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Abstract

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Key words (separated by '-'): Innovation - Integration - Nanotechnology - Precaution - Promotion - Responsible

Chapter 22

Legislating the Laboratory? Promotion and Precaution in a Nanomaterials Company

Robin Phelps and Erik Fisher

Abstract

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Key words: Innovation, Integration, Nanotechnology, Precaution, Promotion, Responsible

1. Introduction

On December 3, 2003 the 21st Century Nanotechnology Research and Development Act (NRDA) was signed into law (1). This legislation established the National Nanotechnology Initiative (NNI) as the National Nanotechnology Program (NNP) and authorized multiyear federal funding for nanotechnology research and development. Since then, more than US$6.5 billion of federal funding has been authorized over the 4-year period, from fiscal year (FY) 2005 to FY 2009, that the legislation has been in effect.

The genesis of the NNP was a series of informal meetings in 1996 of the federal agencies involved in nanotechnology research. In 1998, this informal group became a formal Interagency Working Group (IWG). Over the next year, the IWG issued

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three reports: *Nanostructure Science and Technology* (August 1999), *Nanotechnology Research Directions* (February 2000), and *National Nanotechnology Initiative* (July 2000). Combined, these reports provided a blueprint for the strategic intent of US investment in nanotechnology research and development. One foundational footing of the blueprint was rapid technological development and accelerated market deployment intended to keep the USA competitive in the international arena for economic and other gains projected to be realized from nanotechnology products. Another foundational footing was responsible implementation intended to proactively and adequately address public concern. Eventually, both of these foundations became incorporated into the US nanotechnology legislation. Since the policy foundations of "rapid" and "responsible" nanotechnology research and development appear, at least on the surface, to be contradictory (2), it remains unclear and uncertain whether tensions between the two foundational footings play themselves out in actual research and development contexts. In short, do they coexist, and perhaps even mutually reinforce one another? Or do they remain irreconcilable, competing for focus and attention?

This chapter examines how these two policy foundations manifest themselves in a US nanotechnology research and development laboratory. First, an overview of the tensions as defined in the various Program Activities of the Act provides context for the case study. We then provide a brief review of issues and concerns that have been stated and documented in preparation for the Act's reauthorization. This is followed by a description of the case study including the overarching research project it is situated in, the methodology and methods employed, the initial findings based on a limited analysis, and a discussion of those findings.

2. Discussion

2.1. US Nanotechnology Legislation (See Note 1)

The 21st Century Nanotechnology Research and Development Act (NRDA) defines eleven Program Activities which serve as guideposts for intent and implementation. A reproduction of Section 2(b) of the Act, listing the eleven Program Activities, is contained in Appendix 1. These Program Activities logically cluster into three groups, which we label here as technical, promotional, and precautionary.

Seven of the Program Activities pertain to the technical objectives of nanotechnology research. These consist of the methods and resources for the cultivation of nanotechnology as an interdisciplinary science. Though some have expressed skepticism about the interdisciplinary nature of nanotechnology research and development, case studies of biomedical nanotechnology research settings provide a measure of confirmation of such an interdisciplinarity (3–5).

The four remaining Program Activities address two areas that policy makers deemed crucial to the public business of nanotechnology: promotion of the economic outcomes and precaution regarding the societal dimensions.

2.1.1. Economic-Promotion Considerations

Three Program Activities focus nanotechnology research and development efforts on economic considerations that promote meeting global competitiveness and extensive projected opportunities for nanotechnology applications. These promotional considerations include "ensuring…global leadership," "advancing…productivity and industrial competitiveness," and "accelerating" nanotechnology deployment. These Activities represent a key policy objective behind the NNP: US domination in this new competitive global market. The economic prospect for nanotechnology is projected to be substantial. Lux Research, an international market research firm, projected that between 2006 and 2014 global revenues from nanotechnology-enabled products will grow from $50 billion to $2.6 trillion and will comprise 15% of projected global manufacturing output (6). Notably, nearly every industrialized and developing country has initiated national research programs in nanotechnology to capture a share of the projected economic and societal benefits.

Global competition for the prospective nanotechnology market had reportedly grown over the 5-year period before the NRDA's passage. Mihail Roco, chair of the National Science and Technology Council's Subcommittee on Nanoscale Science, Engineering, and Technology reported that at least 30 countries had created national nanotechnology programs and that international nanotechnology funding increased multiple times for a global investment of approximately US$3 billion (7, 8).

The NRDA specifically requires "accelerating the deployment and application of nanotechnology research and development in the private sector, including startup companies." This language seeks to position nanotechnology deployment on a well-established research-to-technology commercialization path within the US innovation system – a system consisting of academic and federal lab research, startup companies, venture capital firms, and other entrepreneurial supporting infrastructure.

Combined, these promotional activities drive a policy focused on rapid development not only to keep pace with international competition but also to capture the benefits as well as the pervasive impacts of nanotechnology, which have been deemed "crucial" for the country's future economic health (9).

2.1.2. Societal-Precaution Considerations

The single remaining Program Activity contained in the NRDA stands by itself as much for its content as for its intent. Program Activity (10) requires "ensuring that ethical, legal, environmental, and other appropriate societal concerns… are considered during the development of nanotechnology." While this requirement for responsible implementation can be seen as a counterpressure to that of rapid implementation, it is also possible to regard it as a notable recognition of the importance of social trust of institutions for commercial success.

The impetus for this legislative directive came from a number of concerns surrounding nanotechnology that had been expressed in public and political discourses prior to the legislation. Policy makers appeared eager to separate concerns they could regard as credible and convincing from others that could be regarded as too speculative or fictional. One prominent critical theme during this time cited potential harm from exposure to nanotechnology particles, suggesting its potential as the "next asbestos" (10). Additional concerns encompassed other potential health, safety, and environmental risks, and they extended to broad ethical and political questions, including the role of democratic governance in nanotechnology.

Citing a severe lack of governmental monitoring and regulation of nanotechnology, the nongovernmental organization ETC Group (11) called for a global, mandatory moratorium on nanotechnology research and product development to allow time for a closer examination of the potential negative impacts on environmental, health, and safety. The report criticized the "substantial equivalence" regulatory approach being implemented at the time for nanoscale materials, a policy that had been used previously to show the safety of genetically modified organisms (GMOs) without doing full toxicological analysis of GM crops. As applied to nanotechnology, substantial equivalence presumes that novel nanoparticles are similar enough to their larger-scale particles that they do not warrant new toxicology studies. One of the distinctive features of nanomaterials is that they have properties that are different from those of the analogous bulk material; substantial equivalence fails to take this feature into account. The suggested moratorium would remain in effect until scientific communities could come together to develop and adopt monitoring mechanisms and reporting procedures in a "precautionary principle" approach to regulatory governance.

Understanding societal implications and addressing societal concerns about nanotechnology was also a prominent topic within the US government prior to the legislation enactment. It was a frequent topic of discourse among the Government agencies involved directly or indirectly in nanotechnology. Also, the National Science Foundation (NSF) held a national conference in 2000 and issued a subsequent report in 2001 on the topic of societal implications of nanotechnology. More than 50 distinguished professionals and executives from government and national laboratories, academic institutions, and the private sector were among the conference participants and contributors. In April of 2003, the US Congress held a public hearing on the societal implications of nanotechnology signaling recognition among legislators that societal concerns were an important consideration that needed to be addressed publicly.

The NRDA contains provisions outlining how the sociotechnical integration is to be accomplished. General strategies encompass what can be termed both "wide" and "deep" integration, where "wide" consists of research into societal concerns and dissemination thereof, and "deep" consists of feeding research on societal concerns directly into the NNP including the nanoscience research and development itself. The interdisciplinary sociotechnical integration potentially allows research on societal considerations to shape the course and outcomes of nanotechnology research and development. As such, it envisions a new form of scientific research in which explicitly "societal" considerations manifestly influence the design and pursuit of scientific research and the technology it is meant to enable.

2.1.3. Coexisting or Competing Mandates

In total, the legislation is an acknowledgement that the success of any federal nanotechnology program will not occur solely based on best efforts to increase the pace of scientific discoveries and of technology developments. It is a recognition, at least rhetorically, that a broad range of legitimate societal concerns exist, some of which could manifest as health and environmental product-related issues, choice and governance issues, and distribution of benefits and burdens, to name a few examples. Any of these concerns, whether "real" or "perceived" (12), could influence public trust, and hence commercial success. On this view, socially acceptable outcomes and commercially robust products can be seen to result from a dual focus on economic and societal considerations of nanotechnology.

Yet efforts to attempt a dual approach that combines accelerated economic promotion with more deliberative precautionary methods could manifest as dueling pressures on laboratory researchers and administrators, who may be confronted with what appears to be a largely irreconcilable tension between these two policy objectives. Perhaps the key difference between the two objectives is in how societal concerns are factored in to nanotechnology development. In the traditional economic-promotion approach to R&D, societal concerns are to be corrected by mechanisms that are seen to be external to the laboratory, such as market forces and regulation. In contrast, the sociotechnical integration approach present in the NRDA would be an internal mechanism that encompasses and intentionally addresses societal concerns during R&D decisions.

This type of integrated approach represents a small but growing trend in US federal science and technology policy. Yet none of the other programs that have attempted to employ it are as explicit or as high level as the NRDA. The primary previous attempt was the Ethical, Legal, and Societal Implications (ELSI) program of the US Human Genome Project (HGP). The HGP mandate to examine and consider the ethical, legal, and social implications was thought by the program leaders to be both visionary and unique (13). The ELSI program, however, has been criticized for lack of integrative outcomes and in general for failing to fulfill its mandate (13, 14). The NNI has funded two Centers for Nanotechnology in Society, one at Arizona State University (CNS-ASU) and one at the University of California at Santa Barbara (CNS-UCSB). In particular, the CNS-ASU employs an integrative approach to research known as "Real-Time Technology Assessment" (15) and, more recently, has developed the strategic vision of "Anticipatory Governance" (16).

2.1.4. Nanotechnology Legislation Reauthorization

Since its authorization, there have been a number of reviews of the NRDA program performed – some as specified in the NRDA legislation, others independently and externally organized. In 2005, the President's Council of Advisors on Science and Technology (PCAST), an outside advisory board designated in NRDA legislation to provide biennial assessments of the NNI to Congress, acknowledged in its first report that current knowledge and data to assess the actual risks posed by nanotechnology products were incomplete (17). This point was reiterated by House Science and Technology Committee Chairman Bart Gordon in a press release issued after a 2005 committee hearing on the topic

> There seems to still be ample unanswered questions in this field, but what is clear is that commercialization of the technology is outpacing the development of science-based policies to assess and guard against adverse environmental, health and safety consequences. The horse is already out of the gate... Prudence suggests the need for urgency in having the science of health and environmental implications catch up to, or even better surpass, the pace of commercialization (18).

Later that same year, the Nanotechnology Environmental and Health Implications (NEHI) Working Group was established to provide an infrastructure for coordination with and between Federal agencies focusing on nanotechnology environmental, health, and safety research and programs. One year later, a comprehensive examination of the NNP was conducted by the National Research Council of the National Academies of Science (NAS) per their legislative directive to perform a triennial review. Their report noted that there was very little published research addressing the toxicological and environmental effects of engineered nanomaterials and that environmental, health, and safety issues were of "significant concern to and a topic of serious discussion by government agencies and commissions, nongovernmental organizations (NGOs), the research community, industry, insurers, the media, and the public" (19). According to the report, effective solutions required a balancing of promotion with that of precaution and recommended NEHI facilitate research and development in a full life-cycle analysis of the precautionary aspects. In February of 2008, NEHI released its report defining an environmental, health, and safety research strategy and calling for the six regulatory agencies in the NNI to work individually and jointly to implement the strategy (20). A subsequent 2008 National Academy of Science report delivered harsh criticism of the NEHI plan concluding that there was no strategy in place (21).

Reports, analysis, and testimony from nongovernmental sources contained similar conclusions and recommendations. A report by the Project for Emerging Nanotechnologies (22) argued that better and more aggressive oversight and new resources were needed to manage the potentially adverse effects of nanotechnology and promote its continued development. In its 2007 nanotechnology policy report, Greenpeace proclaimed that "no regulatory framework has been developed to address the emerging issues" (23). Richard Denison, a Senior Scientist at NGO Environmental Defense Fund and former analyst with the US Congress Office of Technology Assessment leveled a succinct summation of the criticisms:

> NNI and many of its member agencies are talking and writing a great deal about the need to address nanotechnology's risks as well as benefits…But there is a continuing disparity between NNI's words and actions (24).

Denison reiterated the NRC report call for "a balanced approach to addressing both the applications and implications of nanotechnology [as] the best hope for achieving the responsible introduction" of nanotechnology products. In his 2008 Senate committee testimony, Matthew Nordan, President of Lux Research, echoed this sentiment noting that the current ambiguity and the "glacial pace" of setting specific regulatory guidelines is becoming a gating factor for commercialization (25).

> On January 15, 2009, the US House of Representatives introduced the National Nanotechnology Initiative Amendments Act of 2009 (H.R. 544). In February of 2009, the legislation was passed by the House without amendment and forwarded to the Senate Commerce, Science and Transportation. The bill reauthorizes and makes incremental changes to several key provisions of the NRDA. One intention of the reauthorization bill, as passed in the House, was to better address environmental, health, and safety (EHS) issues associated with nanotechnology while continuing to encourage promotion of the commercialization of the technology for economic growth and competitiveness. As stated by House Science and Technology Committee Chairman Bart Gordon (26) in conjunction with the passage of the House bill in 2009:
>
> It is important that potential downsides of the technology be addressed from the beginning in a straightforward and open way, both *to protect* the public health and to allay any concerns about the validity of the results. A thorough, transparent process that ensures the safety of new products will allow both the business community and the public *to benefit* from the development of these new technologies. (Emphasis added).

In summary, much of the reauthorization discourse has been directed toward developing a national governance framework with coordination amongst agencies and associated increase in funding to better address the precautionary aspects contained in the NRDA mandate to ensure consideration of the ethical, legal, environmental, and other appropriate societal concerns during nanotechnology development. The criticisms of the NNI's approach to responsible implementation suggest that this emphasis has received less attention and may be in direct competition to the emphasis on rapid implementation. It is also noteworthy that the reauthorization discourse focused on a more traditional top-down approach than that outlined in the NRDA's sociotechnical integration mandate. The next section describes a research project that investigates the possibility and utility of sociotechnical integration and then turns to a limited analysis of one of the case studies it has supported.

2.2. Socio-Technical Integration Research Project

The US legislative mandate for sociotechnical integration during nanotechnology R&D has opened up new opportunities to design and conduct experiments aimed at assessing the possibility and utility of sociotechnical integration to influence the direction of R&D. One such undertaking, the Socio-Technical Integration Research (STIR) project, is a three-year program that is administered by the Center for Nanotechnology in Society at Arizona State University. STIR is funded by the National Science Foundation (NSF #0849101) with the specific objective to assess and compare the varying pressures on and capacities for laboratory researchers to integrate broader societal considerations into their work. STIR places ten doctoral students into 20 laboratories in ten countries on three continents to conduct 20 "laboratory engagement studies," a cutting edge form of collaborative participant observation (27). The STIR method builds upon ethnographic qualitative research, a methodological paradigm pioneered by anthropologists and sociologists in the early twentieth century (28, 29). Ethnography uses extended, primarily participant observation, to examine the "shared patterns of behavior, beliefs, and language" of a "culture-sharing group" (29). Traditional laboratory studies employed an ethnographic method for studying science by examining the internal dynamics of scientific work through in situ observation "as it happens" and were pioneered by sociologist of science Bruno Latour (30–32).

The laboratory engagement study also transforms the "reflexive ethnography," which, in Woolgar's account, focuses on the reasoning practices used within the research laboratory to "generate awareness of reasoning practices as they are deployed in analysis" (32). Within STIR, the reflexive awareness is not only applied by the ethnographer to his own thinking about the phenomena they observe but also accomplished through an

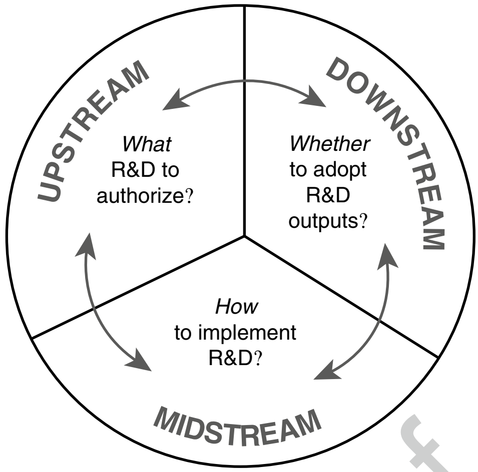

Fig. 1. Stages of science and technology governance (Adapted from STIR: Socio-Technical Integration Research Project Description, p. 6).

interdisciplinary collaboration between natural and social scientists. [AU1] Thus, it is also a methodological practice of introducing ethnographic observations and findings into the laboratory research context itself – both for verification and so as to stimulate mutual learning and reflection by both parties to the sociotechnical collaboration (27).

STIR studies take place over a 4-month period and utilize the novel methodological approach of midstream modulation. As shown in Fig. 1, within laboratories research and development decisions are conceptually situated in the midstream of the science and technology governance process, occurring between upstream policy decisions and downstream regulatory and market activities. Midstream agents, including those who make basic research decisions, thus perform the functional role of implementing authorized research agendas. Research developments, which are measured by mapping the evolution of research decisions over time, are theorized to be modulated or incrementally shaped by a variety of institutional, social, and cognitive factors. Modulation at the midstream is posited to occur in three successive stages: de facto modulation, the factors that influence decisions; *reflexive* modulation, laboratory practitioners' awareness of these factors and of their own roles within larger social systems; and *deliberative* modulation, in which scientists consciously form decisions that are tempered by a reflexive awareness of these factors. Thus, midstream modulation provides a mechanism for evaluating and adjusting research decisions during the research process and constitutes a bottom-up approach for shaping research and development directions in light of relevant societal considerations – what has been termed "governance from within" (33). This unique application of reflexive ethnography to science and engineering research decisions serves to interact with the content of research decisions, thereby in theory lending visibility to both the promotional and precautionary influences on research decisions.

STIR engages in midstream modulation through interdisciplinary collaboration between social and natural scientists. Despite longstanding calls for such sociotechnical integration and collaborations (14), there have been very few laboratory engagement studies conducted using this approach. The NRDA mandate affords a renewed call for and recognition of the need for sociotechnical integration in nanotechnology development. Various types of relationships between social and natural science have recently been initiated in emerging technology research programs including nanotechnology, genetic engineering, and synthetic biology. Often the failed genetically modified crop debate is used as an example of the need and justification for including social scientists in these primarily public-funded research programs. In these relationships, Calvert and Martin (34) suggest two different roles for social scientists: the social scientist can perform the role of either a "contributor" or a "collaborator." A contributor is one who contributes to (at times as a representative of the "public"), facilitates the discussions of, and studies the ethical, legal, and social implications of research. In contrast, a collaborator is one who is involved with the research and interacts with the researchers in ways that can potentially shape the research agenda and influence the research direction. The collaborator role STIR scientist has shown some positive indications of success in initial laboratory engagements (27, 35). The next section offers findings drawn from one such engagement study.

2.3. STIR Case Study: Rocky Mountain Nanomaterials

The site for one STIR case study was a company, Rocky Mountain Nanomaterials (see Note 2), producing novel nanomaterials using a patented application technology. Nanomaterials can be considered a nanotechnology sector with numerous applications across the spectrum from biomedical, energy, and various technology and industrial markets. A report by market analyst firm Lux Research identifies nanomaterials at the beginning of the nanotechnology value chain (36). Thus, the nanomaterials sector represents a major portion of the economic potential for nanotechnology and is therefore posited to exhibit a number of influences for economic promotion. In addition, according to the Nanotechnology Industries Association (NIA), a UK-funded organization formed in 2005 to establish a framework for the safe, sustainable, and socially supportive development of nanotechnology, a complex and convoluted mixture of regional, national, trade, industry, and international voluntary and regulatory governance initiatives for nanomaterials exists (37). These disparate governance initiatives

1) Environmental toxicity and persistence

Material could be degraded rapidly or slowly [the product's intended life cycle needs to be taken into account

2) Human toxicity

Material could be total non-toxic through all routes of exposure, or conversely be highly toxic, a teratogen and possibly transmissible

3) Human exposure

Material might be used in a highly controlled treatment, or used in consumer or environmental quantities

4) In-vivo bio persistence

Material may accumulate and not be removed from body, organism, or organelles

5) Auto activity

Material may have no means of self recognition or environmental awareness, or may activate on response to, and in order to change, the environment

6) Mobility

Material may be permanently immobilized, it may become free as a result of intended use, designed to be free for purpose, transmissible, uncontrollable, and possibly even self-propelling

Fig. 2. Six dimensions of risk for Nanomaterials (see ref. 37).

need to address six dimensions of risk identified for nanomaterials (see Fig. 2). The nanomaterials sector is thus also posited as likely to exhibit evidence of influences for precaution, hence making it a viable source for examining the nature of interactions between the NRDA's promotional and precautionary mandates.

Rocky Mountain Nanomaterials is a university spin-out, a company which emanated from research conducted at a university in Colorado, which utilizes a patented process to create novel nanomaterials. University spin-outs have been shown to be important contributors in the emergence of nanomaterial applications (38). The company has been in business since 2002 and has a staff of four PhD scientists, one operations manager, and two founding executives. In addition, the laboratory has strategic partnerships with departments at the university where two additional founders of the company work.

This laboratory engagement study was conducted from April through August of 2009. The length of the study was predetermined and was consistent across the STIR laboratory sites. The primary empirical data collection methods were participant observation and semistructured and unstructured interviews. The researcher met individually each week with two scientists and participated in the weekly laboratory project review meetings. One scientist ("C4") received his PhD in Chemical Engineering from a university in the US Rocky Mountain region; the other scientist ("M1") received his PhD in Electro Chemistry from the same university. Interview responses and observations were recorded in a field notebook, and many of the individual interviews, with the scientist's permission, were digitally recorded. Documents, obtained with permission from the laboratory, and content from archival research form the remainder of the empirical data sources.

Interviews were guided by a protocol developed during the STIR pilot study (27). The model (see Fig. 3) consists of four distinct conceptual components intended to describe research decisions as well as to capture and make visible – to both the investigating STIR scientist and to the participating laboratory scientists – the de facto influences of societal considerations during research activities. The model was often utilized during the study to initiate the semistructured interviews with the scientists.

The remainder of this chapter presents the results of a limited study of a subset of the data generated in the Rocky Mountain

OPPORTUNITY Perceived state of affairs eliciting a response	**CONSIDERATIONS** Selection criteria that potentially mediate the response
ALTERNATIVES Perceived available courses of action	**OUTCOMES** Effects of selecting alternatives in light of considerations

Fig. 3. Decision protocol components (Adapted from STIR: Socio-Technical Integration Research Project Description, p. 7).

Nanomaterials case study. Rather than attempting to investigate the possibility and utility of sociotechnical integration, this particular study sought to develop broad classification categories which could characterize and relate the "nontechnical" or "societal" influence on technical research decisions.

2.3.1. Findings: Decision Influences

A preliminary analysis of a subset of the data – drawn from interviews, lab meetings, and informal conversations – was conducted using Conceptually Clustered Matrix display format (39). The data were placed into two major categories of influence: external and internal. Internal influences originate from the people and the policies within the company and indicate cultural norms that can guide decisions and behaviors. External influences originate from outside the company and indicate the institutional context of the innovation system, which can also guide decisions and behaviors. Within each category, the type of influence was categorized as either "technical" or "societal." From this grouping of empirical data, four distinct societal influences on the laboratory decisions emerged: economic, intellectual property, university relations, and environment, health, and safety (EHS). Of these, economic considerations had the greatest number of instances and dominated the external societal influences; however, it occurred only in a few instances in the case of internal societal influences. In contrast, university relations considerations were a much stronger internal societal influence but only occurred in a small number of instances as an external societal influence. That university relations were stronger internally is to be expected given the fact that the laboratory is a university spin-out and maintains ongoing ties to the university for research. Similarly, intellectual property was mentioned more often as an internal rather than as an external societal consideration. This may be due to the fact that intellectual property serves as a competitive advantage and as a barrier to entry into the market for others, thus having a significant potential economic impact.

EHS was the only consideration mentioned by all participants, and there was a near balance in the number of EHS considerations between internal and external societal influences. For example, a new opportunity required the use of hydrazine, an inorganic chemical compound. The researchers were aware of the potential negative and positive external societal considerations of hydrazine given its use in a range of applications from rocket fuel to pharmaceuticals to automotive airbags. They were aware that the US Occupational Safety and Health Administration (OSHA) was looking at toxicology, an internal EHS consideration. During the discussions of the opportunity, the question came up about the safe handling of hydrazine, an example of an internal EHS consideration. One of the participants agreed to make contact with the largest producer of hydrazine to find out the standard safe handling practices. In another example, one of the participants was looking at their current use of carbon in a nanomaterials application. He expressed an external EHS consideration and concern that in this specific application their existed the possibility of overheating potentially causing the nanomaterial to catch on fire because carbon, which was selected for this application because of its high conductivity, is combustible at high temperatures.

In addition to these four categories of societal influences, the conceptually clustered matrix also yielded a broader societal influence theme, which is here termed "green-nano." This theme appeared in both economic as well as EHS considerations. A majority of the external economic considerations were focused on so called "green energy," energy developed from renewable sources. This focus can more than likely be associated with the current Colorado and national priorities of becoming a "green economy" by both reducing the country's dependence upon foreign oil and reducing the carbon output during the production of energy from fossil fuels. It must be noted however that the only instance when "green-nano" was used in this latter sense was in the case of "carbon avoidance" as an internal EHS consideration. For the most part when "green-nano" was used as an economic consideration it was in reference to funding that could be obtained from government, venture capital, and/or strategic customers by pursuing green energy opportunities. (This finding is confirmed by one researcher's statement, "We can raise money with green" (see Note 3) and by another participant's statement that a carbon monetization mechanism called carbon credits could be a "cash cow" (see Note 4).) Notably, "green-nano" was employed as an EHS consideration both in pursuit of a green energy funding opportunity for the lab and in critically questioning the same opportunity. (The former inference is based on the potential funding source's emphasis on no carbon byproducts, while the latter is derived from one participant's statement, "How green is it when it uses nasty precursors?" (see Note 5).)

2.3.2. Analysis of Findings (See Note 6)

Analysis of the data subset produced four categories of "societal" influence on laboratory decisions in a nanomaterials laboratory: economic, intellectual property, university relations, and EHS considerations. Of these, both intellectual property and university relations emerged more in relation to economic justification (in cases of competitive differentiation and outsourcing partnership). Accordingly, these two categories fall primarily under economic promotion and appear less frequently under societal precaution. The analysis did find evidence of societal influences present in research decisions; however, economic considerations by far outweighed any other societal consideration. Thus, within the scope of the nanomaterials sector in which the Rocky Mountain

Nanomaterials company operates, promotion far outweighs precaution.

This limited analysis did discover some product-related societal influences concerning EHS; however, broader issues including those of power, choice, and distribution were usually not mentioned by research participants without prompting by the STIR scientist. It is intuitive that promotion considerations would be strongly influential given the fact that this laboratory is a startup company that uses a combination of market signals, customer opportunities, and government sources of funding to derive company growth and survival. It is also not unreasonable to anticipate that there would be a deficit of precautionary influences given the lack of clear downstream regulatory mechanisms governing risk, as previously detailed, and given a relatively unprecedented legislative directive for sociotechnical integration that in effect requires significant changes to the institutional settings governing nanoscale research and development. Such changes in the norms, values, and rules that shape organizational behavior regarding economic promotion and societal consideration would need to occur not only at the microlevel of laboratories but also at the mesolevel of institutional environments that constrain or encourage innovation (40–42). Institutions and organizations constitute primary elements of an established innovation system (43). Though innovation systems are evolutionary in many ways, they can also be slow to change and adapt in others (41, 42, 44). New technologies produce pressures on the institutions and organizations within a sector to change or adapt in response to new concerns such as the precautionary and promotional considerations of US legislation. Institutional and organizational response to these pressures is distinct within a sector and is based in part on the transformative capacity of the technology, whether it is endogenous or exogenous to the sector, and on the sectoral adaptability, the supportive or disruptive effects of the technology on the sector (45). The overall commercial success or failure of a technological regime can be a function in part of in what ways an innovation system retains old characteristics and in what ways it remains flexible and open to adaptation.

A thorough examination of the source and nature of the mesolevel institutions that shape the economic-promotion and societal-precaution influences would be a next reasonable step toward creating insight and understanding for policy and practice. Review of the initiatives of the US agencies involved in nanomaterials risk governance – the Federal Drug Administration, the Environmental Protection Agency, and the National Institute for Occupational Safety and Health – may provide insights into ways the nanomaterials sector may be responding to precautionary issues. A report from a UK pilot study (46) into how public policy might encourage the dual objective of promotion with precaution approach specifically for nanomaterial research and development could provide additional insight.

3. Notes

1. The material in this section draws heavily upon material in ref. 2.
2. The company's name has been changed for confidentiality purposes.
3. Participant interview, May 6, 2009, Laboratory site.
4. Participant interview, May 6, 2009, Laboratory site.
5. Project Review meeting, May 6, 2009, Laboratory site.
6. The limited analysis applied to the subset of data from the Rocky Mountain Nanomaterials case study did not indicate how best to characterize the relation between the two policy goals of promotion and precaution. Whether these two goals coexist or compete remains a broad question that requires more nuanced analysis. While the statements "we can raise money with green" would seem to indicate coexistence, the statement "how green is it?" implies competition. Similarly, this limited analysis did not seek to provide insight into the capacities of laboratories to engage in sociotechnical integration attempts or into how such capacities might be enhanced. We note that throughout this case study, broader societal dimensions of research decisions that were evident to the STIR scientist were not always indicated by the laboratory scientists. This was taken not to be due to intentional efforts by laboratory participants to ignore or negate these dimensions; rather, such dimensions simply did not appear to be in the de facto cognitive frame of decision alternatives of the company scientists. Once societal considerations were brought to the attention of a lab scientist by the STIR researcher through the use of the decision protocol, however, opportunities arose to discuss these dimensions further. Over time, these discussions extended from single decisions to more encompassing ones related to industry, market, and society. Other forms of analysis of the data set, including more narrative-based accounts, are therefore likely to produce more penetrating insights into the possibility and utility of sociotechnical integration mandated by the US legislation and investigated by projects like STIR. It is also worth noting that, in other settings, nanoscientists have been documented to be more concerned about some nanotechnology-associated risks than are members of the public (47).

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Appendix 1. Program Activities of the National Nanotechnology Program Laid Out in Section 2(b) of the 21st Century Nanotechnology Research and Development Act

1. Developing a fundamental understanding of matter that enables control and manipulation at the nanoscale.
2. Providing grants to individual investigators and interdisciplinary teams of investigators.
3. Establishing a network of advanced technology user facilities and centers.
4. Establishing, on a merit-reviewed and competitive basis, interdisciplinary nanotechnology research centers, which shall
   - (a) Interact and collaborate to foster the exchange of technical information and best practices.
   - (b) Involve academic institutions or national laboratories and other partners, which may include States and industry.
   - (c) Make use of existing expertise in nanotechnology in their regions and nationally.
   - (d) Make use of ongoing research and development at the micrometer scale to support their work in nanotechnology.
   - (e) To the greatest extent possible be established in geographically diverse locations, encourage the participation of Historically Black Colleges and Universities that are part B institutions as defined in section 322(2) of the Higher Education Act of 1965 (20 U.S.C. 1061(2)) and minority institutions [as defined in section 365(3) of that Act (2 U.S.C. 067k(3))], and include institutions located in States participating in the Experimental Program to Stimulate Competitive Research (EPSCoR).
5. Ensuring US global leadership in the development and application of nanotechnology.
6. Advancing the US productivity and industrial competitiveness through stable, consistent, and coordinated investments in long-term scientific and engineering research in nanotechnology.

7. Accelerating the deployment and application of nanotechnology research and development in the private sector, including startup companies.
8. Encouraging interdisciplinary research, and ensuring that processes for solicitation and evaluation of proposals under the program encourage interdisciplinary projects and collaborations.
9. Providing effective education and training for researchers and professionals skilled in the interdisciplinary perspectives necessary for nanotechnology so that a true interdisciplinary research culture for nanoscale science, engineering, and technology can emerge.
10. Ensuring that ethical, legal, environmental, and other appropriate societal concerns, including the potential use of nanotechnology in enhancing human intelligence and in developing artificial intelligence which exceeds human capacity, are considered during the development of nanotechnology by
    - (a) Establishing a research program to identify ethical, legal, environmental, and other appropriate societal concerns related to nanotechnology, and ensuring that the results of such research are widely disseminated.
    - (b) Requiring that interdisciplinary nanotechnology research centers established under paragraph (4) include activities that address societal, ethical, and environmental concerns.
    - (c) Insofar as possible, integrating research on societal, ethical, and environmental concerns with nanotechnology research and development, and ensuring that advances in nanotechnology bring about improvements in quality of life for all Americans.
    - (d) Providing, through the National Nanotechnology Coordination Office established in section 3, for public input and outreach to be integrated into the Program by the convening of regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences, and educational events, as appropriate.
11. Encouraging research on nanotechnology advances that utilize existing processes and technologies.

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Query	Details Required	Author's Response
AU1	The sentence "Within STIR, the reflexive ..." has been reworded for clarity. Please check.	