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SPECIAL FOCUS: GOVERNANCE OF NANOBIOTECHNOLOGY

Introduction: designing nanobiotechnology oversight

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Nanobiotechnology has potential for enormous good: the ability to create new and improved health and medical applications to diagnose and treat many diseases and disorders that continue to elude conventional interventions, environmental remediation techniques to treat soil and water contamination, and agricultural products to improve farming practices and enable biorenewable sources of energy. A convergence of nanoscale science and engineering with molecular biology and biomedical engineering, nanobiotechnology involves the use of nanotechnology tools to engineer biological materials with novel properties or to engineer nanomaterials that are derived from or mimic biological materials. Just as nanotechnology expands the boundaries of physics and chemistry by enabling the understanding, manipulation, and control of materials at the nanoscale to produce novel physiochemical properties, nanobiotechnology expands the boundaries of biology that have proven to be obstacles for biomedical and biotechnological advancement.

Yet the same abilities of nanobiotechnology that offer so much promise also create risks that pose significant challenges to existing systems of oversight for occupational health and safety, environmental protection, human subjects research safeguards, and consumer protection. There is much we still do not know about the characteristics and behaviors of nanobio materials, especially of next generation "active" nanostructures that respond to biological or environmental signals. There is considerable debate over the adequacy of existing occupational exposure and toxicological assessment tools for evaluating nanobio materials. Even materials characterization is a work in progress.

Against this backdrop of uncertainty, federal funding for nanotechnology research and development continues to grow, with almost $1.8 billion allotted for the National Nanotechnology Initiative (NNI) in FY2011 (NNI 2010). This investment includes a considerable funding increase for the National Science Foundation (NSF) to research new nanobiotechnology methods and for the National Institutes of Health (NIH) to research nanoscale

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devices and systems for medical applications (NNI 2010). Yet as investment in nanotechnology grows, federal agencies are grappling with the question of whether existing oversight frameworks are sufficient to address the challenges of nanotechnology or whether new oversight systems are needed. The Environmental Protection Agency (EPA), for example, has already determined that carbon nanotubes are new chemicals that require pre-manufacture notice under the Toxic Substances Control Act (TSCA) (EPA 2008), and the Food and Drug Administration (FDA) is requiring additional reporting for new drug applications incorporating nanomaterials (CDER 2010). The Occupational Safety and Health Administration (OSHA) through its research arm, the National Institute for Occupational Safety and Health (NIOSH), has begun to address research needs, to develop guidance, and to provide recommendations for the safe handling of nanomaterials (NIOSH 2009).

A critical challenge for developing nanobiotechnology oversight is ensuring that the progress of science is not unnecessarily impeded while, at the same time, ensuring public health and safety and respecting societal values. The challenge of balancing these competing concerns is especially salient in the context of nanobio, with potential to improve human health and the environment, but also the potential to produce significant harms. Agencies also face capacity-related challenges, as they struggle to evaluate the broad range of nanomaterials and nanoproducts in development and reaching the market. A further difficulty will be deciding the appropriate balance between mandatory laws and regulations and voluntary reporting, standards, and guidelines.

This symposium presents work from an NSF-funded project on "Evaluating Oversight Models for Active Nanostructures and Nanosystems: Learning from Past Technologies in a Societal Context." This project has examined the complex problem of oversight for nanobiotechnology to provide practical recommendations for nanobio oversight in the United States. The project group, based at the University of Minnesota, brings together a multidisciplinary team of investigators and Working Group members with expertise in nanotechnology, public policy, law, health, environment, sociology, ethics, and bioethics. Our interdisciplinary team has devised new analytic techniques and has learned from historical analysis of five historical oversight models relevant to nanotechnology (genetically engineered organisms, drugs and medical devices, chemicals in the workplace, and human gene transfer research). We have comprehensively reviewed recommendations by others for nanotech oversight, conducted interviews with experts involved in nanotech oversight, engaged in scenario analysis of existing and future nanobio products, and pursued project group dialog to help us develop oversight recommendations (Kuzma et al. 2008; Paradise et al. 2009).

This is the second symposium produced by this four-year project (for the first symposium, see Wolf et al. 2009). The centerpiece of this JNR symposium is an article offering our recommendations on oversight of nanobiotechnology (Ramachandran et al. 2010). In that article, we integrate scientific, legal, ethical, business, and public policy perspectives to offer a new model of dynamic oversight, coupled with practical recommendations. In further articles in this symposium, expert authors provide new and cutting-edge analyses of a range of related issues, including: approaches to governing nanobiotechnology; the potential for nanobio oversight to advance science and industry; the challenges of nanobio risk assessment; the role of public engagement in nanobio oversight; recommendations for human subjects research in nanomedicine; and the ethical, legal, and policy dimensions of nanobio governance. Our goal is to present an interdisciplinary and comprehensive collection of perspectives to contribute to progress on nanobio oversight.

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