

Manufacturing the Wings of Icarus: FDA Regulation of Nanotechnology Used in Products for Human Consumption Including Food, Dietary Supplements, Cosmetics and Sunscreens

Katharine Van Tassel and Rose Goldman

Consumers in the United States are being exposed to steadily increasing levels of novel and untested engineered nanoparticles as a result of their contact with everyday consumer products. Nanoparticles are very small particles that are engineered using innovative technologies to be 1 to 100 nanometers in size. Just how small is small? In comparison, a human hair is 80,000 nanometers wide. There are currently hundreds of unregulated and unlabeled consumer products on the market that contain engineered nanotech particles (“nanotech products”), with more on the way. A growing number of these nanotech products are being marketed for human consumption, including food, dietary supplements, cosmetics and sunscreens. This expanding market ignores the growing scientific understanding that these unique substances can create unintended human health and environmental risks.

In spite of this mounting scientific awareness, consumers remain uninformed of their exposure as nanotech ingredients are not listed on product labels. Labeling of nanotech ingredients on product packaging is not required by the Food & Drug Administration (“FDA”) because nanotech ingredients are presumed by the FDA to be bioequivalent to their normal size analogs. In other words, if the large particle version of the product is safe, the FDA presumes that the nanotech version is safe. Thus, manufacturers of nanotech food, dietary supplements, cosmetics and sunscreens are not required to test their nanotech products for safety, are not required to obtain premarket approval from the FDA and are not required to list nanotech ingredients on product labels.

The FDA’s presumption of bioequivalence is based on the scientifically dated position that “[p]article size is not an issue.” In fact, nanotech particles have fundamentally different properties than their larger counterparts. These differences manifest themselves on multiple levels as differences in optical, magnetic, bioaccumulation, toxicity, electrical, chemical, explosiveness and persistence characteristics. Numerous scientific studies over the past several years reveal that these unique properties may create unintended health risks such as mesothelioma, the condition caused by asbestos. These studies establish that the FDA’s presumption of bioequivalence is no longer scientifically supportable and that a new system for nanotech product regulation is required.

This Article discusses the public health, regulatory, legal and ethical issues raised by the new understanding of the health risks associated with nanotech products and is arranged as follows. After this Introduction, this Article describes the new scientific understanding of the health risks associated with the consumption of nanoparticles. Next, a summary of the current FDA regulatory structure that governs food, dietary supplements, cosmetics and sunscreens is provided along with an explanation of why these regulations fail to protect public health when applied to regulate the nanotech versions of these products. The Article goes on to illustrate how the FDA’s current position on bioequivalence, coupled with preexisting regulations, lead to a lack of a labeling requirement which bars a consumer from engaging in self-protection. Compounding this situation, if a consumer is injured from this unavoidable exposure, this Article spells out how the insensitivity of the tort system to injuries from innovative technologies means that an injury from a nanotech product will be borne by the consumer and not the manufacturers who are reaping the profit from product sales. This disconnect violates basic principles of distributive justice. Finally, this Article proposes an alternative method of regulating nanotech products that better protects public health while encouraging technical innovation.