

## Short Communication

# Ten Years After: Ethical Legal and Social Impacts of Nanotechnology

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## Abstract

In 2016 nanotechnology was proclaimed yet again as a "revolution" for science and industry. Costs and benefits of applying this novel technology have been debated in detail throughout the past decade before many legislatures. Ethical and social implications of those costs and benefits have reached the level of debate the Parliamentary Assembly of the Council of Europe, United Nations agencies and the legislatures of every nation on the planet. Planning and implementation of laws regulating commercialization of nanotechnology and the introduction of nano-application products into daily life have proceeded briskly throughout the past decade. Scientists who wish to understand law and policy about nanotechnology therefore need a concise description of important laws that have emerged in the wake of this revolution. This article describes emerging laws and briefly outlines some ethical issues that are raised by these developments. This article concludes that although scientists must be vigilant against premature data evaluation because the law is changing rapidly, the time has come to become familiar with laws if they wish to understand or influence future nanotechnology law and policy.

## Scientists Require a Policy Tool to Track Nanotechnology Developments

The long awaited wrap-up of European efforts called NANOREG will occur in early June 2016. At the time of this writing, therefore the final draft is a mystery. The author of this article views the pending meeting as a window of opportunity, however, for reflection on the immediate past of nanotechnology regulation. It has been a very busy decade. NANOREG and its parallel programming in Asian African and American regions with a mandate for multilateral regulation had not been authorized when the decade began because, the debate whether there should be special laws and regulations governing nanotechnology had not yet been resolved. The NANOREG mission to create a unified regulatory regime throughout the European Union underscores the reality that there is emerging new law governing nanotechnology [1]. The old debate whether there was a need for special laws governing nanotechnology applications began with the start of the 21st century. Some commentators feared that legislation would stifle innovation; others feared that unquantified risks would overtake the benefits of nanotechnology. But ten years later, the volume of new text that has been written by drafting bodies concerned with nanotechnology applications makes it clear the question is moot. More than the seeds but the actual seedlings of nanotechnology

law are growing and an international regulatory network, rife with inconsistencies, is well underway. Yet, stakeholders in the general public and the scientific community remain largely unaware of these changes. Therefore stakeholders also may be unprepared for the operationalization of these changes. None the less, Nano laws are everywhere. And many of those laws are here to stay.

## Costs and Benefits of Expanded Applications for Nanotechnology

Many people are just now discovering the beauty and pitfalls of nanotechnology applications in commerce, but development of the innovative promises of nanotechnology is not really news. Implementation of science laws and policies has started, regardless whether research scientists, policymakers or the general public know about it. "Technology is the fourth industrial revolution", declared Klaus Schwab, Founder and Executive Chairman at the World Economic Forum in Davos, 2016. [2] He further 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". This view is as old as the USA National Nanotechnology Initiative (NNI) itself, founded by President Clinton in the twentieth century. That first President's report called nanotechnology a "revolution" in 2000, because of the rare an unprecedented behavior by materials at the nano scale that changes their chemical properties. In 2000, Presidential Advisors in the USA proclaimed nanotechnology the 'Next Industrial Revolution' [3].

Costs and benefits of nanotechnology applications have been debated in legislatures and discussed in scientific literature for over a decade. These debates were summarized in the report "Nanotechnology: Balancing Benefits and Risks to Public Health" [4]. For example, the reduced costs of precision medicine using

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nanomedicines that can be transported between cell walls or enter the semi permeable membrane as drug delivery systems has the benefit of making cancer therapies and cell regeneration affordable to a variety of populations. But even the best of mathematical models [5] cannot empirically quantify the risks in the context of other illnesses, treatments, cumulative exposures in the environment or pre-existing medicines. Carbon nanotubes may impact ROS generation in a manner that has called into question damage to lungs reminiscent of asbestos. So too, the remarkable antibacterial properties of nanosilver have been litigated in the USA because the benefits of longer shelf life for foods and rodenticides for textiles may be offset once nano silver enters the ecosystem. The very properties of nanosilver that are desirable in commerce may have significant new impacts on the environment. Such data required for baseline risk assessment and long term risk management can only emerge after real-time use across many years [6]. Policymakers therefore view the benefits of promising nanomedicine delivery systems as also offering a dilemma. The German Advisory Council on the Environment (SRU) stated: “The possible consequences of this use have not been sufficiently studied. There is a danger of a widening gap between the technological development and the knowledge about risks ...” [7].

### Ethical and Social Concerns Impacting Nanotechnology Laws: Convergence, Empiricism and Nanoinformatics

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. Rather than a unidimensional approach to law policy and scientific research that is compartmentalized into silos, nanotechnology requires a multidimensional approach to charting and measuring the the social impacts. Each of these disciplines is complex in its own right. Laws that have emerged in the recent decade therefore reflect the convergence of three key areas— 1. Public health principles involved in medicine, 2. Implications of nanotechnology within the context of a variety of new technologies and 3. Emerging universal values regarding health and the environment embodied in international human rights laws. Thus the developments of the past decade make the case for interdisciplinary training and transdisciplinary collaborations that will guide the policy, curricula and implementation of laws throughout the 21<sup>st</sup> century [8].

Examining the context of nanotechnology research reveals its fascinating foundations, but also shows its weakness: each of the major spheres of activity, public health, emerging technology and the law of human rights is complex. Thus the interaction of these three spheres of activity is mysterious and complex. Source: Doctoral thesis Dr Ilise L Feitshans JD and SCM and DIR "Forecasting nano Law: Risk Management Protecting Public Health

Under International Law" Geneva school of Diplomacy Geneva Switzerland, Prize for the Best research in social medicine and prevention University of Lausanne 2014.

This new state of the art for nanotechnology and the policymaker's

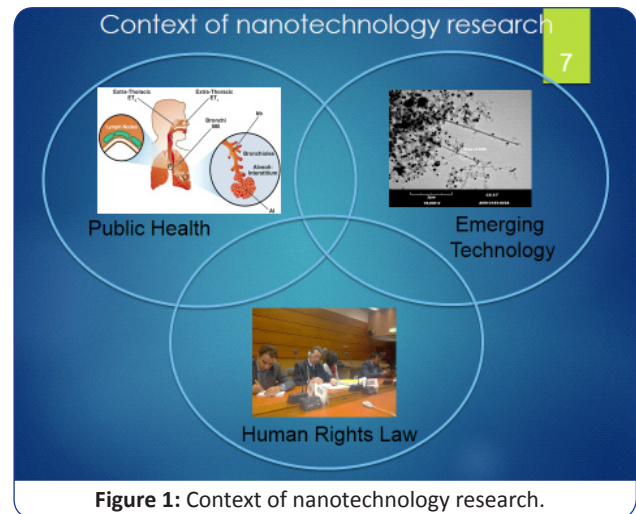


Figure 1: Context of nanotechnology research.

increasingly keen interest in acquiring an awareness of its impact for society provides new challenges for interdisciplinary collaborations and offers exciting opportunities that were fantasized but impossible to realize decades ago. This is a logical progression, however, from the declarations within the scientific community that nanotechnology is a “revolution”, a working assumption that has remained intact across time from the first report of the National Nanotechnology Initiative (NNI) in the USA to the President of the United States in 2000 to the 2015 publication [9]. Similarly, the Council of Europe has moved away from its previous call for a moratorium towards multidisciplinary questions that are difficult to measure, but must be asked consistent with its human rights mandate under the European Charter for Human Rights that forms the base of its operations.

Ethical issues concerning the survival of the planet examined at Council of Europe bioethics meetings regarding the convergence of several new technologies tried to grapple with legislative needs to monitor implications for society. In 2015 the Council of Europe Bioethics committee has taken this analysis a step further, by exploring emerging technologies and human rights. Their bioethics working group included nanotechnologies in its deliberations regarding convergence. Their deliberations revealed that members of academia as well as policymakers are naive about the extent those nanotechnology applications, but their working group posed basic hard questions. The working group expressed concern about survival of the human species, which might be replaced by self-replicating artificial intelligence. Their working group examined the convergence of various new or novel technologies at the same, and then has questioned the collective impact of these developments on daily life, the psychology of collective norms, political will and the quality of life in light of the Council of Europe's European Charter for Human Rights. Such discourse would have sounded abstract at best, if not science fiction, a few years ago, but now has taken center stage in European policy discourse.

Measuring and collecting data about exposures for use in the context of regulatory governance of nanotechnology applications has therefore advanced in the last decade. Projects for the study

of nano safety and determining the impacts for exposure of aerosols and the thresholds for safe exposure have been created embracing all phases from the laboratory to emission into the general environment, including life cycle studies. [10] For example, the "Advanced REACH Tool" (ART) is one of several exposure models for exposure assessment that can be folded into an existing framework in a "risk mitigation" process. [11] Another approach is the application of physiologically based pharmacokinetic ("PBPK") modeling offered as a tool for biologically based nanoparticle risk assessment, which studies the "bodily absorption, distribution, metabolism and excretion of drugs and chemicals". [12] Alternative models, specific for nanosafety include the Stoffen manager Nano Version 1.0 [13]. The criteria for evaluating the applicability for such tools should be embedded into the risk mitigation process, but their importance will vary in each scenario. Each of these tools is however, a product of international scientific collaborations that are based on government funding, with a view to creating robust parameters for emerging regulations

Nanoinformatics has also quickly emerged as an important branch of data management. In 2011 the NANOEH meeting in Boston USA convened a training workshop on the subject of nanoinformatics that embraced legal, statistical, epidemiological and public health data. The group confronted lexicon issues and definitions of terms that sound similar but have different meanings in their professional context across disciplines. Detailed exploration of the problems regarding common language the interface between nanosafety proposals and the need for robust methods to accurately and reliably measure the impact of workplace exposures has become a fundamental quest in subsequent implementation strategies, especially after the completion in 2010 of the major roadmap document for 2020 and beyond [14]. In 2014 [15] the expanded working definition of nanoinformatics discussed at the Nations Science Foundation meeting in Washington DC included, " the science and practice of determining which information is relevant... implementing and developing effective mechanisms to collect, validate store, share, analyse, model and apply the information.. (Eventually) conveying information to the broader community" Multi-factoral concerns for

the planning matrix include a wide variety of health constituencies in addition to workers, managers researchers, educators media consumers and the legal community in this informatics model [16]. This provides an important backdrop for discussions of nanotechnology impacts across a large spectrum of disciplines that have not previously communicated directly. Such informal initial forays across disciplines as seen in the past decade may ripen into legislative mandates for future Tran's disciplinary collaboration.

### Emerging Laws of Nanotechnology

The photo below captures the essence of one of the most metaphysically stunning moments in jurisprudence—the moment when an IDEA becomes a LAW.



**Figure 2:** UN General Assembly NYC 2006 voting in progress to shape international law

Regulators, lobbyists, legislative drafter's research scientists and the general public worldwide can ask, "Will there be such a global convention governing nanotechnology?"

Dr John Howard, Director of the USA National Institute for Occupational Safety and Health (USDHHS/CDC/NIOSH) was prescient when he predicted that nanotechnology as a game-changer in at least two public speeches: one at the 25th anniversary of a NIOSH Education resource center [17] and second, as Guest Lecture at Safe work, International Labor Organization (ILO [18]) Geneva Switzerland at the invitation of the Coordinator ILO Encyclopedia, of Occupational Health and Safety in 2008. In 2004, the presentation "NIOSH Agenda for the New Millennium," analogized nanotechnology to a train having left the station and that the stakeholders in the general public were like the commuter who was running after it to catch up [19] by the time of his speech in Geneva in 2008, the progress was quite startling. There were more nanotechnology applications of products already in commerce in 2008 than could fill several lecture slides, and the revolutionary implications of manipulating nanoparticles for medicines and new products were becoming clear. He correctly predicted that nanotechnology applications would constitute trillions of dollars of commerce in the global economy by 2015 [20].

Turning the political will of opposition to nanotechnology into a driving force for innovative flexible regulations is probably the hallmark trend of the past decade. Opposition to the widespread commercialization of nanotechnology crested in 2011 when the Council of Europe prepared a draft report for its Parliamentary Assembly, accusing nanotechnology of presenting new dangers to the environment [21]. That document was originally planned to support calls for a moratorium on research, development and applications of nanotechnologies in commerce. But, since 2008 research on anti cancer drug delivery systems had already offered promising results; commercialization of nanotechnology applications had advanced far beyond the research and development in planning stages that would be required for a moratorium. Fortunately, this misbegotten notion was changed and a balanced approach recommending a series of Pan-European and international

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reciprocal agreements was offered to the Parliamentary Assembly instead of offering a moratorium. The reality that Council of Europe Parliamentarians who have access to current data entertained the notion of a moratorium, however, suggests that policymakers and the general public were unaware of the magnitude of the assimilation of nanotechnology into general commerce around the world. Acceptance of the Council of Europe report in 2013 by the Parliamentary Assembly with its recommendation for follow up treaty-based activity also underscores the importance of developing nanotechnology laws as a source of activity and paid employment for a broad spectrum of scientists, researchers, data specialists, policymakers, litigators and legislative drafters.

Thus, there has been a shift in the law and policy discourse. Nanotechnology governance debate [22] has moved away from whether to regulate [23] or the urgent need for regulation [24]. Instead, the form and text of legislation is taking shape. A sea change in the maturation of the law, from the days of a twinkle in the eye of a few visionaries who thought it might be a great idea to fund pilot projects about nanotechnology has been overtaken by the demand for intellectual property safeguard, marketing rules and nanosafety regulations. Even stakeholders who initially disagreed with regulation regarding nanotechnology are compelled to participate in the discourse and major multinational projects, such as NANO REG in Europe have been well funded, convened their working groups and their drafts are beginning to take shape. The new decade has seen well vetted activities at OECD, WHO UNDP, and a host of voluntary organizations such as the ISO that have attacked legal problems posed by nanotechnology at every level. One example of the timid first attempt to regulate without touching upon the deeper issues is the WHO Guidelines on "Protecting Workers from Potential Risks of Manufactured Nanomaterials" (WHO/NANO), (Background paper) 2011 [25]. Reflecting detailed regulatory proposals in the USA agencies such as EPA and FDA in partnership with regulated nanotechnology industries, additional professional societies and trade associations have made their views known in draft guidelines and proposed legislation. A voice for exists too for small enterprises that play such a crucial role in the research and development of nanoproducts via organizations such as Nanobca.org, a consortium of small and middle sized nanotechnology enterprises. These nongovernmental branches of legislative communication and policymaking represent coalitions that together to have a more effective voice in policymaking and to share information about emerging nanogovernance strategies in different jurisdictions. On the legislative agenda, each continent has seen similar activity, and many nations have a clear agenda of their own. Thus the hallmark of this period is recognition that regulation is a necessity and that charting the course of the regulatory framework. As scientific data emerges that enables nanotechnology definitions under law to become more refined, the emerging policy demand gives way to the overarching need for harmonization of the law across borders.

Questions about the nature of disease and its treatment, and the prejudices encountered by people who suffer from illness will emerge anew and force collective rethinking about early diagnosis and prophylaxis of diseases. Therefore, an unprecedented opportunity exists to benefit from both the nanotechnology revolution and the revolutionary social change that recognizes individual human potential under international laws preventing discrimination against people with disabilities, undermining women's health or negatively impacting the health of older people. The legislative mandate of the next decade will require harmonization not only of nanotechnology laws themselves, but making the results of those laws consistent with international accepted norms regarding discrimination and disparate health impacts.

Therefore a new focus is emerging regarding the impact of nanotechnology applications and nanomedicine opportunities upon vulnerable populations. Nanomedicine will alter the meaning of health and disabled in daily life, but the bioethical structures just coming into place have not yet prepared to address these concerns. Transition from a standardized view of one size fits all medicine to meet personally individualized needs will be the key focus of the new precision medicine that is expected to follow the advent of nanomedicine in the next decade, but these issues have not yet taken center stage for law and policy attention. Emerging discourse in Europe about access for vulnerable populations, for example access to reproductive technologies for the LGBT populations is consistent with deliberate efforts to remove embedded sexism and racism from regulatory frameworks that have emerged in the

United Nations system For example, The World Health Organization has documented health disparities that exist between men and women (2009) and concluded that women's health lags behind their male cohorts at five key stages of the life cycle.

It remains unknown but an intriguing legislative policy question, to what extent nanotechnology in the workplace and also to what extent the cumulative effect of long term exposures to nanotechnology applications in the ambient environment will either exacerbate or remove those disparities. Women's health disparities will become more difficult to grasp after nanotechnology takes hold because the extent of nanoparticle exposure in cosmetics, food, daily exposure to consumer products (such as automobile tires, paintings and coatings and refrigerators used in food transport) [26]. This potential cumulative effect will be more complex than any synergistic effect that epidemiology has attempted to measure before. These concerns are exacerbated because they have been so long ignored in the occupational health context, where their ill attention to women's health, embedded sexism in some occupational health exposure limits that have relied on male models as a benchmark, and in reproductive health where the literature is fraught with emotional and politically charged ambivalence in every nation [27]. Nanomedicine will require society to rethink ancient notions that are the building blocks of social constructs that confine the societal treatment of vulnerable populations.

## Conclusions: Embedding Empirical Knowledge across Disciplines Instead of Embedded Prejudices in a Harmonized System

In sum, although scientists must be vigilant against premature data evaluation because the law is changing rapidly, the time has come to become familiar with laws if they wish to understand or influence future nanotechnology law and policy. The question may continue to loom whether the law leads or follows the scientific and commercial drivers for nanotechnology, but that question is fading fast into the past of nanotechnology regulations. In the past decade, new programs throughout the world mean that regulation is here to stay. Turning the political will of opposition to nanotechnology into a driving force for regulations is the hallmark of the past decade.

Thus, the trajectory of nanotechnology's impacts for public health, the environment and global economic daily life points towards increased regulation despite worldwide hesitation at the outset of this decade. Yet, the plethora of draft nanotechnology laws in the past ten years has become a morass. New nanotechnology laws and modified amendments to pre-existing legislation exist in every nation, in many municipal subdivisions and at the international level. Additionally, professional organizations have offered guidance through working groups, sometimes in partnership with governments. The inevitable conflicts of law from this incoherent mushrooming of new and modified legislation is likely to impede the very commerce it proposes to foster; it can only be resolved by the creation of a unified regime governing nanotechnology. The question looming ahead for the next decade of nanotechnology therefore will be, whether a United Nations Convention regarding nanotechnology will emerge, similar to the convention preventing discrimination based on disability. Whether one opposes global United Nations convention or not, the reality that an internationally harmonized program for nanotechnology law is likely to dominate the regulatory agenda for the next decade. Data is beginning to mature, the key questions are becoming more refined and methods of measurement are becoming more robust. At the same time, increased international demand for regulation has caused a rethinking of the role in society played by regulatory governance of risk and risk management programs.

In the decade ahead, practical concerns that seemed abstract in the recent past have become real concerns: the cost and access to nanomedicines, the methods requiring human volunteers in clinical trials and in a variety of exposure studies including inhalation studies of volunteers exposed to nanoparticles and at the end of the process, the needs and access of vulnerable populations and protecting the integrity of the system by preventing medicrimes. The time is ripe to ask about the scope of regulations, whom to include in protections, now that the notion that no one will regulate nanotechnology is a concept from the past. An important task for the subtext for these laws is to use the opportunity to write in the wake of the nanotechnology revolution in order to remove (rather

than replicate) embedded sexism and racism from regulatory frameworks. This will require the admixture of multidisciplinary tools for big data set analysis, computer modeling, robust empirical science, and gaps analysis to be placed into one decisional cauldron, in order to forge a harmonized regime for public health protection for researchers, exposed workers, commercial enterprises and the ecosystem. As heralded by John Howard, (USDHHS/CDC/NIOSH Director) *Get aboard the train before it leaves the station!*

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