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**FROM TANNING ACCESSORY TO HEALTH NECESSITY: HISTORY OF THE
OTC SUNSCREEN MONOGRAPH IN LIGHT OF THE SUNSCREEN
REVOLUTION.**

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ABSTRACT:

On August 27, 2007 the FDA published a Proposed Amendment to the Final Monograph for Over-the-Counter Sunscreen Drug Products. The proposed regulations marks major progress in the regulation of sunscreen products, because it includes, for the first time, comprehensive regulations addressing testing and labeling standards for both UVB and UVA regulation. Developing a monograph for sunscreen products, however, has been an arduous administrative process that has spanned over 30 years and produced significant criticism of the FDA. This article examines the regulation of sunscreen products in light of cultural and scientific developments that governed the rise and revolution of the sunscreen industry arguing that, for the most part, FDA has responded with impressive flexibility and attention to dynamic technological advancements, transformation of consumer expectations, and uncertain science.

INTRODUCTION

Man has historically had an ambivalent relationship with the sun.¹ Nowhere has this love-hate affair been played out with more enthusiasm than in the last century in the United States. The fashion of suntanning has endured alongside new scientific evidence warning of the risks of sunburn, photoaging, and skin cancer.² Since first emerging on the market in the 1920s, manufacturers of sunscreen products have had to constantly reinvent the product in response to technological advancements, better scientific information on the health risks of UV radiation, and the evolution of consumer expectations and demands.

Recently, as the agency responsible for regulating sunscreen products³, the Food and Drug Administration [“FDA”] has received much criticism for its failure to adequately protect consumers from the dangers of UV radiation.⁴ However, much of the external pressure and demands⁵ that FDA finalize regulations fails to recognize the difficulty of reviewing for safety and efficacy a product that is at the center of dynamic

¹ See I. Muller, *Sun and Man: An Ambivalent Relationship in the History of Medicine*, in SKIN CANCER AND UV RADIATION 1, 1-12 (P. Altmeyer et al eds. 1997).

² Kerry Segrave, SUNTANNING IN 20TH CENTURY AMERICA 183 (2005) (noting that “[l]ess than 100 years after the suntan’s tentative arrival among white people as a medical aid and fashion, it had been driven back, as a killer. However, it remained a fashion and therefore still claimed adherents.”).

³ “The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.” FDA’s Mission Statement, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited April 3, 2009)

⁴ See, e.g., Who’s Protecting Us, http://www.cosmeticsdatabase.com/special/sunscreens2008/report_protection.php (last visited April 17, 2009) (articulating a diverse range of problems for consumer safety as a result of FDA inaction).

⁵ The FDA’s delay in finalizing sunscreen regulations has not gone unnoticed. See *Id.* (remarking that the delay has spurred nine class-action false advertising suits against sunscreen manufacturers, a petition by a state attorney general, and at least two written requests from seven senators). Members of Congress have also introduced legislation on several occasions in an attempt to mandate the finalization of the sunscreen monograph. See, FDA Modernization Act §129, 21 U.S.C. §393 (2008); Natasha Singer, *Bill Seeks Action on Stricter Sunscreen Rules*, N.Y. Times, August 2, 2008, at A16.

scientific discovery. Furthermore, the critics fail to appreciate the progress made in the proposed regulations as a result of the effort and flexibility of the FDA in adapting sunscreen regulations to the current state of scientific knowledge.

This Note examines FDA's ongoing review of Over-the-Counter ["OTC"] sunscreen drug products in light of cultural and scientific developments that have influenced American consumers' expectations and perceptions of sunscreen products. Part I outlines the birth of the tanning fashion, the subsequent negative media campaign warning of the dangers of UV radiation, and the evolution of the sunscreen market over this period. Part II examines how sunscreen products are regulated under the Food, Drug and Cosmetic Act and outlines the OTC drug monograph system. Examining several notable provisions of the 1999 Final Monograph ["FM"]⁶ and the 2007 Proposed Amendment, Part III demonstrates how drastically sunscreen products have changed throughout the 30-year regulatory process and how FDA has striven to ensure that sunscreen regulations reflect the latest scientific discoveries and technological advances. Finally, Part IV discusses the current obstacles to finalizing the sunscreen monograph and identifies several areas where future action by FDA is necessary to adequately protect consumers.

I. HISTORY OF TANNING AND THE SUNSCREEN INDUSTRY.

⁶ Despite the passage of a final monograph in 1999 in response to the FDA Modernization Act, there still does not exist finalized regulations for sunscreen drug products, because the implementation date for the FM has been stayed indefinitely. *See* Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Partial Stay, 66 Fed. Reg. 67,485, 67,485 – 67,487 (December 31, 2001) (to be codified at 21 C.F.R. pt. 352).

Understanding why “[s]unscreen is the hot potato”⁷ of over-the-counter drug regulations is impossible without exploring the reasons that millions of Americans engage in the obsessive summer suntanning ritual despite inexorable warnings about all the dangers posed by UV radiation. What is most peculiar is that Americans have only been subjecting themselves to the tanning fashion and all its inevitable maladies since the 1920s.⁸ Prior to that time (and for millennia before)⁹ “fair skin had been prized” and the “Gibson Girl with parasol aloft”¹⁰ was the epitome of American beauty. In the early 20th century, however, the forces of medicine, media, and fashion collided, transforming tan skin from a “stigmata of the lower classes” into *the* symbol of “virility and wealth.”¹¹

Much of the “groundwork for establishing the suntan as an admirable, healthy, and worthy goal was laid in the 1890s as medical science refocused¹² on the power of the sun

⁷ Natasha Singer, *Proposed Sunscreen Labels on Hold for Now*, N.Y. Times, June 31, 2008, at G3.

⁸ Virginia Lee Warren, *The Suntan Question: Is the Ritual Worth It?*, N.Y. Times, July 4, 1973 (noting that Caucasians have only “been subjecting themselves to the sun in their present fashion for no more than 50 years (some estimates say less than 30)).

⁹ As early as 2000 B.C. the cultural preference in Egypt for light skin caused women to use preparations consisting of tirmis, lotus oil, henna oil, calcite powder, rice bran extracts, and clay in efforts to protect themselves from the sun’s darkening rays. *See* W. Raab, *History of Therapeutic UV Radiation*, in *SKIN CANCER AND UV RADIATION* 13, 13 (P. Altmeyer, et al eds. 1997); Nadim A. Shaath, *Sunscreen Evolution*, in *SUNSCREENS: REGULATION AND COMMERCIAL DEVELOPMENT* 3, 4 (Nadim A. Shaath ed., 3rd ed. 2005). Likewise, “tan was not palatable to ancient Greeks” and women adorned themselves in protective clothing, hats, and veils to avoid exposure to the sun. Paul U. Giacomoni, *Sunprotection: Historical Perspective*, in *SUNSCREENS: REGULATIONS AND COMMERCIAL DEVELOPMENT* (Nadim A. Shaath ed., 3rd ed. 2005). Even in more modern times, creamy white skin was the epitome of class and the desire to avoid a tan motivated fashionable women since the Elizabethan age too shield their faces with hats and bonnets, draw the curtains, and avoid the outdoors. *See* Lois W. Banner, *AMERICAN BEAUTY* 40-41 (1983).

¹⁰ John J. Abele, *Suntan Lotions Enjoying Day in Sun*, N.Y. Times, July 13, 1957.

¹¹ Warren, *supra* note 8.

¹² In the late 1800s and early 1900s medical Science *re*-focused on the curative power of the sun that was previously touted by Ancient Greek, Roman and Arabic physicians. *See, e.g.* Raab, *supra* note 9, at 14 (explaining that around 400 B.C. Hippocrates recommend sunlight to correct dyscrasias (a false mixture of the four bodily juices) and that both Roman and Arabic physicians prescribed sun treatment to patients with an array of cardiac, pulmonal, and orthopedic problems).

as healer.”¹³ Heliotherapy - the practice of systematically exposing patients to prolonged sunbaths in an effort to cure disease and promote health - became a well-respected and popular medical treatment after experiments and observations in the late 1800s and early 1900s revealed the curative power of the sun.¹⁴ Although modern claims regarding “light and air” treatment were largely ignored at first¹⁵, by the 1890s the medical community had embraced sunlight as a treatment for Tuberculosis.¹⁶ In 1903 the Nobel Prize in Physiology or Medicine was awarded to Danish scientist Neils Ryberg Finsen for his work demonstrating the stimulating effect of the sun’s rays on human tissue and devising a sun treatment for lupus.¹⁷ After the publication of Finsen’s 1893 treatise *Lysets Indvirkninger paa Huden* (On the effects of light on the skin), sunlight was tried as a cure for almost all dermatoses and was also subsequently proven as a cure for Rickets in 1919.¹⁸ Inundated with evidence of the sun’s miraculous powers, physicians soon began to recommend that even healthy individuals take sunbaths whenever and wherever possible.¹⁹ Although many of the claims made by the medical community and reported unflinchingly by journalists were extremely exaggerated,²⁰ the hype began to reverse negative perceptions of the sun and help turn tanning into a huge fad.

¹³ Segrave, *supra* note 2, at 4.

¹⁴ See Segrave, *supra* note 2, at 14.

¹⁵ See *Id.* at 13 (noting that the medical establishment ignored claims by English physician Dr. George Boddington in the 1830s that he successfully cured his consumptive patients with long periods of outdoor exposure).

¹⁶ See *Id.*

¹⁷ See Biography of Niels Ryberg Finsen, http://nobelprize.org/nobel_prizes/medicine/laureates/1903/finsen-bio.html (last visited April 19, 2008).

¹⁸ Raab, *supra* note 9, at 15-17.

¹⁹ See Segrave, *supra* note 2, at 5. See also Simon Carter, RISE AND SHINE: SUNLIGHT, TECHNOLOGY AND HEALTH, 100 (2007) (explaining that articles in medical journals began talking less in terms of curative outcomes for specific diseases and more about general health enhancement from sun exposure).

²⁰ Not all heliotherapy claims were unfounded, but most have been replaced by more efficient modern treatments. “Today there remains three medical indications for ultraviolet rays: (1)

In addition to the promise of health benefits, tanning became more fashionable when the negative connotations of tanned skin began to fade. For centuries smooth fair complexion had been the epitome of fashion. Creamy white skin was not only rare (owing to the high occurrence of deforming disease, such as smallpox) but was a class-marker, reflecting the luxury of remaining away from the fieldwork and out of the sun.²¹ However, the Industrial Revolution “put the lower classes indoors and their interminable hours with never a vacation gave them a pale sickly look.”²² Around the same time, outdoor sports and leisure activities increased in popularity and became status symbols.²³ Tan, not pale skin, came to represent elite leisure and wealth - symbolizing “holidays, sailing and swimming, all of which were highly fashionable pursuits that entailed exposing the body.”²⁴

The rise of a middle class and the women’s movement further increased the popularity of tanning. In the 1920s women’s sports became a notable social revolution advocating freedom of movement and “the casting off of hampering clothes.”²⁵ Tanning was “democratized” in the 1930s as a growing middle class enjoyed greater access to vacation and leisure through expansion of the railroad network and affordability of automobiles, shortening and regulation of the workweek as part of the New Deal, and

Rickets, as first recommended by Hilschinsky in 1919 (2) Jaundice of newborns, a method developed by Cremer in 1959 (3) Season depression, in accordance with Kern 1957.” See Raab, *supra* note 9, at 15.

²¹ See Banner, *supra* note 9, 40-41.

²² See Warren, *supra* note 8.

²³ In the 1920s tanning became fashionable in French Riviera resorts promoted by fashionable tabloid figures such as Coco Chanel and quickly “lost its proletarian connotations of outdoor work.” Rebecca Arnold, *AMERICAN LOOK: FASHION, SPORTSWEAR AND THE IMAGE OF WOMEN IN 1930S AND 1940S NEW YORK* 50 (2009). See Also, Giacomoni, *supra* note 9, at 75. The tanned image of Coco Chanel is so iconic that many accounts attribute the emergence of the tanning fashion entirely to her personal devotion to the sport of sunbathing. See Segrave, *supra* note 2, at 3.

²⁴ Arnold, *supra* note 23, at 50.

²⁵ Segrave, *supra* note 2, at 35.

widespread construction of public tennis courts, golf courts and swimming pools as part of New Deal Social Programs.²⁶ By 1940s sunbathing had so ingrained itself in popular culture, that newspapers, embracing the trend, published tanning-how to articles - the “Tan Commandments” – promising readers the best bronze without the burn in ten easy steps.²⁷

The sunscreen industry was an inevitable byproduct of the tanning fashion, because “[a]long with the fashion of tanning came the bane of sunburn.”²⁸ By 1911 researchers began specifically investigating chemical combinations for sunscreens.²⁹ The first commercial sunscreen product was developed in 1928 in the United States, but solutions also quickly appeared in Australia in the 1930s, and in 1935 L’Oreal launched Ambre Solaire on the French Riviera.³⁰ Even more research was invested in developing effective sunscreen products during WWII when the Army Air Force Material Center contracted with researchers from General Electric Lighting Laboratories and the Western Reserve Medical School to help test substances that could be used to prevent sunburn among

²⁶ See Daniel Delis Hill, AS SEEN IN VOGUE: A CENTURY OF AMERICAN FASHION IN ADVERTISING 158-59 (2004); Banner, *supra* note 9, at 276-277.

²⁷ See, e.g., Carloyn Abbott, “Suntanning Can be Both Painless and Beautifying if Precautions Are Used” The Washington Post August 10, 1941; Carolyn Abbott “City Suntan is as Attractive as Beach Variety” The Washington Post July 2, 1942.

²⁸ Even before specific sunscreen formulations were invented, sunbathers were advised to expose their skin slowly in order to build up a natural tan, touted as the best defense against an unwanted burn. Home remedies such as the application of cold cream, coco butter or zinc oxide were also recommended. See Segrave, *supra* note 2, at 28; Teresa Riordan, INVENTING BEAUTY: A HISTORY OF THE INNOVATIONS THAT HAVE MADE US BEAUTIFUL, 150, (2004)(noting that in 1907 the T.T. Pond Company advertised a “vanishing cream” that promised to help the Out-of-Doors girl easily avoid the unpleasant effects of the sun including sunburn, freckles and Chaps); *Suntan Lotion Sales Booming; Volume, Up 11% at 20 Million*, N.Y. Times July 4th, 1962, 21 (explaining that after years of exposing themselves bare to the sun, people “developed their own home remedies or bought products, like baby oil or mineral oil and iodine which were not made for sun protection but could be used for that purpose”).

²⁹ See Henry W. Lim, *Quantum Leaps: New, Improved Sunscreens have Arrived*, The Skin Cancer Foundation Journal Vol. XXVI (2008), available at <http://www.skincancer.org/scf-journal-2008.html>.

³⁰ See *Id.*; See also Shaath, *supra* note 9, at 4. See also Carter, *supra* 19, at 102.

soldiers serving in the South Pacific.³¹ Benjamin Green (future founder of Coppertone) invented Red Veterinary Petroleum (“Red Vet Pet”), which fulfilled military needs, but the sticky red substance was not conducive, for obvious aesthetic reasons, to civilian use.³² A major development in the technology of the early sunscreen market occurred in 1943 when researchers discovered that Para-aminobenzoic acid, a vitamin B, helped cause sunburn by absorbing UV rays.³³ The researchers patented PABA as a UVB absorber and developed a salve that provided reasonably effective sunburn protection.³⁴

Although sun-protection products were immediately popular with sunbathers and the sunscreen industry grew rapidly, the initial therapeutic purpose of the product was limited.³⁵ Early sunscreens were intended only to serve as tanning aids: “The basic job of the suntan preparation is to screen out the burning rays of the sun - the high-energy ultra-violet rays-and admit the tanning rays.”³⁶ Early sunscreen formulations purposely

³¹ See Lim, *supra* note 29.

³² See *Id.*; See also Shaath, *supra* note 9, at 4; See also June Weir, *Summer Sense*, N.Y. Times, May 9, 1982.

³³ See Segrave *supra* note 2, at 29-31.

³⁴ See *Id.*, at 31 (remarking that PABA-based lotions unlike other sunscreen products of the time, was stable, did not soil clothing, was colorless and odorless, did not irritate the skin and was effective to an extent.). *But See* Lim, *supra* note 29 (describing the sharp decline in PABA’s popularity by the 1980’s due to its causing skin allergies and yellow staining on clothing).

³⁵ See Abbott, *supra* note 27 (extolling on the virtues of suntanning preparations and remarking how the sunscreen market had almost doubled from 1951 until 1956 when the sales were \$9,200,000.); *Suntan Lotion Sales Booming; Volume Up 11%, at 20 Million*, N.Y. Times, July 4, 1963(explaining that “to help them get a glorious tan without the painful sunburn, a major industry has developed supported by 100,000,000 Americans. Today the total market for suntan products stands at an estimated \$20,000,000, up 11 per cent from last year’s total.).

³⁶ See Abele, *supra* note 10 (explaining that “the basic job of the suntan preparation is to screen out the burning rays of the sun –the high-energy ultra-violet rays - and admit the tanning rays); *Suntan Lotion Sales Booming supra* note 28, at 21 (describing how suntan lotions promote tanning that results when melanin rises to the skin’s surface after sun exposure, but block exposure to the solar ultra-violet rays).

protected only against only UVB rays, believing the UVA rays to be both harmless and necessary to produce a tanning reaction.³⁷

The second half of the twentieth century, however, gave birth to a sun-scare that revolutionized sun-protection products. New evidence indicating the relationship between UV rays and skin damage, ominous warnings from Doctor's seeing epidemic-like increases in skin cancer rates, and environmental reports on Ozone depletion finally collided to produce frantic reports from media portraying the sun as a killer.³⁸ Although today it is commonly believed that the sunscreen will help prevent skin cancer, this fact is misleading first, because it fails to distinguish between three distinct diseases - Basal Cell Carcinoma, Squamos Cell Carcinoma, and Melanoma³⁹ - and secondly, because it overstates the scientific evidence supporting this conclusion.⁴⁰ Many medical experts

³⁷ The sun's rays reach earth in 3 main radiation wavelengths. UVC rays are the shortest wavelength, highest energy rays and are potentially the most dangerous to humans, but these rays are absorbed almost entirely by the ozone layer. UVB rays are longer and lower in energy, but penetrate the earth's surface causing erythema. See Rebecca Voelker, SKIN CARE AND REPAIR 5-6 (2002). UVA rays, or "tanning rays" are the longest wavelength and penetrate the skin deep into the dermis layer stimulating the formulation of melanin. Until the 1970s they were considered fairly harmless until more recent evidence implicated contribution of these weaker rays to development of skin cancer, DNA damage and photaging. See Shaath, *supra* note 8, at 5.

³⁸ "In the years prior to 1946, the sun was overwhelmingly portrayed as the health-giving healer, capable of performing miracles through the contact of its rays with the skin... If that period was marked by outrageous claims and excess in favor of the sun - and it was - the post-war period was marked by a reverse trend in which the sun was portrayed as killer. That trend moved very slowly over the 1950s through the 1970s but then picked up speed rapidly in the 1980s; a trend that has continued through the present." Segrave, *supra* note 2, at 61

³⁹ See Nina G. Jablonski, SKIN: A NATURAL HISTORY 137 (2006) (explaining that "skin cancer is not a single entity but rather a family of conditions). See Rebecca Voelker, SKIN CARE AND REPAIR 14-16 (2002). See A. Scholz, *History of Skin Cancer*, in SKIN CANCER AND UV RADIATION 20, 20 (P. Altmeyer et. al. eds. 1997)

⁴⁰ No scientific evidence exists linking regular sunscreen use with reduce risk of basal cell carcinoma or melanoma, and the evidence suggesting that regular use of sunscreen will reduce the risk of squamos cell carcinoma is limited. See H. Lui, R.P. Gallagher, and D.I. Mclean, *Use and Misuse of Sunscreens*, in SKIN CANCER AND UV RADIATION 333, 336-8 (P. Altmeyer et. al eds. 1997). Although evidence linking sun exposure to certain forms of skin cancer has been accumulating since the turn of the century See T.R. Van Dellen, *How to Keep Well*, Chicago Daily Tribune, May 25, 1958, 16 (claiming that "[it] has been known for 60 years that sunlight is a cause of skin cancer); Segrave, *supra* note 13, at 57 (noting that an early warning of the sun's

now believe that UV rays are *risk* factors in the development of all three cancers and most medical experts agree that sunscreen is an important component of a skin cancer prevention regiment, but the science is by no means clear and researchers continue to debate the causal relationships among UV radiation and skin cancer and sunscreen and prevention.⁴¹ Neither the media, consumers, nor sunscreen manufactures have remained so skeptical. The public was quickly gripped by reports of the albeit statistically inconclusive evidence⁴², and their fear over the carcinogenic effects of the sun were exacerbated by environmental reports regarding depletion of the Ozone.⁴³ Responding to increased consumer anxiety, the sunscreen industry transformed its products from

carcinogenic effects can be found in a 1911 article published by Dr. Tozzer of Harvard medical School); See I. Muller, *supra* note 1, at 8. (explaining that by 1928 Finday was able to produce malignant skin tumors in albino mice using ultraviolet lamps and five years later Roffo published the first epidemiological study related to the problem of light induced cancer of the skin), some scientists still find the hypothesized link between UV radiation and melanoma in need of further evaluation. See Lui, *supra* note 40, at 337. *But See*, U. Ringborg, E.W. Breitbart, C.C.E. Meulemans, and C.J. M. De Wolf, *Skin Cancer Prevention*, in SKIN CANCER AND UV RADIATION 795, 812 (suggesting that intermittent sun exposure that produces sunburn is a major risk factor in the aetiology of malignant melanoma).

⁴¹ See World Health Organization, *Sun Protection: Simple Precautions in the Sun*, http://www.who.int/uv/sun_protection/en/ (last visited April 20, 2009) (advising liberal use of a broad spectrum sunscreen containing at least SPF 15 as part of an overall sun protection program); Skin Cancer Foundation, The SCF's guide to Sunscreen, <http://www.skincancer.org/the-scfs-guide-to-sunscreens.htm> (last visited April 20, 2009) (describing the important protective function of sunscreens in association with other sun safety strategies). *But c.f.*, Lui, *supra* note 40, 340 (suggesting that there is no direct evidence that sunscreen use prevents the development of basal cell carcinoma or melanoma”).

⁴² See e.g., Alexandra Greeley, *On the Teen Scene*, 27 FDA CONSUMER 30, 33 (noting that a 1989 survey showed a 27% increase from an earlier survey in the number of the teens who were aware of the dangers of the sun 18% of whom specifically concerned about developing cancer). See also, Segrave *supra* note 2, at 88(explaining that “increasingly strident scare stories had alarmed the general public to worry more about the effects of sun exposure”).

⁴³ See e.g., James C.G. Conniff, *Bask, Don't Burn: Tan is beautiful, red is painful and too much ultraviolet is dumb and dangerous*, N.Y. Times, July 7, 1974, 117. (noting that concern over the Ozone layer has increased fears of a worldwide skin cancer epidemic as a result of the potential increase in solar radiation reaching the earth's surface).

entertainment/cosmetic products, meant to increase time spent having fun in the sun or to help achieve a certain glowing appearance, into a health product.⁴⁴

Many sunscreen products today offer high SPF and Broad Spectrum protection and are promoted not only to prevent sunburn but also to guard against other forms of sun damage such as skin cancer and photoaging.⁴⁵ Furthermore, the sunscreen industry has added daily-wear products to its more traditional beach/recreation lines and advertised sunscreen as a year-round purchase and an indispensable component of any skin care regimen.⁴⁶ It is important to note however, that despite the introduction of UVA protection in sunscreens and the expansion of sunscreen use, skin cancer rates have, so far, continued to climb with 1,00,000 new cases diagnosed every year.⁴⁷

II. FDA & SUNSCREEN REGULATION.

As the government agency responsible for protecting public health by assuring the safety and efficacy of human drugs, cosmetics, and the nation's food supply, the Food and Drug Administration ["FDA"] has authority to regulate sunscreen products.⁴⁸ Since it was first implemented in 1972, sunscreen products have been regulated under FDA's

⁴⁴ See Segrave, *supra* note 2, at 88 (explaining that sunscreen manufacturers began to change their marketing at the end of the 1970s emphasizing sun protection aspects more and tanning aspects less).

⁴⁵ See e.g., Coppertone, http://www.coppertone.com/coppertone/products/products_nutrashield.jsp (last visited April 20, 2009) (advertising that Coppertone Nutrashield Dual Defense helps prevent premature skin aging caused by the sun). Sunscreen products also make subtle skin cancer prevention claims by sporting the Skin Cancer Foundation Seal of Approval. See Breidi Caparatta, *Sunscreen for Skin Cancer Survivors*, Associated Content, June 17, 2008, available at http://www.associatedcontent.com/article/819309/sunscreen_for_skin_cancer_survivors_pg2.html?cat=5.

⁴⁶ See Nadim A. Shaath & Mona Shaath, *Recent Sunscreen Market Trends*, in *SUNSCREENS: REGULATIONS AND COMMERCIAL DEVELOPMENT* 929, 929-31 (Nadim A. Shaath ed., 2005).

⁴⁷ See, What you Need to Know about Skin Cancer, <http://www.cancer.gov/cancertopics/wyntk/skin> (last visited April 3, 2009). Some highly controversial studies have even suggested a correlation between sunscreen use and increased risk of skin cancer. See Lui, *supra* note 40, at 337,

⁴⁸ See FDA's Mission Statement, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited April 3, 2009)

monograph system, which was designed to assure the safety and efficacy of over-the-counter drugs [“OTC drugs”].⁴⁹ Understanding the regulation of sunscreen products requires first an analysis of the both definitions of cosmetics and drugs under the FD&C Act and also the regulatory consequences of that distinction. Furthermore, it is necessary to distinguish the regulatory regime that applies to prescription drug products before exploring the OTC Monograph system.

A. Cosmetics v. Drugs.

Although the FD&C Act subjects cosmetics and drugs to distinct regulatory regimes, placing a product squarely within one definition is often difficult.⁵⁰ Section 201(g)(1) defines drugs, in part, as “articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease” and “articles (other than food intended to affect the structure or any function of the body.”⁵¹ Alternatively, Section 201(i) defines cosmetic as “articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part therefore for cleansing, beautifying, promoting attractiveness or altering the appearance.”⁵² The evolving notion of the purpose of sunscreen, the multitude of diverse suncare products on the market, and the alternative uses of sunscreen active ingredients all complicate FDA’s task of placing these products within a regulatory category.

The FD&C Act regulates drugs and cosmetics differently and the market consequences of this fact are enormous. Cosmetics are not subject to pre-market approval

⁴⁹ See Procedures for Classification of Over-the-Counter Drugs, 37 Fed. Reg. 9,464, (May 11, 1972) (codified at 21 C.F.R. pt. 130.); Charles C. Edwards, *Closing the Gap: OTC Drugs*, 6 FDA Papers 4, 4-8 (February 1972).

⁵⁰ See e.g., Michael Sandier, *Regulation of Toothpaste* (YEAR), in Chapter VI of the Electronic Book. (noting the difficulty of classifying toothpaste as a food, drug, or cosmetic).

⁵¹ Food, Drug and Cosmetic Act §201(g), 21 U.S.C. 321(g) (2008).

⁵² Food, Drug and Cosmetic Act § 201(i), 21 U.S.C. 321(i) (2008).

for safety and efficacy and even post-market enforcement actions have mostly focused on products that endanger public safety.⁵³ The FDA first acquired authority over cosmetics under the 1938 Act, but the Act did not contain a provision for pre-market approval.⁵⁴ As a result “[n]either cosmetic products nor cosmetic ingredients are reviewed or approved by the FDA before they are sold to the public.”⁵⁵ Despite authority under §602 to bring enforcement actions against products with unsupported efficacy claims, FDA has generally failed to regulate unsubstantiated claims as per se misbranding and has instead focused on safety when bring enforcement action.⁵⁶ As a result cosmetic companies continue to make questionable advertising and labeling claims to the detriment of consumers.⁵⁷

Drugs manufacturers, on the other hand, are required to substantiate safety and efficacy prior to consumer marketing. The 1938 Act first established a pre-market approval mechanism to ensure the safety of new drugs.⁵⁸ The pre-market approval process became far more onerous, however, in 1962 with the passage of the Kefauver-Harris Amendments requiring manufacturers to prove both safety and efficacy of all new

⁵³ See Bryan A. Liang and Kurt M. Hartman, *It's Only Skin Deep: FDA Regulation of Skin Care Cosmetic Claims*, 8 CNLJPP 249, 250 (1999); Laura A. Heyman, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 Food Drug L.J. 357, 357 (1997).

⁵⁴ See Heyman, *supra* note 53, at 363.

⁵⁵ Joseph Dinardo, *Regulations affecting cosmetic and over-the-counter drugs products*, in REGULATORY TOXICOLOGY 167, 176 (Shayne C. Gad, ed. 2nd ed. 1995).

⁵⁶ See Food, Drug and Cosmetic Act §602, 21 U.S.C. §362 (2008) (establishing that a product should be considered misbranded if “its labeling is false or misleading in any particular”). See Liang, *supra* note 47, at 251-252 (suggesting that FDA’s policy against challenging such unsubstantiated claims as misbranding may be a result of its early losses court or may just reflect a policy decision to divert scarce agency resources).

⁵⁷ See *Id.* at 251.

⁵⁸ See, Food, Drug and Cosmetic Act §201(p), 21 U.S.C. §321(p) (2008); Peter Temin, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 44 (1980).

drugs, including those approved between 1938 and 1962.⁵⁹ The amendment required that “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application...is effective with respect to such drug.”⁶⁰ The application must include “full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use.”⁶¹ Unlike the passive pre-market approval system established by the 1938 Act, where drug applications automatically became effective after 60 days unless the Secretary objected, the new drug application system required specific approval.⁶²

Defining sunscreens as cosmetics or drugs effects every aspect of sunscreen development and marketing. The FDA determines the legal definition of a product by its intended use.⁶³ Under the modern rule intended use of a product may be based on claims made in labeling or other advertising, consumer perception, product reputation, and inclusion of active ingredients.⁶⁴

Originally, the FDA distinguished sunscreen cosmetics from sunscreen drugs purely on the basis of labeling and advertising claims, effectively leaving the choice to manufacturers. In a 1940 Advisory Opinion, Trade Correspondence 61 (TC-61) the FDA established that “a product promoted for prevention of damage from the sun is a drug, and a product that is promoted solely for the purpose of acquiring an even tan can be

⁵⁹ See Temin, *supra* note 58, at 131-132; W. Steven Pray, A HISTORY OF NONPRESCRIPTION PRODUCT REGULATION 171 (2003); Milestones in Food and Drug Law History, <http://www.fda.gov/opacom/backgrounders/miles.html> (last visited April 4, 2009).

⁶⁰ Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (October 10, 1962).

⁶¹ *Id.*

⁶² See Temin *supra* note 58, 44; Food, Drug and Cosmetic Act § 505, 21 USC § 355.

⁶³ See Is it a drug, cosmetic or is it both? (or is it a soap?), July 8, 2002, <http://www.cfsan.fda.gov/~dms/cos-218.html> (last visited March 19, 2009).

⁶⁴ See *Id.*

considered a cosmetic.”⁶⁵ Products therefore were subject to cosmetic or drug regulations purely on the basis of whether the manufacture employed cosmetic claims or protective claims on its labels and in its advertising.⁶⁶ However, advances in scientific knowledge and consumer expectations caused the FDA to change its position on categorizing sunscreen products.⁶⁷ Sunscreens containing sunscreen active ingredients and making protective claims, typified by the traditional “beach product”, have always been and continue to be regulated as drugs: “essentially sunscreen active ingredient affect the structure and function of the body by absorbing, reflecting, or scattering the harmful, burning rays of the sun, thereby altering the normal physiological response to solar radiation.”⁶⁸ In order to protect the consumer from accidental and unwanted exposure to the sun, however, the FDA extended drug status to all products that “contain sunscreen ingredients, display labeling that identifies those active ingredients, or display labeling claims that allude to the sunblocking or sun-protection properties of those active ingredients.”⁶⁹ Thus suntan lotions – products promoted purely for the cosmetic benefit of obtaining a tan – are drugs if they contain a sunscreen active ingredient and traditional cosmetics containing sunscreen actives are drugs if they are marketed in part for sun-protection capabilities.⁷⁰ Only suntan products without any suntan active ingredients, cosmetics containing suntan active ingredients for a non-therapeutic purpose, and sunless tanners continue to be regulated purely as cosmetics. FDA’s classification of all

⁶⁵ Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 58 Fed. Reg. 2,8194, 28,204 (May 12, 1993).

⁶⁶ *See Id.*

⁶⁷ *See Id.*

⁶⁸ *See Id.*

⁶⁹ *See Id.* at 28,202.

⁷⁰ *See Id.* at 28, 204. It is important to note that a product can be considered both a cosmetic and a drug product and, therefore, subject to compliance with both regulations. *See Id.*; Is it a drug, cosmetic or is it both (or is it a soap) *supra* note 63.

sunscreen products that contain active ingredients and allude to sun-protection capabilities as drugs reflects FDA's recognition of both the grave dangers of UV exposure and the high level of protection expected by today's sunscreen consumers.⁷¹

B. Over-The-Counter Drugs and the History of the Monograph System.

Traditionally most medicines were sold without the intervention of a doctor and prior to 1938 people could purchase any non-narcotic drug without a prescription.⁷² A class of drugs inaccessible to the consumer without the supervision of a physician was first created in 1938 when the FD&C Act permitted drugs to omit directions for consumer use by adopting the statement: *Caution: To be used only by or on the prescription of a Physician.*⁷³ The Act, however, did not specify which drugs were to be sold by prescription, but left the decision entirely to the manufacturers.⁷⁴ In 1951, however, Congress passed the Humphrey-Durham Amendment specifically defining prescription drug as "any habit forming drug, any drug, so toxic or harmful that it required the supervision of a practitioner, or any new drug approved under the safety provision of the 1938 act that had to be used under supervision."⁷⁵ Any new drugs that could be used safely without medical supervision had to be marketed over-the-counter.⁷⁶ This new codified distinction did not have any significant regulatory consequences until the 1962 Drug Amendments required new drugs to prove effectiveness by "substantial

⁷¹ Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 58 Fed. Reg. 2,8194, 28,204 (May 12, 1993).

⁷² See Temin *supra* note 58, at 46.

⁷³ See *Id.*

⁷⁴ See *Id.* at 47.

⁷⁵ Durham-Humphrey Drug Prescriptions Act, Pub. L. No. 82-215, 65 Stat. 648 (October 26, 1951).

⁷⁶ See Stan Stringer, *Open Forum; What has Been Happening with Over-the-Counter Drug Monographs*, 52 Food Drug L.J. 633, 633 (1988)

evidence.”⁷⁷ Because the amendment also authorized FDA to withdrawal approval already granted to an NDA for a variety of causes including “lack of substantial evidence of effectiveness,” even drugs approved for sale prior to 1962 were required to comply with the new standards.⁷⁸

Over four thousand drugs had been introduced between 1938 and 1962 and the FDA recognized that it could not evaluate them for effectiveness and still continue to perform other activities. To implement this new legislation, therefore, the FDA contracted with the National Research Council of the National Academy of Sciences to implement the DESI (Drug Efficacy Study Implementation) program.⁷⁹ Review began in 1966 by 30 panels of experts examining the safety and efficacy of over 4,000 products that had entered the market between 1938 and 1962.⁸⁰ Although most products reviewed under DESI were prescription drugs, 422 OTC drugs were also reviewed.⁸¹

In 1972, with the DESI program well underway, the FDA turned to the formidable task of evaluating the estimated 300,000 to 500,000 over-the-counter drugs on the market for safety and efficacy.⁸² The FDA however recognized that despite the large number of products, little more than 200 significant active ingredients were implicated and most of those ingredients had been marketed for years without negative health effects.⁸³ FDA opted not to implement a case-by-case approach like DESI because of the

⁷⁷ Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (October 10, 1962).

⁷⁸ Temin, *supra* note 58, at 125.

⁷⁹ See Stringer, *supra* note 76, at 633; W. Steven Pray, HISTORY OF NONPRESCRIPTION PRODUCT REGULATION 173 (2003).

⁸⁰ See Edwards, *supra* note 49, at 5.

⁸¹ See *Id.* See Also Pray, *supra* note 79, at 174 (suggesting that the high number of nonprescription drugs found to be ineffective or unsafe in this preliminary group led directly to an FDA decision to undertake a review of all nonprescription drug products).

⁸²⁸² See Edwards, *supra* note 49, at 5; Pray, *supra* note 77, at 174.

⁸³ See *Id.*

practical impossibility, the inherent unfairness of incremental enforcement, and the great number of drugs that would be exempt from safety and effectiveness testing under the grandfather provisions.⁸⁴ Instead FDA chose to proceed against OTC drugs through “rulemaking that will establish, define, and describe therapeutic classes or categories of these products on an industry wide basis and will outline parameters for each class by means of a monograph.”⁸⁵ The intended result was to ensure that only 2 routes to the market exist for manufacturers of OTC drugs (1) compliance with the monograph or (2) approval of noncompliance through a New Drug Application or monograph amendment.⁸⁶

The FDA announced the OTC drug monograph system in 1972.⁸⁷ The project was designed as a three-step public rulemaking process in which active ingredients rather than final product formulations were reviewed for safety and efficacy.⁸⁸ FDA appointed 17 independent advisory review panels, each consisting of scientific experts as well as industry and consumer representatives that were responsible for reviewing a specific therapeutic category.⁸⁹ Review panels (beginning with antacids in February 1972) reviewed each ingredient and published its findings as to whether it was (1) Category I – generally recognized as safe, generally recognized as effective (GRAS, GRAE), (2) Category II – not generally recognized as safe, not generally recognized as effective (Not GRAS, Not GRAE), or (3) Category III – more data needed, cannot determine safety

⁸⁴ *See Id.*

⁸⁵ *Id.* at 7.

⁸⁶ *See Id.* at 8.

⁸⁷ *See* Procedures for Classification of Over-the-Counter Drugs, 37 Fed. Reg. 9,464 (May 11, 1972) (to be codified at 21 C.F.R. pt. 130).

⁸⁸ *See* Matthew R. Holman & Daiva Shetty, *The Role of FDA in Sunscreen Regulation*, in *SUNSCREENS: REGULATIONS AND COMMERCIAL DEVELOPMENT* 85, 90 (Nadim A. Shaath ed., 3rd ed. 2005).

⁸⁹ *See Id.*

and/or effectiveness.⁹⁰ Each Panel also had to include in their findings acceptable active ingredient combinations, acceptable dosage ranges, acceptable indications for use, guidelines for labeling, and directions for consumer use.⁹¹ After reviewing the panel's findings the FDA was to publish in the federal register an Advanced Notice of Proposed Rulemaking (ANPR).⁹² Phase II of the review included an opportunity for manufacturers and other interested persons to respond to the ANPR by submitting data or appearing before the FDA committee.⁹³ After carefully considering all information and comments, the FDA would then issue the "Tentative Final monograph" detailing all research and comments submitted and the agency's response.⁹⁴ In Phase III after permitting additional time for manufacturers to either reformulate or undertake additional investigative studies and considering all objections and comments (and holding hearings if warranted), the FDA was to close the record and issue a Final Monograph with an implementation date that grants industry sufficient time to comply with new provisions.⁹⁵

Once a final monograph is in place, products must conform to monograph conditions, submit NDA for non-compliance, or attempt to have the monograph amended.⁹⁶ Once a monograph is final it can only be amended by a Citizen Petition (for conditions of use on the market prior to 1975) or a Time and Extent Application (TEA) (for new conditions of use).⁹⁷

III. LATEST PROPOSED REGULATIONS REVEAL EFFORTS TO ACCOMMODATE NEW TECHNOLOGY, SCIENTIFIC DISCOVERY, AND CONSUMER EXPECTATIONS.

⁹⁰ *See Id.*

⁹¹ *See Edwards, supra note 49, at 7; Pray, supra note 79, at 176-177.*

⁹² *See Pray, supra note 79, at 177.*

⁹³ *See Id.*

⁹⁴ *See Id.*

⁹⁵ *See Id.* at 178.

⁹⁶ *See Edwards, supra note 49, at 8.*

⁹⁷ *See Holman, supra note 88, at 93.*

The science surrounding skin, UV radiation, cancer, and other forms of UV damage has dramatically expanded since FDA first issued proposed regulations for OTC sunscreen drug products in 1978.⁹⁸ Although critics have attacked the FDA for its failure to keep up with the changing science and adequately protect consumers,⁹⁹ an analysis of the monograph history reveals a concerted effort to incorporate new technologies and address new health concerns at each step in the regulatory process.

A. UVA Regulations.

At the core of the 2007 Amendment is the proposed standard for UVA testing and labeling and no provision reflects more drastically the FDA's efforts keep the sunscreen monograph consistent with advancing scientific knowledge. Incorporating UVA regulations into the sunscreen monograph essentially required entirely redefining the purpose of sunscreen products. Originally sunscreen was designed to protect consumers only from UVB radiation while *allowing exposure* to UVA rays or "tanning rays" to permit a tanning reaction.¹⁰⁰

However, science began to rethink the conclusion that UVA rays were harmless when epidemiological observation revealed "that after years of exposure to solar radiation, notwithstanding the use of anti-UVB sunscreens, the skin of sun worshippers became severely damaged, sagging, and elastatoic."¹⁰¹ It was not until 1969 and into the 1970s that early experiments performed with cultured cells began to reveal the ability of UVA rays to introduce nicks in cellular DNA.¹⁰² The connection between molecular and

⁹⁸ Natasha Singer, *Do Sunscreens have you covered*, N.Y. Times, July 5, 2007.

⁹⁹ *See Id.* (noting that "critics have clamored for the F.D.A. to update the rules, saying that the standards have not kept pace").

¹⁰⁰ *See Abele, supra note 10* (explaining that "[t]he basic job of the suntan preparation is to screen out the burning rays of the sun - the high-energy ultra-violet rays - and admit the tanning rays").

¹⁰¹ Giacomoni, *supra note 9*, at 76.

¹⁰² *See Id.*

tissue effects of UVA radiation were not indicated more clearly until experiments with lab rodents were conducted in the late 1980s.¹⁰³ Even today, however there is only minimal evidence that sunscreen intervention will help prevent some forms of cancer and premature aging.¹⁰⁴ Incorporating UVA standards into the sunscreen monograph required, therefore, a complete redefinition of the purposes of sunscreen and reliance on continually changing and uncertain science.

Although FDA recognized the danger posed by UVA radiation and the need for regulations well over a decade before the publication of the 2007 Amendment,¹⁰⁵ scientific obstacles delayed the proposal of a uniform testing method. A huge impediment to UVA regulations was the lack of a scientifically valid test that could reliably measure all aspects of UVA protection provided by a sunscreen product.¹⁰⁶ Recognizing that the action spectra for UVA-induced skin damage is not well defined, FDA decided it was necessary to develop a method that could measure both the magnitude and the breadth of UVA protection.¹⁰⁷ FDA finally proposed not one, but two required UVA tests: an in-vivo method to measure magnitude, or how well the product absorbs UV radiation and an in-vitro method to determine how broadly a product absorbs UVA radiation across the

¹⁰³ *See Id.*

¹⁰⁴ *See supra* notes 38-39 and accompanying text.

¹⁰⁵ *See* Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph 58 Fed. Reg. 28,194, 28,248-28,250 (May, 12 1993).

¹⁰⁶ *See Id.* (noting that “currently there is no generally acceptable method for determining a meaningful UVA protection factor that is analogous to the SPF”); Sunscreen Drug products for Over-the-Counter Human Use: Proposed Amendment of Final Monograph, 72 Fed. Reg. 49,070, 49,104 (August 27, 2007) (explaining that the difficulty in selecting a UVA testing procedure was due, in part, to disagreement in the scientific community regarding the appropriate method); Sarah Skiff, *Sizing Up Sunscreen*, NEWSWEEK, June 28, 2007, available at <http://www.newsweek.com/id/33384/page/1> (reporting one dermatologist’s view that there is no effective way to measure UVA protection in sunscreen).

¹⁰⁷ Sunscreen Drug products for Over-the-Counter Human Use: Proposed Amendment of Final Monograph, 72 Fed. Reg. 49,070, 49,101-106 (August 27, 2007).

entire UVA spectrum.¹⁰⁸ The two-test method is necessary to compensate for the inherent disadvantages of each individual test.¹⁰⁹ The results of the tests are to be combined into a single labeled UVA rating.¹¹⁰ Products will receive one of four ratings (low, medium, high and highest) corresponding to a four-star symbolic rating system that will allow consumers to use the rating system in combination with the SPF rating to make educated sunscreen purchases.¹¹¹ Furthermore, the FDA purposefully calculated the UVA rating-system so the highest four-star rating is difficult if not impossible for current sunscreen formulations to achieve in order to “foster additional research and development in this area.”¹¹²

B. WARNING STATEMENTS & OTHER CONSUMER EDUCATION EFFORTS

The 2007 Amendment and the FM proposed several labeling conditions in an effort to help consumers make more informed purchases and to better educate consumers about the appropriate use of sunscreen as part of a broader sun-protection strategy. The 2007 Amendment proposes replacing the optional sun alert statement with a mandatory warning: “UV exposure from the sun increases the risk of skin cancer, premature skin, aging and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.”¹¹³ The statement is meant to encourage consumers to adopt a complete sun protection program (sunscreen, sun

¹⁰⁸ See *Id.* at 49119 – 49, 121 (to be codified at 21 CFR 352).

¹⁰⁹ For a description of the advantages and disadvantages of both of the proposed test methods See *Id.* at 49,104 -106.

¹¹⁰ See *Id.* at 49,106.

¹¹¹ See *Id.*

¹¹² See *Id.*

¹¹³ See *Id.* at 49,113; Sunscreen Drug Products for Over-The Counter Human Use; Final Monograph, 64 Fed. Reg. 27,666, 27, 689 (May 21, 1999) (to be codified at 21 CFR 352.52) (permitting sunscreen products to include the following statement in labeling: “Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.”)

avoidance, and protective clothing) and to dispel any association of high SPF/broad-spectrum protection with solar invincibility.¹¹⁴ The Warning also disseminates information regarding the other potential dangers of UV radiation in a manner appropriate to the current state of scientific evidence.¹¹⁵

Both the FM and 2007 Amendment included other minor changes intended to minimize consumer misuse of sunscreen products. The FM prohibited terms like sunblock¹¹⁶ and waterproof¹¹⁷ that have a high potential to mislead consumers about the level of protection provided by the product. To encourage consumers to seek out greater protection but to discourage extended UV exposure, the 2007 amendment proposes to allow the statement “higher SPF products give more sun protection, but are not intended to extend the time spent in the sun” but makes non-monograph an earlier proposed descriptor, “higher SPF products give more sun protection.”¹¹⁸ The 2007 amendment also proposes to change the term Sun Protection Factor (SPF) to Sunburn Protection Factor to help reinforce the UVA/UVB distinction.¹¹⁹ Furthermore, the 2007 Amendment proposes more detailed directions of use in order to reduce the systematic problems of under-application and failure to re-apply that can significantly reduce the projected protection levels.¹²⁰ Although slight, these alterations reflect FDA’s commitment to on-going

¹¹⁴ See Sunscreen Drug products for Over-the-Counter Human Use: Proposed Amendment of Final Monograph, 72 Fed. Reg. 49,070, 49,090-091 (August 27, 2007).

¹¹⁵ See *Id.*

¹¹⁶ See Sunscreen Drug Product for Over-the-Counter Human Use; Final Monograph 64 FR. 27,666, 27,680 (May 21, 1999).

¹¹⁷ See *Id.* at 27,676.

¹¹⁸ See Sunscreen Drug products for Over-the-Counter Human Use: Proposed Amendment of Final Monograph, 72 Fed. Reg. 49,070, 49,090-114 (August 27, 2007).

¹¹⁹ See *Id.* at 49,112.

¹²⁰ See *Id.* at 49,072.

consumer education and desire to mend problems of persistent consumer misuse and misperceptions that systematically undermine the benefits of sunscreen products.

C. ACTIVE INGREDIENTS.

The FDA has also taken steps to ensure that U.S. sunscreen manufacturers have access to a greater number of active ingredients in order to promote the development of newer, more protective products. The OTC drug Review allows for interim marketing of products that do not yet have a final regulation provided that the product meets the material time/extent requirement.¹²¹ Both products that were marketed in the United States prior to December 4, 1975 and products whose conditions (i.e., active ingredients, indications, dosage form, dosage strength, route of administration and active ingredient combinations) are “substantially indistinguishable” from the pre-1975 products presumptively meet the material time/extent provisions.¹²² Inclusion of a new active ingredient in a sunscreen product, therefore, would render the product a “new drug” and require NDA approval.¹²³ Because obtaining an NDA is prohibitively costly and time-consuming for sunscreen manufacturers, few new ingredients have been introduced into the OTC sunscreen marketplace since 1978.¹²⁴

However, in the 1990s FDA considered a new process by which manufacturers could expedite approval of new sunscreen active ingredients called Time and Extent Applications.¹²⁵ The proposed rulemaking was the response to years of petitioning FDA

¹²¹ See Robert G. Pinco, *Implications of FDA's proposal to Include Foreign Marketing Experience in the Over-the-Counter Drug Review Process*, 53 FOOD DRUG L.J 105, 107 (1998).

¹²² See *Id.*

¹²³ See *Id.*

¹²⁴ See Shaath, *supra* note 9, at 13; See Also Pinco, *supra* note 121, 109-110 (explaining that the NDA process is particularly economically unfeasible in the case of sunscreen products that would require the submission of a new NDA or NDA supplement for every different SPF level or product formulation).

¹²⁵ See Pinco, *supra* note 121, at 115.

and lobbying Congress by European sunscreen manufacturers attempting to reverse the FDA policy of limiting OTC Drug Review to products with U.S. marketing experience¹²⁶.

Time and Extent Applications were finally implemented in 2002 as a method by which conditions of use not present in the OTC marketplace prior to 1975 could be considered for inclusion in an OTC monograph.¹²⁷ Conditions may satisfy the material time/extent requirements when (1) conditions of use are found in drug products sold in the USA under NDAs (2) conditions are found in products sold outside the USA.¹²⁸ A TEA is a two-step process.¹²⁹ The manufacturer must first submit information to demonstrate that it has been marketed for a minimum of five continuous years in the same country and sufficient quantity.¹³⁰ After FDA reviews the marketing information and determines it is eligible to be included, FDA publishes a notice of eligibility and a request for data in the Federal Register and proceeds to review the ingredient for safety and effectiveness.¹³¹ Finally a rulemaking is then published regarding FDA's conclusions, and if the condition is considered GRASE, the monograph will be amended to allow the condition to be marketed.¹³² Since implementing this process FDA has issued four eligibility notices proposing the inclusion of 7 active ingredients in the sunscreen FM.¹³³

¹²⁶ *See Id.*

¹²⁷ *See Shaath, supra* note 9, 1t 13.

¹²⁸ Holman, *supra* note 88, at 94.

¹²⁹ *Id.*

¹³⁰ *See Id.*

¹³¹ *See Id.*

¹³² *See Id.*

¹³³ *See* Ecamsule Eligibility for Inclusion in Monograph, 73 Fed. Reg. 53,029; Additional Sunscreen Ingredient, 71 Fed. Reg. 42,405 (July 26, 2006) (announcing a call-for-data on diethylhexyl butamido triazone); Additional Sunscreen Ingredients, 70 Fed. Reg. 72449

D. PHOTOSTABILITY

The 2007 Amendment also addresses photostability (the ability of sunscreen to resist photoinactivation at various wavelengths)¹³⁴ of sunscreen drug products. Interest in sunscreen photostability has grown with the popularity of avobenzone as a sunscreen active ingredient.¹³⁵ Although it is one of the most widely used UVA filters in the world, its absorbance performance has been shown, under certain experimental conditions, to decline with exposure to UV radiation.¹³⁶ This photodegradation can result in consumers receiving less sunscreen protection than they expect.¹³⁷ When FDA first approved avobenzone for inclusion in the FM, the agency recognized “that the photostability of any topical product, particularly a sunscreen drug product, is an important safety and effectiveness consideration” and promised to address the issue of photostability of all OTC sunscreen active ingredients in a future issue of the Federal Register.¹³⁸ Subsequently, a public meeting was held to obtain data and information on the photochemistry and photobiology of all OTC sunscreen drug products.¹³⁹ The FDA expressed particular concern with loss of product effectiveness and safety risks raised by the production of potentially toxic byproducts as a result photodegradation.¹⁴⁰ In the 2007

(December 5, 2005) (announcing notice of eligibility and call-for-data on bisoctrizole and bemotrizinol); Additional Sunscreen Ingredients, 68 Fed. Reg. 41386 (July 11, 2003) (announcing call-for data on amiloxate, enzacamene and octyl trizone).

¹³⁴ See James Ferguson, *How Stable is your Sunscreen?*, JOURNAL WATCH DERMATOLOGY, March 15, 2005, available at, <http://dermatology.jwatch.org/cgi/content/full/2005/315/1> (defining the problem of photostability in sunscreen products).

¹³⁵ Craig A. Bonda, *The Photostability of Organic Sunscreen Actives: A Review*, in SUNSCREENS: REGULATIONS AND COMMERCIAL DEVELOPMENT 321, 323 (3rd Ed. Nadim A. Shaath eds. 2005).

¹³⁶ *Id.*

¹³⁷ See Ferguson, *supra* note 134.

¹³⁸ Sunscreen Drug Products for Over-The-Counter Human Use; Amendment to the Tentative Final Monograph, 61 Fed. Reg. 48,645, 48,652 (Sept 16, 1996).

¹³⁹ See Discussion of the Photochemistry and Photobiology of Sunscreens, 61 Fed. Reg. 42,398, 42,398-42,401 (August 15, 1996).

¹⁴⁰ See *Id.* at 42,400 (requesting information on how to test the photostability of sunscreen ingredients and to identify potential byproducts of photodegradation).

Amendment, in conjunction with the UVA regulations, the FDA proposed a pre-irradiation step to the in vitro test method.¹⁴¹ FDA's proposal of a pre-irradiation step is intended to reduce the number of unstable product formulations and protect consumers from an unexpected loss of product effectiveness during actual use.¹⁴²

Each of the provisions and changes discussed in this section belies criticism that FDA has done little to advance consumer protection in the area of sunscreen drug products. FDA has responded to the sunscreen evolution by completely redefining sunscreen products, educating consumers, creating easier pathways for the introduction of new technology, and devising solutions to novel problems that accompany that technology.

IV. THREATS TO CONSUMER SAFETY.

Although the regulatory history for OTC sunscreen drug products reveals a relatively flexible, albeit prolonged, process that has permitted FDA to adjust the monograph to accommodate ever-changing science and technology in the field of UV protection, the absence of a Final Monograph continues to threaten the public health. This section addresses the pressing need for finalized regulations and analyzes one current source of delay – opposition by industry to certain labeling provisions that allegedly violate their right to commercial free speech. The last part of the section also identifies areas where further action by FDA may be required to adequately protect consumers, including UVA regulations, photostability, nanotechnology, and active ingredient approval.

A. *THE NEED FOR AN FINAL MONOGRAPH.*

¹⁴¹ See Sunscreen Drug products for Over-the-Counter Human Use: Proposed Amendment of Final Monograph, 72 Fed. Reg. 49,070, 49,106-107 (August 27, 2007).

¹⁴² See *Id.*

FDA technically has the power to take enforcement action against sunscreen products that are marketed in formulations not in accordance with the proposed monograph.¹⁴³ However, a well-understood premise of the OTC Drug Review was that FDA would not devote its resources to enforcement actions against individual OTC products even though they might technically be unapproved new drugs...the agency would tolerate continued marketing of most OTC drug products pending completion of the Review.¹⁴⁴ Although the FDA has made clear that it will not hesitate to take action against individual products that pose significant health hazards or are likely to defraud consumers, it has not taken such actions against OTC sunscreen products.¹⁴⁵ As a result sunscreen products have persisted in disregarding FDA determinations of what constitutes safe and effective conditions for sunscreen drug products.¹⁴⁶ FDA must finalize the monograph and strictly enforce its provisions in order to ensure that consumers are adequately protected.¹⁴⁷

B. INFORMAL INDUSTRY FILIBUSTER: COMMERCIAL FREE SPEECH.

The multi-step rulemaking process employed in the OTC Review provides opportunity for any interested person to comment during several stages of the rulemaking and requires FDA to review to review *all* comments and new information before progressing to the next phase of review.¹⁴⁸ As a result, industry's response to FDA's proposed regulations can have a tremendous effect on the pace of the regulatory process. Although the "agency has a history of proposing, amending, and staying sunscreen rules"

¹⁴³ See 21 C.F.R. § 330.13 (2009).

¹⁴⁴ Peter Barton Hutt, Richard A. Merrill, & Lewis A. Grossman, FOOD AND DRUG LAW 796 (3rd ed. 2007).

¹⁴⁵ See *Id.*

¹⁴⁶ For example, despite current 2007 proposed regulations that permit only the collective category of SPF 50+ rather than specific values for very high SPF products, many products on the market claim specific value SPF protection as high as SPF 85. See Banana Boat, <http://www.bananaboat.com/products/14665.aspx?cat=1&curBrowseBy=> Usage (last visited April 20, 2009).

¹⁴⁷ See, Who's Protecting Us?, *supra* note 4.

¹⁴⁸ See 21 CFR § 330.10 (2009).

the current delay has sparked outrage among consumer advocates “who blame sunscreen manufacturers for filibustering.”¹⁴⁹ The Industry opposes an SPF cap and prohibitions of therapeutic claims other than sunburn prevention claiming that the rules impermissibly restrict their First Amendment right to commercial free speech.¹⁵⁰

Although the 2007 amendment proposes to increase the cap on specific SPF value claims to SPF 50 and to allow the use of a collective category SPF 50+, this concession has done little to decrease industry’s concerns over their free speech rights.¹⁵¹ SPF labeling has been a controversial topic throughout the OTC review of sunscreen products.¹⁵² The FDA first proposed the SPF coding system in the ANPR in 1978.¹⁵³ Manufacturers quickly adopted the coding system, but ignored the FDA’s position that SPF’s over 15 were unwarranted.¹⁵⁴ Recognizing the popularity of high SPF products, recommendations by medical professionals, and new evidence that high SPF numbers may be warranted under extreme conditions, for the most light sensitive individuals, or to compensate for systematic under-application, FDA proposed in the TFM to allow for

¹⁴⁹ Singer, *supra* note 7.

¹⁵⁰ See e.g., Johnson & Johnson, Comments and Recommendations in response to FDA’s Proposed Amendment to the Final Monograph, December 20, 2007, Docket # 1978N-0039, RIN 0910-AF43.

¹⁵¹ See *Id.* (J&J recommends no SPF cap or at least that the cap be raised to SPF 85).

¹⁵² See e.g., Patrick R. Jones, *Protecting the Consumer from Getting Burned: the FDA, the Administrative Process, and the Tentative Final Monograph on Over-the-Counter Sunscreens*, 20 AM. J.L. AND MED. 317, 328 (1994) (noting that “significant outcry has accompanied the TFM cap on SPF’s at 30).

¹⁵³ See Sunscreen Drug Products for Over-The-Counter Human Use; Notice of Proposed Rulemaking, 43 Fed. Reg. 38206, 38,264 (August 25, 1978) (proposing five category designations: Minimal (2-4 SPF), Moderate (4-6 SPF), Extra (6-to 8 SPF), Maximal (8 to 15), and Ultra (15 + SPF) or higher SPF).

¹⁵⁴ See Harold C. Hopkins, *Tan Now, Pay Later*, FDA Consumer 9, 11 (1982) (noting that the numerical rating system in fact is already in wide use among manufacturers). Seeing higher SPF values as a valuable opportunity to distinguish their product, manufacturers continued producing more protective formulations. As a result, by 1987 products were available with SPF values as high as 36. FDA did nothing to stop the trend. See Segrave, *supra* note 2, at 96.

specific value claims up to 30, and created a collective category of 30+ in the FM.¹⁵⁵ After publication of the FM, affected companies threatened to bring a lawsuit against FDA challenging the constitutionality of the restrictions on truthful, non-misleading commercial speech.¹⁵⁶ In the 2007 Amendment the FDA has backpedaled further, not only raising the SPF cap to 50 and the collective category to SPF 50+, but also abandoning their prior consumer protection rationale and relying solely on adequate testing procedures.¹⁵⁷ FDA essentially promised to recognize specific values over SPF 50 “upon receipt of data demonstrating that accurate and reproducible results can be obtained from the SPF test for sunscreen products with SPF Values over 50”¹⁵⁸

Despite or perhaps because of FDA’s conciliations, the industry continues to oppose any FDA cap on SPF values and also to advocate for the inclusion of “helps prevent” claims related to photoaging and skin cancer.¹⁵⁹ Both the popularity of high SPF products and the obvious marketing potential for anti-aging/anti-skin cancer claims, make it unlikely that industry will submit to FDA’s regulations without a fight. It is essential that FDA resolve the debate in a manner that is in accordance with the constitutional doctrine, thereby reducing the likelihood of a challenge, but also consistent with its mission of protecting of consumer health.

C. CONSUMER PROTECTION: PERSISTING GAPS IN THE PROPOSED RULES.

¹⁵⁵ See Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 58 Fed. Reg. 28,194, 28,295 (May 12, 1993)(to be codified at 21 CFR §352.3); Sunscreen Drug Products for Over-The-Counter Human Use; Final Monograph 64 Fed. Reg. 27,666, 27,687 (May 21, 1999). (to be codified at 21 CFR §352.3).

¹⁵⁶ See Hutt, *supra* note 144, at 798.

¹⁵⁷ See Sunscreen Drug Products for Over-The-Counter Human Use; Proposed Amendment of Final Monograph, 72 Fed. Reg. 49,070, 49,805-49807(August 27, 2007) (stating that FDA does “not believe it is necessary to arbitrarily limit specific labeled SPF values”).

¹⁵⁸ See *Id.*

¹⁵⁹ See Johnson & Johnson, *supra* note 150.

Despite FDA's efforts to formulate regulations that protect consumers from the dangers of UVA radiation, there remains several gaps in the proposed rules that continue to threaten consumer safety and will require future action by FDA.¹⁶⁰ In particular FDA will likely need to further address some issues with UVA testing and labeling, nanomaterials, photodegradation, and the inability of U.S. consumers to access the newest, most effective sunscreen active ingredients on the world market.

Although the UVA regulations in the 2007 Amendment are undoubtedly a monumental step forward for consumer safety, neither industry nor consumer groups are totally satisfied with the proposed regulation. Consumer advocates are concerned about the failure of the proposed test methods to measure UVA radiation from a statistically significant endpoint.¹⁶¹ Furthermore, the proposed test methods are inconsistent with the foreign standard thereby widening the regulatory gaps that prevent flow of products between markets.¹⁶² Industry also complains that the UVA four-star rating is an arbitrary and impossible standard.¹⁶³ Furthermore, consumer advocates believe that FDA should require manufacturers to include a minimum level of UVA protection, much like a minimum SPF value is required to qualify as a sunscreen.¹⁶⁴ Although future fine-tuning of the UVA regulation will likely be necessary, finalizing the proposed 2007 amendment will provide consumers a solid base of protection even while FDA and sunscreen manufacturers continue to test the best labeling and testing methods for UVA radiation.

¹⁶⁰ See Who's Protecting Us, *supra* note 4.

¹⁶¹ See *Id.*

¹⁶² See Nadim A. Shaath, *Industry's Response to FDA's proposed Rules*, HAPPI, (May 1, 2008), available at, <http://www.happi.com/articles/2008/05/the-sunscreen-filter>; Nadim A. Shaath, *supra* note 4, at 15 (recommending the harmonization and relaxing of International Regulations in order to "permit speedier introduction of new and improved ultraviolet filters and sunscreen products worldwide").

¹⁶³ See Shaath, *supra* note 162. See Johnson & Johnson, *supra* note 150.

¹⁶⁴ See, Who's Protecting US?, *supra* note 4.

Furthermore, FDA's failure to seriously address the use of nanoparticles risks consumer health. Within the last twenty-five years scientists have learned to manipulate nanosized particles and cosmetic and personal product manufacturers have taken advantage of the special properties of nanomaterials and incorporated them into their products.¹⁶⁵ Despite concern over a lack of information regarding the potential health dangers of this new tiny technology,¹⁶⁶ it is estimated that hundreds of products, including many sunscreens, contain nanoparticles.¹⁶⁷ In the FM, "after reviewing limited toxicity data, the FDA expressed the view that 'micronized' titanium dioxide is not a new drug ingredient, despite the functional differences between it and larger particles of the substance."¹⁶⁸ As a result of this decision, sunscreens containing nanomaterials will not be subject to further assessment or oversight.¹⁶⁹ Consumer and environmental advocates indicate that human health and toxicity concerns exist for nano-ingredients and believes that the Agency must establish reporting requirements for manufactures regarding particle size and conduct more thorough investigations to establish safety of use, specifically for titanium dioxide and zinc oxide in order to ensure consumer safety.¹⁷⁰

Furthermore, some consumer groups feel that the pre-irradiation step in the UVA testing procedures is insufficient to address the serious problem of photodegradation.¹⁷¹

Some research shows that as many as 53% of sunscreen products on the market contain at

¹⁶⁵ See Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349, 356 (2007); Nicole Abramowitz, *The Dangers of Chasing Youth: Regulating the Use of Nanoparticles in Anti-Aging Products*, 2008 U. Ill. J.L. Tech. & Pol'y 199, 205 (2008).

¹⁶⁶ For a discussion of some of the potential health dangers of nanoparticles See Lin, *supra* note 165, at 358-359.

¹⁶⁷ See Abramowitz, *supra* note 165, at 205.

¹⁶⁸ Lin, *supra* note 165, at 374.

¹⁶⁹ See *Id.*

¹⁷⁰ See *Who's Protecting Us?*, *supra* note 4.

¹⁷¹ See *Id.*

least one ingredient that may be unstable and a number of scientific studies have shown the potential for sunscreen ingredients and formulations to lose effectiveness or degrade into potentially toxic by-products when exposed to normal exposure levels of UV radiation.¹⁷² Although both the in vivo SPF testing and the proposed UVA pre-irradiation step attempt to address the problem of photostability, these protections may not be sufficient, because manufacturers are not required to ensure the safety of chemical degradation byproducts and the proposed UVA method fails to adequately simulate conditions of actual exposure.¹⁷³

Finally, the number of FDA approved UV filters available to manufacturers remains completely insufficient to allow the production of sunscreen formulations that will best protect the consumer. Although the TEA process was intended to streamline the approval process for new active ingredients, the lag time is still extreme.¹⁷⁴ Only 17 chemicals are approved for use in the U.S. while at least 29 are approved for use in the E.U.¹⁷⁵ The dearth of adequate products has led to both deceptive and inefficient manufacturing processes. For example manufacturers have begun to incorporate anti-inflammatory ingredients into their products to artificially boost SPF, an entire market of photostabilizing methods have been developed to enhance the available UVA ingredients such as avobenzone, and manufacturers have begun incorporating unapproved active ingredients into their formulations as inactive ingredients.¹⁷⁶ Without more expedient review and approval of new UV filters, U.S. consumers will continue to be considerably disadvantaged as newer, safer and more efficient technologies continue to be introduced

¹⁷² *See Id.*

¹⁷³ *See Id.*

¹⁷⁴ *See Who's Protecting Us?, supra* note 4.

¹⁷⁵ *See Id.*

¹⁷⁶ *See Shaath, supra* note 162.

in places like Europe, Australia and Canada where the regulation of sunscreen is more progressive.

CONCLUSION.

FDA's delay in finalizing a sunscreen monograph has been in some ways necessary to accommodate a radical change in the science surrounding sunscreen, skin damage, and UV radiation. However, the lack of a finalized sunscreen regulation is a detriment to consumer health, especially as sunscreen manufacturers persist in marketing non-monograph conditions. FDA's desire to keep the regulations abreast of developing technology and science likely reflects a desire to minimize economic costs to manufacturers.¹⁷⁷ FDA must balance the economic burden to manufactures with the cost of delay to consumers. Although continued flexibility in the sunscreen monograph is essential to accommodate continued research into new conditions and effective uses, FDA must finalize the sunscreen drug monograph and enforce its provisions strictly to ensure that consumers can have confidence in their sunscreen purchases.

¹⁷⁷ See Sunscreen Drug Products for Over-the Counter Human Use; Proposed Amendment of Final Monograph, 72 Fed. Reg. 49,070, 49,109 (explaining that the FDA reduced compliance costs by staying the labeling requirements for the FM "sparing the industry to cost of an additional regulatory mandated label change").