Transnational Models for Regulation of Nanotechnology

Gary E. Marchant and Douglas J. Sylvester

There is much we do not know about nanotechnology. Despite its tremendous promise, nanotechnology today is mostly forecast and fervent hope. Predictions that spending on nanotechnology will increase from current levels of $13 billion to more than $1 trillion by 2015 are no more than that – simply predictions.[1] Hopes that nanotechnology will be an essential part of solving the globe's energy, food, and water problems[2] should be tempered by recalling a century of revolutionary technologies that failed to live up to their early promise such as nuclear energy, supersonic airplanes, or gene therapy. Many other questions continue to nip at nanotechnology's heels, not the least of which are debates about what is and is not technically feasible.[3] Despite these uncertainties, we can have complete confidence in one aspect of nanotechnology's future – it will be subject to a host of regulations.

In some ways, the industry is already regulated. Some aspects of nanotechnology may fall under preexisting regulations or oversight.[4] Funding decisions also work as *ad hoc* regulatory systems, allowing some areas of research to flourish while leaving others to wither. Informal regulation and extensions of existing regulatory schemes will eventually be replaced by more formal and directed regulatory frameworks that seek to cabin nanotechnology's risks, promote its benefits, and temper its social and economic upheavals.

Purposeful regulation will necessarily be enacted through law. Thus, despite nanotechnology's generally unfettered past, its future will, in large part, be determined by the legal choices made in the next few years. Notwithstanding this undeniable fact, legal scholars have been slow to join the fray.[5]

Nanotechnology's coming regulation has not been lost on other commentators. Ethicists and researchers have debated nanotechnology's utopian and dystopian potentials, urging regulation and restraint in various measures.[6] Social activists and economists have debated nanotechnology's disruptive capabilities and theorized about frameworks for minimizing or amplifying those effects.[7] Finally, scholars and other researchers have debated nanotechnology's various implications and urged greater participation for their voices in whatever potential regulation will follow.[8]

Gary E. Marchant, Ph.D., J.D., *is the Lincoln Professor of Emerging Technologies, Law and Ethics at the Sandra Day O'Connor College of Law at Arizona State University, and Executive Director of the Center for the Study of Law, Science and Technology at ASU.* **Douglas J. Sylvester, J.D., LL. M.,** *is Associate Professor of Law, Faculty Fellow, Center for the Study of Law, Science & Technology at the Sandra Day O'Connor College of Law at ASU, and is the founder and law faculty director of the Technology Ventures Clinic and serves on advisory boards for numerous emerging technology institutions.*

The legal academy's quiescence is, we believe, a mistake. Understanding the interplay of regulation and technology is an area where legal scholars and practitioners have much to offer. Indeed, we believe that the law and, in particular, the legal frameworks and principles applied in other areas of technological development, may highlight the risks and benefits of legal regulations of nanotechnology. In particular, we believe that the experience of international regulatory agencies, frameworks, and arrangements will prove to be fruitful areas of research in exploring nanotechnology's coming regulation.

That said, nanotechnology's nascency gives reason for pause. It is impossible to predict or recommend substantive regulatory approaches for a technology that is largely hypothetical and uncertain. We can, however, provide some context for what may be an even more important decision for nanotechnology's future: namely, whether national or international regulatory frameworks will be more effective and appropriate.

Regulatory Imperatives

Leaving aside, for now, the question of whether nanotechnology *should* be regulated, we are confident that it *will* be. The increasing politicization of new technologies and the need for government-sponsored research guarantees that some regulation is forthcoming. In addition, activist groups that have been successful in politicizing prior technologies have placed nanotechnology squarely within their sights and are urging regulatory responses at both the national and international level.[9] Finally, nearly all commentators and industry watchers agree that some form of regulation will be necessary – either to ensure nanotechnology's future success or to prevent it from destroying our future. In these two ways, regulatory responses may play dual roles – either as permissive regulation or prophylactic regulation.

Permissive Regulations

One of the chief impediments to nanotechnology's success is economic and regulatory uncertainty. When we think of regulation, we often think solely of negative regulations – imposing burdens on industry to meet certain standards, creating administrative frameworks to monitor industry practices, or in rare cases even prohibiting certain areas of research entirely. However, regulations may also play a more proactive role – giving industry and researchers clear guidelines about what practices and areas of research will be permitted and, just as important, what kinds of frameworks will govern the fruits of their endeavors.

Regulatory frameworks that, for instance, promote specific areas of research through funding carry with them the implicit promise that such research may be continued in the future. Government's imprimatur may also play an important role in promoting private funding as evidenced by the rapid rise in venture capital investment in nanotechnology since the United States government launched its National Nanotechnology Initiative in 2001.[10] Also notable were the rapid increase in biotechnology funding after the Supreme Court's decision in *Chakrabarty*[11] (which permitted the patenting of living organisms), and passage of the Bayh-Dole Act (which allowed researchers to obtain patents for inventions from federally-funded research),[12] both in 1980. The existence of government regulation can also build public and consumer confidence in a technology and thus again help to create an environment conducive to technology development.[13]

A final form of permissive regulations are, in essence, frameworks to increase cooperation and coordination between governmental units. These regulatory frameworks may aid competing agencies in pooling resources, signaling to industry the appropriate rules and agencies that govern their activities, or, on the international level, may be used to avoid disputes and conflicts over intransigent economic and social problems. In short, tailored regulations can play a positive role in promoting a technology's growth as well as controlling its risks.

Hopes that nanotechnology will be an essential part of solving the globe's energy, food, and water problems should be tempered by recalling a century of revolutionary technologies that failed to live up to their early promise such as nuclear energy, supersonic airplanes, or gene therapy.

Prophylactic Regulations

As already noted, the more traditional role for regulation is to act as a prophylactic against potential dangers and risks. Prophylactic regulations work along a spectrum of applications. On one end, such regulations merely require the reporting and review of new technologies before their introduction to the public. The Bureau of Industry and Security, for example, currently requires notification of all new encryption technologies prior to export.[14] More stringent regulations may require pre-market approvals by administrative agencies. Review and approval of pharmaceutical risks and efficacy by the Food and Drug Administration (FDA) is an example of this kind of regulation.[15] At the farthest end of the spectrum are regulations that work as moratoriums on certain kinds of research.[16] Prohibitions on funding of some kinds of stem-cell research,[17] legal prohibitions on research into human cloning,[18] and some countries' prohibitions on the sale or export of genetically modified foods[19] are examples of these kinds of regulations.[20]

Appeals for these types of regulations have been made in the current debate about nanotechnology's future. In the end, it is entirely possible that some areas of nanotechnology will be regulated in one or more of the ways just described. Despite nanotechnology's substantial promise, numerous areas of concern have motivated current calls for legal regulation. Among the possible risks are:

- Worker safety in the manufacture or use of nano-sized particles;
- Consumer safety in the use or application of nanotechnology-based goods;
- Environmental damage caused by manufacturing waste and finished goods that may contaminate air, water, or soil;
- Socioeconomic upheavals including economic disruptions to economies based on agricultural, raw materials, or labor;
- Unforeseen consequences of uncontrolled nanotechnologies;
- Government use of nanotechnologies to curb civil liberties;
- Military applications;
- Nanotechnologies in the hands of terrorists or other criminals.[21]

Reasons to Regulate Now

Admittedly, many of these risks are so remote and hypothetical that it is impossible to recommend substantive regulations to address them, at least at this time. Nevertheless, experience in many other areas of product and process regulation reveals lawmakers' ability to enact varying regulatory frameworks tailored to the evolving problems and dangers of developing technologies.

Despite the uncertainties, there are plausible arguments for regulators to act now rather than later. Growing public concern about nanotechnology carries the risk that failing to act will turn nanotechnology into "another Frankenfood controversy" for genetically-modified foods where the technology becomes so stigmatized that the public will not accept proof of its safety.[22] Several advocacy groups[23] have already called for a total moratorium on nanotechnologies until such time as they are proven safe in accordance with the precautionary principle,[24] which, in the words of Douglas Parr, Greenpeace's chief scientist, essentially holds that "these materials should be considered hazardous until proven otherwise."[25] In the permissive sense, the failure to regulate breeds uncertainty about nanotechnology's future and chills investment. In prophylactic terms, regulating allows us to "keep the genie in the bottle" and to shield society from the worst possibilities.

Reasons to Postpone

Not surprisingly, many of the factors that support earlier rather than later regulation may equally favor postponing regulatory discussions. Nanotechnology's nascency may mean that regulatory enactments and debates may distract researchers and policymakers from current imperatives of funding and development.[26] In this view, attempting to regulate in the face of such uncertainty will only chill innovation and research rather than promote it. In addition, public policy discussions in the absence of real knowledge of nanotechnology's capabilities and risks may pose a threat to the public's generally positive opinion of the technology.[27] Should current assumptions turn out to be incorrect, the public's opinion of the experts and policy makers could seriously deteriorate.[28]

Finally, regulations possess the same limitations that all laws contain – they often reflect sub-optimal compromises and, once enacted, are often extraordinarily difficult to amend. As a result, decisions made today, in the face of grave uncertainty, may end up regulating the field far beyond the period of the law's efficacy.

National vs. International

As discussed, legal regulations fall along a spectrum of permissive and prophylactic applications and may employ a wide range of rules for protecting against dangers on one hand and promoting beneficial activities (e.g., through providing intellectual property protection) on the other hand. Regulatory choices are not constrained only by these considerations, however. A further important consideration is whether to imbed regulatory choices in domestic legal and political systems or to entrust them to regional or global institutions. Each has its advantages and disadvantages and, indeed, some aspects of regulation may be better suited to national approaches while others would more appropriately and efficiently be handled on the international plane. Just as nanotechnology is at an early stage, the discussions of where best to place regulatory authority, whether in promulgation or enforcement, are only just beginning.

National Regulatory Frameworks

There is little doubt that national regulatory systems have a number of advantages. They may be more closely tailored to the social and cultural preferences of affected polities. They also allow for experimentation and diversity in approaches and provide opportunities for other nations to see what works and what does not. In addition, national approaches may also promote international competition. Some nations may promote one industry over another, may enact lower or higher environmental or labor standards than others, or focus on different funding sources to stimulate research and applications. The values of diversity and experimentation are clearly best served by national approaches.

Transnational regulation not only provides an opportunity to cabin potential risks, it also promises to speed research, share regulatory expertise and resources, and avoid potential "nano divides" in which more advanced nations widen their existing technological and regulatory advantage over more impoverished nations.

Of course, these same benefits can have negative consequences. National approaches may result in race-to-the-bottom environmental and labor standards. They may ignore the transnational impacts of nanotechnology manufacturing and sales, such as cross-border pollution or importation of dangerous goods. Finally, national approaches may not adequately control nanotech's potential security risks, resulting in a possible nanotechnology arms race.

Historically, the majority of new technologies have only been subject to national regulations. In many cases, the varying regimes and approaches have not hindered the advance of technology. The computer, medical, and pharmaceutical industries have flourished in the United States and abroad despite an absence of coordinated transnational regulation. Other technologies, however, have withered under national regulatory schemes that differ from nation to nation. The experience of genetically modified foods is one example. Genetically modified organisms (GMOs) have faced substantial legal and social challenges that vary from country to country. The result has been a substantial burden on GMO researchers and scientists to assure regulatory compliance in the development, export, and use of GMO technologies. Without weighing in on the ultimate desirability of the GMO experience, there is little question that the industry has suffered, and the technology has not been as successful, precisely because of the disparate national approaches to its regulation.[29]

Transnational Regulatory Frameworks

Despite the many commendable aspects of national regulations, it seems apparent that much of nanotechnology's coming regulations will inevitably fall into transnational frameworks. The reasons are manifold. The risks of nanotechnology, if realized, carry cross-boundary impacts including economic upheavals and environmental dangers. The past few decades have witnessed an extraordinary number of transnational approaches for resolving these kinds of cross-border harms.[30] Transnational arrangements also hold the hope for avoiding a race to the bottom where individual countries seek economic advantages through lax employment or environmental regulation.

Finally, transnational regulation not only provides an opportunity to cabin potential risks, it also promises to speed research, share regulatory expertise and resources, and avoid potential "nano divides" in which more advanced nations widen their existing technological and regulatory advantage over more impoverished nations. Of course, transnational regulation does not guarantee these results. These approaches merely hold the promise of avoiding some of the pitfalls of domestic regulation. To realize these potentials, transnational regulation of nanotechnology will necessarily need to take account of the successes and failures of prior regulatory efforts. In the remainder of this article, we take some tentative first-steps in exploring some of the potential analogues for nanotechnology regulation.

Models of Transnational Regulation

If and when regulation of nanotechnology is justified, and if and when international regulation is deemed the appropriate regulatory focus, there is available a broad range of existing regulatory frameworks for technologies that may be worth considering. Given the unique characteristics of nanotechnology, it is doubtful that any existing model for another technology would fit nanotechnology precisely. Nevertheless, existing and past approaches that have attempted to regulate technologies at the international level provide useful analogies and lessons for the potential transnational regulation of nanotechnology. While it is not possible in the space available here to explore these examples in any comprehensive manner, we summarize below pertinent aspects of a small subset of existing regulatory models that may be relevant for regulating nanotechnology at the international level.

International Agreements on Environmental Pollutants

Several multinational environmental agreements restrict or prohibit specific toxic substances based on their harmful environmental effects. Examples include the Stockholm Convention on Persistent Organic Pollutants[31] and the Montreal Protocol on Substances that Deplete the Ozone Layer.[32] These treaties tend to focus on a relatively small number of clear "bad actors" that are known to have well-demonstrated and substantial risks. For example, the Stockholm Convention as initially adopted in 2001 included a dozen highly toxic substances – often referred to as the "dirty dozen" – that all signatory nations were quite prepared to prohibit if they had not done so already.[33] The most controversial part of the Stockholm Convention is the provision providing for additional substances to be added to the Convention in the future, and the issues surrounding this critical provision have been the focus of much debate and disagreement amongst the signatories and potential signatories.[34] This provision for adding additional substances, and the criteria by which additional substances would be listed, has also been the primary impediment to ratification of the Convention by the United States Senate.

Because they tend to focus on a relatively small subset of extremely hazardous agents, these international environmental agreements tend to impose very strict regulations, often in the form of a full or partial prohibition of the hazardous agents covered by the treaty. Thus, unlike many national environmental programs that regulate "acceptable levels" of a large number of pollutants, international environmental regulations tend to be reserved for bans on the most serious pollutants. This limited scope and harsh stringency of international environmental agreements likely reflects the large costs and difficulties of negotiating international agreements, which only make them feasible for the most clearly toxic agents that almost everyone (in government and industry) agrees should be restricted or prohibited. And, since such international agreements tend to be limited to such clear bad actors, imposing the most stringent possible regulatory sanction – that is, prohibition – is a logical consequence.

These international environmental agreements have also proved difficult and time-consuming to negotiate. Agreement is possible often only once the industries that produced or previously produced the restricted substances agree to phase out production of such substances. For example, the Montreal Protocol on ozone depletion only became feasible when DuPont, the principal manufacturer of chlorofluorocarbons (CFCs) that would be the primary focus of the treaty, agreed to stop further manufacturing of such substances after it identified commercially feasible alternatives. Without industry agreement, negotiation of international restrictions on environmental pollutants can continue almost indefinitely without agreement. Consider the United Nations Environmental Program (UNEP), which has been trying for many years to negotiate an international convention on mercury in the environment, so far without agreement.[35]

It is difficult to imagine nations undertaking such a burdensome process for hypothetical risks from future nanotechnology products or processes that have yet to inflict any known significant environmental harm.

Another type of international environmental agreement is a treaty to limit or regulate the transboundary movement of pollutants in the air, water, or as solid wastes. Examples include the European Convention on Long-Range Transboundary Air Pollution[36] and the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal.[37] These agreements also tend to be difficult to negotiate, and tend to focus on well-characterized pollutants that are prevalent in the environment and are known to cause, or are highly suspected of causing, significant damage across national or subnational political boundaries.

These characteristics of international environmental agreements suggest that this model of international agreement is likely to have limited applicability to nanotechnology, at least at the present time. Given the political and practical impediments to negotiating such treaties, nations have only demonstrated the necessary commitment and resources needed to negotiate such agreements for a relatively small subset of clearly harmful substances that are already causing substantial environmental damage. It is difficult to imagine nations undertaking such a burdensome process for hypothetical risks from future nanotechnology products or processes that have yet to inflict any known significant environmental harm. Moreover, it is not possible to identify any highly hazardous nanotechnology applications at this time that could be singled out for regulation as strict as a ban or severe restriction.

Non-Proliferation Arms Control Agreements

Arms control treaties, especially those that seek to prevent the proliferation of weapons of mass destruction, provide another transnational model of potential relevance to nanotechnology regulation. Examples of such treaties include the 1968 Nuclear Non-Proliferation Treaty (NPT),[38] the 1972 Biological Weapons Convention (BWC),[39] and the 1993 Chemical Weapons Convention (CWC).[40] Several aspects of this type of international treaty also limit its applicability and effectiveness for nanotechnology. First, these treaties seek to control technologies (i.e., nuclear, chemical, or biological weapons) that are clearly dangerous and indeed are described as weapons of mass destruction. Notwithstanding some science fiction scenarios, it is highly unlikely that current or near-term applications of nanotechnology would rise to the level of potential weapons of mass destruction. In the longer term, it is possible that some applications of nanotechnology could present a weapon of mass destruction threat, but such possibilities are likely far into the future and governments are unlikely to act to try to prevent such scenarios through international agreements until such risks are more concrete and defined.

Second, existing international arms control treaties only apply to and bind state actors. Their role in controlling non-state actors is therefore incidental and indirect at best. For instance, both the CWC and BWC require signatories to prohibit activities on their territory that each prohibits state parties directly from undertaking. Yet, with the recent rise of international terrorist networks, non-state actors may present the greatest risk of malevolent uses of nanotechnology in the future. Another implication of the focus on and consent of state actors in existing international arms control treaties is that states can choose to opt-out. The NPT, BWC and CWC have all experienced the problem of nations that often present the greatest threat electing not to sign the treaty in the first place, failing to comply with their treaty obligations, or leaving the treaty after they initially signed it.[41] Thus, to the extent some rogue states seek to develop nanotechnology for militaristic, malevolent, or otherwise dangerous uses, the current "Geneva style" of international arms control agreements that rely on national consent is likely to be ineffective.

Nevertheless, if predictions of potential military applications of nanotechnology are borne out,[42] nations are likely to consider in the more distant future the option of arms control agreements as a means to control the risks of a nanotechnology arms race and aggressive state use of nanotechnology weapons, in part because of the lack of alternative risk management approaches. Indeed, some military applications of nanotechnology may even be subject to the BWC or the CWC.[43]

Existing arms control agreements provide some lessons that can help guide the potential development of such an agreement for nanotechnology. For example, one of the primary tensions in the NPT agreement results from the two-tier membership structure in which some nations are permitted to have nuclear weapons while other nations may not. The Director of the International Atomic Energy Agency (IAEA), Mohamed El Baradei, recently emphasized this tension by emphatically stating: "I repeat that it is time to abandon the unworkable notion that it is morally reprehensible for some countries to pursue nuclear weapons but morally acceptable for others to rely on them."[44] This grandfathering of weapons programs among nations that had developed the relevant weapons of mass destruction before the NPT creates a source of inevitable and ongoing tension and conflict between "have" and "have not" signatories. This lesson suggests that any treaty that seeks to control the proliferation of nanotechnology weapons should be negotiated prior to some first adopter nations actually acquiring such weapons, or alternatively requiring all nations to abide by the same rules.

Another lesson from existing arms control treaties is that the technology transfer and assistance provisions of agreements such as the NPT and BWC have been a strong inducement to participation in the treaty for developing nations. These provisions require developed countries to share nuclear or biological research and technologies with developing countries for use in legitimate, peaceful activities. This suggests that provisions for technology assistance and sharing for peaceful and beneficial uses of nanotechnology could provide an incentive for developing countries to enter into agreements that preclude offensive or dangerous applications of nanotechnology.

Additionally, arms control agreements that involve creation of a specific enforcement and oversight body have generally worked better than those without such an entity. Thus, the IAEA has played a critical role in promoting the effectiveness and stability of the NPT – as evidenced for example by the awarding to the IAEA of the 2005 Nobel Peace Prize – while the Organization for the Prohibition of Chemical Weapons has played an equally effective, if less visible role in overseeing the CWC. In contrast, the lack of an oversight body under the BWC, which leaves the UN National Security Council as the effective (although some might say ineffective) enforcer of the BWC, is at least partly responsible for its limited success and sense of instability.[45]

A central issue in all existing arms control treaties is verification. For example, the inability of the parties to agree on a verification regime for the BWC has put into question the continued vitality of that treaty. The verification challenge is particularly acute for so-called "dual use" technologies that can be used for both peaceful and malevolent purposes.[46] Verification and enforcement of the BWC is problematic because much genetic research has dual use potential.[47] Rather than prohibiting certain technologies and applications of biological research altogether, the BWC relies on a "general purpose criterion" under which restrictions depend on the intended use rather than the nature of the technology. When the same technology could have both permissible and proscribed intended uses, verification becomes extremely difficult if not impossible, at least without highly intrusive inspection and enforcement regimes. Governments and private industry are likely to resist such intrusions in order to protect proprietary research with substantial commercial potential.[48] All of these tensions are likely to apply to nanotechnology, including the existence of dual use technologies and resistance to inspections and other intrusive verification mechanisms in order to protect proprietary data. Current attempts to address the dual use and verification problems under the BWC, including the consideration of the role of codes of conduct under such a treaty, may also prove relevant to any future arms control agreements governing nanotechnology.

Global Ethics Treaties

There have been limited attempts, and even more limited successes, in negotiating international agreements governing ethical aspects of new technologies. Nevertheless, these undertakings can provide some models and lessons for any future nanotechnology treaty. An example is the recent attempt by the United Nations to develop an international convention to prohibit human cloning. Although there was widespread agreement amongst UN members to ban "reproductive cloning" or the creation of a cloned human being, the attempt to develop a treaty foundered over disagreement about including a ban on "therapeutic cloning" or the derivation of embryonic stem cells from cloned embryos for potential therapeutic applications.[49] Thus, even when there is broad consensus on the need to restrict one technological application, there will be an incentive for some to seek to expand the scope of any restriction to include other applications for which no consensus exists, thereby creating regulatory controversy and perhaps gridlock. As the UN committee report cautioned, "widening the scope of the potential convention to include issues for which no consensus existed could threaten the entire exercise, leaving the international community without a coordinated legal response."[50] In the end, the UN General Assembly adopted a non-binding resolution favoring an international ban on both reproductive and therapeutic cloning by a divided vote of 84 to 34, with 37 abstentions. The decision to make the provision non-binding in response to the controversy means it is unlikely to have any practical impact.[51]

This precedent has obvious implications for any attempt to place restrictions on nanotechnology. Even if a strong international consensus on opposition to a specific nanotechnology application emerges, negotiating an international prohibition may be complicated by attempts to include related applications that lack such clear consensus. Nanotechnology includes a wide variety of disparate products and processes with a range of risk and benefit profiles. Given that a complete prohibition on nanotechnology is unlikely to ever be popular, a more nuanced and hence complicated approach will be necessary for regulating nanotechnology. When the relevant inquiry investigates which applications should be restricted and which should not, there is bound to be discord and controversy.

Other disagreements encountered in the attempted negotiation of the UN cloning convention may also be relevant to any attempt to regulate nanotechnology. Another disputed issue was whether there should be an international body for administering sanctions for any non-compliance or whether it should be the prerogative of each nation to impose its own sanctions for non-complying activities within its boundaries. Another issue was whether any prohibitions should be permanent or for a limited period. Proponents of a limited duration cited the rapid pace of technological progress which may require periodic reexamination of ethical and legal predicates of any convention. A generic issue facing any future regulation of nanotechnology will be how to keep the regulatory structure current and properly aligned with this rapidly evolving technology.

Framework Conventions

Perhaps one of the more promising models for the transnational regulation of nanotechnology is framework conventions. As their name implies, framework conventions involve setting out a framework for an international agreement on an issue of common concern that will gradually be flushed out with substantive provisions. A framework convention may consist of little more than a general commitment by its signatories to take future action to address an international problem and the establishment of a process and secretariat for further negotiations on the convention's substance. Examples of framework conventions include the United Nations Framework Convention on Climate Change (1992)[52] and the World Health Organization (WHO) Framework Convention on Tobacco Control (2003).[53]

These framework conventions have been "filled" with more substantive provisions through the subsequent agreement of implementing protocols negotiated through the procedural structure created in the initial convention. An example is the 1997 Kyoto Protocol to the UN Framework Convention on Climate Change, which enacted binding emission reduction targets for developed nations.[54]

Customary International Law

Instead of relying on new regulatory structures, it is possible that nanotechnology could be regulated at the international level through customary international law. For example, to the extent that nanotechnology activities in one nation produce pollution that crosses into another nation, the downstream national may be able to bring a legal action for redress in an international forum, such as the International Court of Justice, without the requirement for any substantive treaty in place. One principle of international law that has been proposed for application to nanotechnology is the precautionary principle.[55] The precautionary principle is based on the maxim "better safe than sorry," and, at least in its stronger form, requires shifting the burden of proof to the proponent of a technology or activity to prove it is safe. Advocates have suggested that the precautionary principle require strict limitations if not outright prohibitions on nanotechnology.[56]

Some legal scholars assert that the precautionary principle has attained the status of customary international law given its inclusion in a series of international environmental agreements and international court cases,[57] but this conclusion is called into question by the non-acquiescence to the precautionary principle by some nations, most notably the United States.

The precautionary principle is dubious as a basis for regulating nanotechnology for at least three principal reasons. First, notwithstanding frequent references to "the" precautionary principle, there is no standard or accepted version of the precautionary principle. At least nineteen different versions of the precautionary principle have been identified, differing in important respects in several different dimensions.[58] Without any consensus on what the precautionary principle actually means, it does not provide a robust or reliable foundation for transnational regulation.

Second, every version of the precautionary principle is ambiguous with respect to central risk management decisions such as: (i) What level of risk is acceptable? (ii) What early indications of potential hazard are needed to trigger precaution? (iii) How much data must proponents produce to demonstrate that a product or activity is sufficiently "safe" to proceed? (iv) How are costs and risk tradeoffs factored in? (v) What type of action is required to satisfy the precautionary principle?

Without providing an answer to these questions which are central to any regulatory decision, the precautionary principle fails to provide a credible decision-making framework for nanotechnology or any other technology. Given its imprecision and ambiguity, it is perhaps not surprising that the precautionary principle has been applied arbitrarily, including being used to (i) ban Kellogg's Corn Flakes in the Netherlands and Norway because of the possible risks presented by the various vitamins used to fortify the cereal, (ii) ban cranberry fruit drinks in Denmark because of the possibility, however remote, that the vitamin C in the juice could harm someone unusually sensitive to vitamin C, and (iii) reject U.S. food aid to the starving population of Zambia because the corn may contain genetically-modified kernels eaten by millions of Americans every day.[59]

Finally, the precautionary principle, if applied consistently and diligently, would seemingly prevent any technology from moving forward. Because the earliest steps in technology development involve the greatest uncertainties, an early-stage technology could never satisfy the precautionary principle and move on to more definitive assessments. This technology-freezing effect of the precautionary principle was recently described by Sir Søren Holm and John Harris as follows:

> As a principle of rational choice, the precautionary principle will leave us paralyzed. In the case of genetically modified plants, for example, the greatest uncertainty about their possible harmfulness existed before anybody had yet produced one. The precautionary principle would have instructed us not to proceed any further, and the data to show whether there are real risks would never have been produced. The same is true for every subsequent

Nanotechnology includes a wide variety of disparate products and processes with a range of risk and benefit profiles. Given that a complete prohibition on nanotechnology is unlikely to ever be popular, a more nuanced and hence complicated approach will be necessary for regulating nanotechnology.

> step in the process of introducing genetically modified plants. The precautionary principle will tell us not to proceed, because there is some threat of harm that cannot be conclusively ruled out, based on evidence from the preceding step. The precautionary principle will block the development of any technology if there is the slightest theoretical possibility of harm.[60]

Of course, some precaution and foresight are essential for effectively and responsibly addressing prospective risks of any emerging technology, including nanotechnology. But more than a slogan is needed. The precautionary principle is an overly-simplistic and under-defined concept that seeks to circumvent the hard choices that must be faced in making any risk management decision, and as such fails to provide a coherent framework for the regulation of nanotechnology.

Conclusion

There are many existing models for transnational regulation of nanotechnology that can provide useful lessons about the desirability, feasibility, design, and implementation of any future efforts to regulate nanotechnology at the international level. None of these existing models are likely to fit the needs of nanotechnology regulation exactly, but we can learn from past efforts to regulate other technologies, important lessons about the likely obstacles, challenges, opportunities, and routes to success that will likely confront any effort at transnational regulation of nanotechnology. One major lesson that can be drawn from existing models is that international agreements to regulate technologies generally take considerable effort, time, political capital, and resources, and thus are likely to only be undertaken for the most serious and imminent problems. It is unclear whether and when nanotechnology regulation will become a sufficient priority to justify such an international undertaking.

Another important lesson from past international agreements is that enforcement, non-compliance, and non-participation are persistent and perhaps inevitable problems of any international undertaking that seeks to be universal. A core question that has to be addressed, therefore, is what level of non-compliance and non-participation in any international agreement can be tolerated? In other words, how destabilizing would it be if a few nations refuse to comply or participate in an international agreement and serve as havens for otherwise restricted applications of nanotechnology? Dual-use technologies present particularly difficult verification and definitional challenges for international (or for that matter even national) regulation, and this problem will certainly apply to nanotechnology where many applications are likely to have both beneficial and pernicious potential applications.

Consider some other lessons for nanotechnology from an examination of existing models of transnational regulation of technologies:

- Any regulatory instrument is likely to impose some burden on beneficial uses of the technology as a cost of restricting potentially harmful applications. How these factors are balanced is critical, and different nations with different levels of development and interests in a specific technology may weigh these factors differently.
- A critical and often controversial issue in any international regulatory scheme is deciding the scope of the technology to be regulated, including which applications should be restricted and which should be prohibited, and how clearly this line can be drawn.
- The inclusion of technology-sharing provisions can be a powerful inducement for less developed countries to participate in international agreements.
- As a consequence of global political and technological trends, non-state actors (e.g., industry, international organizations and networks, and non-governmental organizations) will play an increasingly important role in the development of new technologies such as nanotechnology, and must be addressed in any international agreement.
- One of the lessons of the attempts to control dual-use technology is that managing information and knowledge is as important as controlling material and equipment.[61] Because of the ease with which information can be distributed and shared, it is much more difficult to control and regulate information than hard goods in many contexts.
- Any international agreement must have built-in flexibility to evolve given the rapid pace of technological change expected for nanotechnology.

It is clear that any formal international regulatory agreement for nanotechnology will face many obstacles and challenges. It is likely that any formal international regulatory agreement is many years in the future, but this should not prevent analysis and discussion today of the issues involved in regulating nanotechnology in the future. At the same time, it may be worthwhile to consider other, less formal alternatives to binding treaties at the international level.[62] Some options along this line include:

- Transnational dialogue and information sharing forums, like The International Dialogue on Responsible Research and Development of Nanotechnology;[63]
- "Civil-society-based monitoring," as occurs with the BioWeapons Prevention Project, a network of non-governmental organizations which monitor government compliance with the BWC;[64]
- Codes of conduct, like those advanced by the Foresight Guidelines on Molecular Nanotechnology;[65]
- Enlisting a group of experts to issue periodic reports on the state of technological development and related issues, which occurs with the International Panel on Climate Change pursuant to global warming;[66]
- International consensus standards;[67]
- Export controls, such as those provided by the "Australia Group," an informal grouping of thirty-three industrialized nations that seek to prevent the spread of chemical and biological weapons technologies through coordinated export controls and monitoring;[68]
- Confidence building measures, which are incremental steps or actions that build trust and understanding in a dispute context.[69]

In conclusion, existing models of transnational regulation of technologies provide valuable lessons for the feasibility and design of future transnational approaches to the regulation of nanotechnology. Although nanotechnology will likely require its own unique approach, transnational regulatory design and implementation can nevertheless build on and learn from this past record. Creative approaches will be needed to address risks of nanotechnology at the international level, with more informal approaches most likely to succeed in the shorter term, leading possibly to more formal agreements as the risks, benefits, and direction of nanotechnology become more clear. If nations decide that an international agreement is needed, a framework convention similar to that which has been used with global warming and tobacco control may be the most sensible approach because it sets up an ongoing process that can then be used for incremental change, in sync with nanotechnology's development.

References

1. M. C. Roco and W. S. Bainbridge, *Societal Implications of Nanoscience and Nanotechnology* (Boston: Kluwer Press, 2001): 3-4. Lux Research has also predicted that nanotechnology values may rise to $2.6 trillion by 2014. Lux Research, Report, *Sizing Nanotechnology's Value Chain,* as cited in *Nanotechnology: Enabling Technologies for Australian Innovative Industries* (March 11, 2005): 10, *available at* <http://www.dest.gov.au/NR/rdonlyres/1E1B501A-727A-4153-85EF-134B2DAF0925/4112/nanotechnology_pmseic110305.pdf> (last visited August 7, 2006).
2. F. Salamanca-Buentello, et al., "Nanotechnology and the Developing World," *Policy Forum* 2 (2005): 300-303.
3. R. Baum, "Nanotechnology: Drexler and Smalley Make the Case For and Against 'Molecular Assemblers'," *Chemical & Engineering News* (December 1, 2003): at 37-42.
4. In the United States, the Food and Drug Administration regulates nanoparticles used in medicines and medical instruments. "FDA Regulation of Nanotechnology Products," *at* <http://www.fda.gov/nanotechnology/regulation.html> (last visited August 7, 2006). The Environmental Protection Agency may have authority to regulate nanoparticles under the Toxic Substances Control Act. 15 U.S.C. §§ 2601 et seq. (1976), *available at* <http://www.access.gpo.gov/uscode/title15/chapter53_.html> (last visited August 7, 2006). Finally, the Occupational Safety and Health Administration regulates the use of materials in the workplace through, in part, requirements for Material Safety Data Sheets for use of new materials in the workplace. 29 C.F.R. § 1910.1200 (2005).
5. There have been some attempts. See G. H. Reynolds, "Nanotechnology and Regulatory Policy: Three Futures," *Harvard Journal of Law and Technology* 17 (2003): 179-209; F. A. Fiedler and G. H. Reynolds, "Legal Problems of Nanotechnology: An Overview," *Southern California Interdisciplinary Law Journal* 3 (1994): 593-629.
6. B. Joy, "Why the Future Doesn't Need Us," *Wired* (April 2000); M. C. Roco and W. S. Bainbridge, NSET Workshop Report: "Societal Implications of Nanoscience and Nanotechnology," *available at* <http://www.wtec.org/loyola/nano/NSET.Societal.Implications/nanosi.pdf> (last visited August 7, 2006).
7. See R. Bailey, "Rebels Against the Future," *Reason Online*, *available at* <http://reason.com/rb/rb022801.shtml> (last visited August 7, 2006).
8. I. Bennett and D. Sarewitz, "Too Little, Too Late? Research Policies on the Societal Implications of Nanotechnology in the United States," *available at* <http://cspo.org/ourlibrary/documents/SciasCultSubmit.pdf> (last visited August 7, 2006); Center for Responsible Nanotechnology, *Results of Our Ongoing Research*, *at* <http://crnano.org/overview/htm> (last visited August 8, 2006).
9. One of the most vocal of these groups, the Canadian-based environment advocacy group ETC (Action Group on Erosion, Technology, and Concentration), has issued numerous statements and papers calling for a moratorium on nanotechnology research. See ETC, "Size Matters! The Case for a Global Moratorium," *at* <http: www.etcgroup.org/article.asp?newsid=392> (last visited August 8, 2006). ETC has, on occasion, been able to convince politicians to support a total ban on some forms of nanotechnology research. G. Brumfiel, "Nanotechnology: A little knowledge..." *Nature* 424 (July 17, 2003): 246-8.
10. The National Nanotechnology Initiative's website is located *at* <www.nano.gov/> (last visited August 8, 2006).
11. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
12. Bayh-Dole 35 U.S.C.A. §§ 200 to 211 (1980).
13. E.g., National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation* (Washington, D.C.: National Academy Press, 2000): at 178.
14. Through various rules, the BIS has required such items as encryption software, to be registered as munitions and approved prior to export. Rules governing exports and reexports of encryption items are found in the Export Administration Regulations (EAR), 15 C.F.R. Parts 730-774. Sections 740.13, 740.17 and 742.15 of the EAR are the principal references for the export and reexport of encryption items. Bureau of Industry and Security, Encryption Export and Reexport Controls Revisions, *Federal Register* 69 (2004): 71356-71364.
15. The FDA maintains a website specifically covering its regulation and approval of medical devices and drugs that contain nanoparticles. FDA, "Nanotechnology" *at* <http://www.fad.gov/nanotechnology/> (last visited August 8, 2006). The FDA has a more comprehensive site for discussing its drug approval process *at* <http://www.fda.gov/cder/regulatory/applications/default.htm> (last visited August 8, 2006).

16. Moratoria, though, present additional risks in themselves: Although they may prevent the foreseeable development of dangerous or unethical technologies, they may also prevent the unforeseeable development of extremely useful and beneficial innovations.
17. The National Institutes of Health has a website discussing the allowable uses of federal funding for stem-cell research. NIH, "NIH's Role in Federal Policy" *at* <http://stemcells.nih.gov/policy/NIHFedPolicy.asp> (last visited August 8, 2006).
18. The National Conference of State Legislatures (NCSL) maintains a website detailing the various state laws and regulations prohibiting or controlling research into human cloning. NCSL, "State Human Cloning Laws," *at* <http://www.ncsl.org/programs/health/genetics/rt-shcl.htm> (last visited August 8, 2006).
19. The UN Biosafety Protocol allows European Countries to ban importation of food containing genetically modified organisms. UN Biosafety Protocol, *at* <http://www.biodiv.org/biosafety/default.aspx> (last visited August 8, 2006).
20. The United States has also severely restricted private-sector research and development into atomic energy. Atomic Energy Act, 42 U.S.C. §§ 2011-2281 (2005).
21. For a general description of concerns surrounding the health, social and economic impacts of nanotechnology see: W. Luther, "Industrial Application of Nanomaterials: Chances and Risks—Technological Analyses," (2004) *available at* <http://www.nano.uts.edu.au/nanohouse/nanomaterials%20risks.pdf> (last visited August 8, 2006); D. Mark, Report of Presentations from First International Symposium on Occupational Health Implications of Nanomaterials, *Nanomaterials a Risk to Health at Work?* (2004) *available at* <http://www.hsl.gov.uk/capabilities/nanosymrep_final.pdf> (last visited August 8, 2006); Heath and Consumer Protection Directorate General of the European Commission, "Nanotechnologies: A Preliminary Risk Analysis," (2004) *available at* <http://europa.eu.int/comm/health/ph_risk/documents/ev_20040301_en.pdf> (last visited August 8, 2006); SwissRE, "Nanotechnology: Small Matter, Many Unknowns," available for download *at* <http://www.swissre.com/INTERNET/pwswpspr.nsf/fmBookMarkFrameSet?ReadForm&BM=../vwAllbyIDKeyLu/ulur-5yaffs?OpenDocument> (last visited August 8, 2006).
22. K. Proffitt, "Yellow Light for Nanotech," *Science* 305, no. 5685 (2004): 762-5 (quoting Julia Moore).
23. Several groups have called for moratoria on areas of nanotechnology research and distribution of products containing nanoparticles. The group GeneEthics Network has called for a ban of nanoparticles in sunscreens. K. Dearne, "Call for Ban on Nano-particles," *The Australian* (October 4, 2005) *available at* <http://www.moleculartorch.com/2005/10/call-for-ban-on-nano-particles-article.html> (last visited August 16, 2006). ETC, as noted earlier, has made numerous calls for moratoria on the commercial production of nanoparticles. ETC, "No Small Matter," *Communique* 76, *available at* <http://www.etcgroup.org/documents/Comm_NanoMat_July02.pdf> (last visited August 8, 2006).
24. The precautionary principle, widely adopted in European countries, requires that any technology with the capability of causing irreversible damage or negative consequences should be "proven safe" before development of the technology can proceed. See discussion in *infra* section IV(5).
25. See Proffitt, *supra* note 22, at 764.
26. According to one commentator, "the smart approach is to leave nanotech development alone and instead allow individual regulatory agencies to weigh in on specific products and applications before they are introduced to the market." J. Wolfe, "Nanotech vs. The Green Gang," *Forbes.com* (April 6, 2005) *available at* <http://www.forbes.com/finance/2005/04/06/cz_jw_0406soapbox_inl.html?partner=rss> (last visited August 8, 2006).
27. At least one commentator believes that "Americans begin with a basically positive view of nanotechnology…despite its weak factual basis." M. D. Cobb, "Framing Effect on Public Opinion about Nanotechnology," *available at* <http://www2.chass.ncsu.edu/cobb/me/past%20articles%20and%20working%20papers/nano%20framing%20for%20science%20communication.pdf> (last visited August 16, 2006).
28. See Cobb, *supra* note 27.
29. I. Bennett and D. Sarewitz, "Too Little, Too Late? Research Policies on the Societal Implications of Nanotechnology in the United States," *available at* <http://cspo.org/ourlibrabry/documents/SciasCultSubmit.pdf> (last visited August 8, 2006). According to Bennett and Sarewitz, a failure to discuss the range of possible regulation for nanotechnology will result in the repeat of the "brittle, reactive, regulatory governance modes that have characterized responses to technologies from nuclear power to genetically modified foods." *Id.*
30. The chief example is the Kyoto Protocol on Climate Change. *Available at* <http://www.unfccc.int/resource/docs/convkp/kpeng.html> (last visited August 8, 2006).
31. Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, art. 3(2)(b)(i), U.N. Doc. UNEP/POPS/CONF/4, 40 I.L.M. 532, 535 (entered into force May 17, 2004).
32. Montreal Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, S. Treaty Doc. No. 10, 100th Cong., 1st Sess. (1987), 1522 U.N.T.S. 29 (entered into force January 1, 1989).
33. M. Porta and E. Zumeta, "Implementing the Stockholm Treaty on Persistent Organic Pollutants," *Occupational & Environmental Medicine* 59 (2002): 651-653, at 651.
34. P. E. Hagen and M. P. Walls, "The Stockholm Convention on persistent Organic Pollutants," *Natural Resources & Environment* (Spring 2005): at 49-52.
35. L. Miura, "Mercury: Dems Attack U.S. Policy on International Treaty," *Greenwire* 10 (March 3, 2003).
36. Protocol to the Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (Aarhus, 1998), 37 ILM (1998) 505. The only controversial substance on the list is DDT, which has important benefits in fighting malaria, and thus was not prohibited outright like the other eleven substances.
37. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, annex 1, Mar. 22, 1989, 28 I.L.M. 649, 678.
38. Treaty on the Non-Proliferation of Nuclear Weapons, opened for signature July 1, 1968, 21 U.S.T. 483, 484, 729 U.N.T.S. 161,169.
39. Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, opened for signature April 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163.
40. Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, January 13, 1993, 1974 U.N.T.S. 45, 32 I.L.M. 800.
41. M. Barletta, "Cross-Cutting Challenges to the Nonproliferation Regimes," in M. Barletta and A. Sands, eds., *Non-Proliferation Regimes at Risk,* Center for NonProliferation Studies, Monterey Institute of International Affairs, *Occasional Paper* No. 3 (1999): 39-45.
42. J. Altmann and M. Gubrud, "Anticipating Military Nanotechnology," *IEEE Technology and Society Magazine* (Winter 2004): at 33-40; J. Altmann, "Military Uses of Nanotechnology: Perspectives and Concerns," *Security Dialogue* 35 (2004): 61-79.
43. R. D. Pinson, "Is Nanotechnology Prohibited by the Biological and Chemical Weapons Convention?" *Berkeley Journal of International Law* 22 (2004): 279-309, at 281.
44. Quoted in J. Johnson, "An End to Nuclear Nonproliferation?" *Chemical & Engineering News* (July 26, 2004): at 34, 38.
45. J. B. Tucker, "The BWC New Process: A Preliminary Assessment," *The Nonproliferation Review* (Spring 2004): 1-13, at 2-3.
46. National Research Council, *Biotechnology Research in an Age Of Terrorism: Confronting the Dual Use Dilemma* (Washington, D.C.: National Academies Press, 2003).
47. See Tucker, *supra* note 45, at 3.
48. B. Roberts, "Biological Weapons: New Challenges, New Strategies?" in M. Barletta and A. Sands, eds., *Non-Proliferation Regimes at Risk*, Center for NonProliferation Studies, Monterey Institute of International Affairs, *Occasional Paper* No. 3 (1999): at 16-18.

49. S. Baer, "U.N. Mulls Ban on Human Cloning, Including for Research, but Proposals Differ on Cloning of Embryos to Create Stem Cells," *Baltimore Sun*, November 19, 2004, at 13A.
50. United Nations, *Report of the Ad Hoc Committee on an International Convention Against the Reproductive Cloning of Human Beings* (General Assembly, 57th Sess., Supp. No. 51 (A/57/51): 2002): at 3.
51. I. Arieff, "UN Backs U.S. Plea for Total Ban on Human Cloning," *Reuters*, March 8, 2005.
52. U.N. Framework Convention on Climate Change, May 9, 1992, in 31 I.L.M. 849 (1992).
53. WHO Framework Convention on Tobacco Control, WHA Res. 56.1, World Health Assembly, 56th Ass., 4th plen. mtg, Agenda Item 13, Annex, WHO Doc. A56.VR/4 (May 21, 2003), *at* <http://www.who.int/tobacco/fctc/text/en/fctc_en.pdf> (last visited August 8, 2006).
54. Conference of the Parties to the Framework Convention on Climate Change: Kyoto Protocol, December 10, 1997, U.N. Doc. No. FCCC/CP/1997/L.7/Add.1, in 37 I.L.M. 32 (1998).
55. SwissRE, *Nanotechnology: Small Matter, Many Unknowns* (Zurich: Swiss Reinsurance Company, 2004): at 47.
56. See *supra* note 24.
57. James Cameron, "The Precautionary Principle in International Law," in *Reinterpreting the Precautionary Principle*, T. O'Riordan, J. Cameron, and A. Jordan, eds. (Cameron May: London, 2000) 113-124, at 122.
58. P. Sandin, "Dimensions of the Precautionary Principle," *Human & Ecological Risk Assessment* 5 (1999): 889-907.
59. G. E. Marchant and K. L. Mossman, *Arbitrary & Capricious: The Precautionary Principle in the European Union Courts* (Washington: AEI Press, 2004): at 16.
60. S. Holm and J. Harris, Letter, "Precautionary Principle Stifles Discovery," *Nature* 400 (1999): 398.
61. M. Moodie, "Confronting the Biological and Chemical Weapons Challenge: The Need for an Intellectual Infrastructure," *Fletcher Forum of World Affairs* 28 (2004): 43-55, at 49.
62. See G. H. Reynolds, "Nanotechnology and Regulatory Policy: Three Futures," *Harvard Journal of Law & Technology* 17 (2003): 179-209.
63. Meridian Institute, *Report on the International Dialogue on Responsible Research and Development of Nanotechnology* (June 2004).
64. See Bioweapons Prevention Project, *at* <http://www.bwpp.org> (last visited August 8, 2006).
65. Foresight Nanotech Institute, "Foresight Guidelines for Responsible Nanotechnology Development" *at* <http://foresight.org/guidelines/current.html> (last visited August 8, 2006).
66. M. Schrope, "Consensus Science, or Consensus Politics?" *Nature* 412 (2001): 112-114.
67. The ASTM International has established a committee to develop international consensus standards for nanotechnology. ASTM website, *at* <http://www.astm.org> (last visited August 8, 2006).
68. The Australia Group website, *at* <http://www.australiagroup.net/> (last visited August 8, 2006).
69. Confidence building measures are interim steps not requiring formal bilateral or multilateral agreement that can help alleviate tensions and build trust. See G. E. Marchant, "Confidence-Building Measures for Genetically Modified Foods," *Jurimetrics* 44 (2003): 1-4.