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Nanotechnology: The Future Is Now

The Editor interviews ***David L. Wallace****, a partner at Chadbourne & Parke LLP and Chair of the Nanotechnology Law and Commerce Conference scheduled for January 31, 2008, which is detailed on the adjacent page.*

Editor: Please describe your practice for our readers.

Wallace: I am a products liability litigator, focusing (for some 20 years now) on the defense of high-value, high-profile products liability cases both within and without the United States.

Editor: Could you describe what the term "nanotechnology" covers?

Wallace: In a nutshell nanotechnology refers to the science of manipulating and engineering physical matter at the level of 1 to 100 nanometers, with a nanometer equaling one billionth of a meter. More generally, nanotechnology refers to the creation and use of structures, devices and systems at the molecular and atomic level – with novel properties and functions owing primarily to their incredibly small operational size and scale.

Historically, most manufacturing has been done on a "top-down" basis. What nanotechnology does is enable scientists and manufacturers to manufacture things from the bottom up by sticking atoms and molecules together to form unique structures and properties (making old technologies and products smaller, stronger or more durable). Miniaturization is a big part of nanotechnology, but the technology will also lead to the development of altogether new products and markets. The breadth, scope and scale of nanotechnology – its promise – is breathtaking.

Editor: Perhaps you could tell us about some practical applications that you see in products on the market today?

David L. Wallace

Wallace: The Woodrow Wilson International Center's Project on Emerging Nanotechnologies has a website that lists over five hundred consumer products currently on the market that are labeled by the manufacturer as containing nanoparticles or nanotechnology. Some of the more common nanotechnology products already on the market include: paints (with insulating qualities); textiles (that are wrinkle-free and stain-resistant); transparent sunscreens; and personal care products, such as skin cream.

The next generation of nanotechnology products will be more revolutionary: pharmaceuticals offering targeted drug delivery in lower doses with fewer side effects, medical devices that are more resistant to protein adsorption (which can be a problem with conventional medical devices and implants), food products and packaging, energy production and environmental remediation.

Editor: Our readers have previously read in articles in this newspaper that FIFRA regulations have been invoked in the case of certain pesticides. What kind of regulation can we anticipate?

Wallace: Regulation will be a big issue. Nanotechnology is so new, and is unfolding so quickly, that it is prompting calls (predictably) for nanotechnology-specific regulation – grounded on concern that existing regulatory structures are inadequate. No technology, however, has ever been brought to the marketplace that was completely without risk, and nanotechnology will not be any different in that regard.

One of the regulatory flash points surrounding nanotechnology is the fact that the common physical properties of matter at a bulk or macro level often change in unpredictable ways at the nanoscale. Gold, for example, becomes red, reactive and soluble in water. Before we start putting burdensome and potentially disruptive regulatory costs and hurdles in the way of nanotechnology's march, we need first to gather more information – in terms of risk identification, characterization and exposure profiles.

For the near term, it looks as if the *status quo* will prevail, with regulatory authorities like the FDA and the EPA – and those in the EU – taking the view that existing regulatory frameworks are adequate for now based on current understanding of nanoscale science and principles.

Editor: What government agencies oversee its regulation today?

Wallace: There are currently no nanotechnology-specific regulatory bodies, or regulations for that matter. For the immediately foreseeable future, regulatory oversight of nanotechnology products and activities will fall within the ambit of existing laws administered by familiar governmental authorities, such as the FDA, the EPA and OSHA.

Editor: Can government regulations keep up with the pace at which nanotechnology is developing?

Wallace: It remains to be seen, but John Marsburger, President Bush's Science Advisor and Director of the Office of Science and Technology Policy, has expressed confidence in the ability of government regulators to keep pace with breakthroughs in nanotechnology. Others are not as certain. Andrew Maynard, the Chief Scientific Advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars, recently questioned the federal government's approach to nanotechnology in congressional testimony. He's voicing concerns about not only the balance being struck between the government's promotion of

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nanotechnology against the need to address (and reduce) its potential impact on humans and the environment, but also about what he sees as the lack of any centralized strategic governmental framework for ensuring the responsible and successful development of nanotechnology.

There's an awful lot riding on nanotechnology, beginning with predictions that it will in account for upwards of $2 trillion in commerce by the middle of the next decade. Hopefully, Dr. Marsburger's prediction is correct. Of course, a big part of keeping pace will be ensuring that regulation does not needlessly overburden or stifle nanotechnology innovation.

Editor: Have there been any incidents where there was injury to plants or animals or human beings?

Wallace: The only reported recall of a nano-labeled product involved an aerosol tile spray called "Magic-Nano," which was made and distributed in Germany. In March 2006, over a hundred people reported respiratory problems after using the product. Health and safety officials around the world immediately feared that consumers had been injured by the specific action of nanoparticles. A government investigation followed, including two independent chemical analyses, which concluded that the product did not contain any engineered nanoparticles. Apparently, the manufacturer used the word "nano" to name the product because correct application of the product was intended to create a layer of protective film 100 nanometers thick.

Labeling products in this fashion is rather common actually, and – as this example demonstrates – can adversely color public debate over the risks and benefits of nanotechnology. Not surprisingly, the results of the German government's forensic analysis of "Magic-Nano" did not receive near as much publicity as the recall did itself.

Editor: How can a layperson come to understand the vast potential of this new science? Through reading, going to seminars like the one you are chairing, through producers of products using nanotechnology?

Wallace: I think it is going to be some of all those things. One way to begin getting one's arms around the revolutionary nature and vast potential of nanotechnology is to look upon it as the next industrial revolution. Visually, as a layman myself, I've found Adam Kieper's description of nanoscale science a helpful starting point for grasping nanotechnology's scale and magnitude. (He's the founding editor of *The New Atlantis*.) He explains that: "if a nanometer were somehow magnified to appear as long as the nose on your face, then a red blood cell would appear the size of the Empire State Building, a human hair would be about three miles wide, one of your fingers would span the continental United States, and a normal person would be about as tall as six or seven planet Earths piled atop one another."

It can also be helpful to approach the subject from the perspective of more familiar concepts and equivalencies, like seconds and years. In this regard, General David Sarnoff, who headed the RCA Corporation from 1947 to 1971, said that "a nano second is to a second as a second is to thirty years," which means that the 270 or so years since the first industrial revolution began have passed in the nano-equivalent of roughly 8 seconds.

With nanotechnology, small is the new big.

Editor: Who have been the principal financial backers of this research?

Wallace: The usual players have been involved – government, venture capitalists, investment banks, private industry. The George W. Bush administration delivered nanotechnology legislation that has put considerable government time and research dollars behind the development and advancement of nanotechnology, which produced the inter-agency National Nanotechnology Initiative. Billions of dollars are being invested annually in nanotechnology research and development around the world. Right now, government is one of the bigger players in the field.

Editor: What is the role of academicians and how much have they been involved?

Wallace: Many of the building blocks behind the development of nanotechnology – and the heavy lifting needed to cross the "valley of death" from idea and drawing board to commercialization – in large measure are coming from academic research centers, both alone and in collaboration with industry.

Editor: What are the potential liabilities for companies using nano materials?

Wallace: As far as products liability is concerned, familiar ones – failure to warn, misrepresentation, design defect, fraud. Basically, what did the manufacturer know; what should it have known and when? Despite its novelty, the liability issues that will follow nanotechnology-based products and services to the marketplace are not likely to be much different from those traditionally associated with any other product or technology. In the end, the best mitigation strategy will be good product stewardship practices within an overarching risk assessment and management framework across the product's lifecycle – from conception to development, commercialization, use and disposal.

Editor: What types of companies will employ nanotechnology?

Wallace: Nanotechnology can be expected to cut a very wide path through all sectors of the global economy, with pharmaceutical, medical device, information technology and energy companies likely to be prominent players.

Editor: What governmental policies should be adopted so regulation is not reactive but serves as a catalyst for growth and development?

Wallace: It's an age-old problem, really, and there's a good deal of debate and attention quickly attaching to the subject. All things considered, a measured and conservative approach would seem to make the most sense until more is known about the promise and challenge of nanotechnology – all the more so considering the need to protect national leadership and competitiveness in the area of nanotechnology. Ideally, government policy will foster a good deal of dialogue and collaboration between the various stakeholders in the field – government, investors, industry, the scientific community and the public.

The trick is finding the equilibrium point and striking an appropriate balance between encouraging innovation, on the one hand, and responsibly managing environmental, health and safety risk, on the other hand. Overall, my own view is that the best chance of getting the mix right is for government to entrust the issue to scientists, as opposed to politicians. The call and rush in some quarters for aggressive nanotechnology-specific regulation seems a bit premature until more basic research is forthcoming and there is greater fundamental understanding of nanomaterials and nanoscale science generally – to better gauge and inform subsequent regulation.

Overall, we should resist the temptation to regulate first and ask questions later. As Judge Posner cautions, "law should lag science and not lead it." Nanotechnology might be a good place for us to begin practicing that maxim.