Journal of Contemporary Health Law & Policy (1985-2015)

Volume 26 | Issue 1 Article 6

2009

Not in My Makeup: The Need for Enhanced Premarket Regulatory Authority over Cosmetics in Light of Increased Usage of Engineered Nanoparticles

Donald R. Johnson

NOT IN MY MAKEUP: THE NEED FOR ENHANCED PREMARKET REGULATORY AUTHORITY OVER COSMETICS IN LIGHT OF INCREASED USAGE OF ENGINEERED NANOPARTICLES

*Donald R. Johnson**

I. INTRODUCTION

Consumer products containing nanotechnology are appearing in the marketplace at an ever increasing rate. This seems to indicate that nothing short of a scientific revolution is taking place on the nanoscale.[1] Cosmetics comprise a significant market share of the consumer products that are known to contain nanomaterials.[2] However, despite the rapid increase in nanoparticle usage in cosmetics and other consumer products, scientists have only recently started examining the potential health and environmental effects of exposure to these particles. Studies are beginning to show that nanoparticles possess the ability to penetrate the human body's defenses and persist in the environment.[3] Due to the uncertainty about the health effects

---

* J.D. Candidate, The Catholic University of America, Columbus School of Law, May 2010. B.A., Chinese Language and Literature, The George Washington University, 2007. The author wishes to thank his family and friends for their support. The author also thanks Professor Andrea J. Boyack for her excellent editing and suggestions. The biggest thanks go to the two women without whom this Note could never have existed: Dawn Sobol and Glynnis La Garde of the Columbus School of Law's DuFour Law Library. Finally, this Note is dedicated to Dorothy, Blanche, Rose, and Sophia. Thank you for being friends.

1. Jessica K. Fender, *The FDA and Nano: Big Problems With Tiny Technology*, 83 CHI-KENT L. REV. 1063, 1063 (2008) ("We are in the midst of a nanotechnology revolution. Our understanding of the world changed drastically with the advent of quantum mechanics, when scientists discovered that contrary to the rules of classical physics, matter took on novel and unexpected properties when observed at the nanoscale.").

2. *Id.* at 1074.

3. *See infra* Parts III.A, C.

of nanomaterials, even the nanotechnology industry has called for more toxicology research in this area.[4]

Further complicating matters, the United States Food and Drug Administration (FDA) possesses only minimal regulatory authority over cosmetics.[5] Most regulatory activity occurs through the Personal Care Products Council, a voluntary initiative designed by the cosmetics industry itself.[6] Despite the increasing use of nanomaterials, their effects remain largely untested and cosmetic manufacturers have failed to conduct testing to substantiate the safety of products containing nanomaterials.[7] Manufacturers do not label products containing these materials with warnings about the lack of safety substantiation. In fact, companies are not even required by the FDA to inform the consumer of the presence of

---

4. *See* Robert F. Service, *Calls Rise for More Research on Toxicology of Nanomaterials*, 310 SCIENCE 1609, 1609 (2005).

5. *See* Fender, *supra* note 1, at 1074.

6. This Note focuses solely on the FDA's regulatory authority and procedures, but the self-regulating nature of the cosmetics industry is a source of both praise and criticism. *See* Peter Baron Hutt, *A History of Government Regulation of Adulteration and Misbranding of Cosmetics*, *in* COSMETIC REGULATION IN A COMPETITIVE ENVIRONMENT 1, 29 (Norman F. Estrin & James M. Akerson eds., 2000). Hutt states:

> No industry in the history of this country has ever made a greater commitment to self-regulation or has been more successful in achieving it than the U.S. cosmetic industry. Virtually all aspects of the cosmetic industry are subject to some form of voluntary CTFA program initiated by the industry itself to assure FDA, the medical profession, and the public that cosmetic products are safe and appropriately labeled.

Id. at 1. *See also* Thaddeus Herrick, *Amid Health Concern, Nail-Polish Makers Switch Formulas*, WALL ST. J., Apr. 19, 2004, at B1. Ken Cook, President of the Environmental Working Group, noted that the cosmetic industry's self-regulating structure offers little protection to consumers and further stated, "[i]t's not just the fox guarding the henhouse. It's the fox designing and building the henhouse." Thaddeus Herrick, *Amid Health Concern, Nail-Polish Makers Switch Formulas*, WALL ST. J., Apr. 19, 2004, at B1. For further information about the industry-created voluntary regulatory system, *see generally* Gerald N. McEwan, et al., *Voluntary Self-Regulation: A Case Study*, *in* COSMETIC REGULATION IN A COMPETITIVE ENVIRONMENT 185 (Norman F. Estrin and James M. Akerson eds., 2000).

7. *See* Government Accountability Office, *Cosmetics Regulation: Information on Voluntary Actions Agreed to by FDA and the Industry*, HRD-90-58, 4 (1990), *available at* http://archive.gao.gov/d24t8/141081.pdf [hereinafter GAO Report I].

nanomaterials.[8] An Environmental Working Group study of the Cosmetic Ingredient Review,[9] an industry-funded panel of experts whose mandate is to conduct safety assessments of cosmetic products, found that the panel had reviewed only eleven percent of the 10,500 ingredients used in cosmetic products and had fully assessed only twenty-eight of 7,500 cosmetic products.[10] These failings have put consumers in the United States at an unacceptable risk and have strengthened the call for increased regulation of cosmetic products.

As studies continue to weigh the benefits and risks of nanotechnology, the debate over what constitutes appropriate regulation has raged among industry and regulatory officials, elected leaders, and consumer groups, though all agree that there should be further assessment of the risk to human health and the environment posed by nanomaterials.[11] Opinions vary widely from a strict *laissez-faire* approach to a complete ban on all nanotechnology-

---

8. *See infra* note 186.

9. For a comprehensive discussion of the Cosmetic Ingredient Review, *see generally* Wilma F. Bergfeld & F. Allan Andersen, *The Cosmetic Ingredient Review*, *in* COSMETIC REGULATION IN A COMPETITIVE ENVIRONMENT 195 (Norman F. Estrin and James M. Akerson eds., 2000). *See also* Cosmetic Ingredient Review, *How Does CIR Work?*, http://www.cir-safety.org/info.shtml (last visited Oct. 1, 2009).

10. Environmental Working Group Cosmetics Petition, FDA Citizen's Petition Docket No. 2006P-0266/CP 1, 2 (June 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/061704/04p-0266-cp00001-01-vol1.pdf.

11. *See generally* Service, *supra* note 4; *see also Environmental and Safety Impacts of Nanotechnology: What Research Is Needed: Hearing Before the H. Comm. on Sci. and Tech.*, 109th Cong. 6-7 (2005). Organizations as diverse as environmental NGOs [nongovernmental organizations], large chemical companies, nanotech start-ups, insurance companies, and investment firms all agree that the federal government should be immediately directing many more of the dollars it is currently investing in nanotechnology development toward identifying and assessing the potential risks of nanomaterials to human health and the environment. *Environmental and Safety Impacts of Nanotechnology: What Research Is Needed: Hearing Before the H. Comm. on Sci. and Tech.*, 109th Cong. 6-7, 66 (2005) (Statement of Dr. Richard A. Denison, Senior Scientist, Environmental Defense); *see also* Juliet Eilperin, *Nanotechnology's Big Question: Safety*, WASH. POST, Oct. 23, 2005, at A11. "The [FDA]'s decision to approve the company's plan [to produce a product composed of nanoparticles] comes amid an ongoing debate among government officials, industry representatives, academics and environmental advocates over how best to screen the potentially toxic materials." Juliet Eilperin, *Nanotechnology's Big Question: Safety*, WASH. POST, Oct. 23, 2005, at A11.

related research and products.[12] Regardless of the many viewpoints, one thing is certain: nanotechnology is an area in which the FDA must engage in rapid regulatory adaptation.

This Note discusses the health and environmental risks of nanoparticles, provides a history of cosmetic regulation, and proposes a legislative solution that will expand the FDA's regulatory authority over cosmetics while facilitating industrial progress. Specifically, Part II describes nanoparticles, their presence in cosmetics, and explains the unique properties which make them a potential threat to human health and safety. Part III discusses nanotoxicology, examining how these particles enter and cause damage within the body, and briefly touches upon nanotoxicity observed in the environment. Part IV consists of a history of cosmetic regulation, including failed legislative attempts to expand FDA authority over cosmetics, and an examination of the FDA's current cosmetics policies. Part V examines the FDA's current stance on the use of nanoparticles in cosmetics. Finally, Part VI proposes a legislative solution: granting the FDA expanded regulatory authority over cosmetics. This will enable the agency to swiftly and effectively implement a fair regulatory scheme that burdens neither government nor industry. The expanded regulatory authority will also allow the FDA to adapt to the rapid rise in nanoparticle-containing cosmetic products and implement policies to guarantee that the American public is safe from unnecessary harm.

II. NANOPARTICLES

A. Nanoparticles Generally

Nanoparticles are materials so small that their physicochemical properties differ from bulk materials of the same composition.[13] They are defined by ASTM International as ultrafine particles with dimensions greater than one

---

12. *See generally* GLENN REYNOLDS, FORWARD TO THE FUTURE: NANOTECHNOLOGY AND REGULATORY POLICY (Pacific Research Institute 2002) (proposing a *laissez-faire* approach to the regulation of nanomaterials), *available at* http://liberty.pacificresearch.org/docLib/2002_Forward_to_Nanotech.pdf; GARY E. MARCHANT, LESSONS FOR NEW TECHNOLOGIES, 6-7 (Mercatus Center, George Mason University 2008) ("In July 2007, a coalition of forty-five public interest groups issued a position statement calling for a ban on commercialization of any 'untested or unsafe uses of nanomaterials and requiring product manufacturers and distributors to bear the burden of proof.'"), *available at* http://www.mercatus.org/uploadedFiles/Mercatus/Publications/WP0826_RSP_Lessons%20for%20New%20Technologies.pdf.

13. C. Medina et al., *Nanoparticles: Pharmacological and Toxicological Significance*, 150 BRIT. J. PHARMACOLOGY 552, 552 (2007).

nanometer (nm) but smaller than 100 nanometers.[14] To put this size into context, "[a] single human hair is about 80,000 nm wide, a red blood cell is approximately 7,000 nm wide and a water molecule is almost 0.3 nm across."[15]

Nanotechnology has become very attractive for commercial development. Many different types of industry have found them useful in a broad spectrum of products ranging from cosmetics to clothing, electronics to aerospace technologies.[16] Despite the standard provided by ASTM International, the definition of what constitutes "nanotechnology" and, as a result, nanoparticles, remains controversial and unsettled. Though the FDA has not adopted a formal definition of what constitutes nanotechnology, it did participate in the formulation of the definition adopted by the National Nanotechnology Initiative (NNI). Under this definition, something is nanotechnology if it involves:

> Research and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1 - 100 nanometer range. Creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate size. Ability to control or manipulate on the atomic scale.[17]

The FDA essentially adopts this definition by incorporation on its website, stating that "nanotechnology relevant to the FDA might include research and

---

14. ASTM International, E 2456-06, Terminology for Nanotechnology 2 (2006). Originally known as the American Society for Testing and Materials, ASTM International "is one of the largest voluntary standards development organizations in the world—a trusted source for technical standards for materials, products, systems, and services." ASTM International, http://www.astm.org/ABOUT/aboutASTM.html (last visited Oct. 12, 2009). A nanometer is defined as one billionth of a meter. MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 824 (11th ed. 2003).

15. THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES vii (2004), *available at* http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf [hereinafter ROYAL SOCIETY].

16. *Id.* at viii, 9.

17. EPA, CONCEPT PAPER FOR THE NANOSCALE MATERIALS STEWARDSHIP PROGRAM UNDER TSCA 10-11 (July 12, 2007), *available at* http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPPT-2004-0122-0058.

technology development that both satisfies the NNI definition and relates to a product regulated by FDA."[18]

The FDA acknowledges that it is aware of products under its purview that currently contain or claim to contain nanoparticles.[19] One nanotechnology research group lists over 1,000 products that are currently on the market and are manufacturer-identified as containing nanotechnology.[20] Over half of these products are manufactured within the United States[21] and include paints, sunscreens, tennis rackets, golf balls, stain resistant clothing, and cosmetics.[22] Due to their broad range of uses, thousands of tons of nanomaterials are produced each year[23] and the demand for nanomaterial-containing products continues to grow at an enormous rate. According to IndustryWeek, a report by Lux Research indicates that "[t]he market for nanotechnology-based products is expected to reach $3.1 trillion by 2015, up from $147 billion in 2007."[24] As a result of early projections of this trend, Congress passed the 21st Century Nanotechnology Research and

---

18. FDA, SCIENCE & RESEARCH, NANOTECHNOLOGY, FREQUENTLY ASKED QUESTIONS,http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/FrequentlyAskedQuestions/default.htm (last visited Oct. 1, 2009) [hereinafter FDA Nanotechnology FAQs].

19. *Id.* "FDA is aware of several FDA regulated products that employ nanotechnology." *Id.*

20. THE WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, NANOTECHNOLOGY CONSUMER PRODUCTS INVENTORY, http://www.nanotechproject.org/inventories/consumer/ (last visited Oct. 1, 2009) [hereinafter WILSON CENTER] (database includes 803 manufacturer-identified nanomaterial consumer products).

21. *Id.*

22. Rick Weiss, *For Now, Consumer Nanotech Concentrates on the Little Things*, WASH. POST, Mar. 10, 2006, at A3; Garry Kranz, *Buyer Beware: Product List Highlights Both Nanotech and Nano-Marketing*, SMALL TIMES, March 16, 2006, *available at* http://www.smalltimes.com/articles/article_display.cfm?Section=ARCHI&C=Consu&ARTICLE_ID=270536&p=109.

23. ROYAL SOCIETY, *supra* note 15, at 26-27.

24. Jonathan Katz, *Nanotechnology Boom Expected by 2015*, INDUSTRYWEEK, July 22, 2008, http://www.industryweek.com/ReadArticle.aspx?ArticleID=16884&SectionID=35.

Development Act in 2003.[25] This statute authorized $3.6 billion for several federal agencies to engage in research and development in nanotechnology in an effort to ensure the position of the United States at the forefront of this new and burgeoning field.[26]

B. Nanoparticles in Cosmetics

Currently, "some of the most prominent nanotechnology products on the U.S. market are cosmetics,"[27] which comprise over fifteen percent of the market in such products.[28] These cosmetic products include L'Oreal's RevitaLift Double-Lifting treatment anti-wrinkle cream, which contains Pro-Retinol A nanosomes[29] and Zelens' name-brand face cream, which contains C_{60} molecules[30] (also known as buckminsterfullerenes or "buckyballs," but hereinafter "C_{60}"). During a congressional hearing on nanotechnology, Dr. Richard A. Denison, Senior Scientist of Environmental Defense, stated that "[w]e already have nanomaterials of a variety of types in cosmetics, in dispersive applications that are going to introduce these materials in a fairly uncontrolled way . . . ."[31] The uncontrolled introduction of this technology

---

25. 15 U.S.C. §§ 1701-1709 (2006).

26. *Id.* at § 7505.

27. *See* Fender, *supra* note 1, at 1074; *see also* Tim Little, Sanford Lewis & Pamela Lundquist, BENEATH THE SKIN: HIDDEN LIABILITIES, MARKET RISK AND DRIVERS OF CHANGE IN THE COSMETICS AND PERSONAL CARE PRODUCTS INDUSTRY 12 (2007), *available at* http://www.iehn.org/filesalt/IEHNCosmeticsReportFin.pdf. "While questions about the health impact of nanotechnology are certainly broader than the cosmetics industry, their usage in cosmetics and personal care products represents a source of concern to investors since cosmetics companies are already deploying nanotechnology in various applications." *Id.*

28. *See* Fender, *supra* note 1, at 1074.

29. Liesl Schillinger, *Smart Enough To Understand Your Moisturizer?*, N.Y. TIMES, Dec. 22, 2005, at G3.

30. WILSON CENTER, *supra* note 20; Zelens Fullerene C-60 Night Cream, http://www.nanotechproject.org/inventories/consumer/browse/products/5266/ (last visited Oct. 1, 2009). The C_{60} molecule used in this cream is the same molecule that will be later shown to bind to and deform DNA sequences. Zhao, et al., *infra* note 93, at 3856.

31. *Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation Under the National Nanotechnology Initiative: Hearing Before the H. Subcomm. on Research and Science Education of the H. Comm.*

exposes the American people to potentially harmful materials through their daily use of cosmetic products. Dr. Denison's statement refers to the fact that nanomaterials used in cosmetics are free nanomaterials that are not fixed or embedded in another substance[32] and can thus move freely within the medium into which they are introduced. An example of a free nanomaterial is titanium dioxide, which is used extensively in cosmetics and sunscreens.[33] Despite the use of free nanomaterials in cosmetics, there is still relatively little research information on skin penetration by nanoparticles[34] and "none of the nanoscale materials currently used in cosmetics has been substantiated for safety by the FDA . . . ."[35]

The physicochemical properties of nanoparticles require a safety substantiation process. A thorough explanation of these properties demonstrates why stricter regulation and labeling requirements is crucial, particularly for cosmetics.

C. Physicochemical Properties of Nanoparticles

As previously stated, the physicochemical properties of nanoparticles differ from those of bulk material of the same composition. There are two

---

on Science and Technology, 110th Cong. 87 (2007) (statement of Richard A. Denison, Senior Scientist, Environmental Defense).

32. ROYAL SOCIETY, *supra* note 15, at viii; FRIENDS OF THE EARTH, NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS, BIG RISKS (May 26, 2006), nano.foe.org.au/filestore2/download/125/FoEA_nano_cosmetics_report_web.pdf.

33. Borbála Kiss et al., *Investigation of micronized titanium dioxide penetration in human skin xenografts and its effect on cellular functions of human skin-derived cells*, 17 EXPERIMENTAL DERMATOLOGY 659, 659 (2008). Nanoparticles used in cosmetics are free nanoparticles that are not fixed. *See* Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349, 354 (2007) "Nanomaterials may be either fixed as integral features of larger objects (as electronic components, for instance), or used as free nanoparticles (in cosmetics or pharmaceuticals, for example)." Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349, 354 (2007).

34. *See* Kiss et al., *supra* note 33, at 660.

35. Transcript of Public Meeting on Nanotechnology Materials in FDA Regulated Products, Oct. 10, 2006, at 138 (statement by Jane Houlihan, Vice President for Research, Environmental Working Group), *available at* http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForce/ucm111446.pdf.

primary reasons why nanoparticles are subject to these different properties. First, nanoparticles are characterized by a large surface area to volume ratio.[36] Second, particles smaller than fifty nm are subject to the laws of quantum physics and not to the laws of classical physics.[37] These unique characteristics will ultimately contribute to the likelihood of adverse health effects if stronger regulatory authority is not granted to the FDA. In fact, in February 2007, the United States Environmental Protection Agency (EPA) published a white paper on nanotechnology that repeatedly stressed that the differences between nanoparticles and their macro-scale counterparts posed a potential threat:

> It is important to note that nanomaterials have large surface areas per unit of volume, as well as novel electronic properties relative to conventional chemicals. Some of the special properties that make nanomaterials useful are also properties that may cause some nanomaterials to pose hazards to humans . . . . It will be necessary to consider these unique properties and issues, and their potential impacts on fate, exposure, and toxicity, in developing risk assessments for nanomaterials.[38]

1. The Significance of Greater Surface Area to Volume Ratio

The unique surface area to volume ratio seen in nanoparticles may serve to determine reactivity, which is "key to defining the chemical and biological properties of nanoparticles."[39] Interactions and catalytic reactions

---

36. Citizen Petition to the United States Food and Drug Administration filed by the International Center for Technology Assessment, 15-16, *available at* http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf [hereinafter CTA Petition].

37. *Id.*

38. EPA, NANOTECHNOLOGY WHITE PAPER, EPA 100/B-07/001, 30 (2007), *available at* http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf [hereinafter EPA WHITE PAPER].

39. Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622, 622-23 (2006) [hereinafter Nel I] (demonstrating the inverse relationship between the number of surface molecules and particle size).

> In the size range <100 nm, the number of surface molecules (expressed as a % of molecules in the particle) is inversely related to particle size. For instance, in a particle of 30 nm size, about 10% of its molecules are expressed on the surface, whereas at 10 and 3 nm size the ratios increase to 20% and 50%, respectively. Because the number of atoms or molecules on the surface of the particle may determine the material reactivity, this is key to defining the chemical and biological properties of nanoparticles.

occur on the surfaces of particles.[40] As a result of the increased surface area that directly exposes large numbers of molecules or atoms, nanoparticles have an increased potential for biological interaction and may be much more reactive, thus increasing their intrinsic toxicity.[41] Part of this toxicity results from the ability of various nanoparticles to generate free radicals, singlet oxygen, hydroxyls, and other reactive oxygen species (ROS).[42] These chemical forms have been observed in laboratory settings both with and without exposure to light.[43] The ability to create ROS without light implies that the toxicity of nanoparticles can continue even after their penetration into bodily tissues.

Id. at 623, Fig. 1.

40. DR. CHRISTOPH LAUTERWASSER, SMALL SIZES THAT MATTER: OPPORTUNITIES AND RISKS OF NANOTECHNOLOGIES 10 (Allianz Center for Technology 2007), *available at* http://www.allianz.com/static-resources/images-2006-12-13/pdf/saobj_809372_allianz_study_nanotechnology_engl.pdf.

41. Nel I, *supra* note 39, at 622-23; *see also* LAUTERWASSER, *supra* note 40, at 30.

42. Min Chen & Anna von Mikecz, *Uptake and Cytotoxicity of Nanoparticles*, *in* NANOTOXICOLOGY 75, 83-84 (Yuliang Zhao & Hari Singh Nalwa eds., 2007). For an excellent overview of reactive oxygen species and their toxicological nature, *see generally* Barry Halliwell, *Reactive Oxygen Species and the Central Nervous System*, 59 J. OF NEUROCHEMISTRY 1609 (1992) ("A free radical is defined as any species capable of independent existence (hence the term 'free') that contains one or more unpaired electrons."). *See also* Christopher Wanjek, *Mixed Messages – Antioxidants May in Some Cases Do More Harm Than Good*, WASH. POST, Aug. 7, 2001, at HE01. This article reports:

> Free radicals are highly reactive molecules, or single atoms with unpaired electrons, looking for a mate. So they steal an electron from the first thing they encounter, perhaps a cell wall or a strand of DNA. As free-radical damage mounts, cells can no longer perform properly. Tissues degrade. Disease sets in. An excess of free radicals has been cited in the development of cardiovascular disease, Alzheimer's disease, Parkinson's disease and cancer. Aging itself has been defined as a gradual accumulation of free radical damage.

Id.

43. Chen & von Mikecz, *supra* note 42, at 84.

2. Altered Physicochemical Properties in Relation to Macro-scale Counterparts

The effects of reducing materials to the nanoscale are further reaching than simply making them more compact or refined. Rather, these nanoscale materials begin to exhibit fundamental properties that are sometimes radically different from their macro-scale form. These properties include electrical, optical, magnetic, toxicity, chemical or photo-reactivity, bio-accumulation, and explosiveness.[44] Some of the changes from macro to nanoscale are disturbing. At the macro-scale, aluminum is a stable metal; however, at twenty to thirty nm, aluminum becomes explosive.[45] Silicon is an insulator at macro-scale, but becomes a conductor on the nanoscale.[46] Another troubling property exhibited by nanoparticles is that they cannot be viewed with standard optical microscopes because the size of the particles places them below the diffraction limit of visible light.[47] Simply stated, many "breeds" of nanoparticles are invisible without the aid of expensive electron microscopes.

Furthermore, the changes that occur when scaling a material down to the nanoscale are unpredictable. As a National Geographic writer aptly

---

44. *See, e.g.*, Ernie Hood, *Nanotechnology: Looking as We Leap*, 112 ENVTL. HEALTH PERSP. A741 (2004); *see also* EPA WHITE PAPER, *supra* note 38, at 34, 36.

45. Jennifer Kahn, *Nano's Big Future*, NAT'L GEOGRAPHIC, June 2006, at 98, 100, *available at* http://ngm.nationalgeographic.com/2006/06/nanotechnology/kahn-text; *see also* Jeremy Hsu, *New Rocket Fuel Mixes Ice and Metal*, SPACE.COM, Oct. 21, 2009, http://www.space.com/businesstechnology/091021-tw-alice-rocket.html.

46. Nancy J. Brown, *Nanotechnology: Is New Regulation Needed, And If So, By Whom?*, LEGAL BACKGROUNDER, July 25, 2008, at 1, *available at* http://www.wlf.org/upload/07-25-08brown.pdf. *See also* Delara Karkan, Associate Director, Center for Evaluation of Radiopharmaceuticals, Health Canada, Remarks at the Public Meeting on Nanotechnology Materials in FDA Regulated Products 39 (Oct. 10, 2006), transcript *available at* http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/NanotechnologyNanotechnologyTaskForce/ucm111446.pdf.

47. European Commission, Health & Consumer Protection Directorate General Opinion on The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies, at 18 (Mar. 10, 2006), *available at* http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf. *See also*, CIENTIFICA, *NANOPARTICLES*, TECH. WHITE PAPERS NR. 3 at 6 (Oct. 2003), http://images.iop.org/dl/nano/wp/nanoparticles_WP.pdf (explaining that "the fact that nanoparticles have dimensions below the critical wavelength of light renders them transparent.").

described it, "[i]t's like you shrink a cat and keep shrinking it, and then at some point, all at once, it turns into a dog."[48] Not only are these changes unpredictable, they occur regardless of the same material's macro-scale properties. One study concluded, "[e]xperts are *overwhelmingly* of the opinion that the adverse effects of nanoparticles *cannot be reliably predicted* or derived from the known toxicity of the bulk material."[49] The United Kingdom Royal Society and the Royal Academy of Engineering (Royal Society), one of the world's oldest scientific organizations,[50] has repeatedly emphasized that the toxicity of nanoparticles should not be inferred from their macro-scale counterparts: "Free particles in the nanometre size range do raise health, environmental and safety concerns and their toxicology *cannot be inferred* from that of particles of the same chemical at a larger size."[51]

The unpredictable and potentially toxic changes that occur when a material is "nanosized" must be further studied before more products containing nanoparticles are let loose upon the public. One of the leading uses of nanoparticles is in cosmetic products, which are worn directly on the body and sometimes even used on or near mucous membranes.[52] Due to their extensive application directly onto or into the human body, cosmetic products should, at the very least, be subjected to extensive toxicity testing before entering into the marketplace. As a newly developing field, nanotoxicology has begun to demonstrate that the unique properties of nanoparticles can have deleterious effects on human physiology and the environment.

III. NANOTOXICOLOGY

The results of toxicological studies conducted with engineered nanoparticles of the type found in cosmetics are troubling. A report released in April 2008 shows that nanoparticles have had several adverse effects in

48. Kahn, *supra* note 45, at 103.

49. LAUTERWASSER, *supra* note 40, § 6.4, at 30 (emphasis added).

50. The Royal Society, *Brief history of the society*, http://royalsociety.org/page.asp?id=2176 (last visited Oct. 19, 2009).

51. ROYAL SOCIETY, *supra* note 15, at 49 (emphasis added).

52. For example: mascaras, eyeliners, and lipsticks are applied near the mucous membranes in the eyes and mouth, while foundations, blushes, bronzers, and concealers are worn directly on the skin of the face.

toxicology studies done with animals, including nephrotoxicity (causing kidney damage), adverse effects on the reproductive system, and genotoxic effects on the animals' DNA.[53] Some nanoparticles also caused granulomas, fibrosis, and reactions resembling tumors in the lungs of the test animals.[54] Cellular structural damage and oxidative stress have been observed in both *in vivo* and *in vitro* studies.[55] Studies also "suggest that nanoparticles can penetrate the body more readily and more deeply than larger particles."[56] As one author wrote, "a plethora of scientific evidence points to the potential dangers of nanotechnology products."[57] The following sections will show that the potential damage caused by nanoparticles is a serious concern that the FDA cannot continue to ignore by allowing cosmetic products to proceed to market with no premarket testing or enforcement regulations.

---

53. CLAUDE OSTIGUY ET AL., *LES EFFETS SUR LA SANTÉ RELIÉS AUX NANOPARTICULES* ii (2d ed. 2008) ("Chez l'animal, plusieurs effets ont déjà été démontrés dont des effets toxiques au niveau de plusieurs organes (coeur, poumons, reins, système reproducteur...) de même que de la génotoxicité et de la cytotoxicité. Certaines particules, par exemple, causent des granulomes, de la fibrose et des réactions tumorales au niveau pulmonaire.").

54. *Id.* A granuloma is "a mass or nodule of chronically inflamed tissue with granulations that is usually associated with an infective process." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 545 (11th ed. 2003). Fibrosis is "a condition marked by increase of interstitial fibrous tissue." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 465 (11th ed. 2003).

55. Gunter Oberdörster et al., *Principles for Characterizing the Potential Human Health Effects from Exposoure to Nanomaterials: Elements of a Screening Strategy*, 2 PARTICLE & FIBRE TOXICOLOGY § 3.0 (2005), *available at* http://www.particle andfibretoxicology.com/content/2/1/8 [hereinafter Oberdörster I]; Noreen Parks, *New Nano-Headache?*, SCIENCE-NOW DAILY NEWS, June 15, 2006, *available at* http://sciencenow.sciencemag.org/cgi/content/full/2006/615/1 (reporting that even small concentrations of titanium dioxide nanoparticles can produce damaging free radicals in mouse brain cells). Studies done *in vivo* are studies done when nanomaterials are put "in the living body of a plant or animal." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 659 (11th ed. 2003). Studies done *in vitro* are studies done when the effects of nanomaterials are studied "outside the living body and in an artificial environment." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 659 (11th ed. 2003).

56. Lin, *supra* note 33, at 359 (discussing laboratory testing on animal subjects).

57. Fender, *supra* note 1, at 1068-69.

A. Penetration and Absorption of Nanoparticles

The method of penetration and absorption of nanoparticles examined for the purposes of this Note is dermal penetration. Though nanoparticles can enter the body by many means, including inhalation and ingestion,[58] cosmetic products are primarily developed for extended contact with the skin.[59] The skin is the largest organ of the body and is composed of three layers: the epidermis, the dermis, and the subcutaneous layer.[60] The outermost layer of the epidermis is the stratum corneum, a strongly keratinized[61] layer that functions as the skin's primary protector against outside agents, including microorganisms, chemicals, and allergens.[62] However, in the case of nanoparticles, even unbroken skin is not truly unbroken. In most mammalian species, which includes humans, up to one percent of the total skin surface area is made up of sweat glands and hair follicles.[63] The pilot study on dermal penetration found that ten to fifty nm particles of titanium dioxide could penetrate into the dermis layer despite the

---

58. Gunter Oberdörster et al., *Nanotechnology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113 ENVTL. HEALTH PERSP. 823, 837 (2005) [hereinafter Oberdörster II].

59. Yuliang Zhao, et al., *Biological Activities of Nanomaterials/Nanoparticles*, *in* NANOTOXICOLOGY 1, 19 (Yuliang Zhao & Hari Singh Nalwa eds., 2007). "Nowadays, the main route by which nanoparticles can touch human skin is through the use of cosmetic products and sunscreens, etc., which involve various nanoparticles as functional components." *Id. See also* American Academy of Dermatology, Cosmeceutical Facts & Your Skin, http://www.aad.org/public/publications/pamphlets/general_cosmeceutical.html (last visited Oct. 19, 2009) ("It is important to select makeup carefully because it remains in contact with the skin for a long time.").

60. Zhao et al., *supra* note 59, at 6.

61. A very illustrative explanation of keratinized tissue is provided by Nanomaterial Science Lab of National Chung Cheng University in Taiwan, http://www.nmsl.chem.ccu.edu.tw/tea/SKIN_910721.htm (last visited Sept. 30, 2009) ("As skin cells move farther away from their source of nourishment, they flatten and shrink. They lose their nuclei, move [to the outermost layer of the epidermis], and turn into a lifeless protein called keratin. After serving a brief protective function, the keratinocytes are imperceptibly sloughed off.").

62. *Id.*

63. *Id.*

protections of the stratum corneum.[64] Further studies have shown that rubbing and flexing the skin, common actions in the application and removal of cosmetic products, results in faster and deeper penetration by nanoparticles.[65] In addition, damaged skin allows much larger nanoparticles to penetrate the skin more readily.[66]

Scientific data strongly suggests that once in the dermis or subcutaneous layer, nanoparticles can translocate, via the lymphatic system, throughout the body and into vital organ tissue.[67] Further, a 2004 study involving mice and pigs showed that intra-dermally injected nanoparticles will localize in regional lymph nodes.[68] A study conducted with small asbestos fibers suggests that nanoparticles can also translocate into the bloodstream.[69] Although dermal penetration does not appear to be the most efficient method of entry for nanoparticles, the call for continued research in this area[70] demonstrates a legitimate scientific concern with the permeability of the skin to nanoparticles.

---

64. Angela Simonelli et al., *Interactions Between Nanoparticles and Living Organisms: Mechanisms and Health Effects*, *in* NANOTOXICOLOGY 29, 39 (Yuliang Zhao & Hari Singh Nalwa eds., 2007). Further studies demonstrated that the degree of penetration can be greater as a result of the presence of hair follicles and sweat glands on human skin. *Id.*

65. *Repetitive Motion Speeds Nanoparticle Uptake: 'Bucky Amino Acid' Penetrates Faster, Deeper When Skin Is Flexed*, SCIENCEDAILY, Jan. 9, 2007, http://www.sciencedaily.com/releases/2007/01/070104144839.htm; Tinkle et al., *Skin as a Route of Exposure and Sensitization in Chronic Beryllium Disease*, 111 ENVTL. HEALTH PERSP. 1202, 1207 (2003).

66. *See* Oberdörster II, *supra* note 58, at 834.

67. *See* Simonelli et al., *supra* note 64, at 40.

68. *Id.*

69. *Id.*; *see also* Milind Kandlikar, et al., *Health risk assessment for nanoparticles: A case for using expert judgment*, *in* NANOTECHNOLOGY AND OCCUPATIONAL HEALTH 135, 146 (Andrew D. Maynard & David Y.H. Pui eds., 2007).

70. UNITED KINGDOM DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS, CHARACTERISING THE POTENTIAL RISKS POSED BY ENGINEERED NANOPARTICLES, A SECOND UK GOVERNMENT RESEARCH REPORT 26, 56 (2007), *available at* http://www.defra.gov.uk/environment/quality/nanotech/documents/nanoparticles-riskreport07.pdf.

Despite the focus on dermal penetration, one other method by which nanoparticles move must be briefly examined. A study by researchers with Japan's National Institute of Health Sciences demonstrated that C_{60}, once in the bloodstream, passes through the placental barrier and enters into any developing embryo.[71] Not only did the examined nanoparticles enter the embryos, they caused severe abnormalities and death.[72] While the idea of nanoparticles penetrating the skin and causing cellular damage is unsettling, the effect that nanoparticles may have on embryos further strengthens the call for stronger regulatory oversight of these materials in cosmetic products used on a daily basis by millions of people.

B. Cytotoxic, Mutagenic, and Nuclear Effects of Nanoparticles

Studies have demonstrated that nanoparticles are capable of penetrating at least part of the way through the dermal layers and further tests strongly suggest their ability to penetrate completely into the underlying tissues. What nanoparticles do once inside the human body is largely a mystery: only one study has been published that reports on nanotoxicity in humans due to long-term exposure.[73] Most nanotoxicological predictions are gleaned from *in vivo* and *in vitro* laboratory testing on animals and cellular cultures.

Cytotoxic literally means "cell-killing."[74] Therefore, the cytotoxicity of nanoparticles is the measure of how deadly they are to various cell types. One of the primary methods by which nanoparticles cause harm and eventually death to human cells is through the production of free radicals and other ROS.[75] Free radicals are highly reactive molecules that cause cellular damage by reacting with almost anything around them.[76] These chemical forms "damage DNA or cell proteins by changing their proper

---

71. Toshie Tsuchiya et al., *Novel harmful effects of [60] fullerene on mouse embryos in vitro and in vivo*, 393 FEBS Letters 139, 139, 141 (1999).

72. *Id.* at 141.

73. *See* Song et al., *infra* note 99.

74. NIH, National Cancer Institute, NCI Dictionary of Cancer Terms, Definition of cytotoxic, *available at* http://www.cancer.gov/Templates/db_alpha.aspx?CdrID=44020 (last visited Oct. 1, 2009).

75. *See* Nel I, *supra* note 39, at 623.

76. James Yeagle, *Nanotechnology and the FDA*, 12 VA. J.L. & TECH. 1, 7 (2007).

functioning."[77] Such ROS damage leads to deterioration in cellular functions, including, but not limited to, changes in gene expression, alteration of normal mitochondrial functions, and DNA fragmentation.[78] Research has found that "[o]xidant-mediated DNA damage is one of the key factors for the induction of apoptosis," [79] a type of programmed cell death which may be "an important factor in the induction and/or promotion of carcinogenesis and certain proliferative diseases."[80] C_{60}, used in cosmetics, can generate ROS and, in instances where this occurs in sufficient quantities, can result in damage to the cellular membrane and cause cell death.[81] The ROS produced by C_{60} are also the cause of the embryological damage and death seen in the Japanese study referenced earlier.[82] By producing superoxide anions (ions with a negative charge), which decay into hydrogen peroxide, the C_{60} causes cellular lysis (rupture) and growth inhibition.[83] This causes such severe damage that the embryos exposed to such an environment die.[84]

Another form of carbon nanoparticle, the single-walled carbon nanotube (SWNT), is profoundly cytotoxic to macrophages[85] due to "increased

---

77. *Id.*

78. *See* Chen & von Mikecz, *supra* note 42, at 85.

79. *See* Simonelli et al., *supra* note 64, at 44.

80. *Id.*

81. Silvana Fiorito, *Carbon Nanoparticles: Benefits and Risks for Human Health, in* NANOTOXICOLOGY 167, 171 (Yuliang Zhao & Hari Singh Nalwa eds., 2007).

82. *See* Tsuchiya et al., *supra* note 71, at 141-42.

83. *See id.* at 142.

84. *See id.* at 141.

85. Chunhai Fan et al., *Toxicology of Carbon Nanomaterials, in* NANOTOXICOLOGY 181, 188 (Yuliang Zhao & Hari Singh Nalwa eds., 2007). Macrophages are defined as "phagocytic cell[s] of the immune system that may be fixed or freely motile, is derived from a monocyte, functions in the destruction of foreign antigens (as bacteria and viruses), and serves as an antigen-presenting cell." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 745 (11th ed. 2003). Essentially, macrophages seek and destroy invaders in the body.

oxidative stress and accumulation of peroxidative products" in these cells.[86] The SWNT's sister particle, the multi-walled carbon nanotube (MWNT), is cytotoxic not only due to ROS production, but also to their actual physical effects on cells; MWNTs literally tear and rupture the plasma membranes found in cells.[87] Finally, nanoparticles of zinc oxide and iron oxide have "exhibited astonishingly high" levels of toxicity.[88] In fact, these particles, along with MWNTs, are potentially as toxic to humans as asbestos.[89] A June 2009 study demonstrates that MWNTs may cause chronic inflammation in the lung tissues in the same manner as asbestos fibers. With asbestos, this chronic inflammation leads to mesothelioma, making it likely that MWNTs may result in the same condition.[90] Further, zinc oxide has been approved for use in sunscreens by the FDA.[91] While not considered a cosmetic, sunscreens are used in cosmetic products to provide a sun protection factor (SPF). Nano-zinc oxide can result in tissue inflammation, production of ROS, and lysosomal damage.[92]

---

86. *See* Fan et al., *supra* note 85, at 189.

87. Seishiro Hirano et al., *Multi-walled Carbon Nanotubes Injure the Plasma Membrane of Macrophages*, 232 TOXICOLOGY & APPLIED PHARMACOLOGY 244, 249 (2008).

88. Tobias Brunner et al., *In Vitro Cytotoxicity of Oxide Nanoparticles: Comparison to Asbestos, Silica, and the Effect of Particle Solubility*, 40 ENVTL. SCI. & TECH. 4374, 4379 (2006).

89. C. Poland et al., *Carbon Nanotubes Introduced Into The Abdominal Cavity Of Mice Show Asbestos-Like Pathogenicity In A Pilot Study*, 3 NATURE NANOTECHNOLOGY 423-28 (2008); Brunner et al., *supra* note 88, at 4378.

90. Andre Nel, et al., *Understanding the Biophysicochemical Interactions at the Nano-Bio Interface*, 9 NATURE MATERIALS 543, 550 (2009) [hereinafter Nel II]; *see also* NIOSH Science Blog, Persistent Pulmonary Fibrosis, Migration to the Pleura, and Other Preliminary New Findings after Subchronic Exposure to Multi-Walled Carbon Nanotubes, http://www.cdc.gov/niosh/blog/nsb031909_mwcnt.html (March 19, 2009). For an explanation of mesothelioma, see NIH, NATIONAL CANCER INSTITUTE, MESOTHELIOMA: QUESTIONS AND ANSWERS, http://www.cancer.gov/cancertopics/factsheet/Sites-Types/mesothelioma (last visited Oct. 1, 2009).

91. 21 C.F.R. § 352.10 (2000).

92. *See* Nel II, *supra* note 90, at 551 tbl. 4, 553.

Research is still being conducted concerning the mutagenicity of nanoparticles. However, existing data regarding damage to DNA sequences in cells indicates a high probability that genetic mutations will occur. Computer models provide strong evidence that C_{60} will both bind with and cause deformations in the DNA structure, preventing the DNA repair mechanism from working properly.[93] This may also result in cancer-causing genetic mutations.[94] Nano-titanium dioxide, used in cosmetics and sunscreens for its photoprotective effect, also ironically possesses a photocatalytic effect, causing the formation of superoxide and hydroxyl radicals which damage DNA by altering cellular functions and resulting in mutations that lead to either cellular death or proliferative disorders.[95] Dependent on ultraviolet (UV) light, the photocatalytic effects of nano-TIO_2 can occur within the living layers of skin and could cause damage to many different types of skin cells at the varying depths to which UV light can penetrate.[96]

Finally, the nuclear effects on cells must be briefly discussed. Although research is sparse in this area, not all damage to the DNA structures in the nucleus results in cell death. Studies have demonstrated that certain nanoparticles, including silicon dioxide (SiO_2), can cause the development of nuclear aggregates in the nuclei of cells they affect.[97] These abnormal subnuclear structures are present in a variety of neurodegenerative diseases; however, it is unproven whether nanoparticles can cause such diseases as Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis (also known as Lou Gehrig's disease).[98]

---

93. Xiongce Zhao et al., *C_{60} Binds to and Deforms Nucleotides*, 89 BIOPHYS. J. 3856, 3856 (2005).

94. Viola Ellison & Bruce Stillman, *Biochemical Characterization of DNA Damage Checkpoint Complexes: Clamp Loader and Clamp Complexes with Specificity for 5' Recessed DNA*, 1 PLoS BIOLOGY 231, 231 (2003), *available at* http://biology.plosjournals.org/archive/1545-7885/1/2/pdf/10.1371_journal.pbio.0000033-S.pdf.

95. *See* Kiss et al., *supra* note 33, at 660. A proliferative disorder "is any cellular disorder in which the cells proliferate more rapidly than normal tissue growth." U.S. Patent No. 7,374,752 col.7 l.44-45 (filed Aug. 11, 2004).

96. *Id.*

97. *See* Chen & von Mikecz, *supra* note 42, at 89.

98. *Id; see also* Nel II, *supra* note 90, at 546.

C. Yuguo Song, Xue Li and Xuqin Du's Potentially Groundbreaking Report on Human Nanotoxicology

On August 20, 2009, a paper written by three Chinese doctors at Beijing Chaoyang Hospital was published, describing the severe medical conditions of seven women who were exposed to nanoparticles over an extended period of time.[99] This paper demonstrates a conclusive link between nanoparticle exposure and adverse human physiological reactions. The patients in this case were factory workers in China who were exposed to polyacrylic nanoparticles with diameters of approximately thirty nm.[100] In addition to serious lung ailments, including pulmonary fibrosis, granulomas, and hypoxemia (low levels of oxygen in the blood), the patients suffered intensely itchy rashes on their faces, hands, and forearms.[101] Despite bacteriologic, virologic, and immunologic tests, no clinical correlations existed between the test results and the condition of the patients.[102]

The physiological changes seen as a result of the long-term exposure to nanoparticles are severe and disturbing. One eighteen-year old patient's lungs exhibited alterations of the alveolar tissue that resembled emphysema, while a nineteen-year old patient's lung tissues were in some places thickened and "hard like a helmet."[103] All patients suffered from excessive fluid in their lung tissues,[104] with up to 2,000 milliliters (mL) of fluid drained from the eighteen year old patient's chest cavity.[105] To put this into perspective, 2,000 mL is equal to two liters, the same amount found in a bottle of soda in the United States. The nanoparticles were observed to penetrate into the cells of the lung tissues examined, lodging in the cellular cytoplasm, nuclei, and other organelles of the cells.[106] Further, one type of

---

99. Yuguo Song et al., *Exposure to Nanoparticles is Related to Pleural Effusion, Pulmonary Fibrosis and Granuloma*, 34 EUR. RESPIRATORY J. (forthcoming Sept. 2009) (manuscript at 7, on file with author).

100. *Id.* (manuscript at 7, on file with author).

101. *Id.* (manuscript at 7, 13-14, on file with author).

102. *Id.* (manuscript at 8-9, on file with author).

103. *Id.* (manuscript at 11, on file with author).

104. *Id.* (manuscript at 7, on file with author).

105. Song et al., *supra* note 99, (manuscript at 11, on file with author).

106. *Id.* (manuscript at 12, on file with author).

cell examined showed the "characteristic cell morphology of cells undergoing apoptosis," or cellular death.[107]

The outcomes of the patients in this report are grim. Of the seven patients, only five survived their nanoparticle-inflicted ordeal.[108] The nineteen-year old patient died of respiratory failure approximately eighteen months after the initial onset of symptoms, while a twenty-nine-year old patient died of respiratory failure twenty-one months after her symptoms began.[109] Two of the surviving patients continue to suffer from shortness of breath, pleural effusions (excess fluid in the space around the lungs), and slowly progressive pulmonary fibrosis.[110]

After comparing the physiological effects in the patients with those seen in animal tests and testing all other chemicals in their work environment, the team notes that the "patients' illness appears to be a 'nanomaterial-related disease'."[111] The report concludes by suggesting that when working with nanoparticles, protection is extremely important.[112]

D. A Brief Overview of Environmental Effects of Nanoparticles

While this Note focuses on the effects of nanoparticles on the human body, it would be remiss not to include a brief discussion of the adverse impact nanoparticles can have on the environment. Results from studies of these environmental effects demonstrate why substances that can be so harmful to various ecosystems and their resident nonhuman organisms

---

107. *Id.*

108. *Id.* (manuscript at 24 tbl. 1, on file with author).

109. *Id.* (manuscript at 13, on file with author).

110. *Id.*

111. Song et al., *supra* note 99, (manuscript at 14, 17, on file with author).

112. *Id.* (manuscript at 19, on file with author).

> [T]hese cases arouse concern that long term exposure to some nano particles without protective measures may be related to serious damage to human lungs. It is impossible to remove nano particles that have penetrated the cell and lodged in the cytoplasm and caryoplasm of pulmonary epithelial cells, or that have aggregated around the red blood cell membrane. Effective protective methods appear to be extremely important . . . .

Id.

should not be loosely regulated, especially in an industry that produces products that are applied directly to the human body.

The adverse effects of nanoparticles can be seen more broadly by reviewing their effects on various parts of the environment and nonhuman organisms. Nanoparticles have been shown to cause damage to the ecosystem, beginning with the smallest organisms and moving all the way up the food chain. The International Center for Technology Assessment (ICTA) filed a Citizen Petition to the FDA which reveals that "[f]ield tests have shown that engineered nanoparticles remain active in soil and water for several weeks and . . . can travel in groundwater as far as twenty meters."[113] Due to the damaging effects of nanoparticles on cells in the human body, particularly macrophages, one report suggests that the same damage could be done to the simplest of soil organisms.[114] A study in 2005 found that C_{60} is in fact toxic to soil bacteria even in very low concentrations, though further studies are needed to confirm this result.[115] C_{60} also appeared to be bactericidal based on the improvement of water quality after the addition of C_{60} to the water during a study on the effects of nanoparticles on fish.[116] Further up the food chain, this study also found that the presence of nanoparticles resulted in brain damage in fish.[117] Largemouth bass exposed to C_{60} exhibited significant lipid peroxidation,[118] damaging the brains of the fish.[119] In a study of metallic nanoparticle toxicity, researchers discovered

---

113. CTA Petition, *supra* note 36, at 30-31.

114. ROYAL SOCIETY, *supra* note 15, at 45.

115. Press Release, Rice University's Center for Biological and Environmental Nanotechnology, CBEN: Buckyball aggregates are soluble, antibacterial, (June 22, 2005), *available at* http://www.eurekalert.org/pub_releases/2005-06/ru-cba062205.php; *but cf.* Anders Johansen et al., *Effects of C_{60} Nanoparticles on Soil Bacteria and Protozoans*, 27 ENVTL. TOXICOLOGY & CHEMISTRY 1895, 1902 (2008) (concluding that it was not possible to determine whether soil organisms were affected by the fullerenes or by something else in the soil samples and suggested that further study was needed to clarify the ecotoxicology of fullerenes).

116. Eva Oberdörster, *Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass*, 112 ENVTL. HEALTH PERSP. 1058, 1061 (2004).

117. *See generally id.*

118. *Id.* at 1060.

119. *See* Fender, *supra* note 1, at 1069.

that nano-silver and nano-copper were toxic to all aquatic organisms tested, which included zebrafish, daphnids, and an algal species.[120] The particles were especially toxic to the daphnids, invertebrate filter feeding crustaceans,[121] which serve as a food source for fish, birds, and other crustaceans.[122] Finally, studies have shown that even plant life can be adversely affected by nanoparticles. Engineered nanoparticles of aluminum oxide were found to stunt root growth by interacting with the seedlings of several plant species, including corn, cucumber, cabbage, carrot, and soybean.[123]

In consideration of the many possible adverse effects, the Royal Society has recommended that

> [u]ntil more is known about the environmental impacts of nanoparticles and nanotubes, we are keen to manage any potential risk by avoiding their release into the environment as far as possible. Therefore, we recommend that factories and research laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous, and seek to reduce or remove them from waste streams.[124]

E. Testing for Nanotoxicological Effects

The potential toxicological effects of nanoparticles on human tissues and the environment detailed above indicate a serious need for better nanomaterial testing strategies. The testing methods currently used by the FDA rely on the macro-scale equivalents to the nanoparticles in question and thus must be altered to take into account the differences between nanoscale and macro-scale particles, because

> [t]here is a strong likelihood that the biological activity of nanoparticles will depend on physiochemical parameters not

---

120. Robert J. Griffitt et al., *Effects of Particle Composition and Species on Toxicity of metallic nanomaterials in Aquatic Organisms*, 27 ENVTL. TOXICOLOGY & CHEMISTRY 1972, 1972 (2008).

121. *Id.* at 1976 tbl.3.

122. Waterflea.org, Introduction, http://www.waterflea.org/waterflea.org/Introduction.html (last visited Oct. 1, 2009).

123. *Study Shows Nanoparticles Could Damage Plant Life*, SCIENCE DAILY, Nov. 22, 2005, http://www.sciencedaily.com/releases/2005/11/051122210910.htm.

124. *See* ROYAL SOCIETY, *supra* note 15, at 46.

> routinely considered in toxicity screening studies. Physiochemical properties that may be important in understanding the toxic effects of test materials include particle size and size distribution, agglomeration state, shape, crystal structure, chemical composition, surface area, surface chemistry, surface charge, and porosity.[125]

Because of the strong likelihood that the physicochemical properties of nanoparticles will determine how they act within the body,

> any test paradigm must attempt to characterize the test material with respect to size (surface area, size distribution), chemical composition (purity, crystallinity, electronic properties, etc.), surface structure (surface reactivity, surface groups, inorganic/organic coatings, etc.), solubility, shape and aggregation. This should be done at the time of [nanomaterial] administration as well as at the conclusion, if possible.[126]

Thus, as new testing methodologies are implemented, they must ensure that the unique characteristics of nanoparticles are taken into account.

IV. REGULATION OF COSMETICS BY THE FOOD AND DRUG ADMINISTRATION

A. A Brief History of Early Cosmetics Regulation until Passage of the Federal Food, Drug and Cosmetic Act of 1938

In the United States, responsibility for regulating consumer products historically fell to the individual states, not the federal government.[127] These traditional roles were recast in January of 1879 when Dr. E. R. Squibb proposed that the federal government should take action and "the first comprehensive federal food and drug legislation was introduced in Congress."[128] The first successfully enacted regulatory act, the Federal Food and Drugs Act of 1906 (1906 Act), did not explicitly include cosmetics within its regulatory regime.[129] However, cosmetics were not completely unmonitored during the period between 1906 and 1938. The U.S. Postal

---

125. Oberdörster I, *supra* note 55, at Abstract.

126. *See* Nel I, *supra* note 39, at 626.

127. *See* Hutt, *supra* note 6, at 2.

128. *Id.*

129. *Id.* at 5.

Office enforced mail fraud statutes[130] to regulate cosmetics until 1914 when[131] the Federal Trade Commission began implementing the provisions of the Federal Trade Commission Act.[132] While the Postal Office was relatively lax in its enforcement duties, the FTC brought cases against cosmetics manufacturers for false or misleading claims.[133]

Soon after the passage of the 1906 Act, the U.S. Department of Agriculture's Bureau of Chemistry began to advocate for changes in the legislation.[134] However, despite the introduction of legislation in 1933 that encompassed cosmetics, it took five years before the Federal Food, Drug, and Cosmetic Act of 1938 (the FDCA or Act) was finally signed into law.[135] The FDCA defined "cosmetics" to be:

> (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.[136]

The Act further prohibited the sale of adulterated or misbranded cosmetics.[137] The Act considered a cosmetic adulterated, and consequently prohibited its sale, if:

---

130. Hutt, *supra* note 6, at 5; *see generally* Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (1906); *see also* 39 U.S.C. § 3005 (2000). For an interesting discussion of the postal fraud statutes, *see generally* Frederick M. Hart, *The Postal Fraud Statutes: Their Use and Abuse*, 11 FOOD DRUG COSM. L. J. 245 (1956).

131. *See* Hutt, *supra* note 6, at 5.

132. *Id.*; *see also* 15 U.S.C. §§ 41-58 (2000).

133. *See* Hutt, *supra* note 6, at 5.

134. *Id.* at 6. The Bureau of Chemistry stated in its 1917 Annual Report that is was "difficult to control injurious cosmetics." *Id.*

135. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301-901 (2000). The cosmetic provisions are found in 321(i), 361-63.; *see also* Hutt, *supra* note 6, at 6-7.

136. 21 U.S.C. § 321(i) (2000).

137. *See id.* § 331.

> (a) it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual...; . .; (b) it consists in whole or in part of any filthy, putrid, or decomposed substance (c) it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; (d) its container is composed, in whole or part, of any poisonous or deleterious substance which may render the contents injurious to health; or (e) it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.[138]

The Act further provided that a cosmetic is considered misbranded "if its labeling is false or misleading."[139] The most notable shortcomings of the Act resulted from its failure to provide for premarket testing, premarket notification, or premarket approval.[140] The FDCA provisions relating to cosmetics have not been amended since 1938, with the exception of the Color Additive Amendments of 1960, discussed below.[141] This is due primarily to the failure to gain sufficient legislative traction, despite the efforts of interest groups, government officials, and legislators.

B. The Struggle to Strengthen the FDA's Authority over Cosmetics

1. A Long Litany of Failed Attempts to Expand the FDA's Regulatory Authority

In 1952, the Delaney Committee, established by Congress to investigate chemicals in the food supply, "issued a report . . . recommending that cosmetics be subjected to essentially the same safety requirements as . . . drugs."[142] Ten years later, in March 1962, President Kennedy requested that

---

138. *See id.* §§ 361(a)-(e).

139. *See id.* §§ 362(a)-(e); Congress later provided that a cosmetic was also misbranded if it failed to comply with regulations issued pursuant to the Poison Prevention Packaging Act of 1970. *See id.* § 362(f).

140. *See* Hutt, *supra* note 6, at 7.

141. *See id.* at 25.

142. *See id.* (internal quotations omitted).

cosmetics be subjected to premarket approval.[143] In May of that year, legislation was introduced into the House of Representatives to comply with the president's request.[144] Although the FDCA was amended later that year by the Drug Amendments of 1962,[145] premarket authorization authority for cosmetics was not included; however, it was reintroduced every two years for the next sixteen years by Representative Leonor Sullivan of Missouri.[146] Aside from the efforts of Representative Sullivan, many unsuccessful attempts have been made in Congress to grant the FDA the power to conduct premarket authorization for cosmetics.[147]

In a speech in April of 1969, FDA Commissioner Herbert Ley provided his support for premarket approval of cosmetics ingredients and asserted that he believed even the manufacturers who would be affected by such legislation had come to the conclusion that this would be a positive occurrence.[148] In 1972, legislation was proposed that ultimately met

---

143. *Id.*

144. *Id.*

145. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1982). It is interesting to note that the Drug Amendments of 1962 passed unanimously in both houses of Congress. *See* 108 CONG. REC. 17422, 22325 (1962).

146. *See* Hutt, *supra* note 6, 25. *See, e.g.*, H.R. 1235, 89th Cong., 111 CONG. REC. 89 (1965).

147. *See, e.g.*, H.R. 2244, 83d Cong., 99 CONG. REC. 663 (1953); H.R. 4476, 84th Cong., 101 CONG. REC. 2255 (1955); H.R. 4015, 85th Cong., 103 CONG. REC. 1224 (1957); H.R. 4431, 85th Cong., 103 CONG. REC. 1574 (1957); H.R. 9153, 85th Cong., 103 CONG. REC. 13,805 (1957); H.R. 1360, 86th Cong., 105 CONG. REC. 57 (1959); H.R. 5661, 86th Cong., 105 CONG. REC. 4181 (1959); H.R. 1235, 87th Cong., 107 CONG. REC. 61 (1961); H.R. 11582, 87th Cong., 108 CONG. REC. 7753 (1962); H.R. 1235, 88th Cong., 109 CONG. REC. 56 (1963); H.R. 5777, 88th Cong., 109 CONG. REC. 6865 (1963); H.R. 6788, 88th Cong., 109 CONG. REC. 10,175 (1963); H.R. 8418, 88th Cong. 109 CONG. REC. 16,932 (1963); H.R. 1235, 89th Cong., 111 CONG. REC. 89 (1965); H.R. 1235, 90th Cong., 113 CONG. REC. 120 (1967); H.R. 4486, 90th Cong., 113 CONG. REC. 2191 (1967).

148. *See* Hutt, *supra* note 6, at 26. Ley stated:

> It is my impression that the majority, it not all, of the manufacturers who would be affected by the new legislation have come to the conclusion that it is desirable to amend the cosmetic section of the Food, Drug and Cosmetic Act. Certainly we in the Food and Drug Administration see grave deficiencies in the present system of control. Manufacturers do not have to test their products for safety before marketing them (though I am told the more responsible firms do

congressional and presidential approval and became known as the Consumer Products Safety Act of 1972.[149] Initially, this legislation encompassed cosmetics and required ingredient labeling and testing for carcinogenicity, mutagenicity, and teratogenicity.[150] Unfortunately, the legislation was revised before passage and cosmetics were exempted from the regulatory provisions; thus, they remained subject only to the FDCA.[151] Once again, cosmetics fell through the regulatory cracks.

Legislation to expand FDA authority was again introduced in February 1973,[152] February 1974,[153] April 1974,[154] and May 1975.[155] The May 1975

> so). Manufacturers may use new chemical in cosmetics without giving any notice of their use to the Government or to the consumer. Manufacturers are not required to reveal to any Agency the complaints that they may receive about a cosmetic that they have placed on the market, and when a bad product goes on the market, the government is only able to take action to protect the consumer after it has developed proof of the harm that the cosmetic may cause. This is in marked contrast to the philosophy underlying the new drug, pesticide chemicals, food additive and color additive sections of the law. Under these sections it is the responsibility of the person who wishes to market a new product to prove that it is safe rather than leaving it to the consumer-user to find that it is unsafe as a result of injuries that occur after marketing.

Id. Ley is also credited with an unnerving statement in 1969, when he said, "[t]he thing that bugs me is that people think the F.D.A. is protecting them. It isn't. What the FDA is doing and what the public thinks it's doing are as different as night and day." Richard D. Lyons, *Ousted F.D.A. Chief Charges 'Pressure' From Drug Industry*, N.Y. TIMES, Dec. 30, 1969, at A1.

149. Consumer Products Safety Act of 1972, Pub. L. No. 92-573, 86 Stat. 1207 (1972).

150. *See* Hutt, *supra* note 6, at 26. *See also* S. 3527, 92nd Cong. (1972); 118 CONG. REC. 14098-14107 (April 25, 1972). A substance is teratogenic if it causes developmental malformations. *See* MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 1289 (11th ed. 2003).

151. *See* Hutt, *supra* note 6, at 26.

152. S. 863, 93rd Cong., 119 CONG. REC. 3194 (Feb. 15, 1973).

153. S. 3012, 93rd Cong., 120 CONG. REC. 3120 (Feb. 18, 1974).

154. H.R. 14009, 93rd Cong., 120 CONG. REC. 9891 (1974).

155. S. 1681, 94th Cong., 121 CONG. REC. 13298 (May 7, 1975).

legislation, introduced by Senator Thomas Eagleton of Missouri, passed the Senate with a voice vote, but was not taken up by the House of Representatives and was not reconsidered in later years.[156] It must be noted that from 1973 to 1975, the proposed legislation did not contain provisions to provide for premarket *approval* of cosmetics. However, it did require premarket testing and safety substantiation by the manufacturers,[157] something which to this day remains voluntary.[158]

In 1978, the Government Accountability Office (GAO) lent its support to critics of the cosmetic regulatory system with a report titled "Lack of Authority Hampers Attempts to Increase Cosmetic Safety," which stated that "[a]lthough there is increasing evidence that some cosmetic products may carry a significant risk of injury to consumers, the Food and Drug Administration does not have an effective program for regulating cosmetics."[159] The report further found that the FDA failed to make effective use of the authority it did possess by neglecting to inspect most cosmetic manufacturers' facilities and failing to sample their products to test for compliance with the FDCA.[160] In 1990, the GAO published a follow-up report in response to a request from Representative Ron Wyden of Oregon, who, in 1988, had conducted congressional hearings on strengthening cosmetic regulation.[161] This study pointed out the glaring shortcomings of the voluntary regulatory system that remains in place and unchanged to this day. The report found that less than forty percent of the 2,000 to 2,500 cosmetics manufacturers had voluntarily registered with the FDA,[162] and only three percent of the 4,000 to 5,000 cosmetics distributors had filed adverse reaction reports with the FDA.[163] Finally, the report noted that not

156. *See* Hutt, *supra* note 6, at 27.

157. *Id.* at 26-27.

158. James T. O'Reilly, FDA, vol. 1, § 17:8, 17-31 (1997).

159. GAO, *Lack of Authority Hampers Attempts to Increase Cosmetic Safety*, HRD-78-139, at ii (1978), *available at* http://archive.gao.gov/f1002a/106839.pdf (last visited Nov. 7, 2009).

160. *Id.* at 92.

161. GAO Report I, *supra* note 7, at 1.

162. *Id.* at 3.

163. *Id.* at 4.

only did many cosmetics manufacturers lack adequate safety test data, some even refused to disclose test results.[164]

The 1990 GAO report strengthened Representative Wyden's belief that the cosmetic regulatory system needed to be overhauled. In particular, he was concerned with the "wait-and-watch" approach used by the system. This is evidenced by his statement that "it's quite clear that there are major gaps in the safety system. Public health policy should have us get out in front of these problems, rather than waiting until someone is injured and then going in after the fact."[165] Representative Wyden drafted legislation that "included a pre-market testing requirement; increased FDA access to safety and consumer complaint data; mandatory registration of manufacturing establishments, products, and ingredients; and mandatory ingredient listing for professional products."[166] Unfortunately, that legislation was never introduced.[167]

The next major attempt at overhaul occurred in the early 1990s,[168] in the wake of the generic drug scandal of the late 1980s.[169] The FDA sought "broad new administrative power to subpoena industry documents, inspect company records, impose requirements for the maintenance of records and the submission of reports, assess civil money penalties, order product recalls, destroy violative imported articles, and embargo any product for up to thirty

---

164. *Id.*

165. Martin Tolchin, *Consumer's World; Who's Monitoring Cosmetics Safety*, N.Y. TIMES, Apr. 14, 1990, §1, at 40, *available at* http://query.nytimes.com/gst/fullpage.html?res=9C0CE2D91F3EF937A25757C0A966958260&sec=&spon=&pagewanted=1.

166. Personal Care Products Council, Personal Care Products Council History, http://www.personalcarecouncil.org/Content/NavigationMenu/About_Us/History/History_5.htm (last visited Sept. 22, 2009).

167. *Id.*

168. *See* Hutt, *supra* note 6, at 28.

169. The generic drug scandal occurred in 1989, when FDA officials were discovered to have taken bribes to delay the approval of a company's generic drug applications. The scandal was worsened when it was discovered that the bribes were paid by the company's competitors. Opinion, *The Generic Drug Scandal*, N.Y. TIMES, October 2, 1989, at A18, *available at* http://query.nytimes.com/gst/fullpage.html?res=950DE6DE1E38F931A35753C1A96F948260#; *see also* Hutt, *supra* note 6, at 28.

days."[170] Due to fierce opposition from the industry[171] and President George H. W. Bush, the legislation to enact the enforcement changes sought by the FDA never made it to the floor of either chamber of Congress and was never reintroduced.[172]

2. Two Victories in the Fight to Expand the FDA's Regulatory Authority

Despite this long line of failures, two federal premarket clearance requirements for cosmetics were successfully enacted. The first of these derive from the Color Additive Amendments of 1960 (Amendments).[173] This statute amended the FDCA to prohibit the use of a color additive unless the additive was specifically listed in a federal regulation as available for use.[174] The Amendments also provided for what is known as the General Safety Provision, which requires that a petition to use a new color additive must contain "sufficient data to demonstrate that the color additive is 'safe' under its intended conditions of use."[175] Furthermore, manufacturers must substantiate the safety of not only a finished cosmetic product but also each ingredient used in the product.[176] If a manufacturer fails to provide safety data to the FDA, then the product will be deemed misbranded unless the manufacturer places the following warning on the packaging of the product: "*Warning*–The safety of this product has not yet been determined."[177]

---

170. *See* Hutt, *supra* note 6, at 28.

171. *See generally Food, Drug, Cosmetic, and Device Enforcement Amendments: Hearing before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 102nd Cong., 217 (1991); *see also Food, Drug, Cosmetic, and Device Enforcement Authorities Act, Hearing of the S. Comm. on Labor and Human Resources*, 102nd Cong., 143 (1992).

172. *See* Hutt, *supra* note 6, at 28.

173. Color Additive Amendment of 1960, Pub. L. No. 86-618, 74 Stat. 397 (1960).

174. Thomas J. Donegan, Jr., *Fifty Years of Cosmetic Safety: A Government and Industry Partnership*, 50 FOOD & DRUG L.J. 151, 154 (1995).

175. *See* Hutt, *supra* note 6, at 12.

176. 21 C.F.R. § 740.10 (2008).

177. *Id.*

The following statement by the FDA accompanied the issuance of the regulation requiring safety substantiation: "[i]t is not the intention of the regulation to require the warning statement in circumstances where reasonable scientific opinion would *regard the available data as adequate*."[178] Scientific studies regarding the safety of nanoparticles remain inconclusive as to whole-human exposure effects and as a result there can be no reasonable scientific opinion formed that would regard the existing nanotoxicological data as adequate to satisfy the regulation. Thus, this statement in conjunction with the lack of scientific consensus seems to indicate that with regard to cosmetic products containing nanoparticles, the FDA *must* require manufacturers to provide safety substantiation for the products in question or else deem such products mislabeled, something it does not in fact do.

In 1974, the FDA successfully implemented a second round of premarket requirements which compelled manufacturers to provide full ingredient labeling for cosmetic products.[179] The FDA derived this authority from the 1966 Fair Packaging and Labeling Act.[180] The regulations promulgated by the FDA require that ingredients are listed "in descending order of predominance," meaning that the ingredient with the highest concentration should be listed first, the ingredient with the next highest concentration second, and so on.[181] The regulation further provided the method for determining which chemical name to place on the ingredient labeling for each chemical ingredient.[182] Unfortunately, the FDA operates on an assumption of bioequivalence, assuming that nanomaterials are no more inherently dangerous than their macro-scale counterparts.[183] As a result,

---

178. Food, Drug, and Cosmetic Products: Warning Statements, 40 Fed. Reg. 8916 (Mar. 3, 1975) (emphasis added).

179. 21 C.F.R. § 701.3 (2008); Designation of ingredients, 39 Fed. Reg. 10,056-57 (Mar. 15, 1974).

180. Pub. L. No. 89-755, §§ 5, 6, 80 Stat. 1296 (codified at 15 U.S.C. §§ 1454-55 (2000)).

181. 21 C.F.R. § 701.3(a) (2008).

182. §§ 701.3(c)(1)-(4).

183. FDA, FDA Authority Over Cosmetics, http://www.cfsan.fda.gov/~dms/cos-206.html (last visited Sept. 23, 2009); FDA, *Nanotechnology, A Report of the U.S. Food and Drug Administration Nanotechnology Task Force* 11 (2007) [hereinafter Task Force Report] http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/Nanotechnology/ucm110856.pdf.

manufacturers need not label nanomaterials on products and may instead list them under macro-scale materials with the same composition, despite their radically different characteristics.

C. Overview of FDA's Current Cosmetics Authority

Premarket approval of any kind by the FDA of cosmetics remains limited to color additives and not to finished cosmetics or their other ingredients.[184] In other words, the FDA still has no legal authority to require premarket safety substantiation of cosmetic products. This hampers its ability to meaningfully safeguard the American public.[185] Further, "[m]anufacturers are not required to register their cosmetic establishments, file data on ingredients, or report cosmetic-related injuries to [the] FDA" but are "encouraged to register their establishments and file Cosmetic Product Ingredient Statements with the FDA's Voluntary Cosmetic Registration Program."[186] The FDA cannot mandate a recall of a cosmetic product

---

184. John E. Bailey, *Organization and Priorities of FDA's Office of Cosmetics and Colors*, *in* COSMETIC REGULATION IN A COMPETITIVE ENVIRONMENT 217, 218 (Norman F. Estrin & James M. Akerson eds., 2000); *see also* Helen North-Root, *Substantiating the Safety of Cosmetic and Toiletry Products*, *in* COSMETIC REGULATION IN A COMPETITIVE ENVIRONMENT 279, 286 (Norman F. Estrin & James M. Akerson eds., 2000) ("With the exception of color additives and the few restricted substances, no hard and fast rules (or, for the time being, regulations) exist to dictate which ingredients are safe to put into a cosmetic or toiletry and which finished cosmetic or toiletry products are safe to market.").

185. Michael R. Taylor, *Regulating the Products of Nanotechnology: Does the FDA Have the Tools It Needs?* 51 (Woodrow Wilson Center for Scholars, Project on Emerging Nanotechnologies 2006), *available at* http://www.nanotechproject.org/process/assets/files/2705/110_pen5_fda.pdf ("Cosmetics, obviously, comprise the product category for which the FDA's legal arsenal is most lacking if the agency is to play a meaningful pre-market oversight role rather than simply react to products and, possibly, problems after they appear in the marketplace.").

186. *See* Task Force Report, *supra* note 183, at iii. The Task Force Report elaborates that:

> [f]or products not subject to premarket authorization by FDA, such as cosmetics and dietary supplements, the agency generally does not receive data, including safety data, before the products are marketed. Furthermore, there are no post-marketing reporting requirements for adverse events associated with cosmetics. Therefore, FDA receives only cosmetic adverse event reports that are submitted voluntarily.

already on the market and may only request that a manufacturer voluntarily remove a dangerous product from the market.[187] Essentially, cosmetics manufacturers "may use any ingredient or market any cosmetic until the FDA demonstrates that it may be harmful—something that rarely occurs."[188]

However, the FDA is not completely impotent. It does possess *some* regulatory authority under the FDCA. The FDA has general statutory authority to conduct inspections of cosmetics companies without providing prior notice, as long as the inspection occurs at a reasonable time and in a reasonable manner.[189] Due to the limited fiscal resources allocated to the FDA, however, cosmetic companies are inspected infrequently.[190] If the FDA determines that a cosmetics company has violated cosmetics laws and regulations, it has several remedies at its disposal. It may issue a warning letter in order to give the company "an opportunity to take voluntary and prompt corrective action before [the FDA] initiates an enforcement action."[191] As stated previously, the FDA cannot mandate a recall, but may request that the offending company voluntarily recall a product from the market.[192] If the company persists in violating the laws or regulations in question, the FDA may file suit in federal court to institute a civil seizure action,[193] an injunction action,[194] or a criminal prosecution.[195]

Id.; *see* Task Force Report, *supra* note 183, at 15; *see also* 21 C.F.R. § 720 (2003) (providing for the voluntary filing of cosmetic product ingredient composition statements).

187. 21 C.F.R. §§ 7.40-7.59 (2008) (dealing with FDA recalls generally).

188. *See* Lin, *supra* note 33, at 373.

189. 21 U.S.C. § 374(a)(1) (2000).

190. *See* O'Reilly, *supra* note 158, at 17-32.

191. FDA, REGULATORY PROCEDURES MANUAL, 4-1 (Mar. 2008), *available at* http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch4.pdf. The manual further states, "Warning letters are issued to achieve voluntary compliance and to establish prior notice." *Id.*

192. FDA/CFSAN/Office of Cosmetics and Colors, *FDA Recall Policy for Cosmetics* (Jul. 29, 2002), http://www.fda.gov/Cosmetics/ProductandIngredientSafety/RecallsAlerts/ucm173559.htm. *See also* 21 C.F.R. §§ 7.40-7.59 (providing an overview of the FDA's role in recall and the manufacturer's responsibilities).

193. 21 U.S.C. § 334 (2000).

Unfortunately, manufacturers "are willing to take the risk of FDA censure because the chances of getting caught are slim."[196] Even if they are caught engaging in forbidden behavior, "by the time the FDA receives a consumer complaint, sends off a series of warning letters, or issues a summons for an injunction, years might have passed."[197] Currently, manufacturers are willing to pay fines as a cost of business and continue to engage in the behavior which instigated the fines.[198]

The FDA has openly acknowledged its weak statutory authority over cosmetics. Margaret Gilhooley, the FDA's former Associate Chief Counsel for Food and Cosmetics, noted in 1978 that "[t]he existing law has some weaknesses . . . , one of them being that the FDA does not have general authority to obtain manufacturers' records and safety related data."[199] In its official magazine, the FDA Consumer, the FDA admitted that "[t]he regulatory requirements governing the sale of cosmetics are not as stringent as those that apply to other FDA-regulated products . . . . [M]anufacturers may use any ingredient or raw material, except for color additives and a few prohibited substances, to market a product without a government review or approval."[200]

Knowing the details of the FDA's authority over cosmetics, it is now important to know how the FDA applies the various regulatory provisions at its disposal to cosmetic products containing nanoparticles. The FDA's current position on nanoparticles in cosmetics is also of concern and must be examined.

---

194. *See generally id.* at § 332.

195. *See generally id.* at §§ 331, 333.

196. Erika Kawalek, *Artfully Made-Up*, LEGAL AFF. Nov. – Dec. 2005, at 54, 56.

197. *Id.*

198. *Id.*

199. Margaret Gilhooley, *Federal Regulation of Cosmetics: An Overview*, 33 FOOD, DRUG, COSM. L. J. 231, 232 (1978).

200. Carol Lewis, *Clearing Up Cosmetic Confusion*, FDA CONSUMER, May/June 1998, *available at* http://www.pueblo.gsa.gov/cic_text/health/cosmetic-confusion/398_cosm.html. The article quotes John Bailey, former director of FDA's Office of Cosmetics and Colors, as saying, "[c]onsumers believe that 'if it's on the market, it can't hurt me.' And this belief is sometimes wrong." *Id.*

V. THE FDA'S DANGEROUS STANCE ON THE USE OF NANOPARTICLES IN COSMETICS

While the FDA has the ability to regulate in many other areas, "[n]o FDA regulations or guidances to the industry currently exist that address specific problems that nanotechnology may present."[201] The FDA states that it "believes that the existing battery of pharmacotoxicity tests is *probably adequate* for most nanotechnology products that [it] will regulate."[202] It further claims that "*[p]article size is not the issue.* As new toxicological risks that derive from the new materials and/or new conformations of existing materials are identified, new tests will be required."[203]

It is of little comfort to consumers that the laws and regulations under which the FDA oversees cosmetics were written long before the advent of nanotechnology.[204] Due to the failure of Congress to provide the FDA with premarket regulatory authority over cosmetics, the FDA cannot mandate that manufacturers submit data regarding the use of nanoparticles in their products.[205] This is made clear in the FDA's own report, issued by the Nanotechnology Task Force, which states that "[w]hen dealing with products not subject to premarket authorization, the agency has less ability to obtain information about the presence of nanoscale materials."[206] It is of particular concern that, while the FDA can rigorously regulate drugs and medical devices, it has no real teeth when it comes to regulating cosmetic products, which are more likely to contain nanoparticles.[207] As one author has stated:

---

201. Eric M. Kraus, *It's No Small Matter: FDA Task Force and EPA Weigh In on Nanotechnology*, 24 ANDREWS PHARMACEUTICAL LITIG. REP. 2008 at 13, 14.

202. FDA, FDA Regulation of Nanotechnology Products, *available at* http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForce/ucm115441.htm (emphasis added) [hereinafter FDA Nanotechnology Webpage].

203. *Id.*

204. *See* Task Force Report, *supra* note 183, at 4.

205. *Id.* at 30.

206. *Id.*

207. *See* Fender, *supra* note 1, at 1074. ("Some of the most prominent nanotechnology products on the U.S. market are cosmetics, which make up more than 15% of the nanotechnology-product market.").

> Any doubts expressed about the adequacy of the FDA's regulatory scheme become even more pressing once one considers that the FDA has little to no regulatory power over these types of products—products that, if they contain nanomaterials, present the same hazards that exist for pharmaceutical or medical device products.[208]

The limited resources of the FDA have made it difficult for the agency to "assess the risks that would derive to the general population from the wide-scale deployment of nanotechnology products."[209]

Further damaging for the FDA is a report issued by its own Subcommittee on Science and Technology,[210] which came to three major conclusions about the FDA's inability to fulfill its mission. First, the report concluded that "the FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak."[211] This has resulted in the FDA being unable to keep up with scientific advances, which, in turn, is putting the lives of American consumers at risk.[212] The second conclusion of the report is that the FDA's "scientific workforce does not have sufficient capacity and capability."[213] Inadequately trained scientists take longer to make decisions and sometimes make the wrong decisions when it comes to regulatory approval or disapproval.[214] The lack of sufficiently trained employees means that the FDA is unable to respond quickly and effectively to emerging scientific fields.[215] The Subcommittee's third major conclusion is that the information technology infrastructure of the FDA is inadequate.[216]

---

208. *Id.*

209. FDA Nanotechnology Webpage, *supra* note 202.

210. *See generally* Subcommittee on Science & Technology, FDA SCIENCE AND MISSION AT RISK (FDA 2007) [hereinafter Subcommittee Report], *available at* http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf.

211. *See id.* at 3.

212. *Id.*

213. *Id.* at 4.

214. *Id.* at 5.

215. *Id.*

216. *Id.*

Reports of investigators remain handwritten, much of the FDA's critical data is stored in warehouses in hard copy with no backup, and the computer systems frequently fail.[217] The report further found that the FDA has "insufficient capacity in modeling, risk assessment and analysis" and that the FDA's "science agenda lacks a coherent structure and vision, as well as effective coordination and prioritization."[218]

Aside from the deficiencies pointed out by the Subcommittee's report, there is a dangerous flaw in the FDA's belief that the current testing methods for pharmacotoxicity are "probably adequate."[219] These tests are "based on and completed regarding *bulk material states* of many recently engineered nanoparticles."[220] This presumption of bioequivalence is a dangerous error. As seen previously in this Note,[221] experts around the world conclusively and overwhelmingly agree that the unfavorable effects of nanoparticles cannot be determined by examining the toxicity of the same materials in their bulk states.[222] The FDA's stance is thus "at odds with all scientific studies on nanomaterials and their fundamentally unique properties and risks."[223] Given the uncertainty of the effects on the human environment, it is reasonable to conclude that the FDA's current method of gauging nanoparticle safety based on a presumption of bioequivalence cannot effectively protect the American public and may even be considered grossly negligent.[224] Thus, a new regulatory scheme for cosmetics containing nanoparticles is needed to ensure the safety of the consumers of cosmetic products.

---

217. *See* Subcommittee Report, *supra* note 210, at 5.

218. *Id.* at 30, 33.

219. *See* FDA Nanotechnology Webpage, *supra* note 202.

220. *See* CTA Petition, *supra* note 36, at 19 (emphasis added).

221. *See supra* Part II.C.2.

222. *See* CTA Petition, *supra* note 36, at 19-20.

223. *Id.* at 36.

224. *Id.*

VI. A PROPOSAL FOR A NEW COSMETICS REGULATORY SCHEME

Regardless of the method that is adopted to reform the cosmetic regulatory system, regulators must be mindful that increased regulation does not interfere with the effective research and development of newer nanotechnologies. Any regulatory effort that calls for an absolute moratorium on development and use of nanotechnologies is "implausible in an American economy determined to harvest on its public research investments."[225] Nevertheless, the history of cosmetic regulation, the current regulatory abilities of the FDA, and nanotoxicity studies suggest that a more effective and bold course of action must be taken in this area.

In order to prevent the unregulated introduction of nanomaterial-containing cosmetic products into the marketplace, the FDA must return to the method it used in the 1960s and 1970s: pushing Congress for legislative reform in the area of cosmetics regulation.[226] The FDA should join and encourage consumer safety and protection groups to actively lobby Congress to enact legislation that is substantially similar to the bill introduced in May 1975 by Senator Eagleton,[227] with one minor change. The May 1975 legislation was referred to by FDA Acting Commissioner Sherwin Gardner as a "reasonable balance between controlling risks and imposing inappropriate burdens on Government and industry."[228] Senator Eagleton believed this legislation, known as the Cosmetic Safety Amendments of 1975, would be a "step forward" in American consumer safety.[229] Essentially a revised version of previously proposed amendments to the

---

225. Brian Wilhelmi, *Nanosilver: A Test for Nanotech Regulation*, 63 FOOD & DRUG L.J. 89, 110 (2008).

226. *See* Hutt, *supra* note 6, at 27-28.

227. S. 1681, 94th Cong. (1975); 121 CONG. REC. 13,298-302 (1975).

228. *See* Hutt, *supra* note 6, at 27.

229. 121 CONG. REC. 13,299 (1975) (statement of Sen. Eagleton)

> I believe that this bill represents an important step forward in consumer safety. I have sought to strike a reasonable balance between the entirely proper desire of the cosmetic industry to conduct its business with a minimum of Government regulation, on the one hand, and the compelling need of millions of American consumers for some measure of protection against cosmetic-related health hazards on the other.

Id.

FDCA, the new legislation would amend[230] the FDCA as it relates to cosmetics.[231] This Note thus proposes that the FDA lobby Congress to pass the Cosmetic Safety Amendments of 2010.

Title I of the bill would "set forth procedures for the safety substantiation of cosmetics and cosmetic ingredients, placing the burden on manufacturers of thoroughly testing their products for safety before offering them to the public."[232] While Title I does not impose a blanket requirement that cosmetics manufacturers submit safety data prior to sale of their products, it grants the FDA "the authority to require premarket submission of safety test data when it believes such submission would better protect the safety of consumers."[233] While this provision initially seems to grant the manufacturers the same ability to withhold safety test data, the FDA would be empowered to require that any products containing nanoparticles must be substantiated for safety and that the results of the safety tests must be submitted to the FDA, thereby protecting the safety of consumers. This provision provides the FDA with a large loophole through which to require extensive review of cosmetic products containing nanoparticles before they reach the market.

Title I further allows the FDA to order additional specific testing of products[234] and "if it finds that a product or ingredient presents a hazard, [it] can prohibit certain ingredients, prescribe limits of tolerance, require additional labeling, or ban a cosmetic."[235] Here, Title I includes a provision through which the FDA can require even further specific testing of products containing nanoparticles. If the safety data is unsatisfactory, it may impose restrictions on their use or even ban cosmetic products containing particularly harmful nanoparticles. Title I grants the FDA a great deal of authority without mandating constant extensive action on the agency's part. This ensures that the FDA has the discretion and authority to enforce the provisions when it believes it is necessary without creating an infeasible burden on the already overtaxed FDA.

---

230. 121 CONG. REC. 13,298-302 (1975).

231. 21 U.S.C. §§ 361-364 (2000).

232. 121 CONG. REC. 13,298 (1975).

233. *Id.*

234. *Id.*

235. *Id.*

Title II of the legislation would require manufacturers to "register with the FDA, . . . submit formulas of cosmetics products to the FDA, . . . and forward consumer complaints about adverse reactions to products to the FDA."[236] This will serve to "codif[y] and make[] mandatory the FDA's 'voluntary compliance program'" established in the early 1970s.[237] Further, Title II expands the FDA's enforcement and inspection power by authorizing the FDA to administratively detain suspect products for up to twenty days, similar to the Department of Agriculture's power over food products.[238] Requiring manufacturers to register with the FDA will allow it to easily keep track of who and what it is regulating, which will facilitate and encourage regular inspections of cosmetics manufacturing facilities. Granting the FDA statutory authority to detain products will eliminate the need for the agency to seek judicial seizure of suspect products, a deliberate process that often results in the suspect products being shipped before they can be seized.[239] Eliminating this wait time will further allow the FDA to take quick and decisive regulatory action to ensure consumer safety.

Title III requires cosmetics to possess informational, cautionary, and ingredient labeling.[240] Title IV contains general provisions regarding cosmetics and, most importantly, it requires the Secretary of the Department of Health and Human Services, under whose administrative umbrella the FDA falls,[241] to work with the Small Business Administration to recommend loans for small cosmetics manufacturers. This will help these manufacturers bear the cost of complying with the new regulations.[242] It seeks to avoid

---

236. *Id.*

237. *Id.*

238. 121 CONG. REC. 13,299 (1975).

239. *Id.*

240. *Id.*

241. HHS, About HHS, Agencies in HHS, http://www.hhs.gov/about/index.html#agencies (last visited Nov. 20, 2008).

242. 121 CONG. REC. 13,299, 13,302 (1975)

> The Secretary shall cooperate with the Small Business Administration with respect to applications. . . for loans to assist affected small business entities to comply with requirements under sections 604 and 601(f). The Small Business Administration shall direct that applications from such small business entities, regarding proposed additions to or alterations in plants, facilities, or methods of operations which are designed to enable such entities to comply with such

imposing an unfair burden upon the industry as a whole by appeasing smaller industry members who may initially oppose regulatory reform out of financially motivated fear. Title IV also gives the FDA "substantive rulemaking power" and establishes the procedures for issuing rules.[243] Additionally, Title IV in the original legislation provided for the preemption of state laws with respect to the labeling of cosmetic products.[244] It stated that states could petition the Secretary of Health and Human Services for an exemption from preemption if the state's proposed requirement imposed a standard higher than the federal standard, was required by "compelling local conditions," and did not "unduly burden interstate commerce."[245] The statute should be amended in newly introduced legislation to allow for an *automatic* allowance for states whose standards exceed federal levels without the need to petition the Secretary, provided that the standards meet the requirements provided in the original legislation. If a state's proposed standard is lower than that of the federal government, then it would be preempted by the federal standard.

This legislative fix provided for above kills two problematic birds with one pragmatic stone. First, the FDA's regulatory authority over cosmetics is finally strengthened by granting it the authority to demand premarket safety substantiation. This would not impose too severe a burden on the industry because financial assistance would be provided to smaller manufacturers. Second, it alleviates burdens on manufacturers by not requiring them to endure the rigorous premarket approval process, similar to that required for the approval and marketing of new drugs, which can take years to complete and is extremely expensive.[246] By creating a more robust regulatory regime

---

> requirements, small be reviewed by the Secretary. The Secretary shall evaluate each such application and shall report to the Administrator (or to the bank or lending institution) within 60 days to determine if such additions or alterations are appropriate and necessary to assist the applicant to comply with such requirements and whether he recommend that the loan be granted.

Id.

243. *Id.* at 13,299.

244. *Id.*

245. *Id.* at 13,302.

246. American Institute for Medical and Biological Engineering, FDA and the Drug Development Process: How the Agency Ensures That Drugs are Safe and Effective, http://www.aimbe.org/content/index.php?pid=153 (last visited Oct. 18, 2009) ("Today, the process of bringing a drug to a patient's bedside takes an average of 8.5 years, costs

for cosmetics, including a substantive rulemaking power, the FDA could effectively and efficiently adapt its policies to ensure consumer safety. This is particularly important in light of the ever increasing usage of potentially harmful nanoparticles in cosmetic products.

VII. CONCLUSION

While the FDA struggles to adapt to the current "nano-reality," more and more nanoparticle-containing cosmetic products find their way into the marketplace. Despite positive steps toward achieving the goal of obtaining a better understanding of nanotechnology, such as establishing the Nanotechnology Task Force[247] and engaging in internal research to better understand the characteristics of nanomaterials,[248] "the fact remains that the FDA is simply not doing enough to address the challenges that it admits exist."[249] The FDA must join with citizens' groups and lobby Congress to obtain the authority necessary to remedy the asymmetric regulatory regime as it currently stands. While the agency possesses "life or death" authority over proposed new drugs, it is essentially powerless when it comes to regulating cosmetics. In light of the fact that one of the greatest sources of consumer exposure to nanoparticles is cosmetics,[250] which technically fall under the FDA's regulatory umbrella, the legislation proposed in this Note would provide the FDA with the needed flexibility to rapidly adapt to this new reality. By enacting the proposed legislation, Congress would finally enable the FDA to properly perform its role as the guardian of public health.

---

about $500 million, and includes a rigorous review by the Food and Drug Administration.").

247. Press Release, FDA, FDA Forms Internal Nanotechnology Task Force (Aug. 9, 2006), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108707.htm; U.S. Food & Drug Admin., Nanotechnology, http://www.fda.gov/nanotechnology/.

248. *See* FDA Nanotechnology FAQs, *supra* note 18, at § 4.

249. Fender, *supra* note 1, at 1095.

250. *See* CTA Petition, *supra* note 36, at 36.