THE UNMANNED VOYAGE: AN EXAMINATION OF NANOROBOTIC LIABILITY

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I. INTRODUCTION

The book and movie "The Fantastic Voyage"[1] is repeatedly linked to discussions of nanotechnology. The plot consists of a crew of people that are shrunk to what we could call "nanosize" who travel in a submarine throughout a human body.[2] Although the situation seemed unfathomable in 1966, scientists are trying to make it a reality using nanorobots.[3] However, the nanorobots that will possibly venture through our bodies for medicinal purposes will not be manned by miniature humans to control their actions. Instead, the robots could be triggered by chemical stimuli[4] or remotely controlled by doctors.[5] Robot autonomy

[1] ISAAC ASIMOV, FANTASTIC VOYAGE (Bantam Books 1966).

[2] *See generally id.*; Rick Weiss, *Nanomedicine's Promise is Anything but Tiny*, WASH. POST, Jan. 31, 2005, at A-08, *available at* http://www.washingtonpost.com/wp-dyn/articles/A49758-2005Jan30.html.

[3] The terms nanorobot and nanobot are used interchangeably.

[4] *See* Alan H. Goldstein, *I, Nanobot*, SALON.COM, Mar. 9, 2006, http://www.salon.com/tech/feature/2006/03/09/nanobiobot/index.html.

[5] *See* Robert A. Freitas Jr., Foresight Nanotech Institute, Nanomedicine

produces complicated questions of liability for the products liability industry and medical professionals. The actors involved in this dilemma will predictably include the designers and manufacturers of nanorobots and the doctors who may control them. Due to the advent of nanojuries[6] and in response to government agencies requesting public opinion in lieu of implementing strict regulations from the outset,[7] the discussion of liability is complicated by including the public who will later act as the consumers of these products. The liability concerns that have been voiced give rise to discussion of how the nanotech industry can prevent the debacle that occurred with the asbestos industry.[8] The one thing we know for certain is that we do not know the full risk and potential of nanoproducts.

Nanotechnology has become the new biotechnology.[9] It is based on biotech materials, including the human body, and has presented parallel regulatory concerns.[10] The concerns and

FAQ, (1998), http://www.foresight.org/Nanomedicine/NanoMedFAQ.html [hereinafter Nanomedicine FAQ].

6 A forum for lay people who are not trained or specialized in the sciences, to voice their concerns and opinions on nano-science. Nanojury.org, Nanojury: Welcome, http://www.nanojury.org.uk./index.html (last visited Nov. 11, 2007); *see also* Guardian Unlimited, What is NanoJury UK? http://www.guardian.co.uk/life/nanojury/0,16014,1483441,00.html (discussing how the United Kingdom has brought together 20 laypeople for getting nanotechnology policy recommendations) (last visited Nov. 11, 2007).

7 U.S. Food and Drug Administration, Did You Know? Nanotechnology, http://www.fda.gov/oc/initiatives/criticalpath/nanotechnology.html (last visited Feb 6, 2008); Andreas von Bubnoff, *FDA Meeting: Nah, no Consensus*. SMALL TIMES, Oct. 13, 2006, *available at* http://www.smalltimes.com (in "search" field type "*FDA Meeting: Nah, no Consensus*") (convening FDA experts to decide, "whether the agency should regulate nanotechnology products").

8 *See* John C. Monica Jr. et al., *Preparing for Future Health Litigation: The Application of Products Liability Law to Nanotechnology*, 3 NANOTECH. L. & BUS. 54, 55–57 (Feb./Mar. 2006) (describing how the widespread asbestos litigation starting in 1974 resulted in bankruptcy not only for the companies that hid the risks of asbestos but also for companies that were incidentally involved).

9 Morgan O'Rourke, *Smaller and Smaller and Smaller: Examining the Possibilities of Nanotechnology*, 51 RISK MGMT. 8, (Aug. 1, 2004), *available at* http://www.rims.org//Magazine/PrintTemplate.cfm?AID=2442. "Biotechnology is a collection of technologies that capitalize on the attributes of cells, such as their manufacturing capabilities, and put biological molecules, such as DNA and proteins, to work for us." BIO.org, Biotechnology Industry Organization, Biotechnology: A Collection of Technologies, http://www.bio.org/speeches/pubs/er/technology_collection.asp (last visited Nov. 11, 2007).

10 John Miller, *Beyond Biotechnology: FDA Regulation of Nanomedicine*, 4 COLUM. SCI. & TECH. L. REV. 2, 2, 5, 16, (2002/2003), *available at*

unknowns that emerged with the advent of biotech are reappearing with the rise of nanotechnology.[11] Currently, nanotechnology products for consumer use are limited, but some products such as cosmetic products and sunscreens are available.[12] Other potential uses have been suggested.[13] The actual benefits and risks of such products are yet to be proven, but that has not slowed the discussion of potential gains to the medical industry.[14] The use of nanomaterials for medicinal purposes has been dubbed as "Nanomedicine."[15] Nanomedicine is loosely defined by the National Institute of Health as "an offshoot of nanotechnology, refer[ing] to highly specific medical intervention at the molecular scale for curing disease or repairing damaged tissues, such as bone, muscle, or nerve."[16]

The proposed benefits include replacement of damaged cells as well as early disease detection and treatment.[17] Also, due to the nanosize of robots there would be greater precision in their tasks.[18] For example, if a nanorobot is used to remove unhealthy tissue, more healthy tissue can remain undamaged.[19] Research on animals has shown that photo-thermal nano-shells that are

http://www.stlr.org/cite.cgi?volume=4&article=5.

[11] *Id.* at 2, 32–33.

[12] *See* FDA, FDA and Nanotechnology Products Frequently Asked Questions (FAQs), http://www.fda.gov/nanotechnology/faqs.html (last visited Nov. 11, 2007); *see also* NuCelle, Mandelic Sunsense, http://www.nucelle.com/nucelle_companion1a.htm (last visited Nov. 11, 2007); *see also* NanoNordic.com, Moon-Hee Andersson, 2003-Top Ten Nanotech products, http://www.nanonordic.com (in search field enter "Moon-Hee") (last visited Feb. 7, 2008) (explaining the benefits of using nano-crystalline zinc oxide in sunscreen since it allows clear application on the skin while preventing allergic reactions).

[13] *See* Monica Jr. et al, *supra* note 8, at 55 (including "drug delivery systems to environmental remediation and smaller, faster computer processors").

[14] *See* Leslie Rubinstein, A Practical NanoRobot for Treatment of Various Medical Problems, Foresight Nanotech Institute, http://www.foresight.org/conference/MNT8/Papers/Rubinstein/index.html (last visited Feb 7, 2008).

[15] *See* National Institute of Health Office of Portfolio Analysis and Strategic Initiatives, NIH Roadmap for Medical Research, Nanomedicine, http://nihroadmap.nih.gov/nanomedicine (last visited Nov. 11, 2007).

[16] *Id.*

[17] *See id.* (establishing NIH Nanomedicine Development Centers to study the behavior of nano matter because increased knowledge will lead to development of nano tools necessary to fix broken cells and scan for diseases).

[18] *See* Frederick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDIS. L.J. 593, 611 (Winter 1994) (describing the safety benefits of removing plaque using nanorobots).

[19] *Id.*

injected in the body can be used to destroy cancer tumors while leaving the surrounding tissue intact.[20] Additional benefits could come from drug delivery in nanosize since drugs could be targeted to cells with precision while avoiding unnecessary treatment of healthy cells using sensors.[21] "Nanotechnology promises us a radically different medicine than the cut, poke and carpet bomb (think chemo therapy) medicine of today."[22] However, the benefits must be weighed against the potential risks.[23]

The use of nanorobotics in medicine has sometimes been described as remote in practicality, but it appears as though it may not be as far off as the critics once thought. As one commenter observed,

> [m]any classical objections to the feasibility of nanotechnology, such as quantum mechanics, thermal motions and friction, have already been considered and resolved. The presented nanorobot will be required to perform a preestablished set of tasks in the human body similarly like a ribosome, which is a natural molecular machine system.[24]

This Comment will focus specifically on the potential use of nanorobots in medicine and address the major questions that come with such use, as well as providing a solution for potential liability. Part II will define nanorobots despite the lack of a formal definition. Part III discusses the current state of nanorobot technology and other technology that may help us to understand nanorobot potential, including the materials that will make up nanorobots, the devices used to construct them, and the methods of controlling or manipulating them once they are formed. Part IV will discuss the complexity of determining liability for nanorobot error, the current regulation for nanoproducts or lack thereof, and alternatives to nanorobot regulation. Part V will discuss solving the liability issue. Part

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[20] Weiss, *supra* note 2, at A-08 (describing gold coated nanospheres that destroy tumors when exposed to near infrared light).

[21] Michael Berger, *Medicine of the Future: Cell-like Nanofactories Inside the Body*, (Feb. 8, 2007), http://www.nanowerk.com/spotlight/spotid=1418.php (last visited Nov. 11, 2007).

[22] *Id.*

[23] The risks will be discussed later in the comment in the section dealing with liability. *Infra* Part IV.

[24] Adriano Cavalcanti & Robert A. Freitas Jr., *Nanosystem Design with Dynamic Collision Detection for Autonomous Nanorobot Motion Control using Neural Networks,* 1, *available at* http://www.cgg-journal.com/2003-1/03/nano.html (last visited Nov. 11, 2007).

VI provides a conclusion.

II. DEFINING A NANOROBOT

Defining what constitutes a nanorobot is not easy. Presently, there is not a true nanorobot in existence.[25] A nanorobot is a functional device composed of nanoparts with a total size "at or below the micrometer range."[26] Currently nanorobots are in the research and development phase, with emphasis on studying the nanomaterials that will be used to assemble them.[27] However, nanotechnology scholars have proposed potential designs and functions of a nanorobot.[28] It is helpful to understand the broader areas of nanotechnology and nanomedicine prior to studying nanorobots. The National Nanotechnology Institute (NNI) has defined nanotechnology as "the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale."[29] That is the only concrete definition that has been given and widely accepted by other agencies such as the Food and Drug Administration (FDA), which is the agency that will most likely be charged with regulating medical nanodevices and drugs.[30] Support for the creation of nanorobots is emphasized when examining the purposes and goals of nanomedicine. The National Institute of Health (NIH) roadmap dedicated to nanomedicine discusses the application of nanotechnology to medicine in terms of creating devices not only to understand the human body better, but also to

[25] Nathan A. Weir et al., *A Review of Research in the Field of Nanorobtics*, 8, Sandia National Laboratories, (Oct. 2005) *available at* http://www.prod.sandia.gov/cgi-bin/techlib/access-control.pl/2005/056808.pdf.

[26] *See id.*

[27] *Id.* at 7–8.

[28] *See* Nanomedicine FAQ, *supra* note 5; *see* Weir, *supra* note 25, at 8, 11.

[29] National Nanotechnology Initiative, http://www.nano.gov/html/facts/whatIsNano.html (last visited Nov. 11, 2007). The NNI was created in 2001 as "a federal [research and development] program established to coordinate the multiagency efforts in nanoscale science, engineering, and technology." National Nanotechnology Initiative, About the NNI, http://www.nano.gov/html/about/home_about.html (last visited Mar. 31, 2008); *see generally* National Nanotechnology Initiative, History, http://www.nano.gov/html/about/history.html (last visited March 31, 2008).

[30] FDA, FDA and Nanotechnology Products FAQ's, http://www.fda.gov/nanotechnology/faqs.html (last visited Mar. 31, 2008).

be used for the treatment of disease.[31]

Notwithstanding the lack of a formal definition of a nanorobot, one can be gleaned from the use of the term in regards to nanomedicine and from the description by Robert A. Freitas Jr., the first person to write a book discussing medical nanorobotics.[32] Freitas has described a medical nanorobot as the following, "[t]he typical medical nanodevice will probably be a micron-scale robot assembled from nanoscale parts."[33] It appears that nanorobots can be defined as the assemblage of nanomaterials that are currently being researched and using the materials to build devices that can perform more complex tasks within the body. This process is dubbed as molecular manufacturing.[34] Adriano Cavalcanti, a "nanorobot pioneer,"[35] has stated that "[i]n vitro experimentation is at present possible only on the materials we expect to use in the fabrication of nanorobots—and not on entire nanorobots, which are still being developed."[36]

The idea is to build a nanorobot from the ground up rather than scaling down a product to nanosize.[37] It is necessary to create products that will be able to manipulate the nanomaterials for building the nanorobots.[38] Future nanorobots will be complex[39] compared to early basic ones such as respirocytes.[40] Therefore, before we can create complex nanorobots, the ability to precisely control atoms must be developed.[41] There is a product in development called

[31] *See* National Institute of Health, *supra* note 15 (establishing NIH Nanomedicine Development Centers to study the behavior of nano matter in hopes that increasing knowledge in this area will lead to development of the nano tools necessary to fix broken cells and scan for diseases).

[32] Interview by Richard Terra with Robert A. Freitas Jr., Sr. Research Fellow, Institute for Molecular Manufacturing (Sept. 30, 1999), *available at* http://www.foresight.org/updates/update38/update38.2.html.

[33] *See* Nanomedicine FAQ, *supra* note 5.

[34] Fiedler & Reynolds, *supra* note 18, at 595–96.

[35] Jane Salodof MacNeil, *Nanorobot Pioneer Reveals Status of Simulator, Stem Cell Work*, 2 NANOBIOTECH NEWS 36, 1 (Sept. 8, 2004), *available at* http://www.nanorobotdesign.com/papers/nanorobotNanoBiotechNews.pdf.

[36] *Id.*

[37] *See* Fiedler & Reynolds, *supra* note 18, at 596 (noting how "cells and organelles" typically work "from the bottom up").

[38] *See id.* at 599 (noting that nanodevices could be created by various materials to carry out designated tasks).

[39] *See id.* at 624.

[40] *See* Nanomedicine FAQ, *supra* note 5 (defining a respirocyte as an "artificial mechanical red cell" which has sensors that are controlled by a doctor).

[41] *See* Fiedler & Reynolds, *supra* note 18, at 597–98.

"NanoRobot-6AX," which was created by Discovery Technology International- Nanotech.[42] Such a device is essential "for the manipulation and assembly of nanoscale structures into functional nanodevices."[43] Two of the stated purposes for the robot are medical device manufacturing and nanotechnology.[44] While the NanoRobot may not be what we would conventionally think of as a nanorobot, because the robot is not meant to venture throughout blood vessels, it is a step in that direction.[45] This NanoRobot has the capabilities of "micro and nano positioning"[46] and "[u]ltrafine assembly, probing, soldering[,] and testing."[47] A simple explanation of how the device would work is to think of the NanoRobot-6AX as the hands that can manipulate the nanomaterials, just as a child uses his hands to make toy blocks into a building. A tool like the NanoRobot would be used to construct an actual nanorobot. The NanoRobot is an advance from the XYZ micropositioner system.[48] A more precise device than the micropositioner system is achieved by being able to position a tool from any angle through nanoprecision rather than microprecision.[49] Microprecision is distinguishable from nanoprecision due to the microscale being larger than the nanoscale.[50] Essentially the benefit of having manipulation on the nanoscale is comparable to making smaller hands to manipulate smaller building blocks, rather than trying to use larger, less precise hands that already exist.[51] By creating a machine that will be capable of manipulating nanomaterials, we

[42] DTI-NanoTech, Division of Discovery Technology International, *NanoRobot-6AX*, (Aug. 2006), *available at* http://www.dti-nanotech.com/docs/AN6AX.pdf. "DTI-NanoTech is a division of Discovery Technology International, specializing in the design, manufacture and distribution of novel motorized nano-robotic and nanopositioning systems." *Id.*

[43] Weir et al., *supra* note 25, at 8.

[44] *See* DTI-NanoTech, *supra* note 42, at 2.

[45] *Id.* (listing the numerous capabilities for the NanoRobot including applications in science, microinjection, microsurgery, and others).

[46] *Id.* at 2.

[47] *Id.*

[48] *Id.* (explaining that XYZ micropositioning describes precision in movement at the micro level rather than at the nano level).

[49] *Id.* at 1–2.

[50] National Nanotechnology Initiative, The Scale of Things—Nanometers and More, http://www.nano.gov/html/facts/The_scale_of_things.html (last visited Nov. 9, 2007) [hereinafter The Scale of Things].

[51] *See* Weir et al., *supra* note 25, at 8, 15 (discussing how nanotechnology is advancing, resulting in the need to develop devices to manipulate nanoscale structures).

are a step closer to using the materials to construct a nanorobot. While it may seem that NanoRobot is a misnomer for this device, since according to the patent application note, it is a bench-top device; the creation of such devices is instrumental to the potential development of nanorobots.[52]

The steps toward achieving a nanorobot require examining the material that will make up such robots. A large part of current research is devoted to developing the components of a potential nanorobot.[53] By looking at the uses of current nanomaterials, it is possible to surmise the potential capabilities of nanorobots. Quantum dots (qdots) are only a few atoms across and made of materials such as silicon.[54] Qdots are also known as nanocrystals, and are semiconductors, which means that "their electrical conductivity can be greatly altered via an external stimulus;" however their small size creates more prospects for their conductivity.[55] They are being researched as methods of diagnosing disease by attaching to proteins and showing the inner workings of a cell.[56] Carbon nanotubes are tubes made out of carbon atoms, which are another popular nanomaterial due to their strength.[57]

It is beneficial to look at the materials that may ultimately make up a nanorobot, however it is of the utmost importance to understand how the robots will be powered. Creating the "muscle" for the robots is key to ensuring that they will be adequate to perform the minute tasks with which they will be entrusted.[58] Scientists at New York University (NYU) have recently developed the ability to insert a nanorobotic arm into DNA.[59] Control over the arm is manipulated by placing it in different parts of the DNA, and the arm would be moved by a

[52] *See id.* (noting that NanoRobots are important in developing nanorobots).

[53] *Id.* at 8.

[54] *See* Weiss, *supra* note 2, at A-08.

[55] Evident Technologies, How Quantum Dots Work, http://www.evidenttech.com/quantum-dots-explained/180.html (last visited Nov. 9, 2007).

[56] Weiss, *supra* note 2, at A-08.

[57] *Id.*; *see also* Argonne National Laboratory, *'Flying' Nanotubes are Strong and Hard*, (July 16, 2004), *available at* http://www.anl.gov/Media_Center/News/2004/news040716.html.

[58] *See* Royal Science of Chemistry, *Synthetic Muscle Powers Hopes of Building a Nanorobot*, (Jan. 13, 2006), *available at* http://www.rsc.org/chemistryworld/News/2006/January/13010601.asp.

[59] Michael Berger, *Nanorobotic Arm to Operate Within DNA Sequence*, NANOWERK SPOTLIGHT, Jan. 10, 2007, http://www.nanowerk.com/spotlight/spotid=1233.php (last visited Nov. 9, 2007).

rotary device that is attached to the DNA, hence DNA signals would control the arm.[60] Essentially, the DNA of a person is the "muscle" for the robotic arm, but the scientists can control the actions of the arm depending on where it is placed on the DNA.[61] The arm has been called a "controllable device[],"[62] which poses the question of how controllable is the arm when is it positioned on the DNA and supposedly powered by it.

The term nanorobot is frequently used without any regularity as to its meaning. In some cases the term is used to propel the extreme grey goo theory that nanorobots will self replicate and take over the world.[63] For the most part, as mentioned before, the term is used to describe the devices that will be composed of nanomaterials and will be the size of atoms allowing them to perform functions throughout the human body. It should be noted that the machinery that may be used to position the nanomaterials and to manipulate them are sometimes called nanorobots as well.

III. CURRENT STATE OF NANOROBOT TECHNOLOGY

Currently, there are multiple products in development that are being dubbed "nanorobots." These products range from drug delivery devices[64] to the products that will create nanorobots[65], to the nanorobots that will roam the body.[66] In 2005, it was estimated that the first nanorobots would be available within five years, and use of the nanorobots in healthcare would occur

[60] *See id.* (discussing how the rotary device is enabled to move the nanorobotic arm).

[61] *See id.* (describing how the researchers can direct the device to a particular location).

[62] *See id.* (explaining that the DNA-based nanomechanical devices are controlled by many methods).

[63] Fiedler & Reynolds, *supra* note 18, at 605 (citing K. ERIC DREXLER, Engines of Creation 172–73 (Anchor Press/Doubleday) (1986)) (describing the grey goo problem, popularized by Michael Crichton's book Prey, as impracticable since the robots will not "be designed to survive and reproduce in the wild").

[64] *See* Roger Dobson, *Robot that Swims Up Your Spine to Take Pictures of Fractures*, DAILY MAIL, (Nov. 14, 2006), *available at* http://www.dailymail.co.uk/ (follow "advanced search;" then type in the title and publication date; then follow "search") (describing how the robot could deliver drugs specifically to the spinal cord).

[65] *See generally* DTI-NanoTech, *supra* note 42 (noting how nanorobotic and nanopositioning systems are used in various markets such as nanotechnology).

[66] *See* Nanomedicine FAQ, *supra* note 5 (describing types of nanorobots that would swim through blood vessels).

within ten years.[67]

Products that are on a larger scale and are similar in design to projected nanorobots are useful in understanding how future nanosized devices will function. The most illustrative examples are devices sized in micrometers.[68] A number of research facilities dedicate themselves to joint micro and nanoresearch.[69] By doing this, it appears that scientists are hopeful that once a device is perfected at a certain size, there is nowhere to go but smaller.[70] In Israel, a device is being developed that is a 2 millimeter capsule containing a camera.[71] The capsule is injected into the spine of a patient allowing internal images of the body to be taken.[72] The other purpose of the device would be to deliver drugs inside the body and to take tissue samples.[73] The device will be powered by a battery that contains an electric current that is used to move the "tails."[74] It will also be steered by a remote control.[75] A transmitter will send the pictures outside of the body.[76] In the future, these devices could be implanted in bodies as an early method for disease detection.[77]

Although presently there are no nanorobots in practice, there are facilities that are dedicated to their development. In the United States, Carnegie Mellon has a NanoRobotics laboratory.[78] The lab is trying to develop a swimming robot which would be

[67] A. Cavalcanti et al., Nanorobotics Control Design: A Practical Approach Tutorial, 18 ROBOTICS TODAY No. 4, at 2 (2005), *available at* http://www.nanorobotdesign.com/papers/nanoroboticTutorial.pdf.

[68] The Scale of Things, *supra* note 50.

[69] *See* Mike Murphy, NanoRobotics Lab @ Carnegie Mellon, http://nanolab.me.cmu.edu/ (last visited Nov. 11, 2007); MIT, Nano/Micro Engineering Group, http://web.mit.edu/nanomicro/ (last visited Nov. 11, 2007); University of Illinois at Urbana-Champaign, Micro Nano Technology Research Group, http://mass.micro.uiuc.edu (last visited Nov. 11, 2007).

[70] *See* Miller, *supra* note 10 at 5–6 (discussing potential developments and applications of nanomedicine).

[71] Dobson, *supra* note 64.

[72] *Id.*

[73] *Id.*

[74] *Id.* (describing these tails as small wire-like components that the device uses to move itself through the body).

[75] *Id.*

[76] *Id.*

[77] *See* Dobson, *supra* note 64 (describing how the device may someday be implanted to perform procedures like biopsies and noting that it will ultimately be useful in a broad range of applications).

[78] NanoRobotics Laboratory @ Carnegie Mellon, Robotic Micro and Nano-Assembly, http://www.me.cmu.edu/faculty1/sitti/nano/projects/nanomanipulation/ (last visited Nov. 11, 2007).

used in nanomedicine.[79] The robot would be used for early drug delivery and disease detection.[80] The mechanism would be powered by bacterial tails to propel it through the body.[81] However, it is not feasible to shrink the microswimming robot to nanosize since it would be too small to power through the watery environment.[82] Also on the way is a nanorobot "vehicle," which scientists at Rice University have created with buckyball[83] wheels, which are carbon atoms grouped together into a ball by a simpler version of molecular manufacturing.[84] The "car" was driven by a scanning tunneling microscopy (STM) probe tip; however, the range of motion was limited.[85] Scanning tunneling microscopy is within the class of methods considered for nanorobotic manipulation, which allows control over nanodevices.[86] While there is no proposed long-term use for the nanocar,[87] it would appear to be suitable as a drug delivery device since it would be able to maneuver around the body.[88]

IV. LIABILITY FOR NANOROBOT ERROR

Liability for nanorobots is a complex issue that cannot be readily solved and will be mere speculation until an actual nanorobot is created. Cases where traditional Medical

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[79] *Id.*

[80] *Id.*

[81] *See id.* (describing the main impediment to miniaturization as the development of methods for mobility).

[82] *See id.* (lacking an explanation as to why the nanosize would be an impediment to movement).

[83] Press Release, Rice News & Media Relations, *Rice Scientists Build World's First Single-Molecule Car* (Oct. 20, 2005), *available at* http://media.rice.edu (click on "News Releases" and scroll down to the date) (describing buckyballs as "spheres of pure carbon containing 60 atoms apiece") [hereinafter *Single-Molecule Car*]. A new model, built from boron, rather than carbon, was shown in 2006. *See* TFOT The Future of Things, *New Model Nanocar on the Showroom Floor* (Dec. 6, 2006), http://www.tfot.info/articles/41/new-model-nanocar-on-the-showroom-floor.html.

[84] *Single-Molecule Car*, *supra* note 83; *see also* Fiedler & Reynolds, *supra* note 18, at 595 and accompanying text.

[85] *Single-Molecule Car*, *supra* note 83.

[86] *See* Weir et al., *supra* note 25, at 18 (describing the process of dragging the nanocar with a "STM" probe).

[87] *See New Model Nanocar on the Showroom Floor*, *supra* note 83 (describing one short-term use as an enhancement to automotive catalytic converter systems, but projecting the practical benefits to be realized in fifteen to twenty years).

[88] *See Single-Molecule Car*, *supra* note 83 (describing the rolling movement of the nanocar on a surface).

Malpractice and Products Liability jurisprudence apply are outside the scope of this comment. Complex issues arise as to these two theories of liability including medical device products liability. The facts of a case usually draw a bright line as to where liability lies between a doctor's and a manufacturer's negligence. However, the small size of these nanorobots may lead to a grey area where it may be impossible to determine liability.[89] The size of the components will create difficulty in determining where the error originated.[90] The question will arise whether the manufacturer, designer, or doctor failed. Working with nanoproducts is unpredictable since the size results in unusual properties beyond the normal laws of physics.[91] The FDA has conceded that nanomaterials "have chemical or physical properties that are different from those of their larger counterparts."[92] This discussion is devoted to the grey area. While in most cases it will be clear where fault lies and the proper action will be taken against the proper party, there will be ambiguity when exceptional cases arise as to determining causation.[93] It is helpful to look at traditional tort principles, which ultimately lead to a discussion of causation. The Restatement of Torts defines the class of people that are "subject to liability" as those whose conduct is the legal cause of another's injury without a proper defense to the claim.[94]

> [Subject to liability] thus deals with so much of the circumstances and events preceding a plaintiff's injury as are within the *defendant's exclusive ability to control*. Whether he is liable will depend upon the subsequent course of events *which are outside of his control*, and upon other circumstances which may or may not make a defense available to him.[95]

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[89] *See* Evident Technologies, *supra* note 55 (recognizing that materials behave differently at smaller sizes which expands their use). However, the FDA has recognized that smaller scales may also bring safety risks with the benefits. *See infra* pp 17–18.

[90] *See* Weiss, *supra* note 2, at A-08 (stating that the laws of physics become strange at the nanoscale).

[91] *Id.*

[92] FDA, FDA Forms Internal Nanotechnology Task Force (Aug. 9, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01426.html (stating that materials at the nanolevel have special properties which may lead to safety issues) [hereinafter Task Force].

[93] RESTATEMENT (SECOND) OF TORTS § 5 cmt. a (1965) (stating that while a person may be subject to liability, he may escape it if causation cannot be proven).

[94] *Id.* § 5.

[95] *Id.* § 5 cmt. a (emphasis added).

Therefore, the person who may most easily act to prevent or reduce harm must do so.[96]

It will be impossible for a patient to have a legal claim against a nanorobot that performs a medical error just as it is impracticable that a person will sue a failed pacemaker rather than a doctor or manufacturer.[97] The line between manufacturer liability and medical liability becomes blurry as is the case with a "Robodoc"[98] where the device is a "mere extension or instrument guided by a surgeon (with the guidance taking place at the time of programming, rather than in real time)."[99] When the manufacturer programs the Robodoc, error could result from faulty manufacturing. On the other hand, the doctor may be responsible during the surgery for monitoring the tools that he uses. For example, if a doctor notices that he is using a broken device, it would reasonably be his responsibility to ask for a new one. It will be important to delineate the responsibilities between the doctor and the manufacturer in the use of nanorobots to determine which player has control over the device and is best suited to mitigate harm.

In situations where causation of the harm is not clear due to the size of the nanorobots, the length of time they spend in the body, or just due to their novel nature, it is helpful to examine their power source. The technology that fuels the robots could potentially be an external bio-chemical trigger,[100] an internal source of power such as battery power,[101] or the body heat of the person.[102] If the stimulus powering the nanorobot is human body temperature or a chemical reaction, accordingly a doctor's control

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[96] *See id.* § 5.

[97] *See* Leon E. Wein, *The Responsibility of Intelligent Artifacts: Toward an Automation Jurisprudence*, 6 HARV. J.L. & TECH. 103, 111–12 (Fall 1992).

[98] Fiedler & Reynolds, *supra* note 18, at 613–14 (describing Robodoc as "computer-aided manufacturing technology, using an arm and cutting tool that are driven by machine-encoded instructions" for hip replacement surgery). A class action's products liability lawsuit was brought against the creators of Robodoc in 2005; the company subsequently sold its assets in 2006. *See* Celia Lamb, *Developer of Robodoc to Sell Assets for $4M Plus $6M Loan.*, SACRAMENTO BUS. J. (Aug. 11, 2006), *available at* http://sacramento.bizjournals.com/sacramento/stories/2006/08/14/story4.html.

[99] Fiedler & Reynolds, *supra* note 18, at 613.

[100] Goldstein, *supra* note 4.

[101] Adriano Cavalcanti et al, *Computational Nanomechatronics: A Pathway for Control and Manufacturing Nanorobots*, 1, 3 (2006), http://www.nanorobotdesign.com/papers/manufacturing.pdf.

[102] *See id.* at 2, 3 (describing the use of changes in heat to trigger actuators in a nanorobot).

over the functions of the device is likely minimal.[103]

Instead, a person that is adequately trained to monitor the robot could replace a doctor in overseeing it. A nanoexpert could be on hand during procedures utilizing nanorobots to guarantee that the robot is working properly. Creating such a position would be prudent and foreseeable, especially when one takes into account that the National Science Foundation has estimated that the nanotechnology industry will create about 2 million jobs within the next fifteen years.[104] Taking the clamp example, the doctor would clearly notice if a clamp was not doing its job. However, most doctors, while specialists, are not nanotech experts. Additionally, with more complicated machinery, it is difficult to determine if the machine is functional; therefore, patient injury may be the only way of detecting error.

At first blush it appears that examination of design and manufacturing are the focus of liability, especially if nanorobots are compared to how other medical devices are treated, meaning that the doctor is usually not held liable for the failure of a medical device.[105] The presumption is against holding doctors liable.[106] However, despite the fact that the surgeon may have very little control over the nanorobot's activity, if it malfunctions during a procedure it may be up to a doctor to correct the error.[107] "The doctor must always be able to 'pull the plug'[108] on the nanomachines. This is one of the most important design constraints, one that will probably become a strict and universal regulatory requirement for all medical nanodevices."[109] Holding doctors responsible for monitoring the actions of the nanorobot

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[103] *See* Adriano Cavalcanti et al., *Nanorobot for Treatment of Patients with Artery Occlusion* (Proceedings of Virtual Concept, 2006, Cancun, M.X. Nov 26, 2006 – Dec. 1, 2006), *available at* http://www.nanorobotdesign.com/papers/cardiology.pdf (noting that the use of nanorobots creates new possibilities in clinical diagnoses, data collection, and patient monitoring).

[104] National Nanotechnology Initiative, Frequently Asked Questions, http://www.nano.gov/html/res/faqs.html (last visited Nov. 10, 2007).

[105] *See* Jay M. Zitter, Annotation, *Medical Malpractice: Instrument Breaking in Course of Surgery or Treatment*, 20 A.L.R.4th 1179 (1983).

[106] *See id.* at 1199 (describing cases where the breaking of medical equipment was not medical malpractice without evidence that such brakeage was an improper act).

[107] Nanomedicine FAQ, *supra* note 5.

[108] *Id.*

[109] *Id.*

may classify improper monitoring as an omission.[110] Sensors are an obvious method of controlling the nanorobots, and they can be used not only to determine the whereabouts and activity of the robot but to guide its actions as well.[111] The methods that have been suggested for monitoring the robots may be impracticable, including a television camera allowing the doctor to steer the robot, which would require very complex sensors.[112] All of the methods mentioned to control the device do not appear to actually control the actions of the robot but instead direct the focus of the robot's activity.[113]

Simple robots will be relatively autonomous in their actions since they will perform minor functions.[114] A specific example is a proposed nanorobot powered by a biological motor and ATP that takes unused proteins in cells and stores them for later use.[115] However, preliminary nanorobots most likely will require guidance by doctors before they are developed to become autonomous.[116] Therefore, the burden of liability may shift as technology creates a nanorobot that does not need to be controlled by a doctor. When nanorobots become more complex, the hazards will be greater since machines are not capable of thinking on the spot like humans.[117] However, by taking some of the control away from doctors, there will need to be another human agent to blame, predictably the manufacturers of the robots.[118] If the flaw is not due to a manufacturing problem, it will be difficult to prove whether the doctor should have detected

110 *See* Wein, *supra* note 97, at 140 ("[L]egal responsibility for 'transgressions' is invariably assigned to human actors and . . . losses caused by intelligent machinery are conventionally ascribed to the owner of the equipment or whoever permitted the computerized system to make a deleterious decision.").

111 Rubinstein, *supra* note 14.

112 *Id.*

113 *See id.* (describing two necessary types of sensors, both of which are used to guide the robot).

114 *See* Fiedler & Reynolds, *supra* note 18, at 610 (describing a proposed simple robot that would automatically seek out and remove atherosclerotic plaque).

115 Miller, *supra* note 10, at 12.

116 *See* Nanomedicine FAQ, *supra* note 28 (describing a navigational network that can be installed in the body to report the physical locations of nanorobots).

117 *See* Wein, *supra* note 97, at 131.

118 *See id.* at 132; *see also* Linda A. Sharp, Annotation, *Liability of Hospital or Medical Practitioner Under Doctrine of Strict Liability in Tort, or Breach of Warranty, for Harm Caused by Drug, Medical Instrument, or Similar Device Used in Treating Patient*, 65 A.L.R.5th 357, 370–72, 387 (1999) (stating that courts generally disfavor applying strict-liability principles to actions against doctors in cases that involve medical devices such as pacemakers).

the nanorobot's error and intervened or whether the error was out of the doctor's control.[119] Since the robots are meant to perform the complex tasks usually performed by doctors, it will be easier to blame those that construct the robots for their failure. Nanorobots that stay within the body for a short period or that do a single job, for example cleaning arteries,[120] are less likely to create serious problems since the physicians can monitor their activity continuously.[121] Difficulties arise if the nanorobots can use the body as a power source and stay in the body for an extended period, possibly a lifetime in some cases, as would be the case in cancer vaccines.[122] There are different classifications of nanorobots depending on how long they are in the body. Nanorobots that are in the body for a short period and are later removed are known as microbivores.[123]

Once again, implanted devices would pose problems. This could be especially true if the robotic components break down over time, creating a situation where liability may be next to impossible to prove.[124]

> A statute of [limitations] extinguishes a cause of action after a fixed period of time—usually measured from the delivery of the product, the completion of the work, or some other action of the defendant—regardless of when the cause of action accrued, potentially barring a plaintiff's suit before there has been an injury.[125]

If it is true that wear and tear can cause the particles of a medical device to be released throughout the body, the risk of liability is heightened.[126] Also, if the nanorobots stay within the body for an extended period, the question arises whether the doctor has an obligation to continually monitor the patient, and if

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[119] *See* Fiedler & Reynolds, *supra* note 18, at 614 (questioning whether the doctor or the manufacturer is responsible for a nanorobot placed in a patient's bloodstream, where the only control over the device is its computer programming).

[120] *Id.* at 601.

[121] *See* Nanomedicine FAQ, *supra* note 5; *see also* Fiedler and Reynolds, *supra* note 18, at 601.

[122] Goldstein, *supra* note 4.

[123] Miller, *supra* note 10, at 11–12 (describing "microbivores" as "nano-sized devices that bind to targeted bacteria," which are digested by enzymes and discharged into the bloodstream).

[124] *See* Monica, Jr. et al., *supra* note 8 at 61, 63 (discussing the risk of nanomaterial breakdown in the body and the "learned intermediary" exception by which a physician would be liable).

[125] 51 AM. JUR. 2D *Limitation of Actions* § 31 (2000).

[126] Monica Jr. et al., *supra* note 8 at 63.

so for how long. Analogizing how doctors monitor other implanted devices is helpful.

Generally speaking, the cases involving actions for injuries caused by the breaking of surgical or medical instruments have both discussed and applied rules dealing with malpractice generally, so that physicians, in the use of surgical or medical instruments, must observe that degree of learning, skill, care, and diligence ordinarily possessed by the average, competent practitioner in their professions, and must exercise reasonable and ordinary care and diligence in the exercise of such skill and the application of such knowledge.[127]

It appears that as long as doctors have not been negligent, they will not be responsible for the failure of a device. The ordinary standard of care is a low threshold, which does not give rise to heightened liability for the use of medical devices.[128] This makes it easier for doctors to attribute the causation of device error to the manufacturer. Because the devices would be so small, how would we ever know? Since liability is unclear in the case of nanorobots, especially when considering their future designs and method of control are unknown, alternative methods of regulation and spreading the risk of liability should be created.

A. Nanorobot Classification and the Current State of Regulation

Nanorobotic technology in the medical field gives rise to liability issues for nanorobotic failure or error. A preventative measure would be for government agencies to implement regulations controlling the use of products containing nanotechnology. Since regulation in the field of nanotechnology has yet to become a reality, although a large topic of debate, this Comment will only minimally focus on the potential path to such regulation. Discussing regulation of nanorobots is extremely difficult since there are various potential nanorobot models and uses and overall they are not a reality as of yet. Also, the agencies that appear to be the ones charged with regulating products containing nanotechnology have received feedback from some who argue that existing regulations are sufficient.[129] "The FDA classifies medical products for regulatory purposes as drugs,

[127] Zitter, *supra* note 105.

[128] *See id.* (summarizing cases that have found physicians liable for the selection of an inappropriate tool or for improper action taken prior to the instrument's breaking, but not for the breaking of the device itself).

[129] *See* Bubnoff, *supra* note 7.

devices, biologics, or combination products."[130] While these robots fit into multiple categories such as devices or drugs, such classifications would be difficult considering the fact that most products may fit into more than one category.[131] Nanorobots would most likely fall within the classification of a device and drug combination product. Since nanorobots will consist of various nanoparts, which may be considered devices in and of themselves, and the compilation of the parts are used to deliver drugs, they would be a prime example of a nano combination product.[132] While the FDA has an Office for Combination Products, this office does not create additional regulations for nanoproducts; instead it just determines which department is controlling.[133] Ambiguity does not give rise to proper oversight, which leaves these nanorobots virtually unregulated.[134] The current lack of regulations and guidance from the FDA has drawn criticism due to the peculiar nature of nanorobots and their potential abilities.[135] The FDA has defined an example of a nanotechnology combination product as a "[m]ulti-component system that may consist of [a c]arrier/delivery system (drug or device)[or] . . . [t]argeting agent."[136] It should be noted that the attempt to categorize proposed nanorobots for potential regulatory purposes has proven to be difficult.[137] For example, nanorobots that are used to clean arterial walls would be classified as devices, but if they were used to administer cancer-fighting treatment, they would be considered drugs.[138]

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130 Miller, *supra* note 10, at 24–25 (stating that a problem will arise in classification because advanced nanoproducts may fit into multiple categories simultaneously).

131 Fiedler & Reynolds, *supra* note 18, at 607.

132 Miller, *supra* note 10, at 1–2, 6–7, 21–22, 26.

133 FDA.gov, Overview of the Office of Combination Products, http://www.fda.gov/oc/combination/overview.html (last visited Nov. 10, 2007) (stating that an example of a combination product includes drug coated stents).

134 *See* Miller, *supra* note 10, at 21, 25 (noting how the FDA must prepare for nanomedicine problems).

135 *See* Fiedler & Reynolds, *supra* note 18, at 603 ("[P]roblems posed by nanotechnology may be *sui generis*, however, and may therefore be addressable only through the creation of entirely new rules").

136 Nakissa Sadriehn, FDA Considerations for Regulation of Nanomaterial Containing Products, Examples of Nanotechnology Combination Products, http://www.fda.gov/nanotechnology/powerpoint_conversions/NISTHouston0106_files/textonly/slide13.html (last visited Nov. 10, 2007).

137 Miller, *supra* note 10, at 1; *see also* Giorgia Guerra, *A Model For Regulation of Medical Nanobiotechnology: The European Status Quo*, 3 NANOTECHNOLOGY L. & BUS. 84, 86–87 (2006).

138 *See* Fiedler & Reynolds, *supra* note 18, at 610; *see also* Miller, *supra* note

The more functional way to classify the products may be based on the risk of potential harm.[139] Considering the fact that nanoproducts may be more harmful depending on specific factors, the regulations should take into account these risks and examine the products on a case by case basis.[140] Other authors have also suggested that categorization be "process-oriented or functional categories (for example, augmentation, replacement, and repair)."[141] Process-oriented classification is harmonious with risk-based classification since different processes would have inherently different risks.[142] The current method of classifying nanoproducts as just smaller versions of other products creates loopholes in regulating them.[143] Due to the novel characteristics and processes of nanotechnology arising out of the products' small size, it is clear that the field requires a greater degree of regulation.[144]

B. Alternatives to Regulation

As of February 2007, there seems to be no formal regulation for nanotechnology. Therefore, examining existing statutes is necessary to determine how the field will be regulated.[145] Numerous commentators have warned about the lack of formal regulation for nanoproducts.[146] Mandatory post-market surveillance of all nanoproducts would be an effective way of not stifling innovation of nanotechnology, while ensuring safety in the products.

> [The] FDA may order a manufacturer to conduct postmarket surveillance of a medical device under section 522 of the Food,

10, at 6.

139 *See* Bubnoff, *supra* note 7 (noting that there must be a focus on risk analysis when it comes to nanotechnology).

140 *Id.*

141 Fiedler & Reynolds, *supra* note 18, at 616.

142 *Id.*

143 *See* Bubnoff, *supra* note 7 (implying that by not creating new regulations specifically for nanotechnology, agencies are not really regulating nanotechnology and instead are classifying the products as though they utilize nanotechnology).

144 *See id.* (discussing how the FDA must realize that nanoparticles' "[s]ize matters" in regulation); *see also* Fiedler & Reynolds, *supra* note 18, at 603 (noting how "new forms and degrees of regulation" will likely result from nanotechnology).

145 Scott H. Segal, *Environmental Regulation of Nanotechnology: Avoiding Big Mistakes for Small Machines*, 1 NANOTECHNOLOGY L. & BUS. 290, 295 (2004).

146 *See generally* Miller, *supra* note 10, at 19–20 (discussing how individuals such as Bill Joy and Drexler fear that nanotechnology could be harmful).

> Drug and Cosmetic Act [(FDCA)]. [The] FDA has the authority to order postmarket surveillance of any class II or class III medical device, including a device reviewed under the licensing provisions of section 351 of the Public Health Service Act, that meets any of the following criteria:
>
> (a) Failure of the device would be reasonably likely to have serious adverse health consequences;
>
> (b) The device is intended to be implanted in the human body for more than 1 year; or
>
> (c) The device is intended to be used to support or sustain life and to be used outside a user facility.[147]

The nanoproduct end user (in the case of nonmedicine would likely be the physician) will most likely be in charge of such post-market surveillance, although manufacturers have reporting responsibilities as evidenced by the chart on the following page.

TABLE 1 Summary of Reporting Requirements for Manufacturers[148]

REPORTER	WHAT TO REPORT TO FDA	REPORT FORM #	WHEN
Manufacturer	30 day reports of	Form	Within 30 calendar

[147] *See* 21 U.S.C. § 3601(a) (2000) (noting how a manufacturer may be ordered "to conduct postmarket surveillance"); FDA, Postmarket Surveillance Studies, http://www.fda.gov/CDRH/DEVADVICE/352.html (last visited Nov. 11, 2007).

[148] FDA, Medical Device Reporting (MDR), http://www.fda.gov/cdrh/devadvice/351.html (last visited Nov. 10, 2007).

	deaths, serious injuries and malfunctions	FDA 3500A	days from becoming aware of an event
Manufacturer	5-day reports on events that require remedial action to prevent an unreasonable risk of substantial harm to the public health and other types of events designated by [the] FDA	Form FDA 3500A	Within 5 work days from becoming aware of an event
Manufacturer	Baseline reports to identify and provide basic data on each device that is subject of an MDR report. At this time, [the] FDA has stayed the requirement for denominator data requested in Part II, Items 15 and 16 on Form 3417.	Form FDA 3417	With 30 calendar and 5 work day reports when device or device family is reported for the first time. Interim and annual updates are required if any baseline information changes after initial submission
Manufacturer	Annual Certification	Form FDA 3381	Coincide with firm's annual registration dates

If using a medical device results in death or serious injury, a doctor will have to report the event not only to the FDA but also to the manufacturer, who is then responsible for reporting to the FDA.[149] This system does not hold the doctor responsible for malfunctions, but instead, requires manufacturers to report an incident that they are not directly involved in. This is an

[149] *Id.*

interesting situation since there seems to be a presumption that the device was faulty, rather than assuming that physician error was involved. Preventative measures should be put in place, rather than having post-accident measures.

Government regulation of nanotechnology will be difficult, as the FDA has admitted[150]. There are myriad issues that will confront regulation of nanotechnology, including classification.[151] The issue of whether there should be separate regulations for products that contain nanotechnology or whether the products should be governed under existing regulations is a topic of debate.[152] Whether the federal government will adopt regulations for nanotechnology has yet to be seen. New regulations will be necessary since nanoproducts are innovative and the risks are not clear.[153] While government agencies have emphasized their concern for safety regarding nanoproducts, they have not taken concrete steps to ensure such safety. Instead they have placed the burden elsewhere and in some cases, downplayed the risks.

The EPA essentially announced regulation of nanosilver in November of 2006, however it does not appear to be serious about actual regulation and oversight. At one point, it appeared that the Environmental Protection Agency (EPA) was taking the first step toward government regulation of nanotech products.[154] The EPA announced that it would be regulating products utilizing a product known as "nanosilver."[155] The EPA stated, "any company wishing to sell a product that it claims will kill germs by the release of nanotech silver or related technology will first have to provide scientific evidence that the product does not pose an environmental risk."[156] It appears as though the EPA is placing a high burden on companies who wish to sell products containing nanosilver by requiring such companies to research the effects of their products before placing them in the market. However, the

150 *See* Task Force, *supra* note 92 (noting how both "health promotion and protection challenges" may arise).

151 FDA, FDA Nanotechnology FAQ's, http://www.fda.gov/nanotechnology/faqs.html (last visited Nov. 10, 2007).

152 Bubnoff, *supra* note 7.

153 Fiedler & Reynolds, *supra* note 18, at 603–04, 626.

154 Rick Weiss, *EPA to Regulate Nanoproducts Sold as Germ-Killing*, WASH. POST, Nov. 23, 2006, at A-01 (stating that regulations would be published in the Federal Register within a few months of Nov. 2006) [hereinafter Weiss II].

155 *Id.* (describing nanosilver as a germ killing nanomaterial composed of nanosized particles of silver).

156 *Id.*

ultimate burden will truly rest with the designers and manufacturers of the products since they will be competing with other companies to have their products distributed. Companies that distribute the products to the open market are unlikely to assume costs to ensure the safety of a product; instead they will mostly likely require assurances from the manufacturers before agreeing to sell the product. By placing the responsibility of ensuring environmentally friendly products on manufacturers and companies that distribute products, the EPA is less likely to be charged with lax regulation of nanoproducts. This is convenient for the government since the agencies may not have adequate funding to ensure the safety of nanotech products through research and testing.

After the announcement that the EPA would be regulating nanosilver, it backed down from that position and emphasized instead that it is not actually regulating nanosilver. In December of 2006, the EPA said, "[its] initial announcement in November of its interest in having purview over the Samsung washer was misinterpreted as an attempt to regulate nanotechnology."[157] The EPA stated that it would apply existing pesticide regulations to any product that supposedly uses nanosilver.[158] In lieu of creating distinct regulations for the use of nanosilver, the EPA classified it as a pesticide and will regulate it as such. Government agencies recognize that these products, while potentially beneficial, may be harmful as well. The EPA has acknowledged that the small size of nanoproducts may create novel risks.[159] Other government agencies, such as the FDA, may soon follow suit in regulating nanotech products due to this awareness.[160] However, regulation may be illusory, since it does not appear that the agencies want actually want to take proactive steps toward novel regulation tailored to nanotechnology; rather, agencies are trying to classify nanoproducts under existing regulations. It appears that the

[157] ConsumerReports.org, EPA Scrutinizes "Nanosilver" The Federal GovernmentMoves to Regulate a Cutting-Edge Technology, (Jan. 2007), http://www.consumerreports.org/cro/home-garden/news/january-2007/the-epa-scrutinizes-nanosilver-1-07/overview/0701_the-epa-scrutinizes-nanosilver_ov.htm.

[158] *Id.*

[159] *See* Task Force, *supra* note 92 (discussing how nanoproducts have "special properties" and may present "safety issues" as a result).

[160] *See id.* (noting how the FDA will continue to "address product-specific nanotechnology-related issues").

nomenclature used to describe nanoproducts is going to be a fundamental aspect of classification and regulation.

Due to the preliminary nature of nanotechnology in the U.S., it would be wise to follow the path of foreign nations that have studied the technology more extensively. Looking at how other leading nations studying nanotechnology have decided to address regulation may be beneficial for the U.S. Currently the U.S. is lagging in the nanotech field compared to foreign countries.[161] Hence, it appears that nomenclature is going to be an important aspect of classification and regulation.

Europe regulates the process of nanotechnology, while the U.S. regulates the products that utilize nanotechnology.[162] Europe also initiated a voluntary reporting scheme in September of 2006.[163] The program "will run for two years" and requests "data from any company or organisation manufacturing, using, importing, researching[,] or managing wastes consisting of engineered nanoscale materials."[164] However, the scheme is not meant to "replace[] existing legislation."[165] The scheme seems intended to curry public favor by making a show that action is being taken to regulate nanoproducts. In reality, nanotechnology in other countries is not strictly regulated.[166] While other countries may be first in time to develop certain programs, the U.S. has similar programs that follow. Compliance will not be as strictly enforced in a voluntary reporting scheme, where companies have a choice concerning oversight.

The public scrutiny and justifiable suspicion toward nanotechnology should be taken into account when creating

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161 Atkearney.com, Nanotechnology is More Than a Hot New Label, http://www.atkearney.com/main.taf?p=5,3,1,127,4 (last visited Nov. 11, 2007).

162 Josh Condon, *Nanotech: Small Stuff, Big Concerns*, CNN.com, Sept. 4, 2006, http://www.cnn.com/2006/TECH/science/09/01/nanotech/index.html (last visited Apr. 15, 2008).

163 Department for Environment, Food, and Rural Affairs, *UK Voluntary Reporting Scheme for Engineered Nanoscale Materials* 3 (Sept. 2006), http://www.defra.gov.uk/environment/nanotech/policy/pdf/vrs-nanoscale.pdf [hereinafter DEFRA].

164 *Id.* at 5.

165 *Id.* at 3; Department for Environment, Food, and Rural Affairs, *Nanotechnologies Policy Activities* (Dec. 6, 2005), http://www.defra.gov.uk/environment/nanotech/policy/index.htm.

166 *See* Virginia Gewin, *Nanotech's Big Issue,* 443 NATURE 137 (Sept. 14, 2006), *available at* http://www.innovationsgesellschaft.ch/images/fremde_publikationen/Nature137.pdf (discussing the lack of regulations governing nanotechnology and how the European Commission has plans for "crafting future regulation").

regulations. This requires "a proactive approach from the industry with clear and timely communication from all involved parties in order to correctly inform the public to the true measure of the risk associated with these products."[167] We must remember to keep in mind those that would be impacted the most by nanotechnology. The legal maxim that juries are important to provide representation of the public in legal trials has been translated to the nanotechnology field. Britain has implemented "NanoJuries" which consist of twenty people that give their views on information provided to them concerning nanotechnology for impacting policy.[168] The FDA recognized the importance of public input by taking public comments and holding a public hearing on nanotechnology.[169]

It appears as though countries have been lax in regulation in an attempt to be nanotech leaders and additional safeguards may be necessary.[170] There is the problem of a nano race between the nations to create new nanoproducts.[171] An indirect method of regulation would be determining whether product development will be discovery-based or based on industry needs.[172] Rather than deciding what is needed, and then using nanotechnology to create it, the focus should be on perfecting the products that are discovered. This method will ensure control and the markets' steadiness.[173]

V. SOLVING THE ISSUE OF LIABILITY

The inability to see the long-term effects of this supposedly beneficial technology is comparable to the problem with asbestos.[174] Asbestos was an effective insulation material with

[167] O'Rourke, *supra* note 9, at 8.

[168] Guardian Unlimited, *What is NanoJury UK*?, http://www.guardian.co.uk/life/nanojury (last visited Nov. 10, 2007).

[169] *See* FDA, Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force 6 (July 25, 2007), *available at* http://www.fda.gov/nanotechnology/taskforce/report2007.pdf.

[170] *See* Fiedler & Reynolds, *supra* note 18, at 612 (noting that "the old laws will lag behind the new technology").

[171] *See id.* (discussing how today's economies are driven by "[t]he desire for new products").

[172] Andrew Eder, *The Magic of Nanotechnology*, KNOXVILLE NEWS-SENTINEL (Tenn.), Aug. 24, 2006 (Business and Financial News).

[173] *See generally id.* (inferring how "application-based problem solving" that focuses on the production of new products, based on consumer demand, brings stability).

[174] *See* Monica, Jr. et al., *supra* note 8, at 55 (citing Hazards.org, *Dangers*

hidden health risks; unrevealed until a great number of victims' instituted claims.[175] "[A]s of the end of 2002, approximately (i) 730,000 people had filed asbestos related lawsuits; (ii) 8,400 entities had been named as defendants in those lawsuits; and (iii) a total of approximately $70 billion had been spent defending those lawsuits and compensating those with alleged injuries."[176] Concerns have been raised about the health risks of carbon nanotubes which are heavily researched nanomaterials.[177] The nature and size of the materials that make up nanotubes raise questions of their safety.[178] Studies have shown that nanoparts may be able to penetrate the blood brain barrier and that they may cause tumors in fish.[179] Also, consumers in Germany reported respiratory problems after using a cleaning product advertised as "Magic Nano," which was later recalled.[180] It is unknown whether the product contained nanoproducts or not.[181]

A study involving groups of citizens expressed their concerns that the nanotechnology industry is not ensuring the safety of products.[182] Special interest groups have alleged that the industry is focusing on the monetary gains of being the first to discover new products.[183] Those that are putting forth the new

Come in Small Particles, 87 HAZARDS 1 (July–Sept. 2004), *available at* http://www.hazards.org/nanotech/safety.htm).

[175] *Id.* at 56–57.

[176] *Id.* at 56 (citing STEPHEN J. CARROLL ET AL., ASBESTOS LITIGATION 24–26 (RAND Corporation) (2005)).

[177] *Id.* at 55–56 (citing Barnaby J. Feder, *As Uses Grow, Tiny Materials' Safety is Hard to Pin Down*, N.Y. TIMES, Nov. 3, 2003, *available at* http://query.nytimes.com/gst/fullpage.html?res=9E0CE5D81130F930A35752C1A9659C8B63).

[178] Karen Florini, et al., *Nanotechnology: Getting it Right the First Time*, 3 NANOTECHNOLOGY L. & BUS. 39, 41 (2006).

[179] ETCgroup.org, *Nano's Troubled Waters: Latest Toxic Warning Shows Nanoparticles Cause Brain Damage in Aquatic Species and Highlights Need for a Moratorium on the Release of New Nanomaterials*, Apr. 1, 2004, http://online.sfsu.edu/~rone/Nanotech/nanobraindamage.htm (last visited Nov. 10, 2007).

[180] Mark Hillier, *United Kingdom: Science Feature—Nanotechnology*, MONDAQ BUSINESS BRIEFING, Aug. 10, 2006, *available at* http://www.mondaq.com.

[181] *Id.* (citing Rick Weiss, *Nanotech Product Recalled in Germany,* WASH. POST, Apr. 6, 2006, at A-02, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2006/04/05/AR2006040502149.html).

[182] Florini, et al, *supra* note 178, at 41.

[183] Monica, Jr. et al., *supra* note 8, at 55 (citing Hazards.org, *Dangers Come in Small Particles*, 87 HAZARDS 1 (July–Sept. 2004), *available at* http://www.hazards.org/nanotech/safety.htm); *see also* Fiedler & Reynolds, *supra* note 18, at 612 (noting how "modern economies" thrive on emerging

products may later be held accountable for disregarding or even hiding known defects. Keeping in mind that there is a lack of concrete proof that these hazards are happening or will occur, the dangers of nanotechnology may not appear until it is too late. Oversight of nanotech projects is lacking, which leaves plenty of room for sacrificing safety for innovation.[184] Asbestos was very dangerous yet very effective. Companies using asbestos set aside funds for those injured by it since they were withholding the dangers from the public. Nanotechnology is reminiscent of the path that asbestos took; the dangers are unknown and there is a great incentive to hide the risk so that companies can profit.[185] The nanotechnology industry should learn from the mistakes of the asbestos industry.

Congress created the September 11th Victims Compensation Fund to limit tort liability after the terrorist attacks of September 11, 2001.[186] Those that accept damages from the fund are precluded from suing the airlines that were carrying passengers on September 11th.[187] The potential damages could be much larger in a civil suit since the lawsuits would be based on wrongful death and damages are measured by the earning potential of the deceased and would not be determined by the fund.[188] Nanotechnology cases are distinguishable especially since September 11th was an isolated incident. However, this model is useful in preparing an alternative to mass tort litigation.

A fund should be created for those that are potentially harmed by nanotechnology. While at present we are not certain of the risks, the prudent measure would be to prepare anyway. The federal government passed the Superfund law in 1980 for

products).

184 *See* Fiedler & Reynolds, *supra* note 18, at 603, 611–12 (noting that a lack of regulation could lead to hazards relating to safety) (citing *U.S. Promises to Release Data on Plutonium Test*, N.Y. TIMES, Nov. 21, 1993).

185 Monica, Jr. et al., *supra* note 8, at 55–56 (citing Barnaby J. Feder, *As Uses Grow, Tiny Materials' Safety is Hard to Pin Down*, N.Y. TIMES, Nov. 3, 2003).

186 Devlin Barrett, *9/11 Fund Deadline Passes,* CBS News.com, Dec. 23, 2003, http://www.cbsnews.com/stories/2004/01/16/national/main593715.shtml (associated press stating that fewer than 150 victims' families opted not to file for aid) (last visited Nov. 11, 2007).

187 *See generally id.* (discussing how the program ultimately "protects the airlines from liability").

188 *See generally id.* (noting how some individuals still plan on "preserving their right to sue" outside the fund, while others are still weighing their litigation options).

cleaning toxic waste from properties.[189] All companies contributed to the fund even if their liability was not as great in comparison to others'.[190] The Superfund was based on "joint and several liability" provisions.[191]

A nanotechnology fund would limit tort liability. While examples such as the September 11th Fund and the Superfund are useful in creating guidelines, government must construct a nanotechnology fund to encourage contribution to the fund and encourage the due care of designers and manufacturers of nanorobots. The fund should only pay out for unforeseen harm caused by the use of nanorobots. Creating such restrictions on the fund will safeguard against carelessness on the part of manufacturers and physicians and their reliance on the fund to compensate for such carelessness. Companies will want to publicize their participation in such a program to show that they are interested in the safety and well-being of consumers. As an example of how effective public demands can be, the EPA itself, though initially resistant, gave in to pressure from environmental groups and began regulating nanosilver.[192]

Companies have a strong interest in inducing consumer confidence in these products, as evidenced by the creation of nanojuries and the solicitation of public input. By creating a fund to pay for unforeseen harm caused by these products and publicizing the donors, companies will essentially be forced into contributing to show that they are responsible, compared to their counterparts that do not. Creation of a fund would prevent innocent companies, remotely involved in manufacturing, from going under due to mass litigation, comparable to the effects of asbestos litigation.[193] Keeping in mind that some companies may not be financially capable of contribution, allowing for alternative methods can be created. The universities that are currently dedicated to research of nanoproducts can contribute to the fund as well. While educational institutions may not be worried about consumer confidence, a comparable goal of enhancing their reputation would be achieved through donation of funds.

189 Florini, at el., *supra* note 178, at 40.
190 *Id.*
191 *Id.*
192 Weiss II, *supra* note 154, at A-01.
193 *See* Monica, Jr. et al, *supra* note 8, at 57.

VI. CONCLUSION

While it is impossible to predict the future, we may understand the consequences of adding nanorobots to the medical field by looking at experience with asbestos liability and the present growth of nanotechnology. By no means is this discussion exhaustive, especially considering the myriad of potential players. The principles are likely to include the designer and manufacturer, the physician, and government agencies. It is impossible presently to answer many of the questions concerning nanorobot liability since nanorobots do not currently exist in the form envisioned. The liability of the potential myriad characters will be the cause of great confusion and debate. The public may even accept the potential risk of nanotechnology related products to allow for the technology's development and a better understanding of what policies are necessary. The nanorobot designers may try to mitigate their fault by arguing there was strong public support through the nanojuries or other public comment. It is essential not to take settled regulations and laws and apply them to a radically different phenomenon blindly. However, if government agencies do not step up and try to control the litigation before it begins; other methods must be examined to limit tort liability. In essence, if the government does not create regulations at some point, the litigation may come to a point that will put an extreme burden on the judicial system.

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