

NANOTECHNOLOGY - KEY LEGAL ISSUES AND RISKS IN 21ST CENTURY TECHNOLOGY

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Recent years have seen a bust where a boom in nanotechnology was supposed to be. Even if industry advocates are correct in their insistence that their perceived struggles are merely the result of inflated and unrealistic expectations, the symptoms of an ailing nanotechnology sector are there. In the past year, the French government announced a five-year, €107 million bailout of its nanotechnology industry; NanoDynamics attempted the latest in a series of failed IPOs; and even the term “nano” has fallen out of favor with some venture capitalists seeking to distance themselves from concerns hovering over the field. With promises of riches so-far going unfulfilled, the pressing question is: why hasn't nanotechnology lived up to the hype?

An examination of nanotechnology's plight must consider what its properties and potential applications are that shape nanotechnology's role in the market. Compared to other examples of breakthrough technologies, nanotechnology has less to do with semiconductors and more to do with plastics. Whereas semiconductors were a concrete product in the particular field of electronics, nanotechnology's promise is in its fundamentally new approach to building things in general, and its applicability seems to be theoretically limitless. Products currently for sale that utilize nanotechnology include water and stain-resistant clothing, clear zinc oxide sunscreens, antibacterial washing machines, ultra-responsive golf balls and self-cleaning glass.

As illustrated by these examples, many nanotechnology applications are used to improve existing products and the industry's services are often grafted on top of or interwoven with other industries. As with plastics, nanomaterials in and of themselves are not valuable—it is their potential use in a wide variety of other industries that gives them value. As a result, nanotechnology is spread horizontally across the market rather than standing alone as a vertically integrated industry with one key end product in mind.

This practical difficulty faced by the nanotechnology industry is reflected in the debate over how the Food and Drug Administration (“FDA”) should regulate products containing nanomaterials. The FDA's policy currently remains largely the same toward nanotechnology products as toward the rest: the FDA regulates “products, not technology.” That is to say, the FDA determines the testing protocol for a particular product based on its classification into a product type rather than on the technology that it employs. The FDA straightforwardly states on its website that “the existing battery of pharmacotoxicity tests is probably adequate for most nanotechnology products that we will regulate. Particle size is not the issue.”¹

The assertion that particle size is not the issue is rather semantic—certainly, it is the safety risks that nanoparticles pose that concern the FDA, but it is their size that creates the risks. First, at the tiny scale of nanoparticles, the ratio of surface area to volume increases drastically. With more reactive sites of the molecule thus exposed, the particle may have greater reactive potential, and therefore greater potential for toxicity, than its macroscopic cousin. Second, due to their size, nanoparticles can more easily permeate biological membranes, making them more readily absorbed and widely dispersed throughout the

¹ FDA, REGULATION OF NANOTECHNOLOGY PRODUCTS, <http://www.fda.gov/nanotechnology/regulation.html>.

human body. Third, some nanoparticles are actually so small that they are subject not to the laws of classical physics but of quantum mechanics, under which various properties of the substance may change significantly. Each of these qualities presents a novel risk to consumer health.

The potential for harm is not solely hypothetical. One study, for example, found that the use of nanoscale zinc oxide and titanium dioxide—ingredients used in sunscreens—can lead to DNA damage in skin cells.² At the nanometer scale, both substances become highly photo-reactive and can produce harmful free radicals when exposed to ultraviolet rays.

In light of these unique properties, the FDA's relatively passive approach to the emergence of nanotechnology in the consumer marketplace has drawn fire from public health watchdogs, who argue that the inimitable risks presented by nanotechnology require a new, separate regulatory framework. In response, the FDA's Nanotechnology Task Force issued a report in July of 2007 asserting "the need for timely development of a transparent, consistent, and predictable regulatory pathway," and stating that the challenges posed by nanotechnology "may be magnified" in part "because nanotechnology can be used in, or to make, *any* FDA-regulated product." (emphasis added). The question of the adequacy of the existing testing protocol is far beyond the limited scope of this article. More germane is the question of whether a separate regulatory framework for nanotechnology products is even logistically feasible.

The FDA's current regulatory scheme funnels products into various testing centers, each with expertise in a particular type of product. Combination products—"product[s] comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic...and produced as a single entity"—illustrate the process well. Assignment of primary regulatory responsibility of a combination product is made based on a determination of the product's primary mode of action, defined as "the single mode of action of a combination product that provides the most important therapeutic action of the combination product." The center to which the product is assigned—either the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, or the Center for Devices and Radiological Health—will then evaluate the product for approval based on that particular center's guidelines.

As such, the way the FDA regulates nanotechnology (or any other technology) mirrors the way nanotechnology applications are developed and consumed: case-by-case, product-by-product, across a wide array of industries. Nanotechnology-specific testing protocols could either be implemented area by area within the existing framework or performed in a new, centralized testing center through which any product flagged as nanotechnology would have to pass on its way to approval. The different but congruent drawbacks to each option may demonstrate why nanotechnology's rise to commercial prominence has proved elusive.

The first option, to establish nanotechnology-specific tests across the existing framework, could dilute the FDA's expertise with the technology by scattering the procedures throughout the various testing centers. The second option, to create a separate testing center for nanotechnology products, could leave the center without the necessary product-specific expertise to evaluate how safely the nanotechnology functions within the particular product. The problem is that the risk posed by a nanotechnology product depends both on

² Dunford et al., *Chemical oxidation and DNA damage by inorganic sunscreen ingredients*, 418 FEBS LETTERS no. 1-2, pp. 87-90 (1997).

what the nanotechnological component of the product is and on what the product itself is. Conceivably a nanomaterial applied topically could be safe while the same material ingested or injected would not be.

This logistical difficulty encountered in regulating nanotechnology may reflect an inherent inefficiency within the nanotechnology industry that has slowed its commercial development. The age-old adage to do one thing and do it right is hard to follow in the case of nanotechnology, where the product by nature lends itself to a myriad of uses. Furthermore, the practice of nanotechnology is far enough out on the cutting edge that the pool of sufficiently sophisticated research and development bodies may be spread thin by the number of sectors seeking to implement the technology. Consequently, the horizontal orientation of the nanotechnology industry may create similar problems for the industry as it does for those who regulate its products: centralization of expertise in nanotechnology itself might limit its range of use, whereas maximizing the breadth of nanotechnology's applications could hurt the quality of the products by diminishing expertise.

Meanwhile, the uncertainties surrounding the efficacy of nanotechnology regulation spook investors who might otherwise fund the push through these practical obstacles facing the field. Liability concerns are particularly prevalent in some of the areas where nanotechnology's promise is greatest, such as medicine (see, for instance, a 2006 petition by the International Center for Technology Assessment formally requesting an FDA recall of all sunscreens employing nanotechnology).³ Across the board, the unusually wide range of applications for nanotechnology raise the debate of whether to regulate nanotechnology on a case-by-case or product-by-product basis or to route the industry through some centralized oversight process. In this sense, the very fact that nanotechnology is so widely applicable has hamstrung its commercial progress, and the difficulties of regulating the industry can be viewed as both a reflection and a cause of its struggles.

³ The International Center for Technology Assessment, et al., CITIZEN PETITION TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION (2006).