Nanotechnology: Unique Science Requires Unique Solutions

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INTRODUCTION

It has been said that "[i]f a product, device, or item is small and related to technology, it is virtually guaranteed that someone somewhere has branded it nanotechnology."[1] A quick search of the U.S. Patent and Trademark Office website reveals nearly 11,000 existing patents containing the words "nano" or "nanotechnology."[2] On September 7, 2005, Apple Computers joined the frenzy by introducing the iPod nano,[3] claiming that the "pencil-thin iPod" would "take your music places you never dreamed of."[4] Although that may be true, the iPod is not truly "nano."[5]

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[1] Charles Vorndran, *The Many Faces of Nanotechnology*, 7 J. PROPRIETARY RTS. 6, 6 (2004). For a visual representation of the popularity of nanotechnology measured by articles mentioning the subject, see MARK RATNER & DANIEL RATNER, NANOTECHNOLOGY: A GENTLE INTRODUCTION TO THE NEXT BIG IDEA 81 (2005) [hereinafter RATNER & RATNER].

[2] This information is accurate as of May 27, 2006. To conduct a patent search, go to the USPTO website, *available at* http://www.uspto.gov/patft/index.html. Clicking on "advanced search" and running the query "nano or nanotechnology" in the full text field resulted in a list of 10,862 issued patents.

[3] Walter S. Mossberg, *iPod Nano Combines Beauty, Function*, WALL ST. J., Sept. 8, 2005, http://ptech.wsj.com/archive/ptech-20050908.html.

[4] Apple Computer, http://www.apple.com/ipodnano (last visited May 27, 2006).

[5] The prefix "nano" means one billionth (10^{-9}). Merriam Webster Online Dictionary, http://www.m-w.com/dictionary/nano (last visited Aug. 9, 2006). Inside the iPod Nano are memory chips from Samsung, which uses semiconductor manufacturing methods with precision below 100 nanometers.

Nanotechnology, a newly developing field merging science and technology, promises a future of open-ended potential.[6] Its scientific limits are unknown, and its myriad uses cross the boundaries of the technical, mechanical and medical fields.[7] Substantial research[8] has led scientists,[9] politicians[10] and academicians[11] to believe that nanotechnology has the potential to profoundly change the economy and to improve the national standard of living.[12] In addition, nanotechnology may touch every facet of human life because its products cross the boundaries of the most important industries, including electronics, biomedical and pharmaceutical

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Josh Wolfe, *Top Nanoproducts of 2005*, Forbes/Wolfe Nanotech Report, Jan. 10, 2006, http://www.forbes.com/investmentnewsletters/2006/01/10/apple-nano-in_jw_0109soapbox.inl.html (select "Slideshow with the top nanotech products of 2005").

[6] *See generally* K. ERIC DREXLER, ENGINES OF CREATION (1986) (describing potential future applications of nanotechnology).

[7] National Nanotechnology Initiative, Applications/Products, http://www.nano.gov/html/facts/appsprod.html (last visited June 11, 2006) [hereinafter NNI Applications] (examples of available products utilizing nanoscale materials include step assists on vans, metal-cutting tools, and burn and wound dressings).

[8] *See, e.g.,* RATNER & RATNER, *supra* note 1, at 63-81 (describing key nanotechnology research projects occurring around the world); National Nanotechnology Initiative, Research, http://www.nano.gov/html/research/home_research.html (last visited May 27, 2006) [hereinafter NNI Research] (highlighting results of research projects with links to other sources of information on nanotechnology research).

[9] RATNER & RATNER, *supra* note 1, at 3; National Nanotechnology Infrastructure Network, http://www.nnin.org (last visited Feb. 26, 2006) [hereinafter NNIN]. NNIN is a networked partnership of user facilities, supported by the National Science Foundation, integrated to enable rapid advancements in science, engineering and technology at the nano-scale. This is achieved through efficient access to nanotechnology infrastructure, including shared open, geographically diverse laboratories, each with specific areas of technical excellence, as well as fabrication, synthesis, characterization, and integration resources to build structures, devices, and systems from atomic to complex large-scales. Users come from academia, national laboratories, and industry.

[10] RATNER & RATNER, *supra* note 1, at 2 ("[Nanotechnology's] almost universal appeal is indicated by the fact that it has political support from both sides of the aisle . . . ."); National Nanotechnology Initiative, Frequently Asked Questions, http://nano.gov/html/facts/faqs.html (last visited Sept. 26, 2005) [hereinafter NNI FAQs] (part of the answer to "Why fund nanotechnology?").

[11] RATNER & RATNER, *supra* note 1, at 3; *see also* Francisco Castro, *Legal and Regulatory Concerns Facing Nanotechnology*, 4 CHI.-KENT J. INTELL. PROP. 140, 140 (2004) (addressing the legal and regulatory impact of the developing nanotechnology industry); Frederick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L.J. 593, 595 (1994) (describing nanotechnology's social and legal implications); Paul C. Lin-Easton, *It's Time for Environmentalists to Think Small – Real Small: A Call for the Involvement of Environmental Lawyers in Developing Precautionary Policies for Molecular Nanotechnology*, 14 GEO. INT'L ENVTL. L. REV. 107, 107-08 (2001) (examining the potential consequences of molecular nanotechnology on the environment); Glenn Harlan Reynolds, *Nanotechnology and Regulatory Policy: Three Futures*, 17 HARV. J.L. & TECH. 179, 181 (2003) (outlining basic characteristics of nanotechnology and describing technical and social consequences of its development); Jason Wejnert, Article, *Regulatory Mechanisms for Molecular Nanotechnology*, 44 JURIMETRICS J. 323, 329 (2004) (evaluating control and protection regimes necessary following implementation of nanotechnology); Joel Rothstein Wolfson, *Social and Ethical Issues in Nanotechnology: Lessons from Biotechnology and Other High Technologies*, 22 BIOTECHNOLOGY L. REP. 376, 377-382 (2003) (presenting social and ethical issues raised by the use of widespread nanotechnology); Foresight Institute, http://www.foresight.org (last visited Nov. 20, 2005).

[12] *See* JACK ULDRICH & DEB NEWBERRY, THE NEXT BIG THING IS REALLY SMALL 13 (2003) (stating that the market for nanotechnology products and services is expected to reach $1 trillion in the U.S. economy by 2010); NNI FAQs, *supra* note 10 (part of the answer to "What products will be available in the next few years?").

industries, and energy production.[13] In the future, nanotechnology could ensure longer, healthier lives with the reduction or elimination of life-threatening diseases,[14] a cleaner planet with pollution remediation and emission-free energy,[15] and the innumerable benefits of increased information technology.[16]

However, certain uses, such as advanced drug delivery systems,[17] have given rise to an ethical debate similar to that surrounding cloning and stem cell research.[18] Moreover, some analysts have theorized that nanotechnology may endanger humankind with more dangerous warfare and weapons of terrorism,[19] and that nanotechnology may lead to artificial intelligence beyond human control.[20] The widespread use of nanotechnology far in the future threatens to alter the societal framework and create what has been called "gray goo."[21]

Because nanotechnology has the potential to improve the products that most of us rely on in our daily lives, but also imperil society as we know it, we should research, monitor and regulate nanotechnology for the public good with trustworthy systems, and set up pervasive controls over its research, development, and deployment. In addition, its substantial impacts on existing regulations should be ascertained, and solutions incorporated into the regulatory framework.

This paper addresses these concerns and provides potential solutions. Part I outlines the development of nanotechnology. Parts II and III explore the current and theoretical future applications of nanotechnology, and its potential side-effects. Then, Part IV analyzes the government's current role in monitoring nanotechnology, and the regulatory mechanisms available to manage or eliminate the negative implications of nanotechnology. Part V considers the creation of an Emerging Technologies Department as a possible solution to maximize the benefits and minimize the detrimental effects of nanotechnology. Lastly, Part VI examines certain environmental regulations to provide an example of nanotechnology's impact on existing regulatory schema.

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[13] *See* NNI Applications, *supra* note 7 (listing the many industries that use nanomaterials).

[14] Nanotech research and applications in the medical and pharmaceutical fields are discussed at length *infra* in Part II.

[15] Nanotech research and applications in the environmental field and energy production industry are discussed at length *infra* in Part II.

[16] Nanotech research and applications in the electronics and computer fields are discussed at length *infra* in Part II. Additionally, magnetic recording tapes, electroconductive coatings and optical fibers are among the areas producing the greatest revenue for nanoparticles. NNI Applications, *supra* note7.

[17] *See* RATNER & RATNER, *supra* note 1, at 110-11 (By taking advantage of improved bioavailability, advanced drug delivery systems direct drug molecules where they are needed in the body.).

[18] *See* Reynolds, *supra* note 11, at 187 (predicting that further development of nanotechnology will force debate into the mainstream).

[19] *E.g.,* DANIEL RATNER & MARK RATNER, NANOTECHNOLOGY AND HOMELAND SECURITY (2004) (outlining potential military uses of nanotechnology) [hereinafter HOMELAND SECURITY].

[20] Wolfson, *supra* note 11, at 391.

[21] The "gray goo problem" arises when replicators, robotic machines designed to replicate themselves, and assemblers, robotic machines designed to assemble products, produce almost anything, and subsequently spread uncontrolled and obliterate natural organisms, replacing them with nano-enhanced organisms. *Id.* at 172-173.

PART I: NANOTECHNOLOGY DEFINED

Nanoscience is the study of the fundamental principles of molecules and structures with at least one dimension roughly between 1 and 100 nanometers (one-billionth of a meter, or 10^{-9}), otherwise known as the "nanoscale."[22] Called nanostructures, these are the smallest solid things possible to make.[23] Nanofabrication, or nanoscale manufacturing, is the process by which nanostructures are built.[24] Top-down nanofabrication creates nanostructures by taking a large structure and making it smaller, whereas bottom-up nanofabrication starts with individual atoms to build nanostructures.[25] Nanotechnology applies nanostructures into useful nanoscale devices.[26]

The nanoscale is distinctive because it is the size scale where the properties of materials like conductivity,[27] hardness,[28] or melting point[29] are no longer similar to the properties of these same materials at the macro level.[30] Atom interactions, averaged out of existence in bulk material, give rise to unique properties.[31] In

[22] RATNER & RATNER, *supra* note 1, at 6-7. For a more scientific discussion of nanotechnology, see GUOZHONG CAO, NANOSTRUCTURES & NANOMATERIALS: SYNTHESIS, PROPERTIES & APPLICATIONS (2004).

[23] RATNER & RATNER, *supra* note 1, at 7; *see also* George M. Whitesides & J. Christopher Love, *Nanofabrication: The Art of Building Small*, SCIENTIFIC AM. DIGITAL, Sept. 2001, at 40, *available at* http://nano.nd.edu/SC190/NanoFabrication_Whitesides%20.pdf ("A structure the size of an atom represents a fundamental limit: to make anything smaller would require manipulating atomic nuclei - essentially, transmuting one chemical element into another.").

[24] RATNER & RATNER, *supra* note 1, at 12; NNIN, *supra* note 9; SearchTechTarget.com, http://whatis.techtarget.com/definition (last visited Mar. 24, 2006) (defining the word "nanofabrication").

[25] RATNER & RATNER, *supra* note 1, at 12, 24, 32. Traditionally, engineers fabricated nanometer-sized objects through the "top-down" approach by carving them out of lithography from a large substrate. NNIN, *supra* note 9. Yet, the capital requirement made this approach less desirable. *Id.* Bottom up nanofabrication is preferred because of its efficiency, garnered through utilization of chemical properties to promote self-assembly. RATNER & RATNER, *supra* note 1, at 12, 24, 32. Gaining control of molecules and forcing them to "recognize" other molecules makes the molecules organize themselves on their own (self-assembly) to create nanostructures. *Id.* The bottom-up approach may hasten development of future nanotechnology applications by providing a cost-effective route to production of copious quantities of uniform nanostructures, such as quantum dots, nanotubes, and nanowires of various materials. NNIN, *supra* note 9.

[26] RATNER & RATNER, *supra* note 1, at 12, 24, 32.

[27] Conductivity is defined as "the quality or power of conducting or transmitting: as (a): the reciprocal of electrical resistivity (b): the quality of living matter responsible for the transmission of and progressive reaction to stimuli." Merriam-Webster Online Dictionary, http://www.m-w.com/dictionary/conductivity (last visited Mar. 20, 2006).

[28] In chemistry, hardness is defined as "the cohesion of the particles on the surface of a mineral as determined by its capacity to scratch another or be itself scratched." Merriam-Webster Online Dictionary, http://www.m-w.com/dictionary/hardness (last visited Mar. 20, 2006).

[29] The melting point is "the temperature at which a solid melts." Merriam-Webster Online Dictionary, http://www.m-w.com/dictionary/melting%20point (last visited Mar. 20, 2006).

[30] RATNER & RATNER, *supra* note 1, at 12, 24, 32. The macro level is the size scale which is studied in basic chemistry classes – large chemical compounds and structures. Nanomaterials differ from larger materials not just in size, but in surface/interface-to-volume ratio and grain shapes, which are the origins of their unique electrical, optical, thermodynamic, mechanical, and chemical properties. Synthesis and Characteristics of Nanomaterials, http://www.nano.gatech.edu/research/nano-syn-charc.php (last visited Mar. 20, 2006) [hereinafter NanoTECH @ Georgia Tech].

[31] RATNER & RATNER, *supra* note 1, at 12, 24, 32. In addition, nanomaterials and nanostructures will exhibit different characteristics, such as size, shape, composition and crystalline structure, depending on the nanoparticles used in their creation. NNIN, *supra* note 9. Nanoparticles are frequently used as

nanotech research, scientists take advantage of these unique properties to develop products with applications that would not otherwise be available.[32]

Although some products using nanotechnology are currently on the market,[33] nanotechnology is primarily in the research and development stage.[34] Because nanoparticles are remarkably small, tools specific to nanotechnology have been created to develop useful nanostructures and devices.[35] Two techniques exclusive to nanotechnology are self-assembly, and nanofabrication using nanotubes and nanorods.[36]

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building blocks for larger structures while in other instances they may comprise the performance of a system. *Id.*

[32] *Id.* at 16; *see also* NanoTECH @ Georgia Tech, *supra* note 30 ("Because of these unique properties, many scientists believe that nanomaterials hold the key to significant future advances in a wide range of miniaturized consumer products such as miniaturized computer chips, nanoscale sensors, and devices for sorting DNA molecules, including products that are reliant on synthesized nanomaterials and their integration with microsystems and biotechnology.").

[33] *See* NNI Applications, *supra* note 7 (examples of available products utilizing nanoscale materials include step assists on vans, metal-cutting tools, and burn and wound dressings).

[34] *See* Lin-Easton, *supra* note 11, at 109 ("[T]he current state of nanotechnology is estimated to be at the level of development of computer and information technology in the 1950s . . . ."); NNI Applications, *supra* note 7 ("While nanotechnology is in the 'pre-competitive' stage (meaning its applied use is limited), nanoparticles are being used in a number of industries.").

[35] RATNER & RATNER, *supra* note 1, at 39. Many existing scientific tools do not function at the nanoscale. *Id.* at 41-42. For example, spectroscopy is limited to characterizing nanostructures en masse because the size of visible light (e.g., 400-900 nanometers) is too large to allow characterization of individual atoms or molecules. *Id.* Tools must be reformatted or developed to work at the nanoscale and to take advantage of the unique characteristics of nanostructures. *Id.* at 43-44. An example of a scientific tool that has been reformatted for use in nanotechnology is lithography. *Id.* at 44-45. Lithography is the process of patterning in a transfer layer. NNIN Technical Resources, http://www.nnin.org/nnin_technical.html (last visited June 11, 2006) [hereinafter NNIN Tech. Res.].

[36] RATNER & RATNER, *supra* note 1, at 49-50, 54-57. Additional tools used to make nanostructures, comparable to tools used in macro-scale production, are nanoscale lithography, dip pen nanolithography, nanosphere liftoff lithography, electron beam lithography, molecular synthesis, nanoscale crystal growth, polymerization, and etching. *Id.* An example of nanoscale lithography is microimprint lithography, where a pattern is inscribed onto a rubber-like surface (a silicon/oxygen polymer), and the surface is coated with molecular ink and stamped (imprinted) onto another surface. *Id.* at 44-45. Other microtransfer patterning technologies include embossing and microcontact printing. NNIN Tech. Res., *supra* note 35. Dip pen nanolithography and nanosphere liftoff lithography form part of the collection of novel patterning techniques based on printing, molding and embossing using a transparent elastomeric stamp. *Id.* Known as "soft lithography," this represents a new conceptual approach in fabrication and manufacturing of new types of structures and devices. *Id.* In dip pen lithography, the scanning probe tip stores a reservoir of atoms or molecules, and as the tip is manipulated across a surface, it leaves a pattern of the atoms or molecules behind. RATNER & RATNER, *supra* note 1, at 45-46. In electron beam lithography, a beam of electrons is scanned across the substrate under computer control to expose the resist (mixture of a polymer and other small molecules, Wikipedia, http://en.wikipedia.org/wiki/Resist (last visited Sept. 7, 2006).). NNIN Tech. Res., *supra* note 35. In nanosphere liftoff lithography, nanoscale materials are placed very tightly together on a surface, and then the materials are painted (covered) with other molecules to created triangle-shaped dots (circles) with concave sides. RATNER & RATNER, *supra* note 1, at 46-47. Molecular synthesis involves making specific molecules for specific purposes. *Id.* at 47-48. Crystal growth is a type of self-assembly whereby specific choices of seed crystals and growing conditions make it possible to cause the crystals to assume unusual but useful shapes. *Id.* at 52. Plasma assisted chemical vapor deposition can be used to grow films by chemical vapor deposition at lower temperatures, and is generally done in furnace tubes for the growth of a range of silicon compounds on clean wafers. NNIN Tech. Res., *supra* note 35. Controlled polymerization is a technique where monomers are added one at a time to create specific structures. RATNER & RATNER, *supra* note 1, at 53. Thermally grown silicon dioxide is a common building block for nanostructures. NNIN Tech. Res., *supra* note 35. Etching is the ability to selectively remove materials with high

In self-assembly, particular atoms or molecules are put on a surface or preconstructed nanostructure, causing the molecules to align themselves into particular positions.[37] Although self-assembly is "probably the most important of the nanoscale fabrication techniques because of its generality, its ability to produce structures at different length-scales, and its low cost,"[38] most nanostructures are built starting with larger molecules as components.[39] Nanotubes[40] and nanorods,[41] the first true nanomaterials engineered at the molecular level, are two examples of these building blocks.[42] They exhibit astounding physical and electrical properties.[43] Certain nanotubes have tensile strength in excess of 60 times high-grade steel while remaining light and flexible.[44] Currently, nanotubes are used in tennis rackets and golf clubs to make them lighter and stronger.[45]

PART II: NANOTECHNOLOGY'S USES

Researching and manipulating the properties of nanostructures are important for a number of reasons, including, most basically, to gain an understanding of how matter is constructed, and more practically, to use these unique properties to develop unique products.[46] Nanoproducts can be divided into four general categories:[47] smart materials,[48] sensors,[49] biomedical applications,[50] and optics and electronics.[51]

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selectivity and resolution. *Id.* Reactive ion etching and other forms of dry etching are the most common. *Id.* For additional tools used in nanofabrication, visit Cornell NanoScale Science and Technology Facility, http://www.nnf.cornell.edu/cnf5_tool.taf (last visited Mar. 20, 2006).

[37] RATNER & RATNER, *supra* note 1, at 49-50. For a more in depth description of self-assembly, and the potential drawbacks to effective self-assembly, see George M. Whitesides, *Self-Assembly and Nanotechnology*, Abstract for the Fourth Foresight Conference on Molecular Nanotechnology (Nov. 9-11, 1995), http://www.zyvex.com/nanotech/nano4/whitesidesAbstract.html.

[38] RATNER & RATNER, *supra* note 1, at 49-50.

[39] *Id.* at 54-55. This is because it is estimated that it could take nanomachines as much as 19 million years to build nanostructures atom-by-atom. For a recent application of self-assembly techniques, see Researchers Employ Viruses to Build Tiny Batteries, 50 TechTalk no. 23, pg. 1 (Apr. 12, 2006), *available at* http://web.mit.edu/newsoffice/2006/techtalk50-23.pdf.

[40] Carbon nanotubes are hexagonally shaped arrangements of carbon atoms that have been rolled into tubes. These tiny straw-like cylinders of pure carbon have useful electrical properties. They have already been used to make tiny transistors and one-dimensional copper wire. Wise Geek, http://www.wisegeek.com/what-are-carbon-nanotubes.htm (last visited Feb. 26, 2006).

[41] Generally, nanorods (or nanowires) are made out of silicon. RATNER & RATNER, *supra* note 1, at 57.

[42] *Id.* at 55 (Nanotubes and nanorods are used to self-assemble into larger nanoscale structures.).

[43] *Id.* at 56.

[44] *Id.* at 56-57.

[45] RATNER & RATNER, *supra* note 1, at 57.

[46] *Id.*

[47] *See id.* at ix-xi.

[48] *Id.* at 84-95. A "smart" material incorporates in its design a capability to perform several specific tasks. *Id.* at 84. Smart materials can function either statically, meaning they always behave the same way, or dynamically, meaning they react to outside stimuli and actively change their properties. *Id.* Teflon is an example of a smart material because it is engineered to have essentially no stick, and it is static because it is not designed to react to external forces, whereas human skin is an example of a dynamic smart material because it reacts differently to different stimuli. *Id.*

[49] *Id.* at 98-106. Sensors are structures that indicate (detect and give a signal of) the presence of particular molecules or biological structures, as well as the amounts that are present. *Id.* at 98.

[50] *Id.* at 108-119. Nanotechnology will play an integral role in "human repair," which focuses on healing the body, instead of relying on removing or replacing affected areas. *Id.* at 67. Nanoscale biostructures

A "smart" material incorporates in its design a capability to perform several specific tasks.[52] In nanotechnology, that design is done at the molecular level.[53] Clothing, enhanced with nanotechnology, is a useful application of a smart material at the nanoscale. Certain nano-enhanced clothing contains fibers that have tiny whiskers that repel liquids, reduce static and resist stains without affecting feel.[54] Nano-enhanced rubber represents another application of a nanoscale smart material.[55] Tires using nanotech-components increase skid resistance by reducing friction, which reduces abrasion and makes the tires last longer.[56] The tires may be on the market "in the next few years" according to the National Nanotechnology Initiative (NNI).[57] Theoretically, this rubber could be used on a variety of products, ranging from tires to windshield wiper blades to athletic shoes.[58] A more complex nanotechnology smart material is a photorefractive polymer.[59] Acting as a nanoscale "barcode," these polymers could be used as information storage devices with a storage density exceeding the best available magnetic storage structures.[60]

Nano-sensors may "revolutionize much of the medical care and the food packaging industries,"[61] as well as the environmental field because of their ability to detect toxins and pollutants at fewer than ten molecules.[62] As the Environmental Protection Agency (EPA) recognizes:

> Protection of human health and ecosystems requires rapid, precise sensors capable of detecting pollutants at the molecular level. Major improvements in process control, compliance monitoring, and environmental decision-making could

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can mimic or affect a biological process or interact with a biological entity. *Id.* One recently developed example is the self-assembling "artificial bone." *Id.* The molecules in the artificial bone are designed to occupy space in a particular way so that they will assemble spontaneously to form the desired shape, and so that they will be packed densely enough for the bone to be strong. *Id.* The outer shell is designed so that natural bone begins to form around it. *Id.*

[51] RATNER & RATNER, *supra* note 1, at 122-139. Optics includes the nanotechnology applications to light and energy, and electronics focuses on information technology and magnetics. *Id.* at 122.

[52] *Id.* at 84.

[53] *Id.*

[54] Wolfe, *supra* note 5.

[55] NNI FAQs, *supra* note 10.

[56] RATNER & RATNER, *supra* note 1, at 84; NNI FAQs, *supra* note 10. Interestingly, decreased friction increases tire life, but decreases tire utility. This may have an effect on the cost/benefit analysis used when drafting regulatory approaches to problems. *See infra* Part IV (discussing cost/benefit analysis). In addition, prolonged tire life increases the environmental benefits of nanotechnology – everyday products last longer and are more efficient – which effect will also need to be considered in drafting regulations. *See infra* Part VI (discussing the effects of nanotechnology on environmental regulations).

[57] NNI FAQs, *supra* note 10.

[58] *Id.* Nano-enhanced rubber is already being used in certain wetsuits. Xterra Wetsuits, http://xterrawetsuitspro.com/product.html (last visited Sept. 7, 2006). The incorporation of nanotechnology makes the wetsuit more buoyant and decreases the drag a swimmer experiences in the water, making it easier to swim faster. *Id.*

[59] RATNER & RATNER, *supra* note 1, at 64.

[60] *Id.*

[61] *Id.* at 98. A biosensor called a molecular beacon, which uses a single strand of DNA and a fluorescent dye to seek out cancer cells, is being developed as a new method of detecting pancreatic cancer. Nanomedicine and Nano-biotechnology, http://www.nano.gatech.edu/research/nano-med-bio.php (last visited June 11, 2006).

[62] RATNER & RATNER, *supra* note 1, at 65-66.

be achieved if more accurate, less costly, more sensitive techniques were available. Nanotechnology offers the possibility of sensors enabled to be selective or specific, detect multiple analytes, and monitor their presence in real time.[63]

Examples of research in sensors include the development of nano-sensors for efficient and rapid biochemical detection of pollutants; sensors capable of continuous measurement over large areas; integration of nano-enabled sensors for real-time continuous monitoring; and sensors that utilize "lab-on-a-chip" technology.[64]

All fundamental life processes occur at the nanoscale, making it the ideal scale at which to fight diseases.[65] Two quintessential examples of biomedical applications of nanotechnology are advanced drug delivery systems and nano-enhanced drugs.[66] The promise of advanced drug delivery systems lies in that they direct drug molecules only to where they are needed in the body.[67] One example is focusing chemotherapy on the site of the tumor, instead of the whole body, thereby improving the drug's effectiveness while decreasing its unpleasant side-effects.[68] Other researchers are working to develop nanoparticles that target and trick cancer cells into absorbing certain nanoparticles.[69] These nanoparticles would then kill tumors from within, avoiding the destruction of healthy cells, as opposed to the indiscriminate damage caused by traditional chemotherapy.[70] Nano-enhanced suicide inhibitors[71] limit enzymatic activity by forcing naturally occurring enzymes to form bonds with the nanostructured molecule.[72] This may treat conditions such as epilepsy and depression because of the enzyme action component involved in these conditions.[73]

Lastly, nanotechnology has the potential to revolutionize the electronics and optics fields.[74] For instance, nanotechnology has the potential to produce clean,

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[63] Environmental Protection Agency, Nanotechnology: Research Projects, http://es.epa.gov/ncer/nano/research/nano_sensors.html (last visited Mar. 23, 2006).

[64] *Id.* A lab-on-a-chip is a sensor system the size of a microchip. Potential uses of nano-sensors in NASA's space program include life detection, crew health and safety, and vehicle health. Nanotechnology at NASA, http://www.ipt.arc.nasa.gov/nanotechnology.html (last visited Mar. 23, 2006) [hereinafter NASA].

[65] RATNER & RATNER, *supra* note 1, at 108.

[66] *Id.* at 108-113; *see also* NNI FAQs, *supra* note 10 (listing examples of potential drug delivery systems that could be on the market in the next two to five years).

[67] RATNER & RATNER, *supra* note 1, at 110. Another method of nanotechnology advanced drug delivery systems is painless drug delivery via microneedles, where tiny chips containing arrays of needles thinner than a strand of human hair are used for single-use injections or left on the skin for continuous release of a medication under the control of a microprocessor. Nanomedicine and Nano-biotechnology, *supra* note 61.

[68] RATNER & RATNER, *supra* note 1, at 110.

[69] Nanomedicine and Nano-biotechnology, *supra* note 61.

[70] *Id.*

[71] An enzyme inhibitor is a molecule that binds to an enzyme and interferes with how the enzyme works, usually by decreasing the enzyme's rate of reaction. Wikipedia, http://en.wikipedia.org/wiki/Enzyme_inhibitor (last visited Aug. 9, 2006). A suicide inhibitor is an irreversible enzyme inhibitor. *Id.*

[72] RATNER & RATNER, *supra* note 1, at 112.

[73] *Id.*

[74] *Id.* at 122.

renewable solar power.[75] Through a process called artificial photosynthesis, solar energy is produced by using nanostructures based on molecules which capture light and separate positive and negative charges.[76] Certain Swiss watches and bathroom scales are illuminated through a nanotech procedure that transforms captured sunlight into an electrical current.[77] In the electronics field, nanostructures offer many different ways to increase memory storage by substantially reducing the size of memory bits and thereby increasing the density of magnetic memory, increasing efficiency, and decreasing cost.[78] One example is storing memory bits as magnetic nanodots, which can be reduced in size until they reach the super-paramagnetic limit, the smallest possible magnetic memory structure.[79] Advances in electronics and computing brought on by nanotechnology could allow reconfigurable, "thinking" spacecraft.[80]

Some uses of nano-products already on the market include suntan lotions and skin creams, tennis balls that bounce longer, faster-burning rocket fuel additives, and new cancer treatments.[81] Solar cells in roofing tiles and siding that provide electricity for homes and facilities, and the prototypic tires, *supra*, may be on the market in the next few years.[82] The industry expects advanced drug delivery systems with implantable devices that automatically administer drugs and sensor drug levels, and medical diagnostic tools such as cancer-tagging mechanisms to be on the market in the next two to five years.[83]

It is nearly impossible to foresee what developments to expect in nanotechnology in the decades to come.[84] Nonetheless, the book *Engines of Creation* presented one vision of the possibilities of advanced nanotechnology.[85] Nano-machines could be designed to construct any product, from mundane items such as a chair, to exciting items such as a rocket engine.[86] These "assemblers" could also be programmed to build copies of themselves.[87] Known as "replicators," these nano-machines could alter the world by producing an exponential quantity of themselves that are to be put to work as assemblers.[88] The development of assemblers could advance the space

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[75] *Id.* at 126.
[76] *Id.* at 125.
[77] RATNER & RATNER, *supra* note 1, at 68-69.
[78] *E.g., id.* at 135-137.
[79] *Id.* at 135.
[80] NASA, *supra* note 64. Through the integration of computing, memory, sensing and communication, spacecraft will be able to address unexpected situations that arise during flight.
[81] RATNER & RATNER, *supra* note 1, at 3; NNI FAQs, *supra* note 10 (some other uses already on the market include burn and wound dressings, water filtration, catalysis, dental-bonding agents, step assists on vans, coatings for easier cleaning glass, bumpers and catalytic converters on cars, protective and glare-reducing coatings for eyeglasses and cars, other cosmetics, light-weight tennis rackets, stain-free clothing and mattresses, and ink). For a list of the top nanoproducts of 2005, see Wolfe, *supra* note 5.
[82] NNI FAQs, *supra* note 10.
[83] *Id.*
[84] *Id.* (recognizing the difficulty of predicting the products that "will move from the laboratory to the marketplace over such a long period").
[85] DREXLER, *supra* note 6.
[86] *Id.* at 63.
[87] *Id.*
[88] *Id.* at 54-63 (describing the many effects replicators would have on society, both beneficial and

exploration program,[89] biomedical field,[90] and even repair the damage done to the world's ecological systems.[91] Over time, production costs may sharply decrease because the assemblers will be able to construct all future products from an original blueprint at virtually no additional cost.[92]

PART III: NANOTECHNOLOGY'S SIDE-EFFECTS

With the good, however, comes the bad. The "gray goo problem," the most well-known unwanted potential consequence of the spread of nanotechnology,[93] arises when replicators and assemblers produce almost anything, and subsequently spread uncontrolled, obliterating natural organisms and replacing them with nano-enhanced organisms.[94] A more foreseeable issue is environmental contamination.[95] The EPA noted

> As nanotechnology progresses from research and development to commercialization and use, it is likely that manufactured nanomaterials and nanoproducts will be released into the environment. . . . The unique features of manufactured nanomaterials and a lack of experience with these materials hinder the risk evaluation that is needed to inform decisions about pollution prevention, environmental clean-up and other control measures, including regulation. Beyond the usual concerns for most toxic materials . . . the adequacy of current toxicity tests for chemicals needs to be assessed . . . . To the extent that nanoparticles

detrimental).

[89] *Id.* at 90. Assemblers could build entire spacecraft, and once in space, the assemblers will be able to rebuild themselves in flight in order to adapt to changing conditions. Spacesuits could be built having the strength of steel and the flexibility of a human body. *Id.* Recognizing that "advanced miniaturization is a key thrust area to enable new science and exploration missions," NASA already foresees the impact the nano-tech revolution will have on the space exploration program. NASA, *supra* note 64.

[90] DREXLER, *supra* note 6, at 99-129 (including the ability to sustain life indefinitely).

[91] *Id.* at 120-123. For example, "cleaning machines" will render toxic chemicals in the environment harmless by rearranging their atoms. *Id.* at 121. Dangerous atoms, such as lead and radioactive isotopes, could be sealed in self-repairing, self-sealing containers. *Id.*

[92] *Id.* at 93-98.

[93] Many authors mention the gray goo problem as a common fear associated with the development of nanotechnology. *See* Castro, *supra* note 11, at 143 (describing the gray goo problem as the fear that self-replicating nanodevices will escape and attack everything they encounter); Fiedler & Reynolds, *supra* note 11, at 605 (ascribing reasonableness to the fear that self-replicating nanodevices might escape the laboratory and "devour everything"); Lin-Easton, *supra* note 11, at 114 (labeling as a common disaster scenario the idea that runaway self-replicating nanomachines, fueled by ordinary natural elements, could replicate themselves on a global basis); Reynolds, *supra* note 11, at 181 (stating that nanotechnology is no longer too exotic for general discussion, as evidenced by a number of significant leaders expressing growing concern over "gray goo," including Britain's Prince Charles); Wejnert, *supra* note 11, at 328 (citing "gray goo" as something that critics and skeptics of nanotechnology say has catastrophic potential to alter the environment and human society); Wolfson, *supra* note 11, at 382 (comparing the risk of inadvertent spread of nanotechnology to the spread of biotechnology into the wider environment and resulting contamination of the human food chain by genetically altered products).

[94] DREXLER, *supra* note 6, at 172-173. For example, nano-enhanced plants could out-compete real plants, "crowding the biosphere with an inedible foliage." *Id.* at 172.

[95] *See* EPA Nanotechnology, http://es.epa.gov/ncer/nano/research/nano_tox.html (last visited July 4, 2006) (noting several special environmental concerns that will arise as nanotechnology applications reach the public) [hereinafter EPA Nanotechnology].

> . . . elicit novel biological responses, these concerns need to be accounted for in toxicity testing to provide relevant information needed for risk assessment to inform decision making.[96]

In addition, nanotechnology could change the face of global warfare and terrorism.[97] Assemblers could be used to duplicate existing weapons out of superior materials, and chemical and biological weapons could be created with nano-enhanced components.[98] Modern detection systems would be inadequate to detect nano-enhanced weapons built with innocuous materials such as carbon.[99] Luckily, nanotechnology offers responses to these problems, and researchers are already tackling these issues.[100] "Labs-on-a-chip," a sensor system the size of a microchip, could be woven into soldiers' uniforms to detect toxins immediately.[101] Adding smart materials could make soldiers' uniforms resistant to certain chemical and biological agents.[102]

Nanotechnology also enhances threats against citizens. Drugs and bugs (electronic surveillance devices) could be used by police states to monitor and control its citizenry.[103] Viruses could be created that target specific genetic characteristics.[104] Not only is the development of technologically advanced, devastating weaponry itself a hazardous effect of nanotechnology, but also, millions of dollars have already been spent researching potential uses of nanotechnology in the military sphere,[105] thus diverting funds from more beneficial uses such as biomedical applications and clean energy. However, these negative effects are not inevitable. By analyzing the scope of potential drawbacks accompanying these research investments, lawmakers can institute regulatory controls that could mitigate these problems.

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[96] *Id.*

[97] DREXLER, *supra* note 6, at 173-177; Wolfson, *supra* note 11, at 381-382.

[98] DREXLER, *supra* note 6, at 174.

[99] *Id.*

[100] *E.g.,* Institute for Soldier Nanotechnologies, http://web.mit.edu/isn/index.html.

[101] HOMELAND SECURITY, *supra* note 19, at 39-43.

[102] *Id.* at 43-46.

[103] *Id.* at 174-175. Although the use of technology to monitor and control citizens is not a new concept, nanotechnology may make it possible to use more untraceable methods to do so, such as the possibility of invisible (to the naked eye) electronic surveillance devices that could travel through phone wires or be implanted into the bloodstream of a person, and drugs that could target specific personal characteristics to ensure a specific response.

[104] RATNER & RATNER, *supra* note 1, at 160. Nano-enhanced viruses could be programmed to read the genetic makeup of an individual. If the individual possesses a certain genetic quality, the virus would be programmed to infect that person.

[105] The Department of Defense oversees the research programs of the Defense Advanced Research Projects Agency and the Office of Naval Research, both of which are heavily focused on developing applications of nanotechnology. HOMELAND SECURITY, *supra* note 19 at 34. The U.S. Army has spent $50 million creating a Center for Soldier Nanotechnologies at MIT. *Id.* at 49. In addition, private companies, such as Agilent and Affymetrix, and educational facilities, such as the University of Texas, are actively participating in national security research and development. *Id.* at 39, 50-51.

PART IV: MAXIMIZING BENEFITS, MINIMIZING CATASTROPHE

To minimize or eliminate the problems associated with nanotechnology, while maximizing the beneficial effects, nanotechnology research and development should be monitored and regulated by "trustworthy systems."[106] Currently, the federal government oversees a massive funding and research program with the purpose of "ensuring United States global leadership in the development and application of nanotechnology."[107] Nonetheless, as nanotechnology becomes more prevalent, more thorough regulation may be necessary.[108] Nanotechnology may greatly impact some of the largest revenue producing industries in the United States, such as the pharmaceutical and medical fields, utilities and power generation, and computer electronics.[109] Thus, it is clear that nanotechnology will likely touch every facet of human life. In addition, these powerful industries have been known to promote profits over human safety,[110] one of the reasons for their stringent regulation.

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[106] DREXLER, *supra* note 6, at 177-230; *accord* Wejnert, *supra* note 11, at 329 ("[P]roponents and critics alike agree that rational planning is called for to mitigate the fears and prepare for the radical changes that [molecular nanotechnology] will bring."); Wolfson, *supra* note 11, at 377-382 (outlining some key issues concerning the development and use of nanotechnology). An additional problem that may arise with the lack of nanotechnology regulation is the disparity between "haves and have-nots." *Id.* at 377-380. Pointing to computer ownership as a useful analogy, Wolfson identifies the potential gap that may arise between those who can take advantage of products developed from nanotechnology, and those that could not afford to reap the benefits. *Id.*

[107] 21st Century Nanotechnology Research and Development Act, 15 U.S.C. § 7501(b)(5) (2006).

[108] *See, e.g.,* Castro, *supra* note 11, at 141-42 (recognizing that as nanotechnology develops, different regulatory approaches may be necessary); Fiedler & Reynolds, *supra* note 11, at 604, 618 (theorizing that "mature nanotechnology" will present unique regulatory issues that will need to be addressed through unconventional measures); Lin-Easton, *supra* note 11, at 110 (arguing for the implementation of the precautionary principle to avoid a potential international disaster caused by nanotechnology); Reynolds, *supra* note 11, at 187 (noting that "[a]s nanotechnology continues to advance and expand into the mainstream, an increasing number of people can be expected to show interest in its regulation"); Wejnert, *supra* note 11, at 329-30 (proposing to adapt existing regulatory controls to eliminate the risks associated with nanotechnology while continuing to promote active development of nanotechnology); Wolfson, *supra* note 11, at 382 (addressing issues requiring consideration to determine what level of regulation should accompany the development of nanotechnology).

[109] ULDRICH & NEWBERRY, *supra* note 12, at 15-16.

[110] Despite regulatory controls, these industries have found ways to maximize profits to the detriment of human health and safety. Recently, the pharmaceutical industry has been involved in scandals surrounding certain prescription drugs. *E.g.* VIOXX Homepage, http://www.vioxx.com/rofecoxib/vioxx/consumer/press_release_09302004.jsp (last visited Mar. 21, 2006) (bad publicity and a new study showing that VIOXX increased the relative risk for cardiovascular problems, such as heart attack and stroke, prompted Merck to remove VIOXX from the market). In addition, allegations of manipulating research studies necessary before drugs are allowed to be released became the premise for a Law and Order episode. *Coming Down Hard* (NBC Television Broadcast Oct. 6, 2004), *synopsis available at* http://www.nbc.com/Law_&_Order/episode_guide/327.shtml. Power plants constantly lobby against increasing pollution controls because of the high costs associated with eliminating emissions. *Compare* Phillip W. DeVous, *'New Source' Sanity*, ACTON COMMENTARY, Jan. 9, 2002, http://www.acton.org/ppolicy/comment/article.php?id=68 (pro-energy lobby view), *with* ENVIRONMENTAL INTEGRITY PROJECT, SEPARATING EPA AND THE ENERGY LOBBY'S MYTHS ABOUT CLEAN AIR ACT "REFORMS" FROM FACT, http://www.environmentalintegrity.org/pubs/NSRfactsvsmyths2.PDF (pro-increasing pollution control view). The Clean Air Act grandfathered existing power plants. ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY 491-501 (4th ed. 2003). And, the Bush Administration refuses to classify mercury a toxic pollutant so that power plants do not have to reduce their emissions. Gerald Rellick, *George Bush on Mercury Pollution: Don't Eat Tuna Fish*, INTERVENTION MAGAZINE, Apr. 3, 2005,

The federal government must regulate nanotechnology for the public good as it pertains to these industries. The form and scope of the trustworthy systems are being debated.[111] Each system has its advantages and disadvantages.[112] The system should be accountable to judicial review and public comment, as well as transparent,[113] while minimizing "the traditional laments of the bureaucratic agency: lack of efficiency, duplication of effort, and subjection to Congressional and judicial requirements in enacting regulations."[114] Certain proposals are outlined briefly in this article as examples of what can be done to regulate nanotechnology.

A. The Government's Role in Nanotechnology Research and Development

Because of nanotechnology's profound potential and the impact it could have on society, the federal government coordinates a substantial amount of the nanoscale research and development in the United States through the National Nanotechnology Initiative (NNI)[115] and the National Nanotechnology Program (NNP).[116] In addition to providing funding and guidance for the development of nanotechnology applications, these programs provide a framework for researching the scope of nanotechnology's societal impacts.[117]

The federal government created the NNI in 2001 when the Clinton administration raised nanoscale science and technology to the level of a federal initiative.[118] In 2003, the Bush administration elevated the importance of a coordinated federal program for nanotechnology with the enactment of the 21st Century Nanotechnology Research and Development Act (hereinafter, Nanotechnology Act),[119] which

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http://www.interventionmag.com/cms/modules.php?op=modload&name=News&file=article&sid=1053.

111 *See, e.g.,* Castro, *supra* note 11, at 141-43 (summarizing current proposals for regulating nanotechnology); Fiedler & Reynolds, *supra* note 11, at 604-17 (analogizing the development and regulation of nanotechnology to the development and regulation of biological research and medical products); Lin-Easton, *supra* note 11, at 119 (advocating for the use of the precautionary principle); Reynolds, *supra* note 11, at 187-200 (noting that regulatory responses to nanotechnology "fall along a broad spectrum" from complete relinquishment to a laissez-faire approach); Wejnert, *supra* note 11, at 330-39 (analyzing the effectiveness of prohibitory control mechanisms for nanotechnology); Wolfson, *supra* note 11, at 382-86 (addressing who should implement regulations and what level of regulation is necessary) .

112 *See, e.g.,* Castro, *supra* note 11, at 141-43 (evaluating the potential effectiveness of current proposals for regulating nanotechnology); Fiedler & Reynolds, *supra* note 11, at 625-29 (concluding that an open dialogue and fervent analysis are necessary to determine the appropriate regulatory scheme); Lin-Easton, *supra* note 11, at 123 (discussing whether the precautionary principle is appropriate for nanotechnology); Reynolds, *supra* note 11, at 200-206 (pointing out several problems associated with different regulatory schemes); Wejnert, *supra* note 11, at 339-42 (weighing the benefits and disadvantages of several regulatory approaches to nanotechnology); Wolfson, *supra* note 11, at 382-86 (concluding that policy makers and the public must ultimately decide what type of regulatory scheme is required).

113 Wejnert, *supra* note 11, at 338-39.

114 *Id.* at 339.

115 National Nanotechnology Initiative, History, http://www.nano.gov/html/about/history.html (last visited Sept. 26, 2005) (including a complete history of NNI) [hereinafter NNI History].

116 21st Century Nanotechnology Research and Development Act, 15 U.S.C. § 7501 (2006).

117 *Id.* § 7501(b)(10); National Nanotechnology Initiative, Societal Dimensions, http://www.nano.gov/html/society/home_society.html (last visited Sept. 26, 2005) [hereinafter NNI Societal Dimensions].

118 NNI History, *supra* note 117. President Clinton argued that federal funding for nanotechnology is essential for America's scientific and economic leadership. Lin-Easton, *supra* note 11, at 110.

119 15 U.S.C. § 7501.

established the NNP.[120] Funds devoted to nanotechnology research and development have increased from $464 million in 2001 to an estimated $1.054 billion in 2006, evidence that the federal government has made nanotechnology a major priority.[121]

The federal government funnels money to NNI member agencies to conduct comprehensive research projects.[122] The EPA is one example.[123] Some of the

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[120] *Id.*

[121] NNI FAQs, *supra* note 10; NNI History, *supra* note 117. The nanotechnology budget is laid out in the 21st Century Nanotechnology Research and Development Act, 15 U.S.C. § 7505:

AUTHORIZATION OF APPROPRIATIONS:

(a) National Science Foundation.--There are authorized to be appropriated to the Director of the National Science Foundation to carry out the Director's responsibilities under this Act--

(1) $385,000,000 for fiscal year 2005;
(2) $424,000,000 for fiscal year 2006;
(3) $449,000,000 for fiscal year 2007; and
(4) $476,000,000 for fiscal year 2008.

(b) Department of Energy.--There are authorized to be appropriated to the Secretary of Energy to carry out the Secretary's responsibilities under this Act--

(1) $317,000,000 for fiscal year 2005;
(2) $347,000,000 for fiscal year 2006;
(3) $380,000,000 for fiscal year 2007; and
(4) $415,000,000 for fiscal year 2008.

(c) National Aeronautics and Space Administration.--There are authorized to be appropriated to the Administrator of the National Aeronautics and Space Administration to carry out the Administrator's responsibilities under this Act--

(1) $34,100,000 for fiscal year 2005;
(2) $37,500,000 for fiscal year 2006;
(3) $40,000,000 for fiscal year 2007; and
(4) $42,300,000 for fiscal year 2008.

(d) National Institute of Standards and Technology.--There are authorized to be appropriated to the Director of the National Institute of Standards and Technology to carry out the Director's responsibilities under this Act--

(1) $68,200,000 for fiscal year 2005;
(2) $75,000,000 for fiscal year 2006;
(3) $80,000,000 for fiscal year 2007; and
(4) $84,000,000 for fiscal year 2008.

(e) Environmental Protection Agency.--There are authorized to be appropriated to the Administrator of the Environmental Protection Agency to carry out the Administrator's responsibilities under this Act--

(1) $5,500,000 for fiscal year 2005;
(2) $6,050,000 for fiscal year 2006;
(3) $6,413,000 for fiscal year 2007; and
(4) $6,800,000 for fiscal year 2008.

[122] National Nanotechnology Initiative, Funding, http://www.nano.gov/html/about/funding.html (last visited Jan. 14, 2006). The chart below is reproduced from the NNI Funding website to give the reader an opportunity to compare the funding amounts per agency (dollars in millions).

Agency	2004 Actual	2005 Estimate	2006 Request
NSF	256	338	344
DOD	291	257	230
DOE	202	210	207

projects that the EPA has funded to improve environmental protection include the use of sensors for improved monitoring and detection capabilities,[124] treatment and remediation techniques for cost-effective and site specific cleanup,[125] green manufacturing to eliminate the generation of waste products,[126] and green energy technology for the creation of commercially viable clean energy sources.[127] The EPA simultaneously conducts research to assess the risks to human health and the natural environment.[128] In this respect, the EPA funds research projects that study the effects of natural nanoparticles in the air and soil, lifecycle aspects, fate and transport of manufactured nanomaterials, toxicity of nanomaterials, their routes of exposure to humans and other organisms, and the potential for bioaccumulation.[129]

Remarkably, the government's efforts are not limited to nanotechnology research and development, and several governmental programs focus on the scope of nanotechnology's societal impacts.[130] In addition, through appropriate agencies, councils, and the National Nanotechnology Coordination Office, the National Nanotechnology Program (NNP) shall *inter alia* "ensur[e] that ethical, legal, environmental, and other appropriate societal concerns . . . are considered during the development of nanotechnology."[131] Thus, through its efforts, the NNP may

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HHS (NIH)	106	142	144
DOC(NIST)	77	75	75
NASA	47	45	32
USDA	2	3	11
EPA	5	5	5
HHS (NIOSH)		3	3
DOJ	2	2	2
DHS (TSA)	1	1	1
TOTAL	989	1081	1054

[123] *Id. See also* 21st Century Nanotechnology Research and Development Act, 15 U.S.C. § 7505(e). For information regarding the organization of NNI, see NNI History, *supra* note 117. For examples of projects currently underway, see EPA Nanotechnology, *supra* note 97.

[124] EPA, NANOTECHNOLOGY: AN EPA PERSPECTIVE FACTSHEET 1, *available at* http://es.epa.gov/ncer/nano/factsheet/nano_factsheet.pdf [hereinafter EPA FACTSHEET].

[125] *Id.*

[126] *Id.*

[127] *Id.*

[128] EPA FACTSHEET, *supra* note 126, at 1. The EPA recently released a draft Nanotechnology White Paper outlining recommendations on the next steps for addressing science policy issues and research needs. NANOTECHNOLOGY WORKGROUP, SCIENCE POLICY COUNCIL, EPA, EXTERNAL REVIEW DRAFT – NANOTECHNOLOGY WHITE PAPER 1 (Dec. 2005), *available at* http://es.epa.gov/ncer/nano/publications/whitepaper12022005.pdf [hereinafter NANOTECHNOLOGY WHITE PAPER].

[129] EPA FACTSHEET, *supra* note 126, at 1.

[130] *See* NNI Societal Dimensions, *supra* note 119 (describing the variety of ways in which NNI and the federal government are involved in the societal implications of nanotechnology).

[131] 15 U.S.C. § 7501(b)(10) (2006). "This shall be accomplished by--

facilitate the development of regulatory systems that promote human health and safety.[132]

Similarly, NNI provides "a multi-agency framework to ensure U.S. leadership in nanotechnology that will be essential to improved human health, economic well being and national security."[133] Accordingly, with twenty-three federal departments and agencies participating,[134] NNI has four major goals: (1) maintaining a research and development program;[135] (2) facilitating the transfer of new technologies;[136] (3) developing the infrastructure necessary to advance nanotechnology;[137] and (4) supporting the responsible development of nanotechnology.[138]

To achieve its goal of supporting the responsible development of nanotechnology, NNI created the Societal Dimensions Program Component Area.[139] This Component Area coordinates research on the practical implications and cultural context of nanotechnology research.[140] Approximately $39 million is earmarked for programs directed at environmental, and health and safety research and development,[141] and

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(A) establishing a research program to identify ethical, legal, environmental, and other appropriate societal concerns related to nanotechnology, and ensuring that the results of such research are widely disseminated;

(B) requiring that interdisciplinary nanotechnology research centers established under paragraph (4) include activities that address societal, ethical, and environmental concerns;

(C) insofar as possible, integrating research on societal, ethical, and environmental concerns with nanotechnology research and development, and ensuring that advances in nanotechnology bring about improvements in quality of life for all Americans; and

(D) providing, through the National Nanotechnology Coordination Office established in section 3, for public input and outreach to be integrated into the Program by the convening of regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences, and educational events, as appropriate."

132 *See supra* note 133 and accompanying text (describing NNP's statutory duties).

133 National Nanotechnology Initiative, Home, http://www.nano.gov/index.html (last visited Sept. 26, 2005) [hereinafter NNI Home].

134 National Nanotechnology Initiative, About the NNI, http://www.nano.gov/html/about/home_about.html (last visited Sept. 26, 2005) [hereinafter About the NNI]. The participating government departments and agencies include: Consumer Products Safety Commission; Department of Agriculture; Department of Commerce, Technology Administration; Department of Commerce, Bureau of Industry and Security; Department of Commerce, National Institute of Standards and Technology; Department of Defense; Department of Energy; Department of Health and Human Services, National Institutes of Health; Department of Health and Human Services, Food and Drug Administration; Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; Department of Homeland Security (includes Transportation Security Administration); Department of Justice; Department of State; Department of Transportation; Department of Treasury; Environmental Protection Agency; Intelligence Community; International Trade Commission; National Aeronautics and Space Administration; National Science Foundation; Nuclear Regulatory Commission; Patent and Trademark Office; and Department of Agriculture. *Id.*

135 About the NNI, *supra* note 136.

136 *Id.*

137 *Id.*

138 *Id.*

139 NNI Societal Dimensions, *supra* note 119.

140 *Id.*

141 National Nanotechnology Initiative, Environment and Health Safety Issues, http://www.nano.gov/html/society/EHS.html (last visited Sept. 26, 2005) [hereinafter NNI Environment and Health].

$43 million for education-related activities and broad assessment projects[142] for fiscal year 2006.[143]

Moreover, the federal government strives to incorporate public opinion into the ongoing development of nanotechnology. The Nanotechnology Act requires that "insofar as possible . . . research on societal, ethical, and environmental concerns with nanotechnology research and development" be researched simultaneously with other proposed uses,[144] and also that "public input and outreach . . . be integrated into the Program by the convening of regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences, and educational events."[145] In addition, NNI organizes Working Groups to coordinate the efforts of NNI member agencies to identify and prioritize research needed to support regulatory decision-making and to promote better communication with the public.[146] Thus, the federal government places great importance on a comprehensive understanding of the effects of nanotechnology, and is willing to rely on the informed public to assist in the direction of nanotechnology development and implementation.[147]

Thus far, the federal government has limited its involvement in nanotechnology to funding decisions and guiding policy.[148] However, as more nano-products come on the market, increasing the risk of harm from nanotech applications, government regulation will become a necessity to maximize the benefits and minimize the detrimental effects of nanotechnology.[149] The government should include in nanoscience regulation marketable products and uses, and the waste and byproducts created through research, development, and production. Knowledge gained through NNI research projects should be incorporated into existing or proposed regulatory frameworks. For example, resultant environmental effects should become apparent before products utilizing nanotechnology come on the market, allowing this knowledge to be incorporated into regulations. In addition, prudent deployment of nanotechnology could have a tremendous positive impact on the environment regardless if its intended application. It is essential for the government to determine the most beneficial way to incorporate nanotechnology into environmental and public health regulations.

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142 Broad assessment projects identify and quantify the broad societal implications of nanotechnology.

143 NNI Environment and Health, *supra* note 143.

144 15 U.S.C. § 7501(b)(10)(c) (2006).

145 *Id.* § 7501(b)(10)(d).

146 NNI Environment and Health, *supra* note 143. In 2005, the Nanoscale Science, Engineering, and Technology Subcommittee established the Nanotechnology Environmental and Health Implications (NEHI) Working Group to coordinate the efforts of NNI member agencies to identify and prioritize research needed to support regulatory decision-making and to promote better communication with the public. *Id.*

147 *See supra* nn. 141-148 and accompanying text (using the 21st Century Nanotechnology Research and Development Act as a governmental policy statement on nanotechnology).

148 *See supra* Part IV.A (discussing the federal government's current participation in the development of nanotechnology).

149 *See supra* note 110 and accompanying text (discussing the potential for increased harm due to nanotechnology applications coming on the market).

B. Proposed Regulatory Controls

Three potential regulatory approaches to nanotechnology based on existing regulatory schemes are available.[150] The first of these is "relinquishment" and prohibition, which requires stopping all nanoscience research and development.[151] It is highly unlikely that the United States will regulate nanotechnology out of existence because of the drastic effects this would have on the U.S.'s ability to compete in the global marketplace (presuming other countries do not follow suit), the belief that the positive uses of nanotechnology which will improve the national standard of living and quality of life[152] will outweigh any negative uses, and because of its applications in other fields, including national security.[153] In addition to these policy reasons, one practical problem to drafting such regulatory control is that even if 99.999% of nanotechnology research was prohibited, the 0.001% would be just as detrimental, and therefore, would not achieve the regulatory goal.[154]

The second regulatory approach is restriction to the military sphere.[155] Although this satisfies the problem of avoiding national security issues caused by complete prohibition, it does not affect the other issues that overregulation poses such as a limited ability to compete in the global marketplace Restriction to the military sphere would reduce the development of beneficial uses of nanotechnology, and would allow competitor markets to out-produce the U.S.[156]

The third regulatory approach is through modest regulation and robust civilian research.[157] The advantages of this regulatory scheme include the prevention of misuse of nanotechnology, maintenance of public confidence, continuing research and development, and the yielding of many beneficial uses and products.[158] This is the "more plausible alternative"[159] because nanotechnology uses are already being debated in the public arena,[160] and nanotechnology research is in its fledgling

[150] Reynolds, *supra* note 11, at 188-200. An option that always exists when discussing regulation is no regulation. Wolfson, *supra* note 11, at 383. This is highly unlikely for nanotechnology because of its potential for widespread application, and therefore, implications.

[151] Reynolds, *supra* note 11, at 188-193.

[152] NNI FAQs, *supra* note 10.

[153] *See* Lin-Easton, *supra* note 11, at 116 (noting that failing to capitalize on the military applications of nanotechnology will have a negative impact on national security); Wejnert, *supra* note 11, at 330 (providing examples from history where bans on technologically advanced weaponry have detrimentally impacted the banning country); NNI Applications, *supra* note 7 (noting that nanotechnology has national security applications). For a complete discussion of nanotechnology applications in national security, see HOMELAND SECURITY, *supra* note 19.

[154] Reynolds, *supra* note 11, at 192. This is because the technology would be in the hands of a few to use as they please, and non-possessors would not be able to combat or compete with the possessors. *Id.*

[155] *Id.* at 193-198.

[156] Arguably, the "trickle down" of military technology and applications to civilian use, such as GPS systems, Kevlar, consumer radar and sonar for pleasure boats, would occur. Nonetheless, overall nanotechnology production would be less if restricted to the military sphere than if research dollars were spent directly on civilian uses.

[157] Reynolds, *supra* note 11, at 197-201. This approach attempts to maximize the benefits of nanotechnology through independent research, while minimizing the negative implications of nanotechnology through modest, targeted regulation. *Id.*

[158] *Id.* at 197.

[159] *Id.*

[160] As early as 1996, Foresight Institute and Scientific American participated in a public debate about

stage.[161] In addition, this regulatory approach does not act as an impediment to the potential societal benefits.

One approach to modest regulation would base regulatory law concerning nanotechnology on existing laws governing analogous products and processes.[162] As an example, simple regulation should be sufficient to eliminate the gray goo problem.[163] Because the federal government has experience developing regulations to prevent dangerous substances, such as toxic chemicals[164] and viral strains,[165] from escaping their confines and causing harm to humans,[166] it should be possible for the federal government to draft rules to prevent the escape of dangerous nanotechnology.[167] Rules forbidding or limiting the creation of self-replicating devices that can survive outside the laboratory, containment procedures for potentially dangerous nanodevices, and limitations on research into military applications should prove sufficient.[168] A simpler approach would use existing regulatory controls directly to safeguard against the harmful effects of nanotechnology.[169] The Toxic Substances Control Act in particular has been touted

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nanotechnology's uses and its potential consequences. For an overview of the debate, see Foresight Nanotech Institute, http://www.foresight.org/SciAmDebate/SciAmOverview.html (last visited Sept. 7, 2006). For a list of links to current online debates about nanotechnology, see Nanotechweb.org, http://nanotechweb.org/resources/Nanotechnology_debate (last visited Sept. 7, 2006).

[161] Reynolds, *supra* note 11, at 200; *see also* NNI FAQs, *supra* note 10 (listing examples of current nanotechnology uses).

[162] Fiedler & Reynolds, *supra* note 11, at 602-603. *Cf.* Susan Bartlett Foote & Robert J. Berlin, *Can Regulation Be As Innovative As Science and Technology? The FDA's Regulation of Combination Products*, 6 MINN. J.L. SCI. & TECH. 619, 633-39 (2005) (discussing the manner in which the FDA regulates "combination products" made up of drugs, biologics or medical devices). This method is also referred to as a "product regulatory mechanism." Wejnert, *supra* note 11, at 338.

[163] Fiedler & Reynolds, *supra* note 11, at 606. Essentially, the concern is that self-replicating nanodevices might escape the laboratory and convert whatever they contact into more copies of themselves, thereby destroying the world as we know it. For a more detailed description, *see* DREXLER, *supra* note 6, at 172-173.

[164] Toxic Substances Control Act, 15 U.S.C. § 2601 (2006).

[165] *E.g.,* U.S. Department of Health and Human Services, http://www.hhs.gov (last visited Oct. 27, 2005) (HHS is the principal agency for protecting the health of all Americans). HHS oversees the National Institutes of Health, a premier medical research organization, and the Centers for Disease Control and Prevention, which provides a system of health surveillance to monitor and prevent disease outbreaks (including bioterrorism), implement disease prevention strategies, maintain national health statistics, prevent environmental disease, and guard against international disease transmission. *Id.*

[166] 15 U.S.C. § 2603(a) (If certain circumstances exist, "the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.").

[167] Fiedler & Reynolds, *supra* note 11, at 606.

[168] *Id. See also* Lin-Easton, *supra* note 11, at 129-31. Referred to as anticipatory action, many scientists recognize the need to plan technical safeguards before nanotechnology produces harmful results. Lin-Easton, *supra* note 11, at 127. An example would be restricting the development of self-replicating nanostructures unless precautions are taken to prevent them from replicating outside the laboratory. *Id.* at 130.

[169] This would be a "simpler" approach because of its use of existing regulatory schemes. However, this paper outlines several problems with this type of system in Part V.

as a useful tool to monitor the development of nanotechnology.[170]

Modest regulation can be further subdivided into two categories: comprehensive and focused.[171] Comprehensive regulation would prevent natural monopolies and public harm.[172] In contrast, focused regulation is not based on immediate threats to human safety, but is imposed to minimize health or economic loss to consumers.[173] This is a useful regulatory scheme when products are relatively harmless.[174]

Nanotechnology requires some form of comprehensive regulation. Massive research and development costs[175] may make nanotechnology prone to monopoly because it is likely that a very small group of corporations and the government will control access to and production of nanotechnology products.[176] Additionally, nanotechnology can pose a significant risk to individuals and society because many of the applications of nanotechnology are invasive.[177] Some medical applications involve injecting a nano-enhanced drug or device into the bloodstream or affected area;[178] electronic applications may make it possible for humans to be implanted with nanochips that could store and retrieve personal information such as criminal history, political and religious affiliations, and medical history;[179] and terrorism applications make citizens increasingly unsafe in large cities.[180] The conclusion that a small group of corporations and governments could control highly invasive technology that may cause serious public harm mandates comprehensive regulation. However, not all nanotechnology products necessitate comprehensive regulation. For example, using carbon nanotubes in tennis rackets is not likely to be harmful. Therefore, to avoid over-regulation it would be necessary to exempt from comprehensive regulation those uses that are relatively harmless.[181] This calls for

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[170] AHSON WARDAK, NANOTECHNOLOGY & REGULATION: A CASE STUDY USING THE TOXIC SUBSTANCE CONTROL ACT (David Rejeski ed., Woodrow Wilson International Center for Scholars 2003), *available at* http://www.environmentalfutures.org/nanotsca_final2.pdf; Nastassja Lewinski, *Nanotechnology Policy and Environmental Regulatory Issues*, J. ENGINEERING & PUBLIC POLICY, vol. 9 (2005), *available at* http://www.wise-intern.org/journal05/Lewinski.pdf; Lin-Easton, *supra* note 11, at 128 (arguing that the federal government could enact national pre-manufacturing notice and product-approval requirements similar to the Toxic Substances Control Act); EPA Meeting On Possible Voluntary Pilot Program for Nanoscale Materials (June 23, 2005), http://es.epa.gov/ncer/nano/relevant_meetings/archive/2005/index.html. On June 23, 2005, EPA hosted a public meeting to solicit input from industry and stakeholders on the feasibility of establishing a voluntary pilot program for existing nanoscale materials under the Toxic Substances Control Act (TSCA). The agency is considering a pilot program for voluntary industry submission of information on existing chemical substances.

[171] Wolfson, *supra* note 11, at 383.

[172] *Id.* Industries regulated by the comprehensive approach include the utilities, food and drugs, and securities.

[173] *Id.*

[174] *Id.*

[175] NNI FAQs, *supra* note 10.

[176] *But see* Wolfson, *supra* note 11, at 383 (arguing that nanotechnology is not prone to a natural monopoly).

[177] *See infra* nn. 179-181 (giving examples of invasive uses of nanotechnology).

[178] *See* RATNER & RATNER, *supra* note 1, at 110-11 (advanced drug delivery systems are injected directly into the bloodstream).

[179] HOMELAND SECURITY, *supra* note 19, at 174-75.

[180] *Id.*

[181] *See* Wejnert, *supra* note 11, at 329. The author suggests segregating nanotechnology applications into

careful and explicit drafting, an activity with which Congress is familiar.

These approaches assume that standard regulatory schemes are adequate to monitor and eliminate the hazardous effects of nanotechnology. As nanotechnology further develops, however, it may be necessary to create laws particular to unique concerns that arise because "[i]n the early part of ['proof of concept'] phase, legal, social and regulatory concerns will primarily focus on experimentation and its consequences. As products reach the market, however, these problems will be transcended by other considerations."[182] Utilizing a "functional" approach to regulating nanotechnology may prove most workable.[183] A functional approach categorizes nanotechnology applications by their uses, and regulates the products based on that functionality.[184] Processes that introduce entirely new capabilities should receive the highest degree of regulation because of the far-reaching effects they could have on both the individual and society.[185]

Undoubtedly, nanotechnology is sufficiently unique to require a variety of regulatory schemes applicable throughout its life-span and across applications. Therefore, Congress should implement product-dependent regulatory controls.[186] In general, some items should be heavily regulated in the development stage.[187] Stringent regulation over self-assembler production in the development stage would ensure that self-assembler escape from the laboratory and proliferation in the outside world does not occur. Other products require more regulation at the "deployment" stage because of the risk of harmful effects on health and safety when using certain products.[188] The Food and Drug Administration heavily regulates products upon deployment to reduce this risk.[189] Certain beauty products, such as sunscreens and

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those that present a credible hazard and those that are by their nature controlled and thus not appropriate for extensive control and regulation. *Id.* He argues that it is only necessary to strictly regulate those applications that pose the most serious threats, as the relatively risk-free applications are not hazardous to individuals or society. *Id.*

[182] Fiedler & Reynolds, *supra* note 11, at 601-602.

[183] *Id.* at 615-617; *see also* Wolfson, *supra* note 11, at 385 (suggesting that if issues arising from the development and production of nanotechnology products are unique to the field or similar across the field, then it may be better to concentrate oversight within a single agency so that it can form "nano-centric" solutions to specific problems).

[184] Fiedler & Reynolds, *supra* note 11, at 616. The functional groups could be augmentation, replacement, and repair. *Id.* Repair is "the restoration to a previous normal state, analogous to bonesetting or suturing a cut." *Id.* Replacement is "like organ transplants or the introduction of artificial joints." *Id.* Augmentation is "enhancement [where] cells are programmed or modified to perform in ways not called for by nature." *Id.*

[185] *Id.* at 616-617.

[186] A possible way to determine the breadth and depth of regulatory controls would be risk assessments. Lin-Easton, *supra* note 11, at 128-29. "[P]rudent technology management calls for an assessment of the risks that new technologies present and how these risks can be understood, controlled, and mitigated." Wejnert, *supra* note 11, at 340. Risk assessments pose certain problems, such as susceptibility to model uncertainty; allowance of dangerous activities to continue based upon assumptions of acceptable risk; and the use of cost-benefit analysis. Lin-Easton, *supra* note 11, at 129. The complexity of this type of regulatory scheme further supports the conclusion that an Emerging Technologies Department would best oversee regulations regarding nanotechnology.

[187] Wolfson, *supra* note 11, at 384.

[188] *Id.* Medical devices should be regulated upon use.

[189] *Id.* *See also* Foote & Berlin, *supra* note 164, at 619 (discussing the manner in which the FDA regulates "combination products" made up of drugs, biologics or medical devices).

cosmetics, already include nano-enhanced chemicals[190] and presumably are regulated by the Food and Drug Administration.[191] Other applications require regulation evenly throughout all stages of development and deployment.[192] Clearly, nanotechnology used for military purposes would need to be heavily regulated to carefully protect who has access to information at every level of research, development and production because of the serious risks posed to national security if such information became available to terrorist groups or "rogue" nations.[193]

Countries across the globe are developing nanotechnology.[194] One regulatory approach to international nanotechnology regulation is the creation of an international monitoring agreement between nanotechnology-possessing nations and non-possessors.[195] Because of built-in oversight protections, the benefits of this approach include reducing the probability of the gray goo problem, and minimizing the threat of a world hostage situation where a "rogue" nation threatens deployment of a catastrophic nano-enhanced weapon.[196] However, any such agreement would have to be multinational, include all the major nations involved in nanotechnology, and have an enforcement and verification mechanism with teeth.[197] This approach is very impractical, especially because of the U.S.'s history of resisting similar conventions.[198]

The "precautionary principle" presents another regulatory mechanism with a proactive approach to controlling nanotechnology at the international level.[199] The precautionary principle "arose out of the understanding that scientific certainty is often achieved too late for the development of effective legal policy responses to

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[190] NNI FAQs, *supra* note 10. Zelen Fullerene C-60 Day Cream was listed among the *Top Nanoproducts of 2005*. Wolfe, *supra* note 5. The cream incorporates nanoscale Fullerene C-60, a derivative of the buckminsterfullerene carbon because the material has remarkable antioxidant properties. *Id.*

[191] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(i) (2006) ("The term 'cosmetic' means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.").

[192] *See* Wolfson, *supra* note 11, at 384 (discussing different levels of regulation available for different types of activities).

[193] Wejnert, *supra* note 11, at 325; Wolfson, *supra* note 11, at 381-82.

[194] According to the NNI website, worldwide government funding of nanotechnology was estimated at $2 billion in 2002, a five time increase over 1997 levels. NNI FAQs, *supra* note 10. Nanotechnology laboratories and experiments are being conducted in such places as the University of Lausanne in Switzerland, Delft University of Technology in the Netherlands, and the National Nanoscience Center in Beijing, China. RATNER & RATNER, *supra* note 1, at 2, 68. The estimated governmental expenditure for nanotechnology research in the European Union was over $128 million (US) in 1997. Lin-Easton, *supra* note 11, at n.12. Government agencies in Japan spent an estimated $120 million (US) in 1996. *Id.* at n.13.

[195] Wejnert, *supra* note 11, at 331-336.

[196] *Id.* at 328.

[197] *Id.* at 335.

[198] *Id.* (for example, the "Chemical Weapons Convention" (Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, Jan. 13, 1993, S. Treaty Doc. No. 103-21) and the "Biological Weapons Convention" (Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, Apr. 10, 1972, 26 U.S.T. 583)).

[199] Lin-Easton, *supra* note 11, at 120.

environmental threats and that scientific uncertainty, therefore, should not be used as a reason for delaying measures to prevent environmental harm."[200] The precautionary principle requires an evaluation of the possible effect and full range of alternatives to the proposed action,[201] then taking anticipatory action to avoid potential threats.[202] Proponents of the precautionary principle argue that precaution need not lead to categorical prohibition, but that it "does redefine development to not [sic] only include economic well-being but also ecological well-being, freedom from disease and other hazards."[203] Although utilizing the precautionary principle has become a trend in international law,[204] it suffers from similar concerns as a potential international monitoring agreement and is not very likely to come to fruition.[205]

As is apparent from the above discussion, four questions should be considered when deciding on a regulatory scheme.[206] Each regulatory approach addresses some, or all, of these concerns. First, one must ask whether nanotechnology should be subject to comprehensive regulation, to limited subject matter regulation, or left largely unregulated.[207] Because of the substantial risks associated with nanotechnology, zero regulation is not a safe approach. The scope of regulation, however, depends largely on the specific applications of nanotechnology. Second, one must ask if the level of regulation should be different depending on whether the activity at issue is research and development, or commercial deployment.[208] Certain nano-products need to be more heavily regulated at different stages of production depending on the potential applications of the research and development.

Third, because certain types of nanotechnology are already subject to various decentralized regulatory regimes,[209] the question is whether regulation of nanotechnology should be centralized in one agency or decentralized among existing agencies.[210] Nanotechnology's overarching unique properties necessitate centralization of regulation.[211] A functional approach to centralized regulation may prove useful. The other alternative is incorporating nanotechnology into existing regulatory schema. However, existing regulations may prove inadequate to safeguard against nanotechnology's unique concerns.[212] Fourth, there is the question of whether self-regulation would be a sufficient regulatory approach for

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[200] *Id.* at 120.
[201] *Id.* at 122.
[202] *Id.*
[203] *Id.* at 123.
[204] Lin-Easton, *supra* note 11, at 119-120.
[205] *See supra* note 202 and accompanying text (arguing that, historically, the United States minimizes or avoids participation in international agreements that may stifle its economic or foreign relations policies).
[206] Wolfson, *supra* note 11, at 382-383.
[207] *Id.* at 383.
[208] *Id.*
[209] *See, e.g.,* Foote & Berlin, *supra* note 164, at 621-22 (discussing the manner in which the FDA regulates "combination products" made up of drugs, biologics or medical devices which may include nano-enhanced components).
[210] Wolfson, *supra* note 11, at 382-383.
[211] For a full discussion of these themes, see Part VI.
[212] For a full discussion of these themes, see Part VI.

nanotechnology.[213] The Foresight Guidelines, which allows experts to draft their own guidelines, offers one approach to self-regulation.[214] Nevertheless, the obvious drawbacks, such as under-regulation and lack of monitoring, likely outweigh the benefits of self-regulation. In addition, where the costs of understanding a problem, communicating knowledge about the problem, or policing are high, a regulatory approach may be superior.[215]

In sum, the persistence of technology conflicts (conflicts over the use and regulation of a specific type of technology) exacts a substantial social price.[216] The debates themselves create costly inefficiencies by fostering legal and policy paralysis that prevent implementation of socially and widely beneficial solutions to urgent problems.[217] In addition, technology debates consume vast resources that could more valuably be directed towards other problems, resulting in lost opportunities for human health and environmental protection, economic growth, and improvements in social welfare.[218] For these reasons, the debate over the regulatory approach applicable to nanotechnology should be limited to workable and practical solutions, with the goal of maximizing the benefits of nanotechnology, while keeping society safe from the harmful effects. Any solution must recognize that both science and culture strongly influence and generate conflict over technology preferences.[219] This necessitates a careful balancing of acceptable risks, cost-benefit analyses, transparency, and unbiased discussion.

Currently, the federal government "regulates" nanotechnology by controlling the federal budget for research and development projects.[220] Only those projects that federal agencies consider worthy of funding receive sufficient dollars for further development.[221] In this way, the government implicitly regulates the future of nanotechnology. However, research and development will likely become less expensive in the future as research tools become cheaper and easier to obtain.[222] Therefore, it may be easier to find private funding sufficient to run research and development programs with fewer or different restrictions.[223] Thus, the federal

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[213] Wolfson, *supra* note 11, at 383. *See also* Reynolds, *supra* note 11, at 200 (arguing that the field of nanotechnology research should be self-regulated like biotechnology). Biotechnology and nanotechnology are similar in that they are both cutting-edge sciences that are predicted to have profound impacts on the way in which we interact with the world, and the manner in which we continue to live our lives. *See id.* at 198 (describing both potential and real applications of biotechnology research). In addition, it is feared that both sciences could have severe detrimental impacts on individuals, society and the environment. *Id.*

[214] Foresight Institute, *supra* note 11 (Foresight Guidelines).

[215] Daniel C. Esty, *Environmental Protection in the Information Age*, 79 N.Y.U. L. REV. 115, 124 (2004).

[216] Gregory N. Mandel, *Technology Wars: The Failure of Democratic Discourse*, 11 MICH. TELECOMM. & TECH. L. REV. 117, 117 (2005).

[217] *Id.* at 120.

[218] *Id.* at 117, 120.

[219] *Id.* at 119-120.

[220] *See* 15 U.S.C. § 7505 (2006) (quoted in full at *supra* 119); NNI funding scheme discussed *supra* Part IV.A; Wejnert, *supra* note 11, at 336.

[221] *See* Wolfson, *supra* note 11, at 391-392 (discussing the funding schemes of various countries).

[222] *See* RATNER & RATNER, *supra* note 1, at 39 (theorizing that nanotechnology production will become less expensive over time).

[223] *See* note 226 and accompanying text (addressing the decreasing costs of research and development).

government's "regulation" of nanotechnology in this way should decrease, making it necessary to adopt nanotechnology controls. The federal government has implicitly acknowledged the need for future regulatory controls in the Nanotechnology Act[224] by including "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" by the National Nanotechnology Program[225] and requesting a triennial review of the National Nanotechnology Program to receive "recommendations on policy . . . changes with respect to nanotechnology research and development activities."[226] Congress must take this one step further and implement those policy recommendations. A possible solution is the creation of an Emerging Technologies Department. Such a Department would address the numerous concerns outlined in this paper.

PART V: EMERGING TECHNOLOGIES DEPARTMENT

The government's primary reason to take action is to protect human health and safety.[227] Focus on health and safety when analyzing the nanotechnology issue is central to the creation of an adequate response to nanotechnology's special concerns.[228] Because nanotechnology development and production issues are unique, the government should concentrate oversight within a single agency that can form "nano-centric" solutions to specific problems.[229] Considering the prediction that nanotechnology will be a $1 trillion industry by 2010,[230] these facts give rise to the pressing need to develop a comprehensive solution to the nanotechnology problem. The federal government should not rely on the industry to self-regulate, as that may exacerbate the negative implications of nanotechnology. As noted, "[b]y vesting power over the regulation of nanodevices in a body analogous to the [FDA], the federal government could exercise more control over the development and production of . . . [nanotechnology]."[231] Thus, centralized regulation is necessary.

The creation of a Nanotechnology Department is one potential solution. Such a Department would be best able to create regulatory guidelines to assess and address the issues of nanotechnology. However, a nanotechnology department would likely

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[224] *See, e.g.,* 15 U.S.C. § 7504(c) ("Study on the Responsible Development of Nanotechnology.--As part of the first triennial review conducted in accordance with subsection (a), the National Research Council shall conduct a one-time study to assess the need for standards, guidelines, or strategies for ensuring the responsible development of nanotechnology, including, but not limited to--(1) self-replicating nanoscale machines or devices; (2) the release of such machines in natural environments; (3) encryption; (4) the development of defensive technologies; (5) the use of nanotechnology in the enhancement of human intelligence; and 6) the use of nanotechnology in developing artificial intelligence.").

[225] *Id.* § 7501(a)(10).

[226] *Id.* § 7504(a)(9).

[227] *See* Reynolds, *supra* note 11, at 201 (stating the main reason to regulate research is to prevent accidents and to ensure safety).

[228] These concerns arise out of nanotechnology's unique properties, including its size, its many uses and applications, and its potential to self-replicate.

[229] Wolfson, *supra* note 11, at 385.

[230] ULDRICH & NEWBERRY, *supra* note 12, at 13.

[231] Wejnert, *supra* note 11, at 338.

be inefficient, cumbersome and excessive.[232] Considering that similar concerns surround other cutting-edge sciences, including biotechnology,[233] stem cell research[234] and cloning,[235] it would be more efficient to create an overarching Emerging Technologies Department that would address the concerns that arise from these unique, yet similar scientific advances. This would avoid being inefficient, cumbersome, and excessive because the Department would be able to apply uniform solutions to similar potential or unintended consequences, and thus would reap the maximum benefits from these innovative scientific advances.

Often, the government acts in response to an identified problem, instead of acting to avoid or minimize foreseeable problems.[236] By way of example, combination products[237] have become "a major trend" in health care.[238] Regardless, Congress did not change the regulatory scheme affecting drugs, devices and biologics for roughly twenty years.[239] Although this approach provides the benefit of predictability, regulations evolve incrementally in response to past problems.[240] In addition, because the government acts retroactively, industry norms and public expectations limit what Congress can effectively institute.[241] Arguing that "our system does not favor innovation in regulatory agencies, even as it is embraced in our scientists and engineers," some scholars do not believe that regulatory controls will be able to keep pace with technological innovation.[242]

An Emerging Technologies Department would actively anticipate and address problems before they develop. To accomplish this goal, the Department would need sufficient deference to address issues as they arise, instead of suffering from the drawbacks of reactive action. Anticipatory action would facilitate the development

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[232] The government typically combines the regulatory oversight of similar products or issues because often similar products or issues have similar unintended or potential ramifications. Some examples include the Food and Drug Administration, the Environmental Protection Agency, and the Patent and Trademark Office.

[233] Lin-Easton, *supra* note 11, at 129; Reynolds, *supra* note 11, at 200; Wolfson, *supra* note 11, at 377.

[234] *See* Reynolds, *supra* note 11, at 187 (discussing the ethical debate arising from stem cell research).

[235] *See id.* (analogizing the ethical issues of cloning to the development of nanotechnology); Wejnert, *supra* note 11, at 336 (discussing cloning).

[236] *See* Foote & Berlin, *supra* note 164, at 632 (noting that the FDA was developed in response to health problems associated with contaminated food and drugs). Similarly, most environmental statutes are enacted in response to a perceived problem. For example, the Clean Air Act and the Clean Water Act were passed by Congress after those environmental problems became so prevalent that it was impossible to avoid them. PERCIVAL, *supra* note 112, at 566.

[237] A "combination product" is made up of a combination of drugs, biologics or medical devices. Foote & Berlin, *supra* note 164, at 620.

[238] *Id.* at n.4.

[239] *Id.* at 632-38. Although combination products were introduced on the market in the early 1980s, Congress did not pass any law regulating them until the 2002 Medical Devices User Fee and Modernization Act, 116 U.S.C. § 1588 (2002). *Id.*

[240] *Id.* at 637.

[241] For example, as part of its comprehensive amendments to the Clean Air Act, Congress implemented a program that mandated individuals carpool or take public transportation to and from their jobs. PERCIVAL, *supra* note 112, at 552-68. Public outcry quickly convinced Congress to remove this program. *Id.* In addition, regulatory agencies may develop vested interests in their own piecemeal regulation of nanotechnology that may make it difficult to implement overarching controls later. Wolfson, *supra* note 11, at 385

[242] Foote & Berlin, *supra* note 164, at 644.

of safeguards before proceeding with certain research and development projects. Many scientists recognize the need to plan technical safeguards before nanotechnology produces harmful results.[243] The breadth and depth of controls could be based upon risk assessments.[244] Even though risk assessments pose certain problems,[245] it is possible to use them to adequately address the potential harmful effects of nanotechnology because this type of research has been conducted simultaneously with the development of marketable uses.[246]

Using the NNI framework[247] to create the Department would be a good start, enabling the Department to utilize established relationships among existing and participating agencies and departments. However, implementing an independent governing board would be necessary to address specific concerns without potential biases arising out of involvement in other agencies. Such an organizational scheme would enable those involved to address the issues surrounding nanotechnology; uses and applications, research and development, patents, and antitrust issues. Expert involvement would ensure the application of adequacy of effort and efficiency.

The Department, through its governing board, would maximize the benefits of nanotechnology while minimizing the negative effects. It would determine the level of involvement of industry experts and other agencies to minimize squabbling and conflicts of interest. Nanotechnology has such a variety of uses that several existing regulatory schemes may seemingly apply to nanotechnology.[248] Thus, as one of its essential duties, the Department would interpret and disseminate information about how nanotechnology applies to or is restricted by other agencies, departments and regulatory schemes. For example, if nanotechnology is used in medical devices, the Department would first analyze the applicability to nanotechnology of the FDA's approach to its determination that a medical device is safe and effective, and then make any necessary changes to the approach to ensure that the problems uniquely associated with nanotechnology are accounted for and minimized. Alternatively, if the Department found the existing regulatory approach ineffective to counter potential harmful consequences of using nanotechnology, then the Department could decide that this particular use of nanotechnology should be specially regulated or monitored by the Department or another regulatory body.

In addition, the Department would decide, under a variety of possible approaches, which new fields should be subject to its regulatory controls. New scientific fields could be added as they develop. As an anticipatory action approach, the fields would be presumed regulated unless otherwise exempt from the Department's reach.

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[243] Lin-Easton, *supra* note 11, at 128.

[244] *Id.* The EPA used risk assessments in its analysis of the nanotechnology issue. NANOTECHNOLOGY WHITE PAPER, *supra* note 130, at ch. 4.

[245] Lin-Easton, *supra* note 11, at 129. According to Lin-Easton, those additional problems include (1) its assumption of "assimilative capacity;" (2) its susceptibility to model uncertainty; (3) allowance of dangerous activities to continue based upon assumptions of acceptable risk; (4) its undemocratic nature as it often precludes participation of those most affected; and (5) the use of cost-benefit analysis. *Id.*

[246] *See supra* Part IV.A (discussing the benefits of researching the consequences of particular applications simultaneously with their intended uses).

[247] The organizational scheme of the NNI is described on the NNI website, http://www.nano.gov/index.html.

[248] *See e.g.* WARDAK, *supra* note 172 (applying the Toxic Substances Control Act to nanotechnology).

Alternatively, new fields could be added based on a determination of ethical, moral or health concerns.

The advantages of an Emerging Technologies Department include "universal interaction with manufacturers and researchers who seek approval for [nanotechnology] applications, and a standardized mechanism for how appropriate research in [nanotechnology] would be conducted."[249] Additionally, [centralizing information gap filling][250] offers potential efficiency gains in several ways. Centralized data collection and analysis may generate economies of scale in the identification of problem areas, the assessment of impact, and the valuation of harm.[251] Because the federal government and its departments have an overarching perspective spanning a wide array of individual problems, they may be positioned to spot harms that individuals or industries cannot see, recognize trends that might not be visible at a decentralized level, and make judgments about which interventions are most effective on the basis of this broad experience.[252] Moreover, an Emerging Technologies Department would always be on par with the creativity of our top scientists and industries because of the Department's use of experts and its proactive approach to developing regulations. The Department could also require certain disclosures of information. Therefore, it would be possible to implement regulatory proposals before harmful consequences of nanotechnology occur.

PART VI: INCORPORATING NANOTECHNOLOGY INTO THE REGULATORY FRAMEWORK

As stated above, an Emerging Technologies Department would primarily interpret and disseminate information about how nanotechnology applies to or is restricted by other agencies, departments and regulatory schemes.[253] This is necessary because, without a doubt, nanotechnology will dramatically affect existing regulations, creating the need for modifications.[254] As a case study, this section examines certain environmental regulations to determine nanotechnology's impact on existing regulatory schemes to provide an example of the type of analysis the Emerging Technologies Department would undertake. Policy considerations also receive consideration because nanotechnology will give more scientifically robust answers to questions impacting environmental regulations, such as how much harm pollutants cause to particular individuals,[255] and the idea that nanotechnology gains make possible a more empirical and quantitative approach to environmental

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[249] Wejnert, *supra* note 11, at 338-39.

[250] Information gaps exist where regulatory agencies do not have access to all the information necessary to address particular problems. Esty, *supra* note 219, at 144. "Information gap filling" is the process of gaining the necessary information to better address regulatory problems. *Id.* This is usually accomplished through research. *Id.*

[251] Esty, *supra* note 219, at 144.

[252] *Id.*

[253] *See supra* Part V (discussing the purpose of the Emerging Technologies Department).

[254] *See* Fiedler & Reynolds, *supra* note 11, at 607-12 (posing several questions about the effect nanotechnology will have on medical regulators); Wolfson, *supra* note 11, at 385, 393, 395-96 (theorizing about some of the implications nanotechnology will have on the Food and Drug Act, workplace regulations, and patent and trademark laws). *But see* Vorndran, *supra* note 1, at 7 (stating that nanotechnology inventions do not face unique patentability issues).

[255] Esty, *supra* note 219, at 158.

protection.[256]

Even though environmental regulations have not been substantially affected by the revolutionary advances in science and technology in the last century,[257] it is unlikely that the nanotech revolution will leave them unscathed. Regulatory mechanisms, both those that promote human health and welfare, such as the Clean Air Act[258] and the Clean Water Act,[259] and those that protect human health and welfare, such as the Toxic Substances Control Act,[260] should be revisited and reformulated in order to reap the benefits of nanotechnology while minimizing its hazardous effects.[261]

Through emerging nanotechnology, scientists will be able to monitor pollutants at much smaller levels, track the fate and transport of individual pollutants, and understand the adverse health effects of those particular pollutants more accurately and in much finer detail at lower emissions levels than present-day technology permits.[262] Uncovering this information will eliminate the "information gaps and uncertainties [that] lie at the heart of many persistent pollution and natural resource management problems."[263] Thus, policy makers will need to recalculate environmental goals to incorporate the advanced scientific knowledge gathered through nanotechnology, reassess regulatory action plans to determine whether they permit achievement of the goals, and reconsider environmental policy to encourage maximum health benefits at the least cost.

Nanotechnology may not only improve the level of health and safety that can be achieved, but it should also lead to a better evaluation of the harmful effects of pollution and greater opportunities to remediate contaminated sites.[264] When regulatory schemes establish ambient standards to set environmental goals,[265] increases in the ability to monitor and assess the effects of pollutants will lead to

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[256] *Id.*

[257] For example, the 1990 Amendments to the Clean Air Act (CAA) utilized technological advances allowing for the greater ability to monitor tailpipe emissions by requiring the use of the dynamometer to gain more accurate readings of emissions than can be achieved by the stationary tailpipe sensor systems. Clean Air Act, 42 U.S.C. §§ 4201, 7525(a)(4)(A) (2006); PERCIVAL, *supra* note 112, at 552-68. The CAA did not have to be completely redrafted in order to incorporate new technology.

[258] 42 U.S.C. § 4201.

[259] 33 U.S.C. § 1251 (2006).

[260] 15 U.S.C. § 2601 (2006).

[261] One example is the low-volume exemption from the Toxic Substances Control Act, which applies to companies manufacturing 10,000 kg or less of the regulated substance. 40 C.F.R. § 723.50 (2006). This is a substantially high amount considering that a nanostructure is one of the smallest things possible to make. *See* Lewinski, *supra* note 172, at 16 (applying the Toxic Substances Control Act to regulate nanotechnology).

[262] The EPA has a research program dedicated to discovering the variety of ways that nanotechnology will be able to better enable scientists to find, measure, regulate and control pollution emissions. For more information, see EPA Nanotechnology, *supra* note 97. *See also* NNI Research, *supra* note 8 (discussing environmental applications of nanotechnology research).

[263] Esty, *supra* note 219, at 119 ("As data become easier to analyze and disseminate, and dramatically less costly to acquire and use, our capacity to identify and solve environmental problems will increase substantially.").

[264] *See* EPA Nanotechnology, *supra* note 97 (click on "remediation" and "industrial ecology" for EPA's goals and examples of current research projects); NNI Research, *supra* note 8.

[265] *E.g.,* Clean Air Act, 42 U.S.C. § 4201 (where the regulatory standards are ambient standards for the quality of the medium (air), individual polluters determine the method to achieve the standards).

numerical reductions in those standards beyond current levels. Then, the question shifts to whether existing technology could achieve those standards. If not, who is responsible for developing such methods and devices? Other environmental regulations are "technology-based," reducing emissions up to the amount feasible through existing technological capabilities.[266] When regulatory schemes use technology-based standards, improved environmental cleanup devices would lead to higher standards. However, the issue is again one of motivation: who would invent such a device if it would cause pollution control costs to increase? Yet, this is essential if nanotechnology's potential is to be realized to its fullest extent.

Regulated industries do not have the incentive to develop ways to further reduce their emissions because often these systems are very expensive and cut into profits.[267] Private industries may not have the incentive to pour research and development dollars into programs that may not pay off financially. The government must create ways either to encourage or subsidize the production of nano-devices to clean up the environment.[268] Therefore, policies should be drafted to "optimize information generation."[269]

One way to accomplish this goal is through regulations mandating that polluters set aside certain percentages of profits to develop new technologies to reduce pollution. Alternatively, Congress could redraft existing regulations to establish performance standards, thus forcing the technological development implicitly through a system of fines and penalties for failure to reach set goals.[270] The Emerging Technologies Department would bear responsibility for analyzing the alternatives and making recommendations to Congress or implementing new regulations. This is a substantially lengthy process, so it is important to begin to consider the means to achieve optimal public health and environmental protection through the use of nanotechnology. As the EPA conducts research, it should compile the data and make proposals.[271]

Drafting accurate definitions is a major concern in redrafting environmental statutes because of their importance in achieving stated goals. Definitions often outline the breadth and depth of regulatory coverage.[272] Drafting inaccurate, narrow

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[266] *E.g.,* Clean Water Act, 33 U.S.C. § 1251.

[267] *See, e.g.,* Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 (2006) (allowing companies to keep products on the market until regulators prove them to be harmful). *See also* PERCIVAL, *supra* note 112, at 387 (plans to mitigate Alar's harmful health effects would have been very expensive, so the industry abandoned its use).

[268] *See* Esty, *supra* note 219, at 202 (suggesting directly subsidizing information generation).

[269] *Id.* at 120.

[270] *See id.* at 173, 197-199, 200 (suggesting folding a required "information gap analysis" into the existing regulatory process).

[271] The EPA has begun this process by issuing the draft NANOTECHNOLOGY WHITE PAPER, *supra* note 130, at 1.

[272] An example of how definitions outline the breadth of environmental regulations is the phrase "navigable waters" used in the Clean Water Act. Cases interpreting this phrase define the jurisdictional scope of the Act. United States v. Riverside Bayview Homes, 474 U.S. 121, 139 (1985) (holding that extension of the definition of "navigable waters" to include wetlands adjacent to navigable waters not an unreasonable interpretation of the Clean Water Act); Solid Waste Agency of Northern Cook County v. Army Corps of Engineers, 121 S. Ct. 675, 684 (2001) (holding extension of the definition of "navigable waters" to include a gravel pit, based solely on its nature as a bird habitat, was an unreasonable interpretation of the Clean Water Act because the ponds were not adjacent to open water); Rapanos v.

or broad definitions of key terms may unintentionally decrease (or increase) coverage, preventing achievement of the regulatory purpose. "Nanotechnology" itself may prove to be a difficult word to define.[273] NNI has a working definition of nanotechnology applicable to its government-funded program,[274] and the Nanotechnology Act has a separate, though similar, definition for nanotechnology.[275] Because millions of dollars of federal funding are involved in both of these programs, the definition of nanotechnology is very important to all interested parties. It appears that the Act's definition is broader because it fails to clearly define the scale involved, leaving space for interpretation, whereas NNI's definition plainly states that nanotechnology is limited to the 1-100 nanometer scale.[276]

Many environmental standards are broadly or ambiguously phrased, such as "maximum achievable control technology (MACT),"[277] "lowest achievable emissions rate (LAER),"[278] and the "actual, detectable violation" standard.[279] With better detecting mechanisms, these standards will constantly change, calling for increasing levels of control. Congress may necessarily define certain terms with more detail or to call for more frequent review of what meets the standards so that regulations reflect newly gathered information as early as possible.

Another serious issue when redrafting environmental regulations concerns unintended environmental consequences. This significant problem[280] has given rise

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United States, 126 S. Ct. 2208, 2220-21 (2006) (holding that term "navigable waters," under CWA, includes only relatively permanent, standing or flowing bodies of water, not intermittent or ephemeral flows of water, and only those wetlands with a continuous surface connection to bodies that are waters of the United States in their own right are adjacent to such waters and covered by the CWA). An example of how a definition can outline the depth of environmental regulation is the definition of "modification" under the Clean Air Act. Circuits split on the definition of "modification" used to delineate the level of pollution control statutorily mandated for power plants. *Compare* United States v. Duke Energy Corp., 411 F.3d 539, 550 (4th Cir. 2005) (holding definitions of "modification" are the same for the nonattainment, prevention of significant deterioration, new source review and new source performance standards programs), *with* New York v. EPA, 413 F.3d 3, 23-28 (D.C. Cir. 2005) (holding "modification" for purposes of nonattainment, prevention of significant deterioration, and new source review programs could be tied to annual actual emissions whereas the new source performance standards regulations currently are tied to hourly emissions rates) and U.S. v. Cinergy, 2006 US App LEXIS 21057, *13-*16 (Aug. 17, 2006) (same). An example of a definitional problem specific to nanotechnology is where the traditional categories of "drugs, biologics and devices" do not include "combinations," the regulatory controls for nano-enhanced drugs and drug delivery systems are unclear. Foote & Berlin, *supra* note 164, at 640.

[273] *See* Vorndran, *supra* note 1, at 6-7 (noting that providing a standard definition for "nanotechnology" may not be effective).

[274] NNI Home, *supra* note 135 (defining nanotechnology as "research and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1-100 nanometers, creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate sizes, and ability to be controlled or manipulated on the atomic scale").

[275] 15 U.S.C. § 7509(2) (2006) ("Nanotechnology -- The term 'nanotechnology' means the science and technology that will enable one to understand, measure, manipulate, and manufacture at the atomic, molecular, and supra-molecular levels, aimed at creating materials, devices, and systems with fundamentally new molecular organization, properties, and functions.").

[276] *Compare* note 278 *with* note 279.

[277] This standard is used in the air toxics program of the Clean Air Act, 42 U.S.C. § 7412 (2006).

[278] The "LAER" standard is used in the nonattainment program of the Clean Air Act, 42 U.S.C. § 7501(3).

[279] Arkansas v. Oklahoma, 503 U.S. 91, 110-12 (1992).

[280] Utility companies in the 1970s responded to increasingly stringent control of local air pollution by

to the "precautionary principle."[281] This problem comes in two distinct forms: unintended consequences from drafting loopholes or ambiguity, or unforeseen consequences of what appear to be positive regulations.[282] The first problem can be curtailed through extensive data-gathering and extremely careful drafting, whereas the second problem can be reduced only by broad and extensive data-gathering. The nanotechnology industry in the United States currently is set up to produce information on potential side-effects. However, comparatively, applications receive much larger dollar amounts than research into the potential side-effects or unintended implications of nanotechnology.[283] Therefore, applications may be prepared for market before enough research has been done to uncover the implications of the particular application. For this reason, the federal government should increase funding for research into the possible unintended implications of nanotechnology's various applications.[284]

Some argue that nanotechnology may not have a substantial adverse impact on the environment because nano-products are developed from individual atoms and molecules naturally occurring in the environment.[285] However, "nanotechnology presents the first technology that has almost the same power to destroy the environment as it does to restore and replenish it."[286] The byproducts and waste created from developing nanotechnology may have a detrimental effect on the global environment. Carbon dioxide (CO_2), a naturally occurring molecule, has caused the most serious global environmental concern plaguing society today - the "greenhouse effect."[287] CO_2 seems innocuous because of its use in respiration and photosynthesis; however, because its levels have increased exponentially since the Industrial Revolution,[288] the greenhouse effect is causing the destruction of coastline through rising water levels,[289] more severe and recurring storms,[290] and overall

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building tall stacks that could project pollution plumes into the upper atmosphere, sending the pollution long distances. PERCIVAL, *supra* note 112, at 541. More than 175 stacks higher than 500 feet were constructed after the enactment of the 1970 Clean Air Act. *Id.* The practice was terminated in 1977 by 42 U.S.C. § 7423, but not before 111 "big dirties" were built, which are the primary sources of acid rain in the eastern United States. *Id.* Environmental regulations have caused unintended social consequences as well. The Clean Air Act's Title IV program reduced emissions from power plants even further by creating a system of marketable allowances for sulfur dioxide to reduce acid rain. 42 U.S.C. § 7651b; PERCIVAL, *supra* note 112, at 501. By encouraging utilities to switch to low-sulfur coal, this program has had a profound impact on the domestic coal industry in that nearly 1,000 coal mines in the United States have closed since the 1990 Amendments, and many miners have lost their jobs. PERCIVAL, *supra* note 112, at 549, 551-52.

281 Discussed *supra* Part IV.B.

282 *See supra* note 284 (providing an example of each).

283 *See supra* Part IV.A (discussing funding disparity); and *supra* note 124 (chart showing funding discrepancies).

284 Lewinski, *supra* note 172, at 24-25.

285 Reynolds, *supra* note 11, at 181-82. Most nanoproducts are developed from carbon. RATNER & RATNER, *supra* note 1, at 49-50.

286 Wejnert, *supra* note 11, at 349. *See also* Lin-Easton, *supra* note 11, at 112-15 (referring to the potential positive and negative environmental impacts of nanotechnology as the "green double-edge of the [nanotechnology] knife").

287 Environmental Protection Agency Global Warming Emissions, http://yosemite.epa.gov/oar/globalwarming.nsf/content/emissions.html (last visited Sept. 7, 2006).

288 *Id.*

289 Environmental Protection Agency Global Warming Impacts,

changes in global temperatures.[291] Nanotechnology could be the cause of something equally terrible. The EPA and the proposed Emerging Technologies Department must study any and all angles of hazardous effects in great detail so as to be ready with proposed regulations to address and minimize potential concerns.

CONCLUSION

In the last twenty years, nanotechnology has gone from a sparkle in the eyes of science fiction aficionados to real-life applications. Completely unaware, most Americans have seen or used nano-enhanced products, be they golf clubs, tennis balls or stain-resistant pants. This is just the beginning; nanotechnology promises longer, healthier lives through the implementation of advanced drug delivery systems and other biomedical applications, a cleaner planet through greater pollution detection and remediation, and the benefits of increased information technology. However, nanotechnology threatens the safety and existence of humankind with newer and more dangerous warfare and weapons, the gray goo problem, and artificial intelligence beyond human control. Because nanotechnology has both the potential to improve and imperil society, it needs to be researched, monitored and regulated by trustworthy systems.

A variety of potential frameworks exist to ensure the minimization of potential harms. Each requires pervasive controls over nanotechnology's research, development, and deployment throughout its life-cycle, either by the government or through self-regulation. However, the creation of an Emerging Technologies Department represents the best way to ensure the maximization of nanotechnology's potential benefits, while minimizing its negative effects. By anticipating the most effective manner to regulate and employ nanotechnology, society will reap the benefits of this unique technology. Lastly, nanotechnology's substantial impacts on existing regulations need to be ascertained, so that nanotechnology can be incorporated into the existing regulatory framework. Taking these steps will ensure that we maximize the potential of nanotechnology to improve society.

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http://yosemite.epa.gov/oar/globalwarming.nsf/content/impacts.html (last visited Sept. 7, 2006).

[290] *Id.*

[291] *Id.*