

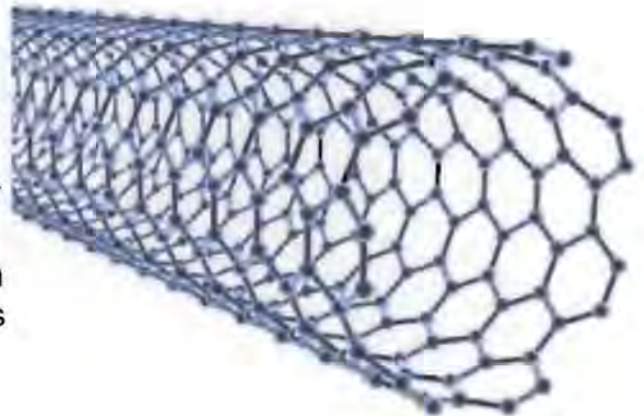
Nanotechnology is Entering a New Legal Frontier

By Krystina Steffen, *staff In Good Practice writer* – June 22, 2011

Nanotechnology is changing the products we use everyday – food, clothes, cars, and even medicine. For some, nanotechnology is a savior and a way to engineer goods and the landscape around us in powerful, novel ways. For others, it is a scary, uncharted territory with huge implications that could create a disaster.

Carbon Nano Tube

In the legal landscape, U.S. and world institutions are only now coming out with some guidance as to how to proceed with nanoparticles infusing almost every industry. To date, there have been no mass lawsuits or big settlements involving nanotechnology. Worldwide, only Germany has had a health recall when a nanotech bathroom cleaner called “Magic Nano” caused serious respiratory issues in 77 people in 2006. [1]



The Centers for Disease Control and Prevention and the National Institute for Occupational Safety and Health only just released their guidance and approaches for safely using nanotechnology in April. The U.S. Food and Drug Administration released their guidelines on FDA products that involve nanotechnology in June. As scientists race to create innovate nano products, companies embrace the technology in their quest for better products and profits, and consumers become surrounded by nanotechnology they might not even know is in their kitchen pantry or medicine cabinet.

Famed theoretical physicist Michio Kaku says that nanotechnology will become more pervasive and cheaper in the future. For example, chemotherapy is an aggressive way to treat cancer today. In the future that he sees, nanos will be able to “...zap cancer cells, individually, one by one. Those [nano] are molecules that hone in on cancer cells like smart bombs. In one trial, they were found to be 90 percent effective against tumors. When we have the capability to knock out cancer cells one by one, we will view chemotherapy like we view the leeches and bloodletting of a 100 years ago.” [2] But before treatment ever occurs, he envisions a future where your health status will be monitored through chips and nanos in the toilet. “Chips in toilets will look at proteins emitted from cancer colonies of just a 100 cancer cells, decades before a tumor actually forms – which means the word “tumor” could disappear from English language. This is going to revolutionize how we diagnose disease.”

Scientists, researchers and proponents of nanotechnology see the opportunity of this tiny structure to create good for the masses. As nanos become better known by regulators and consumer advocates, everyone has begun to try to define it. Overall, nanotechnology is defined by the National Nanotechnology Initiative as: 1) one billionth of a meter, on a scale of one to 100 nanometers; 2) the creation and use of structures, devices or systems with new properties and functions because of their small size; and 3) ability to be controlled or manipulated on the atomic scale. [3] To get a grasp of the

small size, there are 25.4 million nanometers in one inch and a human fingernail grows one nanometer per second. [4]

What nanotechnology lacks in size, it makes up for in power. Research and studies are just being produced that show the good and bad side of nanotechnology. Kaiku's referenced cancer trials are an obvious benefit to society. But other studies show nanotechnology's more disastrous side. Nanoparticles can easily interact with other materials and chemicals, sometimes causing more reactivity and toxicity. These particles can bypass the blood-brain barrier, affecting the central nervous system, organs, tissues, and even an expectant mother's placental barrier. Nanoparticles have been shown to be more absorbed by the body, increasing the bioavailability of how the nanoengineered material can affect the body. As the nonprofit advocacy group Food & Water Watch says, "To avoid similar disasters in the future, nanotechnology's effects should be adequately studied before they are allowed onto the market. Chemicals like PCBs and pesticides like DDT and dieldrin, which were once thought to be safe, were not truly understood until long after human health and environmental damage already occurred." [5]

Not only do consumer advocates push for research on nanotechnology-based products, they also want research on the associated risks nanos can have on the air and soil, their longevity and durability characteristics, potential for bioaccumulation, and risk assessments for workers who produce materials with them. With guided research and open communication, nanotechnology could create some amazing societal and economic impacts. As the authors of the International Handbook On Regulating Nanotechnologies say, "...society will need new thinking, new partnerships, and new mechanisms to balance the benefits of these technologies against their possible downsides. Anything less will prompt cries of illegitimacy and potentially compromise a promising new realm of technology innovation." [6]

Currently, a joint U.S.-U.K. study called "Risk Assessment for Manufactured Nanoparticles Used in Consumer Products" is backed by an almost \$2 million grant through the U.S. Environmental Protection Agency (EPA) to study human and environmental risks of consumer products that use nanotechnology. [7] The most common nano products use nano-based silver, carbon, titanium, silicon, zinc, and gold. [8] Many of the products come from the U.S., yet Europe and East Asia are also big producers. Most of the nanomaterial becomes used in products for health and fitness, home and garden, automotive, food and beverage, electronics and computers, and children's items. [9] Their research plans to assess human-simulated exposure to manufactured nanomaterials to further the EPA's regulatory duties of safeguarding the environment and public health.

Manufactured nano product investments by big multinational companies such as Nestlé, Kraft, Heinz, Altria, and Unilever in the food product category alone are estimated to be \$20 billion annually. [10] From the creation of healthier candy to innovations in non-stick cookware, and even self-cleaning window treatments, companies are vying for the latest in convenience and innovation to earn the consumer's dollar.

The Project on Emerging Nanotechnologies (PEN) says that, "...despite 10 years and billions of dollars of investment through the National Nanotechnology Initiative, oversight challenges for agencies like the Food and Drug Administration, Environmental Protection Agency, and the Consumer Product Safety Commission still exist," PEN research associate Dr. Todd Kuiken said. [11]

For example, the EPA is currently reviewing the presence of manufactured nano products in

pesticides to determine what effects these ingredients could do the environment and individuals. Nanoscale silver is used in such products as an antimicrobial agent to deter pests. [12] The EPA has been getting applications for pesticides and related flooring products that would benefit from these features that use the nanosilver as an active ingredient. "This approach will help ensure that the EPA is informed about the presence of nanoscale ingredients in pesticide products and allows a more thorough review of the potential risks." [13] The EPA is developing Significant New Use Rules (SNUR) that companies would have to use before they are able to manufacture, import, or process nanoproducts. The EPA's SNURs would require such companies to submit product chemistry, toxicology, exposure, and environmental data. [14]

Carbon is another frequently nano-created material. Carbon nanotubes (CNT) and carbon nanofibers (CNF) are being utilized in industrial and biomedical products. The products range from electronics, batteries, and solar cells to plastics, biosensors, biomedical devices, imaging techniques, and drug delivery systems. [15] As these products are being made, use, discarded, or recycled, "workplace exposure measurements of CNT and CNF indicate the potential for worker exposure." [16] The CDC reports that animal studies with CNT and CNF show pulmonary inflammation and fibrosis as a result of these materials.

The CDC now warns that employers should keep airborne concentrations of CNT or CNF below 7 $\mu\text{g}/\text{m}^3$ within a total eight-hour workday. [17] Workers need to be educated about these nanomaterials, wear protective equipment, and avoid handling it in a free particle state, such as in powder form.

This comes on the heels on the European Food Safety Authority (EFSA) publishing the first assessment of nanotechnology in food and feed chain. [18] With the prevalence of nanotech in food additives, enzymes, flavorings, packaging, and feed applications, engineered nanomaterials pose a great challenge, especially with the products we use every day. The EFSA set the framework for risk assessment and testing at the request of the European Commission.

Although hardly any recalls or lawsuits have emerged just yet, as lawyer Ron Wernette and author of the Nanotort Law Blog says, "Experience teaches that when there are concerns about possible health and safety hazards, litigation – feeding on public and political risk perception – is never far behind." [19] From government oversight to product manufacturers, the duties to make products safe and make the public aware are going to become that much more important. The legal field will be a captivating arena to see the intersection of the legal, ethical, and social implications of nanotechnology. Attorneys will want to hone their science skills as these technologies become widely used and their effects seen over the course of decades, not just years. Evidence suggests that as nanotechnology permeates every part of our living and synthetic existence, we will undoubtedly see legal challenges in every type of law practice: personal injury, environmental, consumer protection, real property, class action, and workers' compensation.

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