

# Large Policy Issues for Small Scale Technology

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## **Executive Summary**

Small scale technologies have the potential to improve the lives of every person living in the world today and for generations to come. Current efforts in biotechnology will improve the nutritional value of various foods. Biotechnology will also help people in areas that experience agricultural difficulties, giving them a better opportunity to grow crops to feed their families and their countries. Nanotechnology brings the promise of great leaps in computing power, superior materials, and environmentally friendly manufacturing processes. Advanced nanodevices may allow doctors to detect the development of the first cancer cell in a patient, immediately allowing them to administer a targeted treatment that would eliminate the disease while leaving the rest of the body virtually unharmed.

Unfortunately, a great deal of uncertainty surrounds the development of new technologies. Although the United States currently tasks three agencies with regulation and oversight of biotechnology, critics still argue that the industry has endangered the lives of people around the world by introducing biotechnology into the environment. Even though no one has developed advanced nanodevices, critics such as Bill Joy have already begun to plant seeds of uncertainty about the dangers of nanotechnology.

The government should examine developments in biotechnology policy both here and abroad. This examination will allow scientists and policy makers to determine how to regulate nanotechnology and develop sound policy. Whether or not science determines the validity of critical claims about the dangers of nanotechnology, scientists, engineers, and policy makers should make every effort to find out as much information as possible about nanotechnology and then explain their findings to the public. Failure to explain nanotechnology and biotechnology will only harm the industry and the public, depriving science of a genuine opportunity to improve the lives of people around the world.

## **About the Author**

Kyle Hathaway is a Chemical Engineering student at the University of Mississippi. He gained an interest in nanotechnology while working on micro channels for DNA and blood analysis chips at Oak Ridge National Laboratory. His future plans involve graduate research in both biotechnology and international technology policy.

## **WISE**

The Washington Internship for Student Engineers began as a way to help bridge the gap between science and policy. This ten week program has run for twenty years, bringing together a group of engineers from various disciplines to Washington D.C. The students work with a resident faculty member, mentors, and various representatives from organizations with an interest in public policy to understand the interaction of technology and policy. After gaining an understanding of how policy develops, students write a policy paper on a topic of interest to the student and his or her sponsoring society.

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## **Issue Definition**

In 1959 Nobel Physicist Richard P. Feynman delivered his paper entitled “There’s Plenty of Room at the Bottom.” Feynman said he wanted to describe “the problem on manipulating and controlling things on a small scale.”<sup>1</sup> He went on to describe the field now known as nanotechnology. With a breakthrough in the field of nanotechnology, the world as people know it today has the potential to evolve into something which few people in 1959 could have possibly imagined.

Failure to carefully develop nanotechnology regulation could, as with poor regulation of other emerging technologies, result in either stifling the development of nanotechnology or leaving humanity with a bleak future. Some emerging technologies with great benefits have highlighted the difficulty in developing consistent international regulatory policies. For example, some countries like the United States have embraced and supported biotechnology, while other countries have balked at its use, predominantly in the agricultural sector. Not only are there divergent regulatory approaches across the globe, but there are also various domestic regulatory approaches that the government has implemented with varying degrees of success. This paper will analyze domestic and international regulatory approaches as recently used for emerging fields of technology to provide a basis for recommendations of appropriate development of policy for the regulation of nanotechnology.

## **Examining Nanotechnology with a Biotechnology Background**

Biotechnology is one of the newest technological fields to fall under government regulation and catalyze massive international debates. Biotechnology has the potential to greatly change the way we live by improving crop yields and reducing stress on the environment. The field’s critics think that biotechnology will cause a great deal of harm to the people its proponents want to protect. Either way, anyone who consumes food may eventually feel the effects of agricultural biotechnology. Nanotechnology has emerged as

the next generation of technology, bringing the promise of a fundamental change in the way people live.

The government often develops technology regulation in response to public uncertainty. When the United States developed its biotechnology policy in the 1980's, no one knew how the introduction of genetically modified organisms into the food supply would affect people or the environment. More than a decade later, critics still maintain that the biotechnology industry does not fully understand the long-term effects of their work. Similar concerns about nanotechnology have recently come to light. Critics of nanotechnology feel that scientists do not know how nanomachines may behave or how artificially intelligent computers may interact with humans. Thus, the unknown consequences of new technologies provide a link for using biotechnology policy as a model when looking at the development of nanotechnology policy.

### **Defining Nanotechnology and Biotechnology**

Nanotechnology, for the purpose of this paper, will refer to the science and engineering aspects of nanoparticles, nanostructured materials, and nanodevices.<sup>2</sup> The study of nanoparticles consists of the observation and assembly of particles on a nano (one times ten raised to the negative nine) meter scale. The buckyball (buckminsterfullerene), a special arrangement of 60 carbon atoms is an example of a nanoparticle. Nanostructure materials are assembled at the molecular level to provide novel properties. This nanotechnology class includes dispersions and coatings, high surface area materials, and consolidated materials. One example of a nanostructure material is a molecular wire, a chain of  $C_{12}H_{25}$  molecules connected together for the purpose of conducting current on a molecular level.<sup>3</sup> Finally, nanodevices are the machines or tools designed to perform work on the nano scale. Assemblers, a special class of nanomachinery, represent a widely disputed frontier in nanoscience and technology. A few private organizations are striving to produce a machine that can make a molecular duplicate of itself.<sup>4</sup> The potential benefits of an assembler are truly amazing. Aging and illness alike, stemming from misaligned molecules, could be repaired by nanomachines capable of putting molecules back in a healthy position.<sup>5</sup>

While biotechnology does not yet have the ability to repair damage on a molecular scale, scientists and engineers in this field do have a breadth of knowledge allowing them to significantly improve the health of people around the world. The Economic Research Service (ERS) defines biotechnology as the use of biological processes of microbes, plants, and animal cells for the benefit of mankind.<sup>6</sup> For this paper, biotechnology will only refer to agricultural products modified by the insertion of genetic material from another organism. Other documents may refer to the subject of this paper's definition of biotechnology as genetically modified organisms (GMOs)<sup>7</sup>, genetically engineered crops, or "living modified organisms" (LMOs)<sup>8</sup>.

### **Biotechnology Background**

Scientists in the biotechnology industry refer to techniques for producing agricultural biotechnology products as recombinant DNA processes. Quite simply, this technology is an extension of conventional breeding techniques utilized by farmers and the agricultural industry for many years. Traditionally, a crop, such as corn would be cross pollinated with another variety or a similar plant to instill some positive characteristic of a plant into the staple crop. With traditional breeding, this took some time as the person breeding the crop would have to cross breed the new plants with each other many times in order to single out the desired traits. With modern scientific techniques, researchers can "cut" a specific trait from the DNA of a plant. Then the researchers cut the plasmid, a layer of DNA found in bacteria outside of most cells. The scientist may then splice the desired trait into the plasmid and secure it with an enzyme that acts as a glue.<sup>9</sup> In other words, they cut out a section of the DNA "chain" and replace it with some new links.

The biotechnology industry tries to modify crops for producers and consumers alike. For example, scientists recently produced a variety of corn referred to as Bt Corn. This corn contains genetic information found in *Bacillus thuringiensis* that kills off European and Southwestern corn borers that can dramatically lower the yield of corn in an affected area.<sup>10</sup> The corn borers obviously hurt the farmer, as he loses the crops that provide his livelihood. At the same time, consumers face a rise in cost due to a shortage

of available corn. The genetically modified corn, however, has a natural resistance to the worm that would normally decimate a traditional crop. Thus, farmers do not need to use pesticides, reducing environmental damage and cost. They also have one less factor that may affect their crop.

Similar efforts are underway to improve the pest resistance of other crops as well. In addition, scientists are trying to find ways to improve the nutritional value of various plants. For example, several companies are currently trying to improve genetic information in rice, causing it to have higher concentrations of lysine, a very beneficial amino acid.<sup>11</sup> At the same time, companies are trying to eliminate harmful elements of traditional crops. Companies working with rice and other crops are attempting to remove proteins that are known to cause allergic reactions.

With so many benefits, one would think a minimum amount of regulation would exist. Governments around the world should want to provide for the timely development of advanced agricultural products to improve agrarian elements of their economy while improving the quality of life of their own citizens and people around the world. However, the motivations listed above have to compete with concerns over the safety of modifying the genetic information found in plants.

### **Biotechnology Criticisms**

Critics, including Ralph Nader, assert that “we just don’t know that much about the flora and the fauna and cellular structure.”<sup>12</sup> Some scientists have contended that genetically modified foods will cause increased resistance of bacteria to modern antibiotics.<sup>13</sup> Recombinant DNA techniques often utilize antibiotic resistance markers to designate the plant cells that receive modification as a result of the procedure for splicing genetic material into a plant.<sup>14</sup> Transfer of genetic information from antibiotic resistance markers to bacteria may occur in the intestines of animals feeding on plants that contain the markers. Additionally, genetically modified organisms and their DNA may survive for extended periods in wastewater and sludge, other aquatic ecosystems, soil, and plant surfaces.<sup>13</sup> Recent studies conducted under laboratory and natural conditions show that gene transfer can and does occur in bacterial communities where resistance markers are

found. According to an article by Tappeser, Jager, and Eckelkamp<sup>13</sup>, current guidelines for the use of antibiotic resistance markers do not take into account the robust nature of DNA revealed by up-to-date research. Whether or not other scientists can validate Tappeser's work remains to be seen. While critics of biotechnology point to the possible dangers of resistance markers causing bacterial resistance to antibiotics, they have yet to address other causes of bacterial resistance to modern antibiotics.

Research conducted by Tappeser also criticizes the use of bacillus thuringiensis to make corn resistant to European and Southwestern corn borers.<sup>15</sup> Normal varieties of corn require the use of pesticides to kill those insects, including pesticides utilizing bacillus thuringiensis. To date, only one species (the diamondback moth) has developed a resistance to the traditional pesticide. However, corn modified with the genetic information from the bacteria only uses part of the bacteria's DNA, (65% to be exact).<sup>15</sup> This means that the toxin produced results from only some of the information used by the bacillus thuringiensis to kill corn borers. Calculations put forth in Tappeser's article suggest that certain species may develop a resistance to bacillus thuringiensis modified corn (Bt corn) in three to four years, even with the Environmental Protection Agency (EPA) suggested four percent refuge (planting of traditional corn along with Bt corn to slow the development of resistance). If this does indeed occur, the United States and the rest of the world stand to lose a valuable pesticide, as conventional Bt treatments could lose their effectiveness.

Another problem, according to Tappeser's article and other research, suggests that Bt corn might kill non-target organisms as well. For example, environmental organizations around the globe have touted a study showing that monarch butterfly larvae die when dusted with Bt corn pollen. Thus, the potential for transgenic plants to have a detrimental effect on beneficial organisms does indeed exist. As with the case for resistance markers causing the development of resistant bacteria, one must explore the other side of the issue as well. A University of Illinois study showed that earlier reports of detrimental effects of Bt corn on the monarch butterfly did not accurately depict what occurred under field conditions.<sup>16</sup> Secondly, no biotechnology critics studied the effects of conventional pesticide use on monarch butterfly larvae in order to see which method of pest control had the lowest chance of killing non target organisms.

One of the beneficial organisms subject to harm from transgenic plants includes Homo Sapiens. In 1996, researchers in Nebraska found that soybeans with a gene spliced from the Brazilian nut could cause fatal allergic reactions in people who were sensitive to Brazilian nuts.<sup>17</sup> This result caught many off guard, as animal tests of this product did not indicate any allergy. Thus, people must include themselves among the species that may suffer as the result of unsound biotechnology products. Once again though, one must realize that scientists do extensive testing to examine concerns over allergenic problems in agricultural biotechnology products. No one in industry or government regulatory agencies has ignored the possibilities of a problem. Thus people continually engage themselves in the research that found the allergenic problem with the Brazilian nut bean gene placed in soy.

### **Biotechnology Regulation in the United States**

The United States has developed biotechnology regulation by working with members of industry and academia. Although opponents of biotechnology rarely mention early biotechnology regulation, and often complain about further deregulation,<sup>13</sup> scientists adhered to a self imposed ban on biotechnology research from 1973 until 1980.<sup>18</sup> At the time, they did not have enough knowledge about the effects of modifying the genetic information of various organisms. Today, researchers still use voluntary guidelines published by the National Institute of Health (NIH). However, contrary to claims of deregulation, the United States government has added laws and regulations governing agricultural biotechnology voluntary guidelines. In fact, three separate agencies, the United States Department of Agriculture, the Environmental Protection Agency, and the Food and Drug Administration all work together to examine the safety and impact of biotechnology.

The United States Department of Agriculture (USDA) currently uses one law to regulate biotechnology, the Federal Plant Pest Act.<sup>19</sup> This law allows the USDA to include agricultural biotechnology products under their jurisdiction where they deem it appropriate. Using this law to define and establish procedures for the introduction of

genetically modified plants, the USDA employs four regulations to help guide the Animal and Plant Health Inspection Service (APHIS) a regulatory arm of the USDA.

One of the latest USDA regulations guides the introduction of products modified with genetic engineering into the environment.<sup>20</sup> This regulation allows APHIS to streamline the procedures for reviewing new biotechnology products to determine whether or not farmers may safely introduce them into the US agricultural system. With more than ten years of approved plants and the requisite data supporting their safety in the environment, the USDA now allows manufacturers to submit a request to extend non-regulated status to new organisms that are similar to products which the agency has already approved. This regulation includes guidelines for developers, supplying them with information on methods, procedures, and principles that the manufacturer should examine and address in a request for an exemption.<sup>18</sup> This latest regulation does not undermine earlier policies set by the USDA. Rather, it allows the agency to apply its regulatory funding to research on new products that are substantially different than past products, enhancing the quality of regulatory enforcement.

The Environmental Protection Agency (EPA) has a great deal of responsibility for biotechnology oversight. The EPA employs the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to oversee the research, development, and production of pesticides.<sup>21</sup> The EPA also employs the Federal Food, Drug, and Cosmetics Act (FFDCA), utilizing the federal government's power to regulate interstate commerce to ensure that products are not mislabeled.<sup>22</sup> Under this law, the EPA makes sure that agricultural biotechnology products are just as healthy and safe, if not more so, than the natural foods that preceded them. Finally, the government has charged the EPA with enforcing the Toxic Substances Control Act (TSCA).<sup>23</sup> With this law, the EPA may request data from chemical and agricultural manufacturers, allowing them to gauge the environmental impact of any new products. The Toxic Substance Control Act provides biotechnology manufacturers with guidelines to conduct testing and submit all acquired data. The EPA employs a plethora of toxicologists and chemists to examine the data from manufacturers to help ensure that their products are as safe and environmentally benevolent as possible.<sup>24</sup>

In 1997, the EPA developed a final regulation under the Toxic Substance Control Act, dealing with Microbial Products of Biotechnology. Specifically, the regulation designates “new” microorganisms as organisms formed by combining genetic information from intergeneric organisms, or organisms classified under different genre.<sup>25</sup> EPA scientists believe that intergeneric organisms have an adequately high likelihood of displaying new traits to merit review. Under this regulation, manufacturers now have a reporting vehicle known as the Microbial Commercial Activity Notice (MCAN). Persons wishing to introduce intergeneric organisms must submit a notice of intent to the EPA 90 days in advance, allowing the evaluation of any possible risk to human health or the environment. Research and development entities must also submit a notice of intent to conduct field tests 60 days in advance under the TSCA Experimental Release Application section (TERA) of this regulation. Exemptions do exist, allowing manufacturers who have sufficient data showing the similarity of a new product to a previously examined product to go ahead with their plans without having the EPA review a MCAN.

Finally, the Food and Drug Administration (FDA) uses the Federal Food, Drug and Cosmetic Act (FFDCA), the same law employed by the EPA, to regulate biotechnology. The FDA treats genetic information added to an agricultural product as a food additive. Current FDA policy requires genetically modified foods to meet the same strict criteria as food additives, in order to ensure public safety. Since 1992, the FDA has encouraged manufacturers to consult with the agency on regulatory and safety issues. Recently, the FDA announced that manufacturers must submit notice of the intent to introduce new biotechnology products 120 days in advance of the desired time of introduction. This change in policy provides one more example of the development of more stringent regulations, contrary to the contentions of some critics.

### **Policy and Proposed Legislation**

To date, United States policy has centered around scientifically based regulation of the biotechnology industry. The three regulatory agencies charged with overseeing agricultural biotechnology have adapted existing laws to meet the new needs of this

emerging field. Recently, the White House issued a statement indicating that the government would tighten regulation of agricultural biotechnology.<sup>26</sup>

This announcement continues the trend of using a combination of scientific research and voluntary guidelines to regulate and define policy. This May 3<sup>rd</sup> 2000 announcement called for a six-month study by the Council on Environmental Quality (CEQ) and the Office of Science and Technology Policy (OSTP). This study will evaluate the effectiveness of interagency regulation of biotechnology. The White House also requested expanded measures establishing voluntary food labeling and increased scientific research for evaluating the long-term safety of biotechnology products.<sup>24</sup> This research will supplement studies undertaken by industry, some of which have lasted between five and seven years.

Several bills submitted to the 106<sup>th</sup> Congress parallel issues addressed by the President's initiative. Representative Dennis Kucinich of Ohio introduced a bill calling for the labeling of all foods containing genetically modified material.<sup>27</sup> Stating that consumers have a right to know if the food they are eating contains potential allergens, the bill contains provisions for federal fines of up to \$100,000 for violating labeling laws. Representative Kucinich also introduced the Genetically Engineered Food Safety Act.<sup>28</sup> This bill calls for mandatory testing of toxicity, allergenicity, and other side effects. Versions of both bills have appeared in the Senate as well.

While bills in both houses of Congress have called for tighter science based regulation in the United States, representatives and senators alike have called for government support of biotechnology products around the globe. Senate Resolution 101 of the 106<sup>th</sup> Congress calls for markets to adopt scientific regulation of biotechnology products. Similarly, a later bill, S2106, calls for the international exchange of biotechnology information to promote the benefits of agricultural biotechnology products.<sup>29</sup> Currently, both the House and Senate have referred all bills regarding biotechnology to committees and subcommittees (Note: they will not remain at the close of Congress this year, and will have to be reintroduced). The Senate Bill calling for the international exchange of biotechnology information represents a significant part of the United States policy on biotechnology. Many people believe that biotechnology will help

eliminate starvation and sickness in developing countries. Utilizing this opportunity has increased in importance as biotechnology develops in the United States.

A recent Senate hearing helped provide focus on the direction of the government's international biotechnology policy. Senator John Ashcroft spoke at the hearing, saying that "this is not about science, this is about human beings who are suffering because we did not fully understand the science."<sup>30</sup> In order to develop a better understanding of biotechnology, the US attempts to help other nations consider the "value of consumer confidence" according to Anthony Wayne of the State Department.<sup>31</sup> Developing countries have the largest chance to benefit from agricultural biotechnology due to their often tenuous food supply. Thus the US continues efforts to work with countries around the world to "understand their viewpoints and interests" while sharing concerns as well.<sup>31</sup>

### **International Biotechnology Background in Industrial Nations**

With some exceptions, namely Australia, foreign countries have not accepted agricultural biotechnology products with the degree of fervor as the United States. Recent history provides some insight into Europe's reluctance to accept agricultural biotechnology. Several years ago, the mad cow disease (Bovine Spongiform Encephalopathy) riveted Great Britain.<sup>32</sup> Countries around Europe banned British beef fearing the spread of this deadly disease. The fear of such outbreaks does not dissipate quickly. Although no evidence of BSE ever appeared in German cattle, many Germans still avoid beef.<sup>33</sup>

So, while some members of the European Union (EU) may see many benefits from using biotechnology, such as lower cost, reduced use of pesticides, and increased yields, politicians in Europe must also acknowledge the concerns of European citizens. Many European countries do not have an equivalent of the United States Food and Drug Administration.<sup>31</sup> Thus they lack a regulatory agency charged with using scientific information and testing to evaluate food safety. Without a science agency to oversee biotechnology, the responsibility for regulation in Europe has fallen to other groups. In the end, many people such as EU Commissioner for Health and Consumer Concerns

David Byrne believe that the final say over EU biotechnology policy will rest with politicians, as they have the responsibility to the public.<sup>28</sup>

Recently, both the European Union and the United States worked on the Biosafety Protocol on January 29, 2000.<sup>34</sup> While both sides agree that food safety should remain a primary objective, disagreement still exists. European and American views over the amount of information available to consumers about genetically modified content still conflict. In addition, the two governing bodies have different opinions about defining and evaluating the potential risk of genetically engineered crops.

Both the United States government and the biotechnology industry have worked to provide scientific information to the European Union and other governments. Ambassadors including Cynthia P. Schneider, the US Ambassador to the Netherlands, have made efforts to present information about the benefits of biotechnology and known scientific facts about biotechnology safety.<sup>28</sup> The United States Department of State has also made an effort to support biotechnology. Secretary of State Madeleine K. Albright made a presentation to the American Association for the Advancement of Science (AAAS) where she spoke about the benefits of biotechnology to the world community.<sup>35</sup> She mentioned the strong effort of the United States to base the Biosafety Protocol on sound scientific knowledge. Finally, industry, in large part through the Biotechnology Industry Organization, has provided foreign governments with scientific information gleaned from research of more than 900 companies on biotechnology safety.<sup>16</sup>

An indication of the success of the information sharing set forth by the United States has already emerged. Key international consumers, such as The People's Republic of China have expressed an interest in "improved" varieties of crops such as rice, wheat, and corn.<sup>36</sup> While China has increased its own agricultural production, the country has chosen to remain open to international resources as a "complement" to their own agricultural production. These statements indicate a willingness to remain open to modern crops grown within the U.S.

Even one of Europe's most conservative nations with regard to agricultural biotechnology has shown some signs of moderation.<sup>28</sup> The United Kingdom, which harbors the most vocal resistance to biotechnology has 270 biotechnology companies within its borders, more than any other European nation, with the exception of Germany.

So, while some resistance to biotechnology remains, the industry has made progress all the same.

### **Concerns Over Remaining Policy Conflict**

Both the United States and Europe have concerns regarding the difference in their respective policies on agricultural biotechnology. Europe and the United States both want to avoid environmental problems such as the rapid development of insect tolerance to new and traditional methods of pest control (see the discussion of bacillus thuringiensis in crops and pesticides). With the volume of international agricultural trade, the development of pests or viruses resistant to current agricultural pesticides (whether traditional or genetically engineered) could spread rapidly.

Similarly, the United States and Europe would like to avoid problems that would disallow European importation of agricultural products from the United States. Despite advances in European agriculture, countries in the European Union still look to the United States as a source of agricultural products. In 1997 the United States had an agricultural trade surplus of one billion dollars with Europe.<sup>29</sup> Laws limiting the importation of genetically modified crops would put a strain on the European food supply while stifling the agriculture industry in the United States. As an illustration, farmers growing corn in the United States have lost \$200 million dollars a year since 1998 due to various European Union regulations.<sup>31</sup>

With the spread of genetically engineered crops, farmers in the United States who wish to grow traditional crops may find it increasingly difficult to avoid cross-pollination of their pure crops with genetically modified crops. With the lack of isolation of farms in both the US and EU, in addition to environmental factors that spread pollen from one region to another, great care must be taken if people wish to maintain a source of natural crops.

Efforts by industry, governments, and farmers to provide natural products would not need to serve as a condemnation of the biotechnology industry. Rather, it would showcase respect and understanding for international concerns and preferences. This type of policy would provide a measure of safety should future studies expose problems with some genetically engineered crops. It would also provide the biotechnology and

agricultural industries with additional time to further validate their belief in the safety of their products, further assuaging uncertainties of consumers around the world.

### **Lessons From Biotechnology Policy**

Scientists, industry, and the government must work together to develop future technology policies. *One approach* to dealing with a new technology involves a *ban* on any research in the field. At an early stage in the development of biotechnology, scientists complied with a self-imposed ban on research because they did not have a solid grasp on the full extent of the technology. Later, after lifting the ban on research, scientists agreed to follow research guidelines set by the National Institute of Health (NIH).

The biotechnology industry's model for *self-regulation* can serve as an excellent model of a *second method for regulating future technology development*. Responsible development early on may allow an industry more freedom of development later on, as legislators and consumers alike will have more trust in an industry. Beyond a certain point of development in the industry, the government implemented regulations to guide the biotechnology industry, protect the environment, and ensure consumer safety.

Biotechnology regulations did not originate from any new laws granting the three governing agencies new powers. The United States could have formed a new agency charged with regulating biotechnology. This would have required a great deal of money to set up the necessary infrastructure, employ knowledgeable people, and conduct the necessary scientific work for the development of regulation. Instead, the EPA, USDA, and FDA employed existing laws, such as the Federal Food, Drug and Cosmetic Act. In some cases, agencies formed special groups within their organization, such as APHIS within the USDA. The various agencies then developed new regulations based on those existing laws, such as the 1997 EPA regulation developed around the TSCA.

The United States found itself in a unique position to lead the development of biotechnology regulation. Having the technological lead in research and implementation necessitated the establishment of policy and regulation before other countries with biotechnology industries in their infancy. A lack of incidents such as the mad cow disease created an environment more friendly to technological progress in the biotechnology

field. Biotechnology policy in the United States, after the implementation of regulations in 1986, highlights a *third regulatory approach; moderate government regulation*. *European policy* contrasts with US biotechnology policy, providing a model for more *strict regulation*.

Governments must also act responsibly in the early stages of development of a new technology, interacting with industry, academia, and other nations at the same time. In the United States, a recent tightening of regulations has come in part from pressure exerted by opponents in academia and the development of significantly different policies in other nations. Biotechnology industries have accepted and complied with the new regulations.<sup>37</sup> While updating its own policies in response to developments in the biotechnology field, the United States has tried to lead efforts in providing scientific information on the subject. The US government and industry have done this in order to facilitate the development of more consistent international regulations, promoting economic stability and environmental safety.

### **Differences in the Development of Nanotechnology Policy**

Nanotechnology policy may develop along a similar path to the course of biotechnology. While the government can leave the industry to regulate itself to a point, it should prepare several regulatory options to deal with *possible* courses of development. Divergent regulations around the globe may impede the safe development of nanotechnology. Also, while the United States led the biotechnology field with some of the first regulations following early technology development, it does not have the same advantage with nanotechnology. Thus efforts to develop a coherent “baseline” international policy should also transpire at an early date.

### **Nanotechnology Background**

Nanotechnology has emerged as the next field in engineering and technology. Promises range from improved materials to synthetic nanoscale drugs that seek out and eliminate harmful cells throughout the body.<sup>38</sup> Currently, two schools of thought on nanotechnology exist.

Numerous researchers from traditional fields of science and engineering have undertaken research of particles, materials, and devices on the nanoscale. These scientists feel that nanotechnology has and will allow numerous developments in the creation of advanced materials, the development of new medical technologies, and the use of biological systems as a model for future manufacturing and research.<sup>39</sup> The Breakout Session on Biomimetic Nanostructures at the NIH Nanotechnology Conference included discussion of “self assembling materials” and cellular motors.<sup>36</sup> One example came from Dr. Ilhan Aksay of Princeton, who talked about biological templates, or information carried by biological systems that allows them to create highly ordered structures, such as bone. Scientists can currently synthesize compounds found in bone, but they cannot recreate a bone, forming an ordered structure of specific shape. Dr. Viola Vogel of the University of Washington spoke about the study of molecular motors, and attempts to study and then utilize them for transport in nanosystems. These two examples only scratch the surface of biological work on the nanoscale. Chemists, physicists, and scientists involved with computers have also made great strides in their respective fields of study on the nanoscale.

Currently, another group advocating the benefits of nanotechnology exists outside of the established scientific community, such as the NIH, the National Science Foundation (NSF), and numerous agencies and universities. This group, comprised of the Foresight Institute, the Institute for Molecular Manufacturing, and Zyvex LLC makes more far reaching claims about the benefits of nanotechnology, referred to as Molecular Nanotechnology (MNT). The current focus of this group centers around the aforementioned assembler. This hypothetical device would have the ability to replicate itself, speeding the manufacture of other nanomachines capable of building materials, medical devices such as advanced medicines, and numerous other structures. A great deal of the controversy around nanotechnology arises from fear of the possible consequences of the technology that this group purports to develop.<sup>37</sup> Regardless of the differences between the two schools of thought within nanotechnology, fears of development and regulation of the latter group’s MNT has affected the entire field of nanotechnology. As an example, Bill Joy’s recent article in *WIRED* article about the dangers of assemblers

and artificial intelligence influenced discussion during the development of the National Nanotechnology Initiative.<sup>40</sup>

During the creation of this paper, no nano devices fitting the description of an assembler existed. Neither had any man-made designs for an assembler proved the capability to function when analyzed with the use of advanced modeling techniques.<sup>36</sup> Despite the lack of a man-made assembler, many biological organisms, including people reading this paper, have the ability to reproduce themselves and perform other complex tasks. So, while the current scientific establishment may not endorse the notion of assembler, they may one day come into existence. The possibility of biomimetic devices capable of similar tasks to an assembler may also come to pass. Thus, this paper will outline four basic regulatory approaches. While these approaches will include the analysis of regulations based on assemblers and advanced biomimetic systems, that analysis does not constitute endorsement or condemnation of the idea of an assembler.

### **Basic Regulatory Approaches**

This Section of the report will outline four basic regulatory approaches to nanotechnology. Subsequent sections will discuss policy issues that will likely arise with the development of nanotechnology under any regulatory approach other than an outright ban.

<b>Regulatory Approaches</b>
• Ban
• Strict Regulation
• Moderate Regulation
• Self Regulation

### **Ban**

First, the United States could work with other countries to ban nanotechnology. Such a treaty could prohibit nanotechnology research in a specific area such as

nanomachines, or it could ban research in all areas, including nanoparticles and nanostructured materials.

This approach has several potential benefits. Mainly, it would placate the worries of people who feel that nanotechnology could destroy humanity. In an April article that had significant impact on later developments in the nanotechnology community, Bill Joy of Sun Microsystems pointed out some possible dangers of nanotechnology.<sup>41</sup> He cites several expert opinions that developments in nanotechnology could lead to a dependence on artificial intelligence (AI). At some point, people might develop systems of sufficient complexity that would disallow their direct control. Then, people would be at the mercy of machines.

Another scenario for human destruction due to machines stems from the “grey goo” scenario.<sup>42</sup> In this scenario, nanomachines capable of self-replication convert the natural environment to replicas of themselves or some other nanomaterial. There are significant problems with this scenario, some of which will appear later. However, an effective ban of nanotechnology would eliminate the possibility of the grey goo scenario.

To date, no government has moved to ban nanotechnology. Instead, the United States, Japan, and many European nations have invested billions of dollars in nanotechnology research. All of these countries have predicted the many benefits of this emerging field. With the benefits and significant investment of capital in nanotechnology, few, if any, nations would agree to a nanotechnology ban. Even if one could construct such an agreement, the size of the research and results would make enforceability of the ban extraordinarily difficult at best. Finally, many people in the scientific community do not feel that any man-made machine operating on the nanoscale will overrun the world.<sup>36</sup> Development of regulations to deal with a problem that may not exist could hamper legitimate research.

### **Strict Regulation With Government-Run or Monitored Research**

Under this regulatory policy, nanotechnology research would fall under heavy oversight from the government. This policy could begin as soon as legislation passed, possibly remaining in effect indefinitely. Or, it could come into play as certain parts of nanotechnology, mainly the development of assemblers or systems replicating biological replication processes, came about. Self-regulation could speed up early research with minimal risks, allowing the timely development of an assembler or advanced biomimetic techniques.

The development of advanced nanotechnology may drastically change the face of technology, major industries, and possibly the entire world. However, with this awesome power to shape the world comes the capability to destroy it. Someone might accidentally develop a nanodevice capable of reproducing itself with materials found in the natural environment. Several methods to limit the likelihood of this event will appear later. Unfortunately, the main threat of nanotechnology will not come from accidents. Directed efforts to harm individuals, nations, or the entire world could become more feasible with the development of an assembler.

First, someone could simply design a machine capable of reproducing itself in a natural environment. Bacteria and insects have replicated themselves and brought harm to humans (by causing illness and decimating food sources) for thousands of years, proving the feasibility of such a feat. If someone could find a way to allow such machines to replicate themselves indefinitely using energy and materials from the environment, it could destroy the biosphere in which we live. Someone could also develop a machine that looked for specific genetic traits in people, allowing it to selectively kill, by countless number of means. Someone could easily reconfigure small nanodevices, machines designed to repair damaged tissue by realigning molecules, reworking them to selectively destroy any number of vital parts in the human body. Finally, a terrorist could contrive a machine designed to replicate itself and produce a chemical or biological weapon, allowing one of its byproducts to kill people instead. Strict government regulation would limit terrorist access to advanced forms of nanotechnology.

So, one plausible scenario would have government regulation tighten in a post assembler era. The government could establish labs for the design and testing of assemblers. Before constructing an assembler in a lab, a developer could submit a design

proposal to a regulatory agency or regulatory body established at the lab. Either way, someone could examine the design for safety concerns including, but not limited to the following; making sure the device did not have a hidden, sinister purpose; making sure the device had multiple safeguards designed to limit its reproductive capacity, such as a timer or internal limiter of some other nature; make sure the device could not replicate in a natural environment (i.e. outside of the lab or a controlled nano-factory), limiting the likelihood of a “gray goo” incident; making sure the device did not have the ability to undergo some sort of adaptation or mutation, which could negate safety measure mentioned previously. Proponents of a less strict regulatory approach would allow some devices with the ability to evolve.<sup>37</sup> Nanotechnology labs could have safety measures designed to destroy any devices not performing according to their intended design. Certain types of radiation might be able to make nanomachines or advanced biomimetic systems inoperable. Whether or not this hypothesis holds true, labs could also employ measures to simply destroy everything in a nano test area by more conventional means such as an explosion or a massive feed of electricity.

Once a nanodevice performs satisfactorily, lab personnel could transfer it to an assembly area. This specially designed area could contain monitoring equipment and safeguards similar to those in the test lab to prevent runaway assembly. In this assembly area, a government agency, private company, or individual could run assemblers to make enough devices or product to facilitate a later process. Once the devices had replicated to a desired point, they could begin building machines used for the completion of any other desired process. So long as these machines or building blocks could not replicate themselves, the government could allow the individual utilizing the services of the assembly area to transport the non-replicating machines or other materials to a location where more traditional regulations for manufacturing would remain in effect.

Undoubtedly, researchers in the nanotechnology field and members of industry would find such an arrangement cumbersome at best. However, several arguments in favor of the above exist. First, if nanotechnology truly has all of the wonderful possibilities put forth by its different proponents, then conducting research down the block at a controlled facility should not greatly hinder development. If the technology has

too many gray areas or frailties to stand up to public scrutiny, then many people will think that nanotechnology has a long way to go indeed.

Secondly, strictly monitored use of assemblers or advanced nanotechnologies could help curb the dangerous development of nanoweapons. Any country allowing terrorists to use its facilities to develop weapons of mass destruction would face harsh action from other nanotechnology powers. Although someone or some group might develop advanced nanotechnology on their own, monitoring and control of advanced devices and development technology, such as Scanning Tunneling Microscopes, would greatly reduce the risk of a rogue group gaining access to this powerful technology.

Third, some researchers have argued for the dissemination of assemblers in sealed labs, once such labs came into existence (this regulatory approach will appear later as well).<sup>43</sup> These sealed labs would allow researchers to run an assembler, gleaning data from its operation in a closed environment, but allowing no contact with the outside world. Once an assembler passed a host of regulatory inquisitions, verifying its safety, the designer would have permission to run the assembler in an open area. Allowing people to have such sealed labs would create new regulatory issues and problems. Allowing people to have unlimited access to advanced biomimetic devices could have similar effects. First, governments would have to develop a strict set of guidelines for who could and could not obtain a sealed lab. Why? People with the intelligence to work on nanomachines and the drive to wreak havoc would surely find a way to open a sealed lab. So, after giving someone permission to create or purchase a secure lab, you would have to monitor them closely, and make sure they had more than adequate security to prevent someone else from stealing the lab or its contents.

A few people involved with nanotechnology have also proposed the development of an active shield, a collection of nanomachines strategically placed, poised to neutralize any harmful nanodevices.<sup>36</sup> Unfortunately, advocating an active shield requires one to make several assumptions. One, this approach assumes that a nanoshield will not malfunction and destroy the biosphere on its own. Secondly, it assumes that the designers of a nanoshield will always outsmart the malignant individual designing a nano weapon. Current problems with computer viruses illustrate the prowess of today's technical criminals. With strict, coordinated international efforts to monitor assemblers and their

enabling technologies, people would have a much better chance of combating nanomachines designed to propagate mass destruction, with or without a shield.

If scientists could overcome performance and safety issues with a nanoshield, one downfall to this approach still remains, a problem neglected by all literature to this date. In order for a nanoshield to operate quickly and effectively, it would require a vast amount of sensing power. If the shield couldn't detect a problem, such as a person developing a nanoweapon, how could you deploy it? Quite simply, one could not do so. In order to rapidly deploy a nanoshield before casualties occurred, nanoshield-sensors would have to exist with fairly high density across the globe, if scientists wish to have an open environment for the dissemination of assembler technology. People in charge of the nanoshield would have a tremendous capability to invade the privacy of individuals and the public at large. Secondly, criminals could tap into the nanosensors for this shield to spy on people around the world. Thus even a technologically sound nanoshield still has tremendous downfalls.

So, a strict regulatory approach would involve a combination of self-regulation and government oversight in the development of advanced biomimetic systems or an assembler. In this advanced nano era, work would occur at secure locations to prevent theft or accidental runaway replication. Designs tested at these facilities would pass through strict scrutiny to verify their safety. At the same time, researchers would pursue the development of sealed labs to increase environmental protection. However, development of sealed labs would not lead to proliferation of advanced nanotechnologies. The government would work with academia and industry to evaluate the risks of an active shield. Finally, the government would have to weigh the risk to individual privacy that could result with the development of the shield.

No matter what safety precautions the government chooses to adopt, one should not ignore the benefits of other less stringent regulatory approaches. More people working freely with the latest developments in nanotechnology would allow an increased rate of technological progress. Finally, many aspects of this approach would arise due to the development of assemblers, a feat that has not yet occurred and may never come to fruition.

## **Moderate Government Regulation**

Another course of nanotechnology regulatory development would still involve government oversight, at times, but it would allocate more responsibility to researchers working with the technology. Initially, as with the strict regulatory policy, early development would require little new regulation. Most current research outside of the nanomachinery category (nanoparticles and nanostructured materials) poses few new risks.

Current research in the chemical industry involves risks. Researchers can and do create toxic chemicals. Traditional products assembled on a nanoscale may often have magnified properties of the traditional counterparts they replace. So, more precisely constructed drugs or pesticides may be more effective, but they do not merit a new regulatory approach. Additionally, nanomaterials may, due to their more developed structure, resist methods of recycling. So, the introduction of mass-produced nanomaterials should include a study examining the environmental impact of the resulting waste. However, basic research in nanoparticles and nanomaterials does not necessitate the development of new regulatory approaches.

Thus, current nanotechnology may employ voluntary research guidelines with great success. The United States did not have federal biotechnology regulations until 1986.<sup>17</sup> This time of self regulation by the industry allowed the U.S. to take the lead in the field of biotechnology. Thus the National Science Foundation (NSF), one of the leading bodies organizing the National Nanotechnology Initiative, could work with prominent members in the technology field to formalize a set of guidelines for the conduction of nanotechnology research.<sup>44</sup> The Foresight Guidelines represent an effort to examine and explore the need for the regulation of a type of nanotechnology, referred to as Molecular Nanotechnology (MNT) within the document. The preamble of the Guidelines highlights the need for the development of regulations to limit misuse of MNT. It contends that the US should not sign a treaty similar to those restricting the use of Chemical or Nuclear Weapons, as this would allow non-complying nations to do as they please. One of the main principles of the Guidelines reads as follows; “Access to the end products of MNT should be distinguished from access to the various forms of the

underlying development technology. Access to MNT products should be unrestricted unless this access poses a risk to global security.”<sup>39</sup> Either strict government regulation outlined above or moderate security measure mentioned below could satisfy this requirement.

The age of functional nanodevices will bring a need for new regulations. David Forrest’s paper on regulating nanotechnology proposed the development of regulation to complement different stages of nanotechnology development.<sup>37</sup> First, he advocates a form of self regulation, similar to the Guidelines published by the Foresight Institute. When assemblers arrive, he advocates more government regulation. Technically informed regulators would review proposed designs for safety, making sure that they have neither a malicious purpose by design nor a fault that could cause runaway replication. Researchers should then strive to create sealed assembler labs, vessels for studying and running an assembler. These devices would allow researchers to gain information from the sealed environment while cutting the assembler off from the outside world, eliminating the danger of the “gray goo” scenario. Products containing assemblers would undergo strict review for safety, while replicating assemblers would undergo more stringent review.

After the development of a sealed assembler, but before the development of an active shield, Forrest proposes the dissemination of sealed assembler labs, stating, “experiments on assemblers can be safely performed by anyone.”<sup>37</sup> The government would provide labs for researchers to use and some outlet for turning the designs into functioning assemblers. Widespread availability of labs would deter people from attempting to develop their own assemblers.<sup>37</sup> After the development of an active nanoshield, nanotechnology regulation would enter its fourth phase. Loose regulation would allow the availability of assemblers outside of sealed labs. Additionally, the government might phase out regulatory reviews of machines as the nanoshield could simply eradicate “bad machines.”

Criticisms and pitfalls of this approach when dealing with assemblers appear in the section on strict regulation with government run or monitored research. However, the government may also choose to employ moderate regulation in a future nanotechnology industry lacking in assemblers, should their development elude those people currently

focused on this field. In the case of continued development of more widely accepted nanotechnology, the following could occur.

The government might choose a path quite similar to the approach utilized for the regulation of biotechnology. For example, the government might allow researchers and industry to carry out research under a set of voluntary guidelines. Then, when nanotechnology products came into the marketplace, most products could fall under the oversight of existing federal agencies.

If for example, a new type of nanomaterial used for agriculture came into widespread use, the government could follow an approach that would have strikingly similar characteristics to current biotechnology regulation. The government could allow the EPA, USDA, and FDA to evaluate the impact of the material on people and the environment. The agencies could order tests and review data in a manner similar to the review of new microbial species as currently carried out under TSCA.

### **No Government Regulation**

This final regulatory approach would involve continued self-regulation of nanotechnology after the development of an assembler. Responsible self-regulation will allow the industry to evolve at a rapid pace, paralleling the early development of biotechnology in the United States. The government could allow researchers to continue to follow the Foresight Guidelines after the development of an assembler. This course of action would require no legislation and would also save a considerable sum of money, as no new agencies or funding for existing agencies would be required to regulate the industry. However, according to some people, numerous dangers involving replicating accidents and intentional abuse would almost certainly occur with no regulation after the development of an assembler.<sup>41</sup>

### **Policy Issues With Any Regulatory Approach**

Unless the United States chooses to ban nanotechnology, a plethora of issues will likely arise regardless of the method of implementation employed by the government. Early in the development of nanotechnology, the development of a new agency may be

proposed, charged with overseeing nanotechnology development and regulation in the United States. The establishment of a new agency to oversee an emerging technology can often merit its own paper, such as the discussion over the establishment of the group, the National Institute of Biomedical Imaging and Engineering (NIBIE), to oversee efforts in biotechnology.<sup>45</sup> As with the establishment of NIBIE, benefits from establishing an agency to regulate nanotechnology do exist. First, this agency *could* improve technology transfer and research coordination between agencies. However, at this time, no study has established a problem with research overlap between different government agencies.

The establishment of a government agency to oversee nanotechnology could also improve government support of nanotechnology development. During the budget appropriations of the 106<sup>th</sup> Congress, developments have highlighted problems the scientific community has encountered when trying to obtain funds for nanotechnology research. A press release by AAAS outlined Congressional cuts in the proposed research budget for the NSF, one of the leading agencies in President Clinton's National Nanotechnology Initiative.<sup>46</sup> The NNI currently proposes nanotechnology research funding for six federal agencies.<sup>41</sup> A graph showing funding for the nanotechnology industry showcases the proposed distribution of funds among the key agencies involved in nanotechnology appears below. A centralized nanotechnology agency might provide Congress with a better understanding of nanotechnology and the need for supporting nanotechnology funding.

In the broader sense, nanotechnology differs from biotechnology, as it may affect virtually every branch of science and engineering, possibly catalyzing new fields as well. With such a vast reach, one must ask whether or not any one agency could assemble the necessary personnel from current fields to guide nanotechnology. At first, according to prominent researchers at NIH, people may think that forming a new agency will look "sexy."<sup>47</sup> Many agencies and individuals might oppose the establishment of a nanotechnology agency on the grounds that any failure in forming a truly all-encompassing agency would jeopardize research in a given branch of nanotechnology. For example, an agency formed without sufficient input from the biological community might fail to guide and fund research of biological nanosystems, depriving the scientific

community of fundamental knowledge of the first and most prolific nanomachines the world has today.

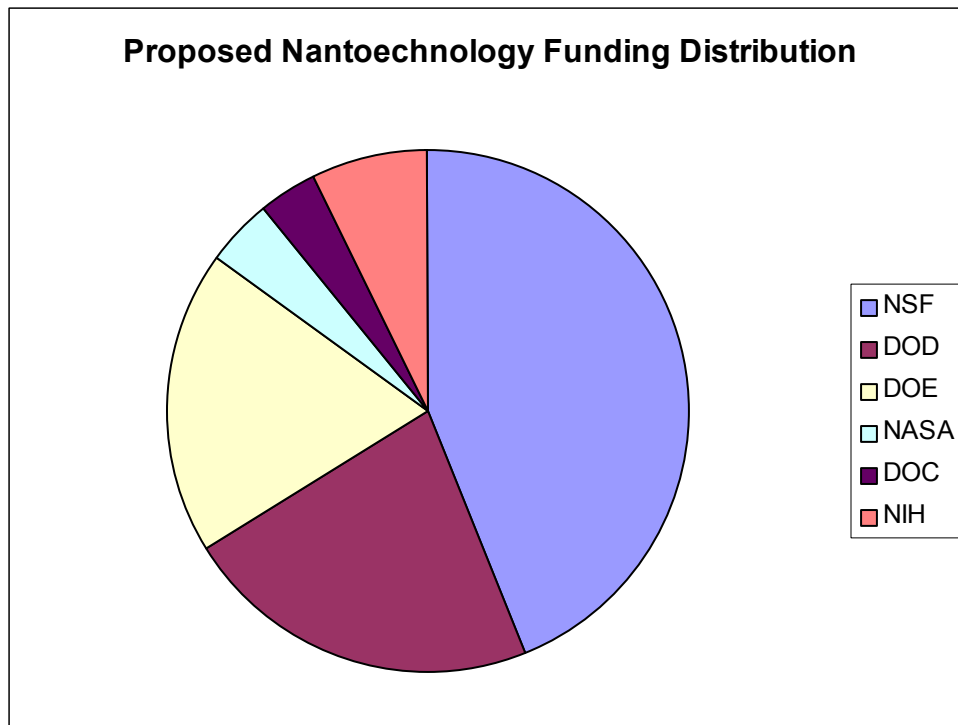
In the end, people may determine that the benefits of funding for nanotechnology led by a new agency might not outweigh the possibility of ignoring key fields within nanotechnology. However, a decentralized approach does carry other dangers for the nanotechnology industry and the world. The biotechnology industry in Europe faced harsh regulation due to the absence of an agency equipped to deal with health and safety concerns of a new technology. The United States had the FDA, a scientifically grounded regulatory agency, largely prepared to deal with emerging issues in biotechnology. While this agency dealt with early concerns over agricultural biotechnology, problems within the United States have persisted. During the study of the industry that culminated in this paper, new concerns emerged on a weekly basis. An American coalition of biotechnology adversaries recently announced a campaign pressuring food companies to discontinue the use of biotechnology products or begin labeling their products as such.<sup>48</sup> Although the biotechnology industry recently launched a \$50 million campaign to explain the safety of its products, this action came after several years of contention in the United States and abroad. If consumers had learned more about the similarity of biotechnology products to naturally bred foods, they might actually look for biotechnology products on the shelves instead of shunning them.

The nanotechnology industry can learn a great deal from the example of the biotechnology industry. Campaigns to explain scientific principles behind products should definitely occur, perhaps even in the early stages of technology development. Without a large nanotechnology industry, no body to conduct such an educational campaign exists right now. A nanotechnology agency or small scale technologies body in the United States could fulfill this role. Additionally, policy issues that fall under several agencies often have difficulties addressing health and safety concerns.

Battling the spread of AIDS continues to constitute a major health policy problem. In January of 2000, the United States described a war on AIDS as “a moral and national security imperative.”<sup>49</sup> However, the president’s interagency group still lacks a director and coherent mission. Six months after a renewed focus on AIDS and two decades after the emergence of AIDS epidemic, the US still lacks leadership in

addressing this problem. Several groups have decided to bicker over jurisdiction instead of dealing with a very serious issue. With the promise of nanotechnology to speed up the pace of development and change beyond the scope of anything the world has seen to date, the United States and the world will certainly have new tools to detect and treat AIDS. Unfortunately, people attempting to employ nanotechnology will encounter great problems if different agencies and departments spend sixth months, or worse yet, two decades fighting over jurisdiction or developing a plan instead of dealing with national security risks.

So, in the end, a new agency may carry the risk of slowing development in a certain area of nanotechnology. However, an central agency could improve funding and research as well. More importantly, it could help nanotechnology avoid unfounded attacks that the biotechnology industry has fallen under. Finally, a central agency could dispel arguments over jurisdiction when important policy issues in nanotechnology pose a serious problem. Scientists and politicians will have to work together to examine the benefits and possible consequences of forming a national agency for nanotechnology.



The above breaks down the distribution of the proposed nanotechnology budget of \$495 million for FY 2001.

### **Developing A Sound Nanotechnology Industry**

International developments in biotechnology help illustrate some of the problems that may face the nanotechnology industry in the United States. Despite some lingering concerns over safety, Germany has recently decided to relax some regulations on the biotechnology industry while providing it with research funding at the same time. Today, Germany has 279 biotechnology firms, a far cry from five years ago when Germany had little in the way of biotechnology industry.<sup>50</sup>

According to Gerd Romanowski, of the German Chemical Industry Association, three factors contributed to the growth of the German biotechnology industry. First, the government amended its genetic engineering law, making it easier for companies to build genetic plants and laboratories. Then, large companies in the chemical and pharmaceutical industries shifted many of their activities to Germany. Possibly the most important factor in the burgeoning biotech industry in Germany was the 1995 “Bio-Regio,” a federally sponsored initiative for regions to form groups supporting research, funding, new companies, and other aspects of the biotechnology industry. Analysts also point to the rise of venture capitalism in Germany as another factor supporting the growth of German biotechnology.

Unfortunately, the German biotechnology industry has several problems. Fifty percent of German biotech companies have 1 to 10 employees. Many fear that these small companies, often the result of academic professors turning their research into a small company, may not succeed. Industry analysts fear that biotech companies that head for the stock market will face an “Icarus-like fall.”<sup>44</sup> Consensus holds that these companies cannot function without government aid, as they currently have a limited product line available for commercialization. So, while Germany has a large biotechnology industry, its long term development prospects are, as yet, uncertain.

## **Funding Nanotechnology Research**

Without federal funding, it is likely that the United States will not emerge as a leader in nanoscience and nanotechnology. Although the government supported isolated projects in nanoscience as early as 1988, concerted efforts did not occur until much later.<sup>51</sup> Japan on the other hand began a great deal of nanotechnology research before the United States.<sup>52</sup> If the United States lags behind the rest of the world in a certain nanotechnology field, it may find itself in a weak position, both economically, and militarily. In addition, if the United States does not lead the world in nanotechnology, it will have less influence over the development of international technology policy.

The concentration of nanotechnology funding will also have an effect on other aspects of nanotechnology policy. If the House of Representatives enacts its FY 2001 budget decreasing non-defense research funding (including funding for nanotechnology), the United States may bring several problems upon itself.<sup>43</sup> Research conducted by the military will differ in focus from research sponsored by civilian agencies, leaving certain aspects of fundamental nanoscience with insufficient development. Secondly, even applicable research might not diffuse to industry and academia due to security concerns. Regardless of funding distribution, technology transfer between academia, industry, and the military will have a significant impact on the success of the United States' efforts in nanotechnology development.

## **Weapons Proliferation**

Any advancements in nanotechnology could facilitate the advancement of modern warfare as well. New materials would allow advanced weapons designs, airplanes and missiles that could reach targets more quickly due to lighter weights and more efficient propulsion units. Advanced biomimetic or molecular machines could enable a new wave of genocide the like of which the world has never seen. A country could develop small devices capable of discriminating between different races, allowing a country with

advanced nanotechnology to wipe out a neighboring nation or ethnic group within its own borders.

The development of advanced nanomachines would also allow the rapid production of more conventional weapons, as a machine placed in a vat of raw material could assemble a weapon at the molecular level without the numerous steps involved in making a weapon today (obtaining and purifying raw material, making the appropriate alloy or composite, shaping and fitting individual pieces, building circuitry and testing). Imagine a tank filled with the appropriate elements to build a nuclear weapon. Just as life forms around the globe use templates to arrange molecules into complex structures like bones or organs, an advanced nanomachine might be able to grow or produce a nuclear weapon.

With new nanodevices and electronics, a new class of weaponry could emerge. Several papers have already appeared dealing with the possibility of nanotechnology initiating a new arms race.<sup>53</sup> With faster computers and manufacturing techniques, weapons buildup could occur more quickly, and deployment times could diminish as well. A country that had an advantage, such as faster assemblers or better sensors might want to eliminate their nearest competitors before they caught up. Part of this new class of weaponry might also include devices capable of disabling nuclear weapons, the most powerful deterrent in the world today. Although nanotechnology would need to reach a great level of refinement in order to do so, the possibility of disarming one's competitors does exist. This possibility brings with it several frightening possibilities.

First, large nuclear arsenals could be constructed as they try to develop nanotechnology. A larger number of warheads would make it more difficult for one's enemies to completely disarm them. Secondly, nanoelectronics, nanosensors, and nanomachines may have particular susceptibility to nuclear radiation. Experts involved with the United States Ballistic Missile Defense Office (BMDO) project can shed some light on this phenomena.<sup>54</sup> Various types of radiation exist and several types can have adverse effects on small electronic systems. As electronic systems diminish in size, they have increased sensitivity to radiation. Thus, smaller devices must employ more complex methods to deal with radiation. These methods include shielding, triple redundancy systems, and detectors that temporarily shut down a device. Unfortunately, all of these

techniques will greatly increase the size of nanomachines. Secondly, even a large amount of shielding will not completely protect a nanodevice from radiation. Thus, a nation that developed a nanoshield or nanosensor array might provoke a nuclear attack by a threatened neighbor, as nuclear weapons currently provide the best counter for such devices.

So, the scientific basis for the scenario of nuclear proliferation does exist. However, that does not mean that one should take drastic measures to curb nanotechnology development due to the remote possibility of such an event. First, many other events, such as the current controversy over a US Ballistic Missile Defense Program, have the potential to cause nuclear proliferation. Second, the likelihood of nanotechnology causing massive nuclear proliferation, although real, appears to be several orders of magnitude smaller than the potential for realizing the many benefits of nanotechnology, according to nanotechnology experts such as Mike Rocco.<sup>55</sup>

## **Recommendations**

The American Institute of Chemical Engineers should make a concerted effort to explore nanotechnology through programming at conventions and the establishment of a task force. A deep understanding of the principles of nanotechnology, possible applications, and safety and health considerations will allow AIChE to make informed policy recommendations on nanotechnology. Efforts to understand nanotechnology will provide a great deal of information about priorities for nanotechnology policy.

AIChE should support the NNI, and funding for defense and civilian oriented research in nanotechnology. Failure to develop a sound base of knowledge in nanoscience will leave the United States in a weak position with regard to technology, the economy, and national security. Conversely, a directed effort to support nanotechnology would strengthen the position of the United States in the global arena. Supporting research and fostering a relationship with agencies administering the initiative will also open opportunities for chemical engineers to study nanoscience and apply their engineering skills to the task of bringing the benefits of nanotechnology to the world.

Although biotechnology advocates touted the benefits of their products for less fortunate countries and people, children still starve to death around the world everyday. The sound understanding of nanotechnology provided by research would present chemical engineers with the opportunity to apply a new technology to dramatically improve the world around them.

In order to apply nanotechnology in a beneficial manner, the United States and the world must develop a strong nanotechnology industry. AIChE should watch the development of the German biotechnology industry in order determine the strengths and weaknesses of new policy on biotechnology. Rapid growth, while attractive initially, might not provide the best way of supporting a new technology. AIChE should support efforts to study the development of emerging technology industries in order to establish strong global and national technology industries in the future.

With the emergence of this new technology, new dangers will arrive as well. AIChE should support a study of the effects of nanotechnology on national security and global stability. A technology capable of improving the quality of life of everyone living on the earth will have less value if it brings about the demise of millions of people in a new era of frighteningly quick war. AIChE should also support efforts to examine other dangers of nanotechnology such as those proposed by Bill Joy in his *WIRED* article.<sup>38</sup> Just as biotechnology brought uncertainty about the introduction of GMO's into the environment, nanomachines and artificial intelligence will bring uncertainty as well.

Efforts to explore the fundamental principles of nanotechnology and examine its potential dangers will provide the best way to develop informed nanotechnology policy. Informed policy debates and decisions will minimize the chance that the United States or other countries will enact unsound regulation. Some countries developed biotechnology regulation as a reaction to untested fears over possible consequences of a new science. Despite the pitfalls of another forming another agency, AIChE should recommend that the government examine the difference in US and European biotechnology policy, including the lack of an equivalent of the FDA in many European countries. A new agency might help the government develop sound policy, public support, and a more beneficial nanotechnology industry.

While this paper contains detailed descriptions of regulatory approaches to guide industry, and the pitfalls of various approaches, the rapid adoption of a policy without proper development is strongly discouraged. AIChE should support efforts to continue the policy of countries like the United States and Australia, policies based on developing regulation with input from the scientific community. The development of effective policy should include efforts to inform both the public and policy makers. Whether or not elected officials see the benefits of nanotechnology, they will hesitate to support it if the scientific community does not make the effort to educate the public.

Finally, AIChE should, after studying nanotechnology, make every effort to lead the technology community in an effort to explain nanotechnology, including its potential for problems while expounding on its virtues. The biotechnology industry did not launch a massive campaign to describe their work before bringing products into the market place. No companies currently label all of their products that are genetically modified so long as they do not differ significantly from traditional products. An informed populace might actually appreciate and seek the benefits of such products, if they knew that current techniques merely extend age old methods of breeding crops, in some cases significantly enhancing them as well. Chemical engineers have worked with catalysts, a type of nanomaterial, for years. Researchers in the related field of biotechnology study biological systems that operate on the nanoscale. An effort to point out how nanotechnology already improves our lives (through the use of nanomaterials, such as catalysts), in addition to pointing out numerous “natural” examples of nanodevices already functioning around us, would only help the advancement of nanotechnology. With an enthusiastic public willing to support nanotechnology, science may one day realize Feynman’s dream of controlling the building blocks of the world, opening unseen possibilities to improving and understanding the world itself.

**Summary of Recommendations to AIChE**

Establish a nanotechnology task force to become an authority in future debates
Support the National Nanotechnology Initiative
Study and recommend action on developing a strong industry
Explain nanotechnology and nanoscience to the public utilizing current expertise and experience with nanomaterials

## **Acronyms**

Economic Research Service	ERS
Genetically Modified Organisms	GMO
Living Modified Organisms	LMO
Environmental Protection Agency	EPA
National Institute of Health	NIH
United States Department of Agriculture	USDA
Animal and Plant Health Inspection Service	APHIS
Federal Insecticide, Fungicide, and Rodenticide Act	FIFRA
Federal Food, Drug, and Cosmetics Act	FFDCA
Toxic Substance Control Act	TSCA
Microbial Commercial Activity Notice	MCAN
TSCA Experimental Release Application	TERA
Food and Drug Administration	FDA
Council on Environmental Quality	CEQ
Office of Science and Technology Policy	OSTP
European Union	EU
American Association for the Advancement of Science	AAAS
National Science Foundation	NSF
Molecular Nanotechnology	MNT
Artificial Intelligence	AI
Ballistic Missile Defense Office	BMDO
American Institute of Chemical Engineers	AIChE

## Endnotes

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