The field of nanotechnology began just 10 years ago, but in this short time, it has become ubiquitous. Nanomaterials have been incorporated into products ranging from sporting goods to drug delivery devices. Use continues to grow, and $1 trillion in sales of products incorporating nanotechnology is predicted by 2015.

As the field has expanded, so too has the study of potential health and safety effects and the regulation of nanomaterials. As with other areas of technological advancement, litigation related to nanotechnology—“nanotorts” for short—is likely to follow. This article briefly discusses steps that nanotech companies can take to prepare for, or fend off, a nanotort lawsuit.

Companies should begin by keeping abreast of ongoing research into the health and safety effects of nanomaterials. While this research is in its infancy, some studies indicate that certain types of nanoparticles may produce toxicological effects.

According to a 2009 National Institute for Occupational Safety and Health (NIOSH) report, nanomaterials can enter the body through inhalation, ingestion, and absorption and be transported via the bloodstream to various organs. NIOSH cited animal studies showing a potential for adverse effects including pulmonary inflammation, tissue irritation and damage, and lung tumors.

Each type of nanoparticle may have unique effects depending on its size, shape, surface area, and chemical properties. One recent study focused on carbon nanotubes commonly used in electronic devices. The “Poland” study, published in *Nature Nanotechnology* in 2008, suggested that this nanomaterial, which physically resembles asbestos fibers, can, like asbestos fibers, cause inflammation and granulomas in the lungs of laboratory mice, raising concerns that carbon nanotubes could cause mesothelioma.

Although mesothelioma was not detected during the Poland study, and despite the fact that its design and implementation have been criticized as not following generally accepted scientific standards, plaintiffs’ lawyers will use these sorts of studies to build a case that exposure to nanomaterials caused or exacerbated diseases and/or created future risks warranting medical monitoring.

In turn, nanotechnology defendants will advance defenses typically asserted in other toxic exposure cases such as: (1) whether plaintiff was exposed to defendant’s product; (2) whether the nanoproduct in question is capable of causing the disease in question and, if so, in what dose; (3) whether the exposure occurred after the disease process commenced; (4) whether this product, in this dose, caused plaintiff’s disease; (5) the materiality of the dose relative to everyday risks; and (6) whether factors other than defendant’s product caused the disease.

Needless to say, nanotech companies will need to remain abreast of a rapidly evolving body of research. A company could rely on its internal environment and safety personnel to track developments, retain experts, pool resources with similarly situated companies to monitor research, or even conduct its own health and safety studies. The more informed a company, the better positioned it will be to ensure worker health and safety.
safety, provide adequate warnings to consumers, and design products with lower health risks, reducing litigation exposure.

To help curtail litigation exposure, nanotech companies should also monitor regulations that are being considered and promulgated at all levels of government as well as industry codes currently being developed by various groups. Although there is no comprehensive regulatory scheme specifically addressing nanotechnology, efforts are under way to regulate specific aspects and potential risks associated with the nanotech industry.

**Regulation**

At the federal level, the most notable steps have been taken by EPA under the Toxic Substances Control Act, adopting or proposing regulations governing carbon nanotubes, siloxane-modified silica, and alumina nanoparticles. The regulations impose notice requirements when a company plans to manufacture or import these materials, as well as restrict their production or use. EPA recently announced its intention to propose a rule that would bring all intentionally manufactured nanoscale chemicals within its oversight. It also has begun to regulate specific nanomaterials in pesticides under the Federal Insecticide, Fungicide and Rodenticide Act.

Meanwhile, the FDA is researching potential health effects via skin absorption. The Consumer Product Safety Commission is planning to develop protocols to assess the potential release of airborne nanomaterials from consumer products. And numerous OSHA standards may be applicable where employees are exposed to nanomaterials.

Even at the state and local level, legislators and city councils have begun addressing nanotech issues. For example, the state of California, to support the eventual adoption of a regulatory program, has issued notices to nanotech companies requesting information regarding toxicity data, worker exposures, and safety measures.

Berkeley, CA, and Cambridge, MA, have established ordinances requiring registration and disclosure of the production and use of nanoscale materials.

NIOSH, the American National Standards Institute, and the International Standards Organization are also working on standards in areas such as testing, material specifications, risk management, and health, safety, and the environment. NIOSH recently issued guidelines for addressing engineering controls (e.g., ventilation systems), selecting and using personal protective equipment, and training workers in the proper handling of nanomaterials.

Courts may judge companies by these regulatory standards and industry-wide codes and practices. In some states, violating a regulation constitutes negligence per se. Where the plaintiff falls within the class of individuals that the regulation was intended to protect, the company may be liable where the violation caused the alleged injury. In other states, it may constitute evidence of a breach of duty. Similarly, where a company has not followed an industry standard, the plaintiff will argue that its conduct was unreasonable and breached the requisite standard of care.

Increasing familiarity with scientific research, the regulatory environment, and applicable industry codes will enable nanotech companies to take affirmative measures, such as improving worker safety or minimizing consumer exposures, to avoid lawsuits altogether. This should not be a one-time occurrence. Companies should establish a process of regular evaluation and risk assessment that will account for the rapidly changing nanotech industry. This comprehensive and interdisciplinary program could include environment, health, and safety personnel, and individuals in the engineering, operations, marketing, and legal fields.

Finally, companies should evaluate their insurance. While general liability policies are intended to cover “new” theories of liability, insurers may be resistant to opening the door on a new liability and paying without a court order. Given the time, expense, and risk associated with securing coverage under existing policies, companies should consider whether additional coverages (such as a nanospecific insurance policy announced earlier this year) are desirable or necessary.

In the years to come, there undoubtedly will continue to be substantial technological developments in the field of nanotechnology. While companies focus on these developments, they should be vigilant of developments in the study of health and safety effects and in the regulation of nanomaterials in order to minimize, if not eliminate, regulatory and litigation risks.