Environmental Reform Organizations and Undone Science in the United States: Exploring the Environmental, Health, and Safety Implications of Nanotechnology

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## Abstract:

Environmental organizations have raised concerns about the environmental, health, and safety (EHS) implications of the hundreds of products containing nanomaterials that are now on the market. In the process they have drawn attention to the "undone science" of EHS research and called for changes in both research and regulatory policy. Environmental and other advocacy organizations have been active in three policy fields in the United States: funding levels for EHS research, moratoria on the production of new nanomaterials largely based on the precautionary principle, and negotiations over definitions of safe or responsible nanotechnology with the private sector and the federal government. During the administration of President George W. Bush, calls for more research and industry guidelines met with greater success than those that called for moratoria and enhanced mandatory regulation. The more successful strategies tend to reproduce scientistic politics associated with risk assessment, whereas the less successful strategies would open up a broader public debate on the extent to which nanotechnology is needed or socially desirable.

Keywords: nanotechnology, regulation, health, risk, social movements

Since the 1990s, there has been growing public and private investment in nanotechnology, with political support across partisan divisions. In the United States, hundreds of products containing nanoscale materials have been developed and commercialized. However, a growing number of environmental organizations and other public advocates have suggested that the release of nanomaterials prior to a full exploration of their safety may be setting the stage for a repetition of toxic exposure similar to the diffusion of asbestos, lead, chlorinated chemicals, and other materials in previous generations of technological enthusiasm. Whereas nanotechnology has been described as the next industrial revolution, it also may be the next toxic exposure story. A question emerges about how to balance the potential benefits and dangers of the new technology.

By 2003 some environmental organizations had become involved in controversies involving the U.S. government's policies for nanotechnology research and regulation. They argued in favor of slowing the speed at which nanotechnology is released in markets and into the environment, and some even suggested a temporary moratorium. In defense of their precautionary approach, the organizations drew attention to the lack of knowledge of the environmental, health, and safety (EHS) implications of nanotechnology, that is, the potential environmental effects of nanotechnology on wildlife and ecosystems; the health effects on the general population due to ingestion, inhalation, and other forms of exposure to nanomaterials; and safety issues such as workplace exposure. However, the organizations differed in their strategies and approaches to the problem. For example, Environmental Defense called for more EHS research, and it also developed a partnership with DuPont to develop industry guidance, whereas other organizations called for a full or partial moratorium on the release of nanotechnology products until the EHS concerns were sorted out.

The discussion that follows will focus on a small group of organizations that have advocated for greater EHS research or changes in regulatory policy that would enhance EHS protections in the U.S. Rather than limit the scope a priori to environmental organizations, the boundary criterion instead includes a more diverse array of public interest organizations that have advocated environmentally oriented reforms in nanotechnology policy. For example, the Woodrow Wilson International Center for Scholars, which in partnership with the Pew Charitable Trusts has sponsored the Project on Emerging Nanotechnologies, is a nonprofit research organization originally established by the U.S. government but now funded mostly by donations and income from its endowment. Although it is not an environmental organization, its staff has played a role in policy issues such as the EHS funding controversy. Likewise, the Calvert Group and Domini Social Investments are for-profit, socially responsible, mutual-fund investment companies that have played a role similar to that of environmental organizations in the development of the politics of the moratorium. As a result, rather than constraining this study to an organizational field based on a predetermined category (such as "environmental nongovernmental organizations"), it will instead focus on organizations that have advocated greater attention to EHS issues and related policy reforms. Together, this group will be referred to as "EHS reform organizations" (or "EROs"), with the understanding that environmental reform is not the primary mission of all of the organizations. This category creates a fairly delimited group of organizations

that will be the focus of attention, and it excludes from analysis organizations that might be included in the broader category of "civil society," such as industrial trade associations or academic centers (e.g., the Center for Biological and Environmental Nanotechnology) that have played a role in the broader controversy over EHS research. The analysis of other organizations in the nonprofit, academic, or civil society sectors remains outside the scope of the present study.

EROs involved in nanotechnology policy draw attention to "science as culture" in the broad sense of the ways in which political decisions and allocations of resources shape what science is funded and left unfunded or undone. In a political culture characterized by a neoliberal approach to regulation and an emphasis on developing new technologies to ensure a competitive position in the global economy, the policy emphasis has been on developing the science that leads to commercializable nanotechnology products and to move more slowly on the science that assesses its potential EHS implications. The EROs have challenged the consensus by drawing attention to the ways in which a field of nanotechnology science is constructed and the policy implications of the shaping of that knowledge.

This essay will focus on the three research questions. What proposals were made by EROs for research and regulatory reform? How have the proposals changed over time? What was the relative success and lack of success of different proposals and reform strategies, specifically strategies focused on a moratorium versus those focused on more research, industrial guidance, or more stringent government regulation? To answer the questions, I explore proposals and interventions for reform in three fields of nanotechnology policy and design in the United States: the controversy over an adequate level of funding for EHS research; calls for a moratorium on research and/or products until safety is determined; and attempts to develop regulations and standards that define some forms of nanotechnology as meeting basic EHS concerns. The three cases will focus on the United States during the period up to the end of 2008. The central research questions can be answered within the time limit of 2008, but it was also clear that the policy environment was changing after the election of President Obama and Democratic Party majorities in both houses of Congress. In 2009 the National Nanotechnology Initiative Amendments bill, the federal stimulus package, and the re-examination of the Toxic Substances Control Act of 1976 all signaled a shift toward greater support for EHS research and potentially more stringent regulation. However, because the changes were not yet defined and implemented at the time this article went to press, the policy shifts of the new administration will be left to future research.

### EHS and Nanotechnology: A Case of Undone STS Research

Given the highly controversial nature of the EHS implications of nanotechnology, it may be surprising that the topic has received relatively little attention in the social studies of nanotechnology. Social scientists have discussed biotechnology regulation and public acceptance with respect to nanotechnology (David and Thompson, 2008; Kearnes *et al.*, 2006; Einsiedel and Goldenberg, 2004; Mehta, 2004), and the comparison with biotechnology provides a useful reference for exploring the EHS implications of nanotechnology. EHS issues and questions of hazards and risk also arise in various studies of public opinion and nanotechnology (Kahan *et al.*, 2008; Scheufele *et al.*, 2007; Toumey, 2009). To avoid future EHS problems and public backlash, some social scientists have suggested the need for more reflexive analysis that involves a broad debate on social progress, the application of STS (science and technology studies) concepts to regulatory foresight, and technology assessment that goes beyond traditional policy approaches of risk assessment (Barben *et al.*, 2008; Guston and Sarewitz, 2002; Kearnes *et al.*, 2006; Marchant *et al.*, 2008; Williams, 2006). Social scientists have also encouraged greater public input into policy debates, and consensus conferences or other deliberative fora represent one avenue for achieving that input, especially in the "upstream" stages that precede the release of materials into the environment (Hodge and Bowman, 2007; Pidgeon *et al.*, 2008; Powell and Kleinman, 2008; Rogers-Hayden and Pidgeon, 2008; Toumey *et al.*, 2006). However, consensus conferences outside Denmark appear to have limited impact on policymakers (Joly and Kaufmann, 2008), and likewise social science researchers and their studies also have had limited impact on policy (Bennett and Sarewitz, 2006; Bowman and Hodge, 2007; Hodge *et al.*, 2007).

There is also relatively little research to date on the role of EROs in public discussions of nanotechnology research and regulation. Again, there are some explorations of the precedent in the genetically modified food controversy (David and Thompson, 2008; Kearnes et al., 2006), and there is inclusion of some statements by environmental organizations in The Yearbook of Nanotechnology in Society (Fisher et al., 2008). There is also some research in progress that promises to bring the topic more into the mainstream of social studies of nanotechnology (Center for Nanotechnology in Society, 2008). Although the topic is beginning to receive some attention, this study will provide the first sustained analysis of the role of environmental and related organizations in nanotechnology policy in the U.S. Building on the insights of the sociology of scientific knowledge that has been oriented toward policy contexts (e.g., Jasanoff, 1990), I will approach the problem of the role of EROs from the perspective of political sociology. Specifically, science and policy is examined less through the lens of close analysis of discourse, laboratories, and networks and instead more based on attention to interactions among the scientific, political, industrial, and civil society fields (Frickel and Moore, 2006; Moore et al., 2010).

One of the central contributions of the new political sociology of science (NPSS) has been to draw attention to the problems of unequal power in the public participation in scientific and technological decision-making, a condition that creates fertile ground for the mobilization of social movements and for the role of EROs in the politics of science and technology (Frickel, 2004; Kleinman, 2000; Moore, 2008; Moore et al., 2010). The problems of unequal power can be seen in the changes in the organizational dimensions of scientific research, in the role of public participation in public policy, and in the emergence of social movements and advocacy groups oriented toward scientific and technological issues. Within this broad set of problems, I focus here on developing one central concept related to the role of public participation in research and regulatory policy: the problem of "undone science" (Hess, 2007; Frickel et al., 2009). The problem refers to a situation that occurs when social movement and other civil society organizations that claim to represent a broad public interest want to make epistemic claims, but they find that the research questions that they are asking have not been funded and are not being addressed by the mainstream of academic, government, and industrial research. Questions of undone science have become increasingly salient as society has become more technology-driven and technology-based, academic research has come to

approximate industrial research (Kleinman and Vallas, 2001), and policymaking and regulations have become more "scientized" (Kinchy *et al.*, 2008). In this case, EROs are not all necessarily defined as social movement organizations, but they play a similar role when they become aware of and draw attention to research programs that they believe would serve a broad public interest if they were funded. The case of EHS research is a good example of undone science, and, as I will discuss in the conclusion, it also provides an opportunity to reflect on the issue and deepen our understanding of it.

EROs that call attention to the undone science of EHS research and the policy implications of commercializing a technology with unknown hazards and risks tend to comprise the subordinate networks of policy fields. Those fields tend to be dominated by more heavily funded networks of nanotechnology firms, the military, and industrysympathetic elected officials and government agencies that prefer to move ahead rapidly with the technology before having a complete picture of its EHS implications. As a result, we would expect that EROs that adopt positions in opposition to those of a technological trajectory that is supported by the dominant agents of military and industry would find that their recommendations fall on deaf ears. However, when one studies the action of EROs in the nanotechnology policy fields in more detail, there is a much greater interplay between agency and structure. There are potential openings for coalitions between some EROs and industrial firms and associations, and there are divisions among government agencies and the branches of government. There are also divisions among EROs that can both weaken the potential for coalitions or open opportunities due to radical flank effects on centrist groups. Consequently, a field approach characteristic of political sociology enables an analysis that can chart out both the underlying structural limitations and the relative efficacy of various strategies for change.

### Nanotechnology EHS Research as Undone Science

The National Nanotechnology Initiative was formally proposed in 1999 as part of the Office of Science and Technology Policy of the White House of President Clinton, and it was established in October 2000 (for the history, see McCray, 2005). The interagency effort was coordinated by a subcommittee of the National Science Foundation (Roco, 2004). The effort was bipartisan in the sense that it was continued under the administration of President George W. Bush, and the "Twenty-First Century Nanotechnology Research and Development Act" was passed in Congress in December 2003. Congress explored emergent societal implications and included their consideration in the act, but it also mandated the rapid development of nanotechnology (Fisher and Mahajan, 2006). Sometimes misconceptualized as a government agency, the National Nanotechnology Initiative is a coordinating effort among agencies.

Other initiatives were occurring at the state government level, such as the launching of the California NanoSystems Institute in 2000. By 2004 the U.S. government was spending about \$1 billion annually in research, compared with \$3.6 billion spent on nanotechnology research worldwide (Roco, 2004). Commercialization proceeded rapidly, and by 2008 there were hundreds of products on the market containing nanoscale materials, with nanoscale zinc, carbon, and silver the most common materials. Products that contained synthetic nanomaterials included cosmetics, sunscreens, sporting goods (such as tennis and golf balls), clothing, electronics, appliances, cleaning goods, and paints (Project on Emerging Nanotechnologies, 2009). In the United States, the materials

were officially presumed to be safe if they were chemically similar to existing materials, a regulatory stance that is consistent with country's generally neoliberal approach to industry regulation in general (Kinchy *et al.*, 2008; Kleinman and Kinchy, 2003, 2007). The assumption that nanoscale materials have the same EHS profiles as structurally similar materials that have been deemed to be safe at a larger scale turned out to be controversial, both scientifically and politically, because nanoscale materials of similar structure to existing molecules may turn out to have different properties and reactivity to biological systems.

### The Growth of EHS Research

The EHS research field for nanotechnology, which includes a subset of research on nanotoxicology, remained nascent, but a growing body of studies suggested that the materials were hazardous to humans and other life, especially nanoparticles and nanotubes that were not embedded in a larger molecular matrix. An inventory of studies completed in 2005 found only 208 research projects worldwide (Rejeski, 2005b), but the field was growing rapidly. By 2007 review articles were becoming more widespread, a sign of the maturation of a research field (e.g., Donaldson *et al.*, 2006; Helland *et al.*, 2007; Lam *et al.*, 2006; Singh and Nalwa, 2007). Nevertheless, researchers in the field and EROs called attention to the gap between the available research and knowledge about what kinds of nanomaterials, if any, were safe enough to be used commercially, especially in consumer products, and to be released widely into the environment.

Federal funding on EHS dimensions of nanotechnology can be identified as early as 1999 for the National Science Foundation and Department of Defense and 2002 for the Environmental Protection Agency (or EPA, Roco, 2004). In August 2003 the NNI formed the Nanotechnology Environmental and Health Implications Working Group, and in 2004 more concerted federal funding efforts for EHS research field began to appear (National Research Council, 2006). Similar developments were occurring in other countries, notably the U.K. (Rogers-Hayden and Pidgeon, 2007; Royal Society and Royal Academy of Engineering, 2004). In 2004 the National Institute for Occupational Safety and Health (NIOSH) launched the Nanotechnology Research Center, with a small (\$2 million) program of support on the toxicity of nanoparticles, and the National Toxicology Program coordinated efforts among government agencies (Roco, 2004). In October, 2004, NIOSH and the Health and Safety Executive of the U.K. cosponsored the First International Symposium on Nanotechnology and Occupational Health (Mark, 2004). A month later the EPA also awarded \$4 million in grants to study EHS implications, representing the first concerted effort by the federal government to attempt to answer the questions of undone science. Grants included research on the absorption and toxicity of nanoparticles on the skin, in drinking water, on cultured lung tissue, and marine life (Weiss, 2004).

In 2005 efforts to coordinate EHS research internationally coalesced when the Chemicals Committee and Working Party on Chemicals, Pesticides, and Biotechnology of the Organization for Economic Co-operation and Development held a special joint meeting on the EHS implications of nanotechnology. The next year the organization formed the Working Party on Manufactured Nanomaterials to coordinate EHS research internationally. The Working Party selected fourteen materials as "representative" of what was either already on the market or soon to be commercialized, and it published

several reports that presented an inventory of research underway and guidelines for evaluation (Organization for Economic Co-operation and Development 2008a, 2008b).

The EPA continued to develop EHS research in coordination with the international effort. Between 2004 and 2008 the amount of EHS research funding grew, and the agency funded (either internally or through grants) about \$33.7 million (Morris, 2008). However, from the perspective of EROs concerned with EHS implications, the amounts appropriated were relatively small in proportion to the overall government investment in nanotechnology research, and there were also concerns raised about the relative emphasis of EHS versus environmental remediation research. For example, in March, 2006, the EPA awarded \$5 million across 14 grants for EHS research, but the agency awarded a much larger amount, \$22 million, for the use of nanotechnology for environmental remediation purposes (National Research Council, 2006, p. 75).

#### EROs and EHS Research Agendas

In 2005 the National Academies held the Workshop on Responsible Development of Nanotechnology, which provided the basis for a report by the National Research Council (2006) that recommended the expansion of EHS research. Here, we begin to see the role of EROs in this field of nanotechnology policy. The stakeholder-based workshop included participation by Richard Denison, a senior scientist at Environmental Defense, who noted that the total federal government budget for EHS research had been \$10 million per year and had increased only recently to about \$40 million. He argued that the budget should be set at a minimum of \$100 million per year for several years in order to have a more adequate understanding of EHS implications (National Research Council, 2006, p. 173; also Denison, 2005). Two months later, the President's Council of Advisors on Science and Technology (2005) released a report that claimed that \$82 million of the FY 2006 budget was dedicated to EHS research. The number conflicted with other estimates of only \$38.5 million (Denison, 2005). One reason for the difference in estimates is work by the National Institute of Standards and Technology on the possible changes of particle properties when they enter the environment; this work either may or may not be counted as EHS research (Morris, 2008).

In April, 2005, a new project emerged on the political landscape that began to play a role in the debate on EHS funding: the Wilson Center's Project on Emerging Nanotechnologies. In testimony before Congress in November, project director David Rejeski stated that not enough was known about risks, regulatory policy needs, or even how much research was being done (Rejeski, 2005a). Within two weeks the organization released an inventory of research that identified only 161 federally-funded projects (and 208 globally) related to EHS (Rejeski, 2005b). The project noted that EHS research at that time was only about \$38 million, or 4% of the total nanotechnology research budget, but it also noted that the U.S. had funded more than three quarters of all research in this area on a global basis. Nevertheless, the report found large gaps in the research and the absence of an overarching research strategy. In addition to research on toxicity and life cycles, research was needed on perception risks, structural risks such as regulatory failures, and "wildcards" such as accidents and terrorists.

In November, 2005, the House Committee on Science held a meeting titled "Environmental and Safety Impacts of Nanotechnology: What Research Is Needed?" Clayton Teague, the head of the National Nanotechnology Coordination Office, told the committee that EHS concerns were not sufficient to warrant the allocation of more funding to the area (Hardin, 2005). At that time the FY-06 budget was set to allocate about \$38.5 million of \$1.05 billion to EHS research. A report by Andrew Maynard of the Project on Emerging Nanotechnologies found that only \$13 million of the \$38.5 million was "highly relevant" in terms of EHS issues, whereas in Europe about \$24 million was being spent in the equivalent category (Project on Emerging Nanotechnologies, 2008b; see also Maynard, 2006). Again, the claim was not accepted by all parties in part due to how NIST research was counted.

Both the committee chair, Republican Representative Sherwood Boehlert, and the ranking Democratic member of the committee, Representative Bart Gordon, called for much more funding, and Denison reiterated the call for a \$100 million allocation (Hardin, 2005). In a follow-up letter sent in February, 2006, to the chairs and ranking members of the House and Senate appropriations committee, Environmental Defense and 13 other organizations noted that research on the health and environmental implications of nanotechnology represented less than four percent of the \$1 billion annual budget of the National Nanotechnology Initiative, and they called for a significant increase in appropriations (Environmental Defense, 2006). Of particular interest in this statement was the fact that the signatories included not only the Natural Resources Defense Council and the Union of Concerned Scientists but also a variety of chemical companies and the NanoBusiness Alliance. On this issue there was an alignment of interests between the industry and EROs. One reason is that the industry recognized the potential for long-term liability, as well as a negative public reaction, if nanoscale materials were to be widely released and later discovered to cause diseases and environmental damage.

Although there was support for an EHS budget of \$100 million, the president's request for EHS research for FY 2007 was only \$44 million. An official report from the National Nanotechnology Initiative (National Science and Technology Council, 2006) painted a picture of growth, noting that EHS research had grown from \$35 million in FY 2005, when it was first tracked, to \$38 million in FY 2006, to \$44 million for the upcoming year. However, the report did not speculate on the crucial and highly charged figure of an appropriate price tag for adequate EHS research funding. In a letter written to Congress in February, 2007, Environmental Defense, Natural Resources Defense Council, the Union of Concerned Scientists, and a variety of chemical companies and associations recommended the allocation of funding to the National Academy of Sciences to develop a roadmap of needed research (Environmental Defense, 2007b). Congress responded favorably and urged the EPA to contract with the National Academy of Sciences to provide the report, but it did not appropriate the \$1.5 million in funds necessary for the report (Morris, 2008).

Later that year Denison noted in testimony before Congress that the EHS research budget for FY 2008 (at about \$58 million, or about 4% of \$1.45 billion) had remained "nearly flat" and well shy of the targeted figure of 10% (Denison, 2007c). The International Center for Technology Assessment also called for more research, again at the \$100 million level (Kimbrell, 2007). The National Research Council (2008) added to the growing number of voices calling for more EHS research. Denison also noted that about half of the risk research dollars went to the National Science Foundation, which funds basic research. He argued that EHS research should be primarily conducted by agencies that have EHS missions, such as the National Institute for Occupational Safety and Health (NIOSH), the EPA, and the National Institute for Environmental Health Sciences (NIEHS). For example, research at NIOSH on nanotechnology had remained relatively small, at \$4.6 million in FY 2007 (National Institute for Occupational Safety and Health, 2007). A 2007 report by the institute noted that the funding levels were accomplished by redirecting internal funds and that significant "research gaps" remained, but they could only be addressed with "new infusions of funding," and a strategic plan in 2008 continued to identify "knowledge gaps" in the EHS field (National Institute for Occupational Safety and Health, 2007, 2008).

Although research appropriations go to individual agencies, over which the National Nanotechnology Initiative has no control, Denison (2007c) argued that a more general conflict of interest existed between the National Nanotechnology Initiative's mission of promoting and developing nanotechnology and the need for EHS research. He suggested that a new entity was needed to oversee and coordinate federal efforts on EHS research, with a "firewall" between it and the NNI, and that the National Academies' Board on Environmental Studies and Toxicology should lead the development of the entity. In response to characterizations by the NNI leaders that Denison was proposing an EHS "czar" and a "silo" approach to research, he noted that a good precedent was the decision by Congress in the mid 1970s to abolish the Atomic Energy Commission (Denison, 2007b). In that case oversight functions were granted to the Nuclear Regulatory Commission, whereas research and development went to the Department of Energy.

Denison's proposals appeared to have had more impact on Congress than on the executive branch. In February, 2008, the National Nanotechnology Initiative released a new report on EHS, which noted that the president's requested budget for FY 2009 had grown to \$76 million, a figure that showed an increase but remained below the target of 10%, given the overall growth in the nanotechnology research budget (National Science and Technology Council, 2009). Denison criticized the report for lack of detailed budgetary information on each project, and he also pointed to an ominous statement in which the NNI stated that EHS research gaps "should not be addressed at the cost of broad-based fundamental research" (Denison, 2008d; National Science and Technology Council, 2009, p. 46). However, in April of that year, Congress developed a draft of the amendment to the National Nanotechnology Act that included the 10% mandate for EHS research. Although the mandate was not included in the bill that was approved by the House of Representatives in June, 2008, the proposed legislation (which did not become law in 2008) did establish a separate advisory panel for EHS issues, an associate director within the Office of Science and Technology Policy to oversee EHS activities, and a mandate for a plan of EHS research (Environmental Defense, 2008b). Thus, one of Denison's proposals, the organizational proposal, was adopted in a modified form, whereas the other, an increase in the budget to 10% of the NNI budget, was not, although the level of funding was changing in the proposed direction.

This history of the politics of EHS funding in the United States suggests that EROs did play a significant role in this policy field. The actual day-to-day work of shifting federal budgets to get undone science done was accomplished largely by a few, well-positioned, well-informed public advocates. The situation is analogous to the role of insider-outsiders also found in the AIDS movement (Epstein, 1996). Unlike in some other cases of undone environmental science, the organizations that have been involved in the EHS research policy controversy did not contribute directly to EHS research by funding scientists to conduct peer-reviewed work in the area (Hess, 2010). Instead, they generated a body of "civil society research" that focused more on the meta-issue of the state of EHS research. The research of the Project on Emerging Nanotechnologies and the advocacy work of Environmental Defense appear to have had some impact on policymaking with regard to funding levels and the organizational structure of government-based EHS research. In a political environment where control of the presidency and Congress were in the hands of different parties (until the end of 2008), there were some opportunities to play one part of the government off against another part. Here, advocates of greater EHS research appear to have found greatest support in Congress, and the support appeared to be bipartisan. In contrast, the government offices and agencies most tightly controlled by the White House were, during this period, less fertile ground for the ERO proposals.

# **The Politics of Partial Moratoria**

As the size and contours of the EHS research field were being negotiated, other EROs focused on shaping the nanotechnology industrial field. One approach to technological controversies involves the politics of industrial opposition, which generally entails a call for a complete or partial moratorium, or a phase out, of a category of industrial technology and/or products. Although most of the social science work on nanotechnology has focused on the case of genetically modified food as the primary point of comparison for industrial opposition politics, there are other precedents of industrial opposition movements, including mobilizations to stop or contain the spread of nuclear energy, nuclear weapons, pesticides, highways, and investments in socially and environmentally detrimental projects (Hess, 2007). Often the organizations that adopt a strategy of moratorium are at the more "social movement" end of the spectrum of a diverse body of "alternative pathways" that are engaged in political reform. In other words, the industrial opposition movements operate more at a grassroots level, are less connected with the corridors of power than the EROs discussed in the previous section, and tend to utilize extrainstitutional repertoires of action, such as street protest, boycotts, and civil disobedience. In the case of nanotechnology opposition, the extrainstitutional repertoires of action have been less evident, but the organizations have been much less intertwined in federal government policy and more connected to grassroots social movements, including antiglobalization, human rights, and labor movements.

Given the state of undone science with respect to the EHS implications of nanotechnology, one policy response might be to delay the commercial release of the products until the EHS research is completed. Such a precautionary policy response has various precedents, including the European Union's temporary suspension in 1998 of the approval of new genetically modified organisms. Although the World Trade Organization ruled against the moratorium, other kinds of moratoria have been instituted in other environmental issues, such as for some pesticides and toxic chemicals. In the case of nanotechnology, the ETC Group, an environmental and human rights organization headquartered in Canada, has been most vociferous in its calls for moratoria.

In 2002, the ETC Group issued what may have been the first report by an environmental organization on the health and environmental risks of nanotechnology, followed by a longer report that was launched at the World Social Forum in Porto Alegre (ETC Group, 2002, 2003a). Subsequent reports by the organization continued to develop

recognition among the media and policymakers of the potential hazards and risks of nanotechnology (ETC Group, 2004a, 2004b). The ETC Group also called for a general moratorium on both laboratory research and commercial products, and it outlined the potential for what it called "green goo": a dystopian future convergence of biotechnology and nanotechnology. The proposed moratorium would end when an "International Convention on the Evaluation of New Technologies" was established.

### The Narrowing of the Moratorium

For industrial opposition movements, the call for a full moratorium is generally not successful, but it sometimes leads to a partial moratorium and product redesign (Hess, 2007). The politics of a full moratorium may have their greatest value as a flanking strategy that contributes to the opening of political opportunities for other, more moderate approaches advocated by reformers within government and industrial organizations and by more moderate EROs. In this case, the call for a moratorium, as a follow-up report indicated, "was almost universally condemned by industry" (ETC Group, 2003b).

Furthermore, other EROs opposed the idea of a full moratorium. The Center for Responsible Nanotechnology (2003), which has focused on molecular manufacturing (using nanoscale tools to build molecular structures), called the moratorium idea "irresponsible and dangerous," even as it advocated an international administration for the more controversial technology of molecular manufacturing. Greenpeace issued a technical report on nanotechnology and artificial intelligence that emphasized the need for more EHS research but did not call for a full moratorium (Arnall 2003). In a later statement, the organization rejected the idea of having a policy on nanotechnology as a whole, noted the potential environmental benefits of some forms of nanotechnology, and called for a moratorium only on "the release of nanoparticles into the environment" until more EHS research had been completed (Greenpeace 2009).

Another example of the call for a partial moratorium occurred in 2006 in a report by Friends of the Earth on the risks of nanomaterials in sunscreens and cosmetics (Miller et al., 2006). Calling the release of nanomaterials "one of the most dramatic failures of regulation since the introduction of asbestos," the report concluded with a call for "a moratorium on the further commercial release of personal care products that contain nanomaterials and the withdrawal of such products currently on the market" until safety studies were completed, product labeling was made mandatory, and a regulatory framework was enacted (Miller et al., 2006). In the case of sunscreens, nanoscale particles are not necessary, but they have become widely used because they make the lotions more transparent. The science behind the report has been contested (e.g., Berube 2008), and it is also possible that even if nanoparticles in sunscreens did create health risks, consumers may use the clearer lotions more often and therefore lower skin cancer risk. Another ERO, the Environmental Working Group (2008), concluded that nanosized zinc and titanium dioxide were not only safe but more effective than many other sunscreen ingredients. However, the organization added, "If this were nano-containing blush, eye shadow, or body glitter, our position would be different—it's not needed, it's not protecting your health, so don't use it" (ibid.). Although the literature to date suggests that nanosized zinc and titanium dioxide particles in sunscreens may be safe, knowledge

about the risks associated with the full range of nanoparticles and other cosmetics remains undone science.

The broader point here for the study of the politics of the moratorium is that for Greenpeace and Friends of the Earth both the scope of the moratorium and the conditions under which it would be lifted were much more restricted in comparison with the proposal by the ETC Group. Furthermore, the concerns expressed may have had some impact on retailers and manufacturers. For example, Whole Foods ended the use of nanoparticles in its Premium Body Care products, and the media oriented toward natural and organic products began to make lists of nano-free personal care products such as sunscreens (Uhland, 2008). Although it is unclear what a "nano-free" product means from a technical or chemical perspective, one can see that even if calls for a moratorium do not lead to regulatory policy changes, they may affect the labeling and manufacturing decisions of consumer products companies.

By 2008 the calls for a moratorium had become even more focused. In May the International Center for Technology Assessment, in a coalition with other groups, petitioned the EPA to ban nanosilver (International Center for Technology Assessment, 2008; Weiss, 2008). The nanoparticle was being used in clothing, personal care products, electronics, and other household goods because of its germicidal effects. The material was known to be toxic to fish and other aquatic organisms, but it was being released into the environment, such as when nanosilver socks were washed. The coalition's petition argued that nanosilver qualified for regulation as a pesticide and that the EPA should stop the sale of over 200 products containing the substance. The petition was joined by Friends of the Earth, Greenpeace, and other consumer, health, and environmental organizations. As of the end of 2008, the product had not yet been banned. However, the EPA had fined one company for putting nanosilver on computer keyboards and "mice" based on the argument that the substance was a pesticide, and it ruled that the Samsung Silver Wash washing machine had to be registered as a pesticide because it emitted nanosilver into wash loads (Luoma, 2008). One can see here how a very focused call for a moratorium is, in this case, associated with an incremental policy change.

Another development was the statement by the Soil Association (2008b), the leading organic food and agriculture organization in the U.K., that it would not allow nanomaterials in its certificational definition of organic products. The boundary line was based mostly on size, not chemical structure, so that any manufactured particles below 125nm or below 200nm in average size were not included in the organic standard. However, the standard did not apply to "established manufactured processes that produce nanoparticles incidentally," such as nano-sized wheat particles that can result from some milling processes (Soil Association, 2008a). Rather than focusing on a regulatory effort to ban a particular nanoparticle, an entire industry has opted to disallow synthetic nanoparticles via an industry standard ruling. In 2008 Friends of the Earth released a report on nanomaterials in food, food supplements, kitchenware, and food packaging, and the Organic Consumers Association (2008) in the U.S. has publicized the potential health risks of nanotechnology and food. As consumer awareness of the release of the substances in the food supply increases, concern with the EHS risks of such exposure is likely to become politically more significant and may affect the organic standards in the U.S. Here, the parallel between nanotechnology and the genetically modified food

controversy, which some have argued may be overstated (Sandler and Kay, 2006; cf. Thompson, 2008), is at its strongest.

A final area of industrial opposition has involved shareholder resolutions on nanotechnology. In late 2007 the Calvert Group and Domini Social Investments filed resolutions with Avon Products and Colgate-Palmolive, but the socially responsible mutual fund companies withdrew the latter resolution after they learned that the company did not use nanomaterials. In the case of Avon the investment firms asked the cosmetics firm to disclose products that contain nanomaterials, and Avon responded by disclosing the use of titanium dioxide and zinc oxide in sunscreens. The fund companies also asked Avon to disclose information about its measures to protect consumer safety and to use labels until safety could be established. Over twenty organizations supported the resolution, and it garnered 25% of the vote, a level that Calvert called "extremely high for a first time toxics issue" (2007). Although the shareholder resolution did not entail a moratorium on the use of nanomaterials in the product, the disclosure of an absence of safety testing together with the use of product labeling would likely lead to a severe drop in consumer demand. As a result, this type of strategy might be considered continuous with the politics of the moratorium. The fact that Colgate-Palmolive claimed that it did not use nanomaterials was also suggestive of the possibility that some companies may begin to list their products as "nano-free" in the same way that some food products companies describe their products as free of genetically modified food.

To summarize the history of the politics of the moratorium on nanotechnology, the original calls for a complete, government-led moratorium have not resulted in any actions, and to date there have been no bans on specific nanomaterials or chemicals in the U.S. However, as EHS research grows and identifies specific materials and usages that are of greatest hazard and risk, the research is likely to converge with the increasingly detailed focus of the calls for moratoria. When the convergence occurs, policy outcomes that result in a partial moratorium in the form of bans on specific nanomaterials or product categories will become more likely. Meanwhile, the politics of the partial moratorium is undergoing differentiation. On the one hand, some organizations continue to seek government bans on specific classes of entities, such as nanoparticles in cosmetics or the use of nanosilver. On the other hand, there is an emerging response from industry, in which specific companies or even whole industries may be moving toward "nano-free" status, a category that undoubtedly will be subject to ongoing definitional disputes. ERO mobilization appears to be having greater success with consumer product companies, and there is considerable potential for the "organic" label in the U.S. to shift in a direction similar to the changes made in the U.K. However, in the U.S. the EROs have had much less success with government regulation, again probably due to the lack of interest in environmental protection shown by the presidential administration during the 2000-2008 period.

### Defining Responsible Nanotechnology

A third policy field for EHS and nanotechnology involves efforts to define a safe and responsible form of nanotechnology. Whereas the politics of industrial opposition involve calls for a full or partial moratorium on products, here the politics center on defining and producing a product that meets EHS or other societal concerns. In the industrial field of nanotechnology, there is no evidence of a "technology- and productoriented" movement (Hess, 2005), that is, a movement of civil society organizations and small firms that are pioneering a safe nanotechnology product and producing consumer demand for the product. A national survey indicated that there is very little consumer awareness of nanotechnology, let alone its EHS implications; indeed, nearly half of the adults in the U.S. have not heard of nanotechnology (Peter D. Hart Research Associates, Inc., 2008; Toumey, 2009). Because of the lack of public awareness, there is no market yet for a grassroots movement of activists and entrepreneurs who develop safe versions of nanotechnology in a manner similar to the alternative entrepreneurship that occurred in the early phases of the organic food and solar energy industries. As seen in the last section, it is entirely possible that "safe nano" will be defined simply as its absence.

However, the technology- and product-oriented movement is not the only form that alternative industrial movements can take. In the case of nanotechnology in the United States, another type of alternative industrial movement, a certification movement, seems more likely (reviewed by Conroy, 2007). Unlike the politics of industrial opposition, the politics of certification are focused on questions of design. Here the role of EROs tends to involve encouraging the development of alternative industrial practices, new standards, and regulatory codes that define an acceptable use of the product. In the case of nanotechnology, EROs have not yet advocated the development of a certification system similar to those in existence for sustainable lumber and dolphin-safe tuna. Instead, the effort to date has been to define what constitutes "safe" and "responsible" nanotechnology by articulating a set of industrial guidelines and regulatory standards that would allow the product to be commercialized with few or no EHS risks. The standards would probably also include best practices for EHS testing.

This section will focus on the role of EROs in building and defining a category of more "safe" and/or "responsible" nano via voluntary industry standards, industrial guidelines, and the regulatory policies. Furthermore, it will focus on the EPA. In the United States the Food and Drug Administration (FDA) has regulatory authority over the safety and efficacy of nanotechnology used in drugs, medical interventions, food, additives, supplements, and cosmetics. Although the FDA's standard of efficacy for drugs based on multiple phases of clinical-trial testing could provide a general template for a rigorous regulatory standard of all nanotechnology with potential human exposure, there is no sign that the rigorous and very expensive regulatory model would be extended to nanotechnology uses outside the area of medical interventions. Rather, the FDA has defined nanotechnology as a "combination product" that is regulated by its primary mode of action, which in turn defines the regulatory framework for the product as a drug, medical device, or biological product. The agency recognizes that it has "only limited regulatory authority over some potentially high-risk products, e.g., cosmetics" (Food and Drug Administration, 2008). The potential gap here suggests that nanomaterials in food products and cosmetics may be a site for the ongoing politics of the ERO action that develops the partial moratorium as discussed in the previous section.

For other products containing nanomaterials, regulation falls under the purview of the EPA, which has been the focus of attention of most of the ERO activity with respect to nanotechnology regulation. One starting point for the recent history is the report of the Royal Society and Royal Academy of Engineering (2004), which provided influential guidance in the discussion of regulatory reform and best practices for nanotechnological product design. The basic features included life-cycle assessment, classification of

nanoparticles and nanotubes as new substances for regulatory and assessment purposes, revision of workplace exposure standards based on the new properties of nanomaterials, safety assessments of consumer products that contain nanomaterials, and transparency measures, including reporting of manufacturers' assessment and product labels. Some of the recommendations of the Royal Society report were found in proposals that emerged in the U.S. For example, in a joint statement to the EPA, Environmental Defense and the American Chemistry Council (2005) argued in favor of increased public participation, higher research funding on risks, the development of international standards, and an assessment of "existing regulatory frameworks." The latter proposal was crucial but not spelled out.

### The Voluntary Program and Industry Guidance

In June, 2005, the EPA held a public meeting to discuss a voluntary framework for nanotechnology regulations (Service, 2005). After the meeting, the agency asked its federal advisory committee to provide advice on the risks of nanotechnology, with an accelerated schedule that led to completion by November (National Pollution Prevention and Toxics Advisory Committee, 2005). The report included a proposal for a voluntary program that would allow the public to learn what chemicals were being released and what hazard or risk information was available on them. The development was consistent with voluntary programs that were emerging in other countries. Environmental Defense participated in the 2005 working group and supported the proposal for a short-term voluntary program, but with the understanding that changes mandatory regulations, which they recognized would take longer to implement, would be coming. The rationale given was recognition "that developing and finalizing regulatory vehicles—even if immediately initiated—would require considerable time, and that a voluntary program could—as an interim measure—both supplement and inform such vehicles" (Denison, 2007d).

During this period Environmental Defense also helped to develop an industrial guidance framework. In 2005 Environmental Defense and DuPont launched a partnership to develop guidance for companies to use in assessing potential hazards and risks for commercial nanomaterials. In an article published in the Wall Street Journal, representatives from the two organizations noted the track history of failed new chemicals, including the use of refrigerants during the 1920s that proved fatal (Krupp and Holliday, 2005). Rather than repeat the errors of previous generations, the partnership called for increased government funding on EHS research and a revision of current regulations to bring them up-to-date for an era of nanotechnology. The partnership led to the development of the "Nano Risk Framework," a guidance document with sample cases for companies that wanted to pursue the "responsible development of nanoscale materials." The framework included six stages: describe the material and application; profile the life cycle; evaluate risks; assess risk management; decide, document, and act; and review and adapt (Environmental Defense-DuPont Nano Partnership, 2007). Environmental Defense and DuPont representatives also offered training workshops for companies that wished to participate (Walsh and Swain, 2008).

As with the EPA voluntary program, the partnership and guidance framework was not intended to replace mandatory regulations. However, other organizations interpreted the effort as a slide into voluntary approaches to regulation. In April, 2007, a coalition of organizations rejected the framework in an open letter that called the proposal "at best, a public relations campaign that detracts from urgent worldwide oversight priorities for nanotechnology" (ETC Group, 2007a). They added, "at worst, the initiative could result in highly reckless policy and a precedent of abdicating policy decision to industry by those entrusted with protecting our people, communities, and land" (ibid). The coalition noted that such efforts could weaken attempts to increase mandatory regulation and could serve as a delaying tactic. The signatory organizations included labor unions and Friends of the Earth, Greenpeace, Natural Resources Defense Council, and Silicon Valley Toxics Coalition. The Natural Resources Defense Council also issued a report in defense of mandatory assessment of nanomaterials as new substances, with a call for a temporary moratorium until new materials were tested (Sass, 2007). Environmental Defense (2007a) replied with a statement that offered agreement on the principle that mandatory government regulations were needed, but it argued that the framework was "intended to provide useful guidance to companies that adopt it on how to address nanomaterials until government regulations are adopted." Subsequently, the organization also criticized the EPA voluntary framework as a "failure" that had "squandered precious time" (Environmental Defense, 2009). In short, although there were some tactical differences, there was general consensus among the EROs that greater mandatory regulation was needed.

# Defining Mandatory Regulation

In a presentation before the Woodrow Wilson International Center for Scholars, Environmental Defense clarified a few of the elements of an improved regulatory framework in the American context (Florini, 2005). First, the organization supported the crucial but controversial proposition that nanomaterials are almost always "new," even if they are structurally similar to existing molecules, because of the different properties that emerge at the nanoscale. Second, companies should file a "premanufacture notice" (PMN) with the EPA under the requirements of the Toxic Substances Control Act (TSCA), and extensive data should be collected. Third, existing exemptions, particularly the weight exemption of 10,000 Kg or less, made little sense for nanomaterials and should be dropped. A fourth proposal involved establishing interim environmental and worker safety measures.

In July, 2007, a coalition of twenty organizations issued a statement titled "Principles for the Oversight of Nanotechnologies and Nanomaterials" (ETC Group, 2007b), which also interpreted nanomaterials as new substances and argued in favor of mandatory regulations that were specific to nanotechnology. The organizations also called for the life cycle assessment of nanomaterials, including environmental impact analysis, prior to commercialization; a dramatic increase in government funding for EHS research; transparency provisions, including labeling of products; public participation; analysis of broader social impact on issues of justice and community preferences; and manufacturer liability. Among the environmental organizations that signed the statement were the ETC Group, Friends of the Earth, Greenpeace, and the Silicon Valley Toxics Coalition. A report from Greenpeace International (Johnston *et al.*, 2007) also recommended better regulation, more EHS research, and public participation and transparency in the decision-making processes.

Although Environmental Defense did not sign the joint statement, the environmental organization supported increased levels of mandatory regulation. The inaction on the part of the EPA on this issue was also leading to increased frustration. The agency had delayed implementation of the voluntary proposal developed in 2005 and, two years later, issued only a new concept paper with a plan for a voluntary program that became the Nanoscale Materials Stewardship Program. Meanwhile, in 2006 the U.K. had begun a similar voluntary program, and participation was negligible (about one submission per month). Given the delay on the part of the EPA and the failure of the voluntary program in the U.K., Environmental Defense became increasingly critical of the voluntary approach and continued to defend mandatory regulation (Denison, 2007a, 2007d; Environmental Defense, 2009).

A central question that has haunted the regulation of nanomaterials is the interpretation of TSCA with respect to the "newness" of nanomaterials. The TSCA Inventory listed existing or "old" chemicals, and companies that used existing chemicals in new products were not required to file a Premanufacture Notice. But were nanomaterials inherently new, as some EROs suggested? The agency's position evolved between October, 2006, and a final Nanoscale Materials Stewardship Program statement issued on January 28, 2008. For the EPA, a chemical with the "same molecular identity" as one already registered was considered an existing chemical. However, a chemical with the same molecular formula could be considered on a case-by-case basis as new under some conditions, such as "different atom connectivities" and "different spatial arrangements of atoms" (Environmental Protection Agency, 2008). In other words, the EPA interpreted the law to apply to nanomaterials on a case-by-case basis, but it did not interpret TSCA to allow the agency to take only particle size into account as a trigger for classification of the material as a new chemical, which in turn would require a Premanufacture Notice. The EPA could defend the position by arguing that the size of a particle does not automatically affect its risk profile.

The EPA's interpretation of the TSCA was roughly consistent with a statement in November 2007 by the Director of the Office of Science and Technology Policy and the Chairman of the Council on Environmental Quality. Their statement of principles for EHS oversight argued that "existing statutory authorities are adequate to address oversight of nanotechnology and its applications" (Marburger III and Connaughton, 2007). Although the statement did not pronounce directly on what would become the EPA's interpretation of nanomaterials, it did reject a "one-size-fits-all" approach, probably a reference to the size-oriented approach to newness advocated by the EROs. Industry also supported the case-by-case approach of the EPA. For example, the agency's approach met with approval by Joseph Acker, the president of the Synthetic Organic Chemical Manufacturers Association (Acker, 2007).

In contrast, Environmental Defense and the Project on Emerging Nanotechnologies criticized the EPA position by claiming that it did not require additional notification for nanomaterials of similar structure to existing chemicals (Denison 2007c, Project on Emerging Nanotechnologies, 2007). Denison noted the irony about the "newness" of nano:

It's like nano promoters who boldly declare in one context—say, when talking to investors—that nano is revolutionary, like nothing that preceded it. But they argue

just as vehemently in another setting—say, when talking to regulators—that it's merely an incremental change in what came before" (Denison, 2008a).

Denison also noted that the EPA would not even know that a chemical was nanoscale unless the firm voluntarily reported it as such (Denison, 2008b). Likewise, the Project on Emerging Nanotechnologies senior advisor J. Clarence Davies stated:

It is essential that EPA move quickly to recognize the novel biological and ecological characteristics of nanoscale materials. It can do this by using the "new uses" provisions of TSCA, a subject not mentioned in the EPA's concept document. With the approach outlined by EPA and because of the weaknesses in the law, the agency is not even able to identify which substances are nanomaterials, much less determine whether they pose a hazard (Project on Emerging Nanotechnologies, 2008a).

There are many other related issues in this unfolding story, including the problem of defining standards for EHS tests of nanomaterials. As of the end of 2008 the TSCA remained the regulatory framework for nanotechnology (with the exception of products falling under the FDA's purview), and there was little incentive for industry to participate in voluntary programs. It was becoming increasingly clear to EROs that changes in TSCA would be necessary in order to give the EPA the authority needed to gather what they considered to be adequate information on nanomaterials and to act on it (Denison, 2008c). Meanwhile, in 2007 the European Union was developing its REACH (Registration, Evaluations, and Authorization of Chemicals) framework for chemicals, which had mandated a shift in the burden of risk assessment to industry (European Commission, 2007). Regulatory developments in other countries, including Canada, and standard-setting procedures in international bodies would create additional pressures for ongoing regulatory reform in the U.S. Furthermore, regulations were beginning to emerge at the local level, such as in the cities of Cambridge and Berkeley and from the state of California as a whole (City of Berkeley Community Environmental Advisory Commission, 2008). As in the case of the harmonization of international regulations, the emergence of diverse state and local regulations would likely increase demand from industry for federal regulation, because the costs and complexities of varying rules for compliance would motivate industry to support the lower costs and liability associated with uniform regulation.

In summary, EROs have been actively involved in the policy debates involving efforts to construct standards and regulations that would define safe and responsible nanotechnology. To date, the nanotechnology field has not seen a certification movement similar to those that have emerged in other industries, such as organic food. The closest to an incipient form of such a movement was the DuPont-Environmental Defense partnership, but this was limited to a guidance framework and was not intended to become a certification process. As of 2008 the voluntary program of the EPA had generated only a small number companies that opted to participate (Environmental Defense, 2008a), and participation in the industry guidance framework was also limited. One reason is probably that nanotechnology is not a consumer product, although it is being embedded, invisibly, in hundreds of consumer products. Another is the potential liability that comes with any kind of voluntary disclosure. Furthermore, there is little public awareness of nanotechnology, let alone its EHS risks. Given the weaknesses of the EPA's voluntary approach and industrial guidance, EROs focused on developing more

comprehensive mandatory regulations at the federal government level. EROs continued to criticize the federal government for failing to extend regulatory authority under the TSCA or to amend the act to enable a much broader scope of mandatory regulation. As of 2008 the organizations had not been successful in achieving the goal of greater mandatory regulation of nanomaterials regardless of molecular structure.

## Conclusion

The political sociology of science draws attention to the role of social movements, government policies, and industrial change in scientific change. In this case, EROs have played an active role in challenging the policy directions charted by industry and government that have defined the contours of nanotechnology as both a research field and an industrial field. To some degree institutional relations can be described as a clash of unequal power and different views of how the public interest is best represented. Is the public interest best represented by rapid commercialization followed by a catch-up period of EHS research and regulation, or is it best represented by a more precautionary approach? Industry and the Bush administration tended to adopt the former positions, whereas the EROs and some segments of the government supported the latter. However, industry was also concerned with a potential public backlash, and there were some openings for EROs to influence an emerging scientific and technological field, especially on the issue of the appropriate level of EHS research funding.

One of the central problems in the political sociology of science, the problem of "undone science" (in this case the problem of understanding the EHS implications of nanotechnology), also draws attention to the political culture in which science is shaped and defined. In a neoliberal political culture that has emphasized the value of developing new technologies for purposes of industrial competitiveness and military prowess, and that has also deemphasized the need for environmental and other regulations, the field of nanotechnology research has moved rapidly ahead toward applications and commercial products. In contrast, research on possible EHS hazards, risks, and implications has tended to operate in a catch-up mode. From the perspective of EROs, EHS research has been significantly underfunded, and regulatory policy needs to be more proactive and precautionary until the EHS questions are more completely addressed.

Turning now to the research question posed at the outset—the relative success and lack of success of different proposals and reform strategies—some general comments are now possible. During the period of the Bush administration, the EROs appear to have been most successful in gaining support from Congress for changes in the budgetary level of EHS research, partly because "more research" is a political issue that industry either supports or does not contest greatly. When the issues of undone science are focused on the government research funding agenda, a small number of EROs, and within them a small number of specialists, appears to have had some impact on policy outcomes. During the period up to the end of 2008, they were able leverage conflicts among branches of the government and political parties to transform their relatively small budgets and organizational resources into incremental policy change.

In contrast, EROs have been less successful in garnering a response to their calls for moratoria of industrial production based on government intervention. Calls for a general moratorium were quickly followed by calls for partial moratoria that were focused on increasingly specific types of objects (e.g., nanosilver, nanomaterials in cosmetics) or on industrial categories (e.g., organic industry standards). When EROs find calls for partial moratoria blocked by the government and the political influence of the nanotechnology industry, they may find that a second target of mobilization—private sector firms in the consumer products industries—may be more open to demands for change. As we have seen more generally in the social movements literature, the EROs have expanded the target of oppositional politics toward firms (Schurman, 2004; Weber *et al.*, 2009). There is some evidence that consumer-oriented firms and industries are responding to popular demand for "nano-free" products, particularly if the firms and industries are marketing to green consumers.

Finally, in the field of regulation and standards, EROs supported stronger mandatory regulations, including reform of the TSCA. There were some differences over the value of the voluntary EPA program and the strategy of developing an industry guidance framework as interim strategies, but in general the EROs that were involved in this issue were most interested in higher levels of mandatory government regulation. As of the end of 2008 their efforts had not seen success. However, local and international regulatory changes, as well as a change of political administration, may also reopen political opportunities that until 2009 remained closed for increased federal government regulation.

ERO involvement in nanotechnology policy is of general interest because the organizations often play a unique role in articulating an alternative construction of the public interest in policy fields that are heavily dominated by antiregulatory, proindustry positions. The organizations also attempt to open public debates that potentially can have some policy impact. Perhaps the most significant role of the EROs has been to call attention to the undone science of the EHS implications of nanotechnology, but recognition of undone science is also the basis for calls for changes in regulatory policy and in the policies and practices of firms. To some degree the call for more EHS research might be interpreted as simply accepting the standard framework of regulatory politics that is based on risk assessment. The framework has been criticized because it tends to limit debates about new technologies by "scientizing" them and narrowing public debate by raising the levels of expertise required to participate in it (Kleinman and Kinchy, 2007; Wynne, 2007). In other words, by accepting the terms of debate over a new technology as limited to a scientific assessment of risk, a broader debate may be foreclosed. For example, the focus on risk tends to exclude the unknown unknowns of ignorance, that is, the unquantifiable and unpredictable effects of a new technology on human health, wildlife, and ecosystems (Gross, 2007; Hoffmann-Riem and Wynne, 2002). Concern that an unwelcome surprise could occur in the future underlies much of the skepticism that EROs, and portions of the public more generally, have for reassurances from experts that new technologies are safe.

From this perspective the politics of undone science with respect to the EHS implications of nanotechnology are divided. On the one hand, calls for increased EHS research funding, better industrial guidelines, and regulatory changes tend to operate within the framework of standard risk assessment politics. On the other hand, the less successful strategy of calling for a full or partial moratorium on the commercialization of nanotechnology suggests the need for a broader public debate about the pace and degree to which new technologies should be introduced in society, if at all. Given this difference in emphasis, I am able to offer a clarification on the concept of undone science with

respect to regulatory politics; it can refer both to the need for quantifiable risk research and to the need for a broader conversation about ignorance, the need for new technologies, and the possibility that the few are making profits at the expense of potential disasters that may await the many.

Furthermore, although the politics of risk assessment may foreclose a broader public debate, one should remember that in a neoliberal political culture it may even be difficult to get full risk assessment enacted. The case of nanotechnology policy in the U.S. through 2008 suggests that both strategies (one focusing on risk assessment and one calling for a moratorium and a broader public debate) are necessary, and that there may even be interactions between them. Having the threat of a possible public opinion shift toward a politics of moratoria may open political opportunities for more moderate reform proposals due to radical flank effects.

Although these insights can help refine and move forward an understanding of the role of EROs in nanotechnology policy, and by implication of social movement organizations and other civil society organizations with respect to the politics of risk assessment and undone science in the study of science as culture, to some degree the elephant in the room is left unstudied. By this I refer to a policy situation that has allowed hundreds of new chemicals to be released into products, buildings, bodies, and ecosystems with only belated attention to EHS issues. Human and animal bodies are already challenged by ongoing exposure to radiation, heavy metals, Bisphenol A, flame retardants, and chlorinated chemicals in general. Given the rather disappointing EHS track record of many new chemicals and materials that were once touted as completely safe, it seems foolhardy to expect that a new generation of nanoscale materials will prove to be safe or that their cumulative impact on human bodies and the environment will be negligible. Although regulatory agencies and government research funding are increasingly attuned to the problem of the EHS implications of nanotechnology, the emphasis of government funding in the United States on commercialization has put EHS research and regulation in a catch-up mode. Growing concern with the EHS implications of nanotechnology is in some ways exemplary of the politics of the "risk society" (Beck, 1992, 1999), in which modern political institutions have not proven capable of keeping up with technological change. However, in the United States in the period up to 2009 the situation went beyond the failure of modern regulatory institutions. Rather, it seems more to be a case of a neoliberal political environment that facilitated a rush toward new industrial development while at the same time limiting and slowing attempts to assess EHS implications, let alone a broad public debate.

Although one might argue that the "newness" of nanotechnology can explain the situation in which EHS research has been put in a catch-up mode, as we have seen the idea of "newness" is used in different ways. Nanotechnology is often welcomed as new and configured as the next industrial revolution, but from a regulatory policy perspective the same chemicals and materials have been redefined as existing or "old." A more convincing explanation of the appearance of undone science and regulatory gaps would turn to the structural problem of why research and regulatory policies have not enabled a temporary moratorium on commercialization until the risks are assessed and a public debate on the need for a full range of nanotechnologies has taken place. It is possible that a full public debate would lead to a highly restricted set of uses for nanomaterials in commercial products that come into direct contact with humans, such as food and

cosmetic products, as well as for nanoparticles that are not embedded in a larger molecular matrix. Certainly, there are potential medical and environmental uses that will make the commercialization of nanotechnology attractive, such as the use of nanomaterials in photovoltaics (Hess, 2011). The United States has a lead in the next industrial revolution (Feder, 2006), which promises to bring new levels of wealth and well-paying jobs to a country that is facing the erosion of its hegemonic position in the global economy. Leadership in nanotechnology, like leadership in computing technology, will also be important should the technology prove to have important implications in warfare. EROs in the nanotechnology policy field may not all speak with one voice, nor may their perspectives always be identical with a broad public interest, but in the case of nanotechnology policy in the United States they have played a crucial role in developing a more reasoned approach to the march of "progress."

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