Risk Management and Minimizing Legal Exposure

October 17, 2013

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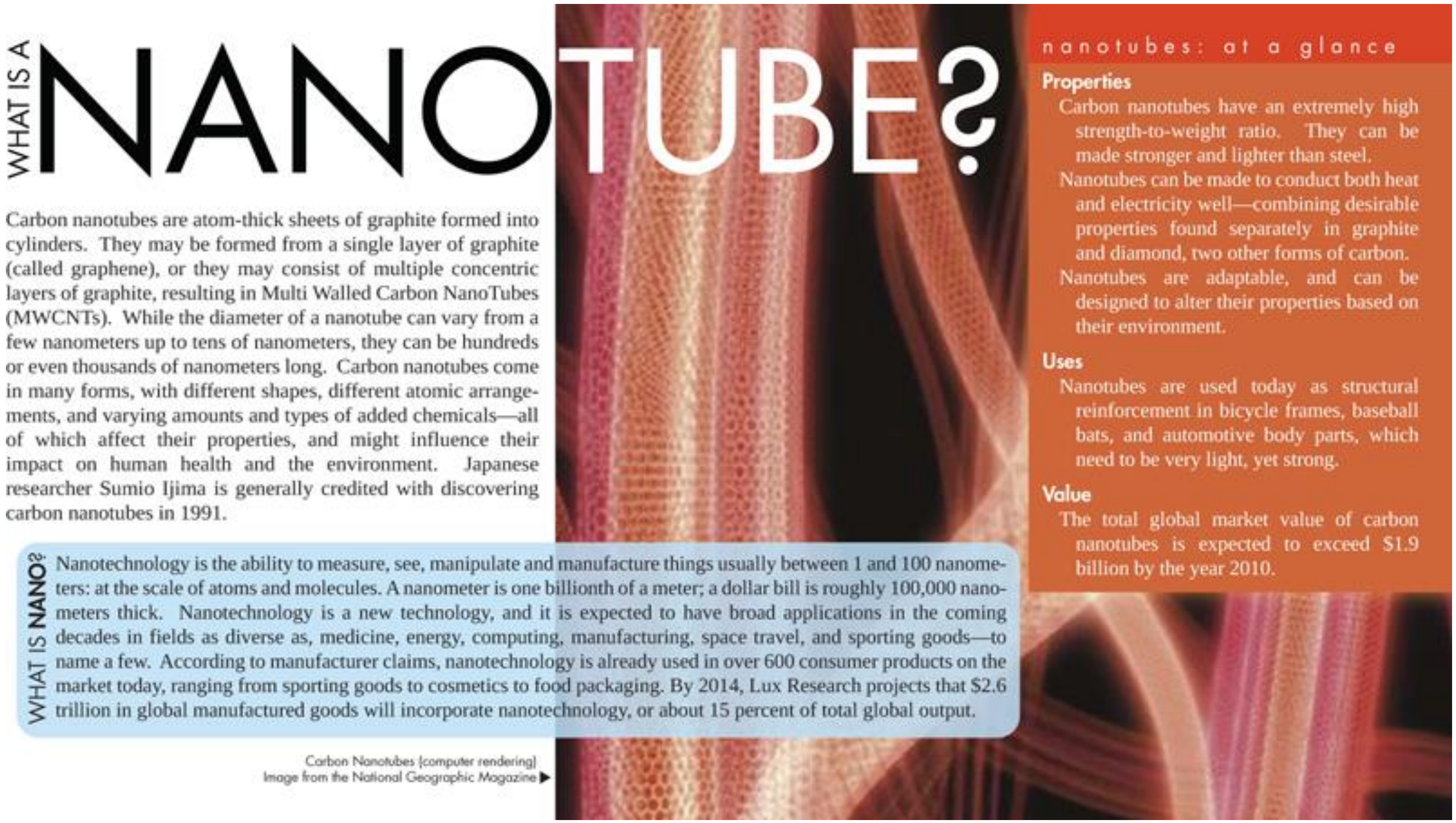
Nanotechnology is in the News



WHAT IS A NANOTUBE?

Carbon nanotubes are atom-thick sheets of graphite formed into cylinders. They may be formed from a single layer of graphite (called graphene), or they may consist of multiple concentric layers of graphite, resulting in Multi Walled Carbon NanoTubes (MWCNTs). While the diameter of a nanotube can vary from a few nanometers up to tens of nanometers, they can be hundreds or even thousands of nanometers long. Carbon nanotubes come in many forms, with different shapes, different atomic arrangements, and varying amounts and types of added chemicals—all of which affect their properties, and might influence their impact on human health and the environment. Japanese researcher Sumio Ijima is generally credited with discovering carbon nanotubes in 1991.

WHAT IS NANO? Nanotechnology is the ability to measure, see, manipulate and manufacture things usually between 1 and 100 nanometers: at the scale of atoms and molecules. A nanometer is one billionth of a meter; a dollar bill is roughly 100,000 nanometers thick. Nanotechnology is a new technology, and it is expected to have broad applications in the coming decades in fields as diverse as, medicine, energy, computing, manufacturing, space travel, and sporting goods—to name a few. According to manufacturer claims, nanotechnology is already used in over 600 consumer products on the market today, ranging from sporting goods to cosmetics to food packaging. By 2014, Lux Research projects that $2.6 trillion in global manufactured goods will incorporate nanotechnology, or about 15 percent of total global output.

Carbon Nanotubes (computer rendering)
Image from the National Geographic Magazine ▶

nanotubes: at a glance

Properties

- Carbon nanotubes have an extremely high strength-to-weight ratio. They can be made stronger and lighter than steel.
- Nanotubes can be made to conduct both heat and electricity well—combining desirable properties found separately in graphite and diamond, two other forms of carbon.
- Nanotubes are adaptable, and can be designed to alter their properties based on their environment.

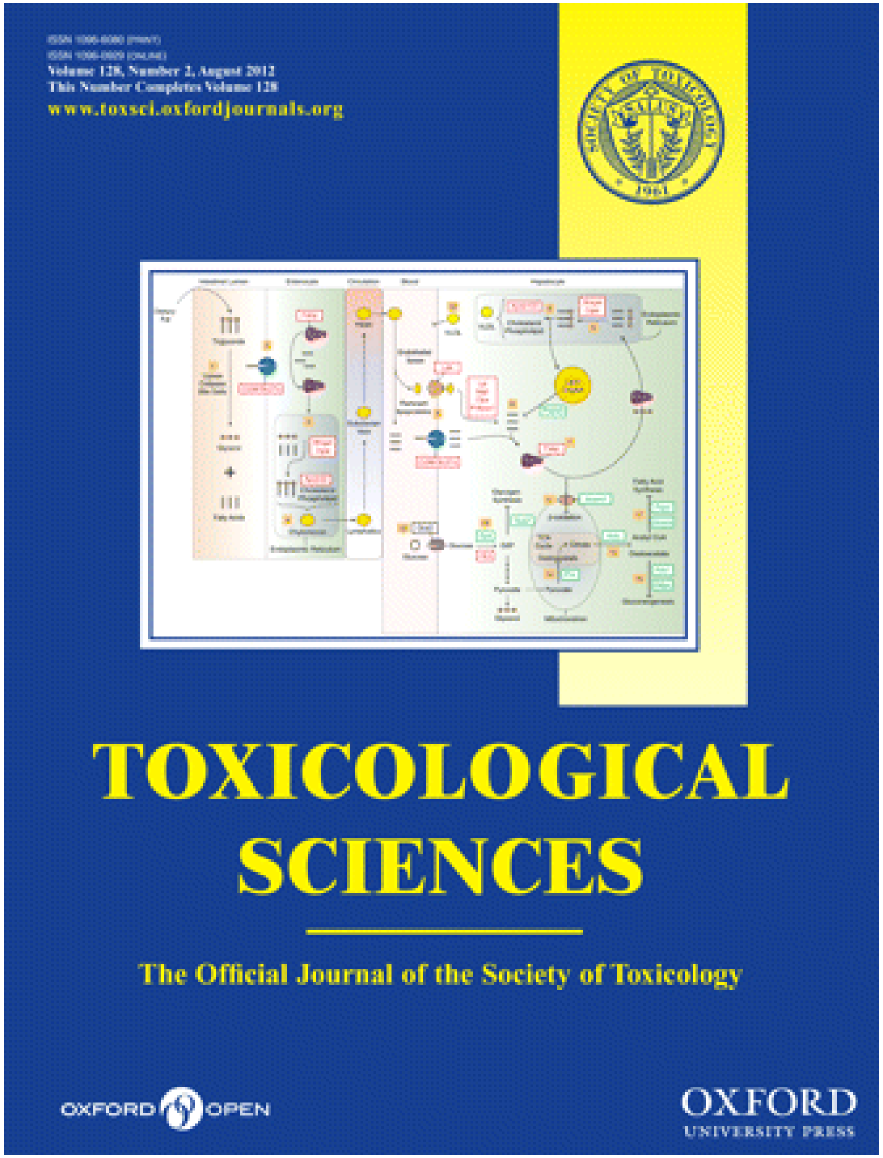
Uses

- Nanotubes are used today as structural reinforcement in bicycle frames, baseball bats, and automotive body parts, which need to be very light, yet strong.

Value

- The total global market value of carbon nanotubes is expected to exceed $1.9 billion by the year 2010.

BUT NOT ALL THE NEWS IS GOOD



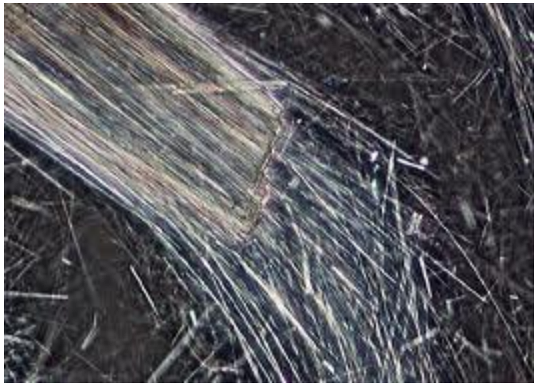
Ken Donaldson, professor of respiratory toxicology at the University of Edinburgh, said: "Concern has been expressed that new kinds of nanofibers being made by nanotechnology industries might pose a risk because they have a similar shape to asbestos."

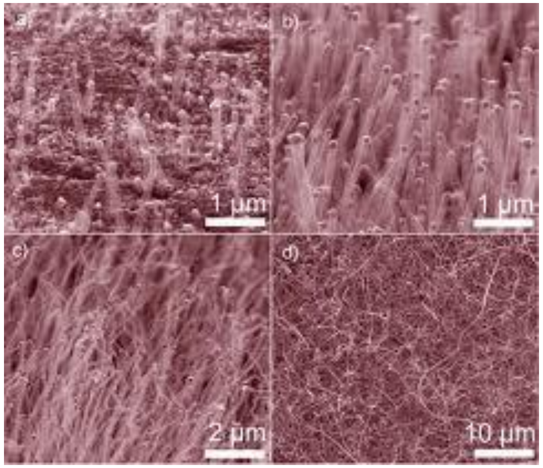
“Nanofibers may pose health risk‘”

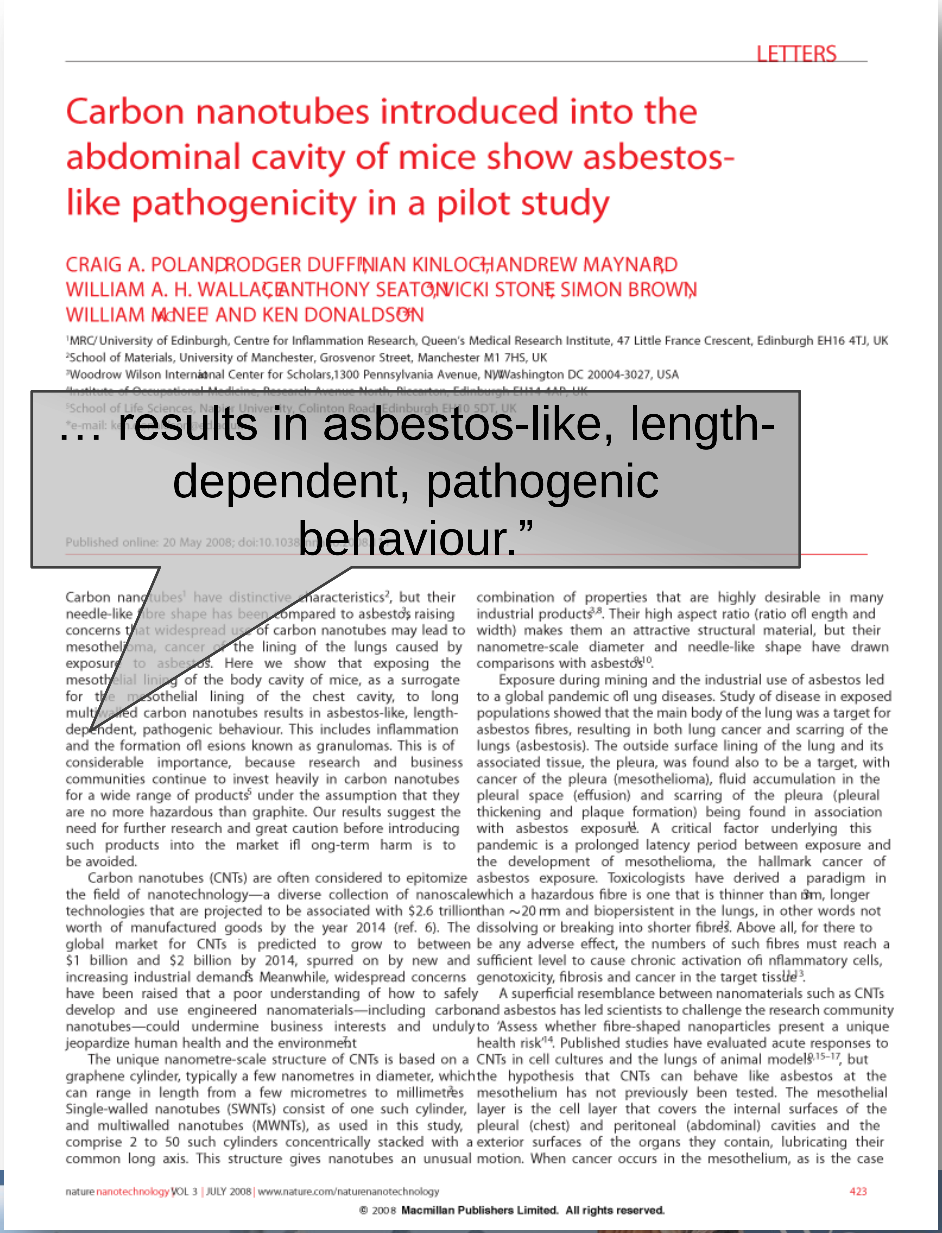
1,000 times smaller than a human hair

“Inhaling tiny fibers made by the nanotechnology industry could cause similar health problems to asbestos,” say researchers.

Earlier Studies Made the Same Comparison







Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study

CRAIG A. POLAND[1], RODGER DUFFIN[1], IAN KINLOCH[2], ANDREW MAYNARD[3], WILLIAM A. H. WALLACE[1], ANTHONY SEATON[4], VICKI STONE[5], SIMON BROWN[1], WILLIAM MacNEE[1] AND KEN DONALDSON[1]*

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“… results in asbestos-like, length-dependent, pathogenic behaviour.”

Published online: 20 May 2008; doi:10.1038

Carbon nanotubes[1] have distinctive characteristics[2], but their needle-like fibre shape has been compared to asbestos[3], raising concerns that widespread use of carbon nanotubes may lead to mesothelioma, cancer of the lining of the lungs caused by exposure to asbestos[4]. Here we show that exposing the mesothelial lining of the body cavity of mice, as a surrogate for the mesothelial lining of the chest cavity, to long multiwalled carbon nanotubes results in asbestos-like, length-dependent, pathogenic behaviour. This includes inflammation and the formation of lesions known as granulomas. This is of considerable importance, because research and business communities continue to invest heavily in carbon nanotubes for a wide range of products[5] under the assumption that they are no more hazardous than graphite. Our results suggest the need for further research and great caution before introducing such products into the market if long-term harm is to be avoided.

Carbon nanotubes (CNTs) are often considered to epitomize the field of nanotechnology—a diverse collection of nanoscale technologies that are projected to be associated with \$2.6 trillion worth of manufactured goods by the year 2014 (ref. 6). The global market for CNTs is predicted to grow to between \$1 billion and \$2 billion by 2014, spurred on by new and increasing industrial demands[5]. Meanwhile, widespread concerns have been raised that a poor understanding of how to safely develop and use engineered nanomaterials—including carbon nanotubes—could undermine business interests and unduly jeopardize human health and the environment[7].

The unique nanometre-scale structure of CNTs is based on a graphene cylinder, typically a few nanometres in diameter, which can range in length from a few micrometres to millimetres[2]. Single-walled nanotubes (SWNTs) consist of one such cylinder, and multiwalled nanotubes (MWNTs), as used in this study, comprise 2 to 50 such cylinders concentrically stacked with a common long axis. This structure gives nanotubes an unusual combination of properties that are highly desirable in many industrial products[3,8]. Their high aspect ratio (ratio of length and width) makes them an attractive structural material, but their nanometre-scale diameter and needle-like shape have drawn comparisons with asbestos[9,10].

Exposure during mining and the industrial use of asbestos led to a global pandemic of lung diseases. Study of disease in exposed populations showed that the main body of the lung was a target for asbestos fibres, resulting in both lung cancer and scarring of the lungs (asbestosis). The outside surface lining of the lung and its associated tissue, the pleura, was found also to be a target, with cancer of the pleura (mesothelioma), fluid accumulation in the pleural space (effusion) and scarring of the pleura (pleural thickening and plaque formation) being found in association with asbestos exposure[11]. A critical factor underlying this pandemic is a prolonged latency period between exposure and the development of mesothelioma, the hallmark cancer of asbestos exposure. Toxicologists have derived a paradigm in which a hazardous fibre is one that is thinner than 3 μm, longer than ~20 μm and biopersistent in the lungs, in other words not dissolving or breaking into shorter fibres[12]. Above all, for there to be any adverse effect, the numbers of such fibres must reach a sufficient level to cause chronic activation of inflammatory cells, genotoxicity, fibrosis and cancer in the target tissue[11,13].

A superficial resemblance between nanomaterials such as CNTs and asbestos has led scientists to challenge the research community to ‘Assess whether fibre-shaped nanoparticles present a unique health risk’[14]. Published studies have evaluated acute responses to CNTs in cell cultures and the lungs of animal models[9,15–17], but the hypothesis that CNTs can behave like asbestos at the mesothelium has not previously been tested. The mesothelial layer is the cell layer that covers the internal surfaces of the pleural (chest) and peritoneal (abdominal) cavities and the exterior surfaces of the organs they contain, lubricating their motion. When cancer occurs in the mesothelium, as is the case

Carcinogenicity is Assumed

"We knew that long fibres, compared with shorter fibres, could **cause tumours**, but until now we did not know the cut-off length at which this happened."

"This research is particularly interesting as it gives us an indication of the size of fibre that might lead to **mesothelioma** if inhaled."

"If confirmed by subsequent studies, this minimum fibre length can be cited in **industry guidelines** to help ensure people are not exposed to the sorts of fibres that may lead to such deadly diseases."

What About Asbestos Litigation?

Rumors of its death are premature, but . . .

Everyone is looking for the next asbestos…

The Comparison is Easily Made

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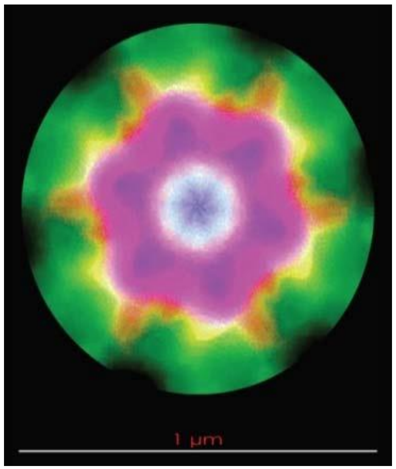
The Literature Stacks Up

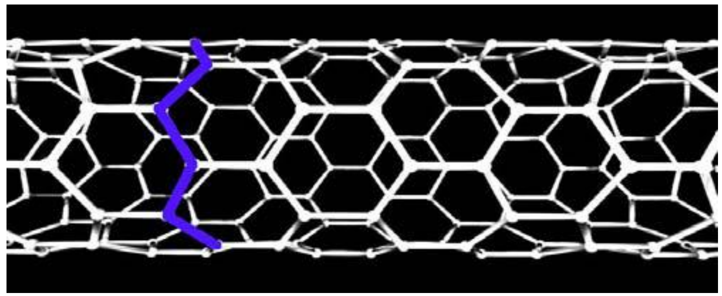
- Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma.
- Song, et al. European Respiratory Journal (Sept. 2009)

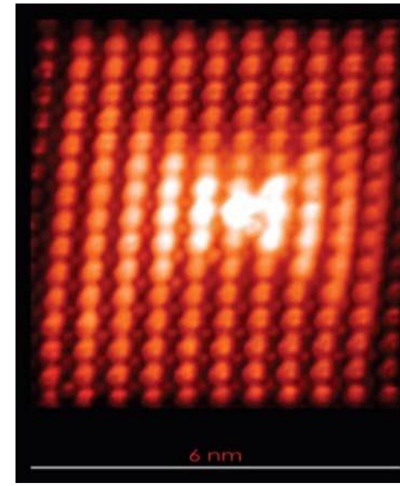
SCCS Calls for Experts on the Safety Assessment of Nanomaterials in Cosmetic Products

Safety Concerns Abound

Risk perception and risk communication with regard to nanomaterials in the workplace







Soybean susceptibility to manufactured nanomaterials with evidence for food quality and soil fertility interruption

Nanotechnology Law Blog
REGULATORY & LEGAL DEVELOPMENTS INVOLVING NANOTECHNOLOGIES & NANOMATERIALS
PUBLISHED BY Bergeson & Campbell, P.C.

ISO Preparing Labeling Guidance for Manufactured Nano-Objects and Products Containing Manufactured Nano-Objects

SCENIHR Issues Call for Information and Experts on Health Effects of Nanomaterials Used in Medical Devices

FDA Directed to Study Nanomaterials

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act became law, charging the Secretary of Health and Human Services to "intensify and expand activities related to enhancing scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated" by FDA.

Industry Safety Assurances Get Little Media Attention

The 2011 Nanodermatology Society Position Statement on Sunscreens

Introduction

The harmful effects of both short-term and long-term sun exposure have been well described and range from accelerated skin aging to skin cancer, a potentially fatal condition. One of the most common approaches to prevent this damage or harm is with the application of sunscreens, which contain a variety of chemicals and minerals that act to block or reflect ultraviolet (UV) radiation, the component of sunlight that is responsible for many of its harmful effects. For years, titanium dioxide (TiO_2) and zinc oxide (ZnO) have been used in sunscreens since they serve as a physical barrier to both short (UVB) and long wave (UVA) UV radiation and thus decrease the amount of radiation to which the skin is exposed. However, these ingredients in their native state are not water soluble, but are opaque and coat the skin when applied with an oily and cosmetically displeasing white residue, resulting in limited consumer use. In recent years, there has been a revival of TiO_2 and ZnO use in sunscreens as the science of nanotechnology has allowed for improved versions of these products.

Nanotechnology involves the design, production, and application of materials that are extremely small, (1 nanometer = one billionth of a meter)[1]. When this technology is applied to sunscreens, specifically nano-sized TiO_2 and ZnO, these products do not have the thick feel or unsightly chalky film as compared to their predecessors. Even more importantly, sunscreens with these nanomaterials offer superior UV protection when compared to conventional formulations[2,3]. However, many organizations and regulatory bodies have raised concerns regarding the safety of nanoparticle sunscreens.

These concerns are based on the unique properties of materials at the "nano" level, which include increased surface area to weight ratio (provides more surface to interact with the environment) and enhanced skin and organ penetration capabilities. As such, agencies wonder if these nanoparticles are toxic to living cells and if they are capable of being absorbed through the skin into the bloodstream. Regulatory agencies have reviewed studies that have focused on the safety of nanoparticle formulations. These results have been presented by the Environmental Protection Agency (EPA), Environmental Working Group (EWG), European Union (EU) and Australia's Therapeutic Goods Administration (TGA), among other groups. This paper reviews important questions regarding titanium and zinc nanoparticles and sunscreen safety.

Are TiO_2 and ZnO nanoparticles toxic to cells?

Recently, it was discove[illegible] nanosized [illegible] and zinc generate free radicals or reactive oxygen species (ROS) when exposed to UV radiation. ROS are chemically-reactive molecules that have the potential to significantly damage proteins, DNA, RNA, and fats within cells. The actual [illegible] depends on a variety of factors including their size, structure, surface properties (coating), and ability to aggregate. For example, several crystal forms of nanosized TiO_2 exist, and differ in the amount of damage they exert on cells. In addition, coating with manganese[4] or other materials[5-7] has been shown to limit the formation of free radicals.

Damage associated with free radical formation is dependent on their ability to interact with living cells. Two barriers must be surmounted for nanoparticle toxicity to occur: penetration in the body via the skin, and host defenses against ROS by neutralizing enzymes and small molecules. It is important to remember that the

1

The Nanodermatology Society (NDS), founded in 2010, is a nonprofit organization charged with the mission to promote and enable a greater understanding of the scientific and medical aspects of nanotechnology in health and disease.

For more information, visit www.nanodermsociety.org or contact us at administrator@nanodermsociety.org

… The Nanodermatology Society believes that nano-based sunscreens do not pose serious health risks to consumers…

Potential Areas of Liability Concern

- “Occupational” Claims
- “Consumer” Claims
- “Environmental” Claims

Worker Exposure is a Concern

Health scare: Labor unions claim that workers in the nanotechnology sector might be facing a health “time bomb “

The July 3, 2012 National Institute for Occupational Safety and Health (NIOSH) *eNews* nanotechnology update states that the critical question to address is whether nanomaterials pose health or safety risks to workers employed in their manufacture and industrial use.

Consumer Health Concerns

NEWS AND ANALYSIS

Nanotechnology risks ignored

MEDIA

Press focus on positives of new technology

A US study has found scant media coverage of the potential risks posed by nanotechnology, with many more articles extolling its future benefits.

In their longitudinal study spanning coverage from 2000 to 2009 – in 20 US, nine UK newspapers and two wire services the US researchers looked for articles that could alert readers to nanotechnology's risks.

Sharon Friedman and Brenda Egolf, from Lehigh University in Bethlehem, found the number of stories that mentioned risks averaged around just 37 per year in each country. Three main narratives prevailed – runaway technology, science-based studies and regulation – and journalists most often covered health risks, followed by environmental and societal risk issues. Regulation coverage was less frequent but increased over time.

The report concludes that given the many articles describing nanotechnology's benefits and the average person's minimal knowledge about the topic, we may be setting the stage for public distrust of nanotechnology in the event that a dangerous event should occur.

Friedman tells *Chemistry World* that there has been a great deal of 'cheerleading' by the US and UK governments, universities, companies and scientists about nanotechnology: 'The number of news releases with "good news" about nanotechnology has been overwhelming,' she says. 'Almost every study in the US and most European countries has found that the dominant narrative or frame for nanotechnology media articles has been positive.'

Positive coverage has focused on the health, energy and computer technology benefits of nanotechnology. Friedman says that editors think readers want to read this. 'With very few risk incidents occurring and many scientists providing either balanced or very positive information about nanotechnology, reporters have had little incentive to follow up on scientific risk messages,' she adds.

Friedman suggests other reasons for simple, positive stories predominating include cutbacks at mainstream US newspapers. 'After the departure of most science writers from [a newspaper's] staff, it is much easier to write an article based on a news release,' she says.

Robin Williams, director of the Institute for the Study of Science, Technology and Innovation at the University of Edinburgh, UK, says that there is no proof that a greater discussion of the assumed risks in the media today will lead to nanotechnology being better accepted and understood in future. Efforts to outline nanotechnology's potential risks or benefits ahead of time are beset by pitfalls and will not necessarily avert public controversy, he argues.

Attempts have been made to anticipate the outcome by extrapolating from previous technologies – such as the recent debate over genetically modified foods. 'However, studies of historical experiences show that the initial conceptions of the implications of a technology are often so far removed from ultimate outcomes as to be uninformative,' he explains. 'Innovation pathways often deviate from their initially expected trajectory.'

Helen Carmichael

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Despite FDA Denials, Nano-Food Is Here

According to a USDA scientist, some Latin American packers spray U.S.-bound produce with a wax-like nanocoating to extend shelf-life. "We found no indication that the nanocoating ... has ever been tested for health effects,"

Environmental Concerns

Dow Corning, a Cautionary Tale

1960s

The first silicone breast implants are developed by two plastic surgeons from Texas.

1976

FDA now has the authority to approve new medical devices. But since silicone breast implants have been on the market for almost 15 years, they are "grandfathered.”

1980s

Ralph Nader's Public Citizen Health Research Group, Washington, D.C. sends out warning signals that silicone breast implants cause cancer.

January 1982

FDA proposes to classify silicone breast implants into a Class III category which would require manufacturers to prove their safety in order to keep them on the market.

December 1990

Program on the dangers of silicone breast implants airs on "Face to Face with Connie Chung."

December 1991
The largest tort award yet, $7.3 million, is given to Mariann Hopkins whose mixed connective- tissue disease is linked to her ruptured silicone breast implants. To date, 137 individual lawsuits have been filed against Dow Corning.

January 1992
FDA Commissioner, David Kessler, calls for a voluntary moratorium on silicone breast implants until the FDA and the advisory panel have an opportunity to consider newly available information. The manufacturers agree.

March 1992
Dow Corning leaves the silicone breast implant business

December 1992
Pamela Jean Johnson wins $25 million tort award in Houston. To date 3,558 individual lawsuits have been filed against Dow Corning.

March 1994
A class action settlement is reached with Dow Corning being the largest contributor. Manufacturers claim there is no scientific evidence linking silicone breast implants with autoimmune diseases

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September 1997
The Journal of the National Cancer Institute publishes a review of scores of medical studies that concludes breast implants do not cause breast cancer. The researchers described the evidence for linking implants to any other disease as "borderline."

November 1998
Dow Corning files for bankruptcy reorganization, which includes the $3.2 billion previously agreed-to settlement and offers claimants several payout options.

December 1998
A panel of four independent experts appointed by Judge Sam C. Pointer, overseer of implant lawsuits in the Federal courts, concludes that scientific evidence so far has failed to show that silicone breast implants cause disease.

June 1999
The Institute of Medicine releases a 400-page report concluding that silicone breast implants do not cause any major diseases such as lupus or rheumatoid arthritis.

LOOK BEFORE YOU LEAP!

Michael Sullivan

Clients turn to Michael Sullivan for senior-level strategic guidance in mass tort product liability litigation and other large-scale commercial litigation. Michael brings nearly three decades of experience in “bet-the-company” cases. He serves in the role of “outside General Counsel” or Coordinating Counsel, providing big-picture advice to craft successful litigation strategies, increase efficiencies and contain costs. Michael collaborates with clients on a wide range of high-end business problems, including mass tort litigation. He spent 10 years as National Coordinating Counsel, Chief Litigator and Case Manager guiding a global automotive company through national asbestos friction litigation. In this role, he coordinated the efforts of a national network of 35 defense firms, as well as the company’s in-house legal team. Michael has particular experience serving the automotive industry, including Tier 1, Tier 2 and Tier 3 suppliers, as well as closely held and family owned businesses. He also has extensive litigation experience in the software, information technology, pharmaceutical and medical device industries. Michael is a member of the International Association of Defense Counsel and a Fellow in the Litigation Counsel of America. He also serves as the Office Managing Partner of Womble Carlyle’s Atlanta office.

Womble Carlyle Footprint

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A full-service business law firm, Womble Carlyle serves a wide range of regional, national and international clients in industries that include health care, life sciences, financial services, commercial real estate, intellectual property, and telecommunications, as well as educational institutions and governmental bodies and agencies.

Questions, Comments and Concerns

Thank you!