Dealing with the Societal Implications of DOE Science

Workshop on Integrating Societal Implications into Science

May 1–2, 2006

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Executive Summary

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A workshop was convened by the Department of Energy (DOE) May 1–2, 2006, in Chantilly, Virginia, to discuss a new program that will explore societal issues arising from DOE studies in nanotechnologies and synthetic genomics. The new program, provisionally named "ISIS" (Integrating Societal Implications into Science) is intended to be broader than ELSI (Ethical, Legal, and Social Issues), the long-running effort from which it derives. The explicit intention of its developers is to interweave thinking about scientific activities with explorations of their potential societal implications as much as possible right from the outset. This approach will be applied first to nanotechnology and synthetic genomics and, over time, will expand to other DOE Office of Science activities. A principal aim is to break down distinctions among science practitioners and those exploring societal implications. ISIS starts with the explicit assumption that society, including scientists and the sciences, benefits directly from considering societal implications ahead of time and at each stage of the research process. While this is not an easy proposition to demonstrate, ISIS will try to make the case convincingly.

The focus of the Chantilly workshop was the intermediate-range "issue spaces" (a term coined to convey a set of potential ELSI issues arising from a particular research area) for nanoscience and synthetic biology. The National Nanotechnology Initiative (NNI) has existed for a couple of years now, with many federal agencies participating. Another major effort, funded principally through the National Science Foundation and the Environmental Protection Agency, is looking at health and safety issues, so this workshop took a longer view. Thus, its aims were to

- Explore intermediate-range issue space for nanosciences and nanotechnology.
- Explore intermediate-range issue space for synthetic biology.
- Discuss the nature of a response capability for future challenges the Office of Science might face.

The 21st Century Nanotechnology Research and Development Act, Public Law 108-153, which authorizes NNI, requires agencies supporting nanotechnology research to consider societal implications, particularly those involving safety and health.

Ray Orbach (Director, Office of Science) discussed integrating ethics at the beginning of a research program. Noting similarities to Office of Science integrated safety management (ISM), where safety is built into programs from the beginning, he said that doing so is cheaper, more effective, and fairer to workers than waiting for an accident to happen and then trying to fix things. Ethics should be treated similarly. Ethics management should enhance the science, and the relationship between the two should be supportive, not punitive. Identifying issues that we will face in defining this territory is important for future integration. The Office of Science believes this essential feature of its function will make nanotech and other realms of advanced science that DOE supports more exciting and productive.

Nanoscience and Nanotechnology

First, what is nanoscience? Its unifying criterion involves objects with at least one dimension on the order of 1 to 100 nanometers (nm). Beyond that, the applicable "rules" seem to be:

- Nano is small—1/100,000 the width of a human hair.
- Nano is not new.
- Nanostructure properties vary with size. This is a controversial definition; for many it is not really nano unless properties do vary with size.
- Nano is where biology meets nonbiology.
- Nanomaterials are very sensitive to changes in structure.

Nanoscience is not one thing but will be many; thus, focusing exactly on the specific topics being discussed and the science reality as we know it will be critically necessary. The current regulatory framework will be strongly challenged by nanotechnologies. How can the *unknown* be regulated? A predictable contentious issue will be intellectual property rights. NNI reports that the federal government provided $1.3 billion to nanotech efforts in 2006. Already, at least 1200 startups have launched to capitalize on this investment. The Patent and Trademark Office (PTO) now is trying to figure out what "nano" is. The NNI definition requires a size range of 1 to100 nm, with unique phenomena that enable novel applications. PTO uses a similar definition of size, along with novel property components. What constitutes inventions vs fundamental principles of biology or physics that should not be patented?

PTO is not the only agency dealing with nanotech. The Food and Drug Administration (FDA) has approved such devices as particles for imaging, wound dressing, dental restoratives, makeup, and sunscreen. Indeed, the FDA regulation of nanotechnology may have implications for PTO. Generally, nanotechnology in the FDA sphere is not looked upon as novel. An analysis of the current intellectual property landscape and comparisons with other technologies suggest that we can expect some contentious debates and litigation arising from the development and patenting of nanotechnologies. In the near future, the difficulty of decision making will be compounded by the unfamiliarity of PTO and the courts with this new science.

Public communications are critical. What gets communicated and what the public hears are two nonidentical things. Social science research indicates that public opinion is formed in complex and subtle ways, creating important implications for successful public outreach and communication.

Synthetic Biology

One current definition of synthetic biology is "the design and construction of new biological parts, devices, and systems and the redesign of existing natural biological systems for useful purposes" (Drew Endy, Massachusetts Institute of Technology, www.syntheticbiology.org). Scientists learn about the natural world by poking, prodding, and testing by building; as true as this is for mechanical devices, so too is it true as we seek to understand living systems. Scientists can go from information and raw materials—DNA bases—to compile a physical piece of DNA that then allows them to determine the potential "parts list" for living cells and make them. Can we as a society accept responsibility for the widespread and direct manipulation of genetic information and material? Some emerging themes include the following:

As synthetic biology advances, we can predict that innumerable legally and intellectually fascinating issues will arise for the courts. A court, however, does not shape law as much as it interprets law in the context of the case before it. This means that the court is always behind the social curve. It also means that scientists—who have a duty to be educators from their laboratory benches, an obligation that well exceeds the needs of individual cases—must participate in societal activities. Their expertise obliges investigators to think seriously about these issues and engage in the public discourse. Without such engagement, we will not have societal understanding or, concomitantly, good laws and regulations applicable to the issue.

Possible Response Models

What should the Office of Science do to establish and inculcate thinking about societal implications in these programs? A variety of possible response models were discussed, among them the following.

"Bedside Consult": A program at Stanford based loosely on the idea of the bedside consultation service used in hospitals. Its key features are that it is proactive, allowing researchers to raise issues before the fact; integrative; anticipatory; and educational in the sense that it educates researchers and consultants.

Asilomar Model: A major cross-disciplinary workshop of relevant scientists and others that explores an issue and determines a short-term policy (e.g., a moratorium) to get a community to coalesce around a path forward.

ELSI Model: Based on a granting program, establishes and cultivates a "bottom-up" capacity in a field by building a stable community of researchers who can take on these issues as a career. They also would stand ready to respond to urgent questions as they came along but would be a reliable resource on which society (including researchers) could draw.

Conference Model: Brings together recognized and up-and-coming experts in a field to discuss timely and familiar topics, making sure to present divergent views to encourage ample discourse and debate. Model also uses conferences that combine a diverse mix of practitioners, academics, poets, media, and artists to talk about topics, issues, or works that take them more or less outside their usual areas.

Regulation: Has four attributes of special importance.

- Nanoscience and technologies often differ in kind rather than degree from their antecedent technologies, making regulation challenging when using established vehicles and possibly requiring development of new approaches.
- Nanotechnologies will arise from science in progress, meaning that decisions will be required before a full understanding of risks is available and may need new approaches to regulatory decision making in the absence of adequate bodies of data.
- Nanotechnologies present special challenges and thus special fears (whether grounded in reality or not) and, as a result, pressures for precaution may increase, with less willingness to compromise or experiment in sensitive areas.
- Nanotechnologies may present significant external costs that are hard to anticipate. When the problems are more complex and the science less clear, choices are less obvious and reliance on values grows. When science is weakest, the regulatory system is forced to place greater reliance on value systems.

What the DOE ELSI Program aims to do next includes defining how studying societal implications can benefit the science DOE supports; making the case to DOE-supported scientists that they need to take studies of societal implications seriously because they are beneficial to science and society (not inhibitions on scientific progress); looking at issues down the road (since ES&H are being looked at already); inviting peer-reviewable studies of the implications of societal issues, while linking these to the ongoing science in tangible ways; building a collaborative environment among scientists and those studying societal implications; and experimenting more with less-conventional funding mechanisms. Program operating principles must include that scientists are well-served by initiating and being involved in discussions of the societal implications of their work; discussions should not be limited to human risks, exploring environmental risks as well; portrayal of benefits should be realistic (i.e., exaggeration will not help to generate trust); and the biggest lesson is that the social context is always changing, and scientists need to adapt along with it in their discussions of societal implications.

This ISIS workshop has resulted in one Request for Applications (RFA) already (www.science.doe.gov/grants/FAPN07-16.html) on "Ethical, Legal, and Societal Implications (ELSI) of Research on Alternative Bioenergy Technologies, Synthetic Genomics, or Nanotechnologies" that will begin funding new research in Fiscal Year 2007. This RFA is expected to recur in subsequent years to sustain and support DOE's interest in conducting advanced explorations of the societal implications of its research activities.

Agenda

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