

FROM BIRTH TO DEATH AND BENCH TO CLINIC THE HASTINGS CENTER BIOETHICS BRIEFING BOOK

for Journalists, Policymakers, and Campaigns

CHAPTER 24 Nanotechnology

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nanotechnology

by Evan S. Michelson, Ronald Sandler, and David Rejeski

Framing the Issue

Nanotechnology—the emerging field of manipulating matter at the nanoscale—is expected to become a key transformative technology of the twenty-first century. A nanometer (nm) is one billionth of a meter, which is the scale of individual atoms and molecules (a gold atom is 0.14 nm in diameter, a water molecule 0.25 nm, and DNA 2.5 nm). Researchers are exploring ways to characterize, control, design, and construct matter at this small scale, thereby reengineering familiar substances like carbon, silver, and gold to create materials with novel properties and functions, as well as designing molecular scale devices.

Nanotechnology is considered a general use or enabling technology because it has applications that span science and engineering fields, in areas as diverse as health care, energy storage, agriculture, water purification, computing, and security. Many experts predict nanotechnology will be as significant as the steam engine, the transistor, and the Internet in terms of societal impact.

The State of Nanotechnology

There are several forms of nanotechnology that must be distinguished. Mihail C. Roco, Senior Advisor for Nanotechnology at the National Science Foundation, has suggested four phases of technological development for the field:

- a first generation of "passive nanostructures" that incorporate nanoscale materials into coatings, aerosols, and colloids;
- a second generation of "active nanostructures" that are biologically or electronically dynamic;
- a third generation of "systems of nanosystems" that more fully integrate these materials into more complex organizational and manufacturing systems; and
- a fourth generation of "molecular nanosystems" that lead to atomic and molecular-level assembly.

At present, nanoscale science and technology research remains primarily at the active and passive nanostructure phases, though some work is being done on nanosystems.

Not surprisingly, given its potential, there has been significant investment in nanotechnology research and development world-

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HIGHLIGHTS

- Nanotechnology—the emerging field of manipulating matter at the nanoscale—has applications in areas as diverse as health care, energy storage, agriculture, water purification, computing, and security.
- There has been significant investment in nanotechnology research and development worldwide, estimated at \$12 billion annually.
- Nanoscale science and technology have an enormous range of potential biomedical applications, and so are implicated in a broad range of bioethical issues.
- Given the diversity of bionanotechnologies, evaluating them on a case by case basis is crucial.
- The primary challenge associated with nanoscale science and technology is how to proceed with research, development, and dissemination responsibly.
- Effective governmental capacity in policy and oversight functions is essential.
- The lack of action at the federal level has led state and local governments to implement their own oversight programs.

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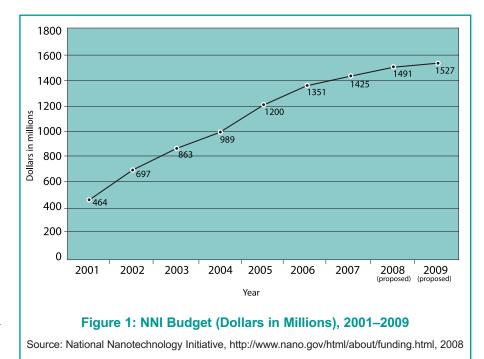
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Josephine Johnston, LLB, MBHL Research Scholar and Director of Research Operations, The Hastings Center • johnstonj@thehastingscenter.org, 845-424-4040, x208 wide, with the combined public and private sector investment estimated at around \$12 billion annually. Countries like India, China, Russia, South Africa, and Israel are focusing on nanotechnology as a pillar of their economies over the coming decades. While the United States retains a strong lead in publication outputs, sizable research contributions are emerging from European countries, including Germany, the United Kingdom, and France, and from Asian countries, including China, and Japan. The United States also remains well in the lead in terms of funding for nanotechnology. As figure 1 indicates, the National Nanotechnology Initiative-the coordinating body for American

nanotechnology research—has a proposed budget of over \$1.5 billion in 2009, up from under \$500 million in 2001.

This high level of investment has begun to translate into new consumer products containing nanomaterials, over 800 of which are already entering the marketplace and can be purchased in stores and over the Internet (see figure 2). These products range across a variety of economic sectors, from clothing and dietary supplements to home furnishings and cleaning supplies. Many of these



products are marketed as providing as-of-yet unverified benefits to the consumer, such as sporting equipment that is lighter and stronger, nanocoated computer devices that kill off unwanted bacteria, and cosmetics that reduce wrinkles and protect against skin damage. Silver nanotechnology particles are currently some of the most commonly used material, followed by carbon, titanium dioxide, and zinc oxide. Lux Research, a research consultancy, calculates that in 2006 there were \$50 billion worth of goods sold in the global marketplace that incorporated nanotechnology, and they esti-

Total Products Listed 900 803 720 Number of Products 606 540 360 356 32 180 230 212 0 3/8/06 9/29/06 11/26/06 5/16/07 10/2/07 2/22/08 8/21/08 4/22/06 Figure 2: Number of Products in the Nanotechnology Consumer **Products Inventory** Source: Project on Emerging Nanotechnologies, http://www.nanotechproject.org, © 2008

mate that by 2014, the value of these goods could reach \$3.1 trillion.

Nanotechnology and Bioethics

Nanoscale science and technology have an enormous range of potential biomedical applications. These include everything from silver particles used in wound dressings and antiseptic coating for surgical implements to pharmacological and vaccine development, and from imaging and visualization technologies to tissue engineering and gene delivery. Among the most immediate and promising applications are in the areas of disease detection and treatment. For example, the sensitivity, precision, and selectivity of nanotechnology allows for diagnostic technologies that detect cancer on the basis of a very low concentration of protein markers in the blood, as well as treatment mechanisms that take advantage of distinctive features of diseased cells to deliver targeted drugs or therapies (see figure 3). The tools and techniques of nanotechnology also increasingly play a crucial role in advancing research in areas such as toxicogenomics, synthetic biology, regenerative medicine, and genetic modification.

Nanotechnology is also likely to make novel forms of information management and medical communication possible—for example, patients might have medical information or records inserted under their skin, as is already done with radio frequency identification (RFID) tags. In addition, it is anticipated that nanoscale science and technology will be crucial to enabling—in combination with biotechnology, information technology, robotics, cognitive science, and computer science—pharmacological, genetic, and biomachine enhancement technologies that either augment some human physical, cognitive, or psychological capabilities that are significantly beyond the range currently attainable, or even introduce novel capabilities.

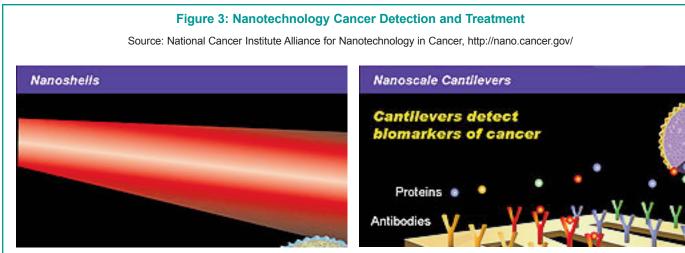
Due to the breadth of its biomedical applications (as well as its agricultural applications, which are not discussed here), nanotechnology is implicated in a broad range of bioethical issues, such as:

• Access to medical technologies

- Privacy of medical information
- End of product (and by-product) disposal
- Informed consent
- Insurance and employment screening
- Human subjects protections
- Global health divide
- Stem cell research
- Regenerative medicine
- Genetic modification
- Synthetic biology
- Biological weapons and biodefense
- Human enhancement

In many of these cases, nanotechnology will promulgate, exacerbate, or provide new variations on familiar issues, due to the distinctive features of nanoscale technologies or the sheer rate and volume of nanotechnology innovation. In other cases, nanoscale science and technology are also crucial to the development of technologies that give rise to novel bioethical issues or that realize bioethical issues that previously have been only hypothetical—for example, whether a person who undergoes radical cognitive and psychological enhancement remains the same person, or even human.

Different bionanotechnology research programs and applications can have very different ethical profiles. Given this diversity, it is crucial that bionanotechnologies be evaluated on a case by case basis. A synthetic biology research program using nanoscale science and technology in a bio-defense



Cancer Detection

Nanocantilever conductance changes as antibodies on cantilever receive molecular expressions of cancer.

Cancer Treatments

Nanoshells attracted to tumors, then using near-infrared light to heat only the nanoshells, tumor cells destroyed without affecting healthy tissue.

ON THE HORIZON

- Reauthorization of the 21st Century Nanotechnology Research and Development Act. The legislation that authorized funding for the National Nanotechnology Initiative—and that mandated that the NNI include research on the social and ethical dimensions of nanotechnology—is pending renewal in 2008. How will the debate surrounding environmental, health, safety, and ethical issues impact its reauthorization and the shifting of funds? Which stakeholders will impact the language and content of the new legislation?
- Implementation of the Environmental Protection Agency's voluntary program. DuPont Corporation announced that it will be the first company to participate in the EPA's voluntary Nanoscale Materials Stewardship Program. How many other companies will follow over time, and will the information provided be suitable for the EPA to make evidence-based regulatory decisions? How will the EPA proceed in the interim, under conditions of information scarcity?
- Implementation of the NNI's strategic plan for environmental, health, and safety research. The NNI released a new risk research framework in February 2008 that may have the potential to answer key questions about the toxicology, fate, and transport of nanomaterials. How will this agenda be operationalized to address critical research needs? What mixture of basic and applied research will be conducted? Will previously low-funded and low-priority areas, such as life cycle assessment, gain increased attention? How will it inform development of EPA, Food and Drug Administration, and Occupational Safety and Health Administration oversight capacities?
- Impact of responsible development and ethics research and activities. In addition to environmental, health, and safety research, the NNI funds public education and outreach and research on public attitudes and opinions, ethical issues, and social and ethical awareness among nanoscale scientists and engineers. What will be the collective outcome of this research? How will it affect public attitudes, government activities, and the behavior of research and industry communities? Can effective models of anticipatory responsible development for emerging nanotechnologies be created and implemented, both in general and with respect to bionanotechnology in particular?

lab raises a host of ethical issues—including oversight, sanctity of life forms, and bioweapon development—that a cancer detection and treatment program employing nanoscale technologies does not (see Chapter 35, "Synthetic Biology"). Discussing the "ethics of nanotechnology" in general is, therefore, not particularly productive. One bionanotechnology might be just, sustainable, and likely to contribute to human well-being, while another might be unjust, unsustainable, reckless, and unnecessary.

Environmental, Health, and Safety Considerations

Over the past 15 years, scientific data on the environmental, health, and safety impacts of nanostructured materials has been growing slowly. Though much of the research undertaken so far has raised more questions than answers, some key points have emerged. Foremost among these is that because the potential applications of nanotechnology are based primarily on the novel physical and chemical properties that emerge when materials are engineered at the nanoscale, risk assessment paradigms that have been developed for bulk materials may not be valid for nanomaterials. In particular, generalizations based simply on the type of substance or exposure levels about the toxicological properties of nanomaterials, or their ability to move and translocate within the body, are not reliable. In short, the ability of a nanomaterial to cause harm in the body depends not only on its small size, but also on a range of other factors, including the structure of the particle, its surface chemistry, and its particular surface area.

For example, a May 2008 article published in *Nature Nanotechnology* presents the results of an experiment designed to mimic potential inhalation exposure to carbon nanotubes by introducing various forms of single- and multiwalled nanotubes into the abdominal cavity of mice. This research found that significant "asbestos-like" responses occurred, including inflammation and formation of lesions, raising concerns that long, multiwalled nanotubes have the potential to lead to similar kinds of mesothelioma, or cancer of the lungs, that asbestos can cause. Due to the potential for this kind of response, the authors recommend "great caution before introducing such [carbon nanotube] products into the market if long-term harm is to be avoided."

Inhaled nanomaterials may also be able to translocate and affect other parts of the body, including the cardiovascular system, the liver, the kidneys, and the brain. Next to nothing is known about the impact of engineered nanomaterials on these organs. Nanometer-diameter materials may also be able to penetrate through the skin in some cases, although chances of penetration appear to be significantly greater for damaged skin than for healthy skin. Very little is known about the hazard of engineered nanomaterials ingested as a food additive or by accident, applied on to the skin by way of a cosmetic or sunscreen, or injected into particular organs for medical treatment.

There is also little information on how manufactured nanomaterials may affect ecosystems, how they might bioaccumulate, and what long-term environmental impacts they may have if they are released into ground water by way of disposal or waste.

Additionally, best workplace and lab practices for nanomaterials are only now beginning to be formulated. For example, a November 2006 study sponsored by the International Council on Nanotechnology that focused on tracking nanotechnology workplace safety practices concluded that many workers and researchers in companies and laboratories are using potentially outmoded and outdated environmental, health, and safety risk management practices when handling, transporting, or disposing of nanomaterials.

Policy and Oversight Considerations

Given its complexity, the primary challenge associated with nanoscale science and technology is how to proceed with research, development, and dissemination responsibly, in ways that promote the benefits of nanotechnology while preemptively addressing environmental, health, safety, and ethical concerns. Crucial to accomplishing this goal is government's capacity to perform its policy and oversight functions effectively. There are several factors that suggest that at present, governmental capacity with respect to emerging nanotechnologies is inadequate.

Lack of trust. There is a lack of public trust in government concerning regulatory and oversight responsibility for different nanotechnology applications due to funding cuts across a range of federal agencies, including the Environmental Protection Agency, the Food and Drug Administration, and the Consumer Product Safety Commission.

Gaps in oversight. Analyses by J. Clarence Davies and Michael R. Taylor of the statutory and

RESOURCES

Web sites

- www.nano.gov The National Nanotechnology Initiative. Includes fact sheets, research, safety information, a newsroom, an education center, and further resources.
- www.nanotechproject.org The Project on Emerging Nanotechnologies. Includes news and events on nanotechnology topics, publications, and a press room.
- http://nsrg.neu.edu The Nanotechnology and Society Research Group at Northeastern University. Includes expert contact information, publications, resources, and links.
- http://powerofsmall.org Fred Friendly Seminars, "Power of Small: Nanotechnology," a program airing on public television that is viewable online.
- www.nanowerk.com Nanowerk LLC's nanotechnology and nanosciences portal. Includes editorial content and news, a nanomaterial database, a directory of companies and labs, and educational resources.

Recent news

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- Aatish Salvi and George Kimbrell, "Nanotech: Yay or Nay?" Los Angeles Times, February 25–29, 2008.
- Carol Bass, "As Nanotech's Promise Grows, Will Puny Particles Present Big Health Problems?" *Scientific American*, February 5, 2008.

- Shankar Vedantum, "Why Voters Play Follow the Leader," *Washington Post*, February 4, 2008.
- James Flanigan, "Nanotechnology Companies Planning to Sell Shares," *New York Times*, December 20, 2007.

Further reading

- Ronald Sandler, *Nanotechnology: The Social and Ethical Issues,* Project on Emerging Nanotechnologies, September 2008.
- E. Marla Felcher, *The Consumer Product Safety Commission and Nanotechnology*, Project on Emerging Nanotechnologies, August 2008.
- Craig A. Poland et al., "Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-Like Pathogenicity in a Pilot Study," *Nature Nanotechnology*, May 20, 2008.
- Fritz Allhoff, Patrick Lin, James Moor, and John Weckert, ed., Nanoethics: The Ethical and Social Implications of Nanotechnology, Wiley-InterScience, 2007.
- David Rejeski, "A Very, Very Small Opportunity: How Science and Society Can Avoid A Collision Over Nanotechnology," *Orion Magazine*, July-August 2007.
- Andrew D. Maynard, et al., "Safe Handling of Nanotechnology," *Nature*, November 16, 2006.



See legislation appendix.

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human resource constraints at the EPA and the FDA have shown that weaknesses and gaps exist in the oversight system for nanotechnology.

Slow response. Frontline federal regulatory agencies have been slow to respond to the particular challenges posed by nanoscale materials. The official position of the FDA remains that no new regulatory tools are necessary, and the EPA has only just initiated its voluntary Nanoscale Materials Stewardship Program to gain information from corporations that manufacture or use nanomaterials in their products. However, in a move that took many in industry by surprise, the EPA recently fined a California company \$208,000 for making unsubstantiated claims concerning a nanoengineered antimicrobial coating applied to a computer keyboard—a violation of the Federal Insecticide, Fungicide and Rodenticide Act.

Overall uncertainty. Much uncertainty remains concerning the adequacy of federal regulations to deal with the increasing number of

nanobased substances and products flooding the marketplace. A high-profile safety or health event concerning nanotechnology cannot be ruled out. Such a mishap could undermine public confidence, engender consumer mistrust, and, as a result, damage the future of nanotechnology before its most exciting applications are realized.

Recently, the lack of action at the federal level has led state and local governments to consider and implement their own oversight programs. In December 2006, the city of Berkeley, California, became the first municipality to regulate nanotechnology by requiring manufacturers to report information about nanomaterial use and disposal practices. In 2007, the city of Cambridge, Massachusetts, established an advisory committee to investigate similar actions, and in 2008, Wisconsin became the first state to publicly discuss creating a registry of businesses that manufacture nanomaterials.