

THE DANGERS OF CHASING YOUTH: REGULATING THE USE OF NANOPARTICLES IN ANTI-AGING PRODUCTS

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I. INTRODUCTION

Forty is the new thirty. This statement succinctly describes the trend of youthful-looking middle-aged men and women in society today. How do people “reverse” the aging process to appear ten (or even more) years younger? Plastic surgery is a possible method, but it is expensive and potentially dangerous.¹ Topically-applied cosmetic products that boast anti-aging properties are more economical and thus more widely used.² They are also safer and less invasive. Or are they? Often topically applied cosmetics contain nanoparticles that may damage a user’s skin or other parts of the body.³ This note will discuss the potential dangers associated with the use of nanoparticles in cosmetic products, especially anti-aging products, and the lack of governmental regulation of their use. It will also address the potential failure of the legal system to hold companies responsible for harm to consumers caused by nanoparticles in their products.

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1. One source states that the average facelift costs between \$7,000 and \$9,000. InfoPlasticSurgery.com, Cost of Plastic Surgery, <http://www.infoplasticsurgery.com/cost.html> (last visited Apr. 8, 2008). Botched surgery can have serious harmful consequences. *See, e.g.*, CosmeticSurgery.com, When Plastic Surgery Goes Bad, <http://www.cosmeticsurgery.com/articles/archive/an~48/> (last visited Apr. 8, 2008).

2. Topically-applied anti-aging cosmetics can cost as little as fifty dollars. *See, e.g.*, Lancôme, <http://www.lancome-usa.com/skincare/moisturizers/hydra-zen-cream.htm> (last visited Apr. 8, 2008).

3. *See generally* THE ROYAL SOC’Y & THE ROYAL ACAD. OF ENG’G, NANOSCIENCE AND TECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES (2004), available at <http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf> [hereinafter ROYAL SOC’Y & ROYAL ACAD.] (discussing potential toxicity problems regarding nanoparticles due to their unique properties and scientists’ limited knowledge of their effects on and inside the body). The Royal Society, “the national academy of science” of the United Kingdom and the Commonwealth, is “an independent, charitable body that derives its authoritative status from its 1400 Fellows and Foreign Members,” and strives, among other things, to support “many top young scientists, engineers and technologists” to influence science policy and to debate scientific issues with the public.” The Royal Society, About the Society, <http://www.royalsoc.ac.uk/landing.asp?id=3> (last visited May. 31, 2008).

Part II gives a brief history of nanotechnology and provides an overview of nanoparticles, their properties, and their uses in the battle against the signs of aging. Part II also summarizes the laws regulating cosmetics and their components. Part III discusses the FDA's failure to effectively regulate products containing nanoparticles, and analyzes the reasons that products liability law may fail to hold companies responsible for any harm caused by their products containing nanoparticles. Part IV offers potential changes to the regulation of nanoparticles, and explores the advantages and disadvantages of these changes.

II. BACKGROUND: A PARTICLE WE DO NOT FULLY UNDERSTAND

This section describes how the field of nanotechnology has changed dramatically since it began centuries ago due to recent technological advancements. In addition, this section explains the properties of nanoparticles that make them both potentially dangerous and incredibly useful. Furthermore, this section details the cosmetic companies that allegedly use nanoparticles in their products and the potential harm such particles may cause consumers. Finally, this section will present an overview of the laws governing the regulation of cosmetics.

A. *History of Nanotechnology*

At the most basic level, everything humans can see in the natural environment was created through interactions between small groups of atoms and molecules called nanoparticles.⁴ Nanoscience is defined as human study, manipulation, and application of these nanoparticles "at atomic, molecular, and macromolecular scales."⁵ Humans have worked with large, visible groups of nanoparticles for centuries.⁶ For example, tenth century alchemists used nanoparticles of gold and silver to create colorful windows of stained glass.⁷ Until recently, however, humans lacked the tools to investigate and manipulate nanoparticles at a microscopic level.⁸ The field of nanotechnology has rapidly advanced during the last few decades due to the development of such sophisticated devices.⁹

Among the first to hypothesize about the potential uses for nanotechnology was physicist Richard P. Feynman in 1959.¹⁰ In his article, "There's Plenty of Room at the Bottom," he suggested the possibility of

4. Frederick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L.J. 593, 596 (1994).

5. ROYAL SOC'Y & ROYAL ACAD., *supra* note 3, at 5.

6. *Id.*

7. *Id.* ("[d]epending on their size, gold particles can appear red, blue or gold in colour. The challenge for the ancient (al)chemists was to make all nanoparticles the same size (and hence the same colour).")

8. *Id.* at 6.

9. *Id.*

10. *Id.* at 5; Center for Responsible Nanotechnology, U.S. Nanotechnology Policy – Missing the Point, <http://www.crnano.org/us-policy.htm> [hereinafter Responsible Nanotechnology] (last visited May 30, 2008).

working with particles at the nanoscale to store large amounts of information in tiny spaces, and to develop tiny machines.¹¹ Until the early to mid-1980s technology was not advanced enough for this vision to begin to be realized.¹² It was during this time that scientists Gerd Binnig and Heinrich Rohrer created a scanning tunneling microscope¹³ powerful enough to illuminate nanoparticles.¹⁴ Thus, humans gained the capability to view nanoparticles and actually rearrange them by particle.¹⁵

Since the creation of these high-powered microscopes, scientists have made discoveries revolutionizing the field of nanotechnology. For example, Robert F. Curl, Richard E. Smalley, and Harold W. Kroto discovered the fullerene in 1985.¹⁶ A fullerene is a heat-resistant and superconductive¹⁷ sixty or seventy-atom cluster of carbon molecules.¹⁸ The molecules form a molecular cage, shaped like a pentagon or hexagon.¹⁹ The cage resembles a soccer ball and is commonly referred to as a “buckyball,” named after the American architect famous for designing geodesic domes composed of pentagons and hexagons, R. Buckminster Fuller.²⁰

In the late 1970s, scientist Eric Drexler became the first person to discuss in detail the idea of molecular manufacturing,²¹ defined as the manufacturing of “extremely high-performance machines [made] out of” nanoparticles that can build nearly anything, including computers and homes.²² Drexler hypothesized that such a machine would consist of a “computer” and molecular assemblers, or nanobots, the size of molecules.²³ The computer would give detailed instructions to the assemblers to build certain products

11. Richard P. Feynman, *There's Plenty of Room at the Bottom*, 23 ENGINEERING & SCI. 22 (1960), available at <http://www.zyvex.com/nanotech/feynman.html>; ROYAL SOC'Y & ROYAL ACAD., *supra* note 3, at 5; Responsible Nanotechnology, *supra* note 10. This is an extremely important idea because it drives the manufacture of smaller and smaller computer chips and technological advancement. See John Markoff, *H.P. to Report an Advance in Adaptable Circuitry*, N.Y. TIMES, Jan 16, 2007, at C2, available at <http://query.nytimes.com/gst/fullpage.html?res=9800E6DA1030F935A25752C0A9619C8B63> (discussing modern applications of nanotechnology).

12. ROYAL SOC'Y & ROYAL ACAD., *supra* note 3, at 6.

13. *Id.* at 6, 16 (stating that this tool uses “nanoscale probes to image a surface with atomic resolution, and [it is] also capable of picking up, sliding or dragging atoms or molecules around on surfaces to build rudimentary nanostructures.”). The atomic force microscope, created in 1986, has similar capabilities. *Id.* at 16.

14. ENCYCLOPEDIA BRITANNICA Vol. 24, 741C (15th ed. 2005) [hereinafter BRITANNICA].

15. *Id.*; ROYAL SOC'Y & ROYAL ACAD., *supra* note 3, at 6.

16. BRITANNICA, *supra* note 14, at 741C; Lynn Yarris, *Carbon Cages: LBL Scientists Study Fullerenes*, LAWRENCE BERKELEY NAT'L LABORATORY RES. NEWS, Summer 1993, <http://www.lbl.gov/Science-Articles/Archive/fullerenes.html>.

17. *Fullerene*, WIKIPEDIA: THE FREE ENCYCLOPEDIA (Mar. 13, 2007), <http://en.wikipedia.org/wiki/Fullerene>. Superconductivity occurs “in certain materials at extremely low temperatures,” and “[s]uperconductors are . . . able to maintain a current with no applied voltage whatsoever, a property exploited in superconducting electromagnets such as those found in MRI machines.” *Superconductivity*, WIKIPEDIA: THE FREE ENCYCLOPEDIA (Mar. 13, 2007), <http://en.wikipedia.org/wiki/Superconductive>.

18. BRITANNICA, *supra* note 14, at 741C.

19. *Id.*

20. *Id.*

21. RAY KURZWEIL, *THE SINGULARITY IS NEAR: WHEN HUMANS TRANSCEND BIOLOGY* 228 (2005).

22. *Id.* at 230.

23. *Id.* at 228-29.

using particles from the environment.²⁴ Chemical or electrical energy would power the nanobots.²⁵ Trillions of assemblers would be necessary to build normal sized products.²⁶ It would cost companies too much time and money to create such a large number of nanobots; thus, they would need to program assemblers to self-replicate.²⁷ Programming such a machine to self-replicate has the potential to be extremely dangerous because humans could lose control over the nanobots, and they could destroy the environment in which they are operating.²⁸ Although the implications of Drexler's molecular manufacturing proposal are far-reaching, this Note will focus on the current and future use of nanoparticles in cosmetics.

Due to the explosion of nanotechnology in recent years, the governments of at least thirty countries have established or are currently developing initiatives to foster the study of the potential benefits and risks associated with the technology.²⁹ For example, the United States Congress passed an act in 2003 that created the National Nanotechnology Initiative ("NNI"), charged with "coordinat[ing] the multiagency effort in nanoscale science, engineering and technology."³⁰

B. What Are Nanoparticles?

To understand why nanoparticles have such extraordinary capabilities, it is necessary to learn about their unique properties. The word "nanotechnology" derives from nanometer ("nm"), which is one-billionth of a meter.³¹ That is about the size of one protein molecule.³² A red blood cell is approximately seven thousand nanometers large.³³ Particles that are smaller than 100nm are now commonly called nanoparticles.³⁴ Nanoparticles exist in the natural environment, for example, in milk and "as the products of combustion and food cooking."³⁵

Due to their size, nanoparticles have different properties than their larger counterparts.³⁶ Their high surface area-to-volume ratio makes them more

24. *Id.*

25. *Id.* at 230.

26. *Id.* at 231.

27. *Id.* at 228-29.

28. *Id.* at 237.

29. James D. Thayer, *The SPS Agreement: Can It Regulate Trade in Nanotechnology?*, 2005 DUKE L. & TECH. REV. 0015, (2005), <http://www.law.duke.edu/journals/dtr/articles/2005dltr0015.html>.

30. *Id.*

31. ROYAL SOC'Y & ROYAL ACAD., *supra* note 3, at vii.

32. *Id.*

33. Peter J. Tomasco, Note, *Manufactured Nanomaterials: Avoiding TSCA and OSHA Violations for Potentially Hazardous Substances*, 33 B.C. ENVTL. AFF. L. REV. 205, 207 (2006).

34. KURZWEIL, *supra* note 21, at 227; BRITANICA, *supra* note 14, at 741A.

35. ROYAL SOC'Y & ROYAL ACAD., *supra* note 3, at 5-6, 35 (stating additionally that "humans have always been exposed to some types of nanoparticles arising from natural sources such as atmospheric photochemistry and forest fires, and exposures to millions of pollutant nanoparticles per breath have been commonplace since the first use of fire.")

36. *Id.* at 5; FRIENDS OF THE EARTH, NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS, BIG RISKS 6 (2006), <http://nano.foe.org.au/node/125>.

chemically reactive.³⁷ Atoms on the surface of a molecule react with atoms on the surface of other molecules.³⁸ Because a nanoparticle is composed of very few atoms, all its atoms are close to the surface. Thus, nanoparticles as a group are more reactive than larger particles.³⁹ For example, particles of aluminum large enough for humans to see are chemically inert,⁴⁰ but nanoparticles of the element are highly reactive.⁴¹ In addition, quantum mechanical effects operate on nanoparticles and can alter their properties.⁴² Energy is transmitted in units called quanta that have a wavelength about the same size as a nanoparticle.⁴³ Whereas the properties of larger particles are not greatly affected by these quanta, they “can significantly change [nanoparticles’] optical, magnetic or electrical properties.”⁴⁴

The properties of all nanoparticles make them potentially harmful to the environment and the human body.⁴⁵ The extent of harm nanoparticles may cause is not completely clear at this time. However, a current body of research suggests that certain types of nanoparticles may be more toxic than their larger counterparts,⁴⁶ and may cause cell damage and diseases such as cancer.⁴⁷ Additionally, initial studies demonstrate that when certain nanoparticles are released into the environment, for example through the sewer system, they can harm plant and animal species.⁴⁸

Studies of nanoparticles in the air and in medicine show that due to their tiny size, cells and organs “may demonstrate toxic responses” to them.⁴⁹ Certain nanoparticles are small enough to enter the body through the intestinal tract, the lungs, and the skin.⁵⁰ Once inside, they can potentially cross into the

37. BRITANNICA, *supra* note 14, at 741A; ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at vii.

38. BRITANNICA, *supra* note 14, at 741A.

39. *Id.*; FRIENDS OF THE EARTH, *supra* note 36, at 6.

40. Chemically inert particles do not react with other atoms or molecules. *Inert*, WIKIPEDIA: THE FREE ENCYCLOPEDIA (Feb. 12, 2007), <http://en.wikipedia.org/wiki/Inert>.

41. Linda K. Breggin & Leslie Carothers, *Governing Uncertainty: The Nanotechnology Environmental, Health, and Safety Challenge*, 31 COLUM. J. ENVTL. L. 285, 290 (2006).

42. BRITANNICA, *supra* note 14, at 741A; ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at vii.

43. BRITANNICA, *supra* note 14, at 741C.

44. ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 5.

45. *See, e.g.*, BRITANNICA, *supra* note 14, at 741E.

46. SCIENTIFIC COMMITTEE ON EMERGING & NEWLY IDENTIFIED HEALTH RISKS, THE APPROPRIATENESS OF EXISTING METHODOLOGIES TO DISCUSS THE POTENTIAL RISKS ASSOCIATED WITH ENGINEERED & ADVENTITIOUS PRODUCTS OF NANOTECHNOLOGIES 45 (2006), available at http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf.

47. FRIENDS OF THE EARTH, *supra* note 36, at 6. These health problems are caused because nanoparticles are more likely than their larger counterparts to produce reactive oxygen species. *Id.* Reactive oxygen species are “generally very small molecules . . . [that] are highly reactive due to the presence of unpaired valence shell electrons.” *Reactive Oxygen Species*, WIKIPEDIA: THE FREE ENCYCLOPEDIA (May 22, 2007), http://en.wikipedia.org/wiki/Reactive_oxygen_species. They can have positive effects in the body but can also damage cell DNA and cause various diseases. *Id.*

48. BRITANNICA, *supra* note 14, at 741E; Friends of the Earth, *supra* note 36, at 11 (“Fullerenes have been found to cause brain damage in large-mouth bass, a species accepted by regulatory agencies as a model for defining ecotoxicological effects.”).

49. ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 40-41 (“[C]ells and organs may demonstrate toxic responses even to apparently non-toxic substances when they are exposed to a sufficient dose in the nanometer size range.”).

50. *Id.* at 36.

bloodstream, cells, and organs, and do other things that larger particles cannot.⁵¹ Once in the body nanoparticles can cause “DNA mutation . . . and even cell death.”⁵² Analyses of fullerenes have shown that “even low levels of exposure to [them] . . . [may be] toxic to human liver cells.”⁵³ In fact, Curl, one of the discoverers of fullerenes, publicly stated that he would not use products containing them until more extensive testing on their properties had been conducted.⁵⁴ Thus, all nanoparticles may have unforeseen negative effects on the environment and the human body.

Furthermore, each type of nanoparticle is unique and has its own distinctive properties.⁵⁵ Naturally occurring nanoparticles may behave differently than engineered nanoparticles.⁵⁶ Consequently, nanoparticles that humans are just beginning to create and to use in products may be harmful even if other types of nanoparticles that have existed in the natural environment for millennia have proven not to be.

Although nanoparticles are potentially dangerous, they also have the potential to dramatically improve every facet of life.⁵⁷ Currently, companies are enhancing the quality of consumer products by building them nanoparticle by nanoparticle.⁵⁸ For example, scientists have created materials that are very strong but lightweight to make the transportation industry more efficient.⁵⁹ In the future, Drexler’s vision of nanobots could be realized, which could lead to very early detection of cancerous cells in the human body,⁶⁰ new methods of fighting diseases,⁶¹ and novel ways of ridding the environment of pollution.⁶² In addition, nanobots that can build products, and even parts of the body, may entirely change the way humans view themselves and their environment.⁶³

51. *Id.* at 40.

52. FRIENDS OF THE EARTH, *Supra* note 36, at 2.

53. *Id.* at 7.

54. *Id.* at 8.

55. See HEALTH AND SAFETY EXECUTIVE, HEALTH EFFECTS OF PARTICLES PRODUCED FOR NANOTECHNOLOGIES 17-19 (2004), available at <http://www.hse.gov.uk/horizons/nanotech/healtheffects.pdf> [hereinafter HSE Report] (comparing the toxicity levels through inhalation of different existing types of nanoparticles and stating that “[t]here is no information on the differences or similarities between nanometre particles of different existing materials in terms of their health effects, either local or systemic, following dermal exposure[, but] it seems feasible that such differences could occur . . .”). The Health and Safety Executive is responsible for protecting “people against risks to health or safety arising out of work activities” in Great Britain. Health and Safety Executive, About Us, <http://www.hse.gov.uk/aboutus/index.htm> (last visited Apr. 10, 2008).

56. See ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 6 (“[N]anotechnologies encompass a broad and varied range of materials, tools, and approaches. Apart from a characteristic size scale, it is difficult to find commonalities between them. We should not therefore expect them to have the same health, environmental, safety, social, or ethical implications.”).

57. KURZWEIL, *supra* note 21, at 226-27.

58. See BRITANNICA, *supra* note 14, at 741D (noting some of the uses of nanotechnology).

59. *Id.*

60. *Id.* at 741E.

61. KURZWEIL, *supra* note 21, at 241.

62. BRITANNICA, *supra* note 14, at 741D.

63. See KURZWEIL, *supra* note 21, at 227 (arguing that nanotechnology will enable the redesigning and rebuilding of human bodies and brains and the “world with which we interact”).

C. Potential Consequences of the Use of Nanoparticles in Cosmetics

The cosmetic industry has recently begun to take advantage of the special properties of nanoparticles.⁶⁴ Currently, L'Oreal, Lancôme, Estee Lauder, Zelens, and Dr. Brandt allegedly use nanoparticles in their skin care products. Although, such products are thought to benefit consumers, more research is necessary to determine whether they will also damage the skin or cause harm inside the body.

1. Products and Their Claims

Many companies claim to be testing the effects of nanoparticles on healthy skin.⁶⁵ Certain types of nanoparticles have apparently shown to increase the elasticity of the skin and to reduce the appearance of wrinkles and other signs of aging.⁶⁶ In particular, fullerenes are thought to prevent premature aging of the skin.⁶⁷ Some companies also purport to test the safety of the use of nanoparticles in their products.⁶⁸ Published research on the implications of the use of nanoparticles in cosmetics, however, is scarce.⁶⁹ Further investigation into the effects of nanoparticles on the human body is necessary to determine whether they pose significant health risks.⁷⁰

Nevertheless, companies are now using or claiming to use nanoparticles in the sunscreens, lotions, and anti-aging products that they produce and distribute to the public.⁷¹ It is estimated that hundreds of products currently on the market contain some type of nanoparticles.⁷² Examples of anti-aging products alleged (by their manufacturers or other groups) to contain nanoparticles are the L'Oreal Revitalift, the Lancôme Hydra Zen, and the Estee Lauder Re-Nutriv and Resilience lines.⁷³

Retailers make varying assertions about the intended effects of such products. For example, L'Oreal claims that Revitalift combats signs of aging.⁷⁴ Its Web site states that Revitalift Double Lifting fights wrinkles by retightening the skin, and that Revitalift Night works all night long to reduce

64. See, e.g., ROYAL SOC'Y & ROYAL ACAD., *supra* note 3, at 44 (discussing the use of nanoparticles in cosmetic products); FRIENDS OF THE EARTH, *supra* note 36, at 14 ("[R]egulators . . . need to take seriously the rapid market expansion of personal care products and cosmetics containing nanomaterials.")

65. See, e.g., ROYAL SOC'Y & ROYAL ACAD., *supra* note 3, at 44; FRIENDS OF THE EARTH, *supra* note 36, at 8.

66. See, e.g., L'Oreal, Advanced RevitaLift Night Cream, http://www.lorealparisusa.com/_us/_en/default.aspx#page=top{nav|media:_blank|overlay:productdetail//objectid+SK3_2//diagnostic|main:brandpage:advancedrevitalift|userdata//d+d//} (last visited Apr. 10, 2008).

67. See, e.g., Zelens, About Zelens, <http://zelens.com/section/8/1/about-zelens> (last visited Apr. 10, 2008) [hereinafter Zelens, About Zelens].

68. See, e.g., Zelens, Scientific Background, <http://zelens.com/section/47/1/scientific-background> (last visited Apr. 10, 2008) [hereinafter Zelens, Scientific Background].

69. FRIENDS OF THE EARTH, *supra* note 36, at 8-11.

70. *Id.* at 12-13; BRITANNICA, *supra* note 14, at 741E.

71. See, e.g., FRIENDS OF THE EARTH, *supra* note 36, at 2; Responsible Nanotechnology, *supra* note 10.

72. FRIENDS OF THE EARTH, *supra* note 36, at 4.

73. *Id.* at 20-22; Nell Greenfieldboyce, *Safety of Nano-Cosmetics Questioned*, NPR HEALTH & SCI., Mar. 13, 2006, <http://www.npr.org/templates/story/story.php?storyId=5257306>.

74. L'Oreal, *supra* note 66.

wrinkles and firm the skin.⁷⁵ While L'Oreal declares that some Revitalift products contain "nanosomes,"⁷⁶ it gives no warning that they may be harmful to the body.⁷⁷

Similarly, Lancôme does not warn consumers that nanoparticles contained in its Hydra Zen Cream may be harmful.⁷⁸ Its Web site states that "nano-encapsulated Triceramides," along with other ingredients in Hydra Zen Cream, help the skin to stay hydrated and moisturized.⁷⁹

Estee Lauder's Web site not only fails to warn consumers of potential risks associated with the use of its products but also fails to mention that Re-Nutriv and Resilience contain nanoparticles.⁸⁰ A consumer would need to look to other sources to discover that those lines contain "novasomes."⁸¹ The Web site claims that users of Re-Nutriv Intensive Lifting Crème will see a reduction in the look of wrinkles and have smoother, firmer skin after eight weeks.⁸² In addition, it asserts that a restorative enzyme in the cream helps the skin to recover from past environmental damage.⁸³ The Web site describes Resilience Lift Extreme OverNight Ultra Firming Crème as a formula that helps to firm sagging skin, smooth out wrinkles and crow's feet, add radiance, and increase the skin's production of natural collagen and elastin.⁸⁴

In addition, companies such as Zelens and Dr. Brandt claim to have used fullerenes to create their anti-aging products.⁸⁵ Zelens specifically boasts on its Web site that Zelens Day and Night Cream each contain Fullerene C60, an extremely powerful anti-oxidant that is one-hundred times more effective than the same concentration of Vitamin E in neutralizing free radicals, which cause premature aging of the skin.⁸⁶ The company claims that the cream helps prevent environmental damage to the skin's DNA.⁸⁷ Moreover, its Web site maintains that Zelens Night Cream stimulates the manufacture of collagen-

75. *Id.*

76. See FRIENDS OF THE EARTH, *supra* note 36, at 20 (stating that L'Oreal claims that Revitalift contains nanosomes, a type of nanoparticle).

77. L'Oreal, *supra* note 66.

78. Lancôme, *supra* note 2.

79. *Id.*

80. See, e.g., Estee Lauder, Re-Nutriv Intensive Smoothing Body Crème, http://www.esteelauder.com/templates/products/sp_nonshaded.tmp?CATEGORY_ID=CATEGORY13534&PRODUCT_ID=PROD12569 (last visited Apr. 10, 2008) [hereinafter Estee Lauder, Re-Nutriv].

81. See FRIENDS OF THE EARTH, *supra* note 36, at 20 (stating that others claim that the Estee Lauder Re-Nutriv and Resilience lines contain "novasomes," a type of nanoparticle).

82. Estee Lauder, Re-Nutriv, *supra* note 80.

83. Estee Lauder, Resilience Lift Extreme, http://www.esteelauder.com/templates/products/sp_nonshaded.tmp?CATEGORY_ID=CATEGORY5865&PRODUCT_ID=PROD9420 (last visited Apr. 10, 2008) [hereinafter Estee Lauder, Resilience Lift].

84. *Id.*

85. See Greenfieldboyce, *supra* note 73 (discussing Zelens' claim that its Day Cream contains fullerenes); Zelens, About Zelens, *supra* note 67; Dr. Brandt, Lineless, <http://www.drbrandtskincare.com/product.php?ck=2&pk=15> (last visited Apr. 10, 2008). Since writing this article Zelens skin care products no longer contain fullerenes. Truth in Aging: Dare to Try It, www.truthinaging.com/2008/01/zelens-skin-1.html (last visited May 31, 2008).

86. Zelens, Press, <http://zelens.com/section/40/1/united-states/2> (last visited Apr. 10, 2008).

87. Zelens, DNA Protection Day Cream, <http://zelens.com/products/5/dna-protection-day-cream---estra-rich> (last visited Apr. 10, 2008).

producing cells.⁸⁸ Like L’Oreal, Lancôme, and Estee Lauder, Zelens does not warn consumers that fullerenes may be dangerous.⁸⁹

The Dr. Brandt Web site also lists fullerenes as a primary ingredient in its Lineless Cream without warning that they may cause harm to the skin or the body.⁹⁰ It states that the fullerenes absorb free radicals to prevent harm from UVA and UVB rays,⁹¹ which is claimed to prevent wrinkles and preserve the skin’s elasticity by prolonging cell life and preventing collagen in the cells from depleting.⁹²

2. Nanoparticles on the Skin and Inside the Body

Although nanoparticles can benefit consumers when used in cosmetics, their special properties also make them potentially harmful to the skin, cells, and organs in the body.⁹³ Certain nanoparticles may be toxic for the skin.⁹⁴ The long-term effects of frequent exposure of the skin to many types of nanoparticles are unknown.⁹⁵ In addition, no studies have compared harm caused by skin exposure to naturally-occurring nanoparticles with harm caused by exposure to engineered nanoparticles.⁹⁶ Thus, more research must be conducted to ascertain the nature of toxicity problems relating to the contact of nanoparticles with the skin.⁹⁷

In addition, nanoparticles in cosmetics may enter the human body and cause harm once inside.⁹⁸ Because cosmetics are applied topically, the nanoparticles they contain can potentially enter the body via the skin.⁹⁹ The skin is designed to present “a barrier to penetration by micro-organisms or other particles.”¹⁰⁰ Although most particles in nature are too large to permeate its outer layers, certain nanoparticles are thought to be tiny enough to slip through them.¹⁰¹ Skin that has been damaged by eczema, severe sunburn, or acne is especially at risk for nanoparticle penetration.¹⁰² Cosmetic companies,

88. Zelens, Cellular Reconstruction Night Cream, <http://zelens.com/products/6/cellular-reconstruction-night-cream> (last visited Apr. 11, 2008) [hereinafter Zelens, Cellular Reconstruction].

89. *Id.*

90. Dr. Brandt, *supra* note 85.

91. *Id.*

92. *Id.*

93. ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 36; Greenfieldboyce, *supra* note 74.

94. ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 43.

95. *Id.*

96. See HSE Report, *supra* note 55, at 19.

97. ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 43 (“It is clear that nanoparticles have different properties to the same chemical at a larger scale, and the implications of these different properties for long-term toxicity to the skin require rigorous investigation on a case-by-case basis.”); Greenfieldboyce, *supra* note 73.

98. ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 36.

99. *Id.*; Greenfieldboyce, *supra* note 73.

100. See ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 36.

101. *Id.* at 44; FRIENDS OF THE EARTH, *supra* note 36, at 7.

102. ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 38. The outer layer of the skin, the epidermis, “is normally impermeable to particles and micro-organisms but is readily damaged (for example, by cuts and abrasions) or perforated (for example, by specialized insects or by therapeutic injections). Several skin diseases such as allergies can also impair its ability to withstand toxic agents.” *Id.*; FRIENDS OF THE EARTH,

however, seem to be testing their products mainly on healthy skin.¹⁰³ Therefore, the ramifications of contact of nanoparticles with less than healthy skin are largely unknown.

As discussed above, once inside the body, nanoparticles react with larger particles in unfamiliar ways that may harm individual cells and organs.¹⁰⁴ One frequently cited example of a nanoparticle that may be harmful in the body is that of zinc oxide, which is commonly found in sunscreens.¹⁰⁵

D. Law Governing the Regulation of Cosmetics

Both federal and state laws regulate cosmetics marketed in the United States. The “two most important [federal] laws pertaining to cosmetics” are the Federal Food, Drug and Cosmetic Act (“FDCA”) and the Fair Packaging and Label Act (“FPLA”).¹⁰⁶ The FDCA “prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce,”¹⁰⁷ and the FPLA requires cosmetic companies to list the ingredients contained in their products on product labels.¹⁰⁸ Congress charged the Federal Drug Administration (“FDA”) with creating regulations to enforce these laws.¹⁰⁹ Under the FDCA, the FDA does not have broad authority to pre-approve cosmetic ingredients.¹¹⁰ Rather, it may enforce the statute through the prosecution of cosmetic companies after they have sold adulterated or misbranded products to consumers.¹¹¹

Under state products liability law, consumers themselves may prosecute cosmetic companies to obtain compensation if they are harmed by their products. This area of law varies from state to state.¹¹² Therefore, a consumer could have a high chance of obtaining redress for a particular injury in one state but a slim chance in another. A number of common themes, however, run

supra note 36, at 7 (“Nanomaterials can gain access to the blood stream . . . possibly . . . via skin absorption, especially if the skin is damaged”).

103. ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 44 (“Cosmetics . . . are intended for use on undamaged skin, and most skin penetration tests [conducted by cosmetic companies] appear to have been designed with this in mind. Few reported studies indicate whether these particles penetrate skin that might have been damaged previously, for example by severe sunburn from sunlight exposure or by disease such as eczema.”).

104. *Id.* at 36-43; Greenfieldboyce, *supra* note 74.

105. ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 36-43; Greenfieldboyce, *supra* note 74.

106. U.S. Food and Drug Administration, FDA Authority over Cosmetics, <http://www.cfsan.fda.gov/~dms/cos-206.html> (last visited Apr. 10, 2008) [hereinafter FDA Authority over Cosmetics].

107. *Id.* The FDCA states that a cosmetic is adulterated “[i]f 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 . . .” and misbranded “[i]f its labeling is false or misleading in any particular.” *Id.*

108. *Id.*

109. *See id.* (“Under the authority of the FPLA, FDA requires an ingredient declaration to enable consumers to make informed purchasing decisions”).

110. *See id.* (“Cosmetic products and ingredients are not subject to FDA premarket approval authority, with the exception of color additives.”).

111. *Id.*

112. *See generally* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998) (discussing the variations among states).

through products liability law in a majority of states.¹¹³

III. ANALYSIS

Although nanoparticles are potentially harmful to the skin and the human body, no governmental group effectively regulates their use in cosmetics. The FDA is not authorized to pre-approve cosmetics in most instances.¹¹⁴ Because anti-aging products containing nanoparticles do not always meet the criteria for classification as a drug, companies that manufacture these products are often only prosecuted for harm suffered by consumers after use. The extent to which cosmetic manufacturers may successfully be held accountable under products liability law for such damage is uncertain.

A. *Limits of FDA Regulation of Nanoparticles in Cosmetics*

The FDA's current system is inadequate to protect consumers from nanoparticles in anti-aging products. It does not require products containing nanoparticles to be pre-approved unless they classify as "drugs" under the FDCA or contain specifically listed "adulterated" materials.¹¹⁵ Some anti-aging products are likely to be classified as "cosmetics" rather than "drugs" under the tests that courts have created to determine whether a product is a drug.¹¹⁶ Furthermore, the FDA has not specifically classified any nanoparticles used in anti-aging cosmetics as "adulterated."¹¹⁷ Therefore, the FDA's authority over anti-aging products classified as "cosmetics" is essentially limited to prosecution after sale for violations of its prohibition on the introduction into interstate commerce of "adulterated" and "misbranded" cosmetics.¹¹⁸

1. *FDA Oversight of Cosmetics*

The FDA regulates prescription and over-the-counter drugs and cosmetics.¹¹⁹ Most cosmetic ingredients, however, need not be pre-approved before they are used in products sold to the public.¹²⁰ The only exceptions are colorants, sunscreen, and certain ingredients that are presumed to be adulterated.¹²¹ Colorants must be approved before sale, and presumptively adulterated ingredients are either prohibited or specifically regulated.¹²²

113. See generally *id.* (discussing the commonalities among states).

114. FDA Authority over Cosmetics, *supra* note 106.

115. *Id.*

116. See discussion *infra* Part III.B.

117. See 21 C.F.R. § 700.11-700.35 (2007) (listing those chemicals designated as "adulterated").

118. FDA Authority over Cosmetics, *supra* note 106.

119. U.S. Food and Drug Administration, What FDA Regulates, <http://www.fda.gov/comments/regs.html> (last visited May 31, 2007).

120. FDA Authority over Cosmetics, *supra* note 106.

121. *Id.*

122. Janet Winter Blaschke, *Globalization of Cosmetic Regulations*, 60 FOOD & DRUG L.J. 413, 414

Products that advertise that they contain sunscreen also must be pre-approved.¹²³ However, the FDA does not regulate these products due to the potentially harmful effects of the active ingredients in sunscreen, which are sometimes nanoparticles of zinc oxide or titanium dioxide.¹²⁴ Rather, it requires pre-approval to shield consumers from deceptive claims that a product will reduce their risk of developing skin cancer.¹²⁵ The FDA has approved all sizes of zinc oxide particles for use in sunscreen.¹²⁶ However, it remains unclear whether the FDA specifically studied the potential for nanoparticles of zinc oxide and other active ingredients in sunscreen to harm the skin or to penetrate into the body.¹²⁷

Although the FDA does gather information from groups that study cosmetics, as well as document and inspect certain cosmetic products, its efforts do not effectively prevent cosmetic companies from including potentially harmful nanoparticles in their products. Cosmetic companies, not the FDA, “are responsible for substantiating the safety of their products and ingredients before marketing.”¹²⁸ An independent body called the Cosmetic Ingredient Review studies certain cosmetic ingredients and recommends whether the FDA should consider them adulterated.¹²⁹ This body, however, does not have the authority to ban dangerous substances.¹³⁰ Currently, the FDA does not list any nanoparticles as adulterated.¹³¹ Therefore, cosmetic companies are free to use nanoparticles in their products without much interference from the FDA.

In addition, although the FDA has created a reporting and registering system for cosmetics, many companies do not participate in the program because it is voluntary.¹³² The FDA conducts occasional inspections of cosmetic factories, but it has limited resources and only inspects factories that are suspected of adulterating or misbranding their products.¹³³ As a result, nanoparticles that companies use in their cosmetic products but do not specifically list on product labels go virtually undetected by the FDA.

Due to concerns and protests about the use of nanoparticles in cosmetics and other products that the FDA is charged with regulating,¹³⁴ the FDA finally

(2005).

123. 21 C.F.R. § 700.35 (2007).

124. *Id.*; FRIENDS OF THE EARTH, *supra* note 36, at 15.

125. 21 C.F.R. § 700.35; FRIENDS OF THE EARTH, *supra* note 36, at 15.

126. FRIENDS OF THE EARTH, *supra* note 36, at 15.

127. *See* ROYAL SOC’Y & ROYAL ACAD., *supra* note 3, at 43-44.

128. FDA Authority over Cosmetics, *supra* note 106.

129. Blaschke, *supra* note 122, at 414.

130. *See id.* (discussing the functions of the Cosmetic Ingredient Review).

131. 21 C.F.R. § 700.11-700.35 (2007).

132. FDA Authority over Cosmetics, *supra* note 106.

133. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., OFFICE OF COSMETICS AND COLORS FACT SHEET: INSPECTION OF COSMETICS (2003), <http://www.cfsan.fda.gov/~dms/cos-214.html>.

134. *See, e.g.*, Rick Weiss, *Nanotechnology Precaution Is Urged*, WASH. POST, July 30, 2004, at A02, available at <http://www.washingtonpost.com/wp-dyn/articles/A25675-2004Jul29.html> (discussing risks of nanoparticles); Simon Pitman, *Lobby Groups Question Cosmetic Nano Ingredients*, NUTRA USA, June 18, 2006, <http://www.nutraingredients-usa.com/news/ng.asp?n=67800-usfda-nanotechnology-regulation-lobby> (discussing lobby group’s efforts to tighten nanotechnology ingredient

held a public meeting on October 10, 2006 to discuss the safety of nanoparticles.¹³⁵ Numerous organizations and educational institutions sent representatives to provide the FDA with the information they had gathered.¹³⁶ Six groups presented information specifically about the use of “nanotechnology material . . . in cosmetics, personal care products, . . . [and] topically applied products.”¹³⁷

Representatives from the International Center for Technology Assessment (“CTA”) and the Personal Care Products Council (“PCPC”) spoke about the general use of nanoparticles in cosmetics, taking opposing positions on how the FDA should regulate such particles.¹³⁸ CTA, a “non-profit, bi-partisan organization committed to providing the public with full assessments and analyses of technological impacts on society,”¹³⁹ recommended that the FDA begin treating nanoparticles as potentially dangerous particles, different from their larger counterparts, which should be studied and regulated differently.¹⁴⁰

In contrast, the PCPC, a national trade organization for the cosmetic and personal care industry composed of cosmetic manufacturers and distributors,¹⁴¹ stated that existing methods for determining whether cosmetic ingredients are safe are adequate for evaluating the safety of nanoparticles.¹⁴² It recommended no new regulations regarding the use of nanoparticles in cosmetics.¹⁴³ The contrasting views taken by these organizations highlights the uncertainty about the safety of cosmetics containing nanoparticles. It also underscores the current debate over the extent of the FDA’s responsibility to study and regulate cosmetic products containing such particles.

2. *Drugs vs. Cosmetics*

The FDA can only minimally regulate certain anti-aging products containing nanoparticles because they are termed “cosmetics” rather than “drugs” under the courts’ interpretation of the language of the FDCA. The statute divides cosmetics and drugs into two distinct groups.¹⁴⁴ Cosmetics are

regulation).

135. U.S. Food and Drug Administration, Public Meeting on Nanotechnology Materials in FDA Regulated Products (Oct. 10, 2006), <http://fda.gov/nanotechnology/agenda1010.html>.

136. *Id.*

137. *Id.*

138. Compare George A. Kimbrell, Int’l Cent. for Tech. Assessment, Presentation at the FDA Public Meeting on Nanotechnology and Nanomaterials in Consumer Products: Regulatory Challenges and Necessary Amendments (Oct. 10, 2006), http://www.fda.gov/nanotechnology/meetings/kimbrell_files/Kimbrell_CTA_Presentation_FDA_Meeting_10_10_06.pps (“[The] FDA should immediately prioritize human health and environmental concerns”), with Annette Santamaria, Environ Int’l Corp., Presentation at the FDA Public Meeting on Nanomaterials (Oct. 10, 2006), available at <http://www.fda.gov/nanotechnology/meetings/santamaria.html> (“[T]he regulatory processes that the FDA currently has for evaluating ingredients used in personal care products are more than adequate . . .”).

139. Int’l Cent. for Tech. Assessment, <http://www.icta.org/about/index.cfm> (last visited Apr. 10, 2008).

140. Kimbrell, *supra* note 138.

141. Personal Care Products Council, http://www.personalcarecouncil.org/template.cfm?section=about_us (last visited Apr. 10, 2008).

142. Santamaria, *supra* note 138.

143. *Id.*

144. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321(i), (g)(1) (2000).

defined as “articles *intended* to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance.”¹⁴⁵ Drugs, however, are “articles *intended* for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) *intended* to affect the structure and function of the body of man or other animals.”¹⁴⁶

Courts’ interpretation of this language determines whether a product is considered a drug and is required to be pre-approved by the FDA. Many courts have examined the difference between cosmetics and drugs, and a test to determine whether a product is a drug has emerged.¹⁴⁷ In 1969, the United States Supreme Court ruled that as a remedial statute, the FDCA should be interpreted broadly.¹⁴⁸ Since then, courts have classified a product as a drug if its manufacturing company intends for that product to affect the structure or function of the body or advertises it by claiming that it affects the structure or function of the body.¹⁴⁹ Courts look to objective evidence, such as a manufacturer’s publications regarding the product, to determine a manufacturer’s intent.¹⁵⁰

For example, in *United States v. Pro-Ag, Inc.*, the U.S. Circuit Court for the Eighth Circuit examined Pro-Ag’s promotional literature regarding their whey-based products to determine whether those products were drugs under the FDCA.¹⁵¹ The court held the literature demonstrated that the primary purpose of the products was to improve feed efficiency and to increase milk production in cows.¹⁵² The court reasoned that “[o]ne of a dairy cow’s primary functions is to produce milk” and “a dairy cow’s production of milk is dependent on its consumption of feed.”¹⁵³ Therefore, the products qualified as a drug because it was “necessarily intended to affect . . . [a] cow’s ‘function.’”¹⁵⁴

Likewise, in *Nutrilab Inc. v. Schweiker*, the U.S. Circuit Court for the Seventh Circuit looked to the company Nutrilab’s advertisements to determine whether its starch blockers were a drug.¹⁵⁵ The advertisements stated that the

145. § 321(i) (emphasis added).

146. § 321(g)(1) (emphasis added).

147. See, e.g., *United States v. Pro-Ag, Inc.*, 968 F.2d 681, 682 (8th Cir. 1992).

148. See *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (“Remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act’s overriding purpose to protect the public health . . .”).

149. See, e.g., *United States v. Article . . . Consisting of 216 Individually Cartonned Bottles*, 409 F.2d 734, 736 (2d Cir. 1969); *United States v. Article of Drug, Etc.* 331 F. Supp. 912, 915 (D. Md. 1971).

150. See, e.g., *Article . . . Consisting of 216 Individually Cartonned Bottles*, 409 F.2d at 739 (“It is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source.”); *Article of Drug, Etc.*, 331 F. Supp. at 917 (explaining how to determine when a product is intended to affect the structure of the body); *United States v. Article Consisting of 36 Boxes, Etc.*, 284 F. Supp. 107, 109 (D. Del. 1968) (“The intended use of a product determines whether or not it falls within the statutory category of a drug.”).

151. 968 F.2d 681, 683 (8th Cir. 1992).

152. *Id.*

153. *Id.*

154. *Id.*

155. 713 F.2d 335, 335-38 (7th Cir. 1983).

purpose of the blockers was to prevent weight gain by stopping consumers' bodies from digesting starch.¹⁵⁶ The blockers accomplished this task by preventing the body's enzyme that normally acts on starch from breaking it down and instead allowing starch to pass intact through the body.¹⁵⁷ The court decided that the starch blockers were indisputably meant to affect the function of the body because they were "intended to affect digestion in the people who take them."¹⁵⁸

Moreover, in *United States v. Undetermined Quantities of Articles of Drug, Street Drug Alternatives*, the U.S. District Court for the District of Maryland examined defendant manufacturers' labeling and promotional claims to determine whether they intended their products to affect the function of the human mind.¹⁵⁹ The companies used language that advertised the substances as substitutes for street drugs, implying that they would give users the feeling of being high.¹⁶⁰ The products were labeled with phrases such as "Rave Energy . . . the Strong Legal X alternative," "Utopia . . . Xperience the natural sensation," and "Shroomz."¹⁶¹ In addition, the product catalog stated that the substances were "for mood enhancement."¹⁶² Thus, the court found that based on this objective evidence, the companies intended for their products to "affect the function or structure of the mind by elevating the psychological condition of users."¹⁶³

Although courts agree that it is appropriate to examine a manufacturer's intent through a product's publications to determine whether that product is a drug,¹⁶⁴ they are divided over the degree to which a product must claim to affect the structure or function of the body before it should be classified as a drug.¹⁶⁵ Some courts have held that even products that claim to temporarily alter the structure or function of the body by enhancing its appearance are drugs.¹⁶⁶

For example, in 1968, the U.S. District Court for the District of Delaware held that a lotion called "Line Away," which was promoted and sold as a temporary wrinkle smoother, was a drug under the FDCA.¹⁶⁷ The court reasoned that Congress defined "drug" extremely broadly in the statute and therefore meant for the definition to encompass all products intended to alter

156. *Id.* at 335.

157. *Id.*

158. *Id.*

159. 145 F. Supp. 2d 692, 698-99 (D. Md. 2001).

160. *Id.*

161. *Id.* at 699.

162. *Id.* at 700.

163. *Id.* at 699.

164. *United States v. Article . . . Consisting of 216 Individually Cartoned Bottles*, 409 F.2d 734, 739 (2d Cir. 1969).

165. *Compare United States v. Article Consisting of 36 Boxes, Etc.*, 284 F. Supp. 107, 107 (D. Del. 1968) *with Article . . . Consisting of 216 Individually Cartoned Bottles*, 409 F.2d at 734.

166. *See, e.g., Article Consisting of 36 Boxes, Etc.*, 284 F. Supp. at 110-11 (holding that a lotion manufactured from bovine albumen was a "drug" within the Federal Food, Drug and Cosmetic Act).

167. *Id.* at 109-11.

the body's structure or function for any duration, even solely its appearance.¹⁶⁸ The court also stated, somewhat cryptically, that "the intended effect of some products may be so 'incidental' to the essential objective of the product as to fall outside of the ambit of the statute."¹⁶⁹ Therefore, under this standard a court must decide whether a manufacturer intended for its product to alter the structure or function of the body for any amount of time, and whether this intended effect was only 'incidental' to the product's main purpose.¹⁷⁰

Many anti-aging products containing nanoparticles are likely to be categorized as drugs under this test. In particular, L'Oreal's Revitalift products, Estee Lauder's Re-Nutriv and Resilience products, Zelens Day Cream and Hydra Zen Night Cream, and Dr. Brandt Lineless Cream would all qualify as drugs. L'Oreal and Estee Lauder make claims similar to those made by the manufacturer of "Line Away." L'Oreal's Web site states that Revitalift Night fights wrinkles and increase skin's firmness.¹⁷¹ Similarly, Estee Lauder's Web site proclaims that Re-Nutriv Intensive Lifting Crème and Resilience Lift Extreme OverNight Ultra Firming Crème help to make the skin appear smoother and firmer and to reduce the appearance of wrinkles.¹⁷² According to the court in the "Line Away" case, this is all sufficient evidence of the manufacturers' intent that their products be viewed as affecting the structure or function of the body.¹⁷³

The Zelens and Dr. Brandt Web sites also contain claims that suggest that their products are meant to change the structure or function of the body. Zelens' Web site proclaims that Zelens Night Cream will stimulate the skin's production of collagen.¹⁷⁴ This assertion is similar to the claim Nutrilab made about its starch blockers.¹⁷⁵ Zelens maintains that its Day Cream actually forces the skin to produce more cells, and thus it necessarily affects the skin's function. Likewise, Dr. Brandt's Web site declares that its Lineless Cream will prolong cell life by preventing "the depletion of collagen."¹⁷⁶ Collagen is one material that gives cells their structure.¹⁷⁷ Therefore, Dr. Brandt intends for its cream to affect the structure of the body, specifically that of skin cells.

Although the L'Oreal, Estee Lauder, Zelens, and Dr. Brandt products would likely be classified as drugs under the broad test adopted by the Line Away court, Lancôme's Hydra Zen Cream may not. Lancôme's Web site

168. *See id.* at 103-10 (interpreting section 321 of the Act defining "drug" to mean articles intended to affect the structure or any function of the body of humans or animals).

169. *Id.* at 110.

170. *Id.*

171. L'Oreal, *supra* note 66.

172. Estee Lauder, Re-Nutriv, *supra* note 80; Estee Lauder, Resilience Lift, *supra* note 83.

173. Article Consisting of 36 Boxes, Etc., 284 F. Supp. at 109-10.

174. Zelens, Cellular Reconstruction, *supra* note 88.

175. *See* Nutrilab Inc. v. Schweiker, 713 F.2d 335, 336-39 (holding that "starch blockers" are a drug, even though they are derived from kidney beans).

176. Dr. Brandt, *supra* note 85.

177. *Collagen*, WIKIPEDIA: THE FREE ENCYCLOPEDIA (Mar. 9, 2007), <http://en.wikipedia.org/wiki/Collagen> ("[T]ough bundles of collagen called *collagen fibers* are a major component of the extracellular matrix that supports most tissues and gives cells structure from the outside.").

claims that the cream keeps the skin hydrated and moisturized.¹⁷⁸ These assertions are similar to those made by companies that manufacture simple moisturizers that help to bind moisture to the skin.¹⁷⁹ They do not inevitably lead to the conclusion that the company intends for the cream to alter the structure or function of the body in a way that is not incidental. Thus, a court applying the first test may not classify Lancôme's Hydra Zen Cream as a drug under the FDCA.

Furthermore, many of the products discussed above would not be classified as drugs under a second test that other courts use to make the determination. These courts have ruled that a product that merely claims to temporarily enhance the body's appearance is never a drug.¹⁸⁰ For example, in *United States v. Article . . . Consisting of 216 Individually Cartoned Bottles*, the United States Court of Appeals for the Second Circuit created a test that requires an "ignorant, unthinking, or credulous' consumer" to expect a product to "affect the structure of the body in some medical . . . or drug-type fashion . . . other than merely 'altering the appearance'" for the product to be classified as a drug.¹⁸¹ The court held that a lotion called "Sudden Change" whose packaging claimed to give a face lift without surgery was a drug because the words "face lift" and "surgery" are "physiological"¹⁸² terms that could convince a vulnerable consumer that the product was intended to have lasting effects on the body.¹⁸³

A few years later, the Maryland District Court applied this test to a lotion called "Magic Secret," which was advertised as a "pure protein" that caused an "astringent sensation" and was intended to "smooth, firm and tighten the skin" for a few hours after application.¹⁸⁴ The court held that the product was not a drug under the FDCA because even an ignorant consumer would not expect the product to do anything but change her appearance for a few hours after use.¹⁸⁵

Under this second test, many anti-aging products containing nanoparticles could potentially be classified as cosmetics. Lancôme's Hydra Zen Cream would very likely be classified as a cosmetic because 'hydrating' and 'moisturizing' are not "physiological" terms as defined by the Sudden Change

178. Lancôme, *supra* note 2.

179. See, e.g., Cetaphil Cleansers and Moisturizers, <http://www.cetaphil.com/Products/Moisturizers.aspx> (last visited Apr. 11, 2008) (stating that Cetaphil Therapeutic Hand Cream is "[d]esigned to give dry, chapped skin a healthy dose of moisture, without the greasy residue" and that Cetaphil Moisturizing Lotion's "cosmetically appealing formulation contains a superior system of emollients and humectants to bind moisture to the skin.>").

180. See, e.g., *United States v. Article . . . Consisting of 216 Individually Cartoned Bottles*, 409 F.2d 734, 741-42 (2d Cir. 1969).

181. *Id.* at 742.

182. *Merriam Webster's Collegiate Dictionary* defines "physiological" as "of or relating to the organic processes and phenomena of an organism or any of its parts or of a particular bodily process." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 877 (10th ed. 1993). The court seems to use the word to refer to a permanent alteration of some part of the body. *Article . . . Consisting of 216 Individually Cartoned Bottles*, 409 F.2d at 741.

183. *Article . . . Consisting of 216 Individually Cartoned Bottles*, 409 F.2d at 741.

184. *United States v. Article of Drug, Etc.* 331 F. Supp. 912, 915 (D. Md. 1971).

185. *Id.* at 917.

court. They do not suggest that the Cream will permanently change the body as surgery would.¹⁸⁶ Even an ignorant consumer would likely understand that the product only temporarily alters the skin's texture and appearance by inducing moisture to bind to its cells.

L'Oreal Revitalift could also be classified as a cosmetic under the second test. It seems more like Magic Secret than Sudden Change because its advertisements state that the product will tighten skin and reduce the appearance of wrinkles, but they do not claim that it will have a permanent "physiological" effect on the body.¹⁸⁷

Likewise, it is unclear whether a court would categorize Estee Lauder's Re-Nutriv Intensive Lifting Crème and Resilience Lift Extreme OverNight Ultra Firming Crème, Zelens Day Cream, or Dr. Brandt Lineless Cream as cosmetics under this second test. Because the descriptions for Resilience, Zelens Day Cream, and Dr. Brandt Lineless Cream proclaim that the products stimulate the skin's production of collagen,¹⁸⁸ each one necessarily affects the body's function. Whether the affect is "physiological" enough for the Sudden Change court,¹⁸⁹ even if the change in the skin's function is only temporary, is difficult to say. Estee Lauder's Web site states that users of Re-Nutriv will see results in eight weeks.¹⁹⁰ Because this implies that the change in the skin's function is longer-lasting, a court may be willing to classify Re-Nutriv as a drug.

Therefore, not all courts would classify today's anti-aging products containing nanoparticles as "drugs." Even under the Line Away court's extremely broad test, a court may not classify Lancôme's Hydra Zen Cream as a drug. Moreover, although companies that manufacture anti-aging products are competing for consumer attention by making increasingly drug-like claims, the FDA has failed to prosecute those companies and require that their products be pre-approved as drugs.¹⁹¹ Because cosmetic companies are not required to report the use of nanoparticles to the FDA, and the FDA is only required to pre-approve drugs before sale, potentially dangerous cosmetics are available to consumers without any warning.

B. Limits on Successful Prosecution Under State Products Liability Law

Although consumers injured by nanoparticles in cosmetics may prosecute the manufacturers of those harmful products under state products liability law, courts may potentially refuse to hold such manufacturers liable. The state products liability claim most applicable to nanoparticles in cosmetics is failure

186. See Lancôme, *supra* note 2.

187. L'Oreal, *supra* note 66.

188. Dr. Brandt, *supra* note 85; Estee Lauder, Re-Nutriv *supra* note 80; Zelens, Cellular Reconstruction *supra* note 88.

189. United States v. Article . . . Consisting of 216 Individually Cartoned Bottles, 409 F.2d 734, 741 (2d Cir. 1969).

190. Estee Lauder, Re-Nutriv, *supra* note 80.

191. Bryan A. Liang & Kurt M. Hartman, *It's Only Skin Deep: FDA Regulation of Skin Care Cosmetics Claims*, 8 CORNELL J. L. & PUB. POL'Y 249, 255 (1999).

to warn.¹⁹² In most jurisdictions, that claim requires a plaintiff to show that an inherent risk of harm was foreseeable by a reasonable person at the time the product was sold.¹⁹³ Because so much is currently unknown about the effects of nanoparticles on and in the body, it may be difficult or even impossible for a consumer to prove this element. Thus, state products liability laws will not adequately hold manufacturers responsible for damage caused by their cosmetics containing nanoparticles.

Under state products liability law, consumers harmed by nanoparticles in cosmetics may potentially sue manufacturers for negligence or strict liability. Within these broad categories, a consumer can theoretically pursue a claim for manufacturing defect, defective design, or failure to warn.¹⁹⁴ Manufacturing defect claims involve the failure of a specific product unit to meet design specifications.¹⁹⁵ Although this type of claim could possibly apply to nanoparticles, it is unlikely because any harm caused by such particles will probably be understood to flow from their inherent chemical nature rather than from the way a product containing them is designed.

Defective design claims, alternatively, involve a product that meets design specifications, but those specifications cause unreasonable risk.¹⁹⁶ In most states, the test for defective design is whether, at the time of manufacture, a reasonable alternative design existed that could have reduced the risk of harm caused by a product.¹⁹⁷ Although this theory could also potentially apply to nanoparticles in cosmetics,¹⁹⁸ a reasonable substitute design for certain uses of nanoparticles may not currently exist because scientists are just beginning to discover their unique benefits. Thus, plaintiffs are not very likely to pursue their cases under either a manufacturing defect or a defective design theory.

Because nanoparticles are potentially fundamentally dangerous, consumers are most likely to sue a manufacturer for failure to warn. They would, however, meet significant obstacles along the way to proving their case under this theory. Failure to warn claims involve products that contain “inherent risks that reasonably foreseeable product users and consumers would reasonably deem material or significant in deciding whether to use or consume

192. See NATURAL RESOURCES DEFENSE COUNCIL, COMMENTS FROM THE NATURAL RESOURCES DEFENSE COUNCIL ON NANOPARTICLES IN SUNSCREENS, COSMETICS, AND PERSONAL CARE PRODUCTS 4 (2007), available at http://docs.nrdc.org/health/hea_08011401A.pdf (discussing manufacturers' reluctance to disclose the presence of nanoparticles in their products).

193. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) (explaining that a product is defective “when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.”).

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.* at § 2(6) (“A product is defective in design when the foreseeable risks of harm could have been reduced or avoided by the adoption of a reasonable alternative design . . .”).

198. See FRIENDS OF THE EARTH, *supra* note 36, at 9 (discussing the possibility that other ingredients present in cosmetics containing nanoparticles may increase the risk that the particles will be able to penetrate the skin and enter the body).

the product.”¹⁹⁹ A manufacturer is required to conduct reasonable tests before marketing a product to determine whether such inherent risks exist.²⁰⁰ A plaintiff could attempt to show that a cosmetic manufacturer did not conduct adequate tests on its products containing nanoparticles before marketing them. This would be difficult to prove, however, due to the vagueness of the requirement and the fact that cosmetic companies are claiming to test the safety of their products.²⁰¹

Assuming a consumer could clear this hurdle, to succeed in most states he would also have to demonstrate that the inherent danger was foreseeable by the manufacturer.²⁰² The most common test that states use to determine foreseeable harm is whether scientists and experts in the particular field knew of the dangerous quality of a product at the time a company was marketing and selling it, or discovered harmful effects after sale.²⁰³ For example, in *Owens-Illinois, Inc. v. Zenobia*, the Court of Appeals of Maryland stated that asbestos manufacturer Zenobia would be accountable for failing to warn consumers about dangers that scientists employed by private companies had already discovered at the time it sold its products.²⁰⁴ The court also held Zenobia responsible for failing to warn the public of any dangers detected by the scientific or expert community regarding the use of asbestos subsequent to the sale of its products.²⁰⁵ At least one court has justified these requirements by reasoning that if it did not require knowledge in the scientific and expert communities to prove strict liability for failure to warn, then manufacturers would become insurers of a product.²⁰⁶

Although a number of courts have modified and made it easier for plaintiffs to prove the expert knowledge requirement,²⁰⁷ it is unclear whether

199. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998).

200. *Id.* (“[A] seller bears responsibility to perform reasonable testing prior to marketing a product.”).

201. See, e.g., Zelens, Q&As, <http://zelens.com/section/11/1/q-amp-a-rsquo-s> (last visited Apr. 10, 2008) (stating that Zelens products have been tested extensively both in test tubes and on human volunteers). Is it reasonable for companies to test their products solely on healthy skin? How extensive must the testing be to meet the reasonableness standard?

202. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) (stating that “[a]n overwhelming majority of jurisdictions support the proposition that a manufacturer has a duty to warn only [if there existed] risks that were known or should have been known to a reasonable person” at the time of manufacture and distribution). Most jurisdictions require essentially the same elements to be proved for both negligence and strict liability claims involving failure to warn. *Id.* In *Feldman v. Lederle Laboratories, Corp.*, the court succinctly makes this point by asserting that “[a] warning that a product may have an unknowable danger warns one of nothing.” 479 A.2d 374, 387 (N.J. 1984).

203. *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633, 639-41 (Md. 1992).

204. *Id.* at 645.

205. *Id.* at 645-46. Similarly, the *Lederle* court held the drug manufacturer Lederle liable for failure to warn that one of its products, the drug Declomycin, could cause tooth discoloration because studies revealing that information came out after Lederle had sold the drug. *Feldman*, 479 A.2d at 386. The *Lederle* court asserted that “[a] manufacturer should keep abreast of scientific advances” and consumer complaints suggesting danger inherent in a product already on the market obligate a manufacturer to inform the public of harm potentially caused by the product. *Id.* at 386-87.

206. *Woodill v. Parke Davis & Co.*, 402 N.E. 2d 194, 199 (Ill. 1980). In *Woodill*, a mother alleged that the drug company Parke Davis failed to warn her that the drug Pitocin could cause birth defects when administered to pregnant women, and the court held that Pitocin was not liable unless it “would have been reasonable for a drug manufacturer to have given a warning” under the circumstances. *Id.* at 196-98.

207. See, e.g., *Feldman*, 479 A.2d at 387 (citing *Skill v. Martinez*, 91 F.R.D. 498, 514 (D. N.J. 1981),

courts would be willing to hold manufacturers of cosmetics containing nanoparticles liable for harm caused by those particles under a theory of failure to warn. The dangers caused by the use of nanoparticles in cosmetics are currently very abstract due to the lack of completed research on the subject. Virtually no information about the differences between natural and engineered nanoparticles is known in the scientific community at present and could take years to discover.²⁰⁸ Courts probably will not require manufacturers to possess knowledge greater than that present in the scientific community. Therefore, state products liability law is insufficient to hold manufacturers of cosmetics containing nanotechnology responsible for its effects.

IV. RECOMMENDATION: TINY PARTICLES NECESSITATE BIG CHANGES IN REGULATION

Due to the inherent problems with the FDA's current system of regulating anti-aging products containing nanoparticles, purchasers of such products may be harmed and fail to obtain compensation for that harm. Even if all injured consumers could prevail in court, there is the potential for a huge number of future lawsuits that could overload the judicial system and impair the functioning of hundreds of businesses.²⁰⁹ The federal government should attack the problem before consumers are forced to attempt to obtain redress by filing suit. Because the FDA is the governmental body that currently handles the regulation of cosmetics,²¹⁰ it is posed to put changes into motion. The most important step the FDA should take at this point is to accept the idea proposed by the PCPC and many scientists²¹¹ that nanoparticles are inherently different from their larger counterparts and should be regulated differently.

The challenge is determining how the government can adequately prevent harm to consumers while staying within a reasonable budget and without completely discouraging companies from experimenting with nanoparticles in

aff'd, 677 F.2d 368 (3d cir. 1982) (3d Cir. 1982) and *Hoffman v. Sterling Drug, Inc.*, 485 F. 2d 132, 146 (3d Cir. 1973)). Many courts have held that a product's inherent danger need not be recognized by a majority of scientists or experts in a field before a manufacturer is required to warn the public after sale. *Feldman*, 479 A.2d at 387 (citing *Skill v. Martinez*, 677 F.2d 368 (3d Cir. 1973)). For example, in *Skill v. Martinez*, the court held the drug manufacturer of a birth control pill liable for failure to warn consumers already using its product after articles of preliminary findings by two leading researchers on drug interactions uncovered potential danger for women who smoked while taking birth control. 677 F.2d at 368.

208. See HSE Report, *supra* note 55, at 19 (demonstrating that the contrasting natures of natural and engineered nanoparticles are unknown).

209. The implications of such a flood of cases can be seen in the wake of the asbestos litigation. See, e.g., The Asbestos Alliance, The Scope of the Asbestos Litigation Problem, <http://www.asbestossolution.org/scope.html> (last visited Apr. 11, 2008) ("The impact of what Supreme Court Justice David Souter terms the 'elephantine mass' of asbestos litigation is vast and far-reaching . . . [t]he flood of claims and resulting settlements are forcing companies into bankruptcy and putting at risk compensation for those who are sick today or may become sick in the future.").

210. See discussion, *supra* Part II.D (stating that Congress has charged the FDA with implementing and enforcing the FDCA and the FPLA, which entails in part pre-approving drugs and certain cosmetics and prosecuting cosmetic companies for placing adulterated and misbranded products on the market).

211. See, e.g., Kimbrell, *supra* note 138; see also discussion *supra* Part II.B.

their anti-aging products.²¹² A variety of alternatives could help achieve this end. One solution is for Congress and the FDA to maintain the existing classification system for drugs and cosmetics but require manufacturers of cosmetic products containing nanoparticles to print a warning about the questionable safety of those products. Although a simple warning would alert consumers of potential danger, it would likely be small and unobtrusive. Many consumers may not even notice it. Furthermore, because the effects of nanoparticles on the skin and in the body are largely unknown at this time,²¹³ the warning would likely be vague. Consumers may simply ignore such a warning. Therefore, merely requiring manufacturers to print a warning on their products probably will not adequately protect consumers from harm.

Another option is for Congress and the FDA to maintain the existing classification system for drugs and cosmetics but for the FDA to actively prosecute companies that market their anti-aging products using drug-like claims. In that case, some anti-aging products would get classified as drugs for at least some period of time. However, if companies are forced to have their anti-aging products pre-approved because their advertisements contain certain language, they are likely to change that language to make it less drug-like. Therefore, this solution is only a temporary one.

A third potential alternative would be for Congress to alter the definition of a “drug” to explicitly include all products that actually do affect the structure or function of the body, even if there is no objective evidence that their manufacturers intend that outcome.²¹⁴ This approach would eliminate the problem of companies changing the language in their promotional materials to get their products classified as “cosmetics” rather than “drugs.” However, it would involve a complete overhaul of the drug and cosmetic classification system, and thus, it would affect *all* cosmetics, not simply those containing nanoparticles. In addition, it would be more likely than the previous solutions to discourage cosmetic companies from using nanoparticles. Finally, it would probably require the FDA to spend much more money than it is currently spending on pre-approval processes.

The fourth, and probably the most prudent, option would be for the government to create a separate body to deal solely with products containing nanoparticles. This organization would study and regulate *all* such products, including drugs, cosmetics, clothing, and machines. It would be charged with discovering the effects of those products on the environment and human health. Such a body would have the authority to require products to be pre-approved before sale.

This solution may be more resource-consuming than the others. It would also make it difficult for companies to include nanoparticles in their anti-aging

212. See discussion, *supra* Part II.B.

213. See ROYAL SOC'Y & ROYAL ACAD., *supra* note 3, at 43 (describing the unknown effects of nanoparticles on the skin and the body); see also discussion *supra* Part II.B.

214. See discussion, *supra* Part III.A.2 (discussing the fact that courts are currently interpreting the definition of a “drug” to encompass only products that manufacturers intend to affect the structure or function of the body).

products because such use would trigger heavy regulation. However, studying the effects of nanoparticles as an entire group could potentially lead to a wealth of information that studying their use in different types of products separately could not yield. In addition, such study would likely expose the harm that nanoparticles can cause on the skin and in the body much faster and more accurately than any of the other potential solutions.

V. CONCLUSION

Our society highly values youth and beauty. Thus, anti-aging products are becoming increasingly popular. A large number of companies already sell anti-aging products containing engineered nanoparticles which, due to their unique properties, may be harmful to the skin and the body once internalized. Little is known about the specific harm that such particles may cause. Cosmetic companies are responsible for verifying the safety of their products because most cosmetics are not required to be pre-approved by the FDA before sale. Evidence suggests, however, that companies are not conducting adequate safety tests on products containing nanoparticles.

Thus, purchasers of anti-aging products may unwittingly apply dangerous nanoparticles to their skin. If those consumers later discover that they have been harmed by those nanoparticles, it is unclear whether they could obtain redress under products liability law common to a majority of states. Therefore, purchasers of anti-aging products containing nanoparticles are not adequately protected under the current law. Consequently, the use of nanoparticles in cosmetics should be more appropriately regulated. To achieve this goal, a body should be created to study and regulate nanoparticles used in all products.