Statement for the Record

on

Nanotechnology

by

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Before the Senate Committee on Commerce,
Science, and Transportation

May 1, 2003

Nanotechnology Activities at the National Institutes of Health

The National Institutes of Health (NIH) wishes to submit the following statement for the record regarding NIH work in the areas of nanoscience and nanotechnology. This work refers to research and development of technologies at the atomic, molecular, or macromolecular levels—research where the characteristic dimensions are less than 1/1,000 the diameter of a human hair. Nanotechnology research provides a fundamental understanding of phenomena and materials that enable the creation and use of structures, devices, and systems that have novel properties and functions because of their extremely small size. Recent advances in the understanding of and the ability to manipulate matter at this scale have resulted in incredible new opportunities for research and technological change in almost every field of science and engineering. Although many of these efforts are still in their early stages, NIH's commitment to biomedical research and development at the nanoscale level is strong.

The potential applications of nanotechnology crosscut the missions of NIH Institutes and Centers (ICs). Seventeen NIH ICs currently fund nanotechnology research in thirty-four states, the District of Columbia, Canada, and the United Kingdom. The nanotechnology research funded by NIH promises to improve the quality of life for countless Americans. To offer a few examples:

- The National Cancer Institute is funding a project that uses nanotechnology to develop a targeted delivery system for anti-cancer drugs. This project, conducted at Imarx Therapeutics in Tucson, AZ, may enable greater use of life-saving anti-cancer drugs with fewer toxic side effects.
- The National Heart, Lung, and Blood Institute is funding researchers at Biomod Surfaces in Salisbury, MA, who hope to use nanofiber technology to create blood vessel replacements for vascular disease and heart bypass surgeries.
- The National Institute on Alcohol Abuse and Alcoholism awarded a grant to researchers at Howard University in Washington D.C. who hope to create injectable nanoparticles that control delivery and availability of naltrexone, a medication for treatment of alcoholism and other addictive disorders. The success of naltrexone, which is already approved by the Food and Drug Administration (FDA), is limited by problems with compliance. Nanoparticle technology promises to increase the success of this treatment for alcoholism through sustained release of naltrexone over several months.

In FY 2002, the NIH spent approximately $59.5 million on nanotechnology research. NIH anticipates that these activities will grow rapidly in 2005 and beyond. We estimate spending $65 million in FY 2003 and $ 69.6 million in FY 2004. This investment demonstrates the strong interest and commitment on the part of the NIH in the field of nanotechnology research. Our hope is that such investments in basic research will ultimately result in the development of technologies that will greatly benefit the health of all.

Nanotechnology has the potential to radically change the study of basic biological mechanisms, as well as to significantly improve the prevention, detection, diagnosis and treatment of diseases and adverse medical conditions. The key to this potential is that nanotechnology operates at the same scale as biological processes, offering an entirely unique vantage point from which to view and manipulate fundamental biological pathways and processes. Most other technologies require the study of large numbers of molecules purified away from the cells and tissues in which they usually function; nanotechnology may offer ways to study how individual molecules work inside of cells. Beyond this, we must develop biomedical applications at the nanoscale in order to integrate unique properties and performance to the macroscopic world of patients. The transfer of information and energy across complex interfaces and multiple length scales is a multidisciplinary problem that requires teams of physical scientists, engineers, life scientists, and clinicians to work closely together.

NIH strongly encourages and supports the interdisciplinary and integrative approaches that characterize nanoscience and nanotechnology in biomedical research. This was emphasized by the creation of the Bioengineering Consortium (BECON), through which the Agency coordinates trans-NIH nanoscale activities, including NIH participation in the National Nanotechnology Initiative (NNI). To date, BECON has hosted a series of five annual symposia to receive community input on integrative research, and all have been extremely well attended. Each of the symposia incorporated discussion of the role of nanotechnology research in advancing specific NIH scientific and technical goals. An important outcome of these symposia has been the release of a series of grant solicitations. Two general bioengineering solicitations, the Bioengineering Research Grants and the Bioengineering Research Partnerships, have been active since 1999 and cite nanotechnology as an area of substantial interest to the NIH. To encourage active partnerships with the small business community, NIH started the Bioengineering Nanotechnology Initiative in 1999. Through these mechanisms, NIH has been actively soliciting nanoscience and nanotechnology grant applications for several years, and continues to build upon these programs.

Recent BECON efforts include a “call for projects” collectively issued by eleven ICs. This initiative, entitled "Nanoscience and Nanotechnology in Biology and Medicine," seeks investigator-initiated research studies and high risk, high impact, exploratory and developmental projects. Several NIH ICs have also issued research solicitations independently of BECON, offering additional funding opportunities. Applications awarded provide a conduit through which nanoscale research can be merged effectively into the fabric of NIH mission-relevant research. Examples of IC-initiated projects include the development of improved imaging contrast agents for the diagnosis of disease, systems for targeted drug delivery, tissue replacement tools for studying the basic functioning of living cells and their constituent proteins, and completely novel ways to sequence DNA (using natural and fabricated nanopores). NIH disseminates information about these nanoscience and nanotechnology funding opportunities by posting the announcements on a dedicated section of the BECON web site and by describing them at numerous conferences of business and academic groups.

Other NIH Nanotechnology Activities

The NIH Director recently conducted a series of exercises to establish a “roadmap” for NIH’s future research priorities. During this process, the scientific community identified nanotechnology as a frontier of biomedicine, and NIH is exploring future research opportunities at the nanoscale level to further the NIH mission and national health care priorities.

Furthermore, through the NNI interagency working group and the National Nanotechnology Coordinating Office, in which NIH is an active participant, NIH representatives are preparing a workshop to identify key research directions for nanobiotechnology. Input from the scientific community will be considered for future program development. This workshop will also facilitate the communication of concepts and recent discoveries in the physical sciences and engineering to members of the biomedical community, thereby identifying key areas for the formation of new disciplinary research partnerships.

Through the activities described here, NIH will build its investment in nanotechnology research by stimulating community interest and participation. As is true for most paradigm-shifting research, it takes a few years for new ideas to take hold and for the research and development community to coalesce around those ideas and formulate thoughtful scientific plans. Nanoscale research has been percolating through the physical sciences and engineering communities for several years, so it is natural that those fields have experienced more rapid expansion in investment during the earliest years of the NNI. In contrast, only recently has an awareness of the exciting possibilities of this field started to permeate the biomedical research community. Through this natural evolution, enhanced by NIH and NNI leadership, the NIH is confident that the research community will develop the concepts and partnerships necessary to submit well designed grant proposals that will advance the NIH mission.

Potential Health Applications

Already we can see potential health applications for nanotechnology. Conceptually, all are within the realm of the foreseeable future and, in many cases, are feasible. However, the ways in which we currently envision the role of nanotechnology in helping the human condition only hint at the ultimate contributions. NIH has a clear leadership role in pursuing these and future biomedical opportunities. Some of the opportunities currently envisioned include:

<u>Biomaterials and tissue engineering</u>. Nanotechnology-based materials may provide solutions for repairing damaged tissues as well as for monitoring critical clinical indicators and interfacing for electrical measurement and stimulation. Such materials introduced into the body would not irritate or damage the surrounding tissues, nor would their function be impaired by long-term exposure to tissue fluids. Instead, they would actively communicate with host tissue and would dissolve into harmless components that could be absorbed or excreted when no longer needed. The synthesis and assembly of biologic materials and scaffolds with homologous structure and function to the human body's own tissues and processes are within the realm of possibility, and research pathways are becoming evident.

<u>Responsive delivery of new generation therapeutics and diagnostics</u>. While knowledge of cellular pathways related to disease has recently burgeoned, the subtleties of how these pathways function remain largely unknown. The ability to target pathway interventions to particular cell or tissue types, and to modulate the release or activation of agents in response to cellular signals, would allow specific interventions into disease pathways while minimizing side effects. This capability would make useful a much wider variety of therapeutic agents. Similar concepts can be used to deliver *in vivo* imaging agents for diagnosis, monitoring of disease and therapy, and early disease detection.

<u>Point-of-care diagnostics</u>. Effective detectors of specific molecules can be developed and integrated into compact devices. Such devices can be used to provide rapid information about diseased cells or tissues, and can be used to determine treatment options. Nano devices could be deployed in physicians' offices or in the field, and related devices would be implanted in patients' bodies to provide real-time records for monitoring disease progression and therapeutic efficacy.

Imaging biological processes and the effects of disease.

Current imaging methods can provide excellent information on the structure of molecules in vitro (e.g., X-ray diffraction) and high resolution of anatomical information in vivo (e.g. computed tomography). However, to understand dynamic living systems, and how they are affected by disease, we need to be able to image biological processes non-destructively *in vivo* in real time. Nanotechnology provides the opportunity for a new generation of imaging tools to probe living processes at the molecular and cellular level, allowing us to study how diseases disrupt normal molecular and cellular signals and pathways.

Implications and Ramifications of Nanotechnology on Society

With the advancements in nanotechnology that are described above, one could envision a world where diseases are diagnosed and prevented or treated at early stages. Implanted nanotechnological materials would become part of the body, and therapeutic agents would be delivered in the precise amount and at the site of action where they are needed. Achieving a substantial portion of these goals in a relatively short time could result in enormous changes in society, as many people's quality and length of life would increase dramatically. As new research projects are launched, it will be important to note the societal implications of these and other aspects of nanotechnology research. Questions to consider in this regard include: What is the long-term impact of incorporating nanoparticles that may be absorbed into the body? As large quantities of nanoparticulates are manufactured for incorporation into other products, what will be the direct heath effects? What will be their environmental impact on biological systems? In order to address some of these questions, the NIH will seek to collaborate with some of its sister agencies within the Department of Health and Human Services, as well as other Federal agencies such as the Environmental Protection Agency and the National Science Foundation.

In summary, the NIH is committed to fulfilling its leadership role in the development of nanotechnologies. While there is a great deal of work ahead before we can achieve some of the goals set forth in this area, the NIH welcomes this challenge and stands ready to address any questions the Congress may have about it activities in this area.