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THESIS

A REGULATORY FRAMEWORK FOR NANOTECHNOLOGY

by

Stephen J. Ridge

March 2018

Thesis Co-Advisors: Carolyn Halladay
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Presently, the regulatory framework for nanotechnology consists of regulating entities addressing concerns about nanotechnology under existing rules and laws. This thesis answers this question: How can regulatory decisions of policymakers regarding the framework of nanotechnology regulation be informed by a map of the regulatory landscape of nanotechnology and a review of the regulatory frameworks for the aviation and biotechnology industries?

To make recommendations about the appropriate regulatory framework for nanotechnology, this thesis reviews the existing regulatory frameworks of aviation and biotechnology and maps the regulatory landscape in the United States by examining stakeholders, regulatory entities, and applicable legislation. The landscape map and review of existing regulatory frameworks reveal that the established regulatory framework could be sufficient for the current state of nanotechnology if the limitations of technical expertise are addressed. This expertise can be provided by advisory committees of technical and industry experts to the Environmental Protection Agency, Food and Drug Administration, Consumer Product Safety Commission, and National Institute for Occupational Safety and Health.

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A REGULATORY FRAMEWORK FOR NANOTECHNOLOGY

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ABSTRACT

Presently, the regulatory framework for nanotechnology consists of regulating entities addressing concerns about nanotechnology under existing rules and laws. This thesis answers this question: How can regulatory decisions of policymakers regarding the framework of nanotechnology regulation be informed by a map of the regulatory landscape of nanotechnology and a review of the regulatory frameworks for the aviation and biotechnology industries?

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LIST OF ACRONYMS AND ABBREVIATIONS

AFRI	Agriculture and Food Research Initiative
BIS	Bureau of Industry and Security
CFS	Center for Food Safety
CNST	Center for Nanoscale Science and Technology
CPSC	Consumer Product Safety Commission
DNA	deoxyribonucleic acid
DOC	Department of Commerce
DoD	Department of Defense
DOE	Department of Energy
DOI	Department of the Interior
DOJ	Department of Justice
DOS	Department of State
DOTreas	Department of Treasury
ED	Department of Education
EPA	Environmental Protection Agency
FAA	Federal Aviation Administration
FHWA	Federal Highway Administration
FDA	Food and Drug Administration
IARPA	Intelligence Advanced Research Projects Activity
FY	fiscal year
IC	U.S. Intelligence Community
IWGN	Interagency Working Group on Nanotechnology
NIJ	National Institute of Justice
OHS	Occupational Health and Safety
OECD	Organisation for Economic Co-operation and Development
OSTP	Office of Science and Technology Policy
PEN	Project on Emerging Nanotechnologies
CPI	Nanotechnology Consumer Products Inventory
NSRC	Nanoscale Science Research Centers
NCI	National Cancer Institute

NASA	National Aeronautics and Space Administration
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIEHS	National Institute of Environmental Health Science
NIFA	National Institute of Food and Agriculture
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute for Standards and Technology
NNCI	National Nanotechnology Coordinated Infrastructure
NNIN	National Nanotechnology Infrastructure Network
NTRC	Nanotechnology Research Center
NSF	National Science Foundation
NSET	Nanoscale Science, Engineering and Technology
NSTC	National Science and Technology Council
NRC	Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
R&D	research and development
STEM	science, technology, engineering, and mathematics
TiO2	titanium dioxide
UNEP	United Nations Environment Programme
USDA	U.S. Department of Agriculture
USGS	U.S. Geological Survey
USITC	U.S. International Trade Commission

EXECUTIVE SUMMARY

Technological advancements are an important part of human existence. From the dawn of humans' emergence as the dominant species on earth, the ability to create and use tools has been a primary accelerator of that dominance. Tools have been used to make life easier but also to make even better tools and later machines, which eventually led to complex computing. Each of these advancements has led to new plains of discovery, capabilities, and achievement, but also to new and unexpected dangers.

As new technologies are developed, there are some that affect only a minute section of the world's population, but others are revolutionary and have the potential to directly or indirectly affect every human on earth and even the earth's ecology. Many scientists suggest that nanotechnology is one of these revolutionary technologies. The idea that nanotechnology represents revolutionary change leads many to believe that regulating this emerging technology is of paramount importance.

Presently, the regulatory framework for nanotechnology consists of existing regulating entities addressing concerns about nanotechnology under current rules and laws. If nanotechnology does develop to be the dramatic influence many predict it will be, it is fair to question whether existing agencies, rules, and laws are sufficient to address regulation, product approval, policy advice, and industry monitoring for the emerging field of nanotechnology.

A. OBJECT, METHOD, LIMITS, AND OUTPUT

The objective of this thesis is to aid and inform the regulatory decisions of policymakers by mapping the regulatory landscape of nanotechnology, reviewing current regulatory frameworks, and making recommendations on the appropriate regulatory framework for nanotechnology. This thesis identifies the relevant federal stakeholders in relation to nanotechnology, gives a brief description of the state of the technology, analyzes applicable laws related to the technology that have already been enacted, and examines the regulatory framework of aviation and biotechnology. This thesis is aimed primarily at those delivering regulation in national agencies, regulatory policymakers, and other concerned stakeholders and citizens focused on the safe development and production of new technologies.

Additionally, this research advances the establishment of a regulatory framework for nanotechnology. As the technology matures, policymakers will be faced with unique regulatory challenges. Now is the time to begin identifying the best regulatory framework for nanotechnology; it is important not to wait until a crisis occurs.

The method used to achieve these thesis objectives was an investigation into the background, current state, and future projections of nanotechnology development, a federal stakeholder analysis, a review of current nanotechnology-related policy and legislation, and an examination of the regulatory framework in the aviation and biotechnology industries. The researcher generated a list of stakeholders based on organizational publications, stated interest in nanotechnology, membership to nanotechnology organizations such as the National Nanotechnology Initiative (NNI), and implied interest in nanotechnology. The scope of this research is focused on mapping the regulatory landscape of nanotechnology and reviewing current regulatory frameworks. The research describes the background, current state, and future projections of some leading minds in the field of the technology, but it does not attempt to predict future advances in nanotechnology. However, it does relate realistic probabilities based on research. The output of this research is a set of recommendations for policymakers and other nanotechnology stakeholders. The goal for these recommendations is that they will serve as a starting point for establishing a regulatory framework for nanotechnology in the United States.

B. FINDINGS

Mapping the regulatory landscape of nanotechnology has revealed several key findings:

1. The regulatory landscape of nanotechnology is vast and has many stakeholders and potential pitfalls to regulation.

2. There is very little consensus on many aspects of nanotechnology. Researchers disagree on the definition, rate of technological advancement, proper regulation, potential dangers, future state, or end use of the

technology. The one thing nearly everyone agrees on is that nanotechnology will potentially be one of the most important technologies of this century.

3. The scope of nanotechnology's influence reaches across several industries and sectors of society. As it matures, there will likely be no part of society untouched by this emerging technology.

4. The current state of nanotechnology is a robust one, with more than 1,800 products known or thought to be using the technology.[1] Despite this proliferation, the environmental, health, and safety implications of nanoengineered materials throughout a nanotechnology product's life cycle remain largely unexplored.

5. The current regulatory approach to nanotechnology is to address it under existing laws; however, these laws may not be sufficient to address the future challenges of nanotechnology. For instance, the Consumer Product Safety Commission, which is tasked with ensuring products are safe for consumers, lacks the funding and personnel to properly address nanotechnology in products already in the marketplace.

6. Nanotechnology is important to the long-term health of the U.S. economy. The U.S. government has invested significant resources in the advancement of nanotechnology research. For instance, the NNI has received nearly $24 billion in federal funding since 2001.[2]

7. There have been many pieces of legislation directly or indirectly related to nanotechnology. Most legislation focuses on research and development, not on regulation.

8. Despite their very disparate missions, many federal agencies are involved in nanotechnology research, development, and regulation.

9. Aviation and biotechnology have different regulatory frameworks that can inform the recommendation for nanotechnology's regulatory framework.

C. RECOMMENDATIONS

The recommendations of this thesis come as a result of identifying obstacles to regulation and determining, based on stakeholder analysis and the regulatory landscape, which would be the best framework for nanotechnology regulation. The first recommendation is to follow the advice of Jeffrey Matsuura and "display confidence in

[1] Marina E. Vance et al. "Nanotechnology in the Real World: Redeveloping the Nanomaterial Consumer Products Inventory," *Beilstein Journal of Nanotechnology* 6 (August 2015): 1769–1780, doi:10.3762/bjnano.6.181, https://www.beilstein-journals.org/bjnano/content/pdf/2190-4286-6-181.pdf.

[2] "NNI Budget," National Nanotechnology Initiative, accessed December 30, 2017, https://www.nano.gov/about-nni/what/funding.

their existing regulatory systems by relying on those rules and processes to oversee the ongoing introduction of nanotechnology into additional commercial applications," while addressing the limitations of this approach.[3] The primary limitation is the high level of technical expertise required for understanding the technology and therefore for recommending policy or enacting rules or regulations. The primary regulatory institutions should be those identified as high-power, high-interest on the stakeholder matrix: the Environmental Protection Agency, U.S. Food and Drug Administration, Consumer Product Safety Commission (CPSC), and National Institute for Occupational Safety and Health. To ensure the appropriate level of expertise is available for regulatory decisions, it is recommended that each of these four agencies sponsor an advisory committee of technical and industry experts under the guidelines of the Federal Advisory Committee Act of 1972 (Public Law 92-463). These advisory committees will provide relevant and objective advice which is open to the public for review. Following this recommendation would set up the United States for success regulating the nanotechnology now and in the future, no matter how it develops.

The second recommendation of this thesis is to conduct, through the National Science Foundation (NSF), a multiyear comprehensive study to determine the environmental, health, safety risks, and impacts of nanoengineered materials. Without knowing the risks associated with the technology, one cannot reasonably determine what future regulation should look like. Once researchers identify the risks, policymakers can enact reasonable regulation.

The third recommendation is to review funding for the CPSC. According to research, the CPSC is too undermanned and underfunded to accomplish its mission, especially in light of the many products now using nanoengineered materials.[4] Congress should review this agency to identify to what extent funding and manning should be increased.

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[3] Jeffrey H. Matsuura, *Nanotechnology Regulation and Policy Worldwide* (Norwood, MA: Artech House, Inc., 2006), 4.

[4] E. Marla Felcher, *The Consumer Product Safety Commission and Nanotechnology* (PEN 14) (Washington, DC: Pew Charitable Trusts Project on Emerging Nanotechnologies, 2008), http://www.nanotechproject.org/process/assets/files/7033/pen14.pdf.

The fourth recommendation of this thesis is to increase public awareness of nanotechnology and promote public engagement through an education program providing government funded literature and public television/radio programming. An engaged and educated public is necessary to guard against the damage of misinformation regarding nanotechnology.

The fifth recommendation is to fund a scholarship program, through the NSF, for students seeking advanced degrees in nanotechnology-related research fields. The research reveals how the United States is falling behind other developed countries in the science, technology, engineering and math fields of learning.[5] A scholarship program designed for nanotechnology will not only help to address this problem, but also provide the expertise of the future needed to guide regulation as the technology matures.

The sixth and final thesis recommendation is to continue funding nanotechnology research in the federal budget. This research shows agencies such as the NNI are playing, and will continue to play, an important role in the future of nanotechnology development.

[5] Niall McCarthy, "The Countries with The Most STEM Graduates" [infographic], *Forbes*, February 2, 2017, https://www.forbes.com/sites/niallmccarthy/2017/02/02/the-countries-with-the-most-stem-graduates-infographic/#267a23ea268a.

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I. INTRODUCTION

Technological advancements are an important part of human existence. From the dawn of humans' emergence as the dominant species on earth, the ability to create and use tools has been a primary accelerator of that dominance. Tools have been used to make life easier and to make even better tools and later machines, which eventually led to the creation of complex computing. Each of these advancements has led to new plains of discovery, capabilities, and achievement, but also to new and unexpected dangers.

As new technologies are developed, there are some that affect only a minute section of the world's population, but others are revolutionary and have the potential to directly or indirectly affect every human on earth and even the earth's ecology. Many scientists suggest that nanotechnology is one of these revolutionary technologies. The idea that nanotechnology represents revolutionary change leads many to believe that regulating this emerging technology is of paramount importance. As Doug Parr, chief scientist for Greenpeace in the United Kingdom asks, "If it will dramatically affect everyone, shouldn't everyone have a say in what developments take place—with what impacts, under whose control, and with who benefiting (and losing)?"[1] Perhaps the idea that *everyone* should have a voice is unachievable at this time, but it is reasonable that at the least some governing body should have oversight of the developing technology. Without sufficient oversight, we run the risk of repeating the mistakes of the past: a promising and advantageous technology applied swiftly and aggressively but without thorough testing, vetting, or limitation. Some examples would the public health risks created by the past use of asbestos and lead.

Presently, the regulatory framework for nanotechnology consists of existing regulating entities addressing concerns about nanotechnology under current rules and

[1] Thomas Theis et al., "Nanotechnology," *Nature Nanotechnology* 1 (October 2006): 8–10. 10.1038/nnano.2006.77, https://www.researchgate.net/publication/51427509_nan'otechnol'ogy_n.

laws.[2] If nanotechnology does develop to have the dramatic influence many predict, it is fair to question whether existing agencies, rules, and laws are sufficient to address regulation, product approval, policy advice, and industry monitoring for the emerging field of nanotechnology.

There are many roadblocks to developing suitable nanotechnology regulation. One major roadblock for nanotechnology regulation stems from the lack of consensus on the definition of nanotechnology. It is difficult to construct an architectural framework for nanotechnology regulation when many leaders within the field cannot agree on what the term even means. According to Andrew Maynard, Professor in the School for the Future of Innovation in Society at Arizona State University and co-chair of the World Economic Forum Global Agenda Council on Nanotechnology, "a sensible definition [for nanotechnology] has proved hard, if not impossible, to arrive at."[3]

A brief perusal of nanotechnology stakeholders reveals a myriad of definitions upon which their interaction with the technology is based. For instance, nanotechnology is defined by the U.S. National Nanotechnology Initiative as

> the understanding and control of matter at dimensions between approximately 1 and 100 nanometers where unique phenomena enable novel applications. Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale.[4]

In 2010, the European Commission released this definition for public comment: "a material that consists of particles with one or more external dimensions in the size range 1 nm-100

[2] Note: regulatory framework is the "existence of the necessary infrastructure which supports the control, direction or implementation of a proposed or adopted course of action, rule, principle or law." "Policy and Regulatory Framework," Caricom Statistics, accessed November 5, 2017, http://www.caricomstats.org/Files/ICT/Justification%20-%20Policy%20and%20Reg%20Framework.pdf.

[3] Andrew Maynard, "Don't Define Nanomaterials," *Nature* 475 (July 2011): 31, http://www.nature.com/articles/475031a.epdf?referrer_access_token=Xd6Zk7tfgqptAa78MNP4eNRgN0jAjWel9jnR3ZoTv0OYyOpxLNnTpRHHZKiBw6QJnExRI4pyD9tghcCOk1GLEc0ZgAeK8i3uLq7skErFqx5LqY3-uZBGG6F-hiC5N-k1vnxmFYktXJyFKfoDkhVWhnda7MDvOub9s7l4yXG21xwaeOIuTelWtCwla_OYMATecSeHUTi8QEX80fh3vFHW9tPhqV4q0ZRqCEWxs3UOeCSNZr4dI8APk00KG-g2yJsuecm5u69fe5FsS6HkFEVT-9QO-6p_eXM1VWoh17UwMj8%3D&tracking_referrer=www.slate.com.

[4] "What is Nanotechnology?," National Nanotechnology Initiative, accessed November 5, 2015, http://www.nano.gov/nanotech-101/what/definition.

nm for more than 1 percent of their number;" and/or "has internal or surface structures in one or more dimensions in the size range 1 nm-100 nm;" and/or "has a greater than 60 m2/ cm3, excluding materials consisting of particles with a size lower than 1 nm, excluding materials consisting of particles with a size lower than 1 nm."[5] In the 2003 law 21st Century Nanotechnology Research and Development Act, the U.S. Congress defines "nanotechnology" as "the science and technology that will enable one to understand, measure, manipulate, and manufacture at the atomic, molecular, and supramolecular levels, aimed at creating materials, devices, and systems with fundamentally new molecular organization, properties, and functions."[6] The inaugural issue of *Nature Nanotechnology* in 2006 asked a wide array of researchers, industrialists, and scientists what nanotechnology means to them. Unsurprisingly, the 13 different individuals queried yielded 13 different responses. This lack of a commonly agreed upon nanotechnology lexicon makes regulation difficult.

Another roadblock arises because nanotechnology is still an emerging technology. When establishing regulation, the regulating entity and those empowering the regulation assume that the regulating entity has the knowledge of what "good behavior" in an industry should be.[7] This assumption is somewhat flawed because predicting the way a new technology will be developed and adopted is very difficult. Therefore, predicting what "good behavior" in an industry will look like is also very difficult.[8] This challenge of regulation does not mean regulation should be ignored until the technology is mature, but rather that it is necessary to implement a regulatory framework that can both address

[5] Janez Potocnik, "Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial," *Official Journal of the European Union* 275 (October 2011): 38–40, https://ec.europa.eu/research/industrial_technologies/pdf/policy/commission-recommendation-on-the-definition-of-nanomater-18102011_en.pdf.

[6] "21st Century Nanotechnology Research and Development Act," Congress, accessed June 20, 2017, https://www.congress.gov/bill/108th-congress/senate-bill/189.

[7] Rodrigo Nieto Gomez, "No Bad Deed Goes Unrewarded: Cause, Consequence, and Deviance in Emerging Technological Regimes," in *Questioning Causality: Scientific Explorations of Cause and Consequence across Social Contexts*, ed., Rom Harre and Fathali M. Moghaddam (Santa Barbara, CA: Praeger, 2016).

[8] Ibid.

problems as they arise and attempt to prevent future problems by exercising foresight into what the near-term and long-term technological developments may be.

Next, the properties of engineered nanomaterials make categorization of these materials difficult under current regulatory definitions. For example, according to the National Nanotechnology Initiative (NNI), at the nanoscale, a particle's properties such as "melting point, fluorescence, electrical conductivity, magnetic permeability, and chemical reactivity change as a function size of the size of the particle."[9] Additionally, according to the NNI "nanoscale materials have far larger surface areas than similar masses of larger-scale materials. As surface area per mass of a material increases, a greater amount of the material can come into contact with surrounding materials, thus affecting reactivity."[10] These physical properties provide much of the basis for why the technology has the potential to be revolutionary. However, according to Beaudrie, Kandlikar, and Satterfield, "not enough is known about the relationship between nanomaterial physicochemical characteristics and behavior to anticipate risks. The result is a serious lack of predictive analytical capacity to anticipate harmful implications."[11]

Also problematic is that nanotechnology research and development encompass many different fields of science and across several sectors of society. These sectors include: energy, electronics, defense/homeland security, chemicals, communications/information technology, manufacturing, government, food and agriculture, pharmaceutical/health companies, transportation, education, and commerce/economics. This broad range of potential application blurs the lines of regulatory responsibility across different regulatory agencies. Also, each of these sectors contains stakeholders who have differing concerns and interests in the technology and are often competing with one another for the funding of research and development.

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[9] "What's So Special about the Nanoscale?," National Nanotechnology Initiative, accessed November 5, 2016, http://www.nano.gov/nanotech-101/special.

[10] Ibid.

[11] Christian E. H. Beaudrie, Milind Kandlikar, and Terre Satterfield, "From Cradle-to-Grave at the Nanoscale: Gaps in U.S. Regulatory Oversight along the Nanometer Life Cycle," *Environmental Science and Technology* 47 (2013): 5524−5534, doi: 10.1021/es303591x.

As scientists, lawmakers, and concerned citizens approach the seemingly intractable task of nanotechnology regulation, it would be useful to have a comprehensive map of the current landscape for nanotechnology regulation in the United States, including a federal government stakeholder review, description of the state of the technology, and applicable laws that have already been enacted related to the technology. That information is presently distributed across diverse industries and stakeholders. This thesis aggregates and analyzes this information to inform the decisions of those who will be making regulatory decisions on nanotechnology development.

A. RESEARCH QUESTION

The emerging field of nanotechnology presents very difficult challenges to policymakers and those interested in guiding its research and development in a responsible way. This thesis maps the regulatory landscape in the United States by examining stakeholders and regulatory entities and reviewing component elements of legislation and policy to provide those with an interest in nanotechnology regulation with a common entry point. This thesis answers the question: How can regulatory decisions for policymakers regarding the framework of nanotechnology regulation be informed by a map of the regulatory landscape of nanotechnology and a review of existing regulatory frameworks?

B. OBJECT, METHOD, LIMITS, AND OUTPUT

The objective of this thesis is to aid and inform the regulatory decisions of policymakers by mapping the regulatory landscape of nanotechnology, reviewing current regulatory frameworks, and making recommendations on the appropriate regulatory framework for nanotechnology. This thesis identifies the relevant federal stakeholders in relation to nanotechnology, gives a brief description of the state of the technology, analyzes applicable laws that have already been enacted related to the technology, and examines the regulatory framework of other industries. Additionally, this thesis is aimed primarily at those responsible for regulation in national agencies, regulatory policymakers, and other concerned stakeholders and citizens focused on the safe development and production of new technologies. Furthermore, this research will advance the establishment of a regulatory framework for nanotechnology. As the technology matures, policymakers will be faced with unique regulatory challenges. Now is the time to begin identifying the best regulatory framework for nanotechnology; it is important not to wait until a crisis occurs.

The method used to achieve these objectives was an investigation into the background, current state, and future projections of nanotechnology development, a federal stakeholder analysis, a review of current nanotechnology-related policy and legislation, and an examination of the regulatory framework in the aviation and biotechnology industries. This researcher generated list of stakeholders based on organizational publications, stated interest in nanotechnology, membership to nanotechnology organizations (such as the NNI), and implied interest in nanotechnology. The scope of this research is focused on mapping the regulatory landscape of nanotechnology and reviewing current regulatory frameworks. The research describes the background, current state, and future projections of some leading minds in the field of the technology, but it does not attempt to predict future advances in nanotechnology. However, it does relate realistic probabilities based on research. The output of this research is a set of recommendations for policymakers and other nanotechnology stakeholders. The goal for these recommendations is that they will serve as a starting point for establishing a regulatory framework for nanotechnology in the United States.

C. OVERVIEW OF CHAPTERS

Following the introduction to research on this topic, Chapter II provides background information on nanotechnology including the history of the technology, the current state of the technology, and where some predict the future of the technology lies as it matures. The information in Chapter II forms the foundation of the thesis. Chapters III–V are the pillars on which the conclusion is formed, and recommendations made. Chapter III examines the regulatory and legislative spaces around nanotechnology. It discusses relevant regulatory theory and examines differing viewpoints on the future of nanotechnology regulation. Additionally, Chapter III contains a look at the legislation that directly relates to nanotechnology. Chapter IV includes a federal nanotechnology stakeholder analysis intended to identify relevant stakeholders and demonstrates how each organization’s disparate mission provides the impetus for involvement in nanotechnology research, development, and regulation. Chapter V examines the regulatory frameworks for the fields of aviation and biotechnology. Finally, Chapter VI reviews the findings of the previous chapters and gives regulatory framework recommendations for nanotechnology. Figure 1 shows the visual overview of thesis chapters.

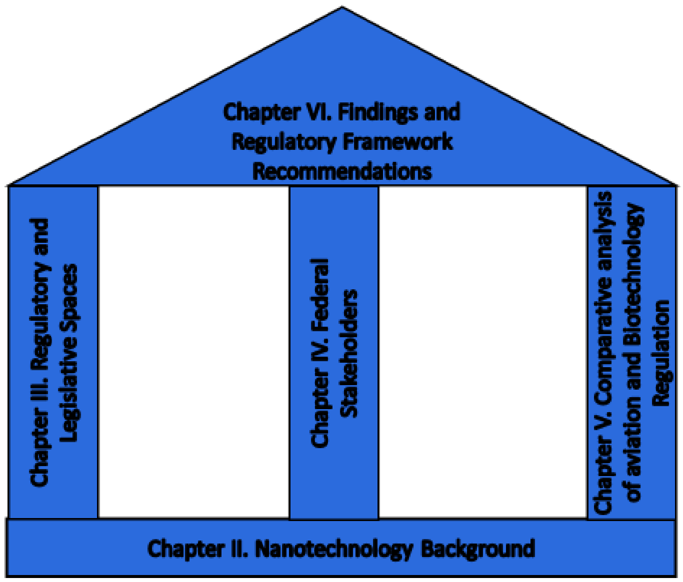

Figure 1. Visual Overview of Chapters

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II. NANOTECHNOLOGY BACKGROUND

This chapter provides background information on nanotechnology, including the history of the technology, the current state of the technology, and where some predict the future of the technology lies as it matures. This background information gives a foundational understanding of nanotechnology and explains how far the technology has advanced in a relatively short amount of time. This background information also reveals why nanotechnology regulation needs to be addressed. Additionally, it shows the potential for future advancements which further highlight the need for a regulatory framework to address regulation, policy advice, product approval, and industry monitoring.

In December 1959, Nobel Prize-winning physicist Richard Feynman delivered his groundbreaking talk "There's Plenty of Room at The Bottom" at the California Institute of Technology.[12] During the few minutes Feynman spoke, he introduced many of the foundational concepts of nanotechnology; however, in 1959, the sophistication of microscopes precluded research into these revolutionary concepts. Nanotechnology remained theory until the development of the scanning tunneling microscope in 1981. This new microscope allowed scientists to "see" at the atomic level.[13] Thus, began the age of modern nanotechnology.

As scientists realized the implications of manipulating matter at this minute level, a vast array of potential applications for nanotechnology began to spring forth from their imagination. In 1986, K. Eric Drexler published *Engines of Creation: The Coming Era of Nanotechnology*. This book set forth several concepts and views of the future that were at once groundbreaking, controversial, and frightening to some. Drexler's work is controversial. He carried on an open debate from 2001–2003 with Nobel Laureate in chemistry Richard Smalley about the feasibility of constructing molecular assemblers—a concept fundamental to many of Drexler's assertions.[14] Despite the controversy, he is cited

[12] "What is Nanotechnology?," National Nanotechnology Initiative.

[13] Ibid.

[14] K. Eric Drexler, *Engines of Creation: The Coming Era of Nanotechnology* (New York: Anchor Books, 1986).

as one of the leaders in the field of nanotechnology, as his work acted as a catalyst for others to speculate about nanotechnology, draw conclusions, and envision applications.

A. APPLICATIONS AND CURRENT USES OF NANOTECHNOLOGY

Nanotechnology has the potential to affect nearly every aspect of human life, from clothing to transportation, agriculture, computing, energy, water treatment/filtration, infrastructure, and healthcare. Below are just a few examples of the many potential possibilities of nanotechnology when the technology reaches maturity.

1. Cancer Detection and Treatment

In 2016, cancer took the lives of 595,690 people in the United States.[15] The ability to detect cancer in its earliest stages is paramount to effective treatment. The National Cancer Institute (NCI), Alliance for Nanotechnology in Cancer has been working to leverage advancements in nanotechnology to drastically improve how cancer is diagnosed, treated, and hopefully prevented.[16] Since its inception in 2004, the NCI Alliance for Nanotechnology in Cancer has generated more than 3,000 peer-reviewed publications, filed more than 220 disclosures and patents, formed more than 85 companies directly associated with the alliance to commercialize technologies developed in academia, and conducted 17 cancer related clinical trials from testing eight alliance-affiliated therapeutics.[17] The alliance hopes the progress of this research will eventually lead to the eradication of cancer.

With many others, alliance scientists are working on the technology to construct sensors that are able to pinpoint specific biomarkers, including unusual genes, which might be the harbinger of later cancer development.[18] Additionally, the development of nanoscale

[15] "Cancer Statistics," National Cancer Institute, accessed June 20, 2017, https://www.cancer.gov/about-cancer/understanding/statistics.

[16] "About OCNR," National Cancer Institute, Office of Cancer Nanotechnology Research, accessed June 21, 2017, http://nano.cancer.gov/about/mission/.

[17] "Research Published by NCI Alliance," National Cancer Institute, Office of Cancer Nanotechnology Research, accessed June 21, 2017, https://www.cancer.gov/sites/ocnr/research/alliance-research.

[18] John F. Sargent, *Nanotechnology: A Policy Primer* (CRS Report No. RL34511) (Washington, DC: Congressional Research Service, 2016), https://fas.org/sgp/crs/misc/RL34511.pdf.

cantilevers, which bend in the presence of cancer causing biomarkers, could be used by doctors for early detection. Nanotechnology cannot only improve the accuracy of initial diagnosis, but it can allow these diagnoses to be made sooner using molecular contrast agents and materials.[19]

To more effectively treat cancer, researchers are developing multifunctional targeted devices able to deliver "multiple therapeutic agents directly to cancer cells."[20] Researchers are also working on engineered nanoshells that would concentrate at cancer lesion sites and release a small energy source, such as a near infrared light, to destroy cancer cells.[21] Another potential treatment involves delivering tiny amounts of chemotherapy drug directly to cancer cells, thereby limiting the damage done to healthy non-cancerous cells.[22] Researchers are also working on developing nanoparticles capable of crossing biological barriers to improve therapies for cancers that are currently very difficult to treat.[23] These examples are just a very small sample of the many exciting possibilities for cancer detection and treatment using nanotechnology.

2. Energy

In the 21st century, it has become clear that existing methods of sourcing, distributing, storing, and consuming energy have put enormous strains on the earth's ecology. Primary energy sources include hydroelectric, fossil and mineral fuels, and

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19 "Impacts on Cancer," National Cancer Institute for Nanotechnology in Cancer, accessed June 21, 2017, https://nano.cancer.gov/learn/impact/

20 "Mission and Goals," National Cancer Institute for Nanotechnology in Cancer, accessed June 21, 2017, http://nano.cancer.gov/about/mission/.

21 Nanoshell is "A spherical core consisting of a particular compound, which is surrounded by a shell of a few nanometer of thickness." "What is a Nanoshell?" IGI Global, accessed October 15, 2016, http://www.igi-global.com/dictionary/nanoshell/19860; Sargent, *Nanotechnology: A Policy Primer*.

22 "Treatment and Therapy," National Cancer Institute for Nanotechnology in Cancer, accessed June 21, 2017, https://www.cancer.gov/sites/ocnr/cancer-nanotechnology/treatment.

23 An example of a biological barrier is the blood-brain barrier. According to May Bates, "The brain is the only organ known to have its own security system, a network of blood vessels that allows the entry of essential nutrients while blocking other substances. Unfortunately, this barrier is so effective at protecting against the passage of foreign substances that it often prevents life-saving drugs from being able to repair the injured or diseased brain." May Bates, "The Blood-Brain Barrier," Brain Facts, July 2, 2014, http://www.brainfacts.org/brain-anatomy-and-function/anatomy/2014/blood-brain-barrier; National Cancer Institute, *Cancer Nanotechnology Plan* (Washington, DC: National Institutes of Health, 2015), https://www.cancer.gov/sites/ocnr/research/plan/cananoplan-2015-complete.pdf.

nuclear sources.[24] Research has shown these are destructive to the environment as they have been linked to global warming, the destruction of the biosphere and geosphere, pollution, the depletion of the ozone layer, and ecological devastation.[25] To address these issues, scientists have begun researching ways to optimize the production of renewable energy using nanotechnology based solutions.[26] Additionally, according to Dr. Wolfgang Luther of VDI Technologiezentrum GmbH (Germany) in the study titled *Application of Nanotechnologies in the Energy Sector*, "Nanotechnologies provide the potential to enhance energy efficiency across all branches of industry and to economically leverage renewable energy production through new technological solutions."[27] See Figure 2.

Examples of enhanced energy production include nanoscale semiconductor catalysts intended to improve the process of using sunlight to produce hydrogen from water, nanostructured solar panels which use a broader spectrum of sunlight to improve efficiency in transforming sunlight into electricity, and carbon nanotubes (using carbon nanotube fibers) that can potentially reduce energy transmission losses by one percent.[28] This reduction of energy transmission losses would be equivalent to saving 24 million barrels of oil annually within the United States alone.[29]

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[24] Elena Serrano, Guillermo Rus, and Javier Garcia-Martinez, "Nanotechnology for Sustainable Energy," *Renewable and Sustainable Energy Reviews* 13, no. 9 (2009): 2373–2384, doi: 10.1016/j.rser.2009.06.003.

[25] Ibid.

[26] "Nanotechnology in Energy," Nanowerk, accessed October 15, 2017, http://www.nanowerk.com/nanotechnology-in-energy.php.

[27] Wolfgang Luther, *Applications of Nano-technologies in the Energy Sector*, Akition Hessen-Nanotech, Vol 9 (Wiesbaden, Germany: Hessian Ministry of Economy, Transport, Urban, and Regional Development, 2008), https://www.hessen-nanotech.de/mm/NanoEnergy_web.pdf.

[28] Sargent, *Nanotechnology: A Policy Primer*.

[29] Ibid.

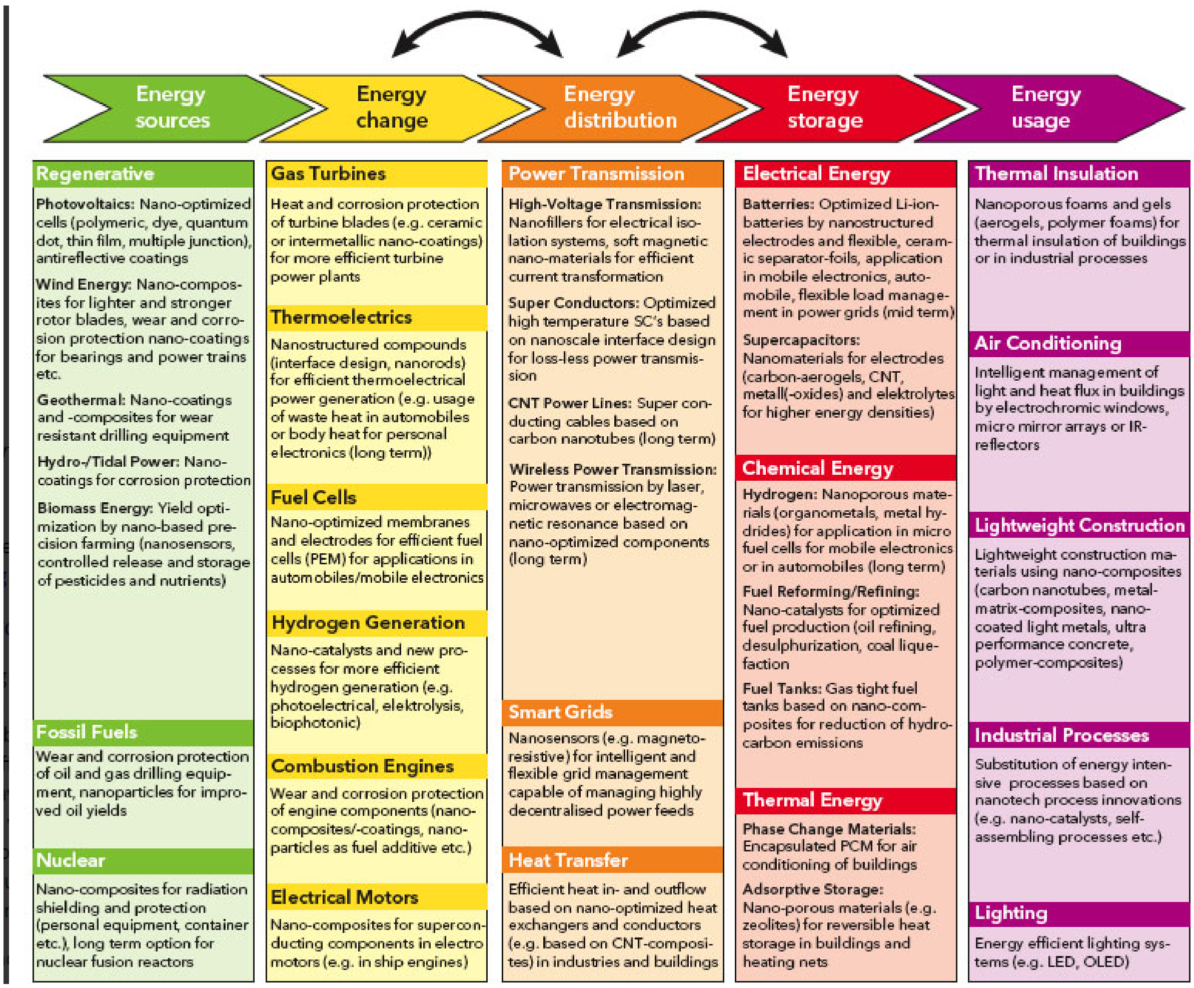

Figure 2. Examples for Potential Applications of Nanotechnology Along Chain in the Energy Sector[30]

3. Water and Food

Nanotechnology has the potential to be used to fulfill the basic human needs for clean water and food. As the world population continues to expand, it is rapidly depleting precious natural resources. In his book *Water: The Epic Struggle for Wealth, Power and Civilization*, the journalist Steven Solomon lays out convincing arguments that water will

30 Source: Luther, *Applications of Nano-technologies*.

soon surpass oil as the world's scarcest critical resource.[31] Figure 3 depicts a map of the countries in the world most stressed by the current and coming water shortages.

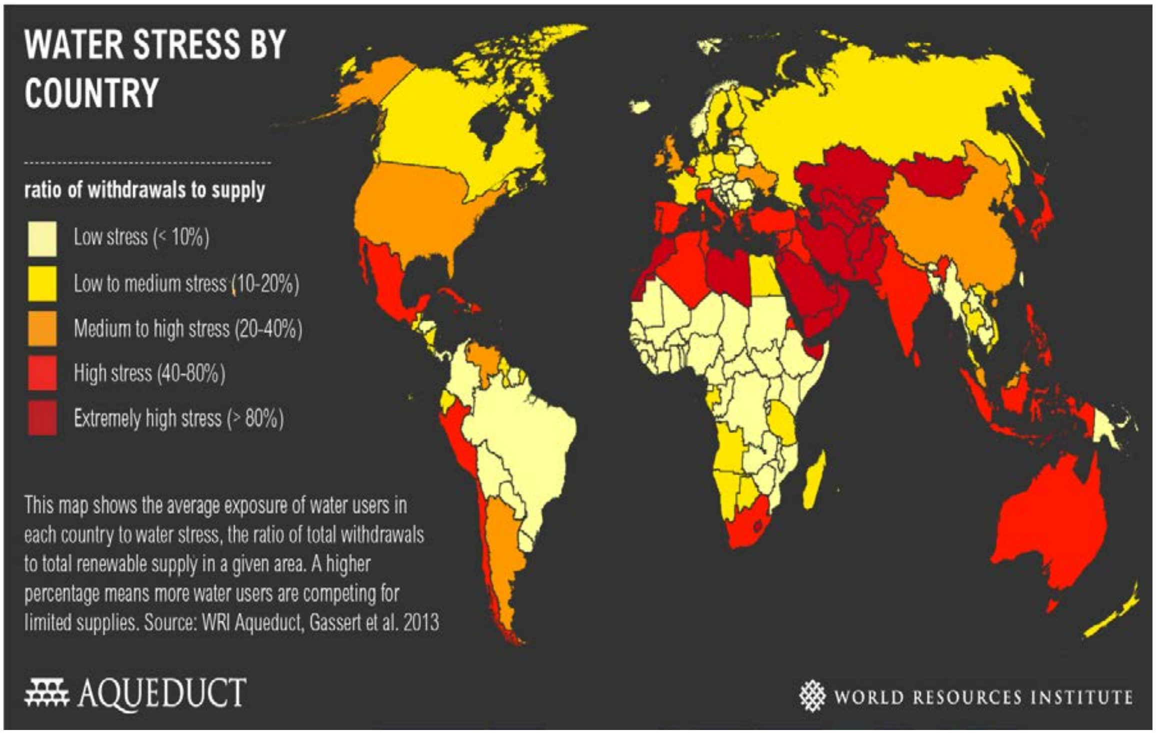

Figure 3. Water Stress by Country[32]

Water desalination and filtration systems that use nanotechnology may provide clean water solutions to the vast portions of the earth in desperate need of clean water. These filtration systems could be portable, affordable, and scalable, granting universal access to clean water.[33]

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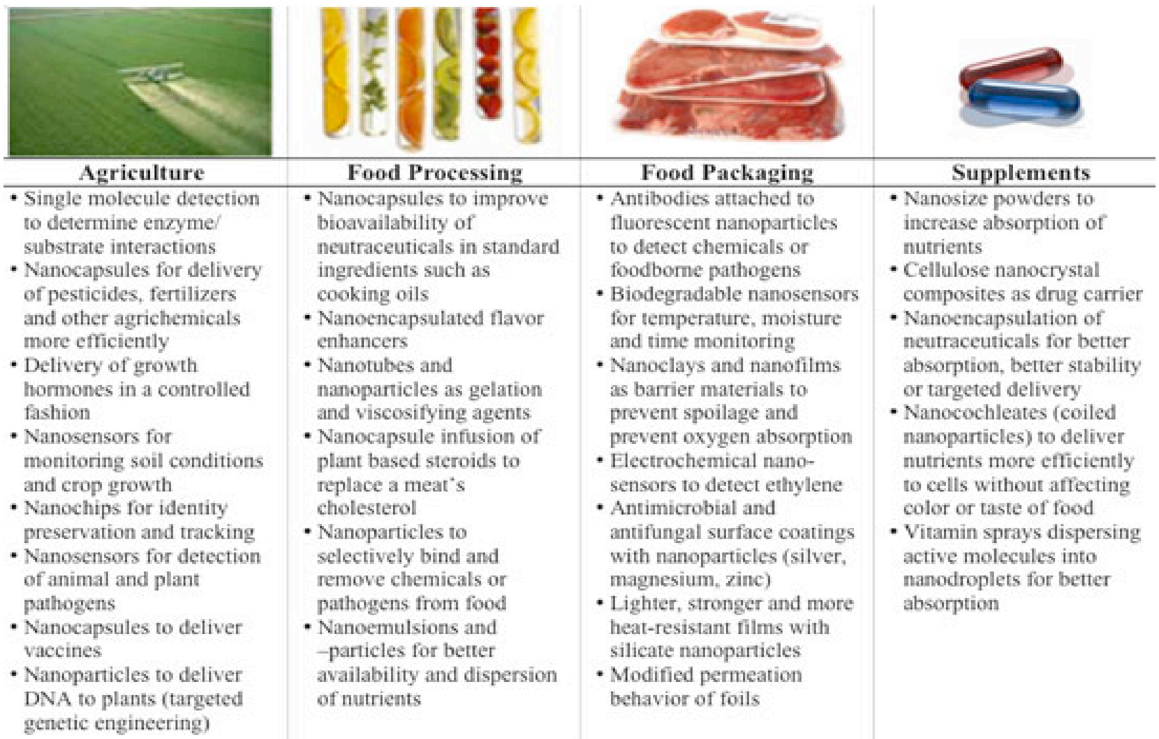
31 "Will the Next War be Fought over Water?," *NPR All Things Considered*, January 3, 2010, http://www.npr.org/templates/story/story.php?storyId=122195532.

32 Source: Paul Reig, Andrew Maddocks and Francis Gassert, "World's 36 Most Water-Stressed Countries," World Resources Institute, December 12, 2013, http://www.wri.org/blog/2013/12/world%E2%80%99s-36-most-water-stressed-countries.

33 Luciana Gravotta, "Cheap Nanotech Filter Clears Hazardous Microbes and Chemicals from Drinking Water," *Scientific American*, May 7, 2013, https://www.scientificamerican.com/article/cheap-nanotech-filter-water/.

Figure 4 offers a glimpse of the nanotechnology applications companies are researching, developing, testing, and in some cases, already actively applied in food technology.[34] Though the following list is quite extensive, it is not exhaustive.



Agriculture	Food Processing	Food Packaging	Supplements
• Single molecule detection to determine enzyme/ substrate interactions • Nanocapsules for delivery of pesticides, fertilizers and other agrichemicals more efficiently • Delivery of growth hormones in a controlled fashion • Nanosensors for monitoring soil conditions and crop growth • Nanochips for identity preservation and tracking • Nanosensors for detection of animal and plant pathogens • Nanocapsules to deliver vaccines • Nanoparticles to deliver DNA to plants (targeted genetic engineering)	• Nanocapsules to improve bioavailability of neutraceuticals in standard ingredients such as cooking oils • Nanoencapsulated flavor enhancers • Nanotubes and nanoparticles as gelation and viscosifying agents • Nanocapsule infusion of plant based steroids to replace a meat's cholesterol • Nanoparticles to selectively bind and remove chemicals or pathogens from food • Nanoemulsions and –particles for better availability and dispersion of nutrients	• Antibodies attached to fluorescent nanoparticles to detect chemicals or foodborne pathogens • Biodegradable nanosensors for temperature, moisture and time monitoring • Nanoclays and nanofilms as barrier materials to prevent spoilage and prevent oxygen absorption • Electrochemical nano-sensors to detect ethylene • Antimicrobial and antifungal surface coatings with nanoparticles (silver, magnesium, zinc) • Lighter, stronger and more heat-resistant films with silicate nanoparticles • Modified permeation behavior of foils	• Nanosize powders to increase absorption of nutrients • Cellulose nanocrystal composites as drug carrier • Nanoencapsulation of neutraceuticals for better absorption, better stability or targeted delivery • Nanocochleates (coiled nanoparticles) to deliver nutrients more efficiently to cells without affecting color or taste of food • Vitamin sprays dispersing active molecules into nanodroplets for better absorption

Figure 4. Nanotechnology in Food Technology[35]

4. Nanosensors

Nanosensors can be engineered to detect particles like pathogens, bacteria, toxins, explosives, or deoxyribonucleic acid (DNA).[36] Recently, researchers have made a breakthrough in the detection of trinitrotoluene, more commonly known as TNT. The new nanosensor technology may allow for not only the detection of the explosive material but

[34] "Nanotechnology in Food," Nanowerk, accessed October 15, 2016, http://www.nanowerk.com/nanotechnology-in-food.php.

[35] Source: "Nanotechnology in Food," Nanowerk.

[36] Mark A. Ratner and Daniel Ratner, *Nanotechnology: A Gentle Introduction to the Next Big Idea* (Upper Saddle River, NJ: Prentice Hall, 2002), 98–106.

also to determine how much of the material is present.[37] This enhanced sensor may eventually replace bomb sniffing dogs.[38] Sensor technology as a means to detect chemical and explosive threats is one of the primary areas of interest for the U.S. Department of Homeland Security, Science and Technology Directorate.[39] Additionally, nanosensors may also be used to detect airborne chemicals for pollution monitoring, for medical diagnostic purposes, to monitor in a more detailed way physical parameters such as temperature, displacement, flow, etc., and as accelerometers in micro-electro-mechanical devices, such as airbag sensors.[40] Additionally, according to Hahm and Lieber in 2004, the development of "detectors for DNA and other biological macromolecules has the potential to impact basic biological research as well as screening in medical and bioterrorism applications."[41]

5. Information Technology

Research into nanotechnology may be used to further miniaturization of computers and simultaneously make them more powerful. Forming nanoscale components through self-assembly may be the next evolution in low cost yet highly effective microscale integrated circuits and possibly replace the use of silicon chips as the standard for computing devices.[42] Nanotechnology applications in the storage of data may offer solutions for the storage of big data. In *Nanofuture: What's Next for Nanotechnology*, Hall

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[37] "New Nanosensors for the Detection of TNT," Phys, November 5, 2016, http://phys.org/news/2016-11-nanosensors-tnt.html.

[38] Ibid.

[39] National Science and Technology Council Committee on Technology, Subcommittee on Nanoscale Science, Engineering, and Technology, *National Nanotechnology Initiative Strategic Plan for 2014* (Washington, DC: Executive Office of the President, 2014), http://nano.gov/sites/default/files/pub_resource/2014_nni_strategic_plan.pdf.

[40] "Nanosensors, A Definition, Applications, and How Nanosensors Work," AZO Nano, February 6, 2007, http://www.azonano.com/article.aspx?ArticleID=1840.

[41] Jong-in Hahm and Charles M. Lieber, "Direct Ultrasensitive Electrical Detection of DNA and DNA Sequence Variations Using Nanowire Nanosensors," *Nano Letters* 4 no. 1 (2004): 51–54, doi: 10.1021/nl034853b.

[42] "Commercial Applications of Nanotechnology in Computing and Information Technology," AZO Nano, accessed October 12, 2016, http://www.azonano.com/article.aspx?ArticleID=1057; Orion Jones, "IBM: Nanotech Computer Chips Soon after 2020," Big Think, accessed October 15, 2016, http://bigthink.com/ideafeed/ibm-nanotech-computer-chips-soon-after-2020.

suggests it will be possible to store up to 500 terabytes of information on a device the size of a fine grain of sand.[43]

A 2013 experiment using the K computer at the Riken research institute in Kobe, Japan, the world's fourth fastest supercomputer, demonstrated the difficulty of replicating the computing power of the human brain. After 40 minutes, the supercomputer, using 82,944 processors, produced just one second of human brain processing time.[44] Despite the difficulty replicating the human brain's computing capacity, computing power leveraging nanotechnology may lead to artificial intelligence that matches and eventually surpasses the capabilities of the human brain. The implications of such a development are as widespread as the imagination allows.

6. Reverse Aging/Anti-aging

In a 2006 interview for *Computerworld*, Ray Kurzweil, recipient of the National Medal of Technology and Innovation (nation's highest honor for technological achievement), presented his beliefs that within the next 40 years, widespread use of nanotech devices will allow humans to overcome disease and aging as well as to reach a state of near immortality.[45] Kurzweil is not alone in this belief. J. Storrs Hall, author of *Nanofuture: What's Next for Nanotechnology*, describes the process whereby nanorobots are introduced to the body either topically, orally, or by injection. These nanorobots would then perform the functions of cell maintenance and cell repair.[46] Theoretically, these nanorobot treatments would eliminate aging; some have suggested one could get yearly treatments to restore to any biological age desired. Additional nanotechnology

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[43] J. Storrs Hall, *Nanofuture: What's Next for Nanotechnology* (Amherst, NY: Prometheus Books, 2005), 110.

[44] Ryan Whitwam "Simulating 1 Second of Human Brain Activity Takes 82,944 Processors," August 5, 2013, Extreme Tech, https://www.extremetech.com/extreme/163051-simulating-1-second-of-human-brain-activity-takes-82944-processors.

[45] Sharon Gaudin, "Nanotech Could Make Humans Immortal by 2040, Futurist Says," *Computerworld*, October 1, 2009, https://www.computerworld.com/article/2528330/app-development/nanotech-could-make-humans-immortal-by-2040--futurist-says.html; "1999 Laureates-National Medal of Technology and Innovation," U.S. Patent and Trademark Office, last updated November 3, 2014, https://www.uspto.gov/learning-and-resources/ip-programs-and-awards/national-medal-technology-and-innovation-nmti.

[46] Hall, *Nanofuture*.

breakthroughs in medical detection and treatment of diseases are expected to dramatically increase lifespans, even if the more radical ideas of youthful restoration remain out of reach.

7. Nantotech Manufacturing/Assemblers

In the popular television show *Star Trek: The Next Generation*, which won 18 primetime Emmy awards from 1987–1994, Captain Jean-Luc Picard can often be seen walking over to a replicator within a wall and saying, "Tea, Earl Grey, hot." The device then produced the tea.[47] Some believe it may actually be possible to create this futuristic device of science fiction and that each household will one day have at its convenience one of these devices capable of assembling whatever a person desires. These devices would theoretically provide the functionalities of 3D printing but with much more precision and flexibility. The desktop nanomanufacturing machine may one day be as prevalent as the modern-day desktop or laptop computer.

The idea of nanotech assemblers is one of the more controversial possibilities of nanotechnology. In his 1986 book, *Engines of Creation: The Coming Era of Nanotechnology*, K. Eric Drexler, in a section called "Engines of Destruction," warned,

> Tough omnivorous "bacteria" could out-compete real bacteria: they could spread like blowing pollen, replicate swiftly, and reduce the biosphere to dust in a matter of days. Among the cognoscenti of nanotechnology, this threat has become known as the gray goo problem.[48]

"Grey goo" has been a boon to science fiction (sci-fi) writers who have used it as a theme for end-of-the-world plots in sci-fi novels such as Michael Crichton's *The Prey*.[49] Nanotechnology in general has been used often over the last 30 years in many science fiction stories, such as *Terminator 2: Judgment Day* by Randall Frakes, *The Diamond Age* by Neal Stephenson, Stel Pavlou's *Decipher*, and Robert Ludlum's *The Lazarus Vendetta*,

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47 "Star Trek: The Next Generation," IMDB, accessed October 15, 2016, http://www.imdb.com/title/tt0092455/; Degirmentas, "Star Trek—Picard 'Tea, Earl Grey, Hot' Clips," YouTube video posted June 27, 2009, https://www.youtube.com/watch?v=R2IJdfxWtPM; Earl Boysen and Nancy Boysen, *Nanotechnology for Dummies* (Indianapolis: Wiley Publishing Inc., 2011), 233.

48 Drexler, *Engines of Creation*.

49 Michael Crichton, *The Prey* (New York: Harper Collins Publishers, 2002).

as well as a host of films and television episodes.[50] One consequence of this is that many in the general public view nanotechnology as either a source of fear or with scorn as simply a sci-fi fantasy. Some have even expressed concern that this negative perception may impede progress of the emerging field as unfounded fears grow into demands for moratoriums on nanotech research.[51]

B. FROM HYPE TO THE CURRENT STATE OF NANOTECHNOLOGY

Similar to other technologies, nanotechnology underwent a stage of hype wherein promoters oversold the technology's near-term capabilities. From a business perspective, this unrealistic enthusiasm cost many investors significant sums of money. However, nanotechnology has emerged from the period of hype as a viable and robust technology, even if some oversold its short-term impact. This section details nanotechnology's growth from an over-hyped technology to a robust field of study with many uses for current consumer products.

As the ideas promoted by Drexler and others have trickled into the mainstream consciousness, they captured the imagination of many, but also, many believe, sparked an unprecedented amount of hyperbole and aggressive timelines for technological maturity. In *Nano-Hype: The Truth Behind the Nanotechnology Buzz*, David M. Berube states, "to justify government spending and media interest in this area [nanotechnology], people at the nanofront have engaged in exaggeration and hyperbole to repackage this idea as something new and exciting." At the same time, he explains that some engage in "equally perverse exaggerations of doom and gloom. It is the inherent linkage with hyperbole of all sorts that has made nano such an incredibly difficult sell."[52]

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50 Randall Frakes, *Terminator 2: Judgment Day* (New York: Bantam Spectra, 1991); Neal Stephenson, *The Diamond Age* (New York: Bantam Spectra, 1995); Stel Pavlou, *Decipher* (New York: Simon & Schuster, 2001); Robert Ludlum, *The Lazarus Vendetta* (New York: St Martin's Griffin 2004).

51 *Societal Implications of Nanotechnology, Hearing before the House of Representatives Committee on Science*, 108th Cong. 27 (2003) (testimony of Nick Smith), http://commdocs.house.gov/committees/science/hsy86340.000/hsy86340_0f.htm.

52 David M. Berube, *Nano-Hype: The Truth behind the Nanotechnology Buzz* (Amherst, NY: Prometheus Books, 2006), Kindle ed., location 291.

After the Dot-com market crash in the early 2000s, investors were still hungry for the next big technology boom. “Nanotechnology” became a buzzword for bringing in money and signified to some the technology of the 21st century.[53] Many companies that had nothing to do with nanotechnology saw their company valuations rise dramatically. Nanometrics, a company established in 1975 well before the popularization of the term “nanotechnology” and which, according to its chief financial officer, “has nothing to do with nanotechnology” nevertheless saw its stock share price inexplicably increase by 25 percent in one month during Wall Street’s nanotech craze.[54] Many startups saw the money flowing to “nano” companies and started adding “nano” to their name in an effort to secure funding. Other companies simply changed their name to take advantage. For example, Sulight Systems became NanoPierce Technologies, and Covalent Materials became Nanomix. As a result of changing their names, many of these companies had vastly inflated market cap compared to revenue (see Table 1).[55] Today, many of the companies listed in the table are traded as penny stocks or have declared bankruptcy.

[53] Charles Q. Choi, “Nano World: Dealing with Too Much Hype,” *United Press International*, October 22, 2004, https://www.upi.com/Nano-World-Dealing-with-too-much-hype/97791098459686/.

[54] Josh Wolfe, “Beware of Nano Pretenders,” *Forbes*, August 1, 2002, https://www.forbes.com/2002/08/01/0801soapbox.html.

[55] John C. Miller et al., *The Handbook of Nanotechnology: Business, Policy, and Intellectual Property Law* (Hoboken, NJ: John Wiley & Sons, 2005).

Table 1. Publicly Traded Companies with "Nano" in the Name (2003)[56]

Publicly Traded Companies with "Nano" in Their Name

(Millions of U.S. Dollars)

Company	Market Cap (12/31/03)	2002 Revenues
Altair Nanotech: ALTI	$128.2	$0.3
NanoProprietary: NNPP	263.1	1.4
NanoPierce: NPCT	25.2	0.2
NanoScience Tech: NANS	86.8	—
U.S. Global Nanospace: USGA	97.2	—
Nanophase:NANX	140.5	5.4
Nanogen: NGEN	230.9	17.2
Nanobac Pharmaceuticals: NNBP	67.0	—
Nanosignal: NNOS	18.1	0.1
Nanometrics: NANO	180.3	34.7
Total	**$1,237.4**	**$59.3**
Implied P/S ratio	20.9x	

After President Bush signed the 21st Century Nanotechnology Research and Development Act on December 3, 2003, which authorized $3.4 billion in federal nanotech spending over fiscal years 2004 through 2008, the investment hype began to crescendo.[57] In 2006, *Businessweek* predicted nanotechnology would represent a $2.6 trillion industry by 2014.[58] Unfortunately, that prediction overestimated the industry's potential by at least $2.5 trillion as the actual technological development that occurred over the next few years severely underdelivered.[59]

Some, such as David M. Berube who served on the steering committee for the International Council on Nanotechnology, believe the hype surrounding nanotech has led

[56] Source: Miller et al., *The Handbook of Nanotechnology*.

[57] Choi, "Nano World."

[58] Palash R. Ghosh, "How to Invest in Nanotech," *Bloomberg Businessweek*, April 17, 2006, https://www.bloomberg.com/news/articles/2006-04-16/how-to-invest-in-nanotechbusinessweek-business-news-stock-market-and-financial-advice.

[59] Street Authority, "Is the Nanotech Craze Over? Not for These 2 Stocks," NASDAQ, April 23, 2014, http://www.nasdaq.com/article/is-the-nanotech-craze-over-not-for-these-2-stocks-cm346626.

to unrealistic expectations on the part of the public and policymakers and at one time actually threatened to derail legitimate research into the field.[60] It is important to manage expectations and recognize that it is nearly impossible to accurately predict the timeline for the field to mature. Many have identified possible applications for nanotech, but these may be years, even decades, away.

Despite these setbacks, nanotechnology research and breakthroughs are occurring at the cross-section of many different fields of science (see Figure 5).[61] This research has lead and is leading to a diverse set of applications across many sectors of society. With these diverse applications come problems formulating a single strategy for nanotechnology regulation.

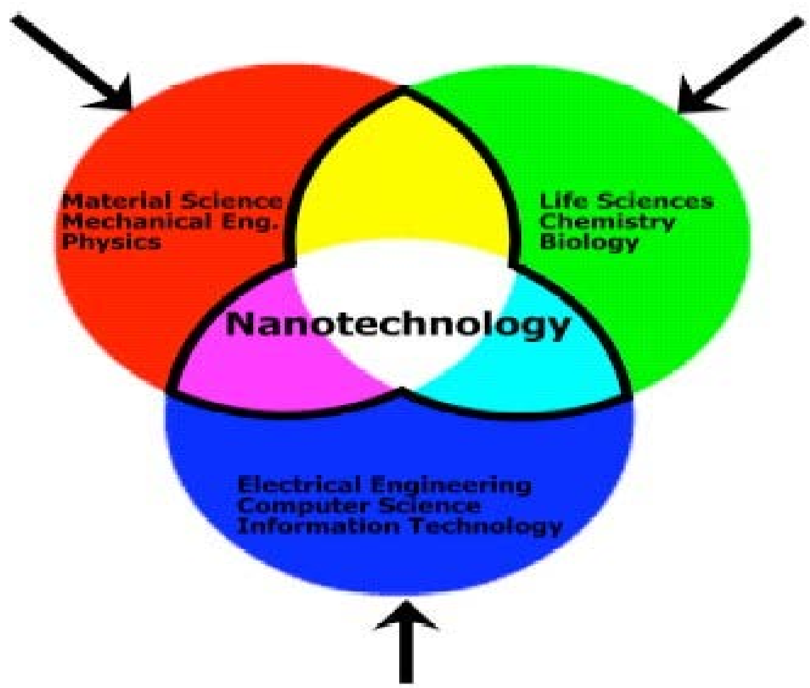

Figure 5. Nanotechnology at the Cross-section of Many Fields of Science

60 Berube, *Nano-Hype*.

61 Sarchin Kumar et al., "Nanotechnology in Computers," *International Journal of Information & Computation Technology* 4, no. 15 (2014): 1597–1603, http://www.ripublication.com/irph/ijict_spl/ijictv4n15spl_15.pdf.

Though nanotechnology is still considered an emerging technology, its current state is that of a robust industry and research field. It would be a mischaracterization to speak of its applications as only futuristic. In fact, using the nanotechnology definition of "control of matter at dimensions between approximately 1 and 100 nanometers," medieval stained-glass artisans used nanotechnology to create their art by adding gold chloride during vitrification to generate the ruby red color in the windows.[62] Thus, nanotechnology can be simultaneously characterized as a very old technology, a robust current technology, and an emerging technology.

As an enabling technology, the introduction and proliferation of nanotechnology products in the marketplace is not dependent on the development of entirely new products or new markets.[63] Rather, existing products can be greatly enhanced by leveraging nanotechnology in the manufacturing process.[64] Therefore, over the last several years, the use of nanotechnology in consumer products has grown rapidly. In 2005, the Woodrow Wilson International Center for Scholars and the Project on Emerging Nanotechnologies created the Nanotechnology Consumer Products Inventory (CPI) in an attempt to document current products introduced into the commercial marketplace.[65] The CPI lists 1800 plus products from 600 plus companies in 32 countries (see Table 2 for a partial list).[66] Each of these companies is a stakeholder for any nanotechnology regulation. The numerous and diverse applications of nanoscale products (see Figure 6) again raise the questions about the safety of these products throughout the product life cycle.

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[62] "From Nanotech to Nanoscience," Chemical Heritage Foundation, accessed August 4, 2017, https://www.chemheritage.org/distillations/magazine/from-nanotech-to-nanoscience; "History," *Nanotechnology Blogspot*, accessed August 4, 2017, http://nano--tech.blogspot.com/p/history.html.

[63] *Oversight of the National Nanotechnology Initiative and Priorities for the Future, Hearing Before the Subcommittee on research and science Education Committee on Science, Space, and Technology, House of Representatives*, 112th Cong. (2011), https://www.gpo.gov/fdsys/pkg/CHRG-112hhrg65702/pdf/CHRG-112hhrg65702.pdf.

[64] Ibid.

[65] Marina E. Vance et al., "Nanotechnology in the Real World: Redeveloping the Nanomaterial Consumer Products Inventory," *Beilstein Journal of Nanotechnology* (August 2015): 1769–1780, doi:10.3762/bjnano.6.181, https://www.beilstein-journals.org/bjnano/content/pdf/2190-4286-6-181.pdf.

[66] Ibid. The entire list can be found at http://www.nanotechproject.org/cpi/products/.

Table 2. Number of Products in the CPI over Time[67]

Year	Added products	Total products	Products archived	Data collection notes
2005	54	54	0	Beginning of CPI as a static pdf document.
2006	356	302	0	Launch of the online CPI.
2007	580	278	0	Nanoscale silver emerged as most cited nanomaterial.
2008	803	223	0	Health and fitness products represented 60 percent of the inventory.
2009	1015	212	107	Added archiving function to the CPI.
2010	1015	0	0	No data collected.
2011	1015	0	0	No data collected.
2012	1438	426	0	Beginning of CPI 2.0 project, focus on adding new products.
2013	1628	190	288	Launch of crowdsourcing component. Extensive effort put into adding and archiving products.
2014	1814[a]	238[a]	223[a]	Extensive effort put into adding and archiving products.

[a] "The CPI now has crowdsourcing capabilities, so these numbers are a snapshot in time and will not represent the CPI at the time of reading."[68]

67 Adapted from: Vance et al. "Nanotechnology in the Real World."

68 "Nanotechnology in the Real World."

Current applications of nanoscale products in consumer products around the world

Automotive Air and Oil Filters Waxes, engine oil Anti-scratch finishes Car wax Air purifiers Catalysts to improve fuel consumption Tires	**Clothing and Textiles** Wrinkle and stain resistant apparel Anti-bacterial and anti odour clothing Anti-bacterial fabrics UV resistant and protective clothing Flame retardant fabrics	**Cosmetics** Skin creams and moisturizers Skin cleansers Sunscreens Lipstick, mascara, make-up foundations Make up removal
Electronics Batteries Displays-electronics Organic Light Emitting Diodes (OLED) and LEDs Data memory Anti-bacterial and anti static coatings on keyboards, mouse, cell phones DVD coatings MP3 players Computer processors and chips	**Food, Food Additives and Food Packaging** Energy drinks Nutritional supplements Food storage containers Anti-bacterial utensils Cutting boards Plastic wrap Food packaging Nano-tea, chocolate shakes, canola active oil	**Household** Anti-bacterial furniture and mattresses Anti-bacterial coatings in appliances Filters Air purifiers Self cleaning glass Anti-bacterial, UV resistant paints Irons, vacuums Solar cells Cleaning products Disinfectant sprays Fabric softeners
Personal Care/Health Hearing aids Contact Lenses Body wash Cellulite treatment Tooth powder Shampoos, hair gels Deodorants Insect repellents Anti-bacterial creams Bandages Home pregnancy tests Drug delivery patches Man-made skin	**Sports Equipment** Golf balls and clubs Tennis rackets and balls Baseball bats Hockey sticks Skis and snowboards Ski wax Bicycle parts Wet suits Shoe insoles Anti fogging coatings	**Toys and Children's Goods** Stain resistant plush toys Anti-bacterial baby pacifiers, mugs and bottles X-boxes and play stations Anti-bacterial stuffed toys **Medical Applications** Drugs Medical Devices

Nielsen, 2008

Figure 6. Current Applications of Nanotechnology in Consumer Products[69]

[69] Source: Elizabeth Nielson, *Nanotechnology and Its Impact on Consumers* (Richmond, Ontario: Consumer Council of Canada, 2008), https://www.consumerscouncil.com/site/consumers_council_of_canada/assets/pdf/Nanotech_report.pdf quoted in Alexandrina Soldatenko, "Current Uses of Nanotechnology" (presentation, 4th Central and Eastern Europe Regional Meeting on SAICM and UNITAR Workshop on Nanotechnology and Manufactured Nanomaterials, Lodz, Poland, June 2011), http://www.unitar.org/cwm/sites/unitar.org.cwm/files/Lodz%20Presentation%20%28Current%20uses%20%20of%20nanotechnology%29.pdf.

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III. REGULATORY AND LEGISLATIVE SPACES

This chapter examines the regulatory and legislative spaces around nanotechnology. The first section reviews some of the literature about regulation theory and details prevailing viewpoints on how best to regulate nanotechnology. The second section shows what legislative actions have been taken regarding nanotechnology. Conspicuously absent from the legislative space are laws or rules for nanotechnology. Legislation signed into law thus far has been intended to fund research rather than to create rules or laws to govern nanotechnology.

A. REGULATION THEORY AND NANOTECHNOLOGY SPACE

In their book, *Understanding Regulation: Theory Strategy and Practice*, Robert Baldwin, Martin Cave, and Martin Lodge suggest that when considering whether or not to regulate, "the market and all its failings, should be compared with regulation and all its failings."[70] This comparison forms a foundational analysis for determining whether or not governments should pursue regulation.[71]

There is no consensus legal or economic definition of regulation.[72] Baldwin, Cave, and Lodge offer three definitions. Regulation is alternately described as 1) A "specific set of commands" given and whereby the agency dictating rules is committed to the purpose of enforcement of these rules; 2) as a "deliberate state influence" encompassing all government action designed to influence the actions of individuals or businesses; and 3) as "all forms of social or economic influence" whereby all instruments of influence affecting conduct are considered regulation—whether the instrument be government, markets, or

70 Robert Baldwin, Martin Cave, and Martin Lodge, *Understanding Regulation: Theory, Strategy, and Practice* (New York: Oxford University Press, 2012).

71 Ibid.

72 Johan den Hertog, "General Theories of Regulation," in *Encyclopedia of Law and Economics*, ed. Boudewijn Bouckaert and Gerrit De Geest (Cheltenham, UK: Edward Elgar Publishing Limited 2000), 223–270. http://dspace.library.uu.nl/bitstream/handle/1874/19806/hertog_99_generaltheoriesofregulation.pdf?sequence=1.

other influences.[73] Johan den Hertog took the term regulation to "mean the employment of legal instruments for the implementation of social-economic policy objectives."[74]

A more general conceptualization of regulation is that regulation is a rule or set of rules designed to restrict bad behavior and/or promote good behavior.[75] However, to promote good behavior or restrict bad behavior, the entity responsible for promotion or restriction must know what good and bad behavior looks like.[76] The underlying assumption of this knowledge is that the regulating authority knows how the technology will develop and how it will be used; however, it is very difficult to accurately predict how a technology will develop and how it will be used. Therefore, it is difficult to determine precisely what good and bad behavior looks like without knowing exactly how this technology will develop in the future.

Baldwin, Cave, and Lodge identified 13 primary reasons for regulation, including

> monopolies and natural monopolies, windfall profits [when a firm receives supply source drastically cheaper than available to competitors], externalities [the price of a product does not factor in the true cost to society—excessive pollution in manufacturing process etc.], information inadequacies [consumers lack adequate information to make informed decisions], continuity and availability of service, anti-competitive and predatory pricing behavior, public good and moral hazard, unequal bargaining power, scarcity and rationing, rationalization and coordination.[77]

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[73] Baldwin, Cave, and Lodge, *Understanding Regulation*, 23.

[74] den Hertog, "General Theories of Regulation."

[75] Nieto Gomez, "No Bad Deed Goes Unrewarded."

[76] Ibid.

[77] Baldwin, Cave, and Lodge, *Understanding Regulation*, 24.

Additionally, Baldwin, Cave, and Lodge identify five key characteristics of good regulation: 1) the regulating body has sufficient legal authority to regulate; 2) accountability for regulating body and regulated firms; 3) due process is observed; 4) the regulating body has expertise in the field they are regulating; and 5) the process is efficient.[78]

Regulators have the difficult task to diminish the possibility of damage or injury to citizens, while simultaneously not restricting useful products or services. As Malcolm Sparrow puts it in *The Regulatory Craft: Controlling Risks, Solving Problems, and Managing Compliance*,

> Regulators, under unprecedented pressure, face a range of demands, often contradictory in nature: be less intrusive—but be more effective; be kinder and gentler—but don't let the bastards get away with anything; focus your efforts—but be consistent; process things quicker—and be more careful next time; deal with important issues—but do not stray outside your statutory authority; be more responsive to the regulated community—but do not get captured by industry.[79]

The Organisation for Economic Co-operation and Development (OECD) (an intergovernmental economic organization with 35 member countries), has identified four integral pieces to the regulation puzzle, as depicted in Figure 7.[80] These and other principles of regulation are in the document *Principles for the Governance of Regulators*, which was discussed at the November 21, 2012 informal meeting of the Ad Hoc Network of Economic Regulators at the OECD, Paris and also at the April 22–23, 2013 meeting of the Regulatory Policy Committee at the OECD, Paris.[81]

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78 Ibid., 27.

79 Malcolm Sparrow, *The Regulatory Craft: Controlling Risks, Solving Problems, and Managing Compliance* (Washington, DC: Brookings Institution Press, 2000), 17.

80 "About," Organisation for Economic Co-operation and Development, accessed November 5, 2017, from http://www.oecd.org/about/.

81 Organisation for Economic Co-operation and Development, *The Governance of Regulators* (Paris: Organisation for Economic Co-operation and Development, 2014), http://www.keepeek.com/Digital-Asset-Management/oecd/governance/the-governance-of-regulators_9789264209015-en#page3.

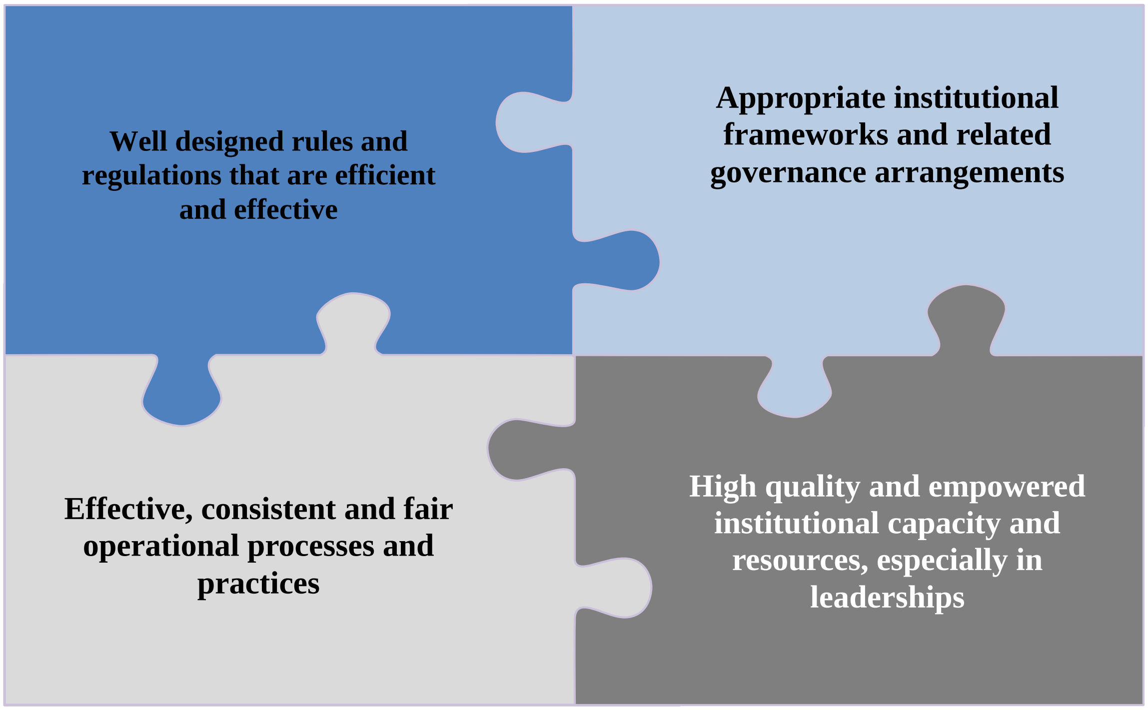

Figure 7. Necessary Elements of Better Regulatory Outcomes[82]

There is little consensus across scholars of regulation as to even fundamental issues such as what regulation is, and much of the literature is based on often unproven hypotheses and theories. However, these theories often have value in explaining potential regulatory framework for nanotechnology as they show pitfalls in the regulatory process but do not offer conclusive evidence as to the best way to guard against these pitfalls.

In their article "A Small Matter of Regulation: An International Review of Nanotechnology Regulation," Diana M. Bowman and Graeme A. Hodge provide an overview of domestic and international regulatory frameworks for nanotechnology. They conclude "regulatory discussion, debate and development will grow on six frontiers—product safety, privacy and civil liberties, occupational health and safety, intellectual property, international law and environmental law" and that "existing regulatory

[82] Source: Organisation for Economic Co-operation and Development, *The Governance of Regulators*.

frameworks will form the immediate basis for regulating nanotechnologies."[83] However, they also state, "there have been no nanotechnology specific regulatory responses thus far. As a result, a range of serious regulatory fissures are now emerging."[84] They argue that nanotechnology will likely follow the same regulatory path of genetically modified organisms: product based in the United States and process based throughout the European Union countries.[85] Additionally, the authors believe this nanotechnology regulation will be undertaken in "a careful and targeted approach in the short to medium term rather than anything more comprehensive," but they caution that the approach could change rapidly given an "industrial accident involving nano-particles and the knee-jerk regulatory reaction that would probably follow."[86]

Alternatively, in an article for the *Harvard Journal of Law and Technology*, Glenn Harlan Reynolds identified three possible futures for nanotechnology regulation. The first possible "future" he names "Relinquishment and Prohibition."[87] Reynolds submits that with any technology that brings radical change there will be calls for prohibition of further research, but acknowledges this scenario is highly unlikely due to the vast applications for nanotechnology.[88] The second possible future is one in which nanotechnology research is restricted to the military sphere. Reynolds suggests that due to the high stakes involved, the U.S. government may pursue a policy of classification. He points out that many new technologies, from high-yield explosives to atomic energy, have been developed under high classification, which has made private research extremely difficult and nested largely within government research facilities or under government contracts.[89] The third possible future Reynolds suggests is one of "Modest Regulation and Robust Civilian Research." He

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[83] Diana M. Bowman and Graeme A. Hodge, "A Small Matter of Regulation: An International Review of Nanotechnology Regulation," *The Columbia Science and Technology Law Review* 8 (2007): 35, http://stlr.org/download/volumes/volume8/bowman.pdf.

[84] Ibid.

[85] Ibid.

[86] Ibid.

[87] Ibid.

[88] Glenn Harlan Reynolds, "Nanotechnology and Regulatory Policy: Three Futures," *Harvard Journal of Law and Technology* 17 (2003): 188.

[89] Ibid.

offers the field of biotechnology as a model for what nanotechnology regulation could/ should be: one of minimally intrusive regulation focused on safety concerns that allows for major civilian investment and research. Reynolds states, “As one might expect, this approach is championed by those who believe the benefits of nanotechnology justify development in the field.”[90]

As articulated in a joint memorandum from the director of the Office of Science and Technology Policy, the administrator for the Office of Information and Regulatory Affairs Office of Management and Budget, and the Chief Agricultural Negotiator Office of the United States Trade sent to the heads of executive departments and agencies of the U.S. government, the current U.S. government policy has been to temper concerns over the possible harmful effects of the technology as it has not been definitively proven these concerns are founded in reality.[91] Also, the memorandum postulates that existing regulatory statutes provide an adequate framework for regulation and oversight of nanomaterials. This *laissez-faire* approach may be the best approach to regulation, but many also fear it leaves the United States vulnerable as existing regulations do not adequately address the unique properties of engineered nanomaterials.

In his book *Nanotechnology Regulation and Policy Worldwide*, attorney Jeffrey Matsuura states,

> At present [2006] regulatory authorities simply do not know the full scope consequences associated with the ever-expanding range of nanotechnology uses…. Instead, governments should display confidence in their existing regulatory systems by relying on those rules and processes to oversee the ongoing introduction of nanotechnology into additional commercial applications.[92]

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90 Ibid.

91 John H. Marburger, III and James J. Connaughton, *Memorandum for the Heads of Executive Departments and Agencies* (Washington, DC: Executive office of the President, 2007), http://nanotech.law.asu.edu/Documents/2009/07/Michael%20Vincent%20%28OSTP%29%202007,%20Principles%20for%20Oversight_173_4135.pdf.

92 Jeffrey H. Matsuura, *Nanotechnology Regulation and Policy Worldwide* (Norwood, MA: Artech House, Inc., 2006), 4.

Conversely, in their book *Nanotechnology and Homeland Security: New Weapons for New Wars*, Daniel Ratner and Mark Ratner state,

> We [the United States] need an FNA (Federal Nanotechnology Agency) to complement the tremendous development efforts of the National Nanotechnology Initiative with appropriate regulation, policy advice, product approval, and monitoring. This agency should undertake development, adoption, and enforcement of statutory and regulatory aspects of nanotechnology and associated advanced technologies.[93]

This approach offers a framework similar to the aviation industry in which a single agency (the Federal Aviation Administration) serves as the regulating entity for the entire field; if it flies, regulatory responsibility is nested within the FAA. This single entity solution is problematic for nanotechnology in that this technology crosses so many disparate sectors of society, but it would be difficult and extremely costly for a new agency to build up the institutional knowledge to address the many regulatory challenges nanotechnology presents.

B. LEGISLATIVE SPACE

The next step to understanding the regulatory landscape of nanotechnology is to examine laws that have been passed. Despite fears that U.S. policymakers may not be giving nanotechnology enough legislative attention, many government officials have indeed recognized the need to address nanotechnology. Since 1999, 185 pieces of legislation either directly or indirectly relating to nanotechnology have been introduced to Congress; however, most of this legislation never passed committee consideration, let alone made it to a congressional vote.[94] This section highlights the legislation that has been passed into law. This legislation is focused primarily on funding research, rather than regulation or rules for industry.

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93 Mark A. Ratner and Daniel Ratner, *Nanotechnology and Homeland Security: New Weapons for New Wars* (Upper Saddle River, NJ: Prentice Hall, 2004), 132.

94 “Nanotechnology,” Congress, accessed July 4, 2017, https://www.congress.gov/search?q={“source”:”legislation”,”search”:”nanotechnology”}&searchResultViewType=expanded&page=1.

1. Agriculture Risk Protection Act of 2000

Section 221 of the Carbon Cycle Research of the Agriculture Risk Protection Act of 2000 granted $15,000,000 to the Consortium for Agricultural Soils Mitigation of Greenhouse Gases, which is comprised of scientists from several institutions, to develop, analyze, and implement carbon cycle research at the national, regional, and local levels.[95] Among other things, the funds were to be used to "conduct research to improve the scientific basis of using land management practices to increase soil carbon sequestration, including research on the use of new technologies to increase carbon cycle effectiveness, such as biotechnology and nanotechnology."[96]

2. Consolidated Appropriations Act of 2001

Section 314 of the Consolidated Appropriations Act of 2001 made available $3 million to the Marine Corps to pursue nanotechnology research related to consequence management.[97] According to the *Air and Space Power Journal*, consequence management is defined as "those individual and organizational activities directed at halting the progress of disease or limiting the damage caused by injury and reducing the long-term social disability produced by any residual impairment."[98] Consequence management is used primarily in a chemical, biological, radiological, nuclear, and explosives environment.

3. National Science Foundation Authorization Act of 2002

The National Science Foundation Act of 2002 appropriated $301 million dollars of the NSF budget for nanoscale science and engineering research and education programs.[99]

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[95] Agriculture Risk Protection Act of 2000, Pub. Law. No. 106-224 (2000), https://www.congress.gov/106/plaws/publ224/PLAW-106publ224.pdf.

[96] Ibid.

[97] Consolidated Appropriations Act, 2001, Pub. Law No. 106-554 (2000), https://www.congress.gov/106/plaws/publ554/PLAW-106publ554.pdf.

[98] Anthony P. Tvaryanas, Lex Brown, and Nita L. Miller, "Managing the Human Weapon System: A Vision for an Air Force Human-Performance Doctrine," *The Air and Space Journal* 23, no. 2 (2009): 34–40, http://www.airuniversity.af.mil/Portals/10/ASPJ/journals/Volume-23_Issue-1-4/2009_Vol23_No2.pdf.

[99] National Science Foundation Authorization Act of 2002, Pub. Law No. 107-368 (2002), https://www.congress.gov/107/plaws/publ368/PLAW-107publ368.pdf.

This act marks the first time NSF funds were specifically appropriated for nanoscale research. This appropriation was to support

> (A) research aimed at discovering novel phenomena, processes, materials, and tools that address grand challenges in materials, electronics, optoelectronics and magnetics, manufacturing, the environment, and health care; and (B) supporting new research and interdisciplinary centers and networks of excellence, including shared national user facilities, infrastructure, research, and education activities on the societal implications of advances in nanoscale science and engineering.[100]

4. Bob Stump National Defense Authorization Act of 2003

Congress established the Defense Nanotechnology Research and Development Program under § 246 of the Bob Stump National Defense Authorization Act of 2003. The purposes of the program are to

> 1) Ensure United States global superiority in nanotechnology necessary for meeting national security requirements. (2) To coordinate all nanoscale research and development within the Department of Defense, and to provide for interagency cooperation and collaboration on nanoscale research and development between the Department of Defense and other departments and agencies of the United States that are involved in nanoscale research and development. (3) To develop and manage a portfolio of fundamental and applied nanoscience and engineering research initiatives that is stable, consistent, and balanced across scientific disciplines. (4) To accelerate the transition and deployment of technologies and concepts derived from nanoscale research and development into the Armed Forces, and to establish policies, procedures, and standards for measuring the success of such efforts. (5) To collect, synthesize, and disseminate critical information on nanoscale research and development.[101]

Section 240 of the fiscal year (FY) 2008 National Defense Authorization Act expanded the administration and reporting requirements and § 242 of the FY 2010 National Defense Act

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[100] Ibid.

[101] Bob Stump National Defense Authorization Act of 2003, Pub. Law No. 107-314 (2002), https://www.gpo.gov/fdsys/pkg/PLAW-107publ314/pdf/PLAW-107publ314.pdf.

modified of reporting requirements associated with the Defense Nanotechnology Research and Development Program.[102]

5. 21st Century Nanotechnology Research and Development Act of 2003

As early as November 1996, representatives from several agencies that would later comprise the National Nanotechnology Initiative (NNI) began having regular meetings to discuss their agency's nanotechnology plans and programs.[103] In September 1998, this informal group became the Interagency Working Group on Nanotechnology (IWGN) under the National Science and Technology Council (NSTC) to formalize this ongoing interagency dialogue.[104]

As an outgrowth of this working group, the Clinton administration founded the NNI in January 2000.[105] Congress approved funding for the NNI in 2001, and NNI has continued receiving bipartisan support from both the White House and Congress.[106] As the NNI was commencing, the NSTC established the Nanoscale Science, Engineering and Technology (NSET) Subcommittee to replace IWGN. The NSET subcommittee coordinates planning, budgeting, program implementation, and review of the NNI, and it is comprised of representatives from the following 20 federal departments (see Table 3).[107]

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102 National Defense Authorization Act for Fiscal Year 2008, Pub. Law No. 110-477 (2008), https://www.gpo.gov/fdsys/pkg/CRPT-110hrpt477/pdf/CRPT-110hrpt477.pdf; National Defense Authorization Act for Fiscal Year 2010, Pub. Law No. 111-84 (2009), https://www.gpo.gov/fdsys/pkg/PLAW-111publ84/pdf/PLAW-111publ84.pdf.

103 National Research Council, *Preliminary Comments, Review of the National Nanotechnology Initiative* (Washington, DC: National Academies Press, 2001), https://doi.org/10.17226/10216, 1.

104 "Coordination of the NNI," National Nanotechnology Initiative, accessed July 13, 2017, https://www.nano.gov/about-nni/what/coordination; National Research Council, "A Review of the National Nanotechnology Initiative," in *Matter of Size: Triennial Review of the National Nanotechnology Initiative* (Washington DC: National Academies Press, 2006), https://www.nap.edu/read/11752/chapter/3#17, 17.

105 "Nanotechnology Timeline," National Nanotechnology Initiative, accessed December 30, 2017, https://www.nano.gov/timeline.

106 Ibid.

107 "The NSET Subcommittee," National Nanotechnology Initiative, accessed July 13, 2017, https://www.nano.gov/nset.

Table 3. NSET Subcommittee Member Organizations[108]

• Office of Science and Technology Policy • Office of Management and Budget • Consumer Product Safety Commission • Department of Commerce • Department of Defense • Department of Education • Department of Energy • Department of Health and Human Services • Department of Homeland Security • Department of the Interior • Department of Justice	• Department of Labor • Department of State • Department of Transportation • Department of the Treasury • Environmental Protection Agency • Intelligence Community • National Aeronautics and Space Administration • National Science Foundation, Nuclear Regulatory Commission • U.S. Department of Agriculture, U.S. International Trade Commission

In 2003, Congress passed the 21st Century Nanotechnology Research and Development Act, and President George W. Bush signed it into law.[109] This law placed the NNI on solid footing requiring, among many other things, the president to implement the National Nanotechnology Program. The law states this program's activities are to include the following:

> (1) developing a fundamental understanding of matter that enables control and manipulation at the nanoscale; (2) providing grants to individual investigators and interdisciplinary teams of investigators; (3) establishing a network of advanced technology user facilities and centers; (4) establishing, on a merit-reviewed and competitive basis, interdisciplinary nanotechnology research centers;…(5) ensuring United States global leadership in the development and application of nanotechnology; (6) advancing the United States productivity and industrial competitiveness through stable, consistent, and coordinated investments in long-term scientific and engineering research in nanotechnology; (7) accelerating the deployment and application of nanotechnology research and development in the private sector, including startup companies; (8) encouraging interdisciplinary research, and ensuring that processes for solicitation and evaluation of proposals under the Program encourage interdisciplinary

108 Adapted from: "The NSET Subcommittee," National Nanotechnology Initiative.

109 "Coordination of the NNI," National Nanotechnology Initiative, accessed July 13, 2017, https://www.nano.gov/about-nni/what/coordination

> projects and collaborations; (9) providing effective education and training for researchers and professionals skilled in the interdisciplinary perspectives necessary for nanotechnology so that a true interdisciplinary research culture for nanoscale science, engineering, and technology can emerge; (10) ensuring that ethical, legal, environmental, and other appropriate societal concerns, including the potential use of nanotechnology in enhancing human intelligence and in developing artificial intelligence which exceeds human capacity, are considered during the development of nanotechnology;…(11) encouraging research on nanotechnology advances that utilize existing processes and technologies.[110]

The law also mandates the president form the National Nanotechnology Coordination Office and the National Nanotechnology Advisory Panel comprised of leaders from academia and private industry to provide advice to the president and council members and establishes guidelines for a triennial review of the program.[111] Also according the law, the panel will assess and report

> 1) trends and developments in nanotechnology science and engineering; (2) progress made in implementing the Program; (3) the need to revise the Program; (4) the balance among the components of the Program, including funding levels for the program component areas; (5) whether the program component areas, priorities, and technical goals developed by the Council are helping to maintain United States leadership in nanotechnology; (6) the management, coordination, implementation, and activities of the Program; and (7) whether societal, ethical, legal, environmental, and workforce concerns are adequately addressed by the Program.[112]

6. Consolidated and Further Continuing Appropriations Act of 2015

Under the Consolidated and Further Continuing Appropriations Act of 2015 Title VII, Revitalize American Manufacturing and Innovation Act of 2014, Congress established the Network for Manufacturing Innovation Program.[113] This program includes Centers for Manufacturing Innovation. These centers

> focus on a manufacturing process, novel material, enabling technology, supply chain integration methodology, or another relevant aspect of

110 "21st Century Nanotechnology Research and Development Act."

111 Ibid.

112 Ibid.

113 Consolidated and Further Continuing Appropriations Act of 2015, Pub. Law N. 113-235 (2014), https://www.congress.gov/113/plaws/publ235/PLAW-113publ235.pdf.

> advanced manufacturing, such as nanotechnology applications…[and also include] active participation among representatives from multiple industrial entities, research universities, community colleges, and such other entities… [to improve the competitiveness of] United States manufacturing, including key advanced manufacturing technologies such as nanotechnology.[114]

C. LEGISLATIVE ANALYSIS

This review of the major legislative acts passed related to nanotechnology reveals the priority of the U.S. government thus far has been to promote and provide funding for the research and development of nanotechnology. There has been very little legislative effort on the regulation of nanotechnology. In fact, no laws have been passed that directly affect nanotechnology regulation. Perhaps this approach is the right one to take for emerging technologies; however, it does leave room to question whether this approach has allowed nanotechnology to develop in a bit of an oversight blind spot. This blind spot is caused by the lack of accumulated research to determine the safety of these nanomaterials. As nanotechnology proliferation within consumer products expands, a growing number of people are exposed to nanomaterials while society still does not yet completely understand the risks.

Despite these concerns, this author does not recommend regulation through legislation as a solution for a regulatory framework because regulation through legislation is nearly always a hindsight 20/20 exercise. This means regulation through legislative action comes as a reaction to the discovery of a major risk or after a calamity. For instance, it is easy to see the oversight and regulation failures in the asbestos industry now; it was not so easy to parse out this deficiency when companies used asbestos in nearly all new construction. Because legislation on regulation usually only passes as a reaction to a calamitous event or overwhelming evidence, it is not be viewed as a viable element of the regulatory framework recommended by this thesis.

The area legislators have done well in is providing funding for many areas of nanotechnology research. This thesis recommends this attention to nanotechnology

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114 Ibid.

research be continued. Further research is vital to understanding the risks of the technology and leveraging the technology's benefits to further U.S. interests. Much of this research is not possible without approved funding.

IV. FEDERAL STAKEHOLDERS

The next pillar comes from the stakeholder analysis of federal stakeholders. As we examine each agency in relation to its mission and nanotechnology stakeholder status, we categorize each agency using the stakeholder analysis matrix mapped according to Mendelow's power-interest grid and place them on the matrix shown in Figure 8.[115] This section is important because it reveals which agencies are best suited to be a part of the recommendations for a regulatory framework for nanotechnology. This analysis also demonstrates the revolutionary nature of nanotechnology by showing the broad array of agencies with expressed interest in the technology. Additionally, it shows which agencies may seek to have a voice in the discussion of nanotechnology regulation based on each agency's expressed interest in the technology.

The stakeholder matrix is a broad overview of stakeholders grouped together based on their attributes, their interest in nanotechnology regulation, and their power to act on that interest. The matrix seeks only to broadly categorize agencies or groups. Within each group, there will obviously be individual agencies or persons who fall in different quadrants of the matrix. This stakeholder matrix is not meant to represent a qualitative analysis; that is, it does not intend to say whether each agency should be more or less interested or involved in the regulation of nanotechnology. Rather the goal is to show each agency's demonstrated interest and their corresponding power to enact or influence regulation. This chapter is organized into four sections, and each section represents one of the four quadrants of the power-interest grid.

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[115] Aubrey L. Mendelow, "Environmental Scanning—The Impact of the Stakeholder Concept," *ICIS 1981 Proceedings* 20 (1981): 407–418, https://pdfs.semanticscholar.org/3579/ca37344c69961bbc2468ef9addf212200e39.pdf.

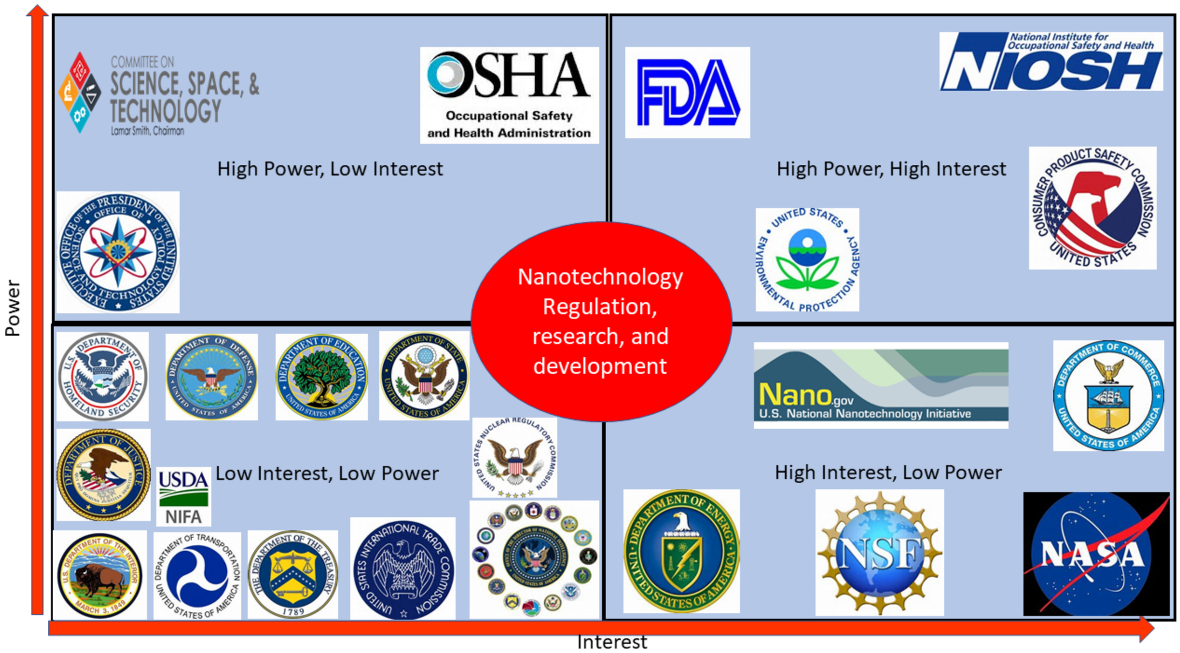

Figure 8. Nanotechnology Regulation Stakeholder Analysis Matrix Mapped According to Mendelow's Power-interest Grid[116]

A. HIGH POWER, HIGH INTEREST

The high power, high interest quadrant consists of those agencies with both a regulatory role that gives them the power to enact and enforce regulation (high power) and a demonstrated interest in nanotechnology regulation (high interest). This section summarizes those agencies that fall in the high power, high interest quadrant.

1. Environmental Protection Agency

The mission of the EPA "is to protect human health and the environment."[117] The EPA's purpose is to ensure Americans are free from significant environmental risks by utilizing the most current scientific data to create regulation that aligns with its mission to "protect human health and the environment."[118] The EPA also seeks to ensure these laws

116 Adapted from: "Environmental Scanning," 412; see appendix for sources within image.

117 "Our Mission and What We Do," Environmental Protection Agency, accessed April 29, 2017, https://www.epa.gov/aboutepa/our-mission-and-what-we-do.

118 Ibid.

are enacted justly to all citizens and communities and promote the United States' leadership role in global environmental protection.[119] Pursuant to this mission, the EPA has sought to understand nanoscale materials and institute precautionary regulation. Thus, the EPA is a vital stakeholder for inclusion in any discussion of nanotechnology regulation.

The EPA has long been at the forefront of nanotechnology regulation. The EPA's regulatory approach to nanotechnology has been to leverage its authority granted under the Toxic Substances Control Act of 1976.[120] Under this authority, the EPA requires "manufacturers of new chemical substances to provide specific information to the Agency for review prior to manufacturing chemicals or introducing them into commerce."[121] This requirement allows the EPA to determine whether the new nanomaterials represent a substantial threat to humans or the environment. The EPA has considered more than 160 notices for nanoscale materials since 2005.[122] Additionally, the EPA issued an "information gathering rule" requiring reporting and subsequent recordkeeping on exposures and any other health or safety related observations regarding commercialized nanoscale chemical substances.[123] Under this rule, companies engaging in the manufacture, import, or processing of identified chemical substances commercialized as nanoscale materials must notify the EPA of the following information: "specific chemical identity; production volume; methods of manufacture; processing, use, exposure and release information; and available health and safety data."[124] Despite these efforts, the EPA has come under fire for allegedly failing to adequately address nanotechnology concerns.

The debate over nanoscale silver particles is a good example of the tension that arises over nanotechnology regulation. It is believed that as early as 400 B.C., Hippocrates

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119 Ibid.

120 "Control of Nanoscale Materials under the Toxic Substances Control Act," Environmental Protection Agency, accessed June17, 2017, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under.

121 Ibid.

122 Ibid.

123 Ibid.

124 Ibid.

noted the healing properties of silver.[125] And the EPA has long recognized silver as an effective biocide.[126] However, since the development of the silver nanoparticle, companies have sought to leverage these biocidal properties by incorporating nanosilver particles into more than 250 products.[127] This widespread proliferation has caused continuing concern among many nonprofit organizations as the long-term effects of this new technology has not been fully investigated or understood.[128]

In 2008, the Center for Food Safety (CFS), in coalition with many concerned non-profit organizations, filed a legal petition calling for the EPA to take swift and decisive action to regulate novel nanomaterial pesticides. Specifically, the action the CFS demanded of the EPA included classifying *all* products containing nanoscale silver particles as pesticides.[129] If classified as pesticides, all products containing nanosilver particles would be subject to the rules of the Federal Insecticide, Fungicide, and Rodenticide Act. This stringent classification would significantly slow the rate of proliferation of nanosilver particles in new products and would likely cause the removal of these particles from existing products. The EPA did not immediately respond to this petition.

In December of 2014, the CFS filed a lawsuit against the EPA claiming the agency failed to answer its petition, and that "the proliferation of nanomaterials in consumer

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[125] Lynn E. Bergeson, "Nanosilver: EPA's Pesticide Office Considers How Best to Proceed," *Environmental Quality Management* 19 no. 3 (2010): 79–85, http://www.lawbc.com/uploads/docs/00069981.pdf.

[126] Amro El-Badawy, David Feldhake, and Raghuraman Venkatapathy, *State-Of-The-Science Review: Everything NanoSilver and More* (EPA/600/R-10/084) (Washington, DC: U.S. Environmental Protection Agency, 2010), https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=226785&fed_org_id=770&SIType=PR&TIMSType=Published+Report&showCriteria=0&address=nerl/pubs.html&view=citation&sortBy=pubDateYear&count=100&dateBeginPublishedPresented=01/01/2010.

[127] "Nano-Silver Products Inventory," Beyond Pesticides, accessed June 17, 2017, http://www.beyondpesticides.org/assets/media/documents/antibacterial/nano-silver_product_inventory.pdf.

[128] "Nanosilver," Beyond Pesticides, accessed June 17, 2017, http://www.beyondpesticides.org/programs/antibacterials/nanosilver.

[129] Jack E. Housenger, *EPA Response to 'Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides* [memorandum to petitioners] (Washington, DC: Environmental Protection Agency, Office of Pesticide Programs, 2015), http://www.centerforfoodsafety.org/files/epa_nanosilver_2015_03_19_icta_petition_response_10041.pdf.

products continues unabated."[130] In addition to the CFS, other plaintiffs included the Center for Environmental Health, the International Center for Technology Assessment, Beyond Pesticides, Clean Production Action, and the Institute for Agriculture and Trade Policy.[131] In a statement in December 2014, senior CFS attorney George Kimbrell criticized the EPA stating, "Six years ago we provided EPA a legal and scientific blue print to address to regulate these novel materials under its pesticide authority. The agency's unlawful and irresponsible delay ends now."[132]

In March of 2015, the EPA responded to the CFS petition, only partially granting its requests.[133] The EPA Office of Chemical Safety and Pollution Prevention noted that several agencies have joined the debate: American Chemistry Council, Crop Life America, the Environmental Defense Fund, the Copper Development Association, the National Association of Clean Water Agencies, Natural-Immunogenics Corporation, Purest Colloids, and several other concerned citizens and field experts.[134] Each of these parties has offered a different viewpoint on how exactly the EPA should address the issue of classification and regulation of nanosilver particles. The EPA acknowledges that products containing nanosilver particles designed to be used as pesticides, as defined by the EPA and FIFRA, are indeed subject to these laws and regulatory controls; however, it explained in 2015, "The EPA does not have the foundation to classify all nanosilver ingredients or products containing nanosilver as pesticides."[135]

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130 "Nonprofits Sue EPA for Failure to Regulate Novel Pesticide Products Created with Nanotechnology," press release, Center for Food Safety, December 17, 2014, http://www.centerforfoodsafety.org/press-releases/3664/nonprofits-sue-epa-for-failure-to-regulate-novel-pesticide-products-created-with-nanotechnology#.

131 "EPA Agrees to Regulate Novel Nanotechnology Pesticides After Legal Challenge," press release, Center for Food Safety, March 24, 2015, http://www.centerforfoodsafety.org/press-releases/3817/epa-agrees-to-regulate-novel-nanotechnology-pesticides-after-legal-challenge#.

132 "Nonprofits Sue EPA for Failure to Regulate Novel Pesticide Products Created with Nanotechnology," press release, Center for Food Safety, December 17, 2014, http://www.centerforfoodsafety.org/press-releases/3664/nonprofits-sue-epa-for-failure-to-regulate-novel-pesticide-products-created-with-nanotechnology#.

133 Housenger, *EPA Response to 'Petition.'*

134 Ibid.

135 Ibid.

As a result of this decision, the EPA ordered Nano Defense Solutions, Inc. in Saint Augustine, Florida to discontinue the sale of two pesticidal products: "BioStorm" and "NanoStrike."[136] These products both listed nanosilver particles in the active ingredients list and made claims these pesticides were extremely successful at countering various microbial pests, such as "bacteria, viruses, fungi, algae and yeasts."[137] The company subsequently pulled these products off the market.

The EPA has a difficult responsibility to protect citizens' health and minimize environmental impacts, while at the same time not imposing such restrictions as would unduly stifle innovation and industry growth. In this case, the EPA ruled in a reasonable manner, restricting only those companies whose products use nanosilver as a pesticide to be held to the standards put forth in the FIFRA. However, groups such as the CFS, the Natural Resources Defense Council, and the International Center for Technology Assessment continue to bring lawsuits concerning regulation of nanotechnology against the EPA.

The EPA is one of the few agencies that has addressed nanotechnology regulation in a direct way. It also has the regulatory power and infrastructure to put in place and enforce regulation as it has already done on a small scale. Therefore, it falls in the high power, high interest quadrant of the matrix from Figure 8.

2. National Institute for Occupational Safety and Health

The Occupational Safety and Health Act of 1970, which created the Occupational Safety and Health Administration (OSHA), also created the National Institute for Occupational Safety and Health (NIOSH). NIOSH is a research agency focused on occupational safety and health and devoted to developing new knowledge in this field and transferring this knowledge into practice by empowering employers and employees to

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[136] "EPA Takes Action to Protect the Public from an Unregistered Pesticide / EPA Issues Order to Stop the Sale of BioStorm and NanoStrike," press release, Environmental Protection Agency, April 4, 2015, https://archive.epa.gov/epa/newsreleases/epa-takes-action-protect-public-unregistered-pesticideepa-issues-order-stop-sale.html.

[137] Ibid.

create safe and healthy workplaces.[138] In 2004, recognizing the rapid growth of the nanotechnology industry and seeing the potential for exponential future growth, NIOSH created the Nanotechnology Research Center (NTRC) to "identify critical issues, create a strategic plan for investigating these issues, coordinate the NIOSH research effort, develop research partnerships, and disseminate information gained."[139]

The NTRC has developed partnerships throughout industry, professional organizations, trade associations, other federal agencies, labor, and academia.[140] Through research conducted by NTRC and input from partner groups, NIOSH pinpointed 10 crucial topics to focus research and recommendations on; they are

- Toxicity and internal dose
- Risk assessment
- Epidemiology and surveillance
- Engineering controls and personal protective equipment
- Measurement methods
- Exposure assessment
- Fire and explosion safety
- Recommendations and guidance
- Global collaborations
- Applications[141]

Despite extensive research efforts, NIOSH's findings thus far are inconclusive and suggest significant research is still required to understand the impact of nanotechnology and nanoengineered materials on human health. Until more conclusive data is available,

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138 "About NIOSH," Center for Disease Control and Prevention, last updated June 15, 2016, https://www.cdc.gov/niosh/about/.

139 "Nanotechnology at NIOSH," Center for Disease Control and Prevention, last updated November 16, 2016, https://www.cdc.gov/niosh/topics/nanotech/nanotechnology-research-center.html.

140 "Nanotechnology Research Center—Program Description," Center for Disease Control and Prevention, last modified November 15, 2017, https://www.cdc.gov/niosh/programs/nano/description.html.

141 Nanotechnology: 10 Critical Topic Areas," Center for Disease Control and Prevention, last updated September 22, 2010, https://www.cdc.gov/niosh/topics/nanotech/critical.html.

NIOSH cannot confidently make reasonable determinations regarding appropriate exposure monitoring and control strategies.[142] As of November 2016, the NTRC maintains this cautionary stance, as evidenced by the Centers for Disease Control and Prevention's statement that,, "the limited evidence available suggests caution when potential exposures to free–unbound nanoparticles may occur."[143]

The NTRC's stance once again highlights the difficulty in determining whether an actual threat exists. Currently, the lack of conclusive evidence leads to cautious advancement of the industry with relatively little government oversight and specific worker protections, as it cannot be said for certain that precautions or protections are even necessary. The NTRC remains at the forefront of research endeavors seeking answers to whether exposure to nanoengineered materials actually poses any health risks. The problem then arises that the first indication of risk might come in the form of irreversible damage to workers and the environment.

Based on its creation of the NTRC and its stance on nanotechnology, it is clear NIOSH falls into the high power, high interest quadrant. It believes more research is necessary before taking action but appears to stand ready to make regulatory decisions quickly once and if the research indicates there is a threat.

3. U.S. Food and Drug Administration

The U.S. Food and Drug Administration (FDA) "is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation."[144] In its regulatory function, the FDA is accustomed to the challenges associated with balancing the frequently volatile

142 "Nanotechnology Research Center—Program Description."

143 Ibid.

144 "About FDA," Food and Drug Administration, last updated April 4, 2017, https://www.fda.gov/AboutFDA/WhatWeDo/default.htm.

"combination of promise, risk, and uncertainty that accompanies emerging technologies."[145]

The FDA concedes it does not have a legal definition for nanotechnology; rather, it adheres to the general scientific size consensus as the dimensions between 1–100 nanometers when referencing nanotechnology.[146] Despite definitional irregularities, the FDA's regulatory approach to nanotechnology follows a similar path to the one it has followed when dealing with other emerging technologies. This approach recognizes both the novel behaviors and unique properties that nanomaterials exhibit as differing from bulk material or products manufactured using traditional methods; however, the FDA does not broadly deem all products containing nanoengineered materials to be inherently dangerous or benign.[147] According to the FDA, "The Agency is taking a prudent scientific approach to assess each product on its own merits, and does not make broad, general assumptions about the safety of nanotechnology products."[148]

The FDA's approach to nanotechnology regulation is to utilize existing statutory authorities in accordance with applicable standards within each product type.[149] According to the FDA, this regulatory approach has the following attributes:

- FDA is maintaining its product-focused, science-based regulatory policy.
- FDA's approach respects variations in legal standards for different product-classes.
- Where premarket review authority exists, attention to nanomaterials is being incorporated into standing procedures.

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[145] "FDA's Approach to Regulation of Nanotechnology Products," Food and Drug Administration, last updated December 15, 2017, https://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm301114.htm.

[146] "Nanotechnology," Food and Drug Administration, last updated November 25, 2017, https://www.fda.gov/cosmetics/scienceresearch/nanotech/default.htm.

[147] "FDA's Approach to Regulation of Nanotechnology Products," Food and Drug Administration, last updated December 15, 2017, https://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm301114.htm.

[148] "Nanotechnology Fact Sheet," Food and Drug Administration, last modified August 5, 2015, https://www.fda.gov/scienceresearch/specialtopics/nanotechnology/ucm402230.htm.

[149] "FDA's Approach to Regulation of Nanotechnology Products."

- Where statutory authority does not provide for premarket review, consultation is encouraged to reduce the risk of unintended harm to human or animal health.
- FDA will continue post-market monitoring. FDA will continue to monitor the marketplace for products containing nanomaterials and will take actions, as needed, to protect consumers.
- Industry remains responsible for ensuring that its products meet all applicable legal requirements, including safety standards.
- FDA will collaborate, as appropriate, with domestic and international counterparts on regulatory policy issues.
- Both for products that are not subject to premarket review and those that are, FDA will offer technical advice and guidance, as needed, to help industry meet its regulatory and statutory obligations.[150]

The FDA has communicated its nanotechnology regulatory posture through a series of guidances issued for industry. In June 2011, the FDA issued the draft guidance titled, "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology." This guidance details the FDA's overall strategic framework to handle nanotechnology regulation in a product-specific manner.[151] The FDA addressed the use of nanotechnology in the cosmetics and food industries through a draft guidance released for public comment in April 2012. After a period of public comment, the FDA considered these comments and issued the final three guidance documents in June 2014. In August 2015, the agency issued a fourth guidance regarding the use of nanomaterials in food for animals. As stated on the FDA website, these final four guidances are:

- Final Guidance for Industry: considering whether an FDA-regulated product involves the application of nanotechnology
- Final Guidance for Industry: safety of nanomaterials in cosmetic products

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[150] Ibid.

[151] "Nanotechnology Fact Sheet," Food and Drug Administration, last modified August 5, 2015, https://www.fda.gov/scienceresearch/specialtopics/nanotechnology/ucm402230.htm.

- Final Guidance for Industry: assessing the effects of significant manufacturing process changes, including emerging technologies, on the safety and regulatory status of food ingredients and food contact substances, including food ingredients that are color additives
- Final Guidance for Industry: use of nanomaterials in food for animals.[152]

Rather than listening to the extremes from both sides of the nanotechnology regulation argument, the FDA has taken measured steps to fulfill its mission to protect the public from harmful products.

Similar to NIOSH, the FDA has taken the stance that more research is necessary before taking action, but it appears to stand ready to make regulatory decisions quickly once and if the research indicates there is a threat. It has actively sought to establish guidance to industry on safe product applications of nanotechnology. The FDA falls in the high power, high interest quadrant.

4. U.S. Consumer Product Safety Commission

The U.S. Consumer Product Safety Commission (CPSC) is an independent government agency created through the Consumer Product Safety Act of 1972 and charged with "protecting the public from unreasonable risks of injury or death associated with the use of the thousands [15,000+] of types of consumer products under the agency's jurisdiction."[153] In 2005, after a commissioner vote of 3–0, the CPSC released a statement declaring its position that existing CPSC statutes and regulations are adequate to address any possible safety and health risks posed by nanomaterials.[154] Additionally, it said that product risk assessments are not made until after the product is available for public use. Thus, nanotechnology may necessitate unique exposure and risk assessment strategies.[155]

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152 Ibid.

153 "About CPSC," Consumer Product Safety Commission, accessed June 21, 2017, https://www.cpsc.gov/About-CPSC.

154 Consumer Product Safety Commission, *CPSC Nanomaterial Statement* (Washington, DC: Consumer Product Safety Commission, 2009), http://nanotech.law.asu.edu/Documents/2009/07/CPSCNanostatement_193_6364.pdf; "CPSC Nanotechnology Statement—Decision," Consumer Product Safety Commission, accessed June 21, 2017, https://www.cpsc.gov/PageFiles/84703/Nanotechnology.pdf. The latter is a record of CPSC action, the commissioner voting on whether to release the statement described above.

155 Ibid.

In 2008, the CPSC received increasing pressure from both within and outside government to improve and expand oversight of nanomaterials within consumer products. In a detailed analysis report titled, *The Consumer Product Safety Commission and Nanotechnology*, E. Marla Felcher concluded,

> The agency [CPSC] lacks the budget, the statutory authority and the scientific expertise to ensure that the hundreds of nanoproducts now on the market…are safe. This problem will only worsen as more sophisticated nanotechnology-based products begin to enter the consumer market.[156]

Recognizing the need to address nanotechnology in support of its mission, the USPC joined the NNI in 2011 and requested additional funding to collect data on the use of nanomaterials in consumer products. Since joining the NNI, as stated on nano.gov, the focus of programs for the CPSC are

- Developing protocols to assess the potential release of airborne nanoparticles from various consumer products and to determine their contributions to human exposure.
- Determining whether nanomaterials can be used for performance improvement in sports safety equipment such as helmets and kneepads without creating other health hazards.
- Expanding consumer product testing using scientifically credible protocols to evaluate the exposure potential from nanosilver in consumer products, with special emphasis on exposures to young children.
- Working across agencies to assure that shared common public health concerns are met in research studies to determine potential impacts on the public health of nanomaterial use in consumer products.[157]

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156 E. Marla Felcher, *The Consumer Product Safety Commission and Nanotechnology* (PEN 14) (Washington, DC: Pew Charitable Trusts Project on Emerging Nanotechnologies, 2008), http://www.nanotechproject.org/process/assets/files/7033/pen14.pdf.

157 “Consumer Product Safety Commission (CPSC),” National Nanotechnology Initiative, accessed April 29, 2017, http://www.nano.gov/node/139.

In 2015, the CPSC co-hosted with the NNI a technical workshop in Arlington, Virginia, which brought together more than 200 people from across the exposure science community.[158] The primary objectives of the workshop were to

> (1) assess progress in developing tools and methods for quantifying exposure to engineered nanomaterials across the product life cycle, and (2) to identify new research needed to advance nanotechnology environmental, health, and safety exposure assessment for nanotechnology-enabled products.[159]

The resulting report, *Quantifying Exposure to Engineered Nanomaterials from Manufactured Products: Addressing Environmental, Health, and Safety Implications* fused the findings from the workshop. The overarching conclusion of the report is that science has achieved important advances over the previous 10 years, including ways to measure exposure, methods, and tools to characterize exposures and methods to simulate and model engineered nanomaterials exposures to determine possible harmful effects.[160] The report recommends follow up actions and suggests areas, such as disease prevention by identifying the biomarkers of exposure that have been linked to the contraction of a disease, for the community to concentrate on.[161]

The CPSC's operating plan for 2017 included an additional $3 million to establish a nanotechnology center, in partnership with the National Institute of Environmental Health Science (NIEHS), focused on the environment, health, and safety.[162] The proposed center would "conduct applied research on exposure to potential chronic hazards related to nanotechnology in consumer products."[163] As stated in the 2017 operating plan, CPSC will commence the following activities and programs:

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[158] Consumer Product Safety Commission, *Quantifying Exposure to Engineered Nanomaterials from Manufactured Products, Addressing Environmental, Health, and Safety Implications Workshop Proceedings* (Arlington, VA: Consumer Product Safety Commission, 2015, https://www.cpsc.gov/s3fs-public/qeenworkshopreport2016.pdf.

[159] Ibid.

[160] Ibid.

[161] Ibid.

[162] "US Consumer Product Safety Commission," Safe Nano, accessed June 21, 2017, http://www.safenano.org/knowledgebase/regulation/substances/us-consumer-product-safety-commission/.

[163] Ibid.

- Collaborate with state and federal authorities, colleges and universities, and other stakeholders to expand the CPSC's effectiveness and reach to address consumer exposures to nanomaterials throughout the life-cycle of the materials;
- Work with the National Institute for Standards and Technology (NIST) to develop protocols to assess the potential release of nanoparticles from selected consumer products and determine their contributions to human exposure;
- Maintain a nanotechnology consumer product database of products that claim to have or are believed to contain nanomaterials;
- Continue to characterize the release of nanomaterials into indoor air and determine the potential exposures to consumers;
- Collaborate with the NSF- and the EPA-funded Centers for Environmental Implications of Nanotechnology to investigate human exposures to nanomaterials, including those released from consumer products; and
- Partner with NIEHS on a nanocenter focused on environment, health, and safety (pending new appropriations).[164]

Moving forward, in its 2018 budget the CPSC requested funding to establish an advanced research center to develop methods to quantify consumer exposure and potential health risks resulting from the use of nanomaterials in consumer products and nanoenabled products.[165]

This research indicates the CPSC has responded to the challenges presented by nanotechnology by transforming its approach to regulation of nanomaterials in consumer products from a reactionary approach to a proactive approach leveraging existing agency knowledge and extensively collaborating with relevant stakeholders. It remains to be seen how successful the CPSC will be in accomplishing its mission regarding nanotechnology; however, the new approach is more likely to yield positive results than the previous hands-off approach. Due to CPSC actions taken to further research on nanotechnology and its incumbent responsibility of product safety, the CPSC falls in the high power, high interest quadrant.

[164] Ibid.

[165] Consumer Product Safety Commission, *Potential Hazards Associated with Emerging and Future Technologies* (Washington, DC: Consumer Product Safety Commission, 2017), https://www.cpsc.gov/s3fs-public/Report%20on%20Emerging%20Consumer%20Products%20and%20Technologies_FINAL.pdf.

B. HIGH POWER, LOW INTEREST

The high power, low interest quadrant consists of those agencies/offices with either a regulatory role that gives them the power to enact and enforce regulation or a position to steer U.S. policy on nanotechnology (high power); however, they lack a demonstrated interest in nanotechnology regulation or deferment of the regulatory role to another agency (low interest).

1. U.S. House of Representatives Committee on Science, Space, and Technology

In 1958, the 85th Congress created the House Committee on Science and astronautics, which would later become the present day Committee on Science, Space, and Technology.[166] The committee has broad jurisdiction over all federal scientific research including energy research, astronomical research and development (R&D), civil aviation R&D, environmental R&D, marine research, commercial applications of energy technology, the NIST, National Aeronautics and Space Administration (NASA), NSF, the National Weather Service, space exploration, scientific scholarships, and other aspects of scientific research.[167] In this role the committee exerts oversight control over many entities within the federal government responsible for nanotechnology research, such as the National Nanotechnology Initiative (NNI). The committee conducts ongoing review of all taxpayer investments in scientific research to ensure all funds are spent prudently.[168] Nanotechnology is at the forefront of much of the research in the fields of artificial intelligence, additive manufacturing, bio-engineering, energy, computer and information science, and photonics.[169]

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166 “History,” Committee on Science, Space, and Technology, science.house.gov, accessed August 7, 2017, https://science.house.gov/about/history.

167 Ibid.

168 Committee on Science, Space, and Technology, *Authorization and Oversight Plan for the 115th Congress* (Washington, DC: Committee on Science, Space, and Technology, 2017), https://science.house.gov/sites/republicans.science.house.gov/files/documents/115th%20SST%20Authorization%20and%20Oversight%20Plan_0.pdf.

169 Ibid.

This committee falls into the high power, low interest quadrant. It would have significant power to sponsor legislation about nanotechnology regulation; however, to this point its members have shown little interest in doing so.

2. Department of Labor, Occupational Safety and Health Administration

Congress passed the Occupational Safety and Health Act of 1970 and created OSHA. The mission of OSHA is "to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance."[170] Although OSHA generally acknowledges there *may* be risks associated with engineered nanoparticles, it has not outlined specific guidelines regarding worker health and safety when working with these materials because potential health effects are not fully known.[171] OSHA notes that most of the activities engaged in by companies researching, developing, and manufacturing nanomaterials fall under the "General Duty Clause" of the 1970 act.[172]The examples of standards that OSHA cites may apply to employees exposed to nanomaterials are general safety precautions, such as recording and reporting illness, eye protection, respiratory protection face protection sanitation hand protection, etc.[173]

In 2013, OSHA published a fact sheet titled, *Working Safely with Nanomaterials*, with the intent to provide "basic information to workers and employers on the most current understanding of potential hazards associated with this rapidly developing technology and highlights measures to control exposure to nanomaterials in the workplace."[174] In this

170 "About OSHA," Occupational Safety and Health Administration, accessed June 18, 2017, https://www.osha.gov/about.html.

171 "Nanotechnology: Health Effects and Workplace Assessments and Controls," Occupational Safety and Health Administration, accessed June 18, 2017, https://www.osha.gov/dsg/nanotechnology/nanotech_healtheffects.html.

172 "Nanotechnology: OSHA Standards," Occupational Safety and Health Administration, accessed June 18, 2017, https://www.osha.gov/dsg/nanotechnology/nanotech_standards.html.

173 Ibid.

174 Occupational Safety and Health Administration, *Working Safely with Nanomaterials* (Washington, DC: Occupational Safety and Health Administration, 2013), https://www.osha.gov/Publications/OSHA_FS-3634.pdf.

document, OSHA reiterates that specific nanomaterial exposure limits do not exist with the exception of respirable carbon nanotubes, carbon nanofibers, and titanium dioxide (TiO_2).[175] OSHA recommends employers limit employee exposure to nanomaterials following established hazard control measures, such as those listed in the previous paragraph.

OSHA has shown a hesitancy to make specific rules regarding nanotechnology. On its website, OSHA defers to NIOSH as "the lead federal agency providing guidance and conducting research on the occupational safety and health implications, and applications of nanotechnology."[176] This lack of specific guidance offered by OSHA highlights some of the uncertainty surrounding the potential hazards posed by nanomaterials.

Despite having the power to make rules about nanotechnology, OSHA has not done so. Due to OSHA's hesitancy to make specific rules or enact regulations regarding nanotechnology in the workplace, it falls in the high power, low interest quadrant.

3. Office of Science and Technology Policy

The Office of Science and Technology Policy (OSTP) was established in 1976 to advise the president and other national leaders within the Executive Office of the President on topics including "scientific, engineering, and technological aspects of the economy, national security, homeland security, health, foreign relations, the environment, and the technological recovery and use of resources."[177] With a mandate to inform policy on scientific matters, the OSTP plays a vital role in steering national nanotechnology policy. The OSTP leads interagency efforts to formulate science and technology policies and budgets and to collaborate with the private sector, state and local governments, scientific and academic communities, and international partners to meet this goal.[178] The OSTP has a three-fold mission:

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175 Ibid.

176 "Nanotechnology: Health Effects."

177 "About OSTP," White House, accessed July 15, 2017, https://www.whitehouse.gov/ostp/about.

178 "Science and Technology Policy Office," Federal Register, accessed July 21, 2017, https://www.federalregister.gov/agencies/science-and-technology-policy-office.

> first, to provide the President and his senior staff with accurate, relevant, and timely scientific and technical advice on all matters of consequence; second, to ensure that the policies of the Executive Branch are informed by sound science; and third, to ensure that the scientific and technical work of the Executive Branch is properly coordinated so as to provide the greatest benefit to society.[179]

In 2015, OSTP requested suggestions on the topic nanotechnology-inspired grand challenges for the next decade.[180] OSTP requested the responses to contain “ambitious but achievable goals that harness nanoscience, nanotechnology, and innovation to solve important national or global problems and have the potential to capture the public’s imagination.”[181] After receiving 100 plus responses, OSTP announced the following grand challenge, “Create a new type of computer that can proactively interpret and learn from data, solve unfamiliar problems using what it has learned, and operate with the energy efficiency of the human brain.”[182] Nanotechnology research is essential to meet this challenge.

With its role in steering national nanotechnology policy, the OSTP falls into the high-power half of the matrix. However, it has not shown high interest to take any action. Therefore, OSTP is in the high power, low interest quadrant.

C. HIGH INTEREST, LOW POWER

The high interest, low power quadrant consists of those agencies/programs with a high interest in nanotechnology regulation based on their role and mission (high interest), but they lack a regulatory role. This leaves them without the direct power to enact and enforce regulation (low power).

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179 Ibid.

180 Lloyd Whitman, Randy Bryant, and Tom Kalil, “A Nanotechnology-Inspired Grand Challenge for Future Computing,” *White House* (blog), October 20, 2015, https://obamawhitehouse.archives.gov/blog/2015/10/15/nanotechnology-inspired-grand-challenge-future-computing.

181 Ibid.

182 Ibid.

1. National Nanotechnology Initiative

Since its inception in 2000, the NNI has functioned as "the U.S. Federal Government's interagency program for coordinating research and development as well as enhancing communication and collaborative activities in nanoscale science, engineering, and technology."[183] This program was the first of its kind in the world; however, many countries have now established similar programs and have begun investing heavily in nanotech research.[184] The vision of the NNI is a future in which applications of nanotechnology spark a revolution in industry and technology in ways benefiting society.[185] The NNI is the highest priority funded science and technology effort since the race to put a man on the moon and is one of the highest priority multiagency research and development programs.[186] The NNI is managed within the framework of a cabinet-level council, the National Science and Technology Council housed under the White House Office of Science and Technology Policy (see Figure 9).[187]The NNI has eight program components that provide the organizational framework for NNI activities (see Table 3).[188]

183 National Science and Technology Council Committee on Technology, Subcommittee on Nanoscale Science, Engineering, and Technology, *Progress Review on the Coordinated Implementation of the NNI 2011, Environmental, Health, and Safety Research Strategy* (Washington, DC: Executive Office of the President, 2014), http://www.nano.gov/sites/default/files/pub_resource/2014_nni_ehs_ progress_review.pdf, 3.

184 John F. Sargent, *Nanotechnology and U.S. Competitiveness: Issues and Options* (CRS Report No. 34493) (Washington, DC: Congressional Research Service, 2008), https://fas.org/sgp/crs/misc/RL34493.pdf.

185 "About the NNI," National Nanotechnology Initiative, accessed July 17, 2017, https://www.nano.gov/about-nni.

186 "Nanotechnology," North Carolina Department of Commerce, accessed July 17, 2017, http://www.nccommerce.com/sti/nanotechnology.

187 "Coordination of the NNI," National Nanotechnology Initiative, accessed July 18, 2017, https://www.nano.gov/about-nni/what/coordination.

188 *Oversight of the National Nanotechnology Initiative*.

Table 4. NNI's Eight Program Components[189]

TABLE 2: PROGRAM COMPONENT AREAS[11]		
No.	**PCA Title**	**Description**
1	Fundamental Nanoscale Phenomena and Processes	Discovery and development of fundamental knowledge pertaining to new phenomena in the physical, biological, and engineering sciences that occur at the nanoscale. Elucidation of scientific and engineering principles related to nanoscale structures, processes, and mechanisms.
2	Nanomaterials	Research aimed at the discovery of novel nanoscale and nanostructured materials and at a comprehensive understanding of the properties of nanomaterials (ranging across length scales, and including interface interactions). R&D leading to the ability to design and synthesize, in a controlled manner, nanostructured materials with targeted properties.
3	Nanoscale Devices and Systems	R&D that applies the principles of nanoscale science and engineering to create novel, or to improve existing, devices and systems. Includes the incorporation of nanoscale or nanostructured materials to achieve improved performance or new functionality. To meet this definition, the enabling science and technology must be at the nanoscale, but the systems and devices themselves are not restricted to that size.
4	Instrumentation, Research, Metrology, and Standards for Nanotechnology	R&D pertaining to the tools needed to advance nanotechnology research and commercialization, including next-generation instrumentation for characterization, measurement, synthesis, and design of materials, structures, devices, and systems. Also includes R&D and other activities related to development of standards for nomenclature, materials characterizations and testing, and manufacture.
5	Nanomanufacturing	R&D aimed at enabling scaled-up, reliable, and cost-effective manufacturing of nanoscale materials, structures, devices, and systems. Includes R&D and integration of ultra-miniaturized top-down processes and increasingly complex bottom-up or self-assembly processes.
6	Major Research Facilities and Instrumentation Acquisition	Establishment of user facilities, acquisition of major instrumentation, and other activities that develop, support, or enhance the nation's scientific infrastructure for the conduct of nanoscale science, engineering, and technology R&D. Includes ongoing operation of user facilities and networks.
7	Environment, Health and Safety	Research primarily directed at understanding the environmental, health, and safety impacts of nanotechnology development and corresponding risk assessment, risk management, and methods for risk mitigation.
8	Education and Societal Dimensions	Education-related activities such as development of materials for schools, undergraduate programs, technical training, and public communication, including outreach and engagement. Research directed at identifying and quantifying the broad implications of nanotechnology for society, including social, economic, workforce, educational, ethical, and legal implications.

189 Source: *Oversight of the National Nanotechnology Initiative*.

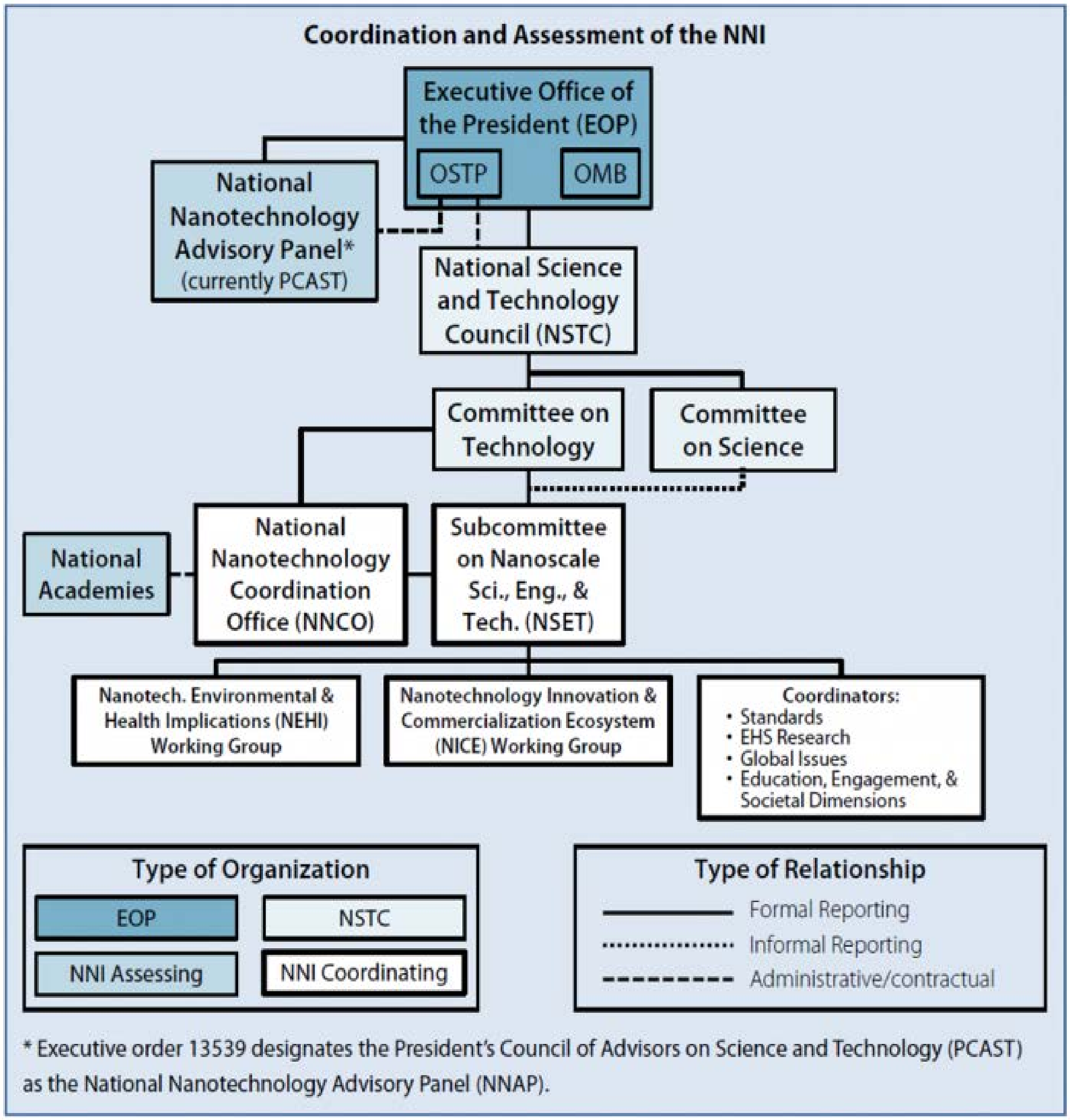

Figure 9. Coordination and Orginazation of the NNI[190]

According to Sargent, some criticisms of the NNI include claims "that the government is not doing enough to move the technology from the laboratory into the marketplace," while others question the government's effectiveness to protect the American consumer from the perceived possible harmful consequences of nanotechnology

190 Source: *Oversight of the National Nanotechnology Initiative*.

in existing products.[191] However, the NNI is not a regulatory agency. Regulation for nanotechnology falls to member agencies, such as the CPSC, FDA, NIOSH, and EPA.

Nonetheless, funding for the NNI has grown from $464 million in FY 2001, to approximately $1.4 billion for the NNI in the FY 17 federal budget (see Figures 10 and 11).[192] Since 2001, the NNI has received nearly $25 billion in federal funding including the 2018 budget request.[193] Many argue this significant investment into nanotech research is essential for the United States to maintain its standing as a world superpower and prevent the United States from being left out of the next technological revolution.[194]

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191 John F. Sargent, *The National Nanotechnology Initiative: Overview, Reauthorization, and Appropriations Issues* (CRS Report No. RL 34401) (Washington, DC: Congressional Research Service, 2010), http://research.policyarchive.org/19412_Previous_Version_2010-01-19.pdf.

192 *Oversight of the National Nanotechnology Initiative*; "NNI Budget," National Nanotechnology Initiative, accessed December 30, 2017, https://www.nano.gov/about-nni/what/funding.

193 Ibid.

194 Sargent, *Nanotechnology and U.S. Competitiveness*; K. Eric Drexler, "Introduction?" in *Nanofuture: What's Next for Nanotechnology*, ed. J. Storrs Hall (Amherst, NY: Prometheus Books, 2005).

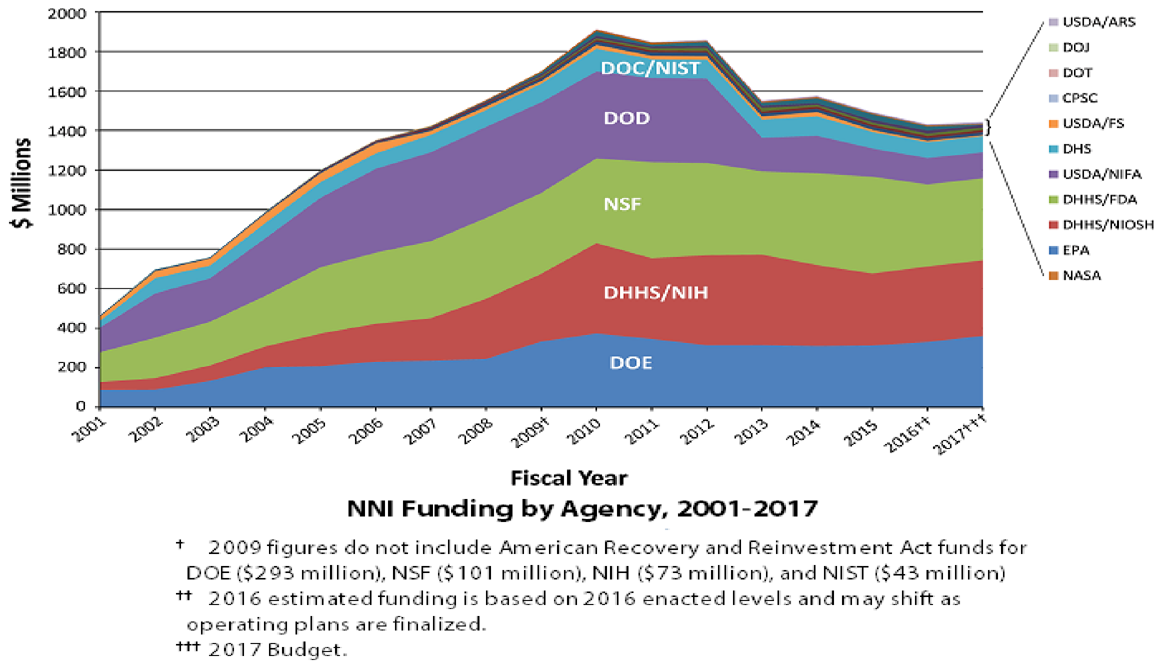

Figure 10. NNI Funding 2001–2017[195]

[195] Source: National Science and Technology Council Committee on Technology, *National Nanotechnology Initiative: Supplement to the President's 2017 Budget* (Washington, DC: Executive Office of the President, 2017), http://www.nano.gov/sites/default/files/pub_resource/nni_fy17_budget_supplement.pdf, 25.

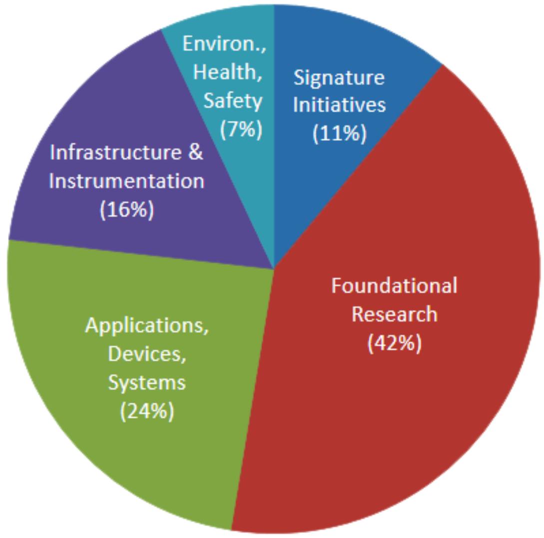

Figure 11. 2017 Investments by Program Component Area[196]

The NNI is comprised of many agencies that fall in all four quadrants of the power-interest grid. However, the program itself has no power to enact regulation. Therefore, the NNI falls in the high interest, low power quadrant.

2. U.S. Department of Commerce

Congress created the U.S. Department of Commerce (DOC) in 1903 as the U.S. Department of Commerce and Labor (renamed in 1913).[197] The mission of DOC is to "create the conditions for economic growth and opportunity" within the United States.[198] The DOC accomplishes this mission by ensuring fair and secure trade, providing the data necessary to support commerce, and fostering innovation by setting standards through the NIST and conducting foundational research and development.[199]

[196] Source: National Science and Technology Council, *National Nanotechnology Initiative: Supplement*, 25.

[197] U.S. Department of Commerce, *Organization and Law of the Department of Commerce and Labor* (Washington: Government Printing Office, 1904), http://library.doc.gov/ld.php?content_id=20863254, 12.

[198] "About Commerce," U.S. Department of Commerce, accessed June 23, 2017, https://www.commerce.gov/page/about-commerce.

[199] Ibid.

Section 7 of the 21st Century Nanotechnology Research and Development Act calls for the director of NIST to establish a program to conduct research into the possibilities and pitfalls of the development and manufacture of nanotechnology.[200] Additionally, the law directs the secretary of commerce to

> establish a clearinghouse of information related to commercialization of nanotechnology research…[to include] information relating to activities by regional, State, and local commercial nanotechnology initiatives; transition of research, technologies, and concepts from Federal nanotechnology research and development programs into commercial and military products; best practices by government, universities and private sector laboratories transitioning technology to commercial use; examples of ways to overcome barriers and challenges to technology deployment; and use of manufacturing infrastructure and workforce.[201]

Accordingly, NIST conducts nanotechnology research to collect data and develop measurement and standards pertinent to a broad scope of private industry and government departments.[202] Specifically, according to nano.gov, "NIST labs develop advanced spectroscopic methods needed to increase efficiency in advanced photovoltaics, and the standard reference materials and data necessary to accurately quantify and measure the presence and impact of nanomaterials in the environment."[203]

Additionally, NIST established the Center for Nanoscale Science and Technology (CNST) in 2007 to assist commercialization of nanotechnology.[204] CNST supports the U.S. nanotechnology enterprise by making available the most sophisticated equipment for nanoscale research.[205] The CNIST fosters nanotechnology advances from the discovery point to production and marketplace introduction.

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200 21st Century Nanotechnology Research and Development Act.

201 Ibid.

202 "National Institute of Standards and Technology—Department of Commerce," National Nanotechnology Initiative, accessed June 24, 2017, https://www.nano.gov//node/145.

203 Ibid.

204 Ibid.

205 "NIST—Center for Nanoscale Science and Technology," National Institute of Standards and Technology, accessed June 24, 2017, https://www.nist.gov/cnst.

The DOC's Bureau of Industry and Security (BIS) mission is to "advance U.S. national security, foreign policy, and economic objectives by ensuring an effective export control and treaty compliance system and promoting continued U.S. strategic technology leadership."[206] The BIS collaborates with the NNI to remain informed of the latest nanotechnology research, which can be an opportunity for national defense industry investment and may reveal possible vulnerabilities of U.S. national defense.[207]

Due to the potential economic impact of nanotechnology in the coming years, the DOC remains very interested in how the technology develops and what regulations will affect the industry's growth. However, it does not have a regulatory role. Thus, the DOC falls in the high interest, low power quadrant.

3. Department of Energy

The oil crisis of 1973 highlighted the need for a consolidated U.S. energy policy. This need led to the Department of Energy Organization Act of 1977, which created the Department of Energy (DOE). DOE's mission is to "ensure America's security and prosperity by addressing its energy, environmental and nuclear challenges through transformative science and technology solutions."[208] Moving into the 21st century, DOE recognizes the critical role nanotechnology has to play in addressing the nation's energy needs as well as in addressing climate change and national security challenges.[209]

Section 8 of the 21st Century Nanotechnology Research and Development Act directs the secretary of DOE to "establish a program to support, on a merit-reviewed and competitive basis, consortia to conduct interdisciplinary nanotechnology research and development designed to integrate newly developed nanotechnology and microfluidic tools

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[206] "Bureau of Industry and Security Mission," Bureau of Industry and Security, accessed June 24, 2017, https://www.bis.doc.gov/index.php/about-bis/mission-statement.

[207] "Bureau of Industry and Security—Department of Commerce," National Nanotechnology Initiative, accessed June 24, 2017, https://www.nano.gov/node/590.

[208] "Energy Department Mission," U.S. Department of Energy, accessed July 6, 2017, https://energy.gov/mission.

[209] "Basic Energy Sciences, Research, NNI," U.S. Department of Energy, Office of Science, accessed July 6, 2017, https://science.energy.gov/bes/research/national-nanotechnology-initiative/.

with systems biology and molecular imaging."[210] It also directs the secretary of DOE to "carry out projects to develop, plan, construct, acquire, operate, or support special equipment, instrumentation, or facilities for investigators conducting research and development in nanotechnology" and provided a $25 million budget from 2005 to 2008 to accomplish these directives.[211]

The DOE Office of Science manages most of DOE's programs that conduct cutting edge nanotechnology research and development designed to enhance DOE's ability to fulfill its mission.[212] These programs engender breakthrough discoveries across a wide array of scientific fields, such as "materials science, physics, chemistry, biology, computational science, and engineering."[213] According to DOE, the agency anticipates these discoveries to significantly advance future technologies in

> solar energy collection and conversion, energy-efficient lighting, stronger and lighter materials for transportation, improved chemical and biological sensing, low-energy catalytic pathways for fuel and chemical production and to break down toxic substances for environmental restoration, and advanced systems for stockpile stewardship.[214]

In addition to the Office of Science, DOE has many other departments that fill a support role in nanotechnology research. These include the Office of Nuclear Energy, the Office of Fossil Energy, and the Office of Energy Efficiency and Renewable Energy. Additionally, DOE also assists research activities in academia, private sector, and throughout its own laboratories.[215]

Furthermore, the DOE funds five state-of-the-art nanoscale science research centers (NSRCs).[216] These facilities for interdisciplinary nanoscale research are an important part

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210 21st Century Nanotechnology Research and Development Act.

211 Ibid.

212 Basic Energy Sciences, Research, NNI," U.S. Department of Energy.

213 Ibid.

214 Ibid.

215 Ibid.

216 "Department of Energy," National Nanotechnology Initiative, accessed July 6, 2017, https://www.nano.gov//node/141.

of DOE's extensive portfolio for nanoscale science and technology. The NSRCs serve as the foundation of nationwide program covering new tools, new science, and new computing capabilities. Each center is unique in expertise for particular theme areas.[217]

Like DOC, the DOE is very interested in how the technology develops and what regulations will affect the industry's growth. However, it does not have a regulatory role. Thus, the DOE falls in the high interest, low power quadrant.

4. National Aeronautics and Space Administration

The National Aeronautics and Space Administration (NASA) has been at the forefront of researching new technologies since its inception in 1958. To fulfill its vision to "reach for new heights and reveal the unknown for the benefit of humankind," NASA needs to leverage advances in nanotechnology for future needs in computing, electronics, materials/structures, sensors, and advanced miniaturization of all systems.[218] NASA's nanotechnology focus also includes development of highly detailed simulations to enable fast-paced development, testing, and validation of new materials and devices (see Figure 12).[219]

NASA's nanotechnology research efforts pre-date the formation of the NNI with the 1996 establishment of the Ames Research Center near San Jose, California. As of October 2012, these efforts have led to more than 350 nanotechnology-related scientific publications.[220] In the aftermath of the Space Shuttle Columbia disaster, the president gave NASA a new mission focused on space exploration, which called for a return to the Moon and a manned mission to Mars; however, this new mission included no new funding, which

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[217] "DOE, User Facilities, Nanoscale Science Research Centers," U.S. Department of Energy, Office of Science, accessed July 6, 2017, https://science.energy.gov/bes/suf/user-facilities/nanoscale-science-research-centers/.

[218] "About NASA," National Aeronautics and Space Administration, accessed July 14, 2017, https://www.nasa.gov/about/index.html; "National Aeronautics and Space Administration," National Nanotechnology Initiative, accessed July 14, 2017, https://www.nano.gov//node/142.

[219] "National Aeronautics and Space Administration," National Nanotechnology Initiative, accessed July 14, 2017, https://www.nano.gov//node/142.

[220] Kirstin R. W. Matthews et al. *NASA's Relationship with Nanotechnology: Past, Present, and Future Challenges* (Baker Institute Policy Report no. 54) (Houston, TX: Rice University, 2012), https://www.bakerinstitute.org/media/files/Research/989865ce/ST-pub-PolicyReport54.pdf.

led to difficult budget decisions by NASA. NASA cut funding for many projects that did not directly support the new presidential direction. These funding cuts hindered NASA's research efforts significantly, as research appropriations were cut by 75 percent; and about 300 scientific programs were ended prematurely.[221] The Ames Research Center was forced to cut its staff from a high of sixty scientists, down to approximately ten scientists.[222] These funding levels improved somewhat during the Obama administration. NASA's R&D budget rebounded to $10.1 billion in 2016; however, these massive fluctuations in NASA's research budget reveal that the agency is vulnerable to the shifting priorities of presidential administrations and budget cycles.[223] These shifts have caused projects to stop and start suddenly, resulting in incomplete projects and wasted resources.[224]

NASA is very interested in how the technology develops and what regulations affect the industry's growth. It is heavily involved in researching applications of nanotechnology. However, it does not have a regulatory role. Thus, NASA falls in the high interest, low power quadrant.

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221 Ibid.

222 Ibid.

223 National Aeronautics and Space Administration, *NASA 2016 Agency Financial Report* (Washington, DC: National Aeronautics and Space Administration, 2016), https://www.nasa.gov/sites/default/files/atoms/files/nasa_fy2016_afr_508.pdf.

224 Matthews et al., *NASA's Relationship with Nanotechnology*.

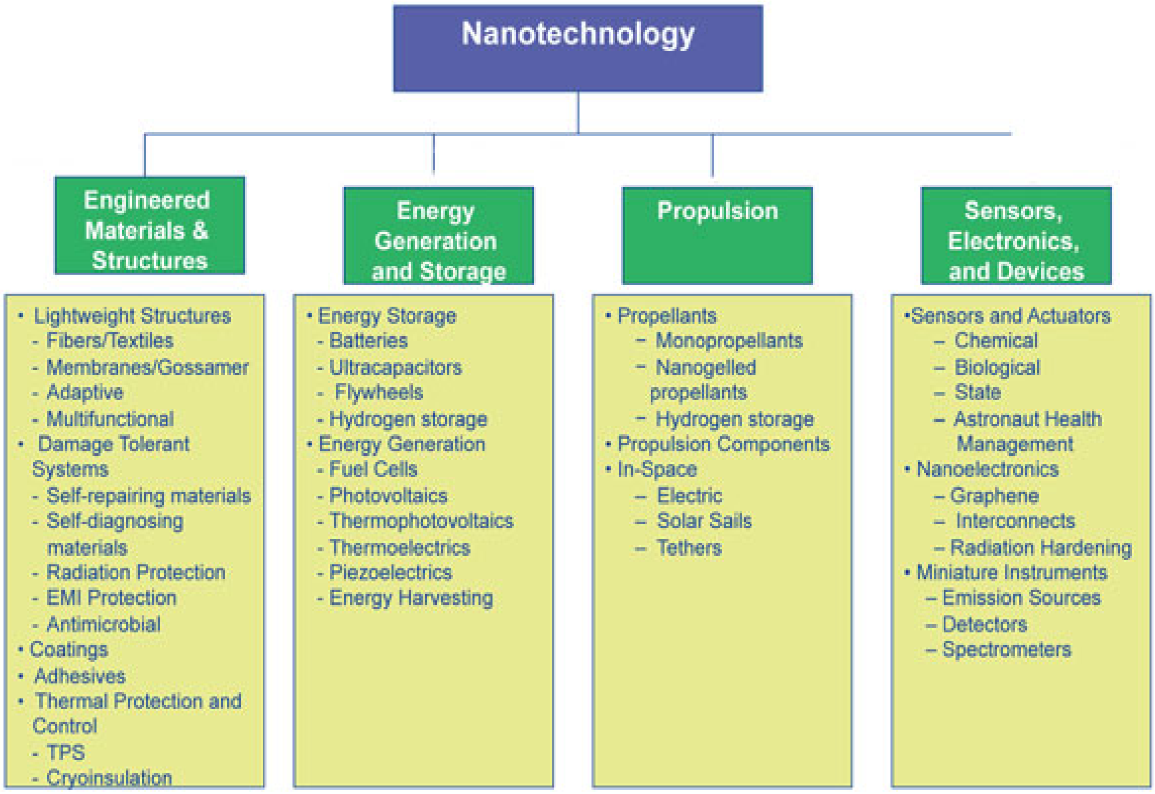

Figure 12. Technology Area Breakdown Structure for Nanotechnology Roadmap.[225]

5. National Science Foundation

In 1950, Congress created the National Science Foundation as an independent agency with a mandate to "promote the progress of science, to advance the national health, prosperity, and welfare; to secure the national defense..."[226] The NSF serves an important role by supporting research and people to make discoveries to transform the future. This type of support serves to drive the U.S. economy, enhances national security, and advances knowledge to maintain global leadership.[227] The NSF serves as the funding source for

[225] Source: "NASA and Nanotechnology," Nanowerk, October 23, 2012, http://www.nanowerk.com/spotlight/spotid=27065.php.

[226] "About the National Science Foundation," National Science Foundation, accessed July 17, 2017, https://www.nsf.gov/about/.

[227] Ibid.

nearly 24 percent of federally-supported basic research conducted by the nation's colleges and universities.[228]

This focus has led to keen interest in nanotechnology research by the NSF. Nanotechnology research requires sophisticated and expensive equipment. These costs are a barrier to research for many smaller universities and companies. Partially in an effort to address this barrier, in 2003 the NSF began funding the National Nanotechnology Infrastructure Network (NNIN) under a 10-year cooperative agreement.[229] The NNIN consisted of several facilities working in partnership to enable rapid research advancements by allowing cost efficient access to nanotechnology infrastructure.[230] On September 1, 2014, funding for the NNIN ended.

Following the conclusion of the NNIN, the NSF held a competition to select the 16 sites from 50 competition proposals that would comprise the National Nanotechnology Coordinated Infrastructure (NNCI).[231] The NNCI serves as the successor to the NNIN and builds upon its framework.[232] The NSF chose 16 sites from across the country (see Figure 13). The NNCI sites "provide researchers from academia, small and large companies, and government with access to university user facilities with leading-edge fabrication and characterization tools, instrumentation, and expertise within all disciplines of nanoscale science, engineering and technology."[233] The NSF gave out the initial awards, with an initial period of five years, in September 2015. In April 2016, the NSF chose the Georgia

228 Ibid.

229 Jeffrey Mervis, "Scientists Puzzled by NSF's Mixed Signals on Nano Network," *Science*, last modified March 11, 2014, http://www.sciencemag.org/news/2014/03/scientists-puzzled-nsfs-mixed-signals-nano-network.

230 "Welcome to NNIN," National Nanotechnology Infrastructure Network, accessed July 17, 2017, http://www.nnin.org/.

231 "About the NNCI," National Nanotechnology Coordinated Infrastructure, accessed July 17, 2017, http://www.nnci.net/about-nnci.

232 "Program Solicitation, NSF 15-519," National Science Foundation, accessed July 17, 2017, https://www.nsf.gov/pubs/2015/nsf15519/nsf15519.htm.

233 "$81 Million to Support New National Nanotechnology Coordinated Infrastructure," National Science Foundation, news release 15-112, September 16, 2015, https://www.nsf.gov/news/news_summ.jsp?cntn_id=136211.

Institute of Technology as the NNCI coordinating office. The total NSF funding for the initial five years is $81 million.[234]

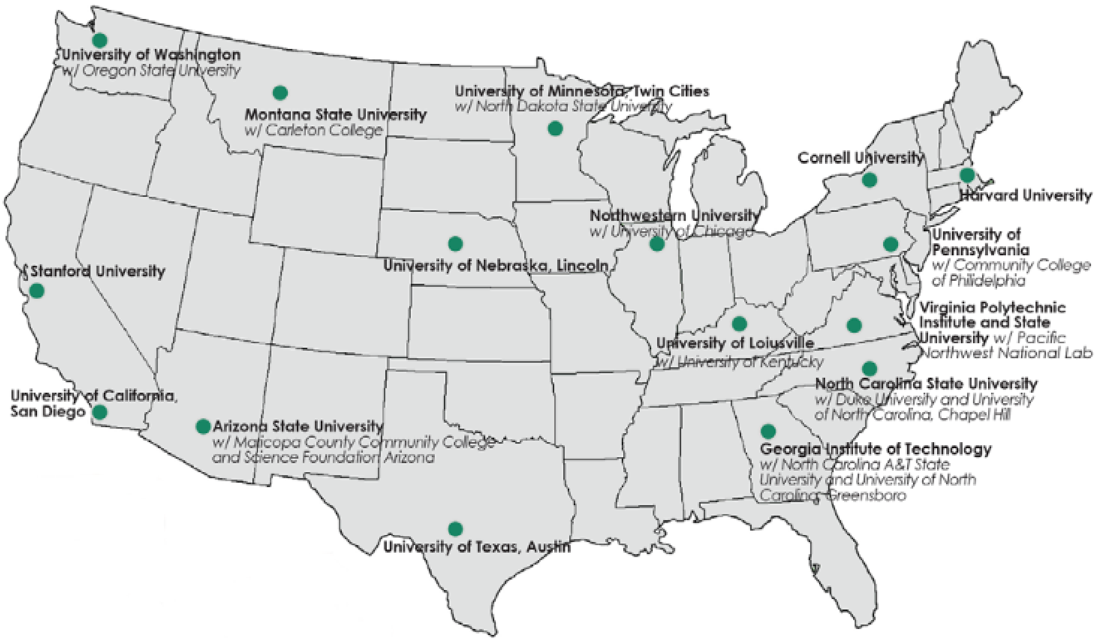

Figure 13. U.S. Map with Locations of the 16 NNCI Sites[235]

The NSF is keenly interested in how the technology develops and is highly involved in researching applications of nanotechnology. However, it does not have a regulatory role. Thus, NSF falls in the high interest, low power quadrant.

D. LOW INTEREST, LOW POWER

The low interest, low power quadrant consists of those agencies/programs that have an interest in nanotechnology based on how it can help the agencies accomplish their missions but have little interest in the regulation of nanotechnology (low interest). These

234 National Nanotechnology Coordinated Infrastructure, *NNCI Coordinating Office Annual Report (Year 1)* (Washington, DC: National Nanotechnology Coordinated Infrastructure, 2017), http://www.nnci.net/sites/default/files/inline-files/NNCI%20CO%20Annual%20Report%202017%20Public.pdf.

235 Source: National Nanotechnology Coordinated Infrastructure, *NNCI Coordinating Office*, 4.

agencies also lack a regulatory role, which leaves them without the direct power to enact and enforce regulation (low power).

1. Department of Homeland Security, Office of Science and Technology

The U.S. Department of Homeland Security is dedicated to safeguarding the American people. This huge responsibility requires a commitment to seeking out technological advances to determine how these advances can benefit the department in accomplishing the mission of securing the homeland. This job of finding and leveraging technological advances falls to the DHS Office of Science and Technology. A representative from the DHS Office of Science and Technology also serves on the NSET subcommittee for the NNI.

In fiscal year 2016, much of the proposed 17-million-dollar nanotechnology budget was used to conduct extensive research in areas related to explosives and the detection of explosives. These areas include:

- Explosive/polymer interactions.
- Understanding heterogeneity of energetic materials.
- Multifunctional nano-electro-optical-mechanical sensing platforms.[236]

While it may be surprising to categorize an agency as large as DHS with the budget it has as a "low power," in this instance the low power designation seems appropriate because it has no regulatory authority. Perhaps because of this lack of regulatory role, DHS has shown little to no interest in regulation. Therefore, it falls in the low power, low interest quadrant of the matrix.

2. Department of Defense

The mission of the Department of Defense is to provide military forces necessary to protect the United States and deter war. This mission requires the utmost attention to technological developments, including nanotechnology. The DoD views nanotechnology

[236] "Department of Homeland Security," National Nanotechnology Initiative, accessed June 19, 2017, https://www.nano.gov/node/592.

as an enabling technology requiring the highest attention from leadership.[237] Congress created the Defense Nanotechnology Research and Development Program under § 246 of the National Defense Authorization Act for FY 2003.[238]

The DoD view of nanotechnology as an enabling technology with force multiplying attributes requires extensive research and development necessary to meet national security goals and avoid technological surprises.[239] This technology is essential for DoD to remain at the forefront of military capabilities.

Many component organizations within DoD are responsible for research and development projects and programs related to nanotechnology. These include:

- Air Force Office of Scientific Research
- Army Engineering R&D Center
- Army Research Laboratory
- Army Research Office
- Defense Advanced Research Projects Agency
- Office of the Director, Defense Research and Engineering
- Defense Threat Reduction Agency
- Office of Naval Research.[240]

As it investigates ways to leverage nanotechnology for the nation's warfighters, the DoD must maintain careful attention to how this technology may interact with the environment and change the landscape of warfare itself. There must be oversight to ensure the primary aim of DoD's nanotechnology is not only maximum lethality for weapons, but that it also retains cognizance of the societal effects of advanced nanotechnology.

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[237] "U.S. Department of Defense," U.S. Department of Defense, accessed June 22, 2017, https://www.defense.gov/; "Department of Defense," National Nanotechnology Initiative, accessed June 22, 2017, http://www.nano.gov/node/144.

[238] Bob Stump National Defense Authorization Act, § 246.

[239] U.S. Department of Defense, *Defense Nanotechnology Research and Development Program* (Washington, DC: U.S. Department of Defense, 2009), https://www.nano.gov//sites/default/files/pub_resource/dod-report_to_congress_final_1mar10.pdf.

[240] "Department of Defense," National Nanotechnology Initiative.

Similar to DHS, it may be surprising to categorize an agency as large as DoD and with the size of its budget as a "low power;" however, in this instance, the low power designation seems appropriate because DoD has no regulatory authority. Perhaps because of this lack of regulatory role, DoD has shown little to no interest in regulation. Therefore, it falls in the low power, low interest quadrant of the matrix.

3. Department of Education

Congress established the Department of Education (ED) in 1980 with a mission to "promote student achievement and preparation for global competitiveness by fostering educational excellence and ensuring equal access."[241] As nanotechnology and other technologies become more advanced, it is vitally important that the U.S. education system keep up with these educational demands of the 21st century. Education, especially in the fields of science, technology, engineering and mathematics (STEM), is crucial for the United States to maintain international competitiveness; however, currently, the United States is indeed falling behind other countries in terms of graduates in the STEM fields (see Figure 14).[242]

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241 "Department of Education Overview and Mission Statement," Department of Education, accessed July 7, 2017, https://www2.ed.gov/about/landing.jhtml.

242 Niall McCarthy, "The Countries with The Most STEM Graduates" [infographic], *Forbes*, February 2, 2017, https://www.forbes.com/sites/niallmccarthy/2017/02/02/the-countries-with-the-most-stem-graduates-infographic/#267a23ea268a.

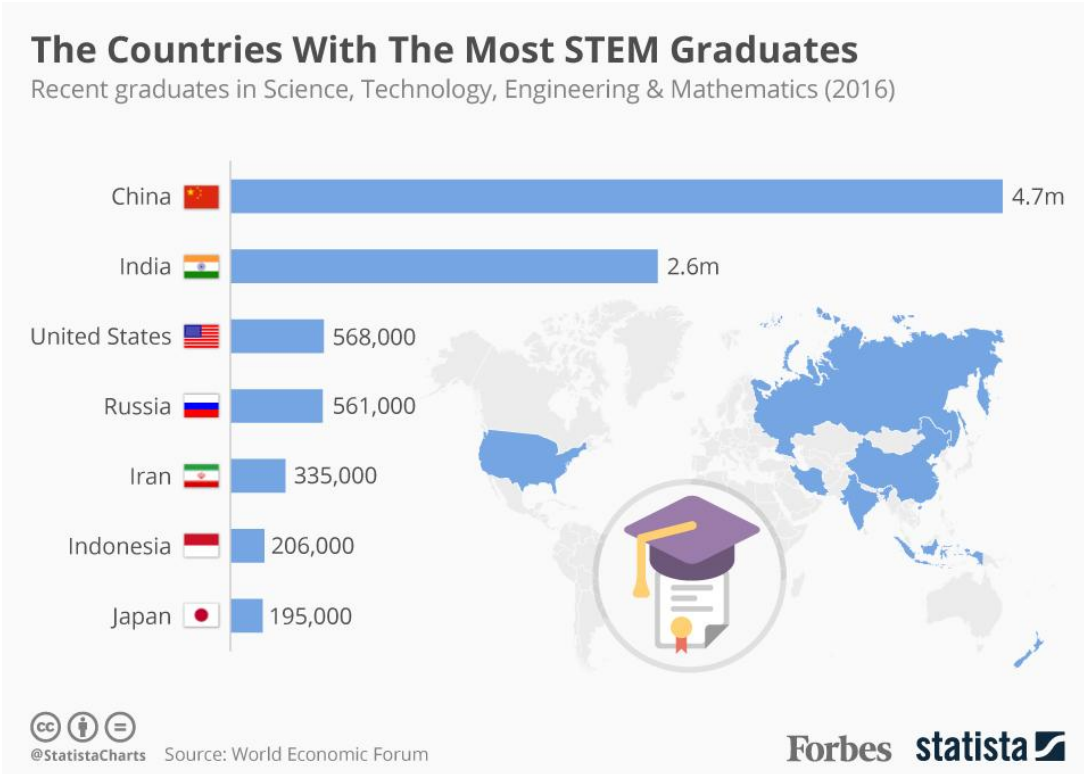

Figure 14. STEM Graduates by Country[243]

Famed theoretical physicist and City College of New York Professor Dr. Michio Kaku has said that the scientific establishment in the United States is facing collapse due to its poor education system and has only avoided this collapse due to the H1B visas program, which allows U.S. companies to hire foreign workers with specialized skill sets into difficult to fill positions.[244] Clearly, the ED has many difficult challenges to fulfill its mission of preparing the next generation of Americans to be globally competitive. In an effort to meet these challenges, specifically nanotechnology education, through the NNI, ED has collaborated with other relevant agencies, such as DOL (which tracks workforce

[243] Source: McCarthy, "The Countries with The Most STEM Graduates."

[244] Simay2k, "Michio Kaku Discusses H1B Visas and US Education System," YouTube video posted February 14, 2012, https://www.youtube.com/watch?v=Qty1xqvQBrA; Nicole Torres, "The H-1B Visa Debate, Explained," *Harvard Business Review*, May 4, 2017, https://hbr.org/2017/05/the-h-1b-visa-debate-explained.

needs), and the NSF, which provides funding for nanotechnology research and funds nanotechnology education.[245]

The research for this section reveals a necessity for a strong focus on expanding the nation's focus on STEM education and leads to the recommendation to create a scholarship program for students seeking advanced degrees in nanotechnology-related research fields (see Recommendations Section). The ED is focused primarily on the technology itself, not on regulation. The low power designation is also appropriate because DoD has no regulatory authority. It is in the low interest, low power quadrant.

4. Department of State

Created in 1789, the Department of State (DOS) was the first U.S. executive department.[246] DOS mission is to "shape and sustain a peaceful, prosperous, just, and democratic world and foster conditions for stability and progress for the benefit of the American people and people everywhere."[247] To aid with this mission, DOS fosters international collaboration on advanced technologies. As a member of the NNI, the DOS assists other member agencies to establish partnerships with counterpart agencies in other countries. These partnerships facilitate the exchange of scientific data including results of experimental research. Additionally, it allows for protection of intellectual property rights and promotion of scientific information sharing by facilitating access for researchers.[248]

The DOS Office of Space and Advanced Technology ensures that bilateral and multilateral science activities support overall U.S. foreign policy objectives, safeguard national security interests, promote economic interests, and enhance U.S. technological

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[245] "Department of Education," National Nanotechnology Initiative, accessed July 7, 2017, https://www.nano.gov//node/591.

[246] "A Short History of the Department of State," U.S. Department of State, Office of the Historian, accessed July 8, 2017, https://history.state.gov/departmenthistory/short-history/framework.

[247] "DOS Bureau of Budget and Planning," U.S. Department of State, accessed July 8, 2017, https://www.state.gov/s/d/rm/index.htm#mission.

[248] "Department of State," National Nanotechnology Initiative, accessed July 8, 2017, https://www.nano.gov//node/596.

competitiveness.[249] The office heads the interagency effort to coordinate U.S. international nanotechnology activities.[250]

DOS collaborates on international nanotechnology efforts with organizations such as the United Nations' environment Programme Strategic Approach to International Chemicals Management, the OECD, and the International Organization for Standardization, and leads U.S. participation in the Organization for Economic Cooperation and Development's Committee for Scientific and Technological Policy and its subsidiary Working Party on Bio-, Nano-, and Converging Technologies.[251] These efforts help advance international commercialization of nanotechnology products, promote innovative ideas, and endeavor to create an international marketplace which encourages the development of nanotechnology while acknowledging and addressing safety concerns.[252]

The DOS has low interest in nanotechnology regulation. The low power designation also is appropriate because DoD has no regulatory authority. It is in the low interest, low power quadrant.

5. Department of Justice, National Institute of Justice

The Department of Justice (DOJ) mission is to enforce the laws of the United States and defend its interests according to national law.[253] The National Institute of Justice (NIJ) is the research, development, and evaluation branch of the DOJ. The NIJ "is committed to improving the knowledge and understanding of crime and justice issues through science."[254] To that end, the NIJ sponsors scientific research to provide tools to inform the

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[249] "DOS—Office of Space and Advanced Technology," U.S. State Department, accessed July 8, 2017, https://www.state.gov/e/oes/sat/.

[250] Ibid.

[251] "Department of State," National Nanotechnology Initiative.

[252] Ibid.

[253] "Our Mission Statement," U.S. Department of Justice, accessed July 11, 2017, https://www.justice.gov/about.

[254] "About the National Institute of Justice," National Institute of Justice, accessed July 11, 2017, https://www.nij.gov/about/Pages/welcome.aspx.

decision making of the criminal justice community in effort to reduce crime and advance justice.[255] This includes investments in nanotechnology research.

The DOJ has little interest in nanotechnology regulation, or power to enact regulation, though it may be called upon to prosecute violators of regulation. It is in the low interest, low power quadrant.

6. Department of the Interior, U.S. Geological Survey

The Department of the Interior (DOI) is responsible for protecting and managing the nation's natural resources as well managing hundreds of millions of acres of land, including national parks through the National Parks Service and rangelands through the Bureau of Land Management.[256] The U.S. Geological Survey (USGS) serves as the only science agency of the DOI. The USGS mission is to serve the United States "by providing reliable scientific information to describe and understand the Earth; minimize loss of life and property from natural disasters; manage water, biological, energy, and mineral resources; and enhance and protect our quality of life."[257]

The USGS is involved in many aspects of nanotechnology research. Currently, scientists are investigating the unique properties of exotic element nanoparticles to identify possible applications to science and industry.[258] USGS also performs toxicological studies to understand the effects of nanoparticles at different levels biological organization.[259] In keeping with its role of evaluating potential risks of resource degradation, USGS is also studying the long-term effect naturally-occurring and engineered nanomaterials have on the environment.[260]

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255 Ibid.

256 "About DOI," U.S. Department of Interior, accessed July 12, 2017, https://www.doi.gov/whoweare.

257 "USGS—Who We Are," U.S Geological Survey, accessed July 12, 2017, https://www.usgs.gov/about/about-us/who-we-are.

258 "Nanotechnology Research Activities," U.S Geological Survey, accessed July 13, 2017, https://microbiology.usgs.gov/nanotechnology.html.

259 Ibid.

260 "USGS—Who We Are," U.S Geological Survey, accessed July 12, 2017, https://www.usgs.gov/about/about-us/who-we-are.

The DOI has low interest in nanotechnology regulation. The low power designation also is appropriate because DOI has no regulatory authority on this matter. It is in the low interest, low power quadrant.

7. Department of Transportation, Federal Highway Administration

The Federal Highway Administration (FHWA) is the agency within the Department of Transportation tasked with the mission to "improve mobility on our nation's highways through national leadership, innovation, and program delivery," and it supports state and local governments in the design, construction, and maintenance of the U.S. highway system.[261] This task is becoming increasingly difficult as the number of vehicles on the nation's roads has increased from 65 million in 1955 to an estimated 246 million in 2008.[262] This traffic and the effects of age and weathering are deteriorating road systems faster than local, state, and federal road crews can perform maintenance. This increased volume of traffic and state of the nation's highways has heightened the need for high-performance, long-lasting materials for roadway pavements.[263] The FHWA has funded targeted research to identify nanotechnology solutions to meet these needs.

In March 2009, FHWA's Exploratory Advanced Research Program sponsored a workshop involving nearly two dozen experts from academia and other federal programs to share their understanding of nanoscale research and to learn about vital highway research issues such as infrastructure, safety, operations, and the environment. The FHWA remains committed to addressing these issues with a long-term strategy of continued targeted investment while fostering an understanding of highway research needs within the nanotechnology research community to leverage new discoveries for improvements to the nation's transportation systems.[264]

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261 "Who We Are," Federal Highway Administration, accessed July 13, 2017, https://www.fhwa.dot.gov/about/

262 Surendra P. Shah et al., "News on Nanotechnology," *Public Roads* 72, no. 3 (2008), https://www.fhwa.dot.gov/publications/publicroads/08nov/06.cfm.

263 Ibid.

264 "Department of Transportation (DOT, incl. Federal Highway Administration, FHWA)," National Nanotechnology Initiative, accessed July 13, 2017, https://www.nano.gov//node/595.

The FHWA has little interest in nanotechnology regulation. The low power designation also is appropriate because the FHWA has no regulatory authority on this matter. It is in the low interest, low power quadrant.

8. Department of the Treasury

According to the NNI, the Department of Treasury (DOTreas) interest in nanotechnology involves monitoring the subsets of "nanotechnology that could most effectively assist the execution of its role as the steward of the U.S. economic and financial systems, and as an influential participant in the global economy."[265] Additionally, DOTreas looks to leverage nanotechnology research in the execution of its role in "advising the President on economic and financial issues, encouraging sustainable economic growth, and fostering improved governance in financial institutions."[266] The DOTreas may also investigate the possibilities of nanotechnology in the production of currencies that are more difficult to counterfeit.[267]

The DOTreas has low interest in nanotechnology regulation. The low power designation also is appropriate because DOTreas has no regulatory authority on this matter. It is in the low interest, low power quadrant.

9. U.S. Intelligence Community

The U.S. Intelligence Community (IC) is a federation of 16 separate agencies working individually and collaboratively to conduct intelligence activities necessary to maintain national security and enhance foreign relations.[268] In terms of devices used to collect intelligence information, the smaller, more lightweight, energy efficient, durable, and sophisticated the device is, the better for the IC agency deploying the device. Intense

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[265] "Department of Treasury," National Nanotechnology Initiative, accessed July 15, 2017, http://www.nano.gov/node/597.

[266] Ibid.

[267] Mohana Ravindranath, "Federal Government Revises Its Big Plans for Little Tech," Nextgov, November 4, 2016, http://www.nextgov.com/emerging-tech/2016/11/nanotechnology-strategic-plan/132944/.

[268] "U.S. Intelligence Community," National Nanotechnology Initiative, accessed July 15, 2017, https://www.nano.gov//node/24.

research into novel applications of nanotechnology is necessary to reach maximum efficiency in each of these areas. The IC is also keenly interested in the collection of data on the capabilities of other nations.

To reach IC research objectives and other areas of technological interest, the Office of the Director of National Intelligence created an organization designed to increase the speed of technical developments and establish a synergy between all members of the IC.[269] This organization, the Intelligence Advanced Research Projects Activity (IARPA) was modelled after the Defense Advanced Research Projects Agency. IARPA does not deploy technologies directly to the field, but rather it collaborates across the IC to facilitate the transition of research from the laboratory to operational application.[270]

The IC has low interest in nanotechnology regulation. The low power designation also is appropriate because the IC has no regulatory authority on this matter. It is in the low interest, low power quadrant.

10. U.S. Department of Agriculture, National Institute of Food and Agriculture

The U.S. Department of Agriculture (USDA) was established by President Lincoln in 1862.[271] The mission of USDA is to provide government "leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on sound public policy, the best available science, and efficient management.[272]" In 1862, more than half of the country's population lived and worked on farms.[273] As the nation's economy changed, USDA has evolved with it. USDA has recognized the importance of new technologies, such as nanotechnology, in fulfilling its agricultural leadership mission.

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[269] Ibid.

[270] "About IARPA," Intelligence Advanced Research Projects Activity, accessed July 15, 2017, https://www.iarpa.gov/index.php/about-iarpa.

[271] "About the U.S. Department of Agriculture," U.S. Department of Agriculture, accessed July 16, 2017, https://www.usda.gov/our-agency/about-usda.

[272] U.S. Department of Agriculture, *Strategic Plan FY 2014–2018* (Washington, DC: U.S. Department of Agriculture, 2014), https://www.usda.gov/sites/default/files/documents/usda-strategic-plan-fy-2014-2018.pdf.

[273] Ibid.

The Farm Bill of 2008 authorized the establishment of the National Institute of Food and Agriculture (NIFA). NIFA administers federal funding through grants provided to Agriculture and Food Research Initiative (AFRI) to address pressing agricultural issues impacting the lives of the U.S. populace.[274] Through collaboration with scientists, experts, policymakers, and educators, NIFA has made important progress toward finding solutions to many of the most time critical local and global problems. In March 2016, the AFRI administered $5.2 million in grants to 11 universities to support research on ways nanotechnology can improve the safety of food, increase efficiency of renewable fuels, improve crop yields, and help manage agricultural pests, among other research topics.[275] In July 2017, AFRI awarded 13 grants worth $4.6 million to fund projects supporting nanotechnology-based solutions, which will improve food production, food safety, nutrition, and sustainable agriculture.[276]

The USDA NIFA has low interest in nanotechnology regulation. The low power designation also is appropriate because the USDA NIFA has no regulatory authority on this matter. It is in the low interest, low power quadrant.

11. Nuclear Regulatory Commission

Congress created the Nuclear Regulatory Commission (NRC) as an independent agency under the Energy Reorganization Act of 1974 to replace the Atomic Energy Commission (AEC).[277] The NRC began operations in January, 1975. The NRC mission is to "ensure the safe use of radioactive materials for beneficial civilian purposes while

[274] "About NIFA," National Institute of Food and Agriculture, accessed July 16, 2017, https://nifa.usda.gov/about-nifa.

[275] "USDA Announces $5.2 Million for Nanotechnology Research," press release no. 0078.16, U.S. Department of Agriculture, March 30, 2016, https://www.usda.gov/media/press-releases/2016/03/30/usda-announces-52-million-nanotechnology-research.

[276] Lynn L. Bergeson and Carla N. Hutton, "USDA Awards $4.6 Million in Nanotechnology Research Grants," *Nano and Other Emerging Chemical Technologies Blog*, July 28, 2017, https://nanotech.lawbc.com/2017/07/usda-awards-4-6-million-in-nanotechnology-research-grants/.

[277] "About NRC," U.S. Nuclear Regulatory Commission, Last updated August 24, 2017, https://www.nrc.gov/about-nrc.html; "NRC History," U.S. Nuclear Regulatory Commission, last updated September 25, 2017, https://www.nrc.gov/about-nrc/history.html.

protecting people and the environment. The NRC regulates commercial nuclear power plants and other uses of nuclear materials."[278]

The NRC's research focus is largely to "verify the safe application of new technologies in the civilian nuclear industry."[279] The agency's nanotechnology focus is to keep abreast of advancements that may affect the nuclear industry and/or assist the NRC in the execution of its mission.[280]

The NRC has low interest in nanotechnology regulation. The low power designation also is appropriate because the NRC has no regulatory authority on this matter. It is in the low interest, low power quadrant.

12. U.S. International Trade Commission

The United States International Trade Commission (USITC) is "an independent, quasi-judicial federal agency with broad investigative responsibilities" on issues relating to international trade.[281] The USITC has a five-fold mission: to

> (1) administer U.S. trade remedy laws within its mandate in a fair and objective manner; (2) provide the President, USTR, and Congress with independent analysis, information, and support on matters of tariffs, international trade, and U.S. competitiveness; and (3) maintain the Harmonized Tariff Schedule of the U.S.[282]

In 2016, the USITC released *The Year in Trade 2016*, its 68th report on the operation of U.S. trade agreements.[283] This report includes updates on the Transatlantic Economic Council meetings held each year to strengthen economic cooperation between the U.S. and the European Union. One of the highlighted topics discussed was

278 "About NRC," Nuclear Regulatory Commission.

279 "Nuclear Regulatory Commission," National Nanotechnology Initiative, accessed July 18, 2017, https://www.nano.gov/node/598.

280 Ibid.

281 "About the USITC," U.S. International Trade Commission, accessed July 19, 2017, https://usitc.gov/press_room/about_usitc.htm.

282 Ibid.

283 U.S. International Trade Commission, *The Year in Trade, Operation of the Trade Agreements Program* (68th Report) (Washington, DC: U.S. International Trade Commission, 2017), https://www.usitc.gov/publications/332/pub4711.pdf.

nanotechnology. According to the report, "regular meetings continued in 2016 to exchange information on regulatory and scientific developments to help inform decision-making in the United States and the EU."[284]

The USITC has low interest in nanotechnology regulation. The low power designation also is appropriate because the USITC has no regulatory authority on this matter. It is in the low interest, low power quadrant.

[284] Ibid.

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V. COMPARATIVE ANALYSIS OF AVIATION AND BIOTECHNOLOGY REGULATION

This chapter examines the current regulatory framework for the aviation industry and for biotechnology. The author chose aviation and biotechnology as case studies specifically because their regulatory frameworks are very different. The aviation industry is regulated by a single agency, the Federal Aviation Administration (FAA). If it flies, the FAA has the regulatory responsibility over it. Conversely, biotechnology is regulated by three agencies (EPA, FDA, and USDA) based on the attributes of the product. These different frameworks provide an interesting contrast to examine.

A. AVIATION REGULATION

When the Wright brothers made the first successful flight of a self-propelled, heavier-than-air, aircraft in December 1903, they could scarcely have envisioned the major airline industries or the other significant technological, social, and environmental changes that grew out of the beginnings of their successful flight.[285] Nor could they have envisioned the major regulatory entities such as the FAA that would be created to enforce rules of behavior on aviators, airlines, and aviation customers.

From the early days of manned flight to today's complex web of international flight routes, aviation regulation has been continually changing to meet the shifting landscape of the aviation industry. According to the FAA, the aviation industry promoted the idea of government regulation out of the belief that the airplane could not reach its full commercial maturity without federal action to enforce safety standards.[286] This attitude toward regulation was unique, as aviation industry regulation came mostly as a response to requests from the industry for oversight.[287] President Herbert Hoover wrote in 1921, "It is

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[285] "The Wright Brothers: Wilbur and Orville Wright," Wright House, last updated December 20, 2011, http://www.wright-house.com/wright-brothers/Wrights.html.

[286] "A Brief History of the FAA," Federal Aviation Administration, last updated January 4, 2017, http://www.faa.gov/about/history/brief_history/.

[287] Federal Aviation Administration, *History of Aviation Safety Oversight in the United States* (Washington, DC: Federal Aviation Administration, 2008), http://www.tc.faa.gov/its/worldpac/techrpt/ar0839.pdf.

interesting to note that this is the only industry that favors having itself regulated by government."[288] The aviation industry has largely maintained this embrace of government regulation through the present day. The first major piece of legislation regulating aviation was the Air Commerce Act of 1926.[289] This new legislation gave the secretary of commerce the responsibility to license pilots, enforce rules of air traffic, maintain navigational aids, promote aviation commerce, certify airplanes, and establish air routes.[290]

By the 1930s, pressure for federal regulation strengthened in the aftermath of crashes that killed high-profile individuals such as University of Notre Dame football coach Knute Rockne and New Mexico Senator Bronson Cutting.[291] To address these concerns, President Franklin Delano Roosevelt signed into law the Civil Aeronautics Act in 1938. This act created the Civil Aeronautics Authority (CAA), with responsibilities to investigate aviation mishaps as a means to formulate recommendations to prevent future accidents. Additionally, the CAA was given the authority to regulate airline fares and regulate the routes individual airlines served. After a mid-air collision in uncongested airspace over the Grand Canyon, Senator A. S. "Mike" Monroney introduced legislation that created the FAA with a broad-scoped mission to ensure the safe and efficient use of U.S. airspace.[292]

The Airline Deregulation Act of 1978 served to eliminate regulation on airline routes and fares. This opened the door for many new entrants into the airline industry. Consequently, the workload of the FAA increased dramatically, as it was responsible for reviewing the hundreds of applications for new airlines and making a decision on their respective ability to operate. Deregulation of the airline industry led to many benefits for

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288 Nick A. Commons, *Bonfires to Beacons: Federal Civil Aviation Policy under the Air Commerce Act, 1926–1938* (Washington DC: Federal Aviation Administration, 1978), 22.

289 Ibid.

290 Ibid.

291 Ibid.

292 The Federal Aviation Agency became the Federal Aviation Administration with the creation of DOT in 1966.

the consumer, including a reduction in airline fares, and the number of destinations increased for several years.[293]

In 1988, 10 years after the Airline Deregulation Act, the Office of Technology Assessment released its report titled, *Safe Skies for Tomorrow: Aviation Safety in a Competitive Environment*. This report was the result of analysis conducted to determine the effectiveness of existing regulations, safety policies, and technologies to address the U.S. government's responsibility for maintaining safety in commercial aviation. The study reached many important conclusions and recommendations. One of the most important conclusions was that despite an exponential increase in the FAA's workload, airline safety did not diminish in the aftermath of deregulation despite the entrance of many new airlines into the marketplace. Rather, airline security increased slightly as crashes decreased over the final four years preceding the study.[294]

The FAA is the sole responsible agency for all air traffic regulation within the United States. If it flies in U.S. airspace, it is regulated by the FAA (see Figure 15). As new technologies and innovations emerge, such as drones, the FAA maintains responsibility for regulation. Mark Ratner and Daniel Ratner suggest nanotechnology may be regulated using a single agency, just as the FAA handles all aviation regulation.[295] Under this framework, if a product utilizes nanotechnology, it would be regulated under a new federal agency.

[293] U.S. Congress, Office of Technological Assessment, *Safe Skies for Tomorrow: Aviation Safety in a Competitive Environment* (Washington DC: U.S. Government Printing Office, 1988).

[294] Ibid.

[295] Ratner and Ratner, *Nanotechnology and Homeland Security*, 132.

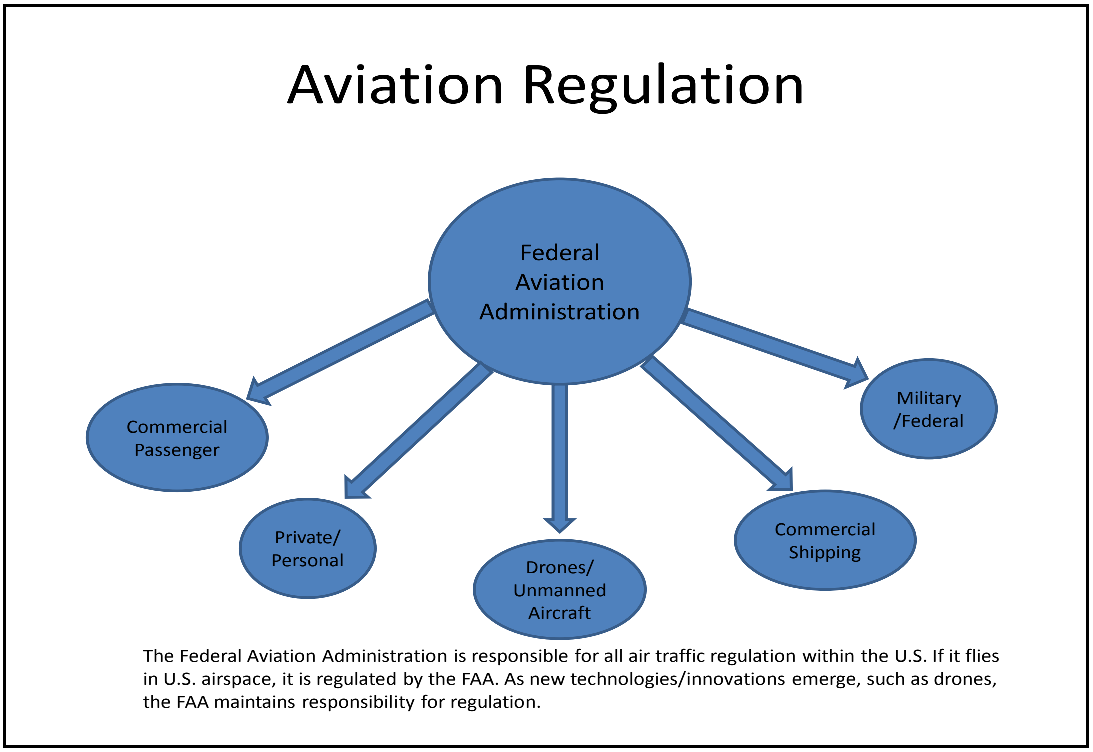

Figure 15. Aviation Regulation Framework

B. BIOTECHNOLOGY REGULATION

Biotechnology has seen radical technological breakthroughs and has also been the source of controversy and debate.[296] In 1986, the Office of Science and Technology Policy released the *Coordinated Framework for Regulation of Biotechnology*.[297] This policy dictated the U.S. government's approach to regulation of biotechnology. This framework utilizes a risk-based approach to regulation of new biotechnology products.[298] Regulation for biotechnology is based on the attributes of the product. There are three primary agencies that assume responsibility for regulation of biotechnology based on the area of

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296 Niel A. Belson, "US Regulation of Agricultural Biotechnology: An Overview," *The Journal of Agrobiotechnology Management & Economics* 3, no. 4(2000): 268–280.

297 Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology* (Washington, DC: Executive Office of the President, Office of Science and Technology Policy, 1986), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.

298 "How the Federal Government Regulates Biotech Plants," U.S. Department of Agriculture, last modified November 18, 2013, http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=biotech-plants.xml.

responsibility of each agency. These agencies are the Environment Protection Agency under the Toxic Substances Control Act, the U.S. Department of Health and Human Services' FDA, and the USDA Animal and Plant Health Inspection Service (see Figure 16). Each of these agencies relies on communications with the others to ensure regulatory issues and potential regulatory issues are addressed properly.[299]

Biotechnology companies accept that regulation is a part of the cost of doing business. However, delays in regulatory approval directly affect a business's net returns and therefore significantly influence investment decisions.[300] Because regulatory costs subtract from the company's profits, industry generally views regulation negatively, though they are rarely openly opposed to regulation.

The regulatory framework for the biotechnology industry is structured very differently from the aviation industry. Regulation for biotechnology is based on the attributes exhibited by the product. Examining this structure reveals possibilities for a similar structure for nanotechnology regulation. If the product utilizes nanotechnology and is primarily designed for health benefits, it would be regulated by the FDA; if the product has telecommunication applications it would be regulated by the Federal Communications Commission; CPSC would address new products; EPA would address environmental concerns, etc.

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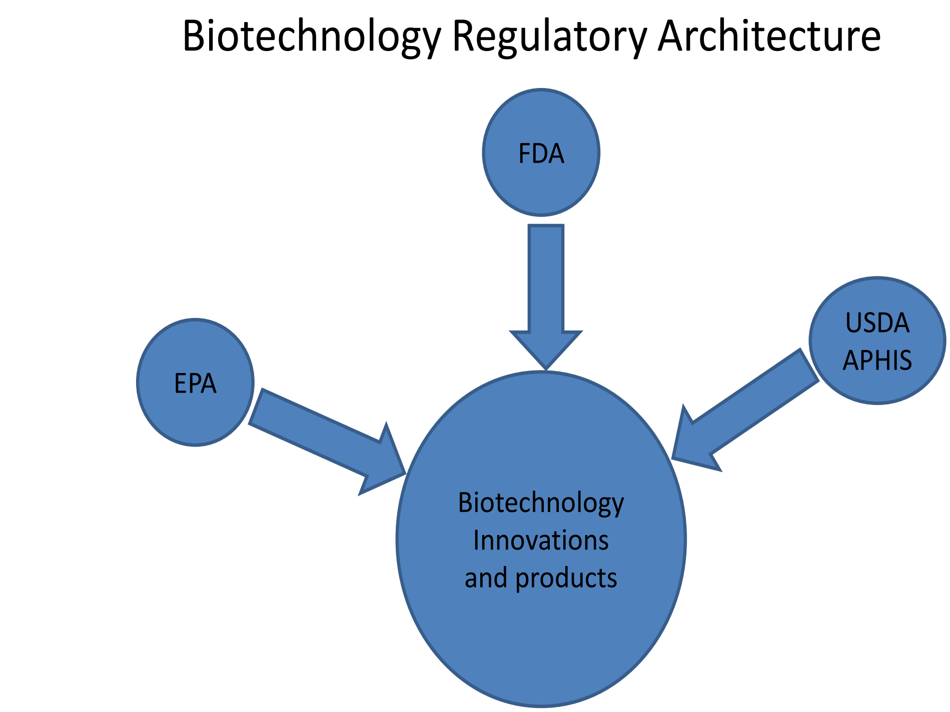
299 Ibid.

300 Vijay Subramaniam and Michael R. Reed, "Issues in Biotechnology Regulation and Its Effects on Industrial Structure," *AgBioForum, The Journal of Agrobiotechnology Management and Economics* 18, no. 1 (2015): 34–43, http://www.agbioforum.org/v18n1/v18n1a05-subramaniam.htm.



Biotechnology regulatory framework consists of three primary agencies which assume responsibility for regulation of biotechnology based on the area of responsibility of each agency. These agencies are the Environment Protection Agency under the Toxic Substances Control Act (TSAC), the U.S. Department of Health and Human Services' Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS).

Figure 16. Biotechnology Regulation Framework

C. AVIATION AND BIOTECHNOLOGY REGULATION ANALYSIS

Both of the aviation and biotechnology frameworks present pros and cons if implemented for the regulation of nanotechnology. Under the aviation framework, one benefit would be the centralization of expertise on the technology. However, the current state of nanotechnology development does not warrant this type of singular oversight structure. Additionally, the cost to create a new agency and bring together the requisite expertise would outweigh the benefits added to regulatory decisions at this point. Under the biotechnology framework, each existing regulatory agency maintains its regulatory responsibility under existing rules and regulations. This is a prudent approach to regulation; however, the problem is that none of these agencies has the requisite expertise to specifically address the unique challenges of nanotechnology regulation.

VI. FINDINGS AND RECOMMENDATIONS

This thesis was designed to map the regulatory landscape of nanotechnology by examining the background of the technology, reviewing the relevant legislation and regulatory spaces, and conducting a nanotechnology stakeholder analysis of federal stakeholders. The researcher categorized these stakeholders based on the power-interest grid. Next, the research included a comparative analysis of the aviation and biotechnology regulatory frameworks. The findings of this research provided the foundation on which to make recommendations for the regulatory framework of nanotechnology.

A. FINDINGS

Mapping the regulatory landscape of nanotechnology has revealed several key findings, as listed below.

1. The regulatory landscape of nanotechnology is vast, with many stakeholders and potential pitfalls to regulation.
2. There is very little consensus on many aspects of nanotechnology. Researchers disagree on the definition, rate of technological advancement, regulation, potential dangers, what the technology will look like, or how it will be used in its mature state. The one thing nearly everyone agrees on is that nanotechnology will potentially be one of the most important technologies of this century.
3. The scope of nanotechnology’s influence reaches across several industries and sectors of society. There will likely be no part of society untouched by this emerging technology.
4. The current state of nanotechnology is robust, with more than 1,800 products known or thought to be using the technology. Despite their proliferation, the environmental, health, and safety implications of nanoengineered materials throughout the product life cycle remain largely unexplored.
5. The current regulatory approach to nanotechnology is to address it under existing laws; however, these laws may not be sufficient to address the future challenges of nanotechnology. The Consumer Product Safety Commission, which is tasked with ensuring that products are safe for consumers, lacks the funding and personnel to properly address nanotechnology in products already in the marketplace.

6. Nanotechnology is important to the long-term health of the U.S. economy. The U.S. government has invested significant resources in the advancement of nanotechnology research. The NNI has received nearly $24 billion in federal funding since 2001.

7. There have been many pieces of legislation directly or indirectly related to nanotechnology. Most legislation focuses on research and development, not on regulation.

8. Despite their very disparate missions, many federal agencies are involved in nanotechnology research, development, and regulation.

9. Aviation and biotechnology have different regulatory frameworks that can inform the recommendation for nanotechnology's regulatory framework. Both industries view regulation differently.

B. RECOMMENDATIONS

These recommendations come as a result of identifying obstacles to regulation and determining, based on stakeholder analysis and regulatory landscape, the best framework for nanotechnology regulation.

The first recommendation is to follow the advice of Jeffrey Matsuura and "display confidence in their existing regulatory systems by relying on those rules and processes to oversee the ongoing introduction of nanotechnology into additional commercial applications," while addressing the limitations of this approach.[301] The primary limitation of this is the high-level of technical expertise required for understanding the technology and therefore for recommending policy or enacting rules or regulations. The primary regulatory institutions should be those identified as high power, high interest on the stakeholder matrix: the EPA, FDA, CPSC, and NIOSH. To ensure that the appropriate level of expertise is available for regulatory decisions, this thesis recommends that each of these four agencies sponsor an advisory committee of technical and industry experts under the guidelines of the Federal Advisory Committee Act of 1972 (Public Law 92-463). These advisory committees would provide relevant and objective advice, which would be open to the public for review. Following this recommendation would set up the United States for success regulating the nanotechnology now and in the future, no matter how it develops.

[301] Jeffrey H. Matsuura, *Nanotechnology Regulation and Policy Worldwide* (Norwood, MA: Artech House, Inc., 2006), 4.

The second recommendation is to conduct an NSF-funded, multiyear, comprehensive study to determine the environmental, health, and safety risks and impacts of nanoengineered materials. Without knowing the risks associated with the technology, one cannot reasonably determine what future regulation should look like. Once researchers identify the risks, lawmakers can enact reasonable regulation.

The third recommendation is to review funding for the CPSC. According to research, the CPSC is too undermanned and underfunded to accomplish its mission, especially in light of the many products that now use nanoengineered materials. Congress should review this agency to identify to what extent funding and staffing should be increased.

The fourth recommendation is to increase public awareness of nanotechnology and promote public engagement through an education program that provides government-funded literature and public television/radio programming. An engaged and educated public is necessary to guard against the damage of “hype” regarding nanotechnology.

The fifth recommendation is to fund a scholarship program, through the NSF, for students seeking advanced degrees in nanotechnology-related research fields. The research reveals how the United States is falling behind other developed countries in the STEM fields of learning. A scholarship program designed for nanotechnology would not only help to address this problem but also provide the future expertise needed to guide regulation as the technology matures.

The sixth and final recommendation is to continue funding nanotechnology research in the federal budget. The research shows agencies such as the NNI are playing and will continue to play an important role in the future of nanotechnology development.

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APPENDIX. LIST OF SOURCES FOR FIGURE 8

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