

## NANOTECHNOLOGICAL EXCEPTIONALISM:

### DISTINGUISHING NANOTECH AS *SUI GENERIS* FROM A LEGAL VANTAGE

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#### I. INTRODUCTION

The advent of nanotechnology, “science and technology that will enable one to understand, measure, manipulate, and manufacture at the atomic, molecular, and supramolecular levels,”<sup>1</sup> has generated a multitude of novel legal and ethical issues that current law is unprepared to address.<sup>2</sup> Nanotechnology entails the study of matter as small as one nanometer (one billionth of a meter)<sup>3</sup> or 1/80,000 the diameter of a human hair.<sup>4</sup> Nanoparticles have already been incorporated into a wide variety of current consumer products.<sup>5</sup> Unfortunately, the general public has little to no familiarity with the concept of nanotechnology, let alone its sweeping ramifications.<sup>6</sup> As it remains a revolutionary but relatively unknown commodity,

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<sup>1</sup>15 U.S.C. § 7509(2) (2006).

<sup>2</sup>See Gregory Mandel, *Nanotechnology Governance*, 59 ALA. L. REV. 1323, 1327 (2008) (noting the difficulties in applying outdated laws to new technologies, such as nanotechnologies).

<sup>3</sup>Nat'l Nanotechnology Initiative, *What is Nanotechnology?*, <http://www.nano.gov/nanotech-101/what/definition> (last visited Oct. 2, 2013).

<sup>4</sup>Rick Weiss, *Nanotechnology Regulation Needed, Critics Say*, WASH. POST (Dec. 5, 2005), <http://www.washingtonpost.com/wp-dyn/content/article/2005/12/04/AR2005120400729.html>.

<sup>5</sup>*Id.*

<sup>6</sup>*Poll Reveals Public Awareness of Nanotech Stuck at Low Level*, THE PROJECT ON EMERGING NANOTECHNOLOGIES (Sept. 25, 2007), [http://www.nanotechproject.org/news/archive/poll\\_reveals\\_public\\_awareness\\_nanotech/](http://www.nanotechproject.org/news/archive/poll_reveals_public_awareness_nanotech/).

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nanotechnology necessitates a new and adaptive regulatory approach.<sup>7</sup>

Nanotechnology has forced legislators to contemplate such potential problem areas as general safety, the latent toxicity of nanoparticles, inequitable risk distribution from exposure to nanoparticles, the role of health insurance with respect to nanomedicine, patent and intellectual property rights for nanotechnological innovations including the licensing of such rights, the transfer of nanotechnology to other nations and developing appropriate universal standards, privacy concerns due to nanosurveillance, issues associated with hypertechnology,<sup>8</sup> and possible weaponization.<sup>9</sup> Nanotechnology is still fairly nascent<sup>10</sup> and requires an individualized, multifaceted strategy of regulation integrating increased funding for research, transparency in the development process, protection of intellectual property rights, international coordination, government agency oversight, and continuous ethical scrutiny.<sup>11</sup> This Article proposes a basic administrative construct to manage the spread of nanotechnology.

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<sup>7</sup>See Frederick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L.J. 593, 603 (1994) (arguing that legislators can only resolve the unique and unorthodox issues accompanying nanotechnology through new legislation).

<sup>8</sup>Davis Baird & Tom Vogt, *Societal and Ethical Interactions with Nanotechnology ("SEIN")—An Introduction*, 1 NANOTECHNOLOGY L. & BUS. 391, 392-95 (2004) (listing a multitude of negative consequences that may result from inadequate nanotechnology legislation).

<sup>9</sup>Keay Davidson, *Big Troubles May Lurk in Super-Tiny Tech / Nanotechnology Experts Say Legal, Ethical Issues Loom*, SFGATE (Oct. 31, 2005, 4:00 AM), <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2005/10/31/MNG28FGMVJ1.DTL> (speculating that scientists could use nanotechnology to create microscopic machines capable of espionage or torture).

<sup>10</sup>See Joachim Schummer, *Identifying Ethical Issues of Nanotechnologies*, in NANOTECHNOLOGIES, ETHICS AND POLITICS 79, 80 (Henk A.M.J. ten Have ed., 2007), available at [http://joachimschummer.net/papers/2007\\_Nanoethics\\_UNESCO.pdf](http://joachimschummer.net/papers/2007_Nanoethics_UNESCO.pdf).

<sup>11</sup>See Mandel, *supra* note 2, at 1373 (advocating for a responsible and ethical approach to nanotechnology regulation that strives for further research but also considers our safety, the environment, and the benefits of cooperation).

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**II. BACKGROUND**

At the risk of sounding hyperbolic, nanotechnology is unlike any other advancement we have previously encountered.<sup>12</sup> Bold predictions about the future of nanotechnology abound.<sup>13</sup> “Full-fledged nanotechnology promises nothing less than complete control over the physical structure of matter.”<sup>14</sup> “[A]pplying nanotechnology to medicine will allow us to literally re-engineer how our cells work.”<sup>15</sup> One computer scientist articulated fears of an impending “gray goo” scenario involving the spawn of self-replicating nanorobots leading to cataclysmic fallout.<sup>16</sup> Although there has been immense speculation about nanotechnology on polar opposite ends of the spectrum, a more realistic assessment of the efficacy and consequences of nanotechnology lies somewhere in the middle.<sup>17</sup> The problem is that the incredible amount of uncertainty surrounding nanotechnology makes it exceedingly difficult to accurately gauge its current and future outcomes.<sup>18</sup>

Nanotechnology is enigmatic in that even its meaning has not

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<sup>12</sup>See Fiedler & Reynolds, *supra* note 7, at 594-95 (noting the dramatic impact of trains, digital computers, and space travel in the last century and recognizing the potential impact that nanotechnology will have on our future).

<sup>13</sup>See Schummer, *supra* note 10, at 79.

<sup>14</sup>Glenn Harlan Reynolds, *Nanotechnology and Regulatory Policy: Three Futures*, 17 HARV. J.L. & TECH. 179, 185 (2003).

<sup>15</sup>Robin Fretwell Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J.L. MED. & ETHICS 704, 705 (2006).

<sup>16</sup>See Bill Joy, *Why the Future Doesn't Need Us*, WIRED, <http://www.wired.com/wired/archive/8.04/joy.html> (last visited Oct. 2, 2013, 10:57 PM) (recognizing the catastrophe that may result if nanorobots were to replicate and spread past the point of our control).

<sup>17</sup>See Schummer, *supra* note 10, at 79 (arguing that most of the hype and speculation surrounding nanotechnology is simple exaggeration).

<sup>18</sup>See Wilson, *supra* note 15, at 707 (recognizing that creating legislation aimed at nanotechnology will be difficult because the legislation often has to meet evidentiary standards requiring “substantial evidence,” which may be impossible to provide due to the current uncertainties of nanotechnology).

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been static, but fluid; the nanotechnology community has attained nothing remotely approaching a consensus characterization of the term.<sup>19</sup> “Nanotechnology” is an inaccurate title because it encompasses several technologies, as opposed to one singular concept.<sup>20</sup> Definitions vary across jurisdictions, cultures, and technical disciplines.<sup>21</sup> This lack of clarity extends to patents too, as applicants are unsure of what explicit terminology to use in order to procure sufficient protection for their discoveries.<sup>22</sup>

The principal body of U.S. law pertaining to nanotechnology is the United States Nanotechnology Research and Development Act of 2003 (“NRDA”).<sup>23</sup> The NRDA calls for the creation of a national nanotechnology program (National Nanotechnology Initiative or “NNI”) aimed at raising awareness and promoting further discovery of nanotechnology.<sup>24</sup> Furthermore, the NRDA authorizes \$3.7 billion to fund the operation of the entire program.<sup>25</sup> It also provides for increased training and education, catalysts for commercialization, and evaluations of societal and ethical concerns.<sup>26</sup> However, the NRDA does not consist of any laws governing the express use or application of nanotechnology and primarily concerns future studies and resource allocation.<sup>27</sup> Moreover, no states have enacted any regulatory laws

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<sup>19</sup>Schummer, *supra* note 10, at 79-84.

<sup>20</sup>Wilson, *supra* note 15, at 704.

<sup>21</sup>Schummer, *supra* note 10, at 79-84.

<sup>22</sup>Michael Berger, *Legal Implications of the Nanotechnology Patent Land Rush*, NANOWERK (May 11, 2007), <http://www.nanowerk.com/spotlight/spotid=1919.php>.

<sup>23</sup>15 U.S.C. §§ 7501-7509 (2006 & Supp. V 2011).

<sup>24</sup>§ 7501.

<sup>25</sup>§ 7505.

<sup>26</sup>§ 7501.

<sup>27</sup>*See* §§ 7501-7509.

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targeting nanotechnology.<sup>28</sup> The reality is that the United States does not specifically regulate nanotechnology use or manufacturing.<sup>29</sup>

For example, regarding environmental protection, it appears that the United States is content to use voluntary measures and existing regulations to deter and address any adverse impact nanotechnology creates.<sup>30</sup> Interestingly, the United States used a similar tactic in the past to regulate genetically modified organisms.<sup>31</sup> Currently, the United States generally attempts to shoehorn nanotechnology products into the scope of, inter alia, the Toxic Substances Control Act, the Occupational Safety and Health Act, the Federal Food, Drug, and Cosmetic Act, the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Consumer Product Safety Act.<sup>32</sup> Congress has not precisely tailored this patchwork mishmash to handle nanotechnology use, and as a result its authority in this domain is tenuous at best.<sup>33</sup> For this purpose, these statutes are ineffectual in practice.<sup>34</sup>

Recently, Congress has proposed new bills to both renew and revamp existing legislation, and new agency protocols are in the

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<sup>28</sup>Nancy J. Brown, *Nanotechnology: Is New Regulation Needed, and if so, by Whom?*, 23 WASH. LEGAL FOUND. 1, 3 (July 25, 2008), <http://www.wlf.org/upload/07-25-08brown.pdf>.

<sup>29</sup>Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349, 361 (2007).

<sup>30</sup>Mark Kalpin & James Votaw, *Prepare Now for Future Nanotech Legal Issues*, BOS. BUS. J. (Nov. 27, 2006, 8:58 AM), <http://www.bizjournals.com/boston/blog/mass-high-tech/2006/11/prepare-now-for-future-nanotech-legal-issues.html>.

<sup>31</sup>Diana M. Bowman & Graeme A. Hodge, *Nanotechnology “Down Under”*: *Getting on Top of Regulatory Matters*, 4 NANOTECHNOLOGY L. & BUS. 225, 227 (2007).

<sup>32</sup>J. Clarence Davies, *Managing the Effects of Nanotechnology*, WOODROW WILSON INT’L CTR. FOR SCHOLARS 1, 10-15, [http://www.nanotechproject.org/process/assets/files/2708/30\\_pen2\\_mngeffects.pdf](http://www.nanotechproject.org/process/assets/files/2708/30_pen2_mngeffects.pdf) (last visited Oct. 8, 2013).

<sup>33</sup>*See id.*

<sup>34</sup>*See id.*

314 *Florida Coastal Law Review* [Vol. 15:309 works.<sup>35</sup> The National Nanotechnology Initiative Amendments Act, reviewed by the U.S. House in 2009, aimed to reauthorize the NNI, solidify funding, and promote focused nanotechnology research.<sup>36</sup> Additionally, the U.S. Senate is currently reviewing the Safe Chemicals Act, which seeks to update and overhaul the Toxic Substances Control Act by compelling manufacturers to disclose minimum data about their chemical products.<sup>37</sup> Finally, the Environmental Protection Agency (“EPA”) is drafting a Significant New Use Rule applicable to nanomaterials covered by the Toxic Substances Control Act, which would require manufacturers to furnish a Significant New Use Notice ninety days in advance of commencing production.<sup>38</sup> While all of these are commendable management efforts, in reality, it still appears that none of them carry any discernible regulatory weight vis-à-vis nanotechnology.<sup>39</sup>

Alternatively, some analysts claim that the legal stagnation of Congress will spur state governments to effectively regulate nanotechnology on their own.<sup>40</sup> Analysts argue that the collective

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<sup>35</sup>See Safe Chemicals Act of 2013, S. 696, 113th Cong. (2013); National Nanotechnology Initiative Amendments Act of 2009, S. 1482, 111th Cong. (2009); *Control of Nanoscale Materials Under the Toxic Substances Control Act*, ENVTL. PROT. AGENCY, <http://www.epa.gov/opptintr/nano/> (last updated Apr. 29, 2011).

<sup>36</sup>S. 1482, 111th Cong. (2009).

<sup>37</sup>S. 696, 113th Cong. (2013).

<sup>38</sup>*Control of Nanoscale Materials Under the Toxic Substances Control Act*, *supra* note 35.

<sup>39</sup>See Richard Denison, *State-Level Nano Regulation: Yes, Indeed, the Industry “Should Have Seen It Coming” – It Caused It!*, ENVTL. DEF. FUND (Sept. 10, 2010), <http://blogs.edf.org/nanotechnology/2010/09/10/state-level-nano-regulation-yes-indeed-the-industry-should-have-seen-it-coming-%E2%80%93-it-caused-it/>.

<sup>40</sup>See John DiLoreto, *We Should Have Seen It Coming: States Regulating Nanotechnology*, NANOTECHNOLOGY NOW (Sept. 7, 2010), <http://www.nanotech-now.com/columns/?article=484>; John DiLoreto, *What Drives the Regulation of Nanomaterials?*, NANOTECHNOLOGY NOW (July 26, 2010), <http://www.nanotech-now.com/columns/?article=473>.

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action of states will generate a snowball effect.<sup>41</sup> Such a view seems to be largely unsubstantiated and driven by industry figures who favor minimal federal intervention.<sup>42</sup> State-by-state regulation could create vast inequities, and may lead to opportunism through the corporate equivalent of forum shopping.<sup>43</sup>

In the global community, many commentators take a laissez-faire position while others contend that a moratorium on all nanotechnology research is necessary.<sup>44</sup> The corresponding international regulatory methods have likewise been inconsistent,<sup>45</sup> for instance, with respect to potentially hazardous nanomaterials, some manufacturers believe that the government should not regulate nanomaterials in an appreciably different manner than other conventional substances.<sup>46</sup> Australia's National Nanotechnology Strategy Taskforce avowed that "there is currently no case for establishing any new, nanotechnology specific regulations, but rather, existing regulations may need some adjustments."<sup>47</sup> Current French and European legislation prevents the collection of companies' inventories of nanoparticulate substances.<sup>48</sup> Conversely, Canada recently took the

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<sup>41</sup>John DiLoreto, *We Should Have Seen It Coming: States Regulating Nanotechnology*, *supra* note 40.

<sup>42</sup>See Denison, *supra* note 39.

<sup>43</sup>See John DiLoreto, *We Should Have Seen It Coming: States Regulating Nanotechnology*, *supra* note 40.

<sup>44</sup>Michael Berger, *Regulating Nanotechnology—How Adequate is Current Regulation?*, NANOWERK (Mar. 4, 2009), <http://www.nanowerk.com/spotlight/spotid=9490.php>.

<sup>45</sup>See Victoria Gill, *Nano-Regulation Creeps Closer*, ROYAL SOC'Y OF CHEMISTRY (Feb. 25, 2009), <http://www.rsc.org/chemistryworld/News/2009/February/25020901.asp>.

<sup>46</sup>Lin, *supra* note 29, at 361, 407.

<sup>47</sup>Bowman & Hodge, *supra* note 31, at 230.

<sup>48</sup>Sonia Desmoulin, *French and European Community Law on the Nanometric Forms of Chemical Substances: Questions About How the Law Handles Uncertain Risks*, 5 NANOTECHNOLOGY L. & BUS. 341, 349 (2008).

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unprecedented preliminary measure of requiring nanomaterial  
manufacturers to submit safety reports detailing the physical and  
chemical composition of their products.<sup>49</sup> This policy is the first of its  
kind in the world and may lead other countries to follow suit in the  
future.<sup>50</sup> Existing U.S. laws categorize materials according to physical  
size or chemical composition.<sup>51</sup> Unfortunately, only sophisticated  
laboratory equipment can reliably detect nanoparticles.<sup>52</sup>

A number of scientists have likened the effects of nanoparticles  
to that of asbestos.<sup>53</sup> Others simply characterize this view as  
questionable and opine that scientists need to conduct further research.<sup>54</sup>  
At any rate, scientists need to closely observe possible resultant  
damage.<sup>55</sup> At the moment, the EPA, Food and Drug Administration  
("FDA"), and Occupational Safety and Health Administration  
("OSHA") have regulatory control over nanomaterials.<sup>56</sup> The EPA is  
responsible for nonoccupational risk assessments, whereas OSHA  
handles occupational risk assessments.<sup>57</sup> In contrast, the European  
Union currently relies on a tiered risk-assessment system referred to as  
REACH (registration, evaluation, authorization, and restriction of  
chemicals), which places the onus on the industry to manage the risks of

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<sup>49</sup>Gill, *supra* note 45.

<sup>50</sup>*Id.*

<sup>51</sup>Kim C. Lohring, *Nanoscale Materials: Can (and Should) We Regulate the Next Industrial Revolution?*, 2006 U. ILL. J.L. TECH. & POL'Y 313, 314 (2006).

<sup>52</sup>Wilson, *supra* note 15, at 707.

<sup>53</sup>Larry Greenemeier, *Study Says Carbon Nanotubes as Dangerous as Asbestos*, SCI. AM. (May 20, 2008), <http://www.sciam.com/article.cfm?id=carbon-nanotube-danger>.

<sup>54</sup>Davidson, *supra* note 9.

<sup>55</sup>*Id.*

<sup>56</sup>Mandel, *supra* note 2, at 1347; Howard Wolinsky, *Nanoregulation: A Recent Scare Involving Nanotech Products Reveals That the Technology is Not Yet Properly Regulated*, 7 EUR. MOLECULAR BIOLOGY ORG. REP. 858, 859-60 (2006).

<sup>57</sup>*Study Suggests New Regulations Needed to Govern Nanotechnology Risks*, NANOTECHWIRE (Mar. 6, 2009), <http://www.nanotechwire.com/news.asp?nid=7508>.

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its products.<sup>58</sup>

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### III. ANALYSIS

*The world's most powerful emerging technology is developing in an almost total political and regulatory vacuum, . . . [b]ecause nanoscale technologies can be applied to virtually every industrial sector, no regulatory body is taking the lead. And because many of its products are nanosized versions of conventional compounds, regulatory scrutiny has been deemed unnecessary.*

—Pat Mooney<sup>59</sup>

Allowing nanotechnological development to burgeon without any type of restraint is both negligent and irresponsible.<sup>60</sup> It would be appalling if some large-scale accident or disaster had to serve as the impetus to jostle lawmakers from their collective slumber on this issue.<sup>61</sup> Current laws are ill equipped to govern the propagation of nanotechnology.<sup>62</sup> Moreover, nanotechnology companies have no motivation to self-regulate as there are no penalties in place, let alone a minimum standard of compliance.<sup>63</sup> Testing and documentation is an expensive endeavor—which requires substantial outlays from producers—so it is not surprising that most would be disinclined to take money out of their own pockets.<sup>64</sup> In other words, it is reckless to allow

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<sup>58</sup>*Id.*

<sup>59</sup>Wolinsky, *supra* note 56, at 859. Pat Mooney is the “Executive Director of the ETC Group, a non-government environmental organization in Ottawa, Canada.” *Id.*

<sup>60</sup>*See* Lin, *supra* note 29, at 379-80.

<sup>61</sup>*See id.* at 407.

<sup>62</sup>*Id.* at 375-76.

<sup>63</sup>*See* Adam Keiper, *The Nanotechnology Revolution*, THE NEW ATLANTIS, no. 2, 2003, at 17, 29-30, available at <http://www.thenewatlantis.com/docLib/TNA02-Keiper.pdf>.

<sup>64</sup>*See* Wilson, *supra* note 15, at 710-11.

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manufacturers carte blanche with respect to nanotechnology; legislators  
must hold them accountable for the products they introduce to the  
public.<sup>65</sup>

Nonetheless, a total suspension of nanotechnological research  
and development is not so much a tenable position as an impulsive  
response to potential risks.<sup>66</sup> Both producers and legislators should  
complete due diligence and ascertain more substantive information  
about nanotechnology before either embracing it without reservation or  
swearing it off completely.<sup>67</sup> Law and technology should develop  
simultaneously, and there should be constant interaction between the  
two.<sup>68</sup> Halting all discovery of nanotechnology in order for the  
regulative ability of the legislature to catch up disregards the copious  
benefits that nanotechnology can provide and runs counter to our long-  
held traditions of progress and societal enhancement.<sup>69</sup>

Another consideration is the alarming prospect of the creation of  
nanoweapons that would enable complete bodily disintegration.<sup>70</sup> Any  
proliferation of military nanotechnology must be nipped in the bud and  
treated as sensitively as biological or chemical weapons, as catastrophic  
levels of destruction are attainable with all of these armaments.<sup>71</sup> A  
nanotechnological arms race would represent a veritable Pandora's box,  
and great care must be taken to ensure that such a scenario does not  
unfold.<sup>72</sup> A doomsday situation is no longer as far-fetched a proposition  
when one considers the possibility of malevolent uses of  
nanotechnology, ranging from the delivery of nanoscale infectious

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<sup>65</sup>See Lin, *supra* note 29, at 379-80.

<sup>66</sup>See *id.* at 383; Fiedler & Reynolds, *supra* note 7, at 603-04.

<sup>67</sup>See Fiedler & Reynolds, *supra* note 7, at 603-04.

<sup>68</sup>*Id.* at 602-03.

<sup>69</sup>*Id.* at 603, 628-29.

<sup>70</sup>Davidson, *supra* note 9.

<sup>71</sup>See Joy, *supra* note 16.

<sup>72</sup>*Id.*

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agents to the production of artificial nanomachines.<sup>73</sup>

It is clear that there is a critical need for comprehensive regulation of nanotechnology research, development, and commercialization.<sup>74</sup> The time has to be right to introduce any legislation, and lawmakers must complete sufficient groundwork.<sup>75</sup> Using existing laws to tackle the novel issues created by nanotechnology is tantamount to bringing a knife to a gunfight and constitutes an abdication of legislative responsibility.<sup>76</sup> Current legislation is simply inadequate and unsuitable to handle the broad gamut of nanotechnological effects.<sup>77</sup> The incredible risk/reward ratio of nanotechnology requires lawmakers to enact regulation with dexterity.<sup>78</sup> Due to the mercurial nature of nanotechnology, it would be ineffectual for any regulatory scheme to deal in absolutes.<sup>79</sup> Laws should not exert total dominance over the nanotechnology industry or become impediments to progress, but they must provide a yardstick for scientists, engineers, and nanotechnology manufacturers.<sup>80</sup>

It will undoubtedly be a laborious process to establish a regulatory framework as nanotechnology blurs the lines between various fields:

Over the next ten years, the fields of chemistry, physics, material sciences, biology, and computational sciences will converge in a way that will define nanotechnology and impact almost every industry, including computers, semiconductors, pharmaceuticals, defense, health care,

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<sup>73</sup>*See id.*

<sup>74</sup>*See Weiss, supra* note 4.

<sup>75</sup>Lin, *supra* note 29, at 388.

<sup>76</sup>*See id.* at 380; Davies, *supra* note 32.

<sup>77</sup>*See* Lin, *supra* note 29, at 374-75; *see also* NANOTECHWIRE, *supra* note 57.

<sup>78</sup>*See* Lin, *supra* note 29, at 374.

<sup>79</sup>*See id.*; NANOTECHWIRE, *supra* note 57.

<sup>80</sup>*See* Lin, *supra* note 29, at 375.

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communications, transportation, energy, environmental  
sciences, entertainment, chemicals, and manufacturing.  
Previously distinct disciplines will also combine:  
medicine and engineering, law and science, art and  
physics, etc. This merging will result in developments  
that are not simply evolutionary; they will be  
revolutionary.<sup>81</sup>

#### IV. PROPOSAL

##### A. *Continuing Research and Requisite Funding*

The current U.S. policy of substantially augmenting financial resources earmarked for nanotechnology research is unquestionably the correct initial course of action as education and discovery are the keys to enhanced knowledge.<sup>82</sup> It is indisputable that nanotechnology is shrouded in uncertainty, and scientists have merely scratched the surface of its capability and potential applications.<sup>83</sup> Research will help to shed at least some measure of light onto the question marks enveloping nanotechnology at this stage.<sup>84</sup> Legislators cannot enact laws unless the scope and context of the subject matter is lucid and apparent.<sup>85</sup>

While the NRDA only authorizes the allocation of funds for nanotechnology research,<sup>86</sup> the Senate and House of Representatives committees that allocate the funds must be sure that actual expenditures

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<sup>81</sup>JACK ULDRICH WITH DEB NEWBERRY, *THE NEXT BIG THING IS REALLY SMALL: HOW NANOTECHNOLOGY WILL CHANGE THE FUTURE OF YOUR BUSINESS* 22 (2003).

<sup>82</sup>*See* Mandel, *supra* note 2, at 1331, 1374.

<sup>83</sup>*See id.* at 1332-40; Wilson, *supra* note 15, at 704, 707.

<sup>84</sup>Mandel, *supra* note 2, at 1374.

<sup>85</sup>*See id.*

<sup>86</sup>*See* 15 U.S.C. §§ 7501-7509 (2006 & Supp. V 2011); Mandel, *supra* note 2, at 1346-47.

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are being made on germane projects.<sup>87</sup> The first step is determining exactly what research is material and constraining the scope of funded studies to only those that pertain to safety.<sup>88</sup> One estimate has placed the amount spent by the U.S. government in 2005 on relevant nanotechnology research at \$11 million, despite a total outlay of nearly \$1 billion on nanotechnology research in that year.<sup>89</sup> This is simply an unacceptable return on investment, and targeted research is necessary to ascertain pertinent results.<sup>90</sup>

The gaps in our overall understanding of nanotechnology must be filled,<sup>91</sup> and the government must give scientists the wherewithal to conduct only appropriate inquiries and provide legislators with the best possible information upon which to base regulatory decisions.<sup>92</sup> Congress has allocated approximately \$1.8 billion for nanotechnology research and development in 2012.<sup>93</sup> It is imperative that Congress continues to give the NNI this level of requisite financial support in order to ensure its efficacy.<sup>94</sup>

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<sup>87</sup>See Mandel, *supra* note 2, at 1374-76.

<sup>88</sup>Sharon McCarter, *International Risk Research Strategy & Funding Needed for Nanotech Safety: Uncertainty Will Hamper Nanotechnology Commercialization*, WOODROW WILSON INT'L CTR. FOR SCHOLARS (Mar. 27, 2007), available at [http://www.nanotechproject.org/process/files/5993/032807nanotechnology\\_intlriskstratfinalpr.pdf](http://www.nanotechproject.org/process/files/5993/032807nanotechnology_intlriskstratfinalpr.pdf).

<sup>89</sup>*Id.*

<sup>90</sup>*Id.*

<sup>91</sup>Mandel, *supra* note 2, at 1368.

<sup>92</sup>Wilson, *supra* note 15, at 711.

<sup>93</sup>JOHN F. SARGENT JR., CONG. RESEARCH SERV., RL34511, NANOTECHNOLOGY: A POLICY PRIMER 6 (2013).

<sup>94</sup>Mandel, *supra* note 2, at 1371.

### 1. Nanotechnology-specific regulatory body

Because nanotechnology is so disparate from other innovations, existing government agencies such as the EPA, the FDA, and OSHA do not have the means to regulate its explosive growth.<sup>95</sup> The government must institute a dedicated government agency to confront issues particularized to the nanotechnology sphere, whether it is associated with the NNI or comprised of its own autonomous entity.<sup>96</sup> This would eliminate the current piecemeal approach and promote a more homogeneous governmental response to nanotechnological concerns.<sup>97</sup> As it stands, the United States is lagging behind the international community in this regard.<sup>98</sup>

The onus is on Congress to draft statutes that both authorize the creation of a nanotechnology-specific regulatory body (possibly named “Nanotechnology Discovery Commission” or “NTDC”) and govern its functions.<sup>99</sup> Although the advent of nanotechnology generally is unprecedented, there is a similar institution from which parallels may be drawn that may inform the direction of nanotechnology regulation. The Nuclear Regulatory Commission (“NRC”) ensures the safety of atomic nuclear materials, which are extremely useful yet prospectively highly hazardous.<sup>100</sup> The risk/reward ratio is comparable between the two classes, the long-term effects of each are not easily discernible, and both remain, to some degree, esoteric quantities.<sup>101</sup> In view of this, the

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<sup>95</sup>*Id.* at 1369.

<sup>96</sup>*See id.* at 1369-71.

<sup>97</sup>*See id.*

<sup>98</sup>*See* NANOTECHWIRE, *supra* note 57.

<sup>99</sup>*See* Lin, *supra* note 29, at 387-90.

<sup>100</sup>*See About NRC*, U.S. NUCLEAR REG. COMM’N, <http://www.nrc.gov/about-nrc.html> (last updated July 18, 2013).

<sup>101</sup>*See Fact Sheet on Biological Effects of Radiation*, U.S. NUCLEAR REG. COMM’N, <http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/bio-effects-radiation.html> (last updated Mar. 29, 2012).

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method by which the NRC supervises commercial nuclear processes is instructive in tackling the management of nanotechnology.<sup>102</sup>

The Energy Reorganization Act of 1974 created the NRC, and the Administrative Procedure Act and the National Environmental Policy Act guide its actions.<sup>103</sup> Among the laws the NRC works to enforce are the Atomic Energy Act of 1954, the Nuclear Waste Policy Act of 1982, and the Nuclear Non-Proliferation Act of 1978.<sup>104</sup> Five commissioners, one of whom appointed as chairman, lead the NRC.<sup>105</sup> The President initially appoints the commissioners, and the Senate subsequently confirms them.<sup>106</sup>

“The Commission as a collegial body formulates policies, develops regulations governing nuclear reactor and nuclear material safety, issues orders to licensees, and adjudicates legal matters.”<sup>107</sup> The NRC divides the United States into four regions and designates an individual administrative office for each.<sup>108</sup> In addition, an executive director for operations (“EDO”) implements and executes the policies and administrative directions handed down by the Commission.<sup>109</sup>

Other key NRC suborganizations include the Advisory Committee on Reactor Safeguards, the Advisory Committee on the Medical Uses of Isotopes, and the Atomic Safety and Licensing Board

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<sup>102</sup>*See Governing Legislation*, U.S. NUCLEAR REG. COMM’N, <http://www.nrc.gov/about-nrc/governing-laws.html#nnpa-1978> (last updated Oct. 21, 2013).

<sup>103</sup>*Id.*

<sup>104</sup>*Id.*

<sup>105</sup>*The Commission*, U.S. NUCLEAR REG. COMM’N, <http://www.nrc.gov/about-nrc/organization/commfuncdesc.html> (last updated June 24, 2013).

<sup>106</sup>*Id.*

<sup>107</sup>*Id.*

<sup>108</sup>*See Organization & Functions*, U.S. NUCLEAR REG. COMM’N, <http://www.nrc.gov/about-nrc/organization.html> (last updated Nov. 27, 2013).

<sup>109</sup>*Id.*

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Panel.<sup>110</sup> All of these bodies work in concert with offices subordinate to the EDO to make certain that the commercial applications of nuclear materials are safe.<sup>111</sup> Finally, the Office of Nuclear Security and Incident Response acts to contain and defuse any crises.<sup>112</sup> Through its National Response Framework, the Office of Nuclear Security and Incident Response synchronizes local, state, and federal emergency personnel to neutralize nuclear disasters.<sup>113</sup>

Overall, the NRC's regulatory mechanism generally consists of:

(1) developing regulations and guidance for [its] applicants and licensees, (2) licensing or certifying applicants to use nuclear materials or operate nuclear facilities or decommissioning that permits license termination, (3) overseeing licensee operations and facilities to ensure that licensees comply with safety requirements, (4) evaluating operational experience at licensed facilities or involving licensed activities, and (5) conducting research, holding hearings to address the concerns of parties affected by agency decisions, and obtaining independent reviews to support [its] regulatory decisions.<sup>114</sup>

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<sup>110</sup>*See id.*

<sup>111</sup>*See id.*

<sup>112</sup>*Emergency Preparedness & Response*, U.S. NUCLEAR REG. COMM'N, <http://www.nrc.gov/about-nrc/emerg-preparedness.html> (last updated Dec. 19, 2013).

<sup>113</sup>*Id.*

<sup>114</sup>*How We Regulate*, U.S. NUCLEAR REG. COMM'N, <http://www.nrc.gov/about-nrc/regulatory.html> (last updated Dec. 19, 2013).

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**Figure 1.** The illustration above displays the progression and interplay between the NRC's elements.<sup>115</sup>

Much of the fundamentals of the NRC model can and should be applied to the instant nanotechnological state of affairs. At the outset, given its novelty, the analogous nanotechnology agency or NTDC should start with a lesser number of commissioners than the NRC, but still an odd number to prevent any voting stalemates. Consequently, the President should appoint and the Senate should confirm three commissioners to direct the NTDC, and one of the three commissioners should have the title of chairman. Due to nanotechnology's rapid rate of change, the commissioners should hold office in three-year increments. The NTDC should establish three field offices across the United States, each being responsible for a designated region: western, central, and eastern. As the nanotechnology industry is cultivated and the associated regulatory burden grows, the appropriate number of commissioners, the length of their terms, and the number of administrative regions should be reviewed and augmented as necessary.

As with the NRC, the NTDC should also feature an executive director for operations, advisory committees, a licensing board, and an emergency counteraction network. The commissioners should comprise the highest entity and have principal duties such as developing protocols, determining standards for reporting, inspections, and enforcement, and issuing orders to the executive director. In addition, the commissioners should encourage Congress to pass germane measures and advise them in their efforts.

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<sup>115</sup>*Id.*

The commissioners should take into account the findings of both the advisory committees and the licensing board where appropriate. Where particularized knowledge is needed, the commissioner should enlist advisory committees consisting of technical experts to clarify discrepancies, make recommendations, and present the commissioners with the best information possible. The commissioners may then use the nonbinding suggestions of the advisory committee in drawing their own final conclusions. The licensing board's primary task should be to review corporate reports, regional inspection analyses, and EDO records in granting, renewing, or reinstating applicants' formal authorization to manufacture or employ nanotechnology products. The NTDC should issue licenses to manufacturers for ten-year terms, with manufacturers tendering one midcycle maintenance report. This process would maintain safety levels and justify upfront costs to the manufacturers.

As for the executive director, in addition to carrying out the directions of the Commission, he or she should have general oversight of the remainder of the administrative bodies, coordinate the activities of the emergency counteraction network, and supervise enforcement. Regional offices should be responsible for ground-level procedures such as classifying nanomaterials, conducting inspections, and ensuring that manufacturer reports are in compliance with NTDC standards. One of the chief objectives of the regional offices should be to furnish internal assessments based on manufacturer disclosures for the licensing board's consideration in conferring operating licenses. Lastly, the emergency counteraction network should provide a synergistic system that liaises with hazmat, fire, police, and ambulance teams across the country to both prevent and respond to substantial incidents involving nanomaterials. The illustration below demonstrates a simplistic overview of the proposed NTDC hierarchy.

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**Figure 2.** The illustration above demonstrates a simplistic overview of the proposed NTDC hierarchy.

## 2. Nanotechnology classification system

The threshold issue in starting regulatory review of a certain type of nanotechnology is that of classification.<sup>116</sup> It is therefore necessary to develop a system and associated nomenclature to categorize nanomaterials into different classes to better distinguish and gauge their potential effects.<sup>117</sup> Researchers and regulatory boards should generally divide nanomaterials according to risk, based on such factors as materials' physical properties and latent health effects.<sup>118</sup> Pertinent physical features include size, surface-area-to-volume ratio, chemical composition, and reactivity.<sup>119</sup> A nanomaterial's capability of

<sup>116</sup>See, e.g., INT'L RISK GOVERNANCE COUNCIL, NANOTECHNOLOGY RISK GOVERNANCE: RECOMMENDATIONS FOR A GLOBAL, COORDINATED APPROACH TO THE GOVERNANCE OF POTENTIAL RISKS 7-8 (2007), available at <http://www.irgc.org/IMG/>

pdf/PB\_nanoFINAL2\_2\_.pdf (stating that in order to create nanotechnology risk governance that it is helpful to understand the different classes of nanotechnology).

<sup>117</sup>See *id.*

<sup>118</sup>See *id.*

<sup>119</sup>See *id.* at 9-10.

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becoming a health hazard depends on its toxicity, carcinogenicity,  
volatility, flammability, and somatic penetrative capacity.<sup>120</sup>

Accounting for all the aforementioned characteristics, regulatory bodies should group nanomaterials into one of five risk classes, ranging from minimal to unacceptable danger. The breadth of safeguards required should be directly proportional to the risk class. Accordingly, a manufacturer endeavoring to produce highly dangerous but acceptable nanomaterials would have to enumerate, through internal reports and records, the onerous precautions it is taking to offset the considerable risk and justify an operating license. If the regional office, licensing board, or executive director concludes that an applicant or current licensee is not complying with the requisite safety parameters, that manufacturer shall be denied a license, be fined, or have its subject facilities shut down as the case dictates. Abbreviated disclosures should also be mandatory in order to renew operating licenses upon their expiration. Full replacement disclosures will be necessary in the event that a manufacturer applies for reinstatement after revocation.

### 3. Compulsory reporting

It is crucial for the government to mandate disclosures from nanotechnology producers regarding their internal studies, experimentation, research, and development.<sup>121</sup> The government cannot incur the cost of policing the entire industry and performing studies that manufacturers should be conducting themselves.<sup>122</sup> Nevertheless, any prospective regulatory scheme would have to incorporate a phased system in which government oversight becomes progressively more stringent as time elapses.<sup>123</sup> The government would have to use

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<sup>120</sup>*Id.* at 9.

<sup>121</sup>*See* NANOTECHWIRE, *supra* note 57 (suggesting that the United States use a tiered risk-assessment system similar to REACH legislation that requires industries to register, evaluate, and receive authorization for production of nanomaterial related products).

<sup>122</sup>*Id.*

<sup>123</sup>Mandel, *supra* note 2, at 1378.

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ancillary technology, as it comes available, to closely monitor the progress of nanotechnology products.<sup>124</sup>

The entirety of the reporting process should consist of three stages: an introductory proposal, an interim disclosure, and a final summary. The proposal should outline the manufacturer's objectives, the known embryonic attributes of the nanotechnology product, and the anticipated outcome.<sup>125</sup> Exploratory research and development may commence and proceed throughout the duration of the first period.<sup>126</sup> The penultimate stage will require the applicant to reveal the salient physical and chemical traits of the proposed nanomaterial.<sup>127</sup> Lastly, before releasing any nanotechnology product to the market, the manufacturer must submit a complete risk assessment and detailed account of the nanomaterial to the appropriate NTDC regional office, which will then convey the information to the licensing board for final evaluation and decision.<sup>128</sup>

The NTDC must implement mandatory safety reporting procedures so that the government may learn the specific characteristics and structure of nanomaterials being released to the public.<sup>129</sup> The reports should include manufacturing processes, toxicology analyses, risk assessments, and containment and disposal protocols.<sup>130</sup> Following authorization by the NTDC to produce nanomaterials, the NTDC should require that manufacturers place elaborate warning labels on all

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<sup>124</sup>*See id.* at 1379; Wilson, *supra* note 15, at 707.

<sup>125</sup>*See* ENVTL. PROT. AGENCY, *supra* note 35 (describing the EPA's proposal to create new regulations on companies participating in nanotechnology by requiring the company to divulge information of the nanotechnology products used).

<sup>126</sup>*See* Jean V. McHale, *Nanomedicine and the EU: Some Legal, Ethical, & Regulatory Challenges*, 16 MAASTRICHT J. EUR. & COMP. L. 65, 68-71 (2009) (describing a proposal to conduct research in the early stages of production for nanotechnology companies).

<sup>127</sup>*See* Davies, *supra* note 32, at 22.

<sup>128</sup>*See* NANOTECHWIRE, *supra* note 57.

<sup>129</sup>*Id.*

<sup>130</sup>*See id.*

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products containing potentially hazardous nanoparticles so as to alert  
the public of latent dangers.<sup>131</sup>

The NTDC should have the ability to perform inspections so that it may scrutinize various stages of nanotechnological production and verify that hazardous materials are treated with proper caution.<sup>132</sup> In addition, the NTDC must institute a hierarchy of sanctions to deter noncompliance and penalize violations.<sup>133</sup> As discussed above, these could include fines, revocation of licenses, and, in extreme cases, shutdowns of production facilities. While some conscientious nanotechnology companies may exist, as a whole, the government cannot rely on the companies to supervise themselves.<sup>134</sup> Having a system in place under which manufacturers execute the diagnostic aspects and the NTDC confirms the results will relieve the government of an unsustainable burden and compel manufacturers to disclose important physical qualities of their nanomaterials.<sup>135</sup>

#### 4. Peripheral issues

Another function of the NTDC should be coordinating with the NNI to raise general awareness of nanotechnology among the American public.<sup>136</sup> Introducing a wider group of citizens to the concept of nanotechnology and educating them on its salient attributes will enable a greater level of discourse and reduce a natural aversion to the unknown.<sup>137</sup> Widespread public support is imperative in order to

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<sup>131</sup>See Lin, *supra* note 29, at 393.

<sup>132</sup>See *Inspection*, U.S. NUCLEAR REGULATORY COMM'N, <http://www.nrc.gov/about-nrc/regulatory/safety-oversight.html> (last updated July 1, 2013).

<sup>133</sup>See *Enforcement Program Overview*, U.S. NUCLEAR REG. COMM'N, <http://www.nrc.gov/about-nrc/regulatory/enforcement/program-overview.html> (last updated July 11, 2013).

<sup>134</sup>Keiper, *supra* note 63.

<sup>135</sup>See NANOTECHWIRE, *supra* note 57.

<sup>136</sup>See Lin, *supra* note 29, at 390.

<sup>137</sup>See *id.*

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facilitate the commercialization of nanotechnology.<sup>138</sup> Coupled with this goal should be continual ethical examinations of nanotechnology applications.<sup>139</sup> Such investigations would help to allay fears of potential moral turpitude arising from the use and application of nanotechnology. Ethics studies could include surveys, simulations, and focus groups aimed at highlighting public reaction and expert opinions on nanotechnology.<sup>140</sup>

With respect to tangential matters, the spread of nanotechnology is a global concern, and therefore, the government should launch and sustain an analogous international organization in the future so as to foster international cooperation and establish a level of uniformity by proposing and promulgating nanotechnological standards for gray areas such as patent terminology.<sup>141</sup> While the cart should not be put before the horse, long-term harmonization across nations is a key step.<sup>142</sup> Such a measure will develop some predictability in the patent process, improve confidence among producers that their intellectual property will be adequately protected overseas, and facilitate dispute resolution in the same vein as the Agreement on Trade-Related Aspects of Intellectual Property Rights.<sup>143</sup> Regarding health insurance, it is simply impractical to establish blanket rules to cover any and every type of scenario. Insurance companies must evaluate cases individually on

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<sup>138</sup>*Id.* at 390-91.

<sup>139</sup>McHale, *supra* note 126, at 70.

<sup>140</sup>*See id.* at 70-71.

<sup>141</sup>Berger, *supra* note 22; *see also* Abu Bakar Munir & Siti Hajar Mohd Yasin, *Nanotechnology in Healthcare: Are Existing Laws Adequate?*, 14 EUR. J. HEALTH L. 261, 270-71 (2007) (noting that “nanomedicine will produce a whole new class of products that will defy easy classification”).

<sup>142</sup>*See* William J. Simmons, *Nanotechnology as a Nascent Technological Model for Immediate Substantive United States and Japan Patent Law Harmonization*, 17 ALB. L.J. SCI. & TECH. 753, 756-60 (2007) (discussing an attempt by the United States and Japan to harmonize nanotechnology patent laws and the obstacles preventing such harmonization).

<sup>143</sup>*See Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG., [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm) (last visited Apr. 2, 2013).

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their merits and predicated on determinations such as manufacturer liability for toxic exposure to nanoparticles.<sup>144</sup> As for weaponry, an international treaty, an outright ban, or other cooperative nonproliferation agreement is an action that countries can and should take preemptively.<sup>145</sup> The United Nations and other disarmament organizations should find this matter one of critical importance.<sup>146</sup>

### C. *Facilitating Future Evolution of the Law*

As there is a vast amount to be learned about nanotechnology, a dynamic framework is needed to provide some guidance for the handling of future problems as they arise.<sup>147</sup> Legislators cannot hope to provide a panacea for nanotechnological difficulties but should seek to build an underpinning upon which branches can be subsequently added

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<sup>144</sup>U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-402, NANOTECHNOLOGY: BETTER GUIDANCE IS NEEDED TO ENSURE ACCURATE REPORTING OF FEDERAL RESEARCH FOCUSED ON ENVIRONMENTAL, HEALTH, AND SAFETY RISKS 17, 19-20 (2008) (exploring the toxicity level of nanoparticles and its effects on the environment, health, and safety of the public).

<sup>145</sup>See Robert D. Pinson, *Is Nanotechnology Prohibited by the Biological and Chemical Weapons Conventions?*, 22 BERKLEY J. INT'L L. 279, 297-305 (2004) (discussing the inadequacies of current treaties such as the Biological Weapons Convention and the Chemical Weapons Convention to regulate nanotechnological developments for military purposes and the need for a new treaty); Gary E. Marchant & Douglas J. Sylvester, *Transnational Models for Regulation of Nanotechnology*, 34 J.L. MED. & ETHICS 714, 716 (2006) (recognizing one side of the argument that there is a need to regulate nanotechnology and that several advocacy groups have called for a moratorium against nanotechnology). See generally Hitoshi Nasu & Thomas Alured Faunce, *Nanotechnology and the International Law of Weaponry: Towards International Regulation of Nano-Weapons*, 20 J.L. INFO. & TECH., 21 (2010) (discussing the dangers of nanotechnology employed as offensive military weapons and the international regulations currently in place to oversee those potential effects).

<sup>146</sup>See Pinson, *supra* note 145, at 304-05.

<sup>147</sup>Mandel, *supra* note 2, at 1378; see also Linda K. Breggin & Leslie Carothers, *Governing Uncertainty: The Nanotechnology Environmental, Health, and Safety Challenge*, 31 COLUM. J. ENVTL. L. 285, 310 (2006) (suggesting a "multi-pronged approach" to regulating the pervasive and uncertain nature of nanotechnology).

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or trimmed to fit contemporary needs.<sup>148</sup> One of the only certain characteristics of nanotechnology is that it is in constant flux and a simple, uniform set of laws cannot govern this emerging field.<sup>149</sup> One of the salient features of a flexible system is ongoing review and reform.<sup>150</sup> We simply do not have access to tools that can accurately forecast the development of nanotechnology or anticipate prospective issues.<sup>151</sup> The rate of change in the nanotechnological field is such that many concerns quickly surface that were not previously within the purview of legislators and industry analysts.<sup>152</sup>

Legislators should reevaluate the amount to designate for research grants every two to three years and the amount should be consistent with the pervading scientific atmosphere and stage of technological refinement at the time.<sup>153</sup> With each passing two- to three-year period, the level of detail required for reporting nanotechnological developments and warning labels associated with nanotechnology products should increase at a level commensurate with the measurement tools available.<sup>154</sup> The regulatory scheme must have

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<sup>148</sup>Mandel, *supra* note 2, at 1378 (suggesting a flexible governing system that can adapt and change with nanotechnology).

<sup>149</sup>*See id.*

<sup>150</sup>*See id.*

<sup>151</sup>*See* Wilson, *supra* note 15, at 707. *See generally* Alan S. Brown, *Nanotech Unbound*, MECH. ENG'G, Nov. 2012, at 26, 26-31 (noting the nanotechnology boom, then the bust, and now returning to the boom); James R. Brindell, *Nanotechnology Demands a New Relationship Between Federal, State, and Local Regulatory Agencies*, 7 NANOTECH. L. & BUS. 144, 144 (2010) (indicating a nearly 400% expansion of nanotechnology since 2006).

<sup>152</sup>*See* Wilson, *supra* note 15, at 707-08 (illustrating nanotechnology's ability to "leap-frog" current regulations such as the Food, Drug, and Cosmetic Act because of an inability to scrutinize nanotechnology for its safety).

<sup>153</sup>*See id.* at 711 (noting the miniscule amount of funding directed toward "highly relevant risk research").

<sup>154</sup>*See id.* (discussing the need to increase research to increase knowledge of potential risks); Lin, *supra* note 29, at 393 (suggesting more stringent labeling requirements to better inform the public of risks from nanotechnology products).

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distinct phases, providing progressive governance over  
nanotechnological development.<sup>155</sup>

There must also be the ability to form and implement highly specialized regulatory committees to address various nanotechnological subissues.<sup>156</sup> Consequently, legislators should organize the NTDC in such a way that it has the ability to easily create subdivisions in order to diversify research, procedural analyses, and manufacturing evaluations.<sup>157</sup> The more focused a regulatory body, the greater the precision it will have in assessing unique problems.<sup>158</sup> A combination of general and specific organizations will enable the effective appraisal of macro- and microissues.<sup>159</sup>

With sanctions for improper or unscrupulous conduct should come incentives for the private sector to maintain elevated safety levels.<sup>160</sup> A chameleonic carrot-and-stick approach would serve to encourage nanotechnology companies to remain in compliance with the aforementioned reporting and labeling requirements.<sup>161</sup> The promise of future subsidization, accelerated licensing processes, or favorable

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<sup>155</sup>See Mandel, *supra* note 2, at 1378.

<sup>156</sup>*Cf. Organization & Functions, supra* note 108 (listing several specialized offices within the NRC).

<sup>157</sup>See *supra* note 147 and accompanying text.

<sup>158</sup>*Contra* Allen Lomax, *Reorganizing the Federal Government to Meet Today's Challenges*, THE PUB. MANAGER, Winter 2012, at 59, 59 (stating that reorganizing agencies and programs created overly broad goals that have led to ineffective program delivery); Edmund C. Stazyk & Holly T. Goerdel, *The Benefits of Bureaucracy: Public Managers' Perceptions of Political Support, Goal Ambiguity, and Organizational Effectiveness*, 21 J. PUB. ADMIN. RES. & THEORY 645, 654 (2011) (stating that a lack of organizational focus can lead to an ineffective organization).

<sup>159</sup>See Brindell, *supra* note 151, at 147-48 (encouraging the cooperation between various levels of governmental organizations to address regulatory issues of nanotechnology).

<sup>160</sup>Mandel, *supra* note 2, at 1376 (“Many of the nanotechnology governance goals . . . can be advanced by developing incentives for nanotechnology industry to act in a socially responsible manner.”).

<sup>161</sup>Lin, *supra* note 29, at 390-95.

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corporate tax provisions may further motivate manufacturers to perform above just the minimum baseline.<sup>162</sup> Penalties will only compel nanotechnology producers to bring their output into basic conformity with guidelines, whereas bonuses may spur them to strive for an upper echelon of safety.<sup>163</sup>

## V. CONCLUSION

Nanotechnology is an avant-garde field and is unique in its prospective uses and applications.<sup>164</sup> It carries with it the potential for both incredible benefits and tremendous risks.<sup>165</sup> As such, legislators need to regulate it in a distinctive fashion, which will require novel solutions.<sup>166</sup> There is a great deal of uncertainty about nanotechnology, including its very definition, thereby obfuscating attempts to effectively regulate it to date.<sup>167</sup> Presently, the United States relies on existing legislation to govern the development of nanotechnology and does not have any specific laws controlling its use or applications.<sup>168</sup> Continued funding for nanotechnology research and increased allocations in the future are essential to furthering discovery and augmenting knowledge.<sup>169</sup> Legislators must strive to fill gaps in understanding and Congress must continue to buttress the NNI.<sup>170</sup> Legislators must

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<sup>162</sup>*See* Mandel, *supra* note 2, at 1376-78.

<sup>163</sup>*Id.* at 1377-78.

<sup>164</sup>*Id.* at 1331-32.

<sup>165</sup>*Id.* at 1332-45 (discussing the benefits and risks of nanotechnology).

<sup>166</sup>*Id.* at 1378-79.

<sup>167</sup>*Id.* at 1374 (“[T]he most critical problem facing nanotechnology governance is the lack of scientific understanding of nanotechnology risks.”).

<sup>168</sup>*Id.* at 1345-47.

<sup>169</sup>*Id.* at 1371-76 (“Nearly every commentator who has considered the issues raised by nanotechnology governance concludes that one of the primary needs is devoting greater resources to studying the human health and environmental impacts of nanotechnology.”).

<sup>170</sup>*Id.* at 1367-69.

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establish a dedicated government agency, or the NTDC, to generally regulate nanotechnology, issue licenses, and make appropriate inquiries. This is also true of the international community, as a multinational administrative body should be instituted to create uniformity in such areas as patent rights.<sup>171</sup> In the United States, a classification system, mandatory reporting procedures, and labeling requirements represent solid initial steps towards compelling nanotechnology manufacturers to conform to a minimum level of safety.<sup>172</sup> Legislators must hold manufacturers responsible for the costs and execution of risk research.<sup>173</sup>

Legislators simply do not know enough to guarantee that any rules enacted in the near future will have long-term efficacy.<sup>174</sup> Therefore, the legislature's establishment of a resolute foundation from which legislators may later draft laws with as little difficulty as possible is vital.<sup>175</sup> A readily divisible regulatory body must be present in order to specialize swiftly and advise Congress.<sup>176</sup> Constant reassessments and review will serve to ensure that laws are up to date and remain relevant.<sup>177</sup> Moreover, legislators should employ a mixture of penalties and incentives to induce manufacturers into compliance.<sup>178</sup> The current regulatory scheme, or lack thereof, is effectively no regulation at all and results in an unbridled expansion.<sup>179</sup> On the other hand, a complete moratorium on nanotechnology research and development would immobilize the entire field and amount to nothing more than a knee-jerk

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<sup>171</sup>*See supra* notes 141-43 and accompanying text.

<sup>172</sup>*See supra* Part IV.B.2-3.

<sup>173</sup>*See supra* notes 121-24 and accompanying text.

<sup>174</sup>*See supra* notes 147-52 and accompanying text.

<sup>175</sup>*See supra* notes 147-52 and accompanying text.

<sup>176</sup>*See supra* notes 156-59 and accompanying text.

<sup>177</sup>*See supra* notes 153-55 and accompanying text.

<sup>178</sup>*See supra* notes 160-63 and accompanying text.

<sup>179</sup>*See Lin, supra* note 29, at 374.

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reaction.<sup>180</sup> Neither course of action yields a reasonable outcome.<sup>181</sup>  
Nanotechnology demands a fine balance, and one can only hope that  
cooler legislative and industry heads will prevail and tread middle  
ground.

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<sup>180</sup>*See id.* at 406-07 (stating that a complete moratorium on nanotechnology would drive nanotechnology research and manufacturing to other countries, depriving the United States of many potential benefits that could possibly impact the U.S. economy and military security).

<sup>181</sup>*See* Mandel, *supra* note 2, at 1364-65.