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OVER THE PROBLEM: A CALL TO
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REGULATE COSMETICS THROUGH AN
AMENDMENT TO THE FEDERAL FOOD, DRUG,
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PULLING OUR HAIR OUT AND GLOSSING OVER THE PROBLEM: A CALL TO STRENGTHEN THE FDA’S POWER TO REGULATE COSMETICS THROUGH AN AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Julie Mueller*

INTRODUCTION

Since the early 1900s, consumers in the United States have had reason to expect that the food they consume and the drugs they ingest will be safe. Beginning with the passage of the Pure Food and Drug Act in 1906 and continuing with the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), the federal government has played a vital role in the regulation of food and drugs consumed in the United States. However, because of various deficiencies in the FDCA’s cosmetic legislation, this expectation of safety and thoroughly vetted products should not extend to cosmetics.

This Note explores these deficiencies by examining the current regulatory system for cosmetics in the United States. Part I scrutinizes the WEN hair conditioner fiasco, a case study that exemplifies the inadequacies of the existing system. Part II details a piece of proposed legislation—the Personal Care Products Safety Act—that would eliminate many of the shortcomings of the current system and ameliorate negative effects on cosmetic consumers. Part III sets out a brief overview of the European Union’s approach to cosmetic regulation—Regulation 1223/2009—which served as a model for the Personal Care Products Safety Act in the United States. Part IV proposes an amendment to the FDCA that blends the European Union’s approach with the Personal Care Products Safety Act in a way that would protect

* Candidate for J.D., 2018, University of Pittsburgh School of Law; B.A. English Literature, 2015, *summa cum laude*, University of Pittsburgh.

consumers by ensuring that their cosmetic products were thoroughly regulated and vetted. This Note also considers the impact of stricter regulations on smaller scale cosmetics manufacturers and seeks to ameliorate these consequences by looking for legislative solutions, both at home and abroad.

I. COSMETICS: THE FORGOTTEN CHILD OF THE FDCA

Despite inclusion of the word “Cosmetic” in the title of the FDCA, the government has been largely reticent in passing comprehensive legislation on the topic and consequently has failed to create a climate where the FDA can proactively regulate the cosmetic industry. The federal government has exercised its regulatory power over the food and drug industries through various mechanisms, such as mandatory pre-market approval of new drugs,¹ an independent recall power on foods,² and mandatory registration of pharmaceutical³ and food-producing companies.⁴ However, although the FDCA contains dozens of sections and subsections setting forth the government’s rigorous expectations for the food⁵ and drug⁶ industries, it contains only a few sections directly addressing the cosmetic industry.⁷ Within the FDCA, the term “cosmetic” has a broad meaning; rather than simply referring to makeup, “cosmetic” includes items like toothpaste, body wash, shampoo, hair dye, mouthwash, etc.⁸ In short, “cosmetic” refers to everyday items that most citizens would consider necessities. This broad definition contrasts with the very narrow scope of extant cosmetics regulation.

One section of the FDCA sets out the definition of adulterated cosmetics,⁹ while another sets out the definition for misbranded cosmetics.¹⁰ Both of these definitions

¹ 21 U.S.C. § 355 (2012).

² § 350*l*.

³ § 360.

⁴ § 350*d*.

⁵ See §§ 341–350*l*-1.

⁶ See §§ 351–360*ff*-1.

⁷ See §§ 361–363.

⁸ See § 201(i). See also *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm> (last updated Aug. 3, 2017).

⁹ § 361.

¹⁰ § 362.

are narrow and create rather high thresholds for deeming cosmetics either adulterated or misbranded.¹¹ For example, to be considered “adulterated” within the meaning of the FDCA and thus subject to intervention by the FDA, a cosmetic must either contain or be packaged in a “poisonous or deleterious substance . . . [or] a filthy, putrid, or decomposed substance . . . [or have] been prepared, packed, or held under insanitary conditions . . . [or contain certain color additives that have been deemed unsafe].”¹² The third and final section of the FDCA devoted to cosmetics simply directs the Secretary of Health and Human Services to promulgate exemptions from labelling requirements for certain types of cosmetics.¹³ These sections only set out narrow circumstances where the FDA can step in and regulate a potentially harmful cosmetic product.

Further, these three sections do not set forth industry-specific frameworks for investigating or penalizing cosmetic manufacturers. Instead, the adultery and misbranding sections merely relate back to general provisions of the FDCA which prohibit the sale of adulterated or misbranded food, drugs, or cosmetics¹⁴ and punish violations with seizure,¹⁵ one to three years of jail time, and \$1,000 to \$10,000 in fines;¹⁶ the severity of the penalty depends on whether the manufacturer acted with intent to defraud and mislead or had previously violated under the section.¹⁷ The FDCA also provides a general power to investigate manufacturers of food, drugs, and cosmetics,¹⁸ but does not set forth the specific circumstances that can prompt an FDA investigation of a cosmetics manufacturer; rather, as is consistent with the rest of the FDCA, the provision permitting FDA investigations lays out zero provisions relating to cosmetics specifically.¹⁹

The relative lack of congressional action at the legislative level has created a *laissez-faire* regulatory climate in which the U.S. cosmetic industry is largely self-

¹¹ See §§ 361–362.

¹² § 361.

¹³ § 363.

¹⁴ § 331.

¹⁵ § 334.

¹⁶ § 333.

¹⁷ § 333(a)(2).

¹⁸ § 372.

¹⁹ See *id.*

regulated.²⁰ The FDA has no power to approve cosmetics before they go on the market.²¹ Furthermore, even in circumstances where cosmetics cause extremely adverse reactions, the FDA cannot recall cosmetics—it can only issue a written request asking the manufacturer to recall the product voluntarily.²² Similarly, the FDA cannot require cosmetic manufacturers to register with the FDA before manufacturers place their products on the market; rather, they can only “request” that the manufacturer register with the agency of its own volition.²³ Correspondingly, the FDA cannot require cosmetic manufacturers to report the complaints they receive from customers to the FDA itself.²⁴

The FDA is not completely feckless; it can, for instance, issue safety alerts about cosmetics and monitor recalls should a cosmetic firm choose to voluntarily recall a product.²⁵ As noted previously, the FDCA does provide the FDA with a general investigation power, but does not set forth what circumstances should prompt an FDA investigation into a cosmetics manufacturer.²⁶ The FDA’s website, however, explains that

[a] number of factors affect how [the] FDA determines that an inspection of a cosmetic establishment may be warranted . . . [including, but not limited to] the type of products, the significance of consumer or trade complaints received, the

²⁰ Sarah E. Schaffer, *Reading our Lips: The History of Lipstick Regulation in Western Seats of Power*, 62 FOOD DRUG L.J. 165, 204 (2007).

²¹ *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm> (last updated Nov. 15, 2016).

²² *Id.*

²³ 21 C.F.R. § 710.1 (2016).

²⁴ Eric Lipton & Rachel Abrams, *Their Hair Fell Out. Should the F.D.A. Have the Power to Act?*, N.Y. TIMES (Aug. 15, 2016), http://www.nytimes.com/2016/08/16/us/politics/cosmetics-industry-congress-regulation-wen.html?_r=0.

²⁵ *See Recalls & Alerts*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/ComplianceEnforcement/RecallsAlerts/default.htm> (last updated Nov. 3, 2017).

²⁶ 21 U.S.C. § 372 (2012).

company's compliance history, FDA surveillance and compliance initiatives, and agency resources.²⁷

Thus, rather than being a proactive regulatory body with the authority to act independently, the FDA tends to be weakly reactive to defects in cosmetics. In the absence of any authority to require pre-market approval of cosmetics, it must use safety alerts, product recall requests, and after-the-fact investigations to *call* for change rather than effect change directly—and can do so only after the cosmetic product has hit the shelves.

The FDA's deficiencies came to a head—excuse the pun—in the form of a hair conditioner that allegedly caused hair loss for hundreds of users. Many consumers who purchased WEN, a “cleansing conditioner” marketed as an alternative to shampoo that “cleanses hair thoroughly without lather or harsh sulfates found in some ordinary shampoos”²⁸ reported significant hair loss after using the product.²⁹ Guthy-Renker (the manufacturer of WEN) and WEN users recently finalized a \$26.25 million settlement agreement addressing the hair loss claims.³⁰ After receiving 127 complaints about WEN—“the largest number of reports ever associated with any cosmetic hair cleansing product”³¹—the FDA began investigating Guthy-Renker's manufacturing and distributing centers.³² Over the course of these investigations, the FDA has discovered that Guthy-Renker has received over 21,000 complaints from WEN users since 2011.³³ However, the FDA has not yet found the cause of the hair loss,³⁴ and because the FDA is powerless to

²⁷ *Inspection of Cosmetics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Cosmetics/Compliance/Enforcement/ucm136455.htm> (last updated Feb. 29, 2016).

²⁸ *Why It's Unique*, WEN, <http://www.wen.com/why-its-unique.html?lang=default>.

²⁹ Lipton & Abrams, *supra* note 24.

³⁰ *Friedman v. Guthy-Renker, LLC*, 2016 U.S. Dist. LEXIS 149900 (C.D. Cal. Oct. 28, 2016).

³¹ *WEN by Chaz Dean Cleansing Conditioners: FDA Statement—Investigation of Adverse Event Reports*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511890.htm> (last updated July 19, 2016).

³² *Id.*

³³ *Id.*

³⁴ *Id.*

even pressure Guthy-Renker to order a recall without a finding of either adulteration or misbranding, the product remains on the shelves.³⁵

The FDA's response to the WEN hair loss fiasco is illustrative of its general powerlessness in the cosmetics arena. The weak regulatory system failed at every turn; when WEN hit the market, it did so without having to gain pre-market approval from the FDA.³⁶ The FDA was alerted to the situation because 127 customers reported their complaints directly to the FDA and because the FDA subsequently deemed the sheer volume of these complaints "significan[t],"³⁷ and not because Guthy-Renker was required to report customer complaints to the FDA.³⁸ Without those 127 complaints, the FDA might never have launched an investigation and may never have discovered the 21,000 complaints lodged with Guthy-Renker. Furthermore, even after launching its investigation, the FDA was powerless to order a recall.³⁹ Because the FDA could not prove that the conditioner was adulterated or misbranded—the only two narrow avenues toward FDA action provided by the legislature⁴⁰—the FDA had to content itself with issuing a safety alert and allowing the product to remain on the market.

This unsatisfying result would not have occurred if WEN was a drug or a food product; in those situations, the FDA is empowered to act through various mechanisms, such as requiring pre-market approval of drugs,⁴¹ an independent food recall power,⁴² and mandatory registration by drug⁴³ and food companies.⁴⁴ Given the disparity among the three areas addressed by the FDCA, it is clear that the legislature should step in and eliminate this incongruity by amending the FDCA to provide the FDA with the authority to promulgate more stringent regulatory

³⁵ Lipton & Abrams, *supra* note 24.

³⁶ See *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated*, *supra* note 21.

³⁷ See Lipton & Abrams, *supra* note 24.

³⁸ *Id.*

³⁹ *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated*, *supra* note 21, <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm> (last updated Nov. 15, 2016).

⁴⁰ Lipton & Abrams, *supra* note 24.

⁴¹ 21 U.S.C. § 355 (2012).

⁴² § 350*l*.

⁴³ § 360.

⁴⁴ § 350*d*.

mechanisms. In short, the FDA has proven that it has the capability to regulate the food and drug industries effectively; thus, it should be given a legislative mandate that allows it to protect cosmetic consumers from potentially dangerous products.

II. THE NEED FOR LEGISLATIVE ACTION: AN AMENDMENT TO THE FDCA'S COSMETIC SECTIONS

Changes to the current regulatory scheme for cosmetics ought to come from the legislature in the form of an amendment to the FDCA. This amendment should grant the FDA the authority to require pre-market approval of cosmetics, order mandatory recalls, require cosmetic manufacturers to register with the FDA, and require cosmetic manufacturers to report adverse events to the FDA.

The legislature is the appropriate source of change in the cosmetics industry for both practical and ideological reasons. Pragmatically, when called on to interpret the FDCA, courts have been very hesitant to expand on or deviate from what little cosmetics-specific legislation the FDCA does provide. Furthermore, in practical terms, the legislature has been successful in regulating both the food and drug industries.⁴⁵ Finally, as a general principle, the legislature is the branch of government with the requisite authority to write and pass laws.⁴⁶

Preliminarily, when considering the validity of cosmetics regulations, courts tend to be industry-friendly. For example, since 1967, the courts have allowed the industry to mount pre-enforcement challenges to cosmetics regulations.⁴⁷ Furthermore, the courts tend to be reluctant to deviate from the scarce statutory language in the FDCA that *does* address cosmetics. For example, in *Toilet Goods Ass'n v. Finch*, the United States Court of Appeals for the Second Circuit refused to broadly construe a provision of the FDCA that required pre-market approval of color additives as *also* requiring pre-market approval of finished cosmetics.⁴⁸ The Secretary had promulgated regulations that required pre-market approval of not only color additives, but also diluents and finished cosmetics.⁴⁹ The court held that these regulations exceeded the statutory authority granted to the FDA by the FDCA; in

⁴⁵ See *supra* text accompanying notes 1–4.

⁴⁶ U.S. CONST. art. I, § 1, cl. 1. In this case, the amendment would be couched under the Commerce Clause. U.S. CONST. art. I, § 8, cl. 3.

⁴⁷ *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 168 (1967).

⁴⁸ *Toilet Goods Ass'n v. Finch*, 419 F.2d 21, 25–27 (2d Cir. N.Y. 1969).

⁴⁹ *Id.* at 23–24.

doing so, it refused to “write in” a pre-market approval power where Congress had not done so.⁵⁰ This decision underscores the fact that the courts will not deviate from the legislative language and will instead wait for the legislature to act to increase FDA authority over the cosmetics industry.⁵¹

More recently, in *Gonzalez v. L’Oreal United States*, the court continued this industry-friendly line of jurisprudence, unequivocally holding that there “is no private right of action for a violation of the FDCA.”⁵² The case in question was somewhat similar to the WEN disaster discussed previously; the plaintiff in *Gonzales* experienced permanent discoloration on her forehead after using a hair care product.⁵³ However, without even deciding whether the product caused the injury, the court refused to allow the claim against the manufacturer to go forward.⁵⁴ Thus, in addition to the various deficiencies in the FDA’s regulatory powers discussed previously, the courts have contributed to the self-regulated cosmetic industry climate by refusing to deviate from what little statutory language exists.⁵⁵

Two United States Senators introduced a bipartisan bill that would change this regulatory climate and could potentially ameliorate the ugly consequences of the largely self-regulated cosmetics industry. The bill, a proposed amendment to the FDCA entitled the Personal Care Products Safety Act, was introduced in April 2015⁵⁶ by Senators Dianne Feinstein (D-California) and Susan Collins (R-Maine).⁵⁷

The Act would amend the FDCA and, among other measures, provide the FDA with an independent mandatory recall power.⁵⁸ This recall power would first give the manufacturer an opportunity to conduct a voluntary recall,⁵⁹ but in the event that the manufacturer refused to conduct such a recall, the Act would then authorize the FDA

⁵⁰ *Id.* at 25–27.

⁵¹ *See id.*

⁵² *Gonzalez v. L’Oreal U.S.*, 489 F. Supp. 2d 181, 185 (N.D.N.Y. 2007) (citing *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 806–07 (1986)).

⁵³ *Id.* at 183.

⁵⁴ *Id.* at 185.

⁵⁵ *See id.*

⁵⁶ Personal Care Products Safety Act, S. 1014, 114th Cong. (2015).

⁵⁷ Lipton & Abrams, *supra* note 24.

⁵⁸ Personal Care Products Safety Act, S. 1014, 114th Cong. § 613 (2015).

⁵⁹ *Id.*

to make the recall order mandatory and require the manufacturer to “immediately cease distribution of such cosmetic; and . . . as applicable, immediately notify all persons [involved in the distribution, transportation, or sale of the cosmetic] to immediately cease distribution of such cosmetic.”⁶⁰ Within two days of issuing this order, the FDA would provide the manufacturer with an opportunity for an informal hearing to determine the necessity of additional steps.⁶¹ After this hearing, if the FDA determined that further measures were necessary, it would have the power to

amend the order to require recall of such cosmetic or other appropriate action . . . specify a timetable in which the recall shall occur . . . require periodic reports to the Food and Drug Administration describing the progress of the recall; and . . . provide notice to consumers to whom such cosmetic was, or may have been, distributed.⁶²

The FDA would also have the power to notify the public of the recall.⁶³ This independent recall power would obviously bolster the FDA's ability to respond to cosmetic complaints, which would in turn encourage compliance from cosmetics manufacturers.⁶⁴

Furthermore, the Act would require all cosmetic manufacturers to register with the FDA within a certain timeframe⁶⁵ and file yearly reports of all adverse events reported to the manufacturer, while mandating more frequent reports of serious, adverse events.⁶⁶ These registration and reporting mechanisms would allow the FDA to keep closer tabs on cosmetics manufacturers and would not force the agency to rely on customer complaints lodged with the FDA.⁶⁷

Though the Act does not go so far as to require pre-market approval of cosmetics, it would require that cosmetics manufacturers include an attestation of the

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ See Lipton & Abrams, *supra* note 24.

⁶⁵ Personal Care Products Safety Act, S. 1014, 114th Cong. § 101 (2015).

⁶⁶ *Id.* § 104.

⁶⁷ See Lipton & Abrams, *supra* note 24.

product's safety when filing an ingredient statement with the FDA⁶⁸ and would establish a framework for the FDA to independently evaluate the safety of ingredients used in cosmetics.⁶⁹ It is the opinion of this author that the Act should be further expanded to require full pre-market approval of all new cosmetics introduced to the market so as to proactively prevent harmful cosmetics from entering the market.

The Act has enjoyed the support of several large cosmetic-manufacturing corporations, which view the new regulations proposed by the Act "as an avenue toward regaining public trust" in the safety of their products.⁷⁰ However, unsurprisingly, it has also encountered opposition from smaller companies, who may not have the "size and muscle" to fully comply with new regulations.⁷¹

However, to alleviate these concerns, the Act makes several allowances for smaller businesses, such as offering them more time to comply with the Act⁷² and technical assistance in complying with the act.⁷³ In addition to these measures, the Act waives registration fees for businesses with a three year average annual revenue of \$500,000 or less⁷⁴ and gives smaller scale cosmetics manufacturers that meet these criteria more lenient standards to abide by, such as allowing such manufacturers to submit a simplified cosmetic ingredient statement.⁷⁵

Furthermore, in this context, it is important to note that the FDCA's purpose is to provide consumers in the United States with safe products,⁷⁶ not to provide corporations with convenient or manageable standards.⁷⁷ The government has created effective regulatory frameworks for the food and drug industries without

⁶⁸ Personal Care Products Safety Act, S. 1014, 114th Cong. § 101 (2015).

⁶⁹ *Id.* § 102.

⁷⁰ *See* Lipton & Abrams, *supra* note 24.

⁷¹ *Id.*

⁷² S. 1014 § 102.

⁷³ *Id.* § 111.

⁷⁴ *Id.* § 202.

⁷⁵ *Id.* § 101.

⁷⁶ 21 U.S.C. §§ 301–399f (2012).

⁷⁷ *See id.*

eliminating smaller-scale producers;⁷⁸ thus, it seems clear that the government could do the same for the cosmetic industry and eliminate threats to consumer safety before they occur.

Furthermore, as Part III explains, the European Union's Cosmetic Directive provides a helpful model. In addition to providing an example of a comprehensive regulatory scheme for cosmetics, it provides built-in flexibility that ensures that small businesses can comply with regulations without compromising consumer safety.

III. A BRIEF OVERVIEW OF EUROPEAN UNION COSMETIC REGULATION

In 2009, the European Union adopted Regulation (EC) No. 1223/2009, a comprehensive update to a 1976 EU Directive that set mandatory cosmetic industry standards for all European Union member states.⁷⁹ Because the proposed Personal Care Products Safety Act was largely based on this regulation, some of its provisions should seem familiar. For instance, one section of the Regulation requires cosmetics manufacturers to gain pre-market approval before they can place products on the market.⁸⁰

Just as the proposed Personal Care Products Safety Act delineates between “adverse events”⁸¹ and “serious adverse events,”⁸² and requires cosmetics manufacturers to report these events to the government,⁸³ the European Union Regulation (“Regulation”) defines both “undesirable effects”⁸⁴ and “serious undesirable effects”⁸⁵ and requires that they be reported. The Regulation requires manufacturers to make information about any “undesirable effects” available to the

⁷⁸ See *supra* text accompanying notes 1–4.

⁷⁹ Regulation 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, 2009 O.J. (L 342) 59.

⁸⁰ *Id.* at ch. III, art. 10, 2009 O.J. (L 342) 59, 67.

⁸¹ Personal Care Products Safety Act, S. 1014, 114th Cong. § 101 (2015).

⁸² *Id.*

⁸³ *Id.* § 104.

⁸⁴ Regulation 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, ch. I, art. 2, 2009 O.J. (L 342) 59, 65.

⁸⁵ *Id.*

public.⁸⁶ An “undesirable effect” is defined as “an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product.”⁸⁷ In the event of a “serious undesirable effect”—“an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation [sic], congenital anomalies or an immediate vital risk or death”⁸⁸—the manufacturer must alert the relevant governmental authority of the member state in which the undesirable effect occurred.⁸⁹

Finally, though cosmetics manufacturers are given a chance to voluntarily recall their products when they do not comply with Regulation standards,⁹⁰ the Regulation grants the government of the member state in which the non-complying cosmetic has been sold the authority to order and carry out the recall itself if the manufacturer does not carry out the recall within a set timeframe.⁹¹ Thus, the Regulation provides each member state with an independent recall power.⁹²

However, some provisions of the Regulation differ from the proposed Personal Care Products Safety Act. Instead of setting a figure (such as \$500,000 average annual revenue over three years) that defines small scale manufacturers and then easing certain requirements for those manufacturers, the Regulation delegates this issue to the more specialized Commission.⁹³ The Commission is then instructed to create guidelines that will make it easier for SMEs (small and medium enterprises) to comply with the regulation.⁹⁴ This flexible approach gives the Commission (analogous in this situation to the FDA) the power and authority to generate guidelines that will enable smaller businesses to comply with all regulations, rather than giving them a different set of guidelines to abide by entirely.⁹⁵ Thus, the

⁸⁶ *Id.* at ch. VI, art. 21, 2009 O.J. (L 342) 59, 74.

⁸⁷ *Id.* at ch. I, art. 2, 2009 O.J. (L 342) 59, 65.

⁸⁸ *Id.*

⁸⁹ *Id.* at ch. VII, art. 23, 2009 O.J. (L 342) 59, 74.

⁹⁰ *Id.* at ch. II, art. 5, 2009 O.J. (L 342) 59, 66.

⁹¹ *Id.* at ch. VII, art. 25, 2009 O.J. (L 342) 59, 75–76.

⁹² *Id.*

⁹³ *Id.* at ch. III, art. 10, 2009 O.J. (L 342) 59, 67.

⁹⁴ *Id.*

⁹⁵ *See id.*

Regulation attempts to ensure that neither consumer safety nor the viability of small businesses are compromised.

The Commission, for its part, conducts research to determine what the costs of compliance with cosmetic directives are and takes into account the impact of regulations on manufacturers.⁹⁶ For instance, in the build-up to the passage of the 2009 Regulation, the Commission determined that the cost of compliance with the previous cosmetic directive was approximately 0.5% to 1% of a cosmetic manufacturer's annual turnover.⁹⁷ Thus, when it promulgates guidelines designed to aid smaller scale manufacturers in complying with the regulations, the Commission can draw from its research and offer manufacturers data that estimates the costs of compliance, thus enabling small businesses to adequately plan for compliance.⁹⁸

Similarly, the Regulation had a built-in gap between enactment and compliance that allowed manufacturers, both large and small, to plan for and implement changes to their practices in light of the incoming regulation.⁹⁹ Though the Regulation was enacted in late November of 2009,¹⁰⁰ it did not fully take effect until July of 2013,¹⁰¹ thus giving manufacturers over three and a half years to prepare to comply with the regulations.¹⁰²

However, the European Union's approach did not perfectly address the needs of all small businesses. Due to the lack of an "automatic" exception for small businesses with average revenues under a certain amount, many very small scale manufacturers were forced to either pay large sums for the safety reports required by the Regulation or cease production entirely.¹⁰³ One small scale cosmetics manufacturer noted that the cost of paying a chemist to conduct the requisite safety assessments for 20 products might range from £13,000 to £30,000, much more than

⁹⁶ See, e.g., *Commission Staff Working Paper Impact Assessment Report on Simplification of the "Cosmetics Directive,"* at 11, COM (2008) 49 final (Jan. 28, 2008).

⁹⁷ *Id.*

⁹⁸ See *id.*

⁹⁹ See Regulation 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, ch. IX, art. 40, 2009 O.J. (L 342) 59, 78.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² See *id.*

¹⁰³ Amanda Saurin, *EU Cosmetic Regulation and the Vanishing Small Producer*, WELLGREEN LEWES: NEWS/BLOG, <https://wellgreenlewes.com/newsblog/> (last visited Sept. 22, 2017).

she expected to make over the course of her career.¹⁰⁴ However, one criticism of the EU approach is unlikely to be a problem in the United States. In the European Union, some dissenters argue that member states differ radically in their adherence to European Union regulations and law, which places small manufacturers in strictly adhering member states at a disadvantage to manufacturers in states that do not always adhere to European Union law.¹⁰⁵ In other words, the manufacturers in strictly adhering member states must comply with the European Union regulations or their government will enforce the standards against them, whereas manufacturers in non-adhering member states will not have to pay the costs associated with compliance because their government will not enforce the standards.¹⁰⁶ In the United States, where the FDA has separate and theoretically consistent federal enforcing power, this unequal enforcement is less likely to be a problem and the playing field is more likely to be level.

On the whole, the European Union's Cosmetics Regulation provides cosmetics manufacturers with workable standards that protect consumers. Through flexible administration of the regulation and prolonged implementation timelines, the European Union's Regulation generally balances the interests of both manufacturers and consumers.

IV. BLENDING FOUNDATIONS: A CALL FOR REFORM IN THE UNITED STATES

Just as it is sometimes necessary to blend one or more shades of cosmetic foundation to get an exact skin tone match, the best regulatory scheme for cosmetics in the United States is one that blends several approaches. In order to protect cosmetic consumers in the United States from the potentially harmful effects of unregulated cosmetics, the FDCA should be amended to give the FDA several new powers. Additionally, the amendment should take into consideration the cost of compliance on small businesses.

First, borrowing from the proposed Personal Care Products Safety Act,¹⁰⁷ the FDA should be given authority to *require* cosmetics manufacturers to register with the agency. Incident to this registration, and again mirroring the Personal Care

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ Personal Care Products Safety Act, S. 1014, 114th Cong. § 101 (2015).

Products Safety Act¹⁰⁸ and the European Union,¹⁰⁹ the FDA should be granted power to require pre-market approval of cosmetics before they can be distributed to consumers. In other words, before a registered manufacturer could sell a product, it would have to submit information to the FDA attesting to the product's safety, just as the Personal Care Products Safety Act and European Union require. Both of these measures—mandatory registration and pre-market approval—would lead to greater transparency and would allow the FDA considerable oversight of the cosmetics industry.

Once products hit the shelves, cosmetics manufacturers should be required to report adverse events to the FDA. Just as the Personal Care Products Safety Act recommends, the FDA should be granted authority to require yearly reports of adverse events¹¹⁰ and to be notified of serious adverse events within 15 days of when the manufacturer learns of the serious adverse event.¹¹¹ However, in addition to the yearly reports of adverse events, manufacturers should also be required to send more immediate reports to the FDA if there is an unusual number of reports concerning the same issues with a product. This sort of requirement would enable the FDA to investigate widespread claims about a product in a timely manner.

Finally, and perhaps most importantly, the FDA should be granted an independent recall power consistent with the ones detailed in the Personal Care Products Safety Act¹¹² and the European Union's legislation.¹¹³ This recall power would allow manufacturers a certain window of time “commensurate with the risk”¹¹⁴ to recall the product on their own. If the manufacturer failed to do so, however, the FDA would have the power to both order and oversee its own recall to the product. Additionally, the FDA should be given the power to alert the public of the recall, just as the Personal Care Products Safety Act recommends.¹¹⁵ This power would increase transparency and allow the FDA to carry out a more effective recall.

¹⁰⁸ *Id.* § 104.

¹⁰⁹ Regulation 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, ch. III, art. 10, 2009 O.J. (L 342) 59, 67.

¹¹⁰ S. 1014 § 104.

¹¹¹ *Id.*

¹¹² *Id.* § 105.

¹¹³ Regulation 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, ch. VII, art. 25, 2009 O.J. (L 342) 59, 75–76.

¹¹⁴ *Id.* at ch. VII, art. 24, 2009 O.J. (L 342) 59, 74.

¹¹⁵ S. 1014 § 105.

Had this proposed framework been in place at the time the WEN conditioner hit the shelves, the entire ordeal could have been avoided. First, mandatory registration of Guthy-Renker and mandatory pre-market approval of the product would have ensured that the product did not contain any known harmful chemicals when it was made available to consumers. If, despite the safety attestation, the conditioner turned out to contain a harmful chemical that caused significant hair loss, the FDA would have been alerted promptly by mandatory frequent adverse event reports. It would have been able to proactively address the situation, rather than having to wait for 127 reports to trickle in to the FDA directly. Finally, if Guthy-Renker refused to order a recall, the FDA would have the independent power to order and carry out the recall itself. In short, the comprehensive cosmetics regulation this Note proposes would likely have stopped the WEN fiasco before it started, and even if it could not prevent the issue entirely, it would have provided a regulatory roadblock at every juncture that would ultimately have protected cosmetic consumers.

The amendment to the FDCA should also contain provisions that address the concerns of smaller scale cosmetics manufacturers and lessen the financial impact of the regulations on such small businesses. An approach that combines the strategies of both the European Union's Regulation and the Personal Care Products Safety Act would be useful in achieving this goal. The amendment could utilize the European Union's long gap (three and a half years) between enactment and full implementation¹¹⁶ to ensure that smaller scale cosmetics manufacturers had adequate time and notice of the regulation to prepare and alter their practices. The amendment could also borrow the European Union's strategy of delegating flexibility in administration to a smaller, more specialized government unit¹¹⁷—in this case, the FDA—and giving it some modicum of elasticity. Finally, just as the Commission conducts independent research to help small businesses by estimating the cost of compliance and looking for ways to reduce these costs,¹¹⁸ the FDA should be tasked with carrying out similar research.

Additionally, the amendment could borrow from the Personal Care Products Safety Act and provide technical compliance assistance to smaller scale cosmetics

¹¹⁶ Regulation 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, ch. IX, art. 40, 2009 O.J. (L 342) 59, 78.

¹¹⁷ *See id.* at ch. III, art. 10, 2009 O.J. (L 342) 59, 67.

¹¹⁸ *See, e.g., Commission Staff Working Paper Impact Assessment Report on Simplification of the "Cosmetics Directive,"* at 10–11, COM (2008) 49 final (Jan. 28, 2008).

manufacturers.¹¹⁹ This technical assistance would make it easier for smaller manufacturers to comply with the regulations without incurring the cost of hiring a compliance manager. The amendment to the FDCA could also introduce an automatic exemption for cosmetic manufacturers with annual revenues under a certain amount, which would ameliorate the problem of small-scale manufacturers who could not feasibly comply with strict regulation.¹²⁰ These various methods would ensure that small businesses followed the regulations and had the time and resources to do so, thus generating a two-fold benefit for consumers and manufacturers alike. Consumers would get safer products, while cosmetics manufacturers would get to enjoy the increase in sales that comes with an increase in public trust and confidence.¹²¹

Others have noted the disparity between the United States' approach to cosmetics regulation and the European Union's scheme,¹²² and have documented the repeated failure of United States legislators to effectively solve the cosmetics regulation problem.¹²³ Many additional pieces of prospective legislation have been introduced to ameliorate the many problems that come from the current *laissez-faire* regulatory climate, but all have failed.¹²⁴ Some scholars, cognizant of these failures, argue that the solution to repeated failures at the federal level is to attempt regulation at the state and local levels.¹²⁵

However, state-by-state approaches to cosmetic regulation are unlikely to provide the kind of comprehensive reform needed to both protect consumers and lower compliance costs for manufacturers. As noted by the European Union Commission's research, the legal "uncertainty" of varying regulatory schemes translates to higher compliance costs.¹²⁶ Because unclear or inconsistent standards

¹¹⁹ S. 1014 § 111.

¹²⁰ *Id.* § 202.

¹²¹ See Lipton & Abrams, *supra* note 24.

¹²² Rajiv Shah & Kelly E. Taylor, Note, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23 FORDHAM ENVTL. L. REV. 203, 242–44, 247 (2012).

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.* at 254–55.

¹²⁶ *Commission Staff Working Paper Impact Assessment Report on Simplification of the "Cosmetics Directive,"* at 10–11, COM (2008) 49 final (Jan. 28, 2008).

can raise the cost of compliance by 10%,¹²⁷ it is important to have comprehensive, coherent, and consistent regulatory schemes. In the United States, a need for consistency necessarily requires the involvement of the federal government rather than individual state governments. Only the federal government can guarantee country-wide application and enforcement of standards. Thus, a state-by-state approach is both fiscally and pragmatically undesirable.

CONCLUSION

The FDCA's cosmetics sections have not been significantly updated since 1938,¹²⁸ and the recent WEN hair conditioner debacle demonstrates that many cosmetic consumers are literally pulling their hair out due to the lack of effective cosmetic regulation in the United States. Given that "cosmetics" refers to many everyday necessities such as toothpaste, shampoo, and body wash,¹²⁹ it is important that the government act to ensure that these ubiquitous cosmetic products are safe for consumers.

Rather than continuing to gloss over the problem, the United States should amend the FDCA in a way that empowers the FDA to proactively and effectively regulate cosmetics. After examining the FDA's regulation of food and drugs, the European Union's Cosmetic Regulation, and proposed legislation in the United States, Congress should pass an amendment to the FDCA that grants the FDA new powers to regulate cosmetics. These powers should include required registration of cosmetic manufacturers, mandatory pre-market approval of cosmetic products, required adverse event reporting, and an independent recall power. Additionally, though the concerns of consumers should be paramount, the new legislation should attempt to accommodate smaller scale cosmetics manufacturers through flexible administration of standards, compliance assistance, a long gap between enactment and full implementation, and a *per se* exemption for small scale manufacturers with annual revenue under a certain amount. This amendment would thus achieve the dual goals of protecting consumers and making compliance feasible for manufacturers.

¹²⁷ *Id.*

¹²⁸ See Lipton & Abrams, *supra* note 24.

¹²⁹ See 21 U.S.C. § 201(i) (2012).