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The need for practical regulation of developing commercial nanotechnology

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1. Introduction

Nanotechnology began as a theoretical concept in 1959 in a talk by Nobel physicist Richard Feynman. By the 1980s the theory of nanotechnology became more of a fact when new microscopes were developed allowing scientists to see nanometers, down to one-billionth of a meter (Brown, 2008).

Commercial development of nanotechnology has expanded significantly as can be seen by the fact that between March 2006 and August 2008 the total number of consumer nanotechnology based products manufactured in the US rose from 125 to 426. In Asia the increase has been from less than 40 products to 227 in the same time period (Project on Emerging Nanotechnologies, 2009). A trip through Google with the search term “nanotechnology development” reveals approximately 5,320,000 different web sites (Google.com, 2009).

It is submitted that nanotechnology is a rapidly growing phenomena that has had and will have profound impact on man and the environment. Some of the impact will be good, especially in the new consumer products becoming available in all kinds of areas from new roofing insulation materials to new, incredible medical devices (McConachie, 2008). It is anticipated and predicted that this same nanotechnology development without regulation to protect the environment, health and safety (EHS) will result in profound and disturbing harm to man and the environment (Renn & Roco, 2006). The purpose of this chapter is to identify nanotechnology regulation that exists, present the rationale for maintaining *status quo ante* as well as for the promulgation of regulation promulgation of further regulation and, with an understanding of what the risks are likely to be, suggest that because there is now no binding regulation of nanotechnology mankind needs to take appropriate action before the EHS goes through its 9/11 event.

2. The State of Nanotechnology Regulation

On October 1, 2007, Dr. Patrick Lin, director of the Nanoethics Group in an article posted on the Nanoethics Group web site compared the development of nanotechnology with playing with fire; this because there is inadequate information and knowledge on the proper control of nanoparticles and what the dangers might be if there is a release of nanoparticles into the

atmosphere. Dr. Lin proposed that sufficient evidence exists to predict the existence of toxicological risks from nanotechnological exposure. As a result in his view nanotechnological particles should be regulated (Lin, 2007).

Ironically, there is at the time this chapter is being prepared, in November 2009, an almost total dearth of governmental regulation of nanotechnology and nanoparticles. Indeed, it was not until December 2006 that any government in the world enacted binding law to regulate nanotechnology, and that government is the Berkeley, California City Council in the US (Phillips, 2008). The City Council promulgated new law amending its hazardous materials law to include nanoparticles (Elvin, 2008). This local ordinance required researchers and manufacturers to report to the City of Berkeley what nanotechnology materials are being worked with and how the articles are handled to maintain safety (Elvin, 2008). Another US city, Cambridge, Massachusetts, considered the same kind of local ordinance, but as of July, 2008, had only gone as far as voting to accept recommendations of an advisory committee to track developments and changes and report back to the council (Bergenson, 2008). Whether it is coincidence or foresight that the only two cities to have preceded this far in nanotechnology regulation happen to be home to two of America's outstanding universities, Harvard and the University of California at Berkeley, is unknown.

As of February 2009 twenty-two states in the US had passed nanotechnology legislation. The various states legislation encompasses grants for research, business development and the like. Not one of these state statutes addresses any regulatory aspect of nanotechnology (Nanotechnology Statutes, 2009).

In the U.S., President Bush in 2004 signed into law the 21st Century Nanotechnology Research and Development Act (21-NRDA, 2004). While 21-NRDA contains important provisions for research and development, again, the Act does nothing to regulate by law nanoparticles. In 2007, and again in 2009 the US House of Representatives passed HR 554, the National Nanotechnology Initiative Amendments Act of 2009. The House passage of HR 554 in 2009 was a part of the February 2009 stimulus package. In both 2007 and 2009 the House without amendment passed the NNIAA. Ironically, the NNIAA has not been reported out of Committee in the Senate as of late August 2009. There are no hearings scheduled for HR 554 by the Senate Committee on Commerce, Science, and Transportation (HR 554, 2009). Even if the US Senate does take action with the NNIAA, the interesting aspect of the 2009 Amendments is that the bill contains any number of provisions for reporting, encouraging, studying, and advancing nanotechnology, while at the same time recognizing there are safety issues in nanotechnology development, and yet there is no new regulation of nanotechnology development or use in the 2009 Amendments.

The perceived need for nanotechnology regulation in the United States is not great while in Europe the official view of the European Commission is that no new regulations in the EU are needed because existing regulation leaves no regulatory void. According to the official responsible for regulatory aspects of nanotechnology at the European Commission, Cornelis Brekelmans, "[w]e are not in a regulatory void." At the Second Annual Nanotechnology Safety for Success Dialogue Workshop in October, 2008, Brekelmans stated that "We may decide to not authorize a product," and later the Commission might review, modify, or cancel an authorization (EurActiv, 2008).

Mr. Brekelman's perspective was challenged at the same Workshop by the leader of Greens/EFA, Axel Singhofen, who argued that "the reality is not quite how you [Brekelmans] present it." Contrary to Mr. Brekelmans stated views, Mr. Singhofen

advocated that developers of nanotechnology products should have to prove their safety before being allowed to enter the market (Azonano, 2008).

In both the US and Europe the prevailing government view either evidenced by word or lack of activity/interest is that the case for nanotechnology regulation of products being developed has yet to be made. On the other hand there are a number of non-governmental organizations (NGOs) such as Greens/EFA, Greenpeace and the International Risk Governance Council (IRGC) that hold to a different line. In a 2006 article published in the *Journal of Nanoparticle Research* entitled "Nanotechnology and the Need for Risk Governance," Renn and Roco held that the novel attributes of nanotechnology require the development of different routes to determine benefit-risk since regulation has not kept up with the development of new nanotechnology products (Renn & Roco, 2006).

3. A Look at the Risks from Nanotechnology

The lack of safety regulation of nanoparticles persists despite considerable work and research. In 2006 the International Risk Governance Council (IRGC) hosted a workshop in Switzerland concerning the "Conceptual Risk Governance Framework for Nanotechnology." The participants agreed that nanotechnology is divided into four broad generations of technology products and processes (Renn & Roco, 2006). With each successive generation the risks increase because the nanoproducts become more active and complicated.

The first generation, post 2000, consists of passive nanostructures. These steady function, or passive, nanoproducts consist for example of coatings, ultra precision engineering, polymers and ceramics. On March 5, 2008 Industrial Nanotech, Inc., announced that it was entering the commercial roof insulation market with lightweight thermal insulation based on its patented product line, Nansulate®, a passive nanoproduct (McConachie, 2008).

The second generation of nanoproducts, in the 2005 time frame, consists of active nanotechnology, which might include transistors, amplifiers, targeted drugs and chemicals, nanoscale fluids and laser-emitting devices. An active nanostructure product changes its state during operation. By way of example, a drug delivery nanoparticle changes its morphology and chemical composition. The new resultant state may also be subject to change from other changes in the biological, electronic, mechanical and magnetic properties (Renn & Roco, 2006).

The third generation or stage to begin next year, 2010, will be a system of nanosystems made up of various syntheses and assembling techniques. The third generation in medicine would include the production of an artificial organ made up of nanoscale cell tissues and scaffolds for cell engineering. In the area of nanoelectronics possible new devices would be based upon variables other than electrical charge. Third generation products with potential high risk include the behavior of engineered robotics, evolutionary artificial organs and modified viruses and brain cells (Renn & Roco, 2006).

The fourth generation, projected to begin in 2015, is where a heterogeneous molecular nanosystem has a specific structure and yet plays a different role. It is envisioned that molecules in devices will be used in new functions with new functions and structures. Nanomedicine products of the fourth generation would include cell aging therapies, stem cell nanocell therapy new genetic therapies (Renn & Roco, 2006).

Nanotechnology is about the creation of new products made up of new parts or ingredients to be used in new ways. In determining whether going forward nanotechnology presents sufficient risk to EHS so as to either regulate or limit its admission to the marketplace, knowledge of what products based upon nanotechnology are being distributed in commerce and what products are being developed for use in commerce is a critical must. A great deal of the problem as pointed out by Renn and Roco is the "... uncertain/unknown evolution of the technology and human effects (for example, health changes at birth, brain understanding and cognitive issues and human evolution), as well as a framework through which organizations and policies can address such uncertainties" (Renn & Roco, 2006). Put another way, the extent of the dangers from nanotechnology development have not been fully appreciated because of the fact that the properties of nanomaterials are not predictable based upon known laws of chemistry and physics. What one thinks *should happen* may very well have a completely different result in a nanotechnological base product. Part of the reason for the quite possible different distinctions, and thus the risk, is the fact that structure in a nanotechnology product is quite important in how both biological and physical behavior play out (Davies, 2006).

Citing Oberdorster and Maynard, Davies states:

"We do not know enough about the toxicity and environmental effects to know whether ... [nanotechnology] materials are also different in these respects, but it is likely, for example, that the toxicity of ... [nanotechnology] materials is more related to their surface area than to their weight" (Davies, 2006).

Another perspective of the EHS risks that come from nanotechnology development are concerns about how penetration of human skin by nanoparticles, inhalation of nanoparticles effecting the lungs and respiratory system, the breach of the blood-brain barrier by nanoparticles in the bloodstream may all cause harm to man. As noted by Brown, a recent experiment reported in *Science Daily* that showed men's socks with an "odor fighting" feature when washed normally released ionic silver which after traveling through the wastewater process and entering natural waterways could very well harm the water ecosystems. This example shows that the law of unintended consequences clearly applies in any evaluation of EHS risks from nanotechnology (Brown, 2008).

4. A Worst Case Scenario?

There has not been a recorded serious EHS event caused by nanoparticles. The technology is new and commercial development is only now becoming common. There has been research into what in the real world might be viewed as a worst case scenario. Research by NASA (Life Sciences), Wyle Laboratories and UT Medical School (Pathology and Laboratory Medicine) in Houston, Texas inquired into the toxicity of carbon nanotubes to the lungs of mice. Five mice treated (under anesthesia) died within one week. All of the nanotubes introduced epithelioid granulomas, or tumor-like nodules, in the lungs. In some instances this resulted in inflammation of the lungs within 7 days. The mice that survived were sacrificed at 90 days and subsequent examination showed pronounced nodules and extensive necrosis (Lam et al, 2004). In the real world such unprocessed nanotubes are quite light. They could become airborne if released and potentially reach the lungs.

The researchers here concluded that carbon nanotubes are “more toxic than carbon black and can be more toxic than quartz” (Lam et al, 2004). The nanotubes used in the test were processed under different conditions with different heavy metals, such as nickel, iron and yttrium.

A nanoparticle that is popular in medical applications consists of metal nanoshells, nanoparticles that are tunable to electromagnetic radiation. The typical metal nanoshell is spherical core, i.e. silica, that is surrounded by a thin – often gold - shell. Such nanoshells are thought to be very beneficial in reducing carcinoma of the breast. Cancerous cells incubated and exposed to infrared light died while cells with no nanoshells were unharmed (Hirsch et al, 2003).

No one knows whether such nanoshells are safe. No one knows what happens to the nanoshells when cleared from the patient’s dead cells by the immune system, or when the nanoshells are discharged or released. Indeed, no one knows what happens to the patient over the long term.

In 2003 the specter of nanotechnology disaster took a new turn when Prince Charles of Great Britain asked the Royal Society, the world’s oldest scientific club to have a dialogue concerning the enormous risks when faced with self-replicating. This examination of the “grey goo” problem that commenced in 1986 when Dr. Eric Hexler first began describing the danger of the grey goo in the context of nanotechnology nanotechnology (Radford, 2003). By 2004 The Prince and Dr. Hexler both recanted on the idea that there is some valid science suggesting that grey goo will likely or even ever be close to rescue. Prince Charles reduced his criticism of nanotechnology from grey goo, acknowledging that it was quite likely such would not take place (Sheriff, 2004). Dr. Drexler, who is regarded as a leading early nanotechnology expert, lost considerable reputation when Richard Smalley, the Rice University chemist who shared the 1996 Nobel Prize for discovering Buckminsterfullerene, called Drexler out in late 2004 by saying Drexler was terribly wrong in predicting grey goo, and this just two days before President Bush signed into law the 21-NRDA in which nanotechnology was recognized as an important link to the future (Regis, 2004).

Even without gray goo being a realistic and serious EHS risk, there are sufficient unknowns to the safe use of nanotechnology so as to make credulous the concerns that developing nanotechnology, especially the third and fourth generations must be considered to contain risks that are not fully appreciated by man.

5. Nanotechnology Products Today

A recent Internet posting contained the first widely available inventory of nanotechnology consumer products (Project on Emerging Nanotechnologies, 2009).

There were more than 1,000 products in the Consumer Products Laboratory in August of 2009. The total number of nanotechnology based consumer products has increased 376 percent since 2006.. A total of 483 companies produced nanotechnology products located in 24 countries. By product category the most prevalent nanotechnology consumer product is in health and fitness. The growth of health and fitness products between 2006. 2009 was from slightly less than 150 to more than 605 of the total 1,015 products. By contrast only one other consumer product category, home and garden, had more than 150 products last year. Within the eight major product categories are found sub-categories. One sub-category of Home and Garden is Paint. Multi-functional products are categorized as “Cross Cutting.”

“Coatings” is the sub-category of Cross Cutting, which means that a Coating consumer product based upon nanotechnology will have more than one purpose (Project on Emerging Nanotechnologies, 2009).

The regions of origin are reported in 2009 to be 540 of the 1,015 total from the US, 240 of 1,015 from East Asia, 154 products come from Europe and 66 products come from the rest of the world (Project on Emerging Nanotechnologies, 2009).

6. Existing Laws That Might Regulate Nanotechnology

With this kind of worldwide breakdown based upon region/country, it is not surprising that in determining what new regulation is necessary to protect man and the environment from the risks commonly recognized in new nanotechnology it is first necessary to have an understanding of what regulatory structures exist at the present, and if such structures are effective. An examination of US federal law that exists today provides a foundation.

The US Food and Drug Administration (FDA) is one of the oldest US consumer protection agencies. To market drugs or biologics in commerce the FDA must first approve an application and determine the product is both safe and effective (21 USC 355, 21 USC 360). Part of the approval process is that the drug or biologic will be manufactured in compliance with good manufacturing practices (GMPs) which include requirements concerning building facilities, such as design, lighting, ventilation, filtration, HVAC, plumbing, equipment and controls as well as controls of production and process (21 CFR 210, 21CFR211). FDA also is responsible for medical devices (21 USC 360). The approval process for medical devices is two-stepped. New, never before used devices must go through the full FDA review in what is described as a Premarket Application (PMA), while a medical device sold before October 1976 or that is substantially equivalent to a device lawfully on the market is submitted to FDA for clearance under what is known as a 510(K) notice (21 USC 360 1(k)). The GMPs for devices, Quality Systems Regulation) mandate, as do the drug GMPs, that the production and process controls include environmental and contamination controls (21CFR820.70). There is support for the conclusion that as to drugs, biologics and medical devices the present US food and drug law is sufficient for purposes of regulating nanotechnology (Davies, 2006).

Unfortunately, the same may not be as true with other existing US regulatory schemes. For example, the Toxic Substances Control Act (TSCA) administered by the US Environmental Protection Agency (EPA) has been described as the primary vehicle to regulate nanotechnology because of its broad scope. One important question yet to be finally decided is whether nanoparticles may under this regulatory scheme be considered “new chemical substances.” Both the National Resource Defense Council (NRDC) and Greenpeace argue that under the TSCA “all engineered” nanoparticles are “new chemical substances.” Because of the divergence of views in the US and the way the US political system operates it is by no means certain that the courts will ultimately agree with NRDC and Greenpeace (Davies, 2006).

If the conclusion is nanoparticles are not “new chemical substances,” Davies argues that the TSCA’s “significant new use” rules (SNUR) could perhaps be utilized. In other words, the Administrator of EPA could conclude an existing chemical is to be regulated as though it were a new one. Whether this approach is practical is quite open to question. TSCA rulemaking is almost always a lengthy administrative process in which one chemical or

chemical group is considered at a time by the Administrator. Besides publishing required notices in the *Federal Register* any affected person could challenge the EPA by filing objections to the proposed rule. The upshot of such an objection may well result in an administrative hearing that is appealed first to the Administrator and then reviewed by the court of appeals. Going through this process one chemical group or one chemical entity at a time is not feasible in a developing new industry where changes, new developments or uses come with lightning rapidity. It should be remembered that of the existing US laws with broad coverage TSCA is considered to be the primary vehicle for regulating nanotechnology (Davies, 2006). This is not a bright prospect.

A second challenge to putting nanotechnology under the TSCA regulatory umbrella is when in the process TSCA should apply. If one assumes nanotechnology products fall under the EPA's jurisdiction by virtue of TSCA, toxicity downstream at the time the final formulation occurs cannot be assumed or predicted. While regulation of nanotechnology would be focused on final products TSCA would look to manufacturers of the basic forms of nanotechnology and expect these entities to anticipate, track and trace all possible final uses of the basic products. Should two or more basic nanoparticles be combined or joined to make a final product the new identity would remove the product from TSCA's present jurisdiction (Davies, 2006).

An additional problem with TSCA being effective to regulate nanotechnology is the requirement that the EPA must first meet a number of requirements prior to taking any regulatory action. This is seen quite clearly in *Corrosion Proof, et al. v. EPA* (Corrosion Proof, 1991). *Corrosion Proof* concerned the EPA's twelve-year proceeding to use the TSCA "to reduce the risk to human health posed by exposure to asbestos" (54 FR 29,460, 1989). The EPA was not the first US regulatory agency concerned over asbestos. In 1971, the Occupational Safety and Health Administration (OSHA) began limiting the exposure limit of asbestos, then @ 12 fibers per cubic centimeter (Corrosion Proof, at 1207, note 1, 1991).

Between 1979 and 1989 the EPA conducted its administrative proceeding leading up to the issuance of a final rule in 1989 that prohibited "the manufacture, importation, processing, and distribution in commerce of most asbestos-containing products" (Corrosion Proof Fittings at 1207-1208, 1991). The Final Asbestos Rule was to be implemented in stages over a six-year period. A number of domestic and foreign parties challenged the Final Rule claiming among other things that the rule-making process was fatally flawed because of a lack of due process and the lack of substantial evidence necessary to support the EPA's decision.

In American administrative law the doctrine of "substantial evidence" as a foundation for regulatory agencies reaching substantive decisions is well established. One seminal case that sets out the basic framework for court's to review EPA rule making for substantial evidence is *Chemical Manufacturers Association v. EPA*, where the appellate court held that determining substantial evidence meant whether (1) the regulated chemical in the environment was substantial in quantity and (2) whether exposure by humans to the chemical was significant/substantial (Chemical Manufacturers Association, 1990). In this context if the agency reaches a decision in exercising its judgment without reliance on set quantifiable risks, etc., it must alternatively "cogently explain why it has exercised its jurisdiction in a given manner" and provide a rational basis for what it did (Motor Vehicles Manufacturers Association, 1983).

In *Corrosion Proof* this is precisely what the court concluded the EPA had failed to do:

We conclude that the EPA has presented insufficient evidence to justify its asbestos ban. We base this conclusion upon two grounds; the failure of the EPA to consider all necessary evidence and its failure to give adequate weight to statutory language requiring it to promulgate the least burdensome regulation required to protect the environment adequately (*Corrosion Proof*, at 1215, 1991).

The courts have also found fault in the process of the rule making itself. The EPA failed to allow cross-examination of all witnesses and failed to notify the parties until after the close of the hearings that it intended to use analogous exposure estimates to support the final rule. By not giving such notice, the petitioners were not able to challenge these estimates and make a record during the hearing. The court found fault with denying cross-examination, but held that defect, alone, was not sufficient to overturn the Final Rule (*Corrosion Proof*, at 1212, 1991).

EPA's failure to give any timely notice of its intent to use analogous exposure data to calculate its benefit risk methodology, however, did not fare as well. The court held that the EPA's analogous exposure data should have been available to the public's scrutiny before the record closed (*Corrosion Proof*, at 1212, 1991). The precedent for this conclusion was a similar instance where the Consumer Product Safety Commission failed to allow the public to comment on a conclusion it made about how its rule would impact the swimming pool slide market in an earlier case, *Aqua Slide 'N' Dive v. CPSC* (Aqua Slide, 1978).

What is seen from this examination of how the court has viewed EPA's efforts to regulate asbestos is the very real chance that EPA would take years to develop a rule under TSCA to control/ban/phase out specific nanoparticles because of risks only to have the reviewing court invalidate the rule due to the failure of the government to follow the law. Given the fact that the pace of nanotechnology technology development is ever increasing such delays in regulatory oversight are simply not acceptable.

OSHA was created in 1970 when the US Congress combined two existing occupational safety programs then located in the Department of Labor and what is now the Department of Health and Human Services (21 USC 651). The lead responsibility for enforcement of the OSHA Act was the Office of Safety and Health Administration located in the Department of Labor.

The key to OSHA regulation is the "occupational safety and health standard," which is "a standard which requires conditions, or the adoption of use of one or more practices, means, methods, operations or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment" (21 USC 651).

While the regulation of nanotechnology could occur under OSHA, it is submitted that using OSHA to protect employees would not be effective. To know which products have a nanotechnology basis is not easy. Fairly sophisticated equipment would be in order and OSHA would have to first determine, for example, the relevant parameters from which to measure toxicity emanating from a factory or the environment around it. Additionally, OSHA lacks the breadth of resources needed to effectively regulate nanotechnology in a growing workplace.

Besides TSCA, the EPA is responsible for the enforcement of a number of other environmental protection laws such as The Clean Air Act, Clean Water Act, and the Resource Conservation and Recovery Act (Davies, 2006). These environmental laws generally authorize EPA to establish standards for acceptable pollution and then issue

permits to applicants that meet the standards. By definition, a firm that emanates waste that does not meet the established standard cannot obtain a permit, which is necessary to discharge the waste at issue (League of Wilderness Defenders, 2002).

All of these environmental laws suffer the same impediment to effective enforcement. Without sophisticated laboratory equipment and well-trained technicians locating nanotechnology products is quite challenging (Davies, 2006). In situations where the presence of nanoparticles is determined the issue then becomes the remedy. The EPA laws are not product specific and a complete ban of one or more nanoparticles from the environment may be fairly considered to be regulatory overkill. A possible exception to this statement is where one or more manufacturing facilities suffer leaks into the general environment of a nanomaterial that presents a substantial risk to the environment.

New industrial and commercial applications of nanotechnology are ever increasing. The estimated 2015 annual nanotechnology market, i.e. the fourth generation discussed above, is estimated at \$1T dollars. Even with or perhaps because of such growth toxicity concerns from nanotechnology products continue to persist. Going back to 2001 safety problems with nanomaterials have been well known (Chenggang Li et al, 2009). Donaldson, Stone et al, of Napier University's Biomedicine Research Group reported in 2001 the very real health risks presented by ultra fine particles to the lungs (Donaldson et al, 2001). It is true, as Donaldson points out, that diseases in the lungs caused by inhaled particles are known as far back as the 14th Century. And while by the close of the 20th Century the significant death toll from asbestos and silica are coming to an end, a new particle-ultrafine is the subject of new concern.

American regulatory agencies have no worldwide monopoly on pre-market review. In the EU the critical document necessary to have a medicinal product distributed and sold commercially is the Marketing Authorization Application (MAA). Without a MAA for a drug, biologic or device the product may not be lawfully sold in the EU. A sponsor of a medicinal product files its MAA with the appropriate authority of a member state or to the European Medicines Agency (Marketing-Authorisation-Applications). Starting in 2005 submissions for oncology, diabetes, HIV and genital diseases must be submitted to the European Medicines Agency (EMA). By virtue of this devolved system there are two approval procedures followed by the EU. The dual application process permits a sponsor of a new drug to apply for marketing authority (MA) in one member state and when approved to then request recognition of the MA by the remainder of the EU states (European Commission, at 28, 2006).

A question raised by some is whether the EU agencies are fully equipped and capable to make decisions that adequately protect EHS. The EMA has conducted meetings among specialists throughout the EU to build expertise, establish professional relationships among different EU experts and to identify and satisfy needs (European Commission, at 34, 2006). In early 2008 the EMA published a paper on regulation of nanotechnology (MHRA, 2008). Medicines for humans other than homoeopathic drugs require pre-market approval based in broad bush upon the US concept of safety and efficacy. The regulation includes authority for inspection by governmental officials, enforcing good clinical practices, good manufacturing and distribution practices and good laboratory practices. Should a regulated entity fail to meet required standards and procedures or produce adulterated mislabeled medicines regulatory officials have authority to inspect the premises and books and documents, to undertake prosecutions for consumer safety and punish wrongdoers

criminally and with confiscation orders. In sum other than the devolved system for medicine approval in the EU the differences between the US and the EU in the area of products requiring pre-market approval are not so different that there are sound reasons for concern.

The same is not necessarily true in the EU for other nanotechnology products. Specifically as to nanotechnology a 2009 “Safety for Success” dialogue took place in Brussels to discuss among other topics regulation (Nanowerk, 2009). In the Safety for Success meeting there was general agreement that in three areas coordinated effort was required:

1. “Developing trustworthy information on products containing nanomaterials that are on or near the market”
2. “Meaningful public engagement on the basis of shared definitions of nanotechnology.”
3. “Ongoing regulatory reviews to provide clear guidance to industry on how to interpret regulatory frameworks”

Additionally, more research on nanotechnology risks was considered a priority, including gaining more knowledge about nanomaterials in the environment to make further clarification regarding existing regulations given the uncertainties of biological properties with nanomaterials. Finally, the stakeholders of the Safety for Success called for the introduction of post-marketing monitoring systems for nanoproducts in commerce.

From the record of the Safety for Success Dialogue it is submitted that the EU is certainly not as far along in the implementation of regulatory safety control of nanoproducts (with the possible exception of medicines and similar products) as the US. The reason may well be that the US has reached the conclusion that more regulation is necessary, but not yet implemented, while in the EU there is not yet general recognition that more regulation of nanotechnology development to protect EHS is indeed necessary. Recall that the official responsible for regulatory aspects of nanotechnology at the European Commission, Cornelis Brekelmans, has stated further regulation is not necessary as “[w]e [EU] are not in a regulatory void” (EurActiv, 2008).

With regard to devices, the EU follows Directive 98/79/EC for in vitro diagnostic devices that took effect in 1998 (In Vitro Directive, 1998). This was the first time that requirements on safety, quality, and performance bringing in vitro devices under regulation have been put in place.

8. How the 9/11 of Nanotechnology Will Occur

The web page *Responsible Nanotechnology* sets out what many consider to be the most likely potential disasters from nanotechnology (CRNANO, 2004). War, economic meltdown, environmental meltdown from overproduction or leakage is the most obvious potential candidates. Without adequate regulation it is impossible to conclude that these risks are not real or cannot occur.

Another view comes from a European team that comprises *Nanologue* (Nanologue.net). Nanologue takes a new look at the potential future, both positive and negative. causing hundreds, perhaps thousands of injuries/deaths. In a time line format going forward advances in nanotechnology as well as disasters are set out. The future events in the time line are, of course, not real, but they do demonstrate how in a real sense the dark side of nanotechnology may impact on EHS. For example,

- 2010 The UK Government publically criticized the Global Framework on Emerging Technologies for moving too slowly and introduced its own, watered down, guidelines. These are voluntary.
- 2011 Workers at a factory in Toulouse went on strike, refusing to work with nanoparticles following a number of medical complaints. Demonstrations spread across Europe. The number of occupational health court cases increased.
A campaign by a major NGO was launched, calling for a moratorium on nanoscience and technologies until more is known about the health and environmental effects.
- 2012 In April, the process for delivering the Global Framework on Emerging technologies broke down and efforts to create a level playing field internationally were abandoned.
A major explosion occurred at a plant on the outskirts of Seoul, which releases several tons of nanoparticles into the environment (Nanalogue.net).

Under this scenario it does not get any better, with the result that the development of nanotechnology slows significantly.

9. Conclusion

Nanotechnology offers great potential in improving the quality of life for man as well as the environment. If this potential is to be achieved nanotechnology must be both fostered and controlled. Government and business realize that the fostering of nanotechnology is best served with the infusion of capital for research, capitalization, manufacturing and distribution. Regulation is not a word normally favored by business and is viewed positively by government only when government is pro-regulation. Of course, not all governments have the same views on regulation at the same time. The US government during President Bush's two terms was as a general rule more inclined to regulate business less than was government the proceeding eight years of President Clinton. Great Britain in the same way viewed regulation with less friendly eyes during the time Margaret Thatcher served as Prime Minister than when Labor and Tony Blair took over control of the Commons.

Nanotechnology, of course, is not political and does not recognize the borders of countries. If a spill of nanoparticles were to occur in Korea and create environmental havoc as postured above, governments and borders mean nothing. To keep the spill in Korea from doing harm to EHS potentially anywhere in the world, governments of countries where nanotechnology is being developed must come together and put into place common regulation that, in sum, will prevent the potential Korean spill from ever taking place. Such international cooperation is quite unusual, but not impossible. For nanotechnology to prosper over the long term, there is no other choice.

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The main purpose of this book is to describe important issues in various types of devices ranging from conventional transistors (opening chapters of the book) to molecular electronic devices whose fabrication and operation is discussed in the last few chapters of the book. As such, this book can serve as a guide for identifications of important areas of research in micro, nano and molecular electronics. We deeply acknowledge valuable contributions that each of the authors made in writing these excellent chapters.

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