

Ingredient in Anti-Aging Cosmetic Re-Ignites Abortion Debate and Raises Questions About Cosmetic Labeling

By Cynthia S. Marietta, J.D., LL.M. Candidate (Health Law)
csmarie@central.uh.edu

Introduction

Over 36 years ago the United States Supreme Court decided the historic case, *Roe v. Wade*,¹ which effectively legalized abortion in the United States. Yet, the debate about the moral and ethical aspects of abortion continues to this day. Now, certain anti-aging cosmetic products are the focus of attention in the ongoing abortion controversy. The anti-aging cosmetics at issue are manufactured by Neocutis, S.A. (“Neocutis”), which is a Swiss bio-pharmaceutical company founded in 2003 that specializes in wound healing, dermatology, and skin care. Neocutis, Inc., is the U.S. subsidiary handling all commercial activities.²

Neocutis states on its web site that its anti-aging products³ contain a proprietary skin care ingredient, Processed Skin Cell Proteins (“PSP®”),⁴ which is derived from cultured fetal skin cells.⁵ Since at least 1992, medical researchers have discovered that fetal skin cells have a unique ability to heal wounds without scarring.⁶ Because aged skin has the same needs as wounded skin for repair, Neocutis claims that its proprietary PSP® ingredient can effectively stimulate the wound healing process,⁷ and improve skin texture and reduce the appearance of wrinkles in the eye and mouth areas.⁸

The Abortion Controversy – Science Versus the Sanctity of Life

Neocutis’ use of the PSP® ingredient derived from fetal skin tissue has become the subject of fodder for religious, ethical, and anti-abortion group bloggers and has ignited an outcry among pro-life⁹ group supporters, and specifically, the pro-life outreach group,

¹ *Roe v. Wade*, 410 U.S. 113 (1973). The U.S. Supreme Court decided this case in 1973, overturning a Texas interpretation of abortion law and making the procedure legal based on the right to privacy. The Court held that a woman, along with her doctor, could choose abortion in the early months of pregnancy without restriction and with restrictions in later months.

² *Id.*

³ The anti-aging products at issue include Neocutis Bio-restorative Skin Cream, Journee Bio-restorative Day Cream, Lumiere Bio-restorative Eye Cream, and Bio-Gel Bio-restorative Hydrogel.

⁴ Neocutis, *PSP® - A New Skin Nutrient*, available at <http://www.neocutis.com/categories.php?catid=10>; Neocutis, *PSP® - High Protein Skin Care*, available at <http://www.neocutis.com/categories.php?catid=13>.

⁵ *Id.*; see also H.P. Lorenz, et al., *Scarless Wound Repair: A Human Fetal Skin Model*, 114 DEVELOPMENT 253-59 (1992), available at <http://dev.biologists.org/content/114/1/253.full.pdf>.

⁶ See Albert-Adrien Ramelet, et al., *Chronic Wound Healing By Fetal Cell Therapy May Be Explained By Differential Gene Profiling Observed In Fetal Versus Old Skin Cells*, 44 EXPERIMENTAL GERONTOLOGY 208-18 (2009).

⁷ Neocutis, *Role of PSP® in Anti-Aging*, available at <http://www.neocutis.com/article.php?sid=78>.

⁸ Neocutis, *Anti-Aging Study*, available at <http://www.neocutis.com/article.php?sid=84>.

⁹ Pro-life individuals believe in the concept that all humans, including the innocent unborn, have an inherent right to life. See generally <http://www.abortionfacts.com>.

Children of God for Life (“COG”). For years, the COG group has served as a self-imposed watchdog of pharmaceutical companies using aborted fetal cell lines in medical products, and they reportedly receive thousands of inquiries from the public on the use of aborted fetal material in cosmetics.¹⁰ Debi Vinnedge, Executive Director of COG, states that use of fetal tissue in anti-wrinkle cream crosses moral and ethical boundaries.¹¹ She claims, “It is absolutely deplorable that Neocutis would resort to exploiting the remains of a deliberately slaughtered baby for nothing other than pure vanity and financial gain...There is simply no moral justification for this.”¹² She objects to the use of fetal cells no matter what their use -- whether medical or cosmetic -- arguing that mature cells are just as effective.¹³

Religious and ethics groups alike have questioned just how many aborted fetuses were involved in the research before Neocutis perfected the cell lines for cosmetic use.¹⁴ Moreover, these groups have raised concerns about wasting fetal tissue resources on the development of beauty treatments instead of focusing on more humanitarian research priorities.¹⁵

COG is calling for a full boycott of all Neocutis products and advises women who are using Neocutis products to throw them in the garbage.¹⁶ Moreover, COG has promised competing cosmetic companies they will receive free advertising and COG’s endorsement if they are willing to confirm in writing they use “moral sources” for their collagen and skin protein ingredients.¹⁷

Neocutis responded to this wave of condemnation by defending its responsible use of fetal tissue for product development. On its web site, Neocutis acknowledges the questions raised by COG and others, stating “We respect differing views on medical research practices and on the development of pharmaceutical and cosmetic treatments.”¹⁸ Neocutis explains that, since the 1930s, the international medical community has used donated fetal tissue as a means to better understand cell biology and as an essential tool in the development of vaccines and for severe wound treatments.¹⁹ Neocutis espouses that its view, as is shared by most medical professionals and patients, is that the limited, prudent and responsible use of donated fetal skin tissue “obtained with consent of parents, ethics committees and others in a well-monitored and respectful manner can be

¹⁰ Christian News Wire, *Aborted Fetal Material Used in Anti-Wrinkle Creams*, Oct. 27, 2009, available at <http://www.christiannewswire.com/news/6048111942.html> (last visited Nov. 20, 2009).

¹¹ Valerie Richardson, *Aborted Fetus Cells Used in Beauty Creams*, WASH. TIMES, Nov. 3, 2009.

¹² Children of God for Life, *Aborted Fetal Material Used in Anti-wrinkle Cream*, Oct. 27, 2009, available at <http://www.cogforlife.org/neocutis.htm> (last visited Nov. 19, 2009).

¹³ Richardson, *supra* note 12.

¹⁴ The American Journal of Ethics, *What is a Blockbuster Anti-Wrinkle Cream Worth, Morally Speaking, or How many Fetuses Does It Take to Make a Great Cosmeceutical?*, available through <http://www.blog.bioethics.net>; see also Steve Weatherbe, *Vanity vs. Moral Stem Cell Study*, NAT’L CATHOLIC REG., Nov. 15-21, 2009.

¹⁵ American Journal of Ethics, *supra* note 15.

¹⁶ Christian News Wire, *supra* note 11; Children of God for Life, *supra* note 13.

¹⁷ *Id.*

¹⁸ Neocutis, *Responsible Use of Fetal Skin Tissue*, available through <http://www.neocutis.com>.

¹⁹ *Id.*

used for significant medical benefit” and “can continue to ease suffering, speed healing, save lives, and improve the well-being of many patients around the globe.”²⁰

History of Neocutis’ Production of PSP® and its Anti-Aging Products

Neocutis claims that the fetal skin specimen serving as the basis for the development of its PSP® treatment originated from cell lines established in the University Hospital of Lausanne, Switzerland.²¹ The cell lines originated from a small fetal skin biopsy obtained after a single terminated pregnancy at 14 weeks gestation that could not survive to term and was deemed medically necessary by the attending physician.²² The parents of the fetus voluntarily donated the fetal tissue sample to medical research, after giving informed and written consent consistent with Swiss laws that regulate organ donations and with approval from the local Medical School Ethics Committee.²³

Medical researchers at the University Hospital of Lausanne recognized the unique ability of fetal skin to heal wounds without scarring and elected to use the donated fetal skin specimen to establish a dedicated cell bank for developing new skin treatments for wound healing and severe burns.²⁴ These researchers created a biotechnology process to extract the rich proteins responsible for scarless wound healing from cultured fetal skin cells.²⁵ The proprietary skin ingredient, PSP®, is obtained through this biotechnology process²⁶ and consists of an “optimal, naturally balanced mixture of skin nutrients including cytokines, growth factors and antioxidants.”²⁷ Neocutis confirms on its web site that it does not directly use the originally donated fetal tissue to produce PSP®, but rather, it uses proteins derived from cultured fetal skin cells grown from the dedicated cell bank.²⁸

Although the dedicated cell bank was originally established for wound healing and burn treatments, Neocutis claims this same cell bank will enable a lasting supply of cells for producing PSP® and some 900 million biological bandages for patients suffering severe wounds, burns, and other serious skin conditions.²⁹ Supposedly, no other fetal tissue donation will ever be necessary.³⁰

²⁰ *Id.*

²¹ *Id.*; see also Albert-Adrien Ramelet, et al., *Chronic Wound Healing By Fetal Cell Therapy May Be Explained By Differential Gene Profiling Observed In Fetal Versus Old Skin Cells*, 44 EXPERIMENTAL GERONTOLOGY 209 (2009).

²² See *Responsible Use of Fetal Skin Tissue*, supra note 19; see also Albert-Adrien Ramelet, supra note 22.

²³ *Id.*

²⁴ Neocutis, *Cosmeceuticals*, available through <http://www.neocutis.com>; see also Albert-Adrien Ramelet, supra note 22.

²⁵ Neocutis, *PSP® in Cosmetic Research*, available at <http://www.neocutis.com/categories.php?catid=11>.

²⁶ Neocutis, *PSP® Production and Safety*, available at <http://www.neocutis.com/article.php?sid=15>.

²⁷ Neocutis, *PSP® - High Protein Skin Care*, supra note 5.

²⁸ Neocutis, *Responsible Use of Fetal Skin Tissue*, supra note 19.

²⁹ Neocutis, *PSP® in Cosmetic Research*, supra note 26; Neocutis, *PSP® Production and Safety*, supra note 27.

³⁰ Neocutis, *Responsible Use of Fetal Skin Tissue*, supra note 19.

What are the Trade Secret Ingredients in Other Anti-Aging Products on the Market?

Neocutis is one of more than 100 other cosmetic companies with anti-aging products on the market.³¹ To date, no cosmetic company has apparently accepted COG's offer for public endorsement in exchange for written confirmation that it uses "moral sources" in its cosmetics. Or at least, COG has not publicly acknowledged or endorsed a cosmetic company on its web site. There could be a number of reasons why no company has accepted the challenge, but probably the most compelling reason is to avoid exposing its trade secret ingredients, whatever they may be, in the public spotlight.

Cosmetics marketed in the United States, whether they are manufactured here or are imported from abroad, must comply with the labeling requirements of the Federal Food, Drug, and Cosmetic Act (FDCA),³² the Fair Packaging and Labeling Act (FPLA),³³ and regulations published by the U.S. Food and Drug Administration (FDA) under the authority of these two laws.³⁴ The FDCA was enacted to protect consumers from unsafe or deceptively labeled or packaged products by prohibiting the distribution of adulterated or misbranded products in interstate commerce.³⁵ The FPLA was enacted to ensure the packaging and labeling of products provide consumers with accurate information about the quantity and contents and facilitate value comparisons.³⁶

Since the FDA does not have the authority to pre-approve the labeling of cosmetic products before they are placed on the market, the manufacturer and/or distributor have the responsibility to ensure their products are labeled properly.³⁷ "Labeling" encompasses all labels and other written, printed or graphic matter on or accompanying a product.³⁸ The FDCA mandates all requisite label statements to appear on the inside as

³¹ On its web site, Neocutis claims that its Bio-restorative Skin Cream is not a drug, but rather is a cosmetic product. See Neocutis, *Frequently Asked Questions*, available through <http://www.neocutis.com>. Neocutis claims that its cosmetic product "restores the normal appearance of sensitive, stressed and irritated skin by nourishing, refreshing and revitalizing the skin's outer layer. *Id.* The FDA defines cosmetics by their intended use, 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." 21 U.S.C. § 201(i). The FDA defines a drug by its intended use, 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 of man or other animals." 21 U.S.C. § 201(g)(1). Recently, the FDA issued an "Import Alert" because there are numerous skin care products on the market with exaggerated "anti-aging" claims which cause the products to be unapproved new drugs. Examples of such claims are that the products "counteract," "retard," or "control" the aging process. Claims that the product will "rejuvenate," "repair," or "restructure" the skin may also be drug claims. See Import Alert # 66-38, available through <http://www.accessdata.fda.gov>. Seemingly, it is based on semantics: Neocutis' claim about its product keeps it in the cosmetic category.

³² 21 U.S.C. §§ 321-392 (2009).

³³ 15 U.S.C. §§ 1451-1460 (2009).

³⁴ U.S. Food and Drug Admin., *Cosmetic Labeling Guide*, available at <http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/CosmeticLabelingManual/ucm126444.htm>.

³⁵ *Id.*

³⁶ *Id.*

³⁷ U.S. Food and Drug Admin., *Cosmetic Labeling & Label Claims*, (Apr. 25, 2006), available at <http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/default.htm>.

³⁸ U.S. Food and Drug Admin., *Cosmetic Labeling Manual, Summary of Regulatory Requirements for Labeling of Cosmetics Marketed in the United States*, available through <http://www.fda.gov>.

well as any outside container or wrapper.³⁹ The FPLA mandates all product ingredients to be listed on the label of the outer container.⁴⁰ If a label on a cosmetic is false or misleading or fails to provide required information, then it is considered misbranded.⁴¹ All misbranded cosmetics are subject to regulatory enforcement and action.⁴²

Under the FPLA, if a product is sold on a retail basis to consumers, the ingredients must conspicuously appear on an information panel and be displayed in such a manner that it is likely to be read at the time of purchase.⁴³ Moreover, the ingredients must be listed in descending order of predominance, with few exceptions.⁴⁴ One such exception includes the listing of trade secret ingredients.⁴⁵ If the FDA pre-approves a company's request for trade secret exemption, then that "trade secret" ingredient does not need to be declared on the label, and in lieu of declaring the name of that ingredient, the company may state the phrase "and other ingredients" at the end of the declaration of ingredients.⁴⁶ The cosmetic company must first obtain FDA approval for trade secret exemption through a confidential application process before the cosmetic company is exempt from publicly declaring all ingredients.⁴⁷

Although Neocutis is not required to do so, it nevertheless outlines on its website the contents of its proprietary ingredient, PSP®, and openly discloses that it is derived from fetal skin cells. To date, no other cosmetic company has taken this same bold step. Perhaps, the reason is because no other company uses fetal cell lines in its product. Or, perhaps, as is more likely the case since fetal skin cell research has been around since at least 1992,⁴⁸ if a company does use fetal tissue or derivations of fetal tissue in a trade secret ingredient, then the company may want it to remain just that -- a secret -- to be disclosed to the FDA, only. Savvy cosmetic companies must now know the sensitive topic of aborted fetal material may cause customers to spurn their products, especially after seeing the public criticism of Neocutis.

Conclusion

Until the FDA changes its labeling regulations to require a declaration of trade secret ingredients or until cosmetic companies voluntarily step forward and declare their secret ingredients, cosmetic customers will be left to surmise what is in their favorite brand of anti-aging cosmetics. Although Neocutis' decision to use fetal cell lines has been the subject of much criticism and consternation, Neocutis nevertheless deserves some credit for being honest and forthright in disclosing its trade secret ingredient. Such open

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ 21 C.F.R. § 701.2; *see also Cosmetic Labeling Guide, supra* note 34.

⁴⁴ 21 C.F.R. § 701.3; *see also Cosmetic Labeling Guide, supra* note 34.

⁴⁵ *Id.*

⁴⁶ 21 C.F.R. § 701.3(a); *see also Cosmetic Labeling Guide, supra* note 34.

⁴⁷ 21 C.F.R. § 720.8; *see also Cosmetic Labeling Guide, supra* note 34.

⁴⁸ H.P. Lorenz, *supra* note 6.

disclosure allows consumers the opportunity to make an informed decision about whether to purchase Neocutis' anti-aging products.

Health Law Perspectives (January 2010)

Health Law & Policy Institute

University of Houston Law Center

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