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Lessons learned from the Ethical, Legal and Social Implications program (ELSI): Planning societal implications research for the National Nanotechnology Program

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Abstract

This paper considers federal requirements to institute a research program on societal and ethical considerations of nanotechnology, and to integrate the results of this research with nanotechnology research and development. It identifies research selection and assessment criteria derived in part from criticism of the Human Genome Project's Ethical, Legal, and Societal Implications program. This criticism concerns the capacity of bioethics research to influence policy. Since integration of societal research with nanotechnology development is meant to influence the direction of nanotechnology development, an explicit emphasis ought to be placed on the capacity of the new program's societal and ethical research to influence federal nanotechnology development policy.

Keywords: Nanotechnology; Science and technology policy; Societal considerations; Integration; Ethics

Nanotechnology, with its mix of potential harms and benefits like biotechnology before it, presents a complex challenge to policy makers. Policy makers who hope to secure public acceptance of the technology ought to weigh not only the accuracy of public risk perceptions, but also the legitimacy of societal concerns. In response to societal concerns over nanotechnology, recent legislation calls for an ethical and societal research program to ensure that such concerns 'are considered during the development of nanotechnology' [1].

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This paper seeks to pinpoint key features likely to signal the success of this program, largely in light of the historical precedent set by the Ethical, Legal, and Social Implications program (ELSI) in the Human Genome Project.

Government literature on the subject routinely touts nanotechnology as 'the next industrial revolution' and celebrates its tremendous economic and societal benefits [2]. Based on the unprecedented ability to understand and control matter at atomic and molecular scales, this emerging field is expected to produce a multitude of 'revolutionary products' with 'widespread applications' in numerous prominent industrial fields [3]. Yet, nanotechnology also raises a host of societal concerns regarding the potential unintended consequences of this new technology ranging from negative human and environmental impacts to questionable military and surveillance applications. I will refer to such concerns generally as 'societal concerns'.

1. Societal concerns over nanotechnology

Proponents of nanotechnology generally recognize the prudence of addressing these concerns in order to garner public acceptance. In the words of one policy maker, 'As a business proposition we must identify legitimate ethical and societal issues and address them as soon as possible' [4]. There is also, however, a moral and political responsibility to 'minimize the potentially disruptive impact of transformational technology developments', as a congressional hearing charter on the societal implications of nanotechnology puts it [5]. While these two motivations for addressing societal concerns could reinforce one another, there is reason to believe that an effective program for influencing nanotechnology policy could easily be sacrificed in favor of a sham program that merely gives the impression of doing so.

The 21st Century Nanotechnology Research and Development Act (NRDA) authorized $3.7 billion over a 5-year period for the creation of a National Nanotechnology Program (NNP). The NRDA laid out multiple objectives that stem from both economic and societal implications of nanotechnology, and it included explicit strategies for addressing societal concerns. Specifically, the Act authorized the creation of an American Nanotechnology Preparedness Center (ANPC), which presumably would play a significant role in implementing and overseeing some or all of the remaining strategies, either independently or in cooperation with the National Nanotechnology Coordination Office. The strategies consist of a research program, various unspecified inter-program activities, a mandate to integrate research on societal concerns with technical research and development, and the use of citizen panels. This paper will focus on the research and integration components, which are assumed to fall under the purview of the ANPC.

2. ELSI as historical precedent

One historical precedent to the ANPC is the Ethical, Legal, and Social Implications (ELSI) program of the Human Genome Project (HGP). A House Science Committee report on the NRDA explicitly upholds ELSI as a model for the societal research

component planned for the National Nanotechnology Program (NNP) [3]. The ELSI program, however, has been criticized for being ineffective as a policy tool. Thus, any lessons learned from this criticism should be taken into account if the ANPC is to be effective in helping to anticipate and minimize potentially negative societal impacts of nanotechnology.

The ELSI program was the first federally funded ethics program to be critical of the very scientific research it was part of. Founded in 1988 at the suggestion of James Watson, the program receives 3–5% of the total budget of the HGP and issued its first grant announcement in 1990. Its basic goal is to 'forestall adverse effects' associated with biotechnology [6]. Through the efforts of several bodies housed in both the National Institutes of Health and the Department of Energy, the ELSI program is formally intended to sponsor research and conferences and also to make policy recommendations [7].

ELSI has funded a large number of publications and is also credited with having influenced Congress to extend the Americans with Disabilities Act. While these achievements are cited by some as evidence of the program's success, critics point to general shortcomings in ELSI's capacity to influence policy. For instance, Kitcher [8] calls the congressional action ELSI's 'one single success'. Additionally, the 'overwhelming' quantity of ELSI-sponsored research, much of which a formal review of the program found to be redundant, has not necessarily led to the goal of limiting adverse effects [9]. As Wolfe observes,

> ELSI's grant structure…was more suited to stimulate discussion across a wide spectrum of scholars than to implement policy decisions.

Scholarly discussion can be an important source of policy alternatives. Yet, it can also act as a surrogate for policy making. In fact, a 1996 review of the ELSI working group by a formal evaluation committee found that it lacked the capacity for efficient policy development and formulation [7].

The 11 member Committee to Evaluate the Ethical, Legal and Social Implications Program of the Human Genome Project was appointed in April 1996 and delivered their report in December of that year. It was co-chaired by Mark A. Rothstein, JD and M. Anne Spence, PhD. The committee's 'assessment of ELSI as an impotent program' led it to recommend changes in the structure of ELSI which would have resulted in separate and expanded capacities for both research and policy. These changes called for (1) a research committee to 'coordinate and follow-up on ELSI grants and prioritize research agendas', (2) an agency-wide policy office to 'formulate policy issues and monitor compliance', and (3) a federally chartered public policy advisory committee [7]. These recommendations were not fully implemented in the ELSI program [7,8].

Why these changes were not made is not clear. Kitcher's view is that the success of a program like ELSI ultimately lies in the political will behind it—a will which, frankly, he finds utterly lacking. As he states,

> if powerful people were going to be sensitive to principled solutions to the problems raised by genomic research, then they would already have responded to the implications of the pertinent principles in a broad range of contexts, and many of the conditions that make genetic research threatening would already have been removed [8].

Such a perspective is not very heartening regarding the prospect of implementing a societal implications research program that would likely serve as no more than political cover for the NNP. In his testimony before the House Science Committee on the societal implications of nanotechnology, Winner offered similar discouraging remarks regarding the appropriateness of the ELSI program as a model for the ANPC activities:

> The professional field of bioethics…(which might become, alas, a model for nanoethics) has a great deal to say about many fascinating things, but people in this profession rarely say 'no' [10].

While others disagree on the level of responsibility that should be assigned to bioethicists themselves, Kitcher, Winner, and the ELSI evaluation committee seem to agree that a successful program would be one capable of influencing policy outcomes.

Clearly, if the ANPC is to function beyond the capacity of a mere public relations shield it must not simply enable proponents of the rapid deployment of nanotechnology to deflect unwanted criticisms of the NNP in order to garner public support for a potentially disruptive technology; it should at the very least not repeat the alleged failures of the ELSI program. How does the ANPC compare to ELSI?

3. From ELSI to ANPC

Structurally, the ELSI evaluation committee specified effectiveness criteria for both research and policy capabilities of the program. In addition to coordinating research grants and prioritizing research agendas, the committee recommended that the program attend to 'back end' issues of assessing completed research [11]—what Wolfe calls 'follow-up' [7]. NRDA legislation does specify that the ANPC will be responsible to 'conduct, coordinate, collect, and disseminate' research, but it says nothing about how research is to be prioritized or assessed [1].

McCain offers several criteria for appraising ELSI research. These criteria, she states, are

> oriented toward advancing the common interest. They encourage and are used to assess responsible and inclusive participation in developing intelligence for policy making [9].

The criteria are derived from the policy sciences and include categories such as *relevance*, *timeliness*, *openness to public input*, and *comprehensiveness* [12]. Similar appraisal criteria with an explicitly normative focus (such as advancing the common interest or the common good) could and probably should be used to prioritize the ANPC research agenda, especially considering the complexities involved in the goal of minimizing the potentially disruptive impact of nanotechnology.

If, as Winner's comments imply, the point of the ANPC research should be to influence policy outcomes, then the ELSI evaluation committee's recommendation that research be followed up on provides a possible means by which to encourage the connection between

research and outcomes. In other words, research on the societal implications of nanotechnology should be assessed not just for its quality, but also for its capacity to effect outcomes, which in this case means the course of nanotechnology research and development (R&D) and, ultimately, the nature of the technology that the NNP helps deploy.

This is where the NRDA is truly creative, for it specifically requires that 'research on societal concerns' be 'integrated with nanotechnology research and development' [1]. Since this phrase is admittedly vague, it is helpful to consult the House Science Committee's report accompanying the legislation, which clarifies the objective of the integration being called for:

> The Committee stresses the importance of integrating research on environmental, societal, and ethical implications with nanotechnology research and development programs to ensure that the…results of the…research influences [sic] the direction of ongoing nanotechnology research and development of commercial applications [3].

This implies that ANPC-sponsored research ought to be able to influence the shape of federally sponsored nanotechnology that finds its way into the public and the natural environment. Thus, the ANPC should operate under clear policies for research that also include criteria for determining and assessing the potential for societal research to be 'integrated' with technical R&D and to thereby influence the nature of nanotechnology.

In addition to making recommendations for research, the ELSI evaluation committee recommended that there be agency-wide and federal policy bodies. The NRDA does call for a National Nanotechnology Advisory Panel (NNAP), which, among other things, is responsible for assessing and making recommendations concerning the NNP activities that are meant to address societal concerns. The legal language does not require panel members to have ethical and societal expertise—although it mentions such expertise as a possible requirement. With or without this expertise, however, the NNAP is, in theory at least, partly responsible for monitoring the effectiveness of the NNP, and by extension the ANPC, in prioritizing and appraising the research it sponsors from the standpoint of 'integration'.

The NNAP is not a public policy panel, since it is only required to focus on National Nanotechnology Program policy. As an agency-wide panel, however, both the National Nanotechnology Coordination Office and the National Science and Technology Council, which together oversee the NNP, are required to take its recommendations into account. Nevertheless, it must be noted that, unless the NNAP has a clear focus upon ensuring that the research on societal concerns actually influences the direction of nanotechnology R&D in an effort to minimize potential negative societal impacts, it will do little to protect the NNP from Kitcher's suggestion that policy makers are not interested in addressing societal considerations for their own sake.

The lack of a federal policy panel only emphasizes Kitcher's concerns, since there would seem to be no mechanism whereby the research sponsored by the ANPC would necessarily lead to tangible outcomes. Dissemination of research, as suggested by the ELSI program, is not necessarily an effective way to influence policy; ironically, it can even be counter-productive. Yet, if the mandate for 'integrating' ANPC research with

nanotechnology R&D is faithfully and effectively discharged, this would be tantamount to a public policy for nanotechnology. In fact, it could quite possibly be a more effective one than previously seen in the United States.

This is because of what is known as the Collingridge dilemma [13]. In order to minimize any negative impacts of a technology, it is theoretically more effective to influence the shape of that technology early on in the development process than it is to attempt to do so at the end of this process. Once a technology has been designed, there is little left for regulators (or the public) to do except either approve or reject it. Needless to say, there will be tremendous pressure to implement the technology given all the resources that have been devoted to it up to that point, even if negative impacts are more clearly anticipated than they were earlier on.

If the ANPC, and any other agencies in the NNP it may be required to work with, can successfully implement the 'integration mandate', it may go well beyond the mere public relations status that Kitcher and Winner are worried about. The ANPC would need to focus on both selecting and appraising the effectiveness of societal concerns research with respect to its capacity for being integrated into technical R&D. Executive program and agency policy makers may or may not perceive strong motivations to actively pursue such an integration policy; but as long as they do not actively oppose it, there is a chance that the ANPC—in cooperation with nano-scientists and nano-engineers—could subtly affect the technological outcomes of the program of which it is a part, rather than merely producing 'impotent' research.

4. Beyond assessment

Critics may argue that it is not possible for humanities and social science research to influence the direction of technological research—that technology proceeds more or less autonomously and irrespective of external societal considerations. Admittedly, factoring 'non-technical' considerations into R&D will take the willingness and cooperation of nano-researchers and their managers. Yet, this technological determinism argument does not stand up well to the study of engineering activities. As Bucciarelli points out, political and societal considerations are hardly incompatible with the engineering process, at least during the design stage:

> Designing and design decisions depend…upon the values and interests of participants. This is not to deny the importance of scientific and technical constraints and specifications, but these are not determinate…participants' interests shape their proposals, explanations, and understandings [14].

The challenge for nano-ethicists, then, becomes encoding their research and conclusions in terms that can be readily translated into design and development constraints and requirements, such as criteria, specifications, and guidelines that can be incorporated into technological decisions and artifacts. In short, social scientists will need to make their research 'user friendly' for nanotechnologists and 'policy relevant' for decision makers. This naturally will require a philosophical understanding of the ways in which scientific and engineering R&D are *potentially able* to respond to 'non-technical' constraints,

including the extent to which it *already* does so. For this reason, the ANPC would do well to maintain a line of research devoted exclusively to developing practical frameworks for implementing the integration of a 'second stream' of societal research into the existing confluence of multidisciplinary research streams that comprise nanotechnology R&D.

Critics may also question the effectiveness of implementing an integration system of this kind—and they ought to. For without clear rules, sanctions, and lines of authority that allow invocation and application of a public law, legislation itself can be impotent. In order to assure that societal research can indeed go beyond assessment, effective institutional and process mechanisms for R&D outcomes policy will be needed.

One form of integration would place societal concerns at the table where research and design decisions are made. This could take several forms. For instance, social researchers could, if familiar with the workings of applied research and engineering practices, participate in research and design team decision-making. Alternatively, scientists and engineers who were thoroughly grounded in appropriate fields or certified in a procedural ethics framework could, in theory, factor in the results of ethical and societal assessments. In either case, participatory technology assessment models would offer useful tools and vital considerations, were such approaches to be developed and employed. Of course, participants in the design and decision making process could conceivably have a hard time honestly admitting their own ethical biases and upholding them to rigorous scrutiny. Such approaches, therefore, would need to be underwritten by comprehensive and effective oversight and appraisal mechanisms.

Past and existing federal precedents may also offer partial paradigms for the NRDA requirement. Sarewitz and Woodhouse [15] suggest four separate possibilities, beginning with institutional (or internal) review boards (IRBs), approval from which is required for any US federally funded project involving human subjects research. They also highlight the role of the (now defunct) Office of Technology Assessment (OTA) in its capacity to 'draw together the best thinking of a wide range of relevant experts, stakeholders, and interest groups'. Noting that 'assessment…cannot substitute for regulation', they suggest two possible regulatory models: the approval regimes of the Environmental Protection Agency in the case of chemicals, and of the Food and Drug Administration in the case of pharmaceuticals.

Some combination of OTA research quality, with its expertise and representation, and IRB procedure, with its monitoring and approval authority, could be a logical start in moving societal concerns research beyond assessment and towards integration. As Sarewitz and Woodhouse imply, the purview of an IRB for nanotechnology would need to be expanded from humans directly involved in nanotechnology research to those potentially affected by *downstream* socially embedded technologies that are enabled by that research [15, see also 16]. Moreover, to take into account ongoing developments in research and their ethical and societal implications, the integration of technology assessment and technology development would itself have to be ongoing during an R&D project, rather than occurring simply before a project begins or after it is largely completed.

One can say that every technological choice is potentially an ethical and political act, insofar as it leads to or influences the creation of a technological artifact with societal implications. Although the prospects for the ANPC to function as an effective research and

policy body are perhaps slim, they are not completely improbable. In taking into account the purported shortcomings of the ELSI program and in recognizing the unique opportunity latent in the NRDA's 'integration policy', determining the shape of technology during development could be a much more broadly informed process than it is now, suggesting that nanotechnology could be both socially acceptable and socially responsible.

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