

The Regulation of Nanomedicine: Will the Existing Regulatory Scheme of the FDA Suffice?

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INTRODUCTION

[1] Nanotechnology is the science and technology of manipulating molecules and atoms at the molecular level to create devices with new molecular properties, organizations and functions.¹ Devices such as new computers that are billions of times more powerful than any currently available² and boxes the size of sugar cubes that can hold the entire content of the Library of Congress are examples of the power of nanotechnology.³ Richard Siegal, director of the Rensselaer

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¹ 15 U.S.C. § 7509 (2006).

² Ralph C. Merkle, *Nanotechnology: What Will It Mean?*, IEEE SPECTRUM, Jan. 1, 2001, <http://www.spectrum.ieee.org/archive/1494>.

³ M.C. Roco, Nat'l Science Found., *Government Nanotechnology Funding: An International Outlook*, July 10, 2008, http://www.nsf.gov/crssprgm/nano/reports/roco_vision.jsp.

Nanotechnology Center, has predicted “that nanotechnology could cause social and industrial rearrangements not unlike the industrial revolution.”⁴ While nanotechnology is taking mankind into a future that resembles science fiction more and more every day, the law is losing its breath as it tries to keep pace with today’s rapid-paced world of technological achievement.⁵

[2] The first glimpse of nanotechnology occurred in 1959.⁶ In a speech entitled, “There’s Plenty of Room at the Bottom,” Caltech physicist Richard Feynman painted his vision of nanotechnology as the future of science.⁷ His hypothesis that scientists could manipulate atoms and molecules into building blocks led to the Hollywood hit *The Fantastic Voyage*, which drew on his theory to create a futuristic world where a surgical team could be miniaturized and injected into a man’s brain for the purpose of operating on a blood clot.⁸ However, it was not until the 1980s that nanotechnology was actually realized with the manipulation of xenon atoms to form the letters “IBM.”⁹

⁴ John Miller, Note, *Beyond Biotechnology: FDA Regulation of Nanomedicine*, 4 COLUM. SCI. & TECH. L. REV. 5, ¶ 5 (2003).

⁵ Joel Rothstein Wolfson, *Social and Ethical Issues in Nanotechnology: Lessons from Biotechnology and Other High Technologies*, 22 BIOTECHNOLOGY L. REP. 376, 389 (2003).

⁶ Miller, *supra* note 4, at ¶ 3. See generally Richard P. Feynman, *There’s Plenty of Room at the Bottom*, Address Before the American Physical Society (Dec. 29, 1959), in ENGINEERING AND SCIENCE, Feb. 1960, available at <http://www.zyvex.com/nanotech/feynman.html> (last visited Oct. 24, 2009) (discussing molecular manufacturing).

⁷ See generally Feynman, *supra* note 6 (discussing the miniaturization of the computer and the rearrangement of atoms).

⁸ Miller, *supra* note 4, at ¶ 3; see FANTASTIC VOYAGE (Twentieth Century-Fox Film Corporation 1966).

⁹ See John Walker, *Writing With Atoms*, http://fourmilab.ch/autofile/www/section2_84_14.html (last visited Oct. 24, 2009).

[3] Nanotechnology has come a long way, but researchers are even more optimistic for the future.¹⁰ Eric Drexler, a leading authority on nanotechnology, predicted that “nanomachines will allow scientists to prevent death by cellular repair, build spaceships, construct computers the size of credit cards that would be billions of times more powerful than existing computers, eliminate pollution, rebuild exact plants and animals, and effectively produce food to end hunger on the planet.”¹¹ Both the government and industry have recognized the impact nanotechnology will have and the role it will play in our future. President Clinton established the National Nanotechnology Initiative (NNI) in 2000 when he launched the \$422 million program to synchronize, at the federal level, the research and development concerning nanotechnology.¹² States have also begun funding research, and universities have even started offering doctorates in Nanotechnology.¹³ Large companies, like HP and IBM, are allocating about one-third of their research budget to nanotechnology.¹⁴

[4] With the excitement of new technology, however, comes the task of determining how best to regulate it so that it is both safe and effective.

¹⁰ In 1990, there were 1000 scientific publications on nanotechnology and 200 patent applications. As of 2002, those numbers had risen to 22,000 and 1900, respectively. Jennifer Whitney, *Sizing Up the Potential of Nanotechnology: Technology Advances Create Opportunity for Revolutionary Medical Applications, But Not Without Some Challenges*, MED. PROD. OUTSOURCING, Sept. 2007, available at <http://www.mpo-mag.com/articles/2007/09/sizing-up-the-potential-of-nanotechnology>. See generally, NAT’L NANOTECH. INITIATIVE, NANOTECHNOLOGY: BIG THINGS FROM A TINY WORLD, http://www.nano.gov/Nanotechnology_BigThingsfromaTinyWorld-print.pdf [hereinafter *NNI*].

¹¹ Miller, *supra* note 4, at ¶ 5. See generally ERIC K. DREXLER, ENGINES OF CREATION: THE COMING ERA OF NANOTECHNOLOGY (1986), available at http://e-drexler.com/d/06/00/EOC/EOC_Table_of_Contents.htm (last visited Oct. 24, 2009) (discussing the science and possibilities of nanotechnology).

¹² Miller, *supra* note 4, at ¶ 6; NAT’L NANOTECH. INITIATIVE, *About the NNI*, http://www.nano.gov/html/about/home_about.html (last visited Oct. 24, 2009).

¹³ Miller, *supra* note 4, at ¶ 6.

¹⁴ *Id.* at ¶ 7.

Many legal issues will inevitably arise concerning ethics, privacy, liability, etc. Part I of this comment will provide a more detailed description of nanotechnology; while Part II will branch off into a discussion of a specific field within nanotechnology called nanomedicine. Part III will then briefly discuss liability issues that may arise from the use of nanomedicine. Part IV contemplates potential regulatory issues, such as who will regulate nanomedicine and what to expect regarding regulations for the future. Part V will follow with some suggestions on what might be helpful in the way of regulating nanomedicine.

I. NANOTECHNOLOGY

[5] A nanometer (nm) is a unit of measurement equal to one billionth of a meter, there being 25,400,000 nm per inch.¹⁵ To put that into perspective, consider the following examples. A single sheet of paper is about 100,000 nm thick.¹⁶ A brunette hair is anywhere from 50,000 to 100,000 nm in diameter, which is about twice the size of a blond hair, which ranges from 15,000 to 50,000 nm across.¹⁷

[6] Nanotechnology is “the science and technology that will enable one to understand, measure, manipulate, and manufacture at the atomic, molecular, and supramolecular levels, aimed at creating materials, devices, and systems with fundamentally new molecular organizations, properties and functions.”¹⁸ It concerns the scientific knowledge and technical capability of manipulating molecules and atoms at dimensions between one and one hundred nanometers in order to exploit the properties of a

¹⁵ Larry Berglas, *Nanotechnology and the Law: How will Intellectual Property Law Adapt to the Development of Nanotechnology?*, http://www.uslaw.com/library/article/TNPCommercialCol090600.html?area_id=44 (last visited Oct. 24, 2009); NNI, *supra* note 10, at 2.

¹⁶ NNI, *supra* note 10, at 2.

¹⁷ *Id.*

¹⁸ 15 U.S.C. § 7509(2) ; *see* Frederick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L.J. 593, 595 (1994) (noting nanotechnology is also referred to as molecular manufacturing).

material at the atomic level.¹⁹ “Nano[technology] is about redoing everything. Everything when miniaturized will be new.”²⁰

[7] Nanotechnology is still in the experimental stage, and it may be another twenty to thirty years before formal introduction into mainstream society.²¹ Yet, there are already so many promising possibilities on the horizon. Some of these possibilities include materials that have ten times the strength of steel but only a fraction of the weight or clothing that cleans itself upon exposure to sunlight.²² A company called 3Netics Corporation is even working to develop a type of electronic paper consisting of thousands of tiny pixels created by using self-assembled monolayers of nanoscale materials.²³ This technology would allow us to download an entire book that would actually look and feel like a real book.²⁴ Of all the awe-inspiring, miraculous accomplishments that nanotechnology may allow society to achieve, perhaps one of the most anticipated and important fields will be that of nanomedicine.

¹⁹ See G. Nagesh Rao, *Nanotechnology: A Look Into the Future of Rising Legal Dilemmas*, 17 ALB. L.J. SCI. & TECH. 835, 839 (2007); Berglas, *supra* note 15.

²⁰ Michael A. Van Lente, Note, *Building the New World of Nanotechnology*, 38 CASE W. RES. J. INT’L L. 173, 176 (2006) (citing Interview with Chad Mirkin, Director, Nw. Univ. for Nanotech., in Evanston, Ill. (Dec. 28, 2004), in *Rebuilding Things “Atom by Atom”*, BUS. WK., Dec. 28, 2004, http://www.businessweek.com/bwdaily/dnflash/dec2004/nf20041228_7625_db083.htm).

²¹ Rao, *supra* note 19, at 838.

²² Van Lente, *supra* note 20, at 173; Berglas, *supra* note 15 (quoting Bill Clinton, President of the United States, Announcement of the National Nanotechnology Initiative at the California Institute of Technology (Jan. 21, 2000); see Richard P. Terra, *National Nanotechnology Initiative in FY 2001 Budget*, FORESIGHT UPDATE 40, Mar. 31, 2000, at 1, available at <http://www.foresight.org/Updates/Update40/Update40.1.html>).

²³ Van Lente, *supra* note 20, at 173.

²⁴ *Id.*

II. NANOMEDICINE

[8] Nanomedicine is “an offshoot of nanotechnology, referring to highly specific medical intervention at the molecular scale for curing disease or repairing damaged tissues, such as bone, muscle or nerve.”²⁵ Using engineered nanodevices and nanostructures, human biological systems can be monitored, repaired, constructed and controlled at the molecular level.²⁶ In the future, it might be possible to vaccinate people with nanoparticles.²⁷ These particles would continuously circulate throughout the body, programmed to identify and eliminate certain diseases.²⁸ With such nanotechnology, it may eventually be possible to eliminate common diseases and alleviate medical pain and suffering.²⁹ Moreover, all this may happen sooner than one would expect. Nobel Prize winner Richard Smalley forecasted that in the not-too-distant future “nanotechnology will have given us specially engineered drugs” that could even make cancer “a thing of the past.”³⁰ Others have predicted that there

²⁵ Shalyn Morrison, Comment, *The Unmanned Voyage: An Examination of Nanorobotic Liability*, 18 ALB. L.J. SCI. & TECH. 229, 231 (2008) (citing National Institute of Health Office of Portfolio Analysis and Strategic Initiatives, NIH Roadmap for Medical Research: Nanomedicine, <http://nihroadmap.nih.gov/nanomedicine>).

²⁶ Miller, *supra* note 4, at ¶ 9.

²⁷ Alan H. Goldstein, *Nanomedicine's Brave New World*, <http://dir.salon.com/story/tech/feature/2005/11/28/nanomedicine/index.html> (last visited Oct. 24, 2009).

²⁸ *See id.*; see Ray Kurzweil, *Bring on the Nanobots, and We Will Live Long and Prosper*, THE GUARDIAN, Nov. 22, 2007, at 36, available at <http://www.guardian.co.uk/commentisfree/2007/nov/22/comment.comment> (noting there have already been successful experiments with such first generation devices and that the devices we will have twenty-five years from now will be a billion times more powerful than those of today).

²⁹ Robert A. Freitas, Jr., *The Foresight Institute: Nanomedicine FAQ*, <http://www.foresight.org/Nanomedicine/NanoMedFAQ.html#FAQ19> (last visited Oct. 24, 2009).

³⁰ Miller, *supra* note 4, at 6.

would be nanorobots available by 2010 and that we would be capable of applying these nanorobots to the healthcare field by 2015.³¹

[9] Nanorobots are the “functional devices composed of nanoparts with a total size ‘at or below the micrometer range,’” which will create and control the other nanotechnology devices.³² Several types of nanomedicine creations already exist at the research and development stage that could change the way doctors practice medicine.³³

[10] A nanomedical creation falls within one or more of seven categories: drugs, drug delivery, diagnostics, devices, gene therapy, cell therapy/tissue engineering and nanorobots.³⁴ Nanomedical drugs can be engineered to target and destroy things like bacteria or cancerous cells.³⁵ An example of such a creation is photo thermal nanoshells.³⁶ Nanoshells are gold-coated spheres about 130 nm in diameter that are very good at absorbing near infrared light, which can harmlessly penetrate several inches into the body.³⁷

³¹ Morrison, *supra* note 25, at 238; see Thomas A. Faunce, *Nanotechnology in Global Medicine and Human Biosecurity: Private Interests, Policy Dilemmas, and the Calibration of Public Health Law*, 35 J.L. MED. & ETHICS 629, 631 (2007) (predicting that clinical use of diagnostic imaging and therapeutic devices will be used individually starting about 2010 and in combination around 2020).

³² Morrison, *supra* note 25, at 233, 237; see Jonathan Strickland, *How Nanorobots Will Work*, <http://electronics.howstuffworks.com/nanorobot.htm> (last visited Oct. 24, 2009) (providing a diagram to explain how a nanorobot will operate).

³³ See Miller, *supra* note 4, at 6–13.

³⁴ *Id.*

³⁵ *Id.* at 6.

³⁶ Rick Weiss, *Nanomedicine’s Promise is Anything But Tiny*, WASHINGTON POST, Jan. 31, 2005, at A08, available at <http://www.washingtonpost.com/wp-dyn/articles/A49758-2005Jan30.html> (last visited Oct. 24, 2009).

³⁷ *Id.* See generally Surbhi Lal et al., *Nanoshell-Enabled Photothermal Cancer Therapy: Impending Clinical Impact*, 41 ACCTS. OF CHEM. RES. 1842 (2008), available at

[11] Scientists have successfully injected nanoshells into the body to destroy cancerous tumors without destroying the surrounding, healthy tissue.³⁸ Blood vessels are normally leaky around tumors; therefore, once nanoshells are injected into the blood stream, they will travel the body through the circulatory system, concentrating around tumors.³⁹ Upon exposure to the infrared light, the nanoshell would absorb that energy, heating up to approximately 122 degrees Fahrenheit, cooking the tumors but leaving the healthy tissue unharmed.⁴⁰ After photo thermal treatment, the immune system eliminates the nanoshells from the body.⁴¹ The most promising fact is that the test subjects are cancer free months after the procedure.⁴²

[12] James K. Baker is a researcher in the field of nanotechnology who is working to develop polymer dendrimers, a type of drug delivery nanorobot.⁴³ Polymer dendrimers are tree-shaped synthetic molecules capable of attaching to certain molecules or carrying molecules internally.⁴⁴ These nanorobots are being designed to infiltrate cells and detect pre-malignant and cancerous changes.⁴⁵ If the changes are detected, the nanorobots would release a chemical substance to kill just those affected cells and finish the job by verifying the destruction of those

<http://pubs.acs.org/doi/full/10.1021/ar800150g?cookieSet=1> (last visited Oct. 24, 2009) (providing a more in-depth study of nanoshells).

³⁸ Morrison, *supra* note 25, at 232; Weiss, *supra* note 36.

³⁹ Weiss, *supra* note 36.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*; see Lal, *supra* note 37, at 1846 (reporting that one hundred percent of the mice treated with nanoshells were cancer free after ten days).

⁴³ Miller, *supra* note 4, at ¶ 15.

⁴⁴ *Id.*

⁴⁵ *Id.*

cells.⁴⁶ Other researchers are working to develop implantable devices that would be programmed periodically to dispense certain medicines, like insulin or morphine into the body.⁴⁷

[13] In the category of Diagnostics, researchers are exploring the possibility of nanorobots that can help people in their everyday life, as well as in life threatening situations. On one end of the scale, there is a nanodevice being researched called carbon nanotubes.⁴⁸ These are hollow tubes made of interwoven carbon atoms, a hundred times smaller than the diameter of a human hair.⁴⁹ Potential uses of carbon nanotubes include implantation under the skin to measure blood sugar, cholesterol, and hormone levels, without ever having to extract a drop of blood from the body.⁵⁰ On the other end of the scale, researchers are working on a nanodevice that could assist with the diagnosis of cancer. Quantum Dots (Qdots) are crystals composed of periodic materials, which are only ten to fifty atoms in diameter.⁵¹ Qdots are unique in that they glow a particular color when illuminated by ultraviolet light.⁵² Which color they glow depends on the size of the band gap of the specific Qdot: Qdots two nm in size glow bright green, while those that are five nm in size glow red.⁵³

⁴⁶ *Id.*

⁴⁷ *Id.* at ¶ 16.

⁴⁸ Peter Harris, *A Carbon Nanotube Page: Carbon Nanotube Science and Technology*, <http://www.personal.rdg.ac.uk/~scscharip/tubes.htm> (defining carbon nanotubes as “molecular scale tubes of graphitic carbon” and adding they are “among the strongest fibers known”).

⁴⁹ Weiss, *supra* note 36.

⁵⁰ *Id.*

⁵¹ Evident Technologies, *How Quantum Dots Work*, <http://www.evidenttech.com/quantum-dots-explained/180.html> (last visited Oct. 24, 2009).

⁵² *See id.*; Weiss, *supra* note 36.

⁵³ Weiss, *supra* note 36.

These characteristics allow for the possibility of programming Qdots to attach to cancer cells, thereby illuminating tumors.⁵⁴

[14] Researchers have also discovered that Qdots, when coated with particular materials, will attach to specific molecules.⁵⁵ This characteristic makes them excellent tracking devices.⁵⁶ They can be injected into cells, which will then be exposed to ultraviolet light, allowing researchers to track the movements of those particular molecules.⁵⁷ Thus, different sized Qdots could be injected simultaneously and allow for more than one molecule to be tracked at a time.⁵⁸ These are merely a few of the numerous examples likely to be seen in the future.

[15] Medical nanorobots are expected to be among the very first types of nanotechnology products on the market; because they can save lives they will be in high demand.⁵⁹ This demand will translate into revenues that can then be invested in the development of other nanotechnology products.⁶⁰ While it is easy to find ourselves ready to jump on board with this promising research, it is best to remember that the actual benefits and risks of nanomedicine have yet to be proven.⁶¹ We may not always be willing to take the risks with the gains.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ See Hitesh R. Patel, *Quantum Dots: A Novel Technique for Drug Delivery and Therapy*, Nov. 17, 2007, <http://www.pharmainfo.net/reviews/quantum-dots-novel-technique-drug-delivery-and-therapy> (stating Qdots may be used for tracking for a long period without losing fluorescence).

⁵⁷ Weiss, *supra* note 36.

⁵⁸ *Id.*

⁵⁹ E-mail Interview with Robert A. Freitas Jr., Member, Lifeboat Foundation, <http://lifeboat.com/ex/interview.robert.a.freitas.jr> (last visited Oct. 24, 2009).

⁶⁰ *Id.*

⁶¹ See Morrison, *supra* note 25, at 231.

III. POTENTIAL ISSUES WITH MEDICAL MALPRACTICE AND PRODUCTS LIABILITY

[16] The extraordinarily small size of nanoproducts results in unusual properties that go beyond the normal law of physics, which makes working with them quite unpredictable.⁶² Until an actual nanorobot is created and tested on humans, there can only be speculation as to issues of liability.⁶³ When it concerns nanomedicine, two parties that are likely to be caught in the crosshairs of a lawsuit are the manufacturers and the doctors who control the devices.⁶⁴

[17] The Restatement of Torts defines a person “subject to liability” as an actor, whose conduct is the legal cause of another person’s injury, thereby making him liable for that person’s particular claim unless he has an applicable defense.⁶⁵ In a typical products liability case concerning a medical device, there is a bright line drawn between the negligence of a doctor and a manufacturer.⁶⁶

[18] The presumption, generally, is against holding the doctor liable and instead turns to the manufacturer of the medical device.⁶⁷ Under products liability law, a manufacturer can be held liable for a defect in design, a defect in the manufacture of the product, or due to a failure to warn about all of the reasonably foreseeable inherent risks.⁶⁸ Beginning

⁶² Morrison, *supra* note 25, at 240.

⁶³ *Id.*

⁶⁴ *Id.* at 230.

⁶⁵ RESTATEMENT (SECOND) OF TORTS § 5 (1965).

⁶⁶ Morrison, *supra* note 25, at 240.

⁶⁷ *Id.* at 242–43.

⁶⁸ John C. Monica, Jr. & Patrick T. Lewis, *Preparing for Future Health Litigation: The Application of Products Liability Law to Nanotechnology*, at 16, 26 (Nov. 3, 2005), <http://www.nanolawreport.com/tags/powerpoint>; *cf.* John C. Monica, Jr., *Products Liability in the Age of Nanotechnology: Understanding a Manufacturer’s Duty to Warn*,

with a look at design defects, there is bound to be ambiguity in the application of the law to nanotechnology. A manufacturer can be held liable for a design defect if the defect made the product unreasonably dangerous, and there was a safer and more practicable, reasonable, alternative design available at the time of production.⁶⁹

[19] When it comes to nanomedical devices, however, it may be impossible to determine liability because the small size of the components of the device makes it incredibly difficult, if not impossible, to determine whether the doctor or manufacturer was negligent.⁷⁰ There will likely be numerous debates on whether nanomedical devices are inherently, unreasonably dangerous and whether more primitive, yet proven successful, designs are not more practicable by that mere fact. I predict it will be a balancing test between the practicality of using a familiar and successful design against the practicality of using a design that is likely to be much more effective and fast-acting, albeit its novelty.

[20] The complexity of nanotechnology may also require a restructuring of the law regarding manufacturing defects. A manufacturing defect occurs when the “product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.”⁷¹ Currently, under the law, “[a] manufacturer is *always liable* for a defectively manufactured product.”⁷² The complexity of the product being manufactured is irrelevant.⁷³ Consequently, manufacturers will be taking a risk creating nanotechnology devices because no matter how

Research, and Test (Nov. 2, 2006), <http://www.nanolawreport.com/tags/powerpoint> (providing suggestions to avoid liability using actual example of “Nano Magic”).

⁶⁹ Monica & Lewis, *supra* note 68, at 17, 23.

⁷⁰ *Id.*

⁷¹ *Id.* at 33.

⁷² *Id.* at 35.

⁷³ *Id.*

complex the design or how unpredictable the consequences, they will be held liable if the product malfunctions.

[21] Finally, I do not predict the failure to warn category to be one under which many would file. This is because nanomedicine will be such a new and developing field that patients who agree to be treated by the devices are likely going to be thoroughly warned and made to sign waivers for quite some time until nanomedicine becomes the norm, if in fact it ever does. If there are any lawsuits under this claim, they would be filed against the doctor because when it comes to prescription drugs and medical devices, the Learned Intermediary Rule allows a manufacturer to “discharge its duty to warn the end-user by warning that person’s doctor,” making the doctor responsible for properly warning the patient.⁷⁴

[22] Despite the presumption for holding manufacturers liable in medical device lawsuits, the doctors controlling the devices must face possible liability for any errors made concerning control of the device.⁷⁵ Some nanorobots will be powered by chemicals or the human body temperature.⁷⁶ This begs the question: what happens when the doctor has minimal to no control over the functioning of the device?⁷⁷ Doctors may also lack the requisite scientific knowledge to adequately monitor the functioning of nanodevices. Therefore, it may be necessary for hospitals to retain nanoexperts to be present during procedures to ensure that the nanodevices are functioning properly.⁷⁸ While this may be very costly,

⁷⁴ *Id.* at 30.

⁷⁵ See Morrison, *supra* note 25, at 245 (stating that “physicians . . . must observe that degree of skill, learning, 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.”).

⁷⁶ *Id.*; see Leslie Rubinstein, *A Practical NanoRobot for Treatment of Various Medical Problems*, The Foresight Institute, <http://www.foresight.org/conferences/MNT8/Papers/Rubinstein> (last visited Oct. 24, 2009) (listing all the different power sources for nanorobots).

⁷⁷ See Morrison, *supra* note 24, at 242.

⁷⁸ *Id.*

perhaps it is not so far-fetched. The National Science Foundation has predicted the nanotechnology industry will create approximately two million new jobs in the next fifteen years.⁷⁹ These liability dilemmas are but a drop in the well of all the issues that will most surely emerge once nanomedicine enters into mainstream society. Because the liability of nanorobots is unclear and the future methods of design and control are unknown, looking at the bigger picture, today's policymakers should be trying to develop new alternative methods of regulation.⁸⁰

IV. THE REGULATIONS OF THE FOOD AND DRUG ADMINISTRATION

[23] The unpredictable nature of nanotechnology, as well as its potential for harm if abused or misused, necessitates the development of a regulation plan for nanotechnology that will foster innovation while keeping the public safe. As noted by Fiedler and Reynolds, "the law of unintended consequences operates with a vengeance where technology is concerned."⁸¹ When it comes to developing a regulation plan for nanomedicine, the focus needs to be on who will be given the responsibility to oversee regulation and whether to operate under the current regulations or write new regulations.⁸²

[24] The future leaps and bounds nanotechnology will be from our current methods of manufacturing and pharmacology are analogous to the technological progress required to move from burning coal to nuclear power production.⁸³ No one would argue that the laws regulating the burning of coal would suffice to regulate appropriately the use of nuclear energy. Likewise, our current laws for regulating medical drugs and devices will not be adequate to regulate, safely and effectively, the

⁷⁹ *Id.*

⁸⁰ Morrison, *supra* note 25, at 245.

⁸¹ Fiedler & Reynolds, *supra* note 18, at 603.

⁸² Morrison, *supra* note 25, at 246.

⁸³ Fiedler & Reynolds, *supra* note 18, at 603.

manufacturing and distribution of nanomedicine. Nevertheless, there is currently a debate over that very issue.⁸⁴

A. REGULATION BY THE FOOD AND DRUG ADMINISTRATION

[25] Under federal law, medical devices are subject to the jurisdiction of the FDA, according to the Food, Drug and Cosmetic Act, for the purposes of ensuring that they are safe and effective.⁸⁵ It is foreseeable that the FDA will be fully charged with regulating nanomedical devices and drugs.⁸⁶ The FDA will need to be able to determine that the nanodevices are safe, that, when used as intended, the probable benefits to health will outweigh any possible risks of harm or injury, and that they are effective, meaning the products do what they are supposed to do in a reliable fashion.⁸⁷ The FDA must also attempt to balance the promotion of timely patient access and the fostering of innovation against the need to protect the public's health by guarding against potentially unsafe technologies.⁸⁸

[26] The FDA has chosen to attempt regulation of nanomedicine by applying current regulations to the emerging technology.⁸⁹ The FDA made a similar decision when it first encountered the issue of regulating biotechnology.⁹⁰ Biotechnology is the "use of living organisms or their

⁸⁴See generally Josh Condon, *Nanotech: Small Stuff, Big Trouble*, Sept. 4, 2006, <http://www.popsi.com/scitech/article/2006-07/small-stuff-big-trouble>.

⁸⁵Wolfson, *supra* note 5, at 384.

⁸⁶Morrison, *supra* note 25, at 233–34.

⁸⁷Wolfson, *supra* note 5, at 384.

⁸⁸Miller, *supra* note 4, at ¶ 36.

⁸⁹See Morrison, *supra* note 25, at 247 (noting that as of February 2007, no formal regulations for nanotechnology have been created; so we must look to the existing statutes to predict how the field will be regulated).

⁹⁰Miller, *supra* note 4, at ¶ 62.

products to modify human health and the human environment.”⁹¹ When first confronted with biotechnology, the FDA did not create any new regulations or establish a new center to handle its regulation; it just incorporated the biotechnology products into the current regulatory scheme by looking at products on a case-by-case basis.⁹² Before attempting to predict issues that might arise by applying the current regulatory scheme to nanomedicine products, it is important to look at how the FDA functions.

B. HOW THE FDA OPERATES

[27] The FDA is organized into several centers that each specialize in regulating particular types of products.⁹³ The ones most likely to be involved in the regulation of nanomedicine products are the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH).⁹⁴ For purposes of regulation, the FDA classifies medical products as either drugs, devices, biologics, or combination products.⁹⁵ When it comes to manufacturing and marketing new drugs, a company is required to submit to the FDA an Investigational New Drug Application (IND) before it can conduct clinical investigations of the drug.⁹⁶ The purpose of the IND is to provide the FDA with information about the drug’s active ingredients and structural formula, as

⁹¹ Pamela Peters, *What is Biotechnology?*, 1993, http://www.accessexcellence.org/RC/AB/BC/what_is_biotechnology.php (last visited Oct. 24, 2009).

⁹² Miller, *supra* note 4, at ¶ 62.

⁹³ *Id.* at ¶ 31.

⁹⁴ *Id.*

⁹⁵ Morrison, *supra* note 25, at 246.

⁹⁶ 21 C.F.R. § 312.1(a) (2009).

well as its chemistry, manufacturing, and controls information.⁹⁷ After the application is approved, but before the company can file for a New Drug Application (NDA) for approval to market the drug,⁹⁸ the CDER must monitor and approve the clinical trials.⁹⁹ The procedure for biologics is substantially the same, except the IND may be submitted to CDER or CBER, and the marketing application is labeled a Biologics License Application (BLA).¹⁰⁰

[28] The procedure for regulating medical devices is slightly different. The CDRH decides whether the device is a Class I, II, or III device depending on its level of risk.¹⁰¹ A Class III device is considered to have the most risk and is subject to a review of its safety and effectiveness.¹⁰² To obtain FDA approval for a clinical investigation, the manufacturer must submit an Application for an Investigational Device Exemption (IDE).¹⁰³ Unlike the procedure for drugs, to be able to market the device, the manufacturer must additionally obtain a Premarket approval application (PMA), which imposes strict conditions on the manufacturing and labeling of the device.¹⁰⁴

⁹⁷ FOOD & DRUG ADMIN. NANOTECH. TASK FORCE, NANOTECHNOLOGY 22 (2007), <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/Nanotechnology/ucm110856.pdf> [hereinafter *FDA Task Force*].

⁹⁸ *Id.*; see also 21 C.F.R. § 314.50 (listing the requirements of the application).

⁹⁹ Miller, *supra* note 4, at ¶ 32.

¹⁰⁰ 21 C.F.R. § 601.2.

¹⁰¹ Miller, *supra* note 4, at ¶ 33.

¹⁰² *Id.*

¹⁰³ 21 C.F.R. § 812.20(a)(4)(i); see FDA Task Force, *supra* note 97, at 25 (holding that an IDE is required where nanoscale materials pose a potential for serious risk to the health, safety, or welfare of a subject).

¹⁰⁴ Miller, *supra* note 4, at ¶ 33.

C. APPLYING FDA REGULATIONS TO NANOSCALE MATERIALS

[29] The two main problems the FDA is likely to encounter in applying its current regulations to nanomedicine products are (1) the issue of appropriately placing those products into its present classification scheme and (2) maintaining an adequate level of scientific expertise in the nanomedicine field.¹⁰⁵ It will be difficult to classify these nanorobots because many of them have multiple functions.¹⁰⁶ For example, a nanorobot can be used to clean arterial walls, which would render it a device, but this same nanorobot can also administer a cancer-fighting treatment, which would make it a drug.¹⁰⁷ This particular nanorobot would be considered a combination product, but having multiple functions is not the main reason classification will be an issue. Rather, it is the miniaturization of medical products that will blur distinctions between different categories.¹⁰⁸

[30] The FDA uses a product's primary mode of action to determine how to classify it and to decide which center will have primary jurisdiction over the product.¹⁰⁹ This is where the current method of classifying nanorobots as smaller versions of other products will lead to loopholes in regulation.¹¹⁰ Nanomaterials have different chemical and physical properties at the molecular level than those of their larger counterparts.¹¹¹ The Federal Food, Drug and Cosmetic Act defines drugs as treatments that rely on chemical effects and devices as treatments that operate through

¹⁰⁵ *Id.* at ¶ 1.

¹⁰⁶ Morrison, *supra* note 25, at 247.

¹⁰⁷ *Id.*

¹⁰⁸ Miller, *supra* note 4, at ¶ 48.

¹⁰⁹ *Id.* at ¶ 49.

¹¹⁰ Morrison, *supra* note 25, at 247.

¹¹¹ *Id.* at 240.

mechanical means.¹¹² Such distinctions, however, are not helpful when looking at individual atoms.¹¹³ “At the atomic level, it becomes virtually impossible to separate mechanical from chemical or electrical effects.”¹¹⁴ Take electrons as an example. “Electrons have mechanical properties that allow them to spin and to maintain their orbits around the atomic nucleus. The electrons, which are electrically charged particles, interact to form chemical bonds with molecules.”¹¹⁵ These blurred distinctions result in difficulties of determining a product’s primary mode of action, which will lead to jurisdictional disputes and delays in approving new products.¹¹⁶

[31] The second problem the FDA will encounter in regulating nanomedicine products is maintaining the requisite level of scientific expertise.¹¹⁷ Former FDA Commissioner Jane Henney pointed out how critical scientific expertise is to regulation: “Those who make decisions at the FDA about such traditional or complex and high-tech products must be scientifically equal to the intellectual cognitive development that has invented these advanced technologies.”¹¹⁸ Because “nanomedicine is a technology that will touch virtually every aspect of modern medicine,” every center at the FDA will need to develop an enhanced expertise in this area.¹¹⁹ Moreover, it will cost a great deal of money to provide education, facilities and equipment necessary to achieve the proper level of knowledge, and the FDA has been experiencing budget shortfalls.¹²⁰ Even

¹¹² 21 U.S.C. §§ 321(g)(1), (h) (2006).

¹¹³ Fiedler & Reynolds, *supra* note 18, at 608.

¹¹⁴ *Id.* at 609.

¹¹⁵ *Id.*

¹¹⁶ Miller, *supra* note 4, at ¶ 53.

¹¹⁷ *Id.* at ¶ 64.

¹¹⁸ *Id.* at ¶ 65.

¹¹⁹ *See id.* at ¶ 78.

though universities have recently starting offering doctorates in nanotechnology, nanotechnology experts are not very common, and they may be lured away be higher salary offers from companies.¹²¹

[32] Despite recent economic shortfalls, the FDA has made an effort to educate itself on the topic. In August of 2006, the FDA launched the Nanotechnology Task Force to “identify and recommend ways to address knowledge or policy gaps and to facilitate the safe and effective use of nanoengineered materials in FDA-regulated products.”¹²² This Task Force investigated topics such as the FDA’s ability to identify products containing nanoscale materials, its scope of authority to evaluate the safety and effectiveness of such products, and whether the FDA should require or permit products to be labeled as nanoscale materials.¹²³

[33] The Task Force’s research led the FDA to realize that its ability to detect nanoscale materials in the body or products is limited and that developing the appropriate analytical methods may require a substantial effort.¹²⁴ It concluded that a case-by-case approach should be taken to determine whether sufficient evidence exists to prove that a product

¹²⁰ *Id.* at ¶ 80. Compare Food and Drug Administration, *FY 2009 Exhibit For Congressional Appropriations*, <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2009FDABudgetSummary/ucm116342.htm> (last visited Oct. 24, 2009) (revealing the annual budget for CDER, CBER, and Biologics is just over \$1 million), with NAT’L NANOTECH. INITIATIVE, RESEARCH AND DEVELOPMENT LEADING TO A REVOLUTION IN TECHNOLOGY AND INDUSTRY: SUPPLEMENT TO THE PRESIDENT’S FY2009 BUDGET 7 (2008), http://www.nano.gov/NNI_09Budget.pdf (stating the 2009 budget for NNI is \$1.5 billion).

¹²¹ Miller, *supra* note 4, at ¶¶ 6, 79.

¹²² Food & Drug Admin., *Did You Know?: Nanotechnology*, <http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/SpotlightOnCPIProjects/ucm083244.htm> (last visited Oct. 24, 2009). See generally FDA Task Force, *supra* note 97 (discussing the results of the Task Force’s research).

¹²³ FDA Task Force, *supra* note 97, at ii.

¹²⁴ *Id.* at 18.

satisfies the applicable statutory and regulatory standards.¹²⁵ The Task Force also decided it would not be necessary for the FDA to label products as containing nanoscale materials because the current science shows nanoscale products present no greater safety concerns than other classes of products.¹²⁶

[34] The FDA Office of Combination Products also created a Nanotechnology Interest Group (NTIG), which is composed of representatives from all of the centers.¹²⁷ The goal of its creation was to facilitate the regulation of nanotechnology products.¹²⁸ The FDA will also receive guidance from the National Nanotechnology Coordination Office, which was established to “serve as the point of contact on Federal nanotechnology activities for government organizations, academia, industry, professional societies, State nanotechnology programs, interested citizen groups, and others to exchange technical and programmatic information.”¹²⁹

D. WHY ADEQUATE PREPARATION IS NECESSARY

[35] If the FDA does not adequately prepare for the regulation of nanomedicine products, it could have a negative effect on public health, nanomedical research and development and its own efficacy.¹³⁰ Professor Wein contends that the law is responsible for “keeping technology within

¹²⁵ *Id.* at 20.

¹²⁶ *Id.* at 35.

¹²⁷ Food & Drug Admin., *Nanotechnology*, <http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm> (last visited Oct. 24, 2009).

¹²⁸ *Id.*

¹²⁹ 21st Century Nanotechnology Research and Development Act, Pub. L. No. 108-153, 117 Stat. 1926 § 3(a)(2) (2003).

¹³⁰ Miller, *supra* note 4, at ¶¶ 37–42.

the bounds of human governance and control.”¹³¹ If problems are not anticipated and studiously addressed in advance, there is likely to be an inappropriate response in regulation.

[36] Under-regulation could come in the form of hasty approvals of dangerous therapies or failures to monitor clinical research effectively, exposing patients to a significant risk of harm, mainly because the centers involved would not be prepared or know how to identify novel issues related to nanomedicine.¹³² But the lack of preparedness could lead to overregulation causing unnecessary delays in patient access.¹³³ FDA reviewers confronted with inadequate resources, an inefficient regulatory structure, lack of expertise, and growing caseloads may exercise extreme caution when reviewing new technology, delaying patient access to potentially life-saving and health-enhancing medical devices.¹³⁴ Such ineffective regulation could have a substantial negative impact on nanomedical research and development.¹³⁵

[37] While too little regulation could cause investors to feel uncertain and forestall research, too much regulation could promote “black market” research and the loss of scientists to these less scrupulous companies.¹³⁶ Additionally, it will likely be difficult, just based on apprehensions about the subject matter, to recruit volunteers for clinical trials involving nanomedical products; if a poor regulatory decision results in a publicized casualty, this could halt the flow of volunteers and, therefore, clinical research altogether.¹³⁷ With no volunteers for clinical trials, companies

¹³¹ Leon E. Wein, *The Responsibility of Intelligent Artifacts: Toward An Automation Jurisprudence*, 6 HARV. J.L. & TECH. 103, 103 (1992).

¹³² See Miller, *supra* note 4, at ¶ 37.

¹³³ *Id.* at ¶ 38.

¹³⁴ *Id.*

¹³⁵ *Id.* at ¶ 39; Fiedler & Reynolds, *supra* note 18, at 603.

¹³⁶ Fiedler & Reynolds, *supra* note 18, at 603.

¹³⁷ Miller, *supra* note 4, at ¶ 39.

would not be able to secure FDA approval for marketing, not to mention that such a casualty would only fan the flames of opponents of nanotechnology in their argument for a legislative ban on all nanotechnology research.¹³⁸ The result of such a showing of inefficacy could further reduce confidence in the FDA and the public's support of nanotechnology.¹³⁹ "Regulators suffer more criticism when a new drug causes a single death than they do when the absence of a new drug causes a thousand deaths."¹⁴⁰ Therefore, I predict that overregulation will be more of a problem than under-regulation.

V. SUGGESTIONS FOR REGULATING NANOMEDICAL PRODUCTS

[38] The nanoscale technology of today is actually relatively simple in comparison to the long-term molecular manufacturing that we may achieve.¹⁴¹ It has been argued that the risks associated with those longer-term creations should not be placed on the same level as the nanotechnology today for policy consideration purposes.¹⁴² Perhaps this could facilitate the process by drawing a more narrow focus. Yet, the two biggest issues remain: classification and funding. There have been suggestions that instead of classifying nanoproducts according to their primary mode of action, they could be classified based on risk of potential harm.¹⁴³ Another suggestion is to categorize them according to function.¹⁴⁴ Such categories would include repair (referring to restoration

¹³⁸ *Id.* at ¶¶ 39–40.

¹³⁹ *Id.* at ¶ 42.

¹⁴⁰ Wolfson, *supra* note 5, at 389 (quoting K. ERIC DREXLER, *ENGINES OF CREATION: THE COMING ERA OF NANOTECHNOLOGY* (Anchor Books 1986), available at http://e-drexler.com/d/06/00/EOC/EOC_Chapter_13.html).

¹⁴¹ See Ctr. for Responsible Nanotech., *What is Nanotechnology?*, <http://www.crnano.org/whatis.htm> (last visited Oct. 24, 2009).

¹⁴² *Id.*

¹⁴³ Morrison, *supra* note 25, at 247.

¹⁴⁴ Fiedler & Reynolds, *supra* note 18, at 616.

of a previous state), replacement (procedures like organ transplants or connecting artificial joints), and augmentation (enhancing cells to perform in ways not called for by nature).¹⁴⁵ Perhaps using these categories would eliminate current problems with classification and alleviate the difficulty of creating proper regulations.

[39] No matter how the FDA determines to handle the issue, funding will always be a concern. Perhaps the best step to take is to persuade Congress to increase funding.¹⁴⁶ With regard for the potential problems of liability, it may also be helpful to create a nanotechnology fund to limit liability.¹⁴⁷ Such a fund would pay for unforeseen harm caused by nanorobots, on the condition that the person not bring a tort claim in court.¹⁴⁸ By making the payout available for unforeseen harm only, manufacturers would be encouraged to exercise due care and doctors to safeguard against carelessness.¹⁴⁹ This approach would likely ease the apprehension of the FDA in approving products.¹⁵⁰

CONCLUSION

[40] Nanotechnology is within our grasp. It is better to plan now than to suffer the consequences of poor planning later. Nanotechnology will already have enough ethical and legal obstacles to overcome. For instance, nanodevices may become available that will enable constant monitoring of a person's health, opening the door for potential abuse and a discussion of how this will affect privacy rights.¹⁵¹ Nanodevices that

¹⁴⁵ *Id.*

¹⁴⁶ *See* Miller, *supra* note 4, at ¶ 79.

¹⁴⁷ Morrison, *supra* note 25, at 256.

¹⁴⁸ *Id.*

¹⁴⁹ *See id.*

¹⁵⁰ *Id.*

¹⁵¹ Miller, *supra* note 4, at ¶ 44.

allow gene alteration, say of hair and eye color, and neurobiochips that stimulate brain function, possibly giving the human machine-like qualities, will no doubt dredge up ethical debates.¹⁵²

[41] Although the FDA appears to be planning to apply the existing regulation scheme to nanomedicine, there are likely to be *sui generis* problems only addressable through the creation of entirely new laws.¹⁵³ The bottom line is that nanomedicine will bring miraculous benefits as well as risks. Therefore, we should make efforts now to mitigate foreseeable problems and insure that nanotechnology will benefit us instead of hamper us.

¹⁵² *Id.* Perhaps the worst fear of all is the potential realization of the “grey goo theory,” in which nanorobots self-replicate to the point that they take over and eat away the world. Paul Burall, *Will Grey Goo Take Over the World?*, CHALLENGE, Sept. 1, 2003, available at http://www.greenlibdems.org.uk/articles/000008/will_grey_goo_take_over_the_world.html.

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