INTRODUCTION

The Challenge of Developing Oversight Approaches to Nanobiotechnology

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Nanotechnology is being hailed by many as the "next industrial revolution."[1] A convergence of scientific fields including chemistry, biology, physics, optics, and mechanics, nanoscale science and technology operates at the scale of 1-100 nanometers where structures, devices, and systems have novel functions and properties because of their size.[2] One area with tremendous promise for health and medical applications — "nanobiotechnology" — specifically refers to nanotechnology designed for use in biological systems, in which nanomaterials are derived from biological molecules, or in which nanomaterials mimic biological systems. This convergence of nanotechnology and biology has been envisioned from the inception of the National Nanotechnology Initiative (NNI) at the beginning of this decade. As Dr. Mihail C. Roco, the Senior Nanotechnology Advisor at the National Science Foundation (NSF), notes, "Nanotechnology provides the tools and technology platforms for the investigation and transformation of biological systems, and biology offers inspiration models and bioassembled components to nanotechnology."[3]

Federal and state funding for research and development of nanotechnology is rising, with over 1,000 manufacturer-identified nanoproducts on the market already.[4] Despite substantial financial funding and rapid advances, public awareness of the science and applications is strikingly low. A 2008 Hart Research Poll of 1000 U.S. adults reports that 75% have heard "little or nothing at all" about nanotechnology.[5] When the public does hear about nanotechnology, it is often to emphasize peril rather than promise. While concern over nanotechnology has calmed from the original hype and threat of self-replicating nanobots and grey goo, there remains an active controversy about the safety of nanotechnology in consumer products, environmental effects, and the potential for uses that would threaten national security and public health.

The interaction of biology and nanotechnology challenges existing systems of oversight for laboratory research, human subjects research, manufacturing, marketed products, and disposal. Any new technology faces hurdles in its development, implementation, and public acceptance, including balancing public health and safety with scientific progress and innovation. Nanobiotechnology is no exception. Issues loom large. Among the most important is design of appropriate governance systems. Federal agencies are already grappling with the question of whether they should use existing oversight frameworks or create new ones. Developing an oversight system or method of governance becomes complicated when the scope of the technology is broad and when the range of products and processes is expansive.

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A core challenge for nanobiotechnology is finding the appropriate balance between accelerating innovation and maintaining public health and safety. The science offers tremendous potential to improve human health and the environment, but also the potential for harm. Scientists, the public, and policy makers are beginning to weigh in on measures to ensure responsible development of nanotechnology that protects public health and safety. In the last few years, nongovernmental organizations have petitioned both the Food and Drug Administration (FDA) regarding the potential negative health effects of nanoparticles in sunscreen[6] and the Environmental Protection Agency (EPA) regarding the toxicity risks of silver nanomaterials for humans and ecosystems;[7] each petition requested the federal agency to develop new mechanisms of regulation for nanotechnology in consumer products. The EPA has determined that, for regulatory purposes, carbon nanotubes are new chemicals requiring advance notice prior to manufacturing;[8] states[9] and municipalities[10] have initiated reporting mechanisms for nanomaterial manufacturing; and industry has begun partnering with non-governmental organizations in order to develop corporate frameworks for assessing risks of nanoparticles and nanomaterials.[11]

As the United States and other countries struggle with how to oversee nanobiotechnology science and technology, they are grappling with big questions: What is the scope of nanobiotechnology for oversight purposes? What is the life cycle of nanomaterials, nanoparticles, and nanoproducts, and how does this differ depending on the product or application? What is the role of existing law, policy, industry standards, and guidance documents? What is the role of relevant stakeholders, including the public, scientists, clinicians, industry, and policy makers? What oversight mechanisms are already in place that reach or can be adapted to nanobiotechnology? What can discussions in other technological contexts regarding property rights, oversight models, and appropriate safeguards tell us?

For nanobiotechnology, oversight could encompass a number of models, including mandatory laws and regulations, voluntary reporting, standards, and guidelines. Oversight may involve federal, state, and local government, as well as non-government players such as industry and professional groups. Nanobiotechnology raises pressing issues of international harmonization of oversight efforts.

This NSF-funded project sets out to examine these questions and develop much-needed recommendations for the oversight of nanobiotechnology. We do that by pioneering a new kind of analysis of the history of oversight for cognate science and technology. The project, based at the University of Minnesota, brings together a national and multidisciplinary group of investigators and senior personnel with strengths in nanotechnology research and development, public policy, law, health, environment, sociology, economics, and bioethics. Our interdisciplinary team has integrated a range of analytic methods and criteria to evaluate oversight systems for five historical oversight models that are germane to active nanostructures and systems: oversight of genetically engineered organisms (GEOs) in the food supply, drugs and medical devices, chemicals in the workplace, and human gene transfer research (or "gene therapy"). These areas were chosen because each is relevant to a particular type of emerging nanobiotechnology and yields an important oversight story with major lessons for the oversight of nanotechnology, especially nanobiotechnology. The goal of this analysis is to learn from the past. The 20th century offers a wealth of lessons for science and technology oversight. Nanobiotechnology oversight should learn from those experiences.

This symposium collects articles resulting from our NSF-funded project evaluating the five historical oversight models. We integrate legal, ethical, and policy analysis using both qualitative and quantitative approaches. Part I presents the individual case studies: oversight of GEOs in the food supply, drugs and medical devices, chemicals in the workplace, and gene therapy. Commentaries from prominent scholars and participants in the nanotechnology debate complement the case studies and offer different perspectives. Part II presents a comparative article integrating the core findings across these case studies and offering lessons for nanobiotechnology oversight. Part III consists of articles by project members on cross-cutting topics related to the science, law, policy, social implications, and the ethics of nanobiotechnology.

Our aim is to provide a rich set of perspectives, interdisciplinary approaches, and findings as a means to advance the oversight debate. In the process, we offer groundbreaking new approaches for evaluating and designing the oversight of emerging science and technology.

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