## Beefing Up FDA Oversight of Nano-Sunscreens and Nano-Cosmetics by Professor Robin Fretwell Wilson

The makers of cosmetics and sunscreens arguably have capitalized on nanotechnology more aggressively than any other industry. The appeal of using nano-sized particles in sunscreens and cosmetics rather than their conventional counterparts comes from their small size—they can provide UV protection while remaining transparent, avoiding the pasty white appearance of conventional sunscreens. With cosmetics, nano-sized particles hold the promise to provide deep, targeted delivery of moisturizers to the living layers of skin. Makers of nanocosmetics and nano-sunscreens not only acknowledge that they will penetrate the skin more deeply, but tout their health effects.

With any new or powerful technology, there is the potential for bad along with the potential for good. However, until recently, the possibility for harm has been largely ignored by the U.S. Food and Drug Administration. Unlike the FDA's robust regulation of drugs, which requires drug makers to secure approval for marketing by showing safety and efficacy through human trials, cosmetics can be marketed without such proof.

This paper will explore the FDA regulation of nano-cosmetic and nano-sunscreen products in light of the FDA's draft April 2012 guidance. An emerging body of evidence calls into question the wisdom of leaving nano-sunscreens and nano-cosmetics largely unregulated. A number of studies show that nano-sized particles have different toxicity because of their small size and high reactivity, and sometimes exert drug-like effects on the body. The weight of the evidence suggests that, at a minimum, questions about safety need to be addressed.

This paper will argue that concerns over the safety of nano-cosmetics and nanosunscreens have moved rapidly from the realm of speculation to grounds for real concern. Against this emerging evidence of biological impacts, this paper will assess the sufficiency of new guidance issued by the FDA. Specifically, it will ask whether Congress and the FDA should do more to strengthen the regulation of nano-cosmetics and nano-sunscreens to better ensure the public's safety.

## **Biography**

Robin Fretwell Wilson is the Class of 1958 Law Alumni Professor of Law at Washington and Lee University School of Law, where her scholarship focuses on questions at the intersection of law and science (or social science). She has co-authored or edited six books, including HEALTH LAW AND BIOETHICS: CASES IN CONTEXT (Sandra H. Johnson, Joan H. Krause, Richard S. Saver, & Robin Fretwell Wilson, eds., Aspen Publishers, 2009). Professor Wilson served as co-investigator for the National Science Foundation Grant, "From Laboratory to Society: Developing an Informed Approach to Nanoscale Science and Technology" in connection with which she hosted a Nanotechnology Regulatory Roundtable. Her work has been featured in the *New York Times*, the *Washington Post*, the *Los Angeles Times*, and the *Wall Street Journal*. A member of the American Law Institute, Professor Wilson has worked extensively on behalf of state and national law reform. Professor Wilson is the past Chair of the Section on Law, Medicine, and Health Care of the Association of American Law Schools.