PUBLIC CHALLENGES OF NANOTECHNOLOGY REGULATION

Elizabeth A. Corley, Youngjae Kim, and Dietram A. Scheufele*

ABSTRACT: Regulatory decisions are often approached with the assumption that decision making would be easier with full public knowledge of the topic and complete scientific certainty about risks and benefits. Unfortunately, for emerging technologies with potentially far-reaching and long-term societal implications, the assumption that regulatory decisions can be made with all relevant facts on the table is unrealistic. More importantly, however, many of the ethical, legal and social questions surrounding these technologies in public debate are inherently political questions, and—as a result—the technical or scientific facts behind these new technologies are only a small part of how societies come to agreement about the various regulatory options surrounding these emerging technologies. Given the growing presence of nanomaterials in consumer end markets worldwide and the uncertainties about the risks and benefits of nanomaterials, the development of nanotechnology regulations must move forward in the absence of full public knowledge and scientific certainty.

In this article, five core public challenges are identified that face regulators and policymakers as they move forward with nanoregulation in the United States. Within the context of introducing these challenges, data are presented that illuminate why these issues could be challenges for the development of nanotechnology regulations. The paper concludes with priority areas for nanoregulation based on the perceptions of leading U.S. nanoscientists. The data presented in this article were collected through the Center for Nanotechnology in Society at Arizona State University (CNS-ASU), which is funded by the National Science Foundation (NSF).

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The purpose of this article is to use recent empirical data to highlight five core public challenges that regulators and policymakers face moving forward with nanoregulation in the United States. These challenges highlight why full public knowledge about nanotechnology, along with complete scientific certainty about the risks and benefits, might not make engaging the public any easier. Multiple studies have shown that technical or scientific knowledge is only a small part of how the public develop perceptions about nanotechnology,

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with other heuristics mattering as much or more when the public make policy decisions about nanotechnology.[1] Given this social and scientific environment, an argument can be made that scholars and decision makers must move forward with the development of nanotechnology regulations in the absence of complete public knowledge and scientific certainty.

The first public challenge highlights that while overall public support of nanotechnology is solid, the public are uncertain about how well existing regulations protect them from nanotechnology risks and benefits. The second challenge outlines that public knowledge about nanotechnology is low and there are widening knowledge gaps among different educational groups of the public. The third challenge illustrates that some groups of experts that are the most trusted by the public are not regularly engaging in public communication about nanotechnology. The fourth challenge emphasizes the need to prioritize nanotechnology regulation in areas where leading U.S. nanoscientists say scientific risks are high and current nanoregulations are not adequate. The fifth challenge stresses the importance of using a variety of regulatory mechanisms to address the current nanotechnology policy vacuum while long-term regulatory solutions are being developed. Parts I–V of this article present data that illuminate why these issues could be challenges for the development of nanotechnology regulations. The conclusion provides some comments about priority areas for nanoregulation based on the perceptions of leading U.S. nanoscientists.

I. CHALLENGE 1: THE PUBLIC ARE UNCERTAIN ABOUT NANOTECHNOLOGY REGULATIONS

The first significant challenge for nanoregulators and policymakers is that the public are generally supportive of nanotechnology, but they feel uncertain about whether existing regulations are sufficient. Uncertainty about regulations could lead to future public rejection of nanotechnology if consumers feel that risks are high and unchecked by regulations. In addition, this public uncertainty about nanoregulations could result in the public shying away from some existing commercial nanotechnology products that are relatively safe and have low risk levels.

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1. *See* Susanna Hornig Priest et al., *The "Trust Gap" Hypothesis: Predicting Support for Biotechnology Across National Cultures as a Function of Trust in Actor*s, 23 RISK ANALYSIS 751 (2003) (questioning the traditional assumption that higher levels of science education and literacy result in greater acceptance of scientific discoveries); Chul-Joo Lee et al., *Public Attitudes Toward Emerging Technologies: Examining the Interactive Effects of Cognitions and Affect on Public Attitudes Toward Nanotechnology*, 27 SCI. COMM. 240 (2005) (arguing that cognitive and affective factors have both important separate effects on public perceptions and a key synergistic effect when combined); Dietram A. Scheufele et al., *Religious Beliefs and Public Attitudes to Nanotechnology in Europe and the United States*, 4 NATURE NANOTECHNOLOGY 91 (2009) (exploring a link between higher levels of religiosity and lower levels of nanotechnology acceptance in the United States and Europe); Dietram A. Scheufele & Bruce V. Lewenstein, *The Public and Nanotechnology: How Citizens Make Sense of Emerging Technologies*, 7 J. NANOPARTICLE RES. 659 (2005) (arguing that cognitive shortcuts and media heuristics play a key role in shaping public perceptions of science and creating opinion).

Table 1: General Public Perceptions about Nanotechnology (N=1,015)

	Mean	SD
(1= Do not agree at all; 10=Agree very much)		
"Overall, I support the use of nanotechnology."	6.47	2.52
"Overall, I support federal funding for nanotechnology."	5.90	2.85
"The government should protect the public from the unknown risks of nanotechnology."	5.91	2.73
(1= Not confident at all; 10=Very confident)		
"How confident would you say you are in the safety and regulatory approval systems governing nanotechnology?"	4.65	2.73
(1= Nothing at all; 10=Very much)		
"How much you have heard, read or seen about nanotechnology."	3.99	2.47
(1= Not informed at all; 10=Very well informed)		
"How well informed you would say you are about nanotechnology."	3.39	2.18

The overall public support levels for nanotechnology are demonstrated in Table 1, which summarizes responses from a 2007 public opinion survey conducted by CNS-ASU. In the survey, individuals were asked to respond to two statements: "Overall, I support the use of nanotechnology," and "Overall, I support federal funding for nanotechnology." In Table 1, a mean score of about 6 on a 1–10 scale, where 1 represents "do not agree at all," and 10 represents "agree very much," demonstrates that the public are generally supportive of nanotechnology and federal funding. The table also shows that the public support government regulations to protect them from risks, but they do not have high levels of confidence in existing nanotechnology regulations.

The public also rated their level of approval for nanotechnology based on different regulatory conditions. As seen in Figure 1, individuals were asked which of the following statements best fit their views about nanotechnology: (A) I approve of nanotechnology as long as the usual levels of governmental regulation are in place, (B) I approve of nanotechnology if it is more tightly regulated, (C) I do not approve of nanotechnology except under very special circumstances, and (D) I do not approve of nanotechnology under any circumstances.

Figure 1: Public Nanotechnology Approval Levels Based on Regulations (N=1,015)

Survey Question: "Now, thinking about your personal views about nanotechnology overall, which of the following best describes your views about nanotechnology."
A - I approve of nanotechnology as long as the usual levels of government regulation are in place.
B - I approve of nanotechnology if it is more tightly regulated.
C - I do not approve of nanotechnology except under very special circumstances.
D - I do not approve of nanotechnology under any circumstances.

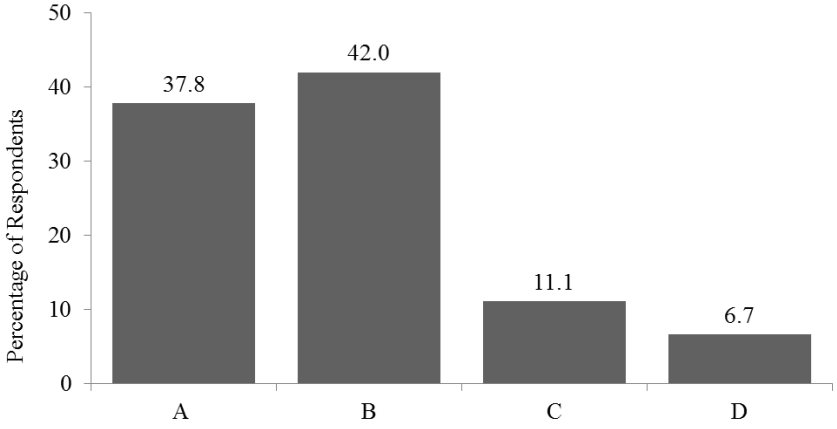

Figure 1 demonstrates that the largest proportion of the public (about 42 percent) would approve of nanotechnology if stricter regulations were enforced. This group is not satisfied with the existing regulations, but it is generally supportive of nanotechnology. The second largest group (about 38 percent) approves of nanotechnology with the existing regulations and is satisfied with the current state of nanotechnology research and regulation. The last two groups represent about 18 percent of the sample, and they do not generally support nanotechnology. In summary, this first public challenge requires regulators and policymakers to address the public's general uncertainty and concern about whether government regulations are protecting them from nano risks.

II. CHALLENGE 2: PUBLIC NANOTECHNOLOGY KNOWLEDGE IS LOW, AND THERE ARE WIDENING GAPS

A second major public challenge for nanotechnology regulations, as indicated in Table 1, is that public knowledge about nanotechnology is relatively low, and there are widening knowledge gaps across education groups.[2] Using survey data, nanotechnology knowledge levels were explored in a variety of ways, including self-reported awareness of the issue, as well as responses to factual statements about the technology.

The public survey data collection included two questions about self-reported awareness of nanotechnology: how much they had heard about nanotechnology and how well informed they felt about nanotechnology. The results of these questions are presented in Table 1. Not surprisingly, the U.S. public have heard little about nanotechnology in general, and they do not feel well informed about the issue.

Because these data only report on the public's *perceptions* about their nanotechnology knowledge levels, it also is important to analyze the public's *knowledge levels* about nanotechnology based on science-driven statements about the technology. To do this a series of six true-false survey questions was compiled to measure knowledge levels about nanotechnology. Data were collected from the public on these six questions in both 2004 and 2007. Panel data were not used, so the respondents were not the same across the two years, but both surveys were nationally representative.

Based on the analysis of the public's response to these six true-false statements, the findings suggested that public nanotechnology knowledge levels changed little between 2004 and 2007, despite large scale nanoscience outreach efforts funded by public money.[3] In both years, the respondents answered about four of the six true-false questions correctly.[4] This result was surprising because the United States has made large-scale time and money investments in nanotechnology outreach efforts over the past decade, including activities like Science Cafés, Nanodays, and nanotechnology museum exhibits.[5]

To further explore why public nanotechnology knowledge levels have not changed much in the United States between 2004 and 2007, an in-depth analysis of knowledge levels across different segments of the public was conducted. From this analysis, increases in nanotechnology knowledge were found between 2004 and 2007, but they occurred only for the most highly educated members of the U.S. public—those that have completed college.[6] Among indi-

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2. See Elizabeth A. Corley & Dietram A. Scheufele, *Outreach Going Wrong? When We Talk Nano to the Public, We Are Leaving Behind Key Audiences*, 24 THE SCIENTIST 22 (2010); Michael A. Cacciatore et al., *Another (Methodological) Look at Knowledge Gaps and the Internet's Potential for Closing Them*, PUB. UNDERSTANDING SCI. (forthcoming), for detailed presentations of these data as well as statistical analysis.

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

viduals with lower formal education levels—less than a high school degree—a decrease in average nanotechnology knowledge levels over time was observed.[7] The results presented here suggest that existing U.S. nano-outreach efforts are reaching more educated members of the public, such as those that can and do attend museums, while outreach efforts are less likely to reach those with lower education levels. These widening knowledge gaps can have serious implications for public engagement efforts and outreach. Therefore, the second public challenge requires rethinking how public outreach efforts for nanotechnology are currently conducted to ensure that *all* segments of the interested public are being adequately reached.

III. CHALLENGE 3: TRUSTED EXPERTS NEED TO ENGAGE IN PUBLIC COMMUNICATION ABOUT NANOTECHNOLOGY

The third challenge is focused on encouraging trusted groups, such as university scientists and medical doctors, to engage in public communication about nanotechnology more than they do currently. While some scientists engage in this type of discourse with the public, many do not. There are rational reasons why there is a lack of expert public engagement on nanotechnology; for example, the incentive systems at universities are not typically designed to encourage faculty members to spend time on these activities, and public engagement efforts are not considered equal to peer-review publications or grants when a faculty member is evaluated for promotion or tenure.

Yet, when experts engage in public communication activities about scientific research, there can be positive implications for both public acceptance of the technology and public knowledge levels about the technology. A series of previous studies demonstrate that the public use trust in experts as a key heuristic to make decisions about support for nanotechnology.[8] The public are especially likely to use this trust in experts to make decisions about nanotechnology when their knowledge levels about the technology are low. Because it is important for trusted experts to engage in public communication about technologies, determining which expert groups have the highest public trust levels is important.

Figure 2 illustrates levels of public trust across a variety of expert groups for the issue of nanotechnology. The three groups with the highest levels of public trust are university nanoscientists, medical professionals, and consumer organizations. The public also trust industry-based nanoscientists and regulators, but they are both slightly less trusted than the top three groups. The least trusted groups are business, Congress, the White House, environmental or-

7. *Id.*

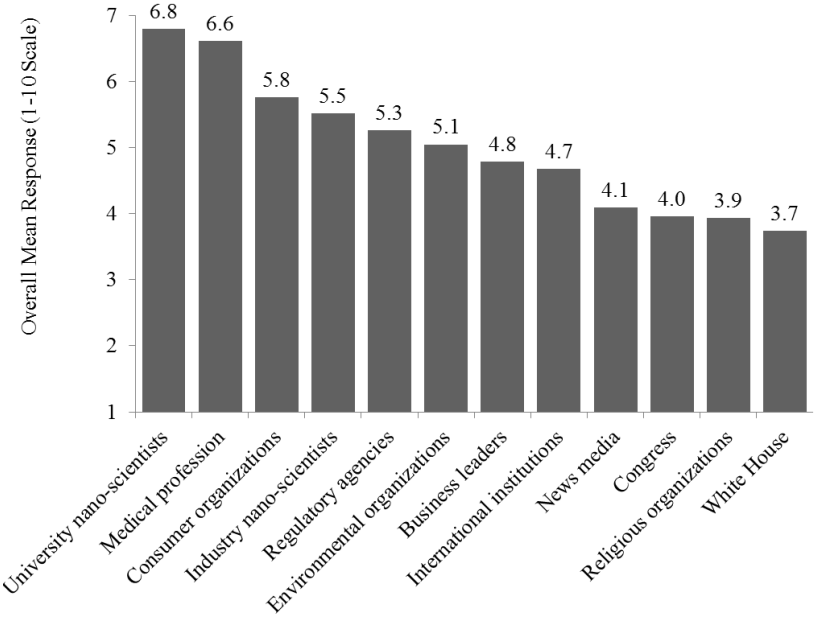
8. *See* Hui Liu & Susanna Priest, *Understanding Public Support for Stem Cell Research: Media Communication, Interpersonal Communication and Trust in Key Actors*, 18 PUB. UNDERSTANDING SCI. 704 (2009) (investigating which types of public influences are likely to produce a change in opinion of stem cells); Priest et al., *supra* note 1.

ganizations, religious organizations, international organizations, and news media.

These 2007 public opinion survey results demonstrate that reliance solely on governmental agencies or nonprofit organizations to communicate with the public about nanotechnology risks is not effective. Although these groups can play a role in the communication, they are not the most trusted experts by the public. The third public challenge requires increasing public engagement by university scientists doing nanotechnology research, as well as medical professionals.

Figure 2: Levels of Public Trust in Experts for Communicating about Nanotechnology Risks and Benefits (N=1,015)

Survey Question: "Now I would like to ask you which of the following sources of information, if any, you trust to tell you the truth about the risks and benefits of nanotechnology. On a scale from 1 to 10 where 1 means you do not trust their information at all and 10 means you trust their information very much, how much do you trust…"



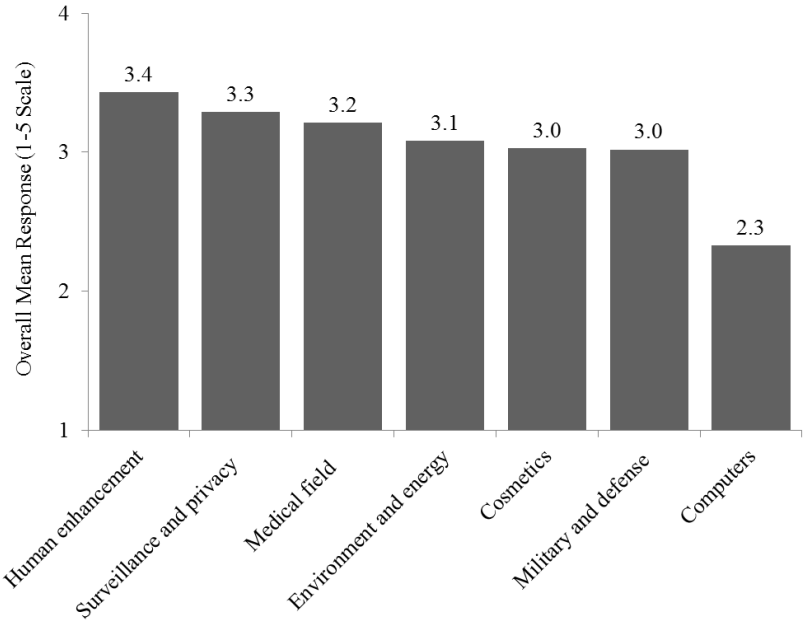
IV. CHALLENGE 4: PRIORITIZE NANOREGULATION IN AREAS WHERE SCIENTIFIC RISKS ARE HIGH AND CURRENT REGULATIONS ARE INADEQUATE

The fourth public challenge involves assessing which areas of nanotechnology have the most urgent need for regulatory change. This challenge can be addressed by identifying the key policy priority areas highlighted by leading U.S. nanoscientists.

In addition to conducting a public opinion survey in 2007, CNS-ASU also conducted an expert survey. In the 2007 expert survey, 363 of the most productive U.S. nanoscientists were asked to report on the adequacy of nanoregulations in seven general areas: human enhancement, privacy, medicine, environment, cosmetics, national defense, and computers. As Figure 3 illustrates, the nanoscientists reported that existing regulations are at least somewhat insufficient in six main areas: (1) human enhancement, (2) privacy, (3) medicine, (4) environment, (5) cosmetics, and (6) defense.

Figure 3. Scientists' Perceptions about Priority Areas for Nanotechnology Regulation (N=1,015)

Survey Question: "Thinking about applications of nanotechnology in each of the following areas, please indicate to which degree you think current regulations are sufficient or we need new regulations in order to address the new realities created by nanotechnology." (1= Current regulations are sufficient; 5= We need new regulations)



Because policy formulation and implementation are often slow steps within the policy process, the fourth public challenge highlights the importance of focusing initial governmental resources in nanotechnology areas that have inadequate existing regulations. The results presented here suggest that federal agencies should focus their development of new nanotechnology regulations in the areas of human enhancement, privacy, and medicine. Even though different expert groups might argue for slightly different priority areas for nanoregulations, the above three areas seem to be the most important according to leading U.S. nanoscientists; therefore, they are a good place to begin concentrating limited resources as nanoregulations move forward.

V. CHALLENGE 5: ADDRESS THE CURRENT NANOTECHNOLOGY POLICY VACUUM WHILE LONG-TERM REGULATIONS ARE DEVELOPED

Currently in the United States, government oversight of products containing nanomaterials is exerted only when a product is subject to an existing regulatory scheme that includes consumer products, such as foods, drugs, or toxic chemicals.[9] Even though the development of long-term regulations for nanotechnology is a priority for federal agencies like the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA), these formal regulations take time and significant resources. In the meantime, commercial and academic research using nanomaterials continues to increase at a rapid rate. For instance, the Project on Emerging Technologies, established in 2005 as a partnership between the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts, provides an online inventory of nanotechnology consumer products. The number of products outlined in the inventory increased by 521% between March 2006 and March 2011.[10]

This significant increase in commercial use of nanomaterials, combined with a typically slow policy process, means that U.S. federal agencies might need to explore shorter-term options for the regulation of nanotechnology risks while formal regulations are being developed. One recent example of this move towards a nontraditional approach for regulating nanotechnology is highlighted in the EPA's Nanoscale Materials Stewardship Program (NMSP), which was a voluntary program that encouraged businesses to report the nanomaterials they used and how those materials were being used.[11] The program started in January 2008 and lasted about two years, ending in December 2009 following the release of an interim program evaluation report in January 2009.[12] While the January 2009 EPA interim report outlined difficulties asso-

9. Gary Marchant et al., *Nanotechnology Regulation: The United States Approach*, *in* NEW GLOBAL FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 189 (Graeme Hodge et al. eds., 2007).

10. *Analysis*, PROJECT ON EMERGING NANOTECHNOLOGIES, http://www.nanotechproject.org/inventories/consumer/analysis_draft/ (last visited May 18, 2012).

11. U.S. ENVTL. PROT. AGENCY, NANOSCALE MATERIALS STEWARDSHIP PROGRAM: INTERIM REPORT 3 (2009), *available at* http://epa.gov/oppt/nano/nmsp-interim-report-final.pdf.

12. *Id.*

ciated with the implementation and effectiveness of the NMSP program, this was an innovative management step for the agency—the organization was exploring faster and more flexible policy mechanisms for addressing nanotechnology risks.

This type of policy innovation will be increasingly important in the future for nanotechnology given the pace of the policy process in the United States. To balance public protection from nano risks with the rapid development of new nanotechnology products, regulatory agencies will have to continue to experiment with flexible, rapid, and responsive policy supplements to traditional regulations. This type of policy innovation is not mutually exclusive with formal regulations and could function alongside more traditional regulation development. While this balancing act presents a significant challenge, it also can be an important opportunity for U.S. regulatory agencies to prepare for better management of future emerging technologies. As the rate of technological development increases each year, it is likely that in the future, governmental agencies will face an increasing number of emerging technologies that require intermediate, short-term policy solutions while formal regulations are being mapped out. Therefore, this fifth challenge is not specific to nanotechnology; it is applicable to any rapidly developing emerging technology area.

Using empirical research on public and scientist perceptions about nanotechnology, five important public challenges facing regulators and policymakers for nanotechnology regulation have been identified in this article. Even though the public are in favor of nanotechnology, their knowledge levels about the technology are relatively low, and there are troubling disparities among education groups. Moreover, the public are still uncertain about whether existing regulations are sufficient to protect them from nanotechnology risks. One way to help the public understand more about nanotechnology risks and regulations is to encourage trusted experts to engage in public communication about nanotechnology. So far, trusted experts, such as university scientists and medical doctors, have been slow to engage the public in a dialogue about nanotechnology. Increasing the frequency of this public communication about scientific risks and regulation could not only increase public knowledge about nanotechnology, but also help the public better understand the role of governmental regulations in protecting them from nanotechnology risks. Certainly it continues to be important for policymakers to prioritize nanoregulation in areas where scientific risks are high and current regulations are inadequate. Given the complexity of regulating nanotechnology, federal agencies will not be able to formulate and implement formal policies in all areas at the same time. Therefore, prioritizing nanotechnology areas where existing regulations are less likely to protect the public from risks, such as human enhancement, privacy, and medicine, will be an important strategic policy move for federal agencies. Lastly, governmental agencies need to use

flexible, innovative, and responsive policy tools to develop new regulations for emerging technologies. The development of regulations for these technologies (for example, nanotechnology) can be particularly challenging for traditional, slow-moving regulatory frameworks, especially in cases where rapid technological development is coupled with significant scientific uncertainty.