

# GLOBAL HEALTH IMPACTS OF NANOTECHNOLOGY

## LAW

**A Tool for Stakeholder Engagement**

**Ilise L. Feitshans**





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*Dedicated to my children,  
Jay Levy Feitshans and Emalyn Levy Feitshans,  
my nephews, Jason Levy and David Levy,  
and my grandchildren and their grandchildren.*

*With special thanks to  
my beloved new spouse, Dominique Charoy  
And with undying gratitude to my parents,  
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## **Books by the Same Author**

1. *Designing an Effective OSHA Compliance Program*
2. *Bringing Health to Work*
3. *Walking Backwards to Undo Prejudice: Report of the US Capitol Conference Including Disabled Students; What Works What Doesn't*
4. *Genetic Destiny: Today's Science Tomorrow's Laws*



# Foreword

The mission of the US National Institute for Occupational Safety and Health (NIOSH) is to generate new knowledge in the field of occupational safety and health and to transfer that knowledge into practice for the benefit of workers and their families. Emerging nanotechnology applications promise great societal benefits. There is a need to be sure that both the commercial applications and risk implications of nanotechnology are communicated to consumers, workers, and those who value the environment.

While much has been published about the various applications and risk implications of nanotechnology from scientific, ethical, and legal perspectives, publications aimed at a nontechnical, nonlegal audience are less common and are usually oriented to a particular country's legal rules. This is why *Global Health Impacts of Nanotechnology Law: A Tool for Stakeholder Engagement* by Dr. Ilise L. Feitshans fills a void in addressing the legal, social, and policy implications of nanotechnology from a global governance perspective.

The book makes the nanotechnology applications of daily life accessible to readers who are curious about this new scientific and legal field but do not have a doctorate in either aerosol physics or administrative law. Dr. Feitshans wants her readers to feel comfortable moving across the fields of science, ethics, and law in order to obtain a fuller understanding of how nanotechnology can reshape both commerce and public health, producing social benefits globally.

The benefits and risks of nanotechnology will be felt broadly across industries and countries. Nanotechnology will usher in new and improved methods for information technology, homeland security, medicine, transportation, energy, food safety, environmental science, and advanced manufacturing. It is important for all of us to understand this emerging technology. I invite you to read *Global*

*Health Impacts of Nanotechnology Law*. I think you will enjoy reading this book.

**John Howard**

Director, US National Institute for Occupational Safety and Health

2018

# Preface

Small things add up: products applying nanotechnology have been marketed to consumers for over a decade, and therefore nanotechnology applications represent a huge slice of daily economic life [1], whether people know it or not [2]. “The impact of nanotechnology on the health, wealth, and lives of people could be at least as significant as the combined influences of microelectronics, medical imaging, computer-aided engineering, and man-made polymers,” according to the report to the president of the United States, which launched an international vision of new materials and new products for the 21st century. “Developments in these emerging fields are likely to change the way almost everything – from vaccines to computers to automobile tires to objects not yet imagined . . . Such new forms of materials and devices herald a revolutionary age for science and technology,” according to that report [3]. Long-term nanoscale research and development . . . materials and manufacturing, nanoelectronics, medicine and health care, environment, energy, chemicals, biotechnology, agriculture, information technology, and national security . . . . *How can the benefits of nanotechnology be realized, while reducing risk to public health?*

The sheer economic importance of nanotechnology will change several antiquated systems regarding industrial processes, scientific understanding and categorization of chemical informatics, and, ultimately, the health care delivery systems that must use or correct the end products of these changes anyway. The global health package embraces nanotechnology: new economic frontiers with wide horizons, promising new medicines, strong packaging to protect goods from contamination, cheaper consumer products, and new medicines to fight cancer. Nanotechnology’s revolution provides the perfect vehicle to fix old problems. Therefore, its arrival in commerce provides an unprecedented, excellent opportunity to change society for the better. This book examines the following:

- Definition of nanotechnology under law

- The role of stakeholders in setting society's standards for acceptable nanosafety and risk management
- Emerging laws of risk management for nanotechnology; to be harmonized in a unified risk governance framework that will have positive impacts on global health

The conclusions include draft text based on legal principles for harmonizing risk management, as applied to emerging nanosafety laws, with a goal to incubate new products, while having positive global health impacts.

### **Nanotechnology's Revolution for the Global Economy Can Also Revolutionize Public Health!**

Law and science have partnered together in the recent past to solve major public health problems using *global health diplomacy* [4], woven from international scientific collaborations and emerging multinational efforts for risk prevention. Global health diplomacy embraces nanotechnology—a revolutionary approach to the long-established rules in science and nature about matter and the properties of key elements such as titanium, silver, and gold. Nano-enabled products manipulate these properties to improve the quality of life worldwide. Using international collaborative research and treaty-based tools of diplomacy for global commerce, nanotechnology, nano-enabled applications of new knowledge, and nanomedicine bring products from lab to market, which, in turn, impact global health concerns about food, clothing, shelter, transportation, and medical care. Nanotechnology products and the local, national, and international laws that may govern them therefore touch the life of everyone. “It is expected that nanotechnology will play the role electronics played in the 20th century and metallurgy played in the 19th. . . . Manufactured nanomaterials are expected to yield significant innovation . . . a new competitive edge to European industry and strong benefits . . . from medicine to agriculture, from biology to electronics” [5].

Nanotechnology is here. Not only is it true that “you can't put the toothpaste back into the tube,” but the toothpaste you use already also has the latest nanotechnology inside: a quiet but important example of the daily application of nanotechnology to consumer

products [6]. The greatest challenge for successfully applying nanotechnology's promises involves designing and implementing flexible laws that will both incubate new commerce and ensure global health protections. This beautiful, bouncing new arrival in commerce, however, is well planned and therefore should not surprise policymakers, consumers, or stakeholders.



**Figure P.1** Examples of nanotechnology products already in commerce. Courtesy: Dr. John Howard, Director, US National Institute of Occupational Safety and Health (NIOSH), as presented during his guest lecture at the International Labour Organization (ILO), Geneva, Switzerland: “Nanotechnology: The Newest Slice of Global Economic Life,” November 27, 2008. Source: US government.

Opinion leaders in science, law, and health policy have heralded nanotechnology as a revolution [7] destined to realize unprecedented economic growth by applying smart new scientific developments since the beginning of the 21st century. In 2000, presidential advisers in the United States proclaimed nanotechnology the “next Industrial Revolution” [3, 8]. “The impact of nanotechnology on the health, wealth, and lives of people could be at least as significant as the combined influences of microelectronics, medical imaging, computer-aided engineering, and man-made polymers developed in this century,” according to the report to the president of the United

States at the outset of the 21st century from the National Science and Technology Council. “Compared to the physical properties and behavior of isolated molecules or bulk materials . . . exhibit important changes for which traditional models and theories cannot explain. Developments in these emerging fields are likely to change the way almost everything – from vaccines to computers to automobile tires to objects not yet imagined – is designed and made. . . . Such new forms of materials and devices herald a revolutionary age for science and technology, provided we can discover and fully utilize the underlying principles,” according to the US government’s report in 2000 [9].

That same report to the president of the United States also successfully advocated for nearly a quarter of a billion dollars for research and development in 2001, which rose to 23 billion dollars a decade and a half later. Anticipating the cross-cutting importance of nanotechnology in every facet of commerce and daily life, the Executive Office of the President of the United States created a network of federal agencies within its government, spanning health [10], homeland security, space exploration, food and drug regulation, environmental protection, household and consumer goods, the Department of Commerce, the Department of Justice, and branches of the government associated with military defense [11]. The network is called the National Nanotechnology Initiative (NNI). Similar programs exist around the world. The NNI is credited with having tagged nanotechnology as a “revolution” [12] for industry and commerce, in 2000 [3]. Under the 21st-century Nanotechnology Research and Development Act of 2003 [13], NNI agencies are required to develop an updated NNI strategic plan. The Office of Science and Technology Policy (OSTP) describes the NNI mission as “the vision of the NNI is a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society” [14].

Policymakers and scientists have consistently agreed. These sentiments have been echoed by the Woodrow Wilson Center for Scholars [15]. By 2013, this mantra was unchanged: the European Union (EU) NanoSafety Cluster praised nanotechnology as “one of the key technological drivers in building an innovation [sic] European Union based on smart, sustainable and inclusive growth.”

Scientists in the NanoSafety Cluster use policy words, not scientific terms, describing “tremendous growth potential for a large number of industry [sic] sectors.” The EU has also committed billions to baseline nanotechnology research and commercialization of nano-enabled products [17]. Basic research building on the foundation of knowledge that has been developed in areas such as precision medicine and precision materials has expanded the already large range of applications for nanomaterials and nano-enabled products. Recognizing this evolution, the focus of the NNI has broadened in the 2016 draft strategy to embrace the evolving importance of previously unmet needs.

The EU, in collaboration and sometimes competition with the NNI, has kept pace with every facet of the NNI strategy. The EU NanoReg2 program is tasked with charting a path for registering, licensing, and certifying the nanosafety of a wide variety of substances and end products. The clear role of science policy in new laws at the national and international levels demonstrates that technology and economic factors in the globalization of commerce have transformed laws governing risk. In the 20th century, the main focus of international law strategies and national public health law agendas concerned law balancing diversity by maintaining cultural differences without reinforcing cultural prejudices such as racism and sexism. The 21st century has overcome many of those challenges and confronts the needs for one world with new institutions for governance and a new role for the rule of law. Nanotechnology is a key component of the social forces shaping society in the wake of legislated prohibitions on discrimination. Nanotechnology therefore will have a major impact on government and the shape of risk governance as a social good under law. The social determinants of health will also be influenced by nanotechnologies, offering researchers, policymakers, and stakeholders in greater society the possibility of removing the health disparities that were the result of culturally embedded prejudices. This crossroads in science influencing social policy raises new questions about how people will survive when applying nanotechnology across a gamut of medical, security, travel, housing, and nutrition venues. It is not surprising, therefore, that the perception that nanotechnology is a revolution remains successfully echoed in the literature ranging from clinical nanomedicine [17] to the popular press.

“Nanotechnology represents the possibility of revolutionizing many aspects of our lives,” according to Dr. Varvara Karagkozaki, a cardiologist and a leading researcher in nanomedicine.

“Nano-architecture is a new architectural style of the 21st century that will revolutionize architecture in every aspect” because nano applications in architecture can change the architect’s vision, design techniques and ideas, construction methods, structure technologies, statics, form and aesthetics of mechanical systems, lighting, topic of energy, maintenance and repair techniques, decoration and interior design” [18].

“Nanomedicine is expected to dramatically exceed what has occurred in the field thus far, and our belief is that it will revolutionize medicine,” said Dr. Gangs Bao regarding the opening of the Center for Pediatric Nanomedicine (CPN) at Emory University, Pediatric Nanomedicine Center, in partnership with Georgia Tech and Morehouse School of Medicine in Atlanta in March 2011. “We plan to make this new pediatric nanomedicine center a leader in applying these unique discoveries to treating and curing children’s diseases.” And he further noted that “because nano-scale structures are compatible in size to biomolecules, nanomedicine provides unprecedented opportunities for achieving better control of biological processes and drastic improvements in disease detection, therapy and prevention” [19].

“From a fundamental point of view, it is very interesting to investigate nano systems like nanoparticles,” said Alexander Fabian from Justus-Liebig University, Giessen, Germany. “Since they can be fabricated in a very controlled manner, they can also be studied in a systematic approach. Properties of the nanoparticles different from the bulk, or even new properties like superparamagnetism in nanoparticles, make them also interesting for fundamental research” [20].

Echoing both government voices and the boasts of scientific research academia, delegates at the World Economic Forum (WEF) in Davos, Switzerland, declared, “Technology is the fourth Industrial Revolution” embracing nanotechnology in 2016 [21]. Klaus Schwab, founder and executive chairman of the WEF, stated, “We feel we are not prepared sufficiently for this fourth industrial revolution which will come over us like a tsunami which will change whole systems.”

Putting all these attributes together, in totality, the arrival of nanotechnology and nano-enabled products in commerce means improved security, while reducing the price of goods used in health care, thus positively impacting not merely the global economy but also the global quality of life. Therefore the nanotechnology revolution for scientific theory brings important health impacts with its new economic frontiers with wide horizons, promising new medicines, strong packaging to protect goods from contamination, cheaper consumer products and new commerce from their trade, and new approaches to governance for their control. Dr. John Howard, director of the US National Institute for Occupational Safety and Health (NIOSH) openly predicted the advent of nanotechnology as a game changer [22]. In 2004, Dr. Howard predicted that nanotechnology was at that time already like a train having left the station and the general public was like a commuter who was running after it to catch up [22]. Nevertheless, he noted that such new technologies may reshape our understanding of the interaction between human health and the context of work as well as the nature of work itself. “These are exciting times,” he said. “This time, we may be on the train [of technologic change], not just running behind it” He urged the leaders to “leap on that train before it leaves the station—if it hasn’t left already.”



**Figure P.2** Photo of Einstein thinking. Final slide from the guest lecture by Dr. John Howard, Director, US NIOSH, at the ILO, Geneva, Switzerland: “Nanotechnology: The Newest Slice of Global Economic Life,” November 27, 2008. Source: US government.

The progress between the 2004 speech and his lecture at the International Labour Organisation (ILO) in Geneva, Switzerland, just four years later in 2008 was startling. By 2008 research for anticancer drug delivery systems was well underway and lists of products using nanotechnology filled an entire slide (which Dr. Howard later humbly apologized was outdated). As Dr. Howard concluded in his pathbreaking lecture [6] about nanotechnology in 2008:

“In the long term, nanotechnology will demand a revolutionary re-thinking of . . . health and safety.”

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of the Industrial Revolution, . . . Industrial revolution II,” preface on page xii.

8. *National Nanotechnology Initiative: The Initiative and Its Implementation Plan*. The report further states, “The development of a healthy global marketplace for nanotechnology products and ideas will require the establishment of consumer confidence, common approaches to nanotechnology environmental, health, and safety issues, efficient and effective regulatory schemes, and equitable trade practices for nanotechnology worldwide.”
9. “The initiative will support long-term nanoscale research and development leading to potential breakthroughs in areas such as materials and manufacturing, nanoelectronics, medicine and healthcare, environment, energy, chemicals, biotechnology, agriculture, information technology, and national security. The effect of nanotechnology on the health, wealth, and lives of people could be at least as significant as the combined influences of microelectronics, medical imaging, computer-aided engineering, and man-made polymers.”
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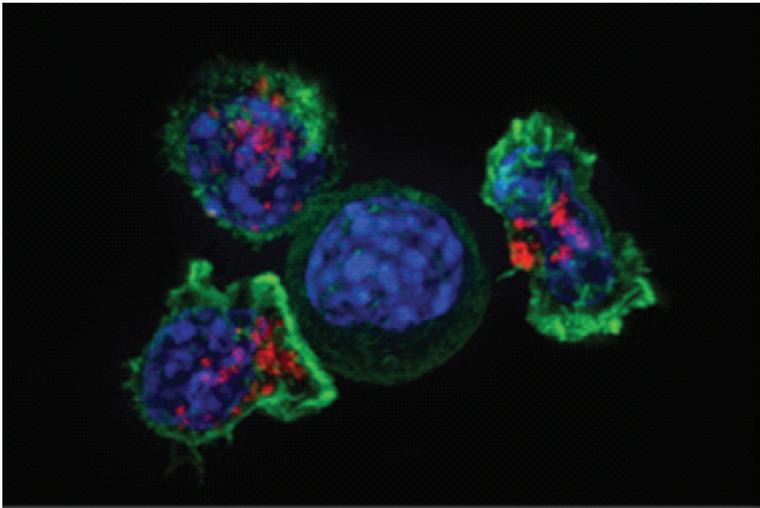
# **Introduction: Crossing Impermeable Borders (The Uncharted Frontier of Law and Science Governing Nanotechnology)**

Nanotechnology's revolution for commerce can revolutionize global public health: the scientific revolution that began at the dawn of the 21st century has taken hold, surpassing 3 trillion dollars in 2015 [1]. Every nation has a nanotechnology science strategic program under law, and most universities have big-ticket programs for nanoresearch and training, including nuclear research, nanomedicine, and genetic research using nano-enabled products. International treaties and national laws from countries where nanotechnology is a rapidly growing part of their economy abound, impacting every facet of production, storage, transport, distribution, use, and end-of-life-cycle removal or waste from manufactured goods.

This book brings together law and science for people who wish to understand the amazing role of nanotechnology in the global economy. People who use nanotechnology every day in their homes, for personal medical needs, and in cars, buses, airplanes, trains, and workplaces, need basic science policy information in order to (i) make informed choices of their own use of nano-enabled products, (ii) understand the information that is disclosed on labels regarding nano-enabled products, and (iii) have their say about laws and regulations pertaining to nanosafety in order to make the best use of these new technologies.

Global health impacts provides a brilliant example of how a dynamic moment in history finds society at an unusual policy crossroads: the changes wrought by technology offer the opportunity to choose which old values will be kept by the new order and which values will be thrown away. People who ignore vital social issues raised by the implementation of nanotechnology

applications in commerce, or who shy away from discourse with people who disagree with them, risk ignoring the importance of these revolutionary developments. On the sidelines as spectators to nanotechnology's revolution reshaping society, they will then be clueless when old inequitable prejudices are accidentally embedded into the matrix for new nanotechnology laws or when prejudiced old rules no longer apply. Exploring key questions about nanotechnology offers people a unique window of opportunity to understand the cultural matrix shaping the laws, regulations, policies, and use of nanotechnology and then to seize the opportunities brought by the nanotechnology revolution to institute meaningful, long-needed social change to improve public health without sacrificing economic benefits promised by nanomedicine and other nanotechnology applications. This book therefore offers basic information to inform policy and future research for lawmakers, politicians, business leaders, and citizens throughout the world.

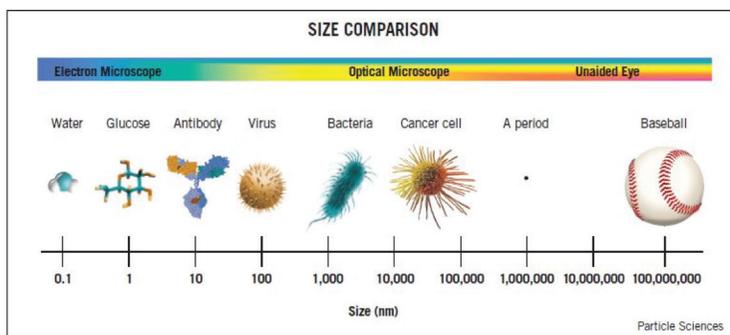


**Figure I.1** Killer T-cells surround a cancer cell. Source: US National Institutes of Health (NIH).

Nanotechnology involves manipulating known chemicals at the molecular and atomic levels in order to create smaller, faster, stronger, lighter, reliable products [2]. The “nanoscale,” which measures

activities that apply nanotechnology, is very small. A human hair has a diameter of 100,000 nm. Within a few nanometers, nanoparticles can alter the biology of life. For example, natural mechanisms with complicated names such as “high-density lipoproteins” range from 8 to 10 nm, and ribosomes, the building blocks of DNA, are between 25 and 30 nm. This means that regulatory discussions about discoveries at the nanoscale under 100 nm might include many proteins that are ingredients for key genetic material. Additionally, there are new elements and substances with fancy names such as 1D and 2D matter and special properties for matter at the nanoscale: nanogold is combustible, nanosilver is antibacterial, and nanoscale titanium dioxide makes marvelous, frothy white foam for filling donuts, making whipped cream, and making shaving cream that billions of consumers use every day!

The prefix “nano-” is derived from the Greek word “dwarf” [3]. Yet nanotechnology is quite big! As predicted, the value of nanotechnology for commerce and industry rose to trillions of dollars by 2015 [4]. As nanotechnology’s trajectory moves from experiments in laboratories into products in commerce, it becomes ubiquitous in daily life. Touching health care products, cosmetics [5], electronics, apparel, and automobiles, nanotechnology in the global economy impacts health. Miraculous-sounding developments that appear as if they are scenes from science fiction movies will enable patients to use nano-enabled medical products for new bones and organs from their own stem cells to defeat cancer or degenerative neurological diseases! And, engineered or manufactured nanoparticles are believed to traverse such historically mysterious places as the human placenta and the blood–brain barrier [6], thus offering new possibilities for treatment of illness or disease. Some of these treatments will use nanoparticle drug carriers to move between cells; others will enter cells such as those in tumors in order to alter them. Widespread application of nanotechnology in health care for drug delivery, and applications that regenerate tissue, teeth, and cells will redefine “health” and “disability” under law and in daily life by changing the nature of treatment for disability and redefining the population considered disabled culturally and under law.



**Figure 1.2** Nanoparticles always existed. Photo source: Dr. John Howard, Director, US National Institute of Occupational Safety and Health, PowerPoint presentation at the United Nations ILO, Geneva, Switzerland, November 2008.

According to the White House Office of Science and Technology Policy (OSTP) created by the US Congress to advise the president of the United States about major issues in science, whole careers will someday be dedicated to advancing human understanding about the so-called *bio-nano interface* [7], then applying this understanding to medicine and commercial products, and then creating new methods to study its impact [8]. New uses for old materials, such as gold, silver, and diamonds, have already brought a breath of new life into old industries, where supply has diminished but not depleted, because industrial processes at the nanoscale require so much less in order to deliver their final product. And the same attributes of nanomaterials, although in different substances, are already in industry, making airplanes lighter and stronger, producing eyelashes longer and more alluring, and constructing houses and buildings that can withstand natural disasters.

Having new materials is very exciting! New materials and new methods for using those materials offers rejuvenating promising for commerce, for stock exchanges, for startup companies, for large-scale employers who use nano-enabled products, and for the future of humanity. Yet, the ubiquitous character of nano-enabled products may be a weakness as well as a strength. The very attractive feature of small nanoparticles that can traverse previously impermeable barriers also means that little is known about how to stop them from migrating, how to predict where they will go on their own despite human calculations, or how to predict which substances can interact as a trigger to make the nanoparticles cluster together or adhere to other substances.

Mystery surrounds the behavior of nanoparticles and the subsequent impacts. Estimating risk is problematic because so little is known about the emerging field of nanotoxicity. Therefore questions about so-called fate of nanoparticles loom important about controlling risk at the nanoscale. Thus, short-term benefits for the intended use of manufactured nanomaterials (MNMs) must be followed by vigilant attention to health and environmental concerns throughout the life cycle of the products in order to discover and understand results that cannot be predicted yet. Trying to stop nanoparticles from continuing to migrate elsewhere once the desired job is done, and then determining whether they cluster together or whether their collection in large clusters is useful, presents many questions. Some of these questions are already well understood about the same substances in a larger size, but the established rules of science do not apply to the same substance in the nanoscale.

Debating this dilemma of how to regulate unquantifiable risk in order to protect public health, while also protecting a culture of innovation, has been the hallmark of the first decade of juridical discussion regarding the application of nanotechnology to daily life [9]. There is an important but inescapable policy dilemma: whether unquantifiable risks can coexist with public health protections as the market expands for needed nano-enabled medicines and a wide variety of consumer products. Debate has not stopped the infusion of revolutionary nanotechnology into products across society. Nor has this debate stopped jurisdictions from writing laws about nanotechnology. Scientists and governments agree there are unknown risks. Examples include the Swiss Federation (Precautionary Matrix 2008) Royal Commission on Environmental Pollution (UK; 2008), the German Governmental Science Commission, public testimony sought by the US National Institute for Occupational Safety and Health (NIOSH; February 2011), the Organisation for Economic Co-operation and Development (OECD) working group (since 2007), the World Health Organization (WHO) working group (in process of formation), the International Organization for Standardization (ISO), the World Trade Organization (WTO), several industrial groups, and various nongovernmental organizations (NGOs). Legislators, therefore, have begun drafting laws despite the absence of clear and compelling information. Legislation is keeping surprisingly close pace with the rapid pace of emerging technology through global partnerships to draft treaties about nanosafety. The

form of multinational regulation and its substance are reshaping government globally.

One of the fascinating features of nanotechnology is that it is not born of any specific discipline; the science is inherently interdisciplinary, and therefore the governance of social impacts must also be derived from a cluster of disciplines that have not previously worked closely together. This requires also a multidimensional approach to charting and measuring the social impacts. Lawyers can contribute information to this discourse [10]. Good legal training can inform every phase of this process. Creativity, however, is not random; cultivating innovations that save money and reduce duplication of efforts requires much forethought as well as new ideas. This means that policy documents and their regulatory content must be filled with more than compromise; it requires training outside one's own professional career path and then applying the lessons learned from that training outside of the academic bubble. Bringing together a diverse group of thoughtful people to create an accurate big picture is therefore one of the great challenges for people who wish to maximize the benefits of nanotechnology's revolutionary change. One former staffer in high-level science policy complained, "People in grad school end up being in their own little bubble."



**Figure I.3** The fascinating convergence of public health technology and law, prepared for the doctoral thesis "Forecasting Nano Law: Risk Management Protecting Public Health under International Law" by Dr. Ilise L. Feitshans, Geneva, Switzerland. Special thanks to the thesis advisor, Dr. Mark Hoover, NIOSH, USA.

**Choice of Outcomes for Regulatory Policy**

Key public health policy questions to explore regarding nanotechnology, nanomedicine, and their impact upon human health worldwide include:

- Rethinking the role of key illnesses and injuries in terms of the global disease burden when setting global health priorities
- Rethinking notions of informed consent and the right to refuse consent once presymptomatic testing diagnosis and treatment using nanomedicine become a reality, demanding new consent paradigms
- Rethinking the role of rehabilitation as a source of return to gainful work among aging populations who might not have considered working without the benefits of nanomedicine

This dilemma applies across many disciplines, including but not limited to, law, bench science, municipal bureaucracies, and academia. Science policy emerges with great difficulty when people from these various narrow tracks attempt to work together for the first time, as each discipline tries to surmount the learning curve for respecting the disciplines in other professions. International projects that require a delicate mix of law and science in global health diplomacy are therefore on the front lines, at the beginning stages of major bilateral and multilateral partnerships. At the highest levels, decisions can have lasting influence, but measuring the direct impacts is difficult when evaluating the long-term impact of research or diplomacy. Each facet of the new synthesis of disciplines for nanotechnology law and policy requires input from people who think logically about how to solve problems, how to work in teams, how to think across disciplines, and how to do so with respect for parallel professions. The seemingly impermeable barriers between disciplines in the life sciences, physics, and jurisprudence across professions must therefore also be crossed in order to create meaningful policies that are both workable and fair. This book attempts to prick a hole in the graduate school “bubble” that keeps people away from related disciplines, without destroying the sheltering structures that enable each discipline to flourish and gather stronger expertise in their own right.

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Generally, the concept refers to the impact of nanoparticles upon the behavior, outcomes, and sustainability of ongoing biological processes. Use of the term “bio–nano interface” as an anchor for a sound legal definition remains limited, however, by the primitive state of the art regarding human understanding of these potential interactions. Despite the reality that some nanoparticles may have a biological life of their own that is not part of existing biological systems, setting forth the parameters of that interaction under law would be premature. A future legal definition of biological systems may be altered to reflect knowledge and discoveries that do not exist now but that are projected on the research horizon. For example, nanoparticle clusters that gather along the corona of proteins and the so-called fate of such nanoparticles may resemble existing biological processes that are not yet understood.

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