

The Implications of Recent Nanomaterials Toxicity Studies for the Nanotech Community

PAUL STIMERS*

ABSTRACT

The nanotech community continues to wrestle with questions regarding the toxicity of engineered nanomaterials. One recent study that has received substantial attention shows that certain types of multi-walled carbon nanotubes may be toxic in animal models. It is unclear what this study means for companies working with these materials and other types of carbon nanomaterials. In this article, lawyer Paul Stimers addresses the implications of this study on the nanotech community. He reviews recent data, identifies issues posed by the study for companies working with engineered nanomaterials, describes the potential risks and benefits of the study to the nanotech community, and discusses federal policy concerning the toxicity of engineered nanomaterials.

I. INTRODUCTION

In a study published in *Nature Nanotechnology* on May 20, 2008, a group of scientists reported that “carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study.”¹ As reported by the non-technical media, the study appeared to suggest a broad similarity between nanotechnology and asbestos—one that might have harmful results in terms of human health, corporate liability and nanotechnology market development.

Although the study presents a clear challenge to the nanotechnology community, there may be a silver lining if it stimulates additional research and development and the adoption of precautionary measures by companies handling nanomaterials. The nanotechnology law and business community must understand the study and its implications, or risk regulation, lawsuits, and loss of market. This article reviews study, assesses the study’s implications for nanotechnology companies, suggests avenues for further research, and describes the ongoing response of the nanotechnology field in the federal policy arena.

* Paul Stimers is an attorney at K&L Gates LLP, public policy counsel for the NanoBusiness Alliance. The views expressed in this article are his own, and not necessarily those of K&L Gates or the NanoBusiness Alliance.

¹ Craig A. Poland et al., *Carbon Nanotubes Introduced Into the Abdominal Cavity of Mice Show Asbestos-like Pathogenicity in a Pilot Study*, NATURE NANOTECHNOLOGY 423, 423 (May 20, 2008).

II. THE STUDY

The study involved exposing the mesothelial lining of the body cavity of mice to four different samples of multi-walled carbon nanotubes from three different suppliers. The samples varied in their composition, with nanotubes of different lengths, diameters, soluble metal compositions, and morphology (some were balled agglomerates, some were tangled, some were regular bundles of nanotubes, some were “ropes,” and some were single nanotubes). Each material was injected into the body cavity, which was later washed to provide a mixture of cells and molecules. This mixture was assessed by measuring protein levels and cell populations. The researchers looked for scar-like structures (lesions) called granulomas, which would appear in the case of exposure to long asbestos fibers.

Controlling for other variables, analysis showed that samples containing long, needlelike carbon nanotube fibers caused granulomas, while the samples that did not contain long fibers did not. The researchers noted that differences in the source, preparation, and purification of different commercial carbon nanotubes could lead to potential differences in physicochemistry and contaminating metals in the samples, and suggested that more research be conducted to verify their conclusion.²

The researchers stated that while long, needlelike fibrous carbon nanotubes could cause a hazard, the only published study on workplace exposure to carbon nanotubes found airborne particles that resembled the tangled morphology described above—particles that would not be predicted to behave like asbestos.³

The researchers concluded that asbestos-like pathogenic behavior associated with carbon nanotubes is based on length.⁴ They did not address whether nanotubes would be able to reach the mesothelium of humans in sufficient numbers to cause mesothelioma following inhalation exposure, or whether the granulomas that developed would go on to cause mesothelioma. The study also did not rule out the possibility that shorter, balled, or tangled nanotube agglomerations may present other health effects. The researchers pointed to several areas in which they believe further research is warranted.⁵

III. ISSUES FOR COMPANIES

No company that manufactures or uses carbon nanotubes should be pleased to have them linked with asbestos, which has cost companies tens of billions of dollars. The risks for carbon nanotube manufacturers, those that employ carbon nanotubes in their manufacturing processes or include them in final products, and users fall into three categories: regulation, liability, and loss of market.

1. Regulation

Studies such as this one are viewed in many quarters as invitations—even imperatives—to regulate. Unions may call for the Occupational Safety and Health Administration (OSHA) to develop standards and protections for workers exposed to carbon nanotubes, and consumer advocates may prod the Consumer Product Safety Commission (CPSC) to examine carbon nanotubes in consumer products. The Environmental Protection Agency (EPA) may become more involved if carbon nanotubes appear to be damaging wildlife or human health in the environment. And the Food and Drug Administration (FDA) is exploring how best to address nanotechnology in the many products it regulates.

Most nanotechnology companies already incorporate significant safeguards, including containment, air filtering, and protective gear, to prevent carbon nanotubes from coming into direct contact with

² *Id.* at 4.

³ *Id.*

⁴ *Id.* at 5.

⁵ *Id.*

humans or the environment. Many companies take precautions that go well beyond what appears to be needed, out of an abundance of caution. In all cases, however, these are measures that each company has determined are appropriate, economical, and compatible with the business.

What works for an individual company may not be at all what a regulatory agency decides to impose. Nanotechnology companies—especially small, growing businesses without large regulatory compliance teams—may soon find themselves faced with burdensome and expensive requirements that make little sense when applied to their individual situation.

2. Liability

As nanotechnology applications penetrate the marketplace, the risk of litigation increases. Plaintiff's attorneys are beginning to pay attention to studies such as this one for possible future use in product liability and negligence lawsuits. Expect to see this study as an exhibit supporting the claim that a defendant company knew or should have known that carbon nanotubes posed a hazard to employees or customers.

Carbon nanotube manufacturers and users should view this shot across the bow as an opportunity to reexamine the safeguards that protect their workers and their customers. As mentioned above, most nanotechnology companies already take strong safety precautions, but now would be a good time for a careful review of those precautions. And while it is important for executives to know the strength of their companies' safeguards relative to the industry as a whole, plaintiff's lawyers may claim that the appropriate standard of care is one that nobody in the industry is meeting.

3. Loss of Market

As challenging and expensive as regulation and liability can be, they pale in comparison to the danger that consumers will simply decide that the benefits of nanotechnology are not worth the perceived risks. If this happens, as it so famously did with genetically-modified food, large portions of the consumer nanotechnology market could be heavily impacted. Consumer resistance to nanotechnology could increase dramatically, bringing with it suspicious scrutiny and public outcry. Consumers are unlikely to differentiate between types and configurations of carbon nanotubes; indeed, they may not differentiate between nanotubes and other types of nanoparticles. In such an environment, nanotechnology start-ups could find it more difficult to develop a market, while major consumer products companies that incorporate nanotechnology into their products could face backlashes that extend to other product lines. The nanotechnology economy and nanotechnology R&D could be set back years or decades.

IV. POTENTIAL SILVER LINING

1. Stimulation of Further Research

The researchers strongly recommended that further research regarding carbon nanotubes' physiological effects be conducted as a result of their findings. They suggest that the following issues be examined: biopersistence of carbon nanotubes; carbon nanotube buildup in the mesothelium; linkage between inhalation exposure, granulomas, and mesothelioma; and various tests of carbon nanotube samples to determine whether other factors or impurities may have had an unmeasured impact. More broadly, the researchers suggest that further research into other potential causes of carbon nanotube pathogenicity would be warranted as well.⁶

⁶ *Id.* at 6.

The researchers make a good case for their proposals. Further examination of several related issues may also be warranted. These include: the respirability of different types of carbon nanotubes at various stages in the production process and after integration into final products; total lifecycle research; and investigations of threshold dosage levels. This research would build on health studies already conducted on ultrafine particles such as quartz.

The nanotechnology business community has joined environmental and consumer organizations in calling for increased federal funding for research into the environmental, health, and safety (EHS) effects of nanoparticles. In the ongoing effort to reauthorize the National Nanotechnology Initiative in Congress, nanotechnology EHS research has been a top priority. There is broad agreement that EHS research funding should be increased substantially, and a consensus has developed around a needs-based, strategy-driven research agenda that aims to spend approximately ten percent of total annual federal R&D funding on EHS research.

Additional research will likely result in a clearer understanding of which nanomaterials are non-toxic in which configurations and in which circumstances. Eventually, EHS researchers hope to develop a characterization regime that includes predictive modeling—one that will help nanoparticle manufacturers anticipate EHS problems and design their nanoparticles with characteristics that avoid those problems. For nanomaterials that cannot be designed to be safe, further research will likely indicate how best to handle them so that hazards are contained and exposure is limited.

2. Review of Safety Measures

As discussed above, most nanotechnology companies already take significant measures to ensure that they are handling their nanomaterials safely. However, this study will serve as an impetus for these and other companies to review their safety procedures carefully. The study may provide motivation for many companies to participate in industry-wide standards and best practices development efforts, as well as cooperative industry-agency nanomaterial management partnerships.

V. THE FEDERAL POLICY RESPONSE

Organizations such as the NanoBusiness Alliance—the voice of the American nanotechnology business community—have worked over the past several years to help policymakers understand nanotechnology. They have been careful to address potential risks and hazards, in addition to the many benefits of nanotechnology, and have consistently called for increased funding for the EHS research described above. As a result, when this study was released, policymakers turned to the Alliance to help put it in context.

The Alliance has reiterated its support for increased EHS research to help identify potential risks and hazards, with the goal of giving companies the information they need to eliminate or design around them. The Alliance noted, for example, that the study found that only certain types of carbon nanotubes behaved like asbestos. If the other types provide the desired capabilities, perhaps those can be used instead in most cases.

The Alliance has also reminded policymakers that a facile comparison between asbestos and carbon nanotubes obscures important differences. Asbestos was widely used for decades before its health effects were understood; carbon nanotubes are only just being introduced and being carefully studied. Asbestos involved widespread exposure of large numbers of workers; carbon nanotubes, because of the process controls required to make them, generally involve minimal or no exposure to small numbers of workers. Additionally, for many commercial applications of carbon nanotubes, the nanotubes are embedded in layers of polymers and not capable of being released into the environment. Asbestos solved some problems while creating others; carbon nanotubes can help solve many more problems, and can be

designed, manufactured, processed, and incorporated into products safely. Asbestos manufacturers had little incentive to “get it right” when it came to mining, processing, and deploying asbestos; nanotechnology companies have every incentive to do so.

The “asbestos” study was released just as Congress was considering reauthorizing the 21st Century Nanotechnology Research and Development Act. The reauthorization bill expands EHS research as requested by the nanotechnology business community, but does not—at this point—overreact to the study through regulation or other mandates. So far, Congress has acted responsibly in conjunction with an industry that has acted responsibly itself. However, continuous engagement is necessary to prevent fear and confusion from gaining a foothold.

