

Product Liability & Toxic Torts

Nanotechnology: Evaluate the Product Liability Risks

Be mindful of the human health and safety concerns

By Michael Dore

Nanotechnology involves the manipulation of matter at the nanometer scale. (A nanometer is one billionth of a meter. To get a sense of just how small this is, the reader should understand that the paper, on which this article is printed, is approximately 100,000 nanometers thick.)

Nanotechnology has been defined as the science that enables one to understand, measure, manipulate and manufacture materials at the atomic, molecular and supra molecular levels — aimed at creating materials, devices and systems with fundamentally new molecular organization, properties and functions.

This technology has been used in a wide variety of commercial products. These include wound dressings, pregnancy tests, toothpastes, lubricants, paints, non-

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stick coatings, tennis racquets, air filters and many other products. In each of these products, the nanoscale materials exhibit dramatically different characteristics than would be true of those materials in their normal size. By way of illustration at normal scale, gold is an excellent conductor of heat and electricity — but nothing happens when you shine light onto a piece of gold. When properly structured, however, gold nano particles absorb light and can actually convert light into heat (which, in turn, can be used for cutting purposes in thermal scalpels).

Product Liability Concerns

While nanotechnology offers great commercial promise, however, numerous commentators have raised alarms with respect to human health and safety issues associated with this entire field. Indeed some insurers have gone so far as to exclude coverage for nanotechnology injuries before any claims with respect to those injuries have even been presented.

These product liability concerns are a function of both the unique characteristics of nano materials themselves and

the markets in which those materials have been and will in the future be introduced. Compounding these nanomaterial product and market issues is the uncertain regulatory structure applicable to these substances.

The purpose of this discussion is to explore these concerns and to examine the characteristics of nanotechnology that make it particularly susceptible to products liability exposures.

Unique Characteristics of Nano Materials

The most significant (indeed the definitional) characteristic of nano particles is their size. The fact that these materials have external dimensions in the size range of approximately 1-100 nanometers, permits them to be used in a wide variety of commercial applications and to have characteristics which make the particular products into which they are integrated far more valuable to their users. A good illustration of this is the use of nanotechnology in sunscreen products — where nanosized particles of titanium dioxide provide UV protection while remaining transparent and thereby allowing for clear and efficient application. Another illustration is the use of nano-scale materials in thin films applied to eyeglasses, computer displays and cameras to make them water repellant, anti-reflective or give them other useful physical characteristics.

The small size of nanomaterials, however, also presents risks with respect to product liability issues. One of the most significant reasons for this is that it is clear

that size alone may change the risk component of these materials. See, *Special Report*, "Nanotechnology: Benefits vs. Toxic Risks, Functional Foods And Nutraceuticals" (Feb. 2007) ("[nanosized particles] were found to traverse through lung tissue in unexpected ways, gaining access to blood and lymphatic systems").

Thus, nano materials not only have different mechanical and electrical characteristics, such as tensile strength and conductivity, than their non-nano counterparts, but they also exhibit different human health-related characteristics, such as enhanced adhesion, reactivity and absorption. Exactly how these different physical properties impact the safety of these materials is largely unknown. The risk profile presented by these materials, however, is extremely high, in part, because safety data associated with non-nano counterpart materials offers relatively little comfort in addressing nanotechnology exposure/safety questions. An illustration of this concern is that, when inhaled, nano particles are deposited more efficiently and deeply into the respiratory tract than non-nano materials, and these nano materials may evade human body defense mechanisms that trap larger particles.

This "size" issue is a particular concern because human impacts and sometimes even human toxicity have been demonstrated with respect to some nano materials. In addition, nano materials themselves have sometimes been the subject of problematic animal studies. See, Lynn, "Size Matters: Regulating Nanotechnology," 31 *Harv. Envtl. L. Rev.* 349 (2007).

The extrapolation of these adverse nano-material results to humans and the appropriate basis for human risk assessment with respect to exposures to nano materials is far from clear. See, Fischer "Nanotechnology — Scientific and Regulatory Challenges," 19 *Villanova Envt. L. J.* 315 (2008). What is clear, however, is that traditional "route of the administration" factors involved in traditional risk assessments are open to question since nano materials may enter and potentially impact the body in ways in which non-nano materials cannot.

This size issue also impacts prophylactic efforts associated with nano materials. While structures exist for appropriate safety precautions associated with nano materials — many traditional precautions, such as the

use of facial masks, may not be effective in this area.

Market For Nano Materials

Moreover, it is not merely the characteristic of the nano materials themselves which raise product liability concerns but also the markets in which products containing those materials are distributed. There is a high concentration of nanotechnology applications in pharmaceutical, food and cosmetics applications. These industry segments with their direct and immediate human interactions present far greater product liability concerns than other commercial activities.

In addition, the fact that nano materials are often undifferentiated components of consumer products, makes traditional product liability defenses such as "product identification" and "restricted chain of distribution," far less likely to be effective with respect to nano material based claims.

Regulatory Issues

Enhancing these product and market-related risks are the fact that effective regulatory controls in this area are limited. Lack of scientific knowledge as to the risk characteristics of nano materials has led to an intense regulatory focus on developing an appropriate scientific basis for ensuring that nano materials do not present unreasonable human health concerns. See eg., Dept. of Health and Human Services, "Approaches To Safe Nanotechnology — Managing The Health And Safety Concerns Associated With Engineered Nanomaterials" (March 2009).

Domestic and international government agencies are actively involved in this scientific oversight effort. The present status of nanotechnology science, however, has prevented these regulatory authorities from confirming for industry that present regulations ensure the elimination of human health risks in this area.

Risk Evaluation

These nanotechnology product and market characteristics and regulatory concerns have led the premier experts on risk evaluation — the insurance industry — to express great concern in this area. Insurance

industry studies have expressed significant reservations about liability issues associated with nano materials. See Lloyd's of London, "Emerging Risks Team Report, Nanotechnology — Recent Developments, Risks and Opportunities" (2007). Indeed, one insurance carrier (Continental Western Insurance Group) has gone so far as to impose nano-technology exclusions in their standard CGL policies notwithstanding the fact that no such claims have yet been presented.

Similarly, an investment management advocacy group recently issued a report identifying nanotechnology as a significant potential source of liability and questioning the adequacy of corporate disclosure in this area. See, "Bridging The Credibility Gap — Eight Corporate Liability Accounting Loopholes That Regulators Must Close" (Investor Environmental Health Network 2009). In essence, this report focused on the nature of nanomaterials and the markets in which those materials were sold and concluded that the liability risks associated with nanomaterials are both substantial and insufficiently disclosed to investors.

Nanotechnology product liability concerns have also been heightened by an article recently published in the *European Respiratory Journal* in which researchers reported that seven young women suffered permanent lung damage following months of unprotected exposures to fumes and smoke containing nano particles in spray painting operations in China. The researchers concluded that the patients' illnesses appeared to be "nanomaterial-related disease" based upon the presence of the nanomaterials in the lung tissue and fluids, the similarity of the symptoms to the outcomes of prior animal studies, and the low toxicity of the other conventional chemicals used in the factory processes. While the results of this study have been questioned, it does confirm the legitimacy of product liability concerns with respect to high level environmental exposures to these materials.

It is clear that nanotechnology offers tremendous scientific and commercial opportunities in the future. These opportunities, however, are fraught with health- and safety-based product liability risks, and those risks need to be taken into account in the development and exploitation of these products. ■