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# ESSAY

# Regulatory Concerns and Health/Hazard Risks Associated with Nanotechnology

LOUIS THEODORE* & LEO H. STANDER**

## I. INTRODUCTION

Many environmental and toxic tort attorneys are either directly or indirectly involved with nanotechnology issues. Although nanotechnology is a relatively new technology, nanomaterials are being manufactured and have found their way into the environment, creating two pressing societal and legal issues:

1. Current and proposed environmental regulations, and;
2. Procedures for quantifying and assessing health and hazard risks.

These two concerns dealing with the environmental risk implications and regulatory compliance encompass potential practice areas for attorneys.

Environmental risk has now become a topic of major concern to society. People face a variety of risks every day; some risks are

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faced voluntarily, such as air travel, driving a car, etc. and others involuntarily, such as adverse weather conditions, e.g., wind, storms, earthquakes, etc. Risk plays a very important role in our lives. Unfortunately, the word "*risk*," particularly as it applies to the environment, means different things to different people. As defined in a dictionary, *risk* is "a situation involving exposure to danger."[1] Shaefer and Theodore have defined it as "a combination of uncertainty and damage."[2] A third definition as provided by the U.S. Environmental Protection Agency (EPA) characterizes risk as: "a measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard."[3]

In addition to the multiple definitions for *risk*, many environmental professionals also identify risks differently. For example, in an industrial setting, environmental professionals are concerned with hazard risks as well as health risks. As these two types of risk are often used interchangeably, one of the objectives of this article is to clarify and explain the differences.

Virtually all the environmental concerns about nanoparticles are associated directly or indirectly with risk. As a result, any discussion regarding environmental health and hazard concerns associated with these materials or their processes must also include a discussion of risk.

The environmental health and hazard risks associated with nanoparticles and the applications of nanotechnology by commercial and industrial users have not come under scrutiny in recent years and have thus not been fully identified or addressed. Although these risks may prove to be minor and/or avoidable, practicing engineers and scientists are duty-bound to determine whether there are in fact any health, safety, and environmental impacts associated with the use and application of

1. *Risk,* OXFORD DICTIONARIES, http://oxforddictionaries.com/us/definition/american_english/risk (last visited Mar. 15, 2013).

2. Stacy Shaefer & Louis Theodore, *Environmental Implications of Nanotechnology – An Update,* 8 INT'L J. ENVTL. RESEARCH & PUB. HEALTH 470, 472 (2011).

3. *Terms & Acronyms*, U.S EPA, http://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/termsandacronyms/search.do (last visited Feb. 13, 2013).

nanotechnology. In addition, this information is important to those who may be involved and engaged in the legal arena.[4]

Regarding health risk, alarms arise because nanomaterials, as with other chemicals, can bypass defense mechanisms and enter the body. Following exposure, nanomaterials enter the body via various pathways including inhalation, skin absorption (referred to as absorption), and ingestion (through the digestive system). It is fair to say that a dominant route of entry into the body is inhalation.[5]

For the purposes of this article, the following two types of potential exposures are discussed:

1. *Chronic*: Continuous exposure occurs over long periods of time, generally months to years. Exposures to substances are often relatively low.
2. *Acute*: Exposures occur for relatively short periods of time, generally minutes to 1-2 days. Exposures to substances are usually higher than chronic exposures.[6]

Alternatively, hazard risk—which is typically classified in the acute category—involves a triple combination of event, probability, and consequences.[7] This risk can provide a measure of potential economic loss or human injury in terms of both the incident likelihood and the magnitude of the loss or injury.[8]

As noted in the title, this paper on nanotechnology discusses not only the regulatory concerns but also health risk and hazard assessment. The next section examines present and potentially future regulatory issues. The following two sections review traditional and time tested-methods that the practicing engineer and scientist employ in health and risk analysis assessment—procedures that are also employed in the nanotechnology field today.[9] This paper concludes with a discussion of nanotechnology's future and other associated concerns.

4. Shaefer & Theodore, *supra* note 2, at 472.

5. LOUIS THEODORE, NANOTECHNOLOGY: BASIC CALCULATIONS FOR ENGINEERS AND SCIENTISTS (2006).

6. LEO STANDER & LOUIS THEODORE, ENVIRONMENTAL REGULATORY CALCULATIONS HANDBOOK (2008).

7. Shaefer & Theodore, *supra* note 2, at XXX.

8. *Id.*

9. LOUIS THEODORE & ROBERT G. KUNZ, NANOTECHNOLOGY: ENVIRONMENTAL IMPLICATIONS AND SOLUTIONS 276-84 (2005).

## II. REGULATORY CONCERNS

In Europe and in the U.S., many environmental concerns are addressed through existing health and safety legislation. Health and safety assessments are required for new chemicals before they can be marketed in many countries. For example, in 2006, regulations were adopted by the European Union (EU) (EC 1907/2006) concerning chemicals and their safe use.[10] These regulations established the European Chemicals Agency, which manages the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emical (REACH) substances system, a database for information provided by manufacturers and importers listing the properties of their chemical substances.[11] Materials such as PCBs, dioxins, furans, plus a variety of unintended effects of drugs such as thalidomide, have provided companies and governments with incentives to keep vigilant for potential negative environmental health and hazard effects.

It should be noted that no nano or nano-related regulations exist in the U.S. or the EU at this time, which require controls on process releases or production activities or prescribe specific workplace safety measures. To protect the public and the environment from the possible adverse effects of nanotechnology, completely new legislation and regulatory efforts will be necessary. Until the health and environmental effects are identified and control or mitigation procedures and requirements are developed, one can only speculate on how the existing regulatory framework might be applied over the next several years for this emerging field. Detailed analyses of various existing U.S. and EU laws and requirements are discussed in the literature.[12]

10. LINDA BREGGIN ET AL., SECURING THE PROMISE OF NANOTECHNOLOGIES: TOWARDS TRANSATLANTIC REGULATORY COOPERATION 19 (2009).

11. *Id.*

12. *See* DANIEL J. FIORINO, VOLUNTARY INITIATIVES, REGULATION, AND NANOTECHNOLOGY OVERSIGHT: CHARTING A PATH (2010); BREGGIN ET AL., *supra* note 10; Leo Stander & Louis Theodore, *Environmental Regulations and Nanotechnology: An Update, Address at the Air and Waste Management Association Annual Conference and Exhibition* (June 26, 2008) (on file with author); *Laws and Executive Orders*, U.S. EPA, http://www.epa.gov/lawsregs/laws/index.html (last visited Jan. 16, 2013); M. Murphy & Louis Theodore, Address at the Consumers Union Symposium on Nanotechnology in Consumer

In the U.S., the principal federal agencies charged with mitigating environmental and health risks are the Occupational Safety and Health Administration (OSHA) and the EPA. Both agencies are directly concerned with the health and environmental implications of nanotechnology. The mission of OSHA is to ensure safe and healthful working conditions for working men and women.[13] A major role for the EPA is to protect all Americans from significant risks to human health and the environment where they live, learn, and work.[14] In both agencies, this is accomplished by setting and enforcing standards, and by providing training, outreach, education, and assistance.

It is a challenge to describe or predict future requirements that might come into play for nanomaterials. Regulations, in the past, have been both a moving target and confusing. In the future, we can predict that there will be new regulations and that, unfortunately, there is a high probability that they will also be contradictory and confusing. By reviewing past and current regulations, one can anticipate what can be expected. Requirements concerning the production and use of nanomaterials are most likely to occur under the Clean Air Act (CAA)[15] and the Toxic Substances Control Act (TSCA).[16] These laws are discussed in the following paragraphs.

No specific requirements or regulatory procedures currently exist for nanoparticles within the CAA. Regulations concerning the use and production of nanomaterials could be implemented in the following circumstances (neither of which is under consideration at this time):

First, a facility that manufactures or uses nanomaterials may become subject to the requirements of State Implementation Plans. These plans were developed by each State to ensure attainment and maintenance of National Ambient Air Quality Standards for criteria pollutants, including particulate matter

Products: Environmental Impacts of Nanotechnology: Consumer Issues (Apr. 2006).

13. *About OSHA*, U.S. DEP'T OF LABOR, http://www.osha.gov/ about.html (last visited Jan. 16, 2013).

14. *Our Mission and What We Do*, U.S. EPA, http://www.epa.gov/ aboutepa/whatwedo.html (last updated Dec. 10, 2012).

15. 42 U.S.C. §§ 7401–7671q (2000).

16. 15 U.S.C. §§ 2601–2692 (2006).

with a diameter that is smaller than 2.5 μm ($PM_{2.5}$).[17] While nanoparticles may not be specifically identified as subject to the various regulations, the processes involved with manufacturing such substances may result in emissions of criteria pollutants, which must be controlled.

Second, if adverse health and environmental effects are encountered as a result of emissions from the use or manufacture of nanomaterials, Section 112 of the CAA requires EPA to list such substances as hazardous air pollutants.[18] Emission controls would be required for those facilities that use or manufacture such substances. Currently, the CAA provides a list of 189 substances that have been determined to be hazardous air pollutants. It also stipulates procedures for adding and deleting substances from this list.[19]

Requirements and regulations for the commercial applications of nanotechnology are more likely to be implemented under TSCA. TSCA authorizes EPA to review and establish limits on the manufacture, processing, distribution, use, and/or disposal of new materials that pose an unreasonable risk of injury to human health or the environment.[20] The term "chemical" is defined broadly under TSCA.[21] Unless particular nanomaterials qualify for exemptions under the law, prospective manufacturers with low-volume production, with low volume along with low-level environmental releases, or with plans for limited test marketing would be subject to the full evaluation procedures prescribed by the law.[22] These procedures include submittal of a premanufacturing notice, along with toxicity and other data, to EPA at least ninety days prior to commencing production of the substance, followed by recordkeeping and reporting.[23] Requirements will differ depending on whether EPA determines that a particular application constitutes a "significant new use" or

17. Lynn Bergeson, *Nanotechnology Trend Draws Attention of Federal Regulators,* MANUFACTURING TODAY, Mar./Apr. 2004, at 15.

18. *Id.*

19. 42 U.S.C. § 7412 (2000).

20. 15 U.S.C. § 2601(b)(2) (2006).

21. *Id.* § 2602(2)(a).

22. Bergeson, *supra* note 17.

23. *Id*. at 14-15.

a "new chemical substance."[24] EPA can impose limits on the manufacture or production of such chemicals. These limits can include outright bans when it is deemed necessary for adequate protection against "an unreasonable risk of injury to health or the environment."[25] The EPA may re-evaluate a chemical's status under TSCA and change the degree or type of regulation when new health or environmental data warrant.[26] When taking into account experiences encountered with production of genetically altered plant and animal products, we anticipate a push for EPA, and also OSHA, to update regulations to reflect changes, advances, and trends in nanotechnology.

## III. RISK EVALUATION PROCESSES

As previously indicated, many environmental practitioners, researchers, and regulators have misrepresented the terms "health risks" with "hazard risks" and have interchanged them inappropriately. Although both utilize a multi-step method of analysis, the actual procedures are quite different. Each procedure may provide different results, information, and conclusions.[27] Both terms share a common trait in that they may have a negative impact on individuals, society, and the environment. Environmental health risk and environmental risk assessment processes have been widely discussed in the technical literature and serve as the bases for many health, safety, and environmental management activities.[28]

24. 15 U.S.C. § 2604(1) (2006).

25. *Id.* § 2604(f)(2).

26. *Id.*; Lynn Bergeson & Bethami Auerbach, *The Environmental Regulatory Implications of Nanotechnology*, BNA DAILY ENV'T REPORTER, Apr. 14, 2004, at B1.

27. THEODORE & KUNZ, *supra* note 9, at 276.

28. *See id.*; National Emission Standards for Halogenated Solvent Cleaning, 73 Fed. Reg. 62,384 (proposed Oct. 20, 2008) (to be codified at 40 C.F.R. pt. 63); CTR. FOR CHEM. PROCESS SAFETY OF THE AM. INST. OF CHEM. ENG'RS, GUIDELINES FOR CHEMICAL PROCESS QUANTITATIVE RISK ANALYSIS (1989); NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES OF SCI., RISK ASSESSMENT IN THE FEDERAL GOVERNMENT MANAGING THE PROCESS (1983) [hereinafter RISK ASSESSMENT IN THE FEDERAL GOVERNMENT]; NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES OF SCI., SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT (2009) [hereinafter SCIENCE AND DECISIONS].

**A. The Health Risk Evaluation Process**

The health risk assessment process provides an orderly, explicit, and consistent way to deal with scientific issues in evaluating whether a health problem exists and determining its magnitude.[29] This evaluation process typically involves considerations of large uncertainties, as the available scientific data are limited. Also, "the mechanisms for adverse health impacts or environmental damage are only imperfectly understood."[30]

Regulatory agencies typically evaluate health risks by utilizing a standard risk assessment process.[31] In this risk assessment process, most human or environmental health problems are considered by dividing the evaluation into four parts: problem identification, dose-response assessment, exposure assessment, and risk characterization (see Figure 1).[32] This four-step process has been widely utilized by U.S. federal and state agencies, as well as international organizations to assess and manage health and environmental issues.[33]

29. THEODORE & KUNZ, *supra* note 9, at 275.

30. *Id.*

31. RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 28, at 40 (generally discussing agencies and the risk assessment process).

32. *See infra* Figure 1.

33. National Emission Standards for Halogenated Solvent Cleaning, 73 Fed. Reg. 62,384 (proposed Oct. 20, 2008) (to be codified at 40 C.F.R. pt. 63); CTR. FOR CHEM. PROCESS SAFETY OF THE AM. INST. OF CHEM. ENG'RS, *supra* note 28; RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 28; SCIENCE AND DECISIONS, *supra* note 28.

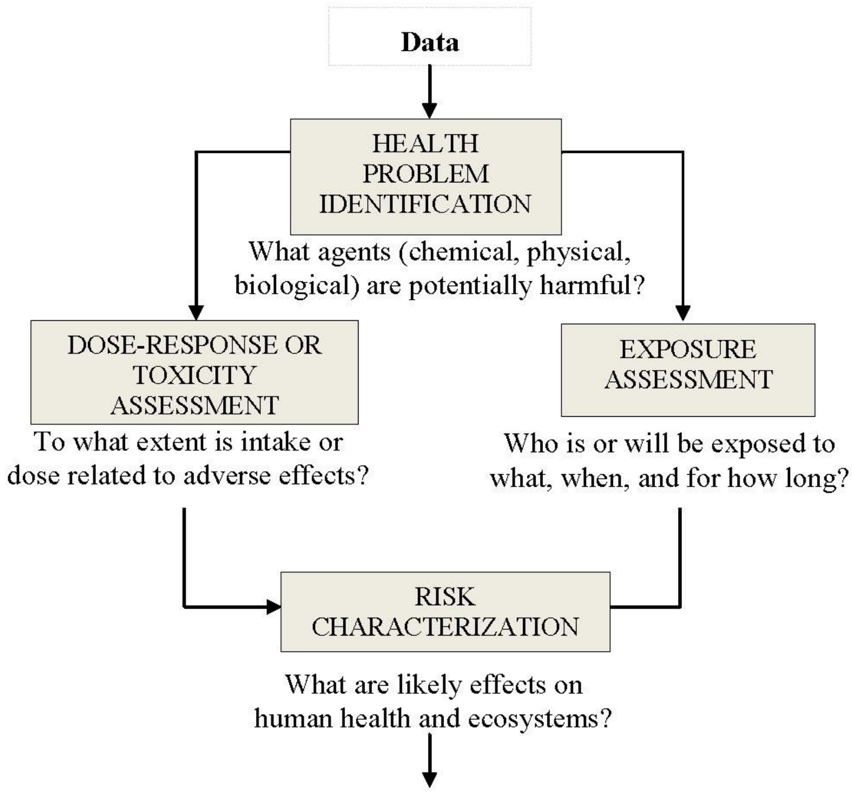


Figure 1. The Health Risk Assessment[34]

For some perceived problem, a risk assessment might stop after completing the first step in the process (i.e., problem identification) if no adverse effect is observed or identified or if the agency elects to take regulatory action without further analysis.[35] Regarding health problem identification, a disorder may be attributed to a toxic agent or conditions that have the potential to trigger adverse effects to human health or the environment. Dose-response or toxicity assessments are required as chemicals and contaminants vary in their capacity to cause adverse effects. As a part of this step, assumptions are required

34. THEODORE & KUNZ, *supra* note 9, at 277.
35. THEODORE, *supra* note 5.

to extrapolate experimental data involving animals to human situations. Exposure assessment is the determination and prediction of the magnitude, frequency, duration, and routes of exposure for human populations and ecosystems. Finally, in the risk characterization step, the aforementioned toxicological and exposure data/information are combined to provide a qualitative or quantitative expression for health and environmental risk. Additional details are available in the literature,[36] as well as health risk assessment calculation details.[37]

The health risk evaluation process may be problematic. When applied to nanomaterials, there are just not enough published data available on the environmental health effects resulting from exposure to nanoparticles, nor are there protocols or methodologies to make such evaluations.[38] Entities such as the U.S. National Institutes of Occupational Safety and Health have issued interim guidance regarding medical screening for workers exposed to engineered nanoparticles.[39] Although some information is available concerning the fates and effects of some classes of nanomaterials in the environment—procedures to predict environmental exposures to engineered nanoparticles[40] and techniques that might be used to model environmental

36. STANDER & THEODORE, *supra* note 6; VICKI STONE ET AL., EUROPEAN COMM'N, ENGINEERED NANOPARTICLES: REVIEW OF HEALTH AND ENVIRONMENTAL SAFETY (2010); MARY THEODORE & LOUIS THEODORE, INTRODUCTION TO ENVIRONMENTAL MANAGEMENT (2009).

37. LOUIS THEODORE & R. RYAN DUPONT, ENVIRONMENTAL HEALTH RISK AND HAZARD RISK ASSESSMENT: PRINCIPLES AND CALCULATIONS (2012); LOUIS THEODORE ET AL., HANDBOOK OF ENVIRONMENTAL MANAGEMENT AND TECHNOLOGY (2d ed. 2002).

38. VICKI STONE ET AL., *supra* note 36, at 37; Steffen F. Hansen, *A Global View of Regulations Affecting Nanomaterials*, 2 NANOMED. & NANOBIOTECH. 441, 443 (2010).

39. *See* U.S. NAT'L INSTS. OF OCCUPATIONAL SAFETY & HEALTH, CURRENT INTELLIGENCE BULLETIN 60: INTERIM GUIDANCE FOR MEDICAL SCREENING AND HAZARD SURVEILLANCE FOR WORKERS POTENTIALLY EXPOSED TO ENGINEERED NANOPARTICLES (Ctrs. for Disease Control & Prevention 2009).

40. ALISTAIR B.A. BOXALL ET AL., CURRENT AND FUTURE PREDICTED ENVIRONMENTAL EXPOSURE TO ENGINEERED NANOPARTICLES (Cent. Sci. Lab. 2008).

concentrations[41]—additional information on occupational, consumer, and environmental exposure is needed.[42]

## B. The Hazard Risk Evaluation Process

As is the situation with regard to environmental health risk, there is a serious lack of information concerning hazard risks and the associated implications of these hazards, particularly when discussing the production and use of nanomaterials.[43] It is the authors' opinion that hazard risks have unfortunately received less attention than they deserve.

In a previous section, we defined both "chronic" and "acute" exposures. When the two terms are applied to emissions, the former usually refers to ordinary round-the-clock, everyday emissions while the latter term applies to short term, out-of-the-norm, or accidental emissions. Thus, acute problems can be referred to as accidents and/or hazards.

As with assessing environmental health risks of a substance, several steps are involved in evaluating a hazard risk. These steps include anticipating and estimating the effects of upset conditions, malfunctions, or accidents at a facility. For a chemical plant, this type of analysis is detailed in Figure 2. The core of the hazard risk assessment algorithm is enclosed in the dashed box of Figure 2. This algorithm allows for a process reevaluation if the risk is deemed unacceptable. We presume that similar approaches will be utilized in the manufacture of nanomaterials.[44] The reader should note that Figure 2 describes the hazard assessment process that can be used for an individual accident at a single processing unit. In the real world, an accident at a single processing unit in a manufacturing facility can trigger a whole host of additional accidents. In this setting, each process should be carefully evaluated to predict potential hazard risks, such as a matrix analysis, to determine the most

41. Fadri Gottschalk et al., *Modeled Environmental Concentrations of Engineered Nanomaterials (TiO2, ZnO, Ag, CNT, Fullerenes) for Different Regions*, 43 ENVTL. SCI. & TECH. 9216 (2009).

42. STONE ET AL., *supra* note 36, at 361.

43. *Id.*

44. Shaefer & Theodore, *supra* note 2, at 474.

appropriate and cost-effective preventative measures (including the use of personal protective equipment).

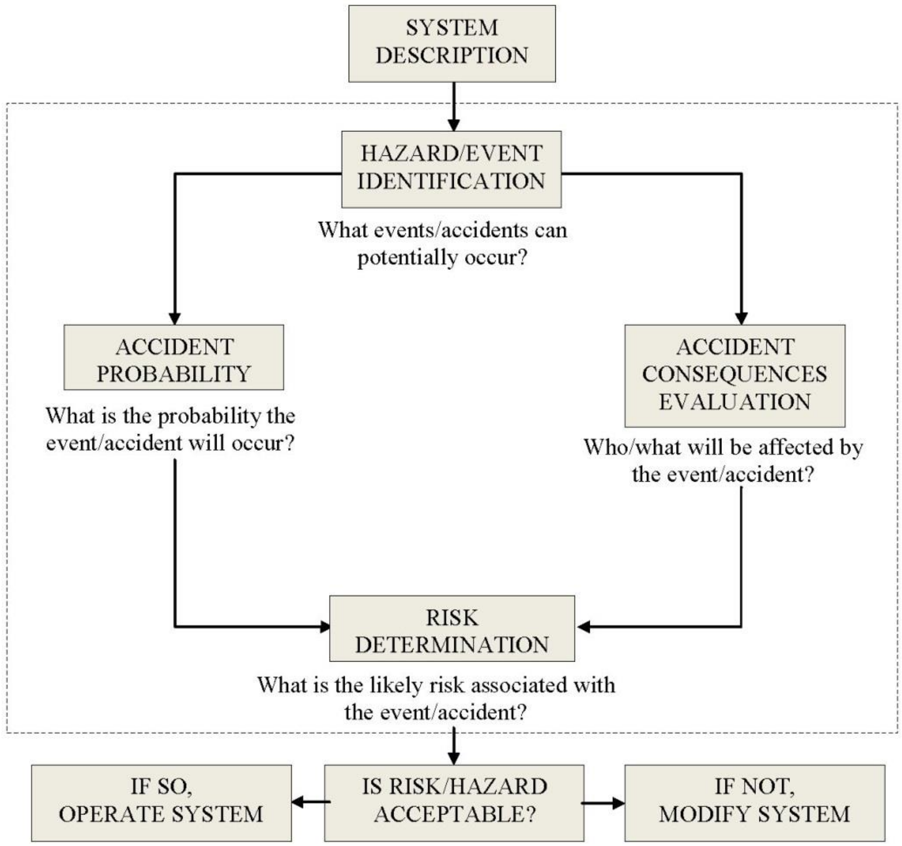


Figure 2. Hazard Risk Assessment Flowchart.[45]

Thus, the health risk and hazard risk assessment process both employ a four-step method of analysis. Though the assessment procedures are quite different, with each providing different data and each providing different environmental risk results, information, and conclusions, each share a common concern; each assessment process is concerned with minimizing

45. *Id.*

the potential for negative impacts on consumers, workers, and the environment.[46]

The level of data available for health risks directly impacts decision-making activities for hazard risks. If there is limited information on the health hazards for a particular substance, then the associated uncertainties will impact hazard risks. The unknowns in this risk area may be larger in number and greater in potential consequences. Hazard risk analysis details are available and traditional approaches have been successfully applied in the past. Theodore and Dupont provide extensive hazard risk assessment calculation details.[47]

## IV. THE FUTURE AND ASSOCIATED CONCERNS

For nanotechnology's most ardent supporters, the scope of this emerging field seems to be limited only by the imaginations of those who would dream at these unprecedented dimensions. However, considerable technological and financial obstacles and challenges still need to be reconciled before nanotechnology's full promise can be realized.

Ranking high among the challenges and obstacles facing nanotechnology in the future is the continuing need to develop and perfect reliable techniques to manufacture (and possibly mass produce) nanoscaled particles. These manufactured particles must have not just the desirable particle size(s) and particle size distribution(s) but must have acceptable purity levels and a minimal number of structural defects, as well. These latter attributes can drastically alter the anticipated properties and behavior of the manufactured nanoscaled particles. Experience to date has shown that the scale up issues associated with moving today's promising nanotechnology-related developments from various laboratory bench- and pilot-scale demonstrations to full-scale commercialization will be formidable.[48]

Most believe nanotechnology will have a major impact on war, crime, terrorism, and the massive companion industries,

46. *Id.* at 474-75.
47. THEODORE & DUPONT, *supra* note 37.
48. THEODORE & KUNZ, *supra* note 9, at 62.

particularly security and law enforcement. The military has a significant interest in nanotechnology, including such areas as optical systems, nanorobotics, nanomachines, "smart" weapons, nanoelectronics, virtual reality, massive memory, specialty materials for armor, nanobased materials for stopping bullets, and bio-nanodevices to detect and destroy chemical and biological agents. Most of this activity is concerned with protection against attack and minimizing risk to military personnel, e.g., devices that may be able to repair defective airframes or the hulls of ships before any damage develops. But make no mistake, the rush is on (as with the development of the atomic bomb) to conquer this technology; the individual, or organization, or country that successfully conquers this technology will almost certainly conquer the world. Society as well as the technical community also has to understand that the misuse of this new technology can lead to catastrophic damage. Alternatively, nanotechnology could be used to provide not only sophisticated sensors and surveillance systems to identify military threats but also weapons (or the equivalent) that will eliminate these threats.[49]

Regarding crime, the techniques of nanoscience will have a lot to offer forensic investigations, both for biological analysis, and materials and chemical studies. Portable instruments with sophisticated nanosensors will be able to perform accurate high-level analyses at crime sites. These instruments should greatly improve conviction rates and the ability to locate real clues.[50]

Nanotechnology may create new ways of making both computer systems and message transfer secure using special hardware keys that are immune to any form of hacking. Very few current computer protection systems are able to keep out really determined hackers. Nano-imprinting, which already exists, could be used to make "keys," or even special nano-based biosensors coded with a dynamic DNA sequence. Nano-imprinting is already used to make bank notes virtually impossible to forge by creating special holograms in the clear plastic. Forgery would be possible only if the master stamps were

49. Louis Theodore, *Nanotechnology II, As I See It*, WILLISTON TIMES, Apr. 23, 2004.

50. *Id.*

actually stolen, but in that situation a new hologram could be made.[51]

Nanoparticle-related developments are also being actively pursued to improve batteries and solar devices, fuel cells, advanced data-storage devices such as computer chips, hard drives, sensors, and other analytical devices. Meanwhile, nanotechnology-related developments are also being hotly pursued in other medical applications, including the development of more effective drug-delivery mechanisms and improved medical diagnostic devices.

The unbridled promise of nanotechnology-based business opportunities has inspired academic, industrial, and government researchers around the world to investigate and invent nanoscaled materials, devices, and systems with the hope of production and implementation at the commercial-scale. Today, the private-sector companies that have become involved in nanotechnology run the gamut from established global chemical process industries to countless small, entrepreneurial startup companies, many of which are spin offs of targeted research and development efforts at universities and research institutions.

In the United States, the principal entity responsible for coordinating federal efforts in nanotechnology is the National Nanotechnology Initiative (NNI). Established in 2000, the NNI serves as the focal point of communication, cooperation, and collaboration for all federal agencies engaged in nanotechnology research. This initiative is an ongoing program that synchronizes the nanotechnology-related activities of twenty-seven departments and independent agencies of the U.S. government, fifteen of which have specific budgets for nanotechnology research and development activities. As an interagency effort, the NNI informs and influences the federal budget and planning processes through member agencies. A major mission is to provide guidance to agency leaders, program managers, and the research community concerning planning and implementation of nanotechnology research and development investments and activities.

51. *Id.*

Beyond their efforts in producing and using the nanometer-sized particles of various materials, some scientists and engineers are designing and inventing far more ambitious—and some would say fantastic or futuristic—applications for this powerful new technological paradigm. For instance, researchers are working to design and produce nanoscaled objects, devices, and systems by the manipulation of individual atoms and molecules. These revolutionary researchers hope that by using atom-by-atom construction techniques they will someday be able to create not just new substances with remarkable functionality, but also tiny, bacterium-sized devices and machines (thus far dubbed nanobots), that could be programmed to repair clogged arteries, kill cancer cells, and even repair cellular damage caused by aging.[52]

## V. CONCLUSION

Any new technology can have diverse and imposing effects on the environment and society. Nanotechnology is no exception, and the consequences will be determined by the extent to which the technical community manages this technology.

The reason for this description is as simple as it is obvious: the technical community is dealing with a significant number of unforeseen effects that could have disastrous impacts on society. Fortunately, the probability for such dire consequences actually occurring is near zero . . . but not zero. Air, water, and land (solid waste) concerns regarding emissions from future nanotechnology production processes, as well as companion health and hazard risks, will receive extensive consideration. All of these issues arose earlier with the Industrial Revolution, the development/testing/use of the atomic bomb, the arrival of the Internet, Y2K, and so forth. The engineers and scientists of that period successfully (relatively speaking) resolved these problems as they were encountered.

Although the scientific literature includes discussions of potential health problems, the authors are not aware of any documented human health hazards resulting from the production or use of nanomaterials. One of the authors has speculated on

52. THEODORE & KUNZ, *supra* note 9.

the need for future regulations of nanomaterials. His suggestions and potential options are provided elsewhere.[53] He noted that the ratio of pollutant nanoparticles being released (from conventional sources such as power plants) to engineered nanoparticles being released into the environment may be as high as a trillion (i.e., $10^{12}$) to one.[54] If this ratio is correct the environmental concerns for nanoparticles can almost certainly be dismissed.

The concerns about nanotechnology will eventually lead to significant activities in the legal arena, as the health risks and hazard risks associated with nanotechnology are certain to generate legal conflicts in the future.

53. THEODORE ET AL., *supra* note 37; Louis Theodore, Presentation at the Nanotechnology and Office of Solid Waste and Emergency Response (OSWER) Symposium 2006: Nanotechnology: Environmental Implications and Solutions (July 2006), *available at* http://www.epa.gov/oswer/nanotechnology/events/OSWER2006/pdfs/nd-waste-management-presentation-slides.pdf.

54. Louis Theodore, Personal Notes, (2006) (unpublished notes – Discussions Regarding Nanoparticles) (on file with author).