while not trying to completely overtake an industry.

While I agree with the basic elements of these proposals, and do not propose any substantive changes, I do recognize the importance in considering whether these proposed ideas would sufficiently encompass biotechnology-based cosmetics as well, and whether this category of cosmetics would even fall under the new laws, were they to ever be imposed. It has been a topic of legislation in more recent years to define the term "natural" in order to prevent deceitful companies from misrepresenting their products as "natural" as a result of there being no oversight or legal standards that must be met to allow you to label your products as such.[211] Similarly, it would be fundamental to have the FDA specify whether the current definition of "cosmetic"—a "product" (excluding purse soap) intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance" would remain, or whether there would need to be an updated definition, given how much the cosmetic industry has advanced over the years.[212] Provided that the goal of implementing stricter cosmetic regulations and oversight is to improve consumer safety and overall public health, the definition should be amended to include products that are created using genetic engineering and/or biotechnology. I anticipate this being opposed by some biotechnologists who have been taking advantage of the lightly

[208] *Id.*

[209] *Id.*

[210] *Id.*

[211] Richard B. Newman, *Legislation Introduced to Define the Term "Natural"*, NAT'L L. REV. (Dec. 13, 2019), https://www.natlawreview.com/article/legislation-introduced-to-define-term-natural.

[212] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, 321(i) (2020).

regulated cosmetic industry to further their research objective while avoiding the hassle of having to go through lengthy and costly safety trials as drugs. The fear surrounding biotechnology for many cosmetic corporations is that if the product looks too much like a drug, or makes specific claims about the effects the product may have, then it may tilt the scale towards being a drug, if the FDA were to intervene and make a determination as to the classification of the product. As we have learned, landing yourself in "drug land," leads to much stricter parameters. For a "cosmeceutical" you have to lean much stronger towards the "cosme" and less towards "ceutical" if a company wanted to take advantage of the lightly regulated cosmetic industry. As many of these biotechnology-based cosmetic products are essentially prototypes that are making pharmaceutical-like claims, it is essential that safeguards are in place for consumer protection.

What is arguably most puzzling about this situation is that there is clearly a need and desire for stricter oversight of the cosmetic industry. This is evident for a few reasons. First, is simply the rapid movement towards the use of organic, vegan, cruelty-free, paraben/pthalate/fragrance-free products. This indicates the desire and demand for safe cosmetics. Second, there has been proposed legislation, by various state representatives, during multiple legislative sessions. It is not as if this is a public health issue that we are unable to address. This is an issue that is top of mind for lawmakers, parents, consumers, doctors, and scientists. For this reason, it is perplexing that safe cosmetic legislation has not been successful. There is still such skepticism surrounding the promotion of a healthier society. The public should not have to wonder whether the chemicals that are in their personal care products are carcinogenic or endocrine disrupting. Parents should not have to question whether the baby powder they are using on their baby contains cancer causing asbestos, or whether the fragrances used in their soaps contain toxic chemicals. Why is it that in such a modern and outspoken society, we are remaining passive on such a grave issue? We are trusting regulations that were in place when Franklin D. Roosevelt was our president, when the average rent was $27 a month, and tuition to

Harvard was $420/year.[213] In attempting to figure out what the hesitancy is to enact federal legislation, there are minimal statements by anyone providing a rational argument as to why we should keep the regulatory framework as it currently is. However, a few Republican lawmakers have expressed their concern, framing their argument as a harmonization issue. For example, Representative Michael Burgess from Texas reasoned that the proposed Safe Cosmetics and Personal Care Products Act of 2019, discussed earlier in this comment, did not "adequately address the issue of harmonization" between federal and state law when it comes to regulation.[214] Further, he made it a point to emphasize that any law passed in relation to this issue should emphasize that national law is superior to state law.[215] Clearly, we are struggling getting any federal legislation passed. Therefore, it makes sense to ease into it by starting at the state level. This too, has not been easy, but it is possible. The "cruelty-free" animal rights movement has become very popular, as it should. With the research and science we currently have, there is no reason to subject animals to the harms of testing unknown products on them. However, it is crucial to step back and really process this. What we are saying, is 'it is not okay to test products on animals because it might cause them harm, which is unethical', yet we are okay with essentially, doing the testing on humans. The lack of oversight over the cosmetic industry leads humans to be the guinea pigs for cosmetic products.

CONCLUSION

In sum, a majority of the population in the United States uses some form of cosmetic product on a regular basis. Consumers purchase various products at the store and reasonably assume that they have

[213] Henry Blodget, *For a Reminder of What Inflation Does to Your Money, Check Out the 'Cost of Living' in 1938*, BUS. INSIDER (Oct. 3, 2014, 6:02 AM), https://www.businessinsider.com/the-cost-of-living-2014-10.

[214] Isaacs-Thomas, *supra* note 201.

[215] *Id.*

been tested for safety and efficacy. However, that is usually not the case. The cosmetics industry is essentially a self-regulating industry with extremely minimal federal oversight, and this may be leading to negative health consequences for consumers in the United States. Cosmetics as defined by the FDCA are not subject to pre-market approval by the FDA.[216] Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. As the cosmetic industry has evolved, there has been a shift towards the use of biotechnology to create cosmetics in an entirely different manner, which may be transforming the industry.

Despite the numerous adverse health reports and lawsuits regarding cosmetic products, no changes have been made to the law in over 80 years. As such, cosmetics companies are still able to take advantage of an extremely lightly-regulated industry, and consumers are the ones suffering the harms.

While we recognize an abundance of correlations between exposure to certain chemicals and negative health effects, there is simply a lack of evidence strong enough to indicate the causal connection that is needed for action. Because of this difficulty, successful lawsuits are far and few. Additionally, biotechnology-based cosmetics have created even more complexities by deepening the gray area between drugs and cosmetics. For the sake of human health, it is crucial that we pave a regulatory pathway for cosmetic oversight sooner rather than later.

[216] U.S. FOOD & DRUG ADMIN., *supra* note 1.