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Nano-Cosmetics: Beyond Skin Deep

Law360, New York (February 15, 2011) -- It is not news to cosmetic companies that nanotechnology is the way of the future. The Food and Drug Administration has hailed nanotechnology, the manipulation of particles on the nanoscale engineered to exhibit special qualities or functions, as the next industrial revolution. Cosmetic manufacturers use nanoscale versions of ingredients to provide better UV protection, deeper skin penetration, longer-lasting effects, and increased color and finish quality, among other benefits. The global market for cosmetics using nanotechnology is projected to reach an estimated $155.8 million in 2012.[1]

Cosmetic manufacturers using nanotechnology confront an uncertain future from both consumer response and a regulatory standpoint. Despite the prevalence of nanotechnology in cosmetics, consumers remain largely unaware of its use.[2] In a survey by WHICH?, a U.K. consumer watch group, only 5 percent of consumers claimed to be aware of nanotechnology use in skincare and cosmetic products, and two-thirds of adults said they would assume and expect that cosmetics using nanotechnology are tested for safety and clearly labeled."[3]

Regulatory-wise, to date, the FDA has done little to oversee use of nanotechnology in cosmetics. This is likely to change soon, however, with the introduction of two proposed safety acts — The Nanotechnology Safety Act of 2010 and the Safe Cosmetics Act of 2010 — aimed at use of nanotechnology generally and in cosmetics specifically.

While cosmetic companies may have used nanoparticles for the past decade or more without manifest threat of litigation, the risks are increasing as consumers (and plaintiffs' lawyers) become more aware of wide-scale use of this technology and advancing science regarding possible human health effects. Industry critics will no doubt claim that nanoparticles present novel toxicity risks and that existing studies show cause for concern.[4]

For example, in a recent pre-clinical study, researchers found that some nanomaterials may pass through the transplacental barrier, underscoring the need for further research.[5] And in a *Journal of Cancer Research* study, the authors surmised that exposure to nano-titanium dioxide (often found in personal care products, including sunscreen, foundation, facial moisturizer, lipstick, facial powder, vitamins and toothpaste) could lead to genetic damage because such exposure led to double-strand DNA breaks in mice.[6] One study author advised against the use of spray-on sunscreens as these could lead to titanium dioxide inhalation.[7]

Easy access to widely available information about nanoproducts through tools such as "findNano" — a free interactive application that "lets users discover and determine whether consumer products are nanotechnology-enabled" — might be enough to make consumers leery. More likely, however, consumers will continue to use these products, deferring concern until a government or consumer advocacy group claims a viable health risk, and then pursue their perceived rights in court. Cosmetic companies must be on the forefront of safety and labeling issues to mitigate potential litigation risk and public relations problems.

EU and U.S. Regulators Take a Hard Look at Potential Nano Risks

Risk mitigation starts with understanding the current regulatory environment and anticipating the direction of future regulatory action. In comparison to efforts by U.S. agencies, EU action on nanoparticles in cosmetics has been much more robust.

In November 2009, EU member states approved an updated cosmetic regulation that will apply to all 27 member states.

Starting in 2013, the regulation requires labeling of all cosmetics containing nanomaterials by printing "nano" in brackets after any ingredient smaller than 100 nanometers.[8] It also requires cosmetic companies to notify the European Commission six months before marketing any product containing nanomaterials.[9] If the cosmetic product is already on the market, the manufacturer must notify the European Commission and submit safety data.[10] By July 2013, the regulation also requires that all marketed cosmetics and sunscreens using nanoparticles be individually tested for safety.[11]

In contrast, the FDA has not yet explicitly regulated nanoparticles and manufacturers are not required to inform consumers about the presence of nanoscale materials in their products. Cosmetics are not subject to pre-market authorization or post-marketing reporting requirements. While the FDA requires adequate substantiation of the safety of each ingredient, such data are not required to be submitted to the FDA.[12]

Many commentators believe the FDA can, should and will regulate nanocosmetics within its existing regulatory authority.[13] One potential area for expansion within the existing regulatory framework is through the FDA's authority over adulterated and misbranded products. "Adulterated" cosmetics, among other descriptors, contain "deleterious" substances.[14] "Misbranded" cosmetics, among other matters, have labeling that is false or misleading, fails to disclose material facts, or lacks required information.[15] Agency action in this arena, though rare, is not unprecedented.

For instance, in 2007, the FDA challenged a cosmetic company's labeling promoting an anti-aging cream and several facial sprays based on claims touting the products' nano-composition and cellular interaction. The FDA ruled that statements claiming that a product affects the structure or function of the body warranted treating the product as a drug, which would necessitate pre-approval and a new drug application. This approach could signal how the FDA may treat nanocosmetics in the future.

That the FDA does not require pre-market testing or labeling of nanocosmetics underscores the agency's arguable "late in the game" approach to this technology. But some efforts have been made.

In 2006, the FDA established an internal Nanotechnology Task Force to address ethical and best practices for manufacturing products with nanotechnology. The Task Force's findings culminated in a 2007 report that did not suggest implementation of any nano-specific regulations or labeling for any product.

Instead, the report recommends that manufacturers contact the FDA early in the product-development process to "help ensure timely consideration of any potentially novel issues that products using nanoscale materials may arise," as well as various "guidances" for products not subject to premarket authorization, including a guidance describing safety issues manufacturers should consider to ensure that cosmetics made with nanoscale materials are not adulterated.[16]

In January 2010, the Nanotechnology Safety Act of 2010 was introduced in the Senate. Senators who co-sponsored the act have said that it "would establish a program within the [FDA] to assess the health and safety implications of nanotechnology in everyday products and develop best practices for companies who employ nanotechnology. The legislation authorizes $25 million each year from 2011 through 2015 to assess the health and safety implications of nanotechnology in everyday products . . . ."[17]

The senators noted the importance of nanotechnology, but that as development continues, the "public's safety and confidence" in the marketplace must be ensured. The act has been referred to the Health, Education, Labor and Pensions Subcommittee.

On July 21, 2010, another new bill, the Safe Cosmetics Act of 2010, was introduced in the House, proposing a regimen for cosmetics much more closely resembling regulatory requirements for drug products. At a minimum, the bill would require:

1) manufacturer and other chain-of-commerce entities' registration

2) fee payment proportionate to gross receipts or sales for companies with over $1 million of the same annually

3) ingredient labeling

4) submission of various data and information to the FDA including adverse event reporting

5) subsequent promulgation by the FDA of regulations to classify ingredients as "prohibited," "restricted," or "safe without limits," as well as providing for authority to impose market restrictions.

Additionally, and with special importance to this article, the bill would give the FDA authority to require labeling of cosmetics including nanoscale materials.[18]

In the meantime, inconsistency between U.S. and EU nanocosmetic labeling requirements raises potential risks. Even though the FDA may not require a "warning," legal activists may tout EU labeling as a minimum standard. As most major cosmetic manufacturers sell their products in both markets, uniformity in product labeling is one potential strategy to mitigate litigation risk.

On the other hand, manufacturers in other industries have seen how undertaking labeling or other measures exceeding the exact, strict mandates of the FDA regulation have prevented them from using federal regulation as a shield against state tort liability. These risks and benefits must be weighed in the context of a company's specific objectives and circumstances.

Beware of Pseudo-Standards Set By Industry Critics

Federal inactivity means that meeting FDA's current minimum standards may not be enough and may not be what consumers and juries will expect. Any regulations adopted under either of the 2010 Safety Acts (if passed) will likely take years to become effective. Meanwhile, consumer advocacy groups have their own ideas about how cosmetic companies should be working to mitigate potential health risks.

These groups are organized, well-funded and do much of plaintiffs' attorneys' initial legwork — including providing centralized information about potential health concerns raised to date. Industry critics may assert that standards advanced by consumer groups have created a de facto regulatory environment and attempt to hold cosmetic companies to such standards, however far-fetched.

For example, the EWG helped fuel a nationwide "Compact for Safe Cosmetics," with "a coalition of public health, educational, religious, labor, women, environmental and consumer groups working to protect the health of consumers and workers by requiring the health and beauty industry to phase out the use of dangerous chemicals and replace them with safer alternatives."[19]

Six steps are required to meet the Compact, and the first is compliance with the EU Cosmetics Directive.[20] The Compact also asks manufacturers and retailers to sign and commit to "1) label all products they sell that contain nanomaterial ingredients, 2) request data from suppliers and manufacturers on the environmental, public health, and worker safety impacts of nanomaterial ingredients, and 3) prohibit the unsafe or untested use of nanomaterial ingredients in personal care products."[21] To date, more than 500 manufacturers, distributors and retailers have signed the Compact for Safe Cosmetics.[22]

While some major manufacturers and retailers have not signed the Compact, they have apparently taken note of the campaign.[23] CVS Caremark's Website states that it "promotes and carries natural beauty brands, some that meet . . . EU standards and some that have signed the Compact for Safe Cosmetics."[24] Cosmetic manufacturer L'Oreal has stated on its website that it will not sign the Compact because its safety standards are higher than most regulatory boards and, by signing, cosmetic companies are giving activist groups the authority to define "safe."[25]

Other consumer groups have called for measures more drastic than the Compact. Billed as an effort to avoid a repeat of the "asbestos tragedy," for instance, Friends of the Earth Australia has called for "an immediate moratorium on the commercial use of carbon nanotubes and the sale of these products until research can demonstrate whether or not there is any safe level of exposure to them."[26] This followed a 2008 study concluding that inhalation of carbon nanotubes has the same harmful effect on the lungs as asbestos.[27]

Anticipate and Take Charge — Litigation Risks Can Be Managed

While no product liability lawsuits involving nanocosmetics specifically have yet been reported, it is not a stretch to anticipate such litigation, especially if even a single study is published suggesting human health risk. And perhaps a more imminent threat is the possibility of consumer fraud litigation.

Typically brought as putative class actions, consumers may claim they paid a premium for a nanocosmetic that was fraudulently promoted as having benefits that did not exist or that they would never have purchased had they been fully informed of the potential risks. These claims pose a serious and significant threat as the class usually seeks damages including return of the purchase price to thousands, if not millions, of consumers for years of sales, as well as treble or punitive damages and attorneys' fees.

Other litigation risks include potential strict liability claims for harms caused by an unreasonably dangerous product, even if the manufacturer or seller had no reason to know of a defect or unreasonably dangerous condition resulting from use of nanomaterials, failure to warn of alleged risk, and the potential for medical monitoring claims.

Given this landscape, cosmetic companies cannot protect business interests by taking a "wait and see" approach. Cosmetic companies that recognize and anticipate litigation risk associated with nanotechnology will be better positioned to mitigate the risk, avoid adverse outcomes, and implement crisis management strategies if necessary. Cosmetic companies should:

- Stay apprised of and comply with applicable standards set by EU regulations
- Stay informed about what your competitors are doing in areas of testing and labeling
- Monitor developing nanotechnology science and new studies
- Monitor progress of and anticipate and prepare for new regulations
- Be aware of all regulatory "guidances" and "recommendations" — consider these a floor not a ceiling
- Avoid making health benefit claims in marketing and advertising
- Consider labeling for presence of nanoparticles, especially if required by the EU
- Follow all internal company policies, industry guidelines and standards
- Be aware of document creation and e-discovery rules that can reduce risk of adverse litigation outcomes.

Risk Management Has a Vital Role to Play in the Nanotechnology Frontier

Nanotechnology holds great potential, but also risk, for cosmetic companies; taking the initiative to adopt or consider the measures outlined above will better position your company to avoid and address potential litigation and public relation risks no matter what the future holds for this emerging technology.

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[1] BBC Research 2007.

[2] Small Wonder? Nanotechnology and Cosmetics, Nov. 2008, available at http://www.nano.org.uk/news/nov2008/WhichBrief.pdf. WHICH? states that it "campaigns actively for all consumers. With around 675,000 members in the UK, we are the largest consumer organisation in Europe."

[3] Id.

[4] Shatkin, JoAnne, Assessing the Benefits and Risks of Nanotechnology, Sept. 23, 2009, available at

http://www.naturalproductsinsider.com/articles/2009/09/assessing-the-benefits-and-risks-of-nanotechnology.aspx.

[5] Wick, et al., Barrier Capacity of Human Placenta for Nanosized Materials, National Institute of Environmental Health Sciences (Nov. 12, 2009), available at http://ehp.niehs.nih.gov/members/2009/0901200/0901200.pdf.

[6] Trouiller, et al., Titanium Dioxide Nanoparticles Induce DNA Damage and Genet Instability in vivo in Mice, Journal of Cancer Research, 2009, vol. 69, issue 22.

[7] Id. It is believed by some that nanoparticles cannot penetrate through healthy skin and into the body. Thus, inhalation of nanoparticles is perceived as more of a risk.

[8] European Union, Regulation of the European Parliament and of the Council on cosmetics products PE-CONS 3623/09 (Nov. 10, 2009).

[9] Id.

[10] Id.

[11] Kelly Burke, Nanotech widespread in cosmetics, report finds, THE SYDNEY MORNING HERALD (Nov. 24, 2009).

[12] 21 C.F.R. § 740.10. Under industry standards, substantiation is conducted through an independent safety assessment by the Cosmetic Ingredient Review. See Personal Care Products Council, Questions and Answers - Consumer Commitment Code, available at http://www.personalcarecouncil.org/Content/NavigationMenu/About_Us/Consumer_Commitment_Code1/Questions_and_Answers_-_Consumer_Commitment_Code/Questions_and_Answers_-_Consumer_Commitment_Code.htm .

[13] See The International Center for Technology Assessment et al., Citizen Petition to the U.S. Food and Drug Administration, at 16 (lobbying for an FDA determination that nanoparticles are uniformly unsafe due to their diminished size), available at http://www.foe.org/camps/comm/nanotech/NanoFDApetitionfinal.pdf); PERSONAL CARE PRODUCTS COUNCIL, COMMENTS OF THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION (CFTA) REGARDING THE SCIENTIFIC AND LEGAL ISSUES ASSOCIATED WITH NANOTECHNOLOGY IN PERSONAL CARE PRODUCTS. 13 (describing how existing law ensures and authorizes FDA regulation of safety with respect to nanocosmetics), available at http://www.fda.gov/ohrms/dockets/dockets/06n0107/06n-0107-c000014-03-vol16.pdf.

[14] 21 U.S.C. § 361.

[15] 21 U.S.C. § 362, 321(n).

[16] See FDA, NANOTECHNOLOGY: REPORT OF THE U.S. FOOD AND DRUG ADMINISTRATION NANOTECHNOLOGY TASK FORCE 33-34 (2007), at 21, available at http://www.fda.gov/nanotechnology/taskforce/report2007.pdf.

[17] Press Release, Senator Mark Pryor, Pryor, Cardin Call for Increased Research to Ensure Product Safety (Jan. 21, 2010) (available at http://pryor.senate.gov).

[18] Proposed section 618(e) provides that: (1) Minerals and other particulate ingredients be labeled as 'nano-scale' on a cosmetic ingredient label . . ., (2) Other ingredients in a cosmetic be designated with scale specific information on a cosmetic ingredient label or list if such ingredients possess scale-specific hazard properties.

[19] www.cosmeticsdatabase.com.

[20] For a list of all six steps, visit http://www.safecosmetics.org/article.php?id=341.

[21] See Position Statement on Nanotechnology at http://www.safecosmetics.org/article.php?id=336.

[22] For a complete list of compact signatories visit http://www.safecosmetics.org/downloads/Compact%20Signers_11.09.pdf.

[23] See EWG's press release at http://www.safecosmetics.org/article.php?id=253.

[24] http://info.cvscaremark.com/our-company/corporate-responsibility/products/cosmetics-and-personal.

[25] http://www.elcompanies.com/citizenship/product_safety_testing/product_safety_faqs.asp.

[26] Friends of the Earth Australia, Mounting Evidence That Carbon Nanotubes May Be the New Asbestos, available at http://hesa.etui-rehs.org/uk/dossiers/files/FriendsofEarth-2008.pdf.

[27] Poland, Craig, et al., Carbon Nanotubes Introduced Into the Abdominal Cavity of Mice Show Asbestos-like Pathogenicity in a Pilot Study, Nature Nanotechnology 3, 423-28 (2008). See also http://www.scientificamerican.com/article.cfm?id=carbon-nanotube-danger.