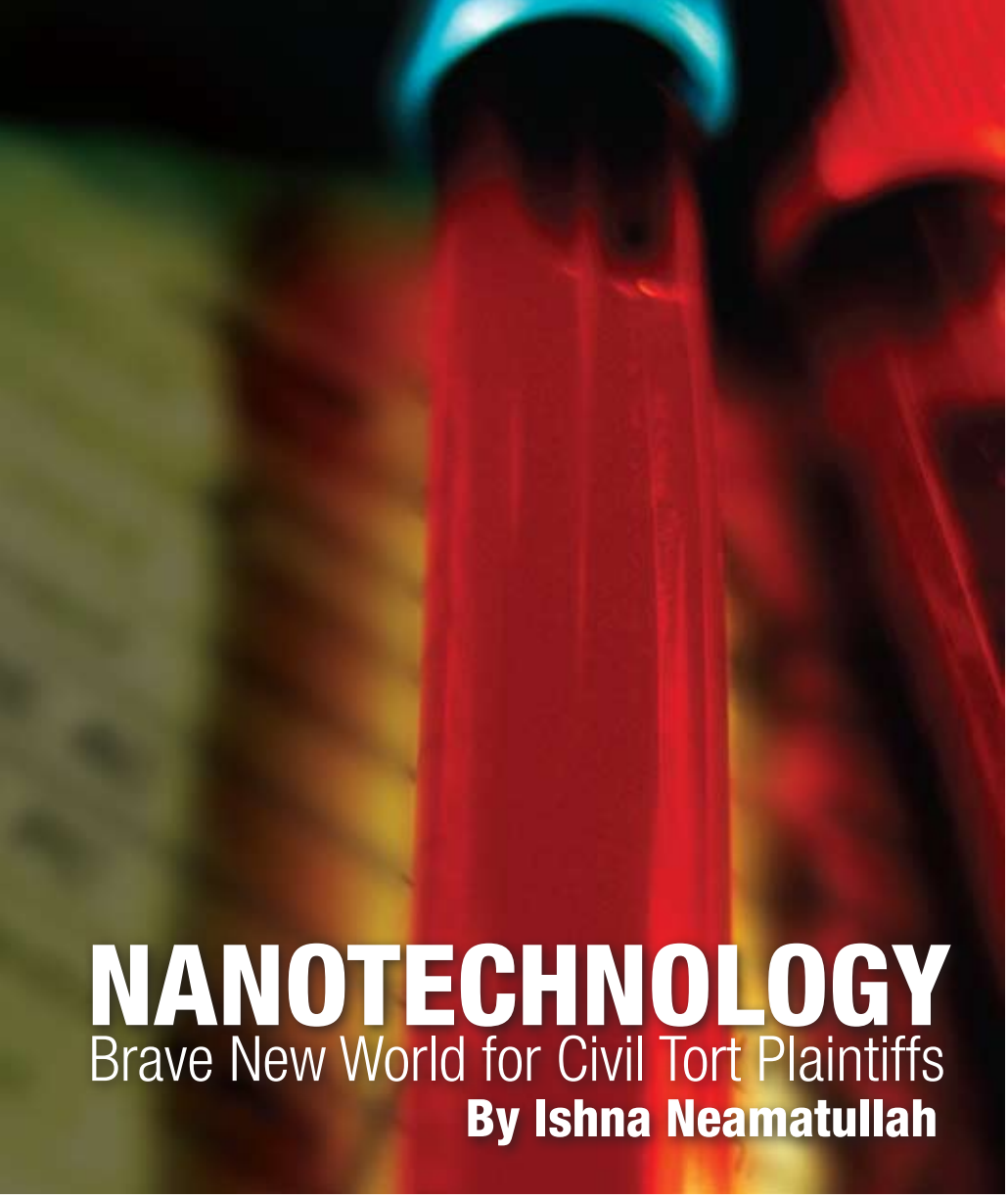

NANOTECHNOLOGY

Brave New World for Civil Tort Plaintiffs

By Ishna Neamatullah

In the popular imagination, nanotechnology is associated mainly with machines and computers. For example, 84 percent of people surveyed in the Public Awareness of Nanotechnology Study—the first national survey to examine public opinion on the use of nanotechnology for human enhancement—associated "nanotechnology" with machines and computers, while only 47 percent associated the term with consumer products.[1] If you, like more than half of those surveyed, do not associate nanotechnology with consumer products, consider any of the following. Eddie Bauer Ruston Nano-Care® khakis use a nanoscale coating to make the fabric resistant to water and stains.[2] Wilson Double Core tennis balls use a nanomaterial coating to preserve internal air pressure and prolong bounce.[3] Many sunscreens use nanoparticles to make typically white sunblocking ingredients appear transparent.[4]

In fact, in 2006, health and cosmetics comprised the majority of nanotech products, with about 125 products in the marketplace, followed by electronics and computers, with about 30 products.[5] Strong global R&D activity makes it certain that these tiny chemicals will continue to grow in their use and importance in our lives. And grow they will. By 2014, nanotechnology is estimated to be involved in the manufacture of $2.6 trillion of goods.

What Is Nanotechnology?

What is nanotechnology, and why has its use proliferated in so many industries? The NNI defines *nanotechnology* as the understanding and control of matter at dimensions between approximately 1 and 100 nanometers.[6] To visualize the minute dimensions involved, consider that a sheet of paper is about 100,000 nanometers thick.[7] At the nanoscale (1–100 nanometers), materials can exhibit chemical and toxicological properties that differ from their bulk counterparts, even though the material may have the same chemical formula at the nano and macro scales. It is these different properties at the nanoscale that are opening up new and improved uses of materials in almost every major industry.

Humans and the environment are vulnerable to adverse effects of nanomaterials in products, the workplace, and the environment. Although many resources are being used to discover the potential benefits of nanomaterials, our knowledge of their potential risks has tended to lag far behind. Comprehensive risk analysis, for example, has not yet been performed on most of the nanomaterials that are already under production and use. Nonetheless, recent animal testing has shown the adverse health effects of certain nanomaterials.[8] It would be silly at this stage to get carried away imagining the worst possible scenarios that could be brought about by nanotechnology, or by any new technology for that matter. Still, all parties involved—manufacturers, the federal government, and consumers—ought to be vigilant about what nanomaterials are being introduced in our cosmetics, drugs, food, and environment.

Regulatory Difficulties

Although proposals have been made to create a new set of regulations specifically directed at nanotechnology, federal regulatory agencies are currently struggling to force-fit existing regulations to nanomaterials that open up new dimensions of chemical and toxicological properties. Regulation of nanomaterials falls under the purview of several federal agencies. The Occupational Safety and Health Act (OSHAct) regulates occupational safety with regard to nanomaterials in the workplace.[9] Difficulties in effectively using the act result from technological limitations

in detecting nanomaterials and lack of information on their health risks.[10] The Food, Drug, and Cosmetic Act (FDCA) regulates nanomaterials used in drugs, medical devices, biologics, cosmetics, and food.[11] This act is considered to be effective in regulating drugs, biologics, and medical devices.[12] In these industries, manufacturers must show that a product is safe before being approved for sale.[13] However, the FDCA falls short in regulating cosmetics because it does not place any burden of reporting risk or injury on the manufacturer. A number of other laws regulate nanomaterials in other industries, most notably the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[14]

In all other industries, nanomaterials are regulated by the Toxic Substances Control Act (TSCA), which covers new chemical substances and their effects in all mediums (for example air, water, and so forth).[15] The TSCA requires manufacturers of "new" chemical substances to provide specific information for review prior to manufacturing the chemicals or introducing them into commerce. Under the TSCA, chemical substances that have no counterpart on the TSCA inventory (like buckyballs and carbon nanotubes) are considered "new."[16] However, the TSCA does not take into account the size of a substance or any other property in determining the newness of a substance. As such, there is a risk that many nanomaterials—which are different from their bulk counterparts precisely because of their new properties—will be registered as already "existing" substances under the TSCA, thereby removing the premanufacture review requirement. These factors make the TSCA ineffective in regulating the full and rapidly growing array of nanomaterials.

In view of these regulatory deficiencies, it is noteworthy that, in 2006, under its national Nanotechnology Initiative (NNI), the U.S. federal government spent less than 3 percent of its almost $1.3 billion nanotechnology budget primarily on risk research.[17] This disproportionately low-risk research spending raises questions about whether the U.S. federal government is taking reasonable care in the nanotechnology activities it is funding. Thus, on one hand, current regulator schemes are handicapping the government from effectively regulating nanotechnology in all industries and, on the other hand, the government is failing to take measures to regulate its own nanotechnology R&D activities. The party bearing most of the risk of nanotechnology is the consumer of nanoproducts, nanotech workers, the environment, and the large number of people who may become exposed to nanomaterials in the environment. It is unfortunate that the party that is best positioned and funded to mitigate or at least investigate these risks—the federal government—appears to be operating under the postcautionary principle.[18]

Negligence in the Nanotechnology Regime

A plaintiff who has been injured by nanotechnology may pursue a civil tort action as a means of redress. Tort law imposes on the members of a society guidelines on reasonable care, and provides remedies for behaviors that cause injury to other people or their property. By making remedies available, tort law imposes a risk of financial loss to the tortfeasor, and creates a more equitable allocation of the risk of injury.

Under the theory of negligence, for example, each person has a duty to moderate his or her actions by taking into account the interests of those who fall within the scope of foreseeable risk. In order to establish a negligence claim, the plaintiff makes a showing that the defendant failed to conform to a reasonable standard of care, and that the defendant's failure resulted actually and proximately in the plaintiff's injury. Injuries caused by nanomaterial may pose special problems in pursuing negligence actions against offending manufacturers or importers.

Take for example, the lack of a clear standard of care for manufacturers of nanomaterials or nanoproducts. Most manufacturers of nanomaterials and nanoproducts are not required to adhere to strict standards of risk research and monitoring before introducing their products in the marketplace. As a result, research on the harmful effects of nanomaterials in the human body and in the environment has been far outpaced by their production and use. The lack of comprehensive risk data has left federal regulatory agencies without a clear formulation of the standard of care that should be required of manufacturers and importers of nanomaterials and nanoproducts. It was only in 2008 that the EPA launched the Nanoscale Materials Stewardship Program (NMSP), which invites manufacturers and importers to voluntarily report available information on their engineered nanoscale materials.[19] Although the NMSP aims to encourage risk management practices, the NMSP leaves participation voluntary and does not define a standard of care with regard to adequate monitoring and testing of nanomaterials. This lack of an articulation of a reasonable standard of care will make it difficult for a plaintiff to show a deviation from such a standard in a negligence claim.

A defendant manufacturer may additionally introduce evidence of custom to show that its practices conformed to the customary practices of the nanotechnology industry as a whole. Following or disregarding a custom is not determinative of negligence, but may be used as one factor in determining negligence. For example, a manufacturer may argue that its risk monitoring and mitigation, although inadequate, comported with what has always been done and accepted by federal regulations. In some cases, an entire industry may be found to be lagging in its standard of care. However, it is difficult to foresee how a court may come to such a conclusion without comprehensive information of the risks posed by the nanotech industry, which is necessary to the formulation of a reasonable standard of care.

A negligence plaintiff is also likely to face difficulties in showing that a particular defendant's deviation from the

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reasonable standard of care is the cause of the plaintiff's injuries. People may come into contact with nanomaterials with or without their knowledge, in consumer products, in the nanoindustry workplace, or in the environment. For most of these nanomaterials, we don't yet have a comprehensive understanding of their toxicological properties, how they can enter the human body, how the body might react to them, their interactions with other materials in the environment, or how they might age in the body or in the environment. In addition, detection of nanomaterials remains difficult and requires sophisticated and expensive equipment. Thus, it is unclear how a doctor could reliably attribute a health problem to a particular nanomaterial.

What's more, current technologies do not permit reliable tracing of a particular offending nanomaterial back to its manufacturer. Traceability is valuable not only in giving consumers broader freedom in selecting or forgoing certain products, but it also may be critical to identifying the tortfeasor in a tort action. In 2002, for example, similar considerations motivated the Organization for Economic Co-operation and Development (OECD) to introduce unique identifiers for all approved genetically modified organisms.[20] Current technology, however, does not allow uniquely identifying nanomaterials. With the number of nanomaterials under research and in production multiplying rapidly each year, it is virtually impossible to tie an offending nanoproduct back to its manufacturer. And no tortfeasor means no tort claim, at least against the manufacturer.

Although approval by a federal regulatory agency generally does not preclude a civil tort action, manufacturers may defend themselves from a negligence action by pointing to federal approval. More alarmingly, in the case of medical devices, the Supreme Court has ruled that the Medical Device Amendments (MDAs) preemption clause insulates manufacturers from state tort claims challenging the safety and effectiveness of a medical device that received premarket approval from the FDA.[21] Thus, limitations of current regulatory schemes are not only allowing nanotech products to proliferate and enter markets with inadequate safety measures, but are also likely to contribute to the difficulties in pursuing state tort claims as a means of consumer redress.

Nanotechnology is dramatically increasing the usefulness of existing chemicals at the nanoscale, and promises technological breakthroughs in fields ranging from medicine to computing to cosmetics. Although the federal government is doing its part in nurturing and developing this promising new area of human innovation, it has not adequately addressed the fact that the consumers of nanoproducts and nanotech workers are being left vulnerable to all the unknown risks of nanotechnology. Civil tort actions—a popular means of redress for personal injuries—remain an impractical option for nanotechnology plaintiffs. The federal government should thus take a greater precautionary role, under the auspices of the NNI and its regulatory agencies, in identifying and mitigating the risks imposed by nanotechnology. ◆

Endnotes

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