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INTERNATIONAL REGULATORY REGIMES FOR NANOTECHNOLOGY

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INTRODUCTION

There is much we do not know about nanotechnology (NT). Despite its tremendous promise, NT today is mostly forecast and fervent hope. Predictions that NT's value will increase from current levels of $13 billion to more than $1 trillion by 2015 are no more than that, predictions.[1] Hopes that NT will go far toward solving the globe's energy, food, and water problems[2] are tempered by a century of revolutionary technologies that failed to live up to their early promise. Many other questions continue to nip at NT's heels – not the least of which concern what is or is not technically feasible.[3] Despite these uncertainties, we can have complete confidence in one aspect of NT's future: it will be subject to a host of regulations.

Indeed, the NT industry is already regulated in some ways. Funding policies and decisions function as *ad hoc* regulatory systems, allowing some areas of research to flourish while others wither. Some aspects of NT will also fall under existing regulations or forms of oversight.[4] Yet we can expect that informal regulation and extensions of current regulatory schemes will eventually be replaced by more formal and directed regulatory frameworks that seek to cabin NT's risks, promote its benefits, and temper its social and economic impacts. What is more, because much of the promise and many of the potential pitfalls of NT are transnational in scope, we must consider not only national regulation in individual countries, but also the potential for regulation by multiple nations – almost certainly inconsistent, if not conflicting, in the absence of coordination – and for transnational regulation of varying forms.

Much of this regulation, both national and transnational, will be adopted in the form of law. Law has long been the interface between science, technology and regulation. Legal frameworks developed for other scientific innovations – from common law property and liability rules to more elaborate regulatory approaches – may well be applied to NT, or provide models for its regulation. Hence we believe that law as a discipline is essential to the study of future NT regulation, although it has to date been largely silent on the subject. Some legal scholars have begun considering the regulation of NT,[5] and a few have focused on specific solutions to transnational NT problems.[6] Yet there has been little general discussion of transnational regulatory frameworks, with most authors focusing solely on NT's intellectual property implications.[7]

Because of the unique characteristics of the international system, we believe it is also essential to introduce an international law (IL) perspective into the study of transnational NT regulation. The sub-discipline of IL builds on general legal principles and understandings, but takes account of the political and institutional realities of international affairs and focuses on the mechanisms characteristic of transnational governance. In recent years, moreover, IL has engaged deeply with the discipline of international relations (IR) after decades of separation.[8] The resulting interdisciplinary IR-IL perspective is well-suited to addressing questions of institutional design. As one of us has written, "IR helps lawyers and other policy makers to analyze social problems in theoretically informed ways and develop a wide range of ameliorative responses." [9]

This paper represents a very early stage of a collaborative research project on transnational NT regulation. In this project, we seek to apply the rich multidisciplinary perspective just described. At this preliminary stage, however, we do not purport to offer firm conclusions or recommendations. Instead, we set more modest goals.

We begin in Section I by considering the nature of NT and some risks it may pose as it is more fully developed and utilized over time. We next consider the nature of transnational "regulation," suggesting the range of legal, institutional and substantive forms this term can encompass. Because NT and its regulation are (like our project) at such early stages of development, we emphasize the importance of regulatory flexibility.

In Section II, we consider a series of strategic choices that must be faced in designing transnational regulation in any issue area, including NT; these include the level and scope of regulation, the actors authorized to promulgate regulatory norms, the legal and institutional form of regulation, and finally its substantive content.

In Section III, we argue that it is useful, although not definitive, to study models of transnational regulation developed for similar issues arising out of other forms of technology. While few if any of these models will be directly applicable to the unique characteristics of NT, the designers of these regulatory regimes faced similar strategic choices as well as similar problems, and the models they created can offer useful lessons. We briefly discuss a few potential models to illustrate the approach. Our larger research project will expand the study of transnational models beyond those discussed here, with a view to developing more specific recommendations for NT regulation.

Consistent with our emphasis on regulatory flexibility, we conclude by tentatively suggesting a sequencing of regulatory approaches designed to allow NT regulation to develop over time into broader, more elaborate and more highly legalized form as we gain greater knowledge of, and experience with, the benefits and costs of NT.

II. NANOTECHNOLOGY, RISK AND REGULATION

A. NT and Its Potential Risks.

NT, which involves the manipulation of particles, structures, and devices at the scale of 1 to 100 nanometers, is often described as "the next big thing" (Feynman, 1959). In terms of funding, there is very little "next" about it. Over a dozen countries – from the United States, the EU and Japan to China, Taiwan and Korea – are heavily engaged in NT R&D, and in most of those countries governments actively support and coordinate the work (IRGC 2005). An increasing share of the US government's more than $100 billion annual investment in R&D (Guston, Woodhouse & Sarewitz, 2001) is being allocated to NT (Roco, 2003; Melman, 2002), and industry forecasts predict NT's future at more than $1 trillion in less than a decade (Roco & Bainbridge, 2001; Enabling, 2005). Indeed, estimates of annual worldwide investment in NT already exceed $3 billion (Nanotech

Report, 2003). Yet while the "bigness" of NT usually refers to its potential applications and benefits, the term could also refer to the challenges and opportunities NT presents for national and transnational regulation.

While NT is still an emerging technology, observers have identified a range of potential health, safety and environmental risks (Colvin, 2003; Michelson, 2004), based both on initial toxicological tests and by analogy to particulates such as asbestos or carbon dust (Calderon-Garciduenas, 2002; HSE/NIOSH, 2004; Mark, 2004; Oberdorster, 2004; Swiss Re, 2004). The unique characteristics of nanomaterials, which provide many of the potential benefits and much of the excitement about NT, may also result in unique and previously unpredicted toxic effects. Researchers, workers and consumers (CRN, 2003; ETC, 2002 & 2003) may be at special risk.

Others have focused on the potential for misuse and mayhem in the application of NT. As a classic dual-use technology, NT may have significant military uses, and even hold potential for terrorists (CRN, 2003; Drexler & Phoenix, 2004). Observers further agree that the NT revolution could disrupt economic conditions around the globe (CRN, 2003), while increasing the gap between developed and developing nations (Wolfson, 2003; Luther 2004). Some argue that governments could use NT to curb civil liberties (Mnyusiwalla, 2003). NT may pose ethical issues by extending life and otherwise transforming biological systems. At the current stage of NT's development, none of these risks has come to pass, yet some feel threatened by the very uncertainty and opacity of future developments, concluding either that progress should be halted before it is too late or that steps should be taken to allow society to act quickly as specific risks are observed.

At the same time, poorly designed NT regulation, justified by such risks and fears, would create significant problems of its own. Inappropriate regulation in any one country would impose unnecessary costs on researchers, firms and potential users there, slowing development and commercialization. Inconsistent national regulation – whether reflecting distinct nomenclatures and standards or substantively different policy choices – would multiply the costs, hampering international commerce as well as research, development and commercialization. Subsidies, especially if competitive, would impose other economic and social costs and skew the trajectory of development.

Crucially, most of these issues will be transnational in scope. As science and business globalize, research and industrial collaborations will become multinational. Health and safety risks will cross borders, carried by traded products or resulting from scientific and industrial processes. They may affect global commons, such as the atmosphere and the seas. Military and terrorist uses raise obvious international concerns. Other disruptive innovations such as biotechnology, moreover, offer many examples of transnational social, political and economic conflict, including protectionism and trade disputes (e.g., between the US and the EU over genetically modified foods), intellectual property disputes, and concern over the equitable distribution of benefits across countries.

Table 1 suggests the range of potential problems arrayed roughly along the likely life cycle of the technology, with pervasive uncertainty and R&D issues currently on the agenda, and more concrete and serious risks likely to appear further in the future.

Table 1

Nanotechnology Issues
With Transnational Dimensions
Along Technology Life Cycle

1. Uncertain, unknown future risks; Social flexibility to address future risks
2. R&D/ information flows
3. Broad ethical concerns
4. Manufacturing operations – e.g. OSH
5. Environmental release
6. Social/economic concerns
7. Inappropriate regulation
8. Human health – e.g. medical uses
9. Intentional misuse – e.g. terrorism

Experts from various disciplines have weighed in on the wisdom of NT regulation, some advocating stringent controls (ETC, 2002; ETC, 2003; Joy, 2000; Dearne, 2004), others a hands-off approach (Wolfe, 2005). Some have addressed specifically transnational risks and opportunities. Dr. John Marburger, the President's Chief Science Advisor, has highlighted several transnational issues, including harmonization of standards, intellectual property protection, oversight and regulation of hazards and North-South benefit sharing (Meridian, 2004). Others have also discussed these issues (HSE/NIOSH, 2004; Luther, 2004; Roco & Bainbridge, 2005; Berube, 2005; Royal Society, 2004). Recent publications have heightened the public's attention both to the overhyping of nanotechnology (and its potential failures) (Berube, 2005) and to its potential dangers to health and human safety (Davies, 2005).

Yet transnational responses remain in their infancy. An International Risk Governance Council survey identified no international agreements, and few formal transnational arrangements of any kind, that specifically address NT, except for technical work in the ISO (IRGC, 2005). As one expert has noted, "We need an international nanorisk research program built on shared knowledge and a clear set of priorities" (Service, 2005). Despite this felt need, to date most transnational activity has involved merely exploratory discussions, convened by national agencies (e.g., US NIOSH), international organizations (e.g., OECD), and research groups (e.g., Meridian Institute). In one significant gathering, held in June 2004, Meridian and the National Science Foundation convened representatives from twenty-five national governments and the EU. The group called for continued dialogue and coordination on NT R&D, and agreed to meet annually as the International Dialogue on Responsible Research and Development in Nanotechnology (Meridian, 2004). Yet as this call for dialogue suggests, much remains to be done to develop workable and responsible transnational NT governance.

B. Transnational "Regulation"

We use the term "regulation" expansively. Scholars in law and public administration now recognize and support social interventions much more varied than the welfare state model of command-and-control regulation built around mandatory law, specific prohibitions, expert agencies and centralized enforcement (Ayers & Braithwaite,

2002; Gunningham, 1999; Freeman, 1997). Numerous government programs in the US, the EU, Australia, Scandinavia and other areas are built around new approaches to social ordering, often drawing on private sector management techniques.

According to one scholar, these wide-ranging developments reflect a common paradigm that favors "governance" over "regulation" (Lobel 2004; but see Karkkainen 2004). Among other principles, the governance paradigm favors (i) transferring authority for the promulgation and implementation of norms to lower levels of government (as does the principle of subsidiarity) and to non-state actors, subject to various forms of state orchestration (e.g., policy steering, audited self-regulation; Wood 2002-03); (ii) flexible policies and rules, including "soft law," negotiated rule-making and even non-binding private norms arising, e.g., from business self-regulation; (iii) reliance on information disclosure, incentives and market forces; and (iv) an ethic and process of continuous improvement.

Transnational "regulation" already resembles the governance paradigm in many ways. To be sure, treaties and many other international agreements are publicly created and legally binding; a growing number are also legalized in other ways, e.g., with quasi-judicial bodies authorized to apply agreed rules (Goldstein et al., 2001). International organizations are often charged with implementing agreed rules, analogous to domestic administrative agencies (Abbott & Snidal, 1998). Indeed, significant recent research in IL focuses on similarities to domestic administrative law (Kingsbury et al., 2005).

Yet international governance still differs from traditional regulation in many ways. Because states are jealous of their sovereignty, "soft law" is widely used, much more often than in domestic regulation. While soft law represents a political or moral commitment, it does not impose legal obligations. As a result, its use may facilitate agreement among states with differing interests, especially in conditions of uncertainty. Similarly, states often favor informal arrangements for information sharing and discussion among peers, rather than binding rules; peer networks are often created and managed by national regulators rather than "states" as such (Slaughter, 2004).

C. Permissive and Prophylactic Regulation

One further distinction is important at both the domestic and the transnational levels: regulatory responses may be either "permissive" or "prophylactic." Both types have been proposed in recent debates about the future of NT.

When we think of "regulation," we often think solely of negative prescriptions and proscriptions — requiring researchers or business firms to meet certain standards, creating administrative mechanisms to monitor their behavior, or even prohibiting certain areas of research or production entirely. Yet regulation can also play a more positive role: giving researchers and firms clear guidelines about what practices and areas of activity will be permitted and, just as important, what frameworks will govern the results of their endeavors. Such permissive regulation addresses one of the chief impediments to the success of a technology like NT: economic and regulatory uncertainty.

Funding programs that promote specific areas of research carry with them the implicit promise that such research may be continued in the future. The imprimatur of government may also facilitate private funding, as evidenced by the rapid rise in venture capital investment in NT since the US government launched its NNI initiative in 2001,[10] or the rapid increase in biotechnology funding after the Supreme Court's decision in *Chakrabarty*[11] and passage of the Bayh-Dole Act both in 1980.[12] Regulation can build public and consumer confidence in a technology.[13] Permissive regulation can also create a framework for coordination between units of government. Such frameworks help competing agencies pool resources, signal to industry the agencies and rules that will govern their activities, and avoid inter-agency or transnational disputes. In short, tailored regulations can play a positive role in promoting a technology's growth.

The more traditional role for regulation is as a prophylactic against potential dangers. Prophylactic regulations cover a broad spectrum of restrictiveness. At one end, they may merely require the reporting and review of new technologies before their introduction. The US 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, such as the Food and Drug Administration's (FDA) review of new pharmaceutical for risk and

efficacy.[15] At the opposite end of the spectrum are regulations that prohibit or establish moratoria on certain kinds of activity.[16] Prohibitions on funding some kinds of stem-cell research,[17] on research into human cloning,[18] and on the sale or export of genetically modified foods[19] are examples.[20]

D. Regulate Now or Regulate Later?

Many of the suggested risks of NT are either hypothetical or remote, in terms both of probability and of time. Yet there are plausible arguments for acting now rather than waiting until concrete threats have appeared. Growing public concern over NT carries the risk that failing to act will allow this technology to develop into "another Frankenfood controversy," with NT stigmatized to the point that the public will not accept proof of its safety.[21] Some advocacy groups[22] have already called for a moratorium on NT development in accordance with the precautionary principle, until the technology is proven safe.[23] According to Douglas Parr, chief scientist of Greenpeace: "with the precautionary principle applied, these materials should be considered hazardous until proven otherwise."[24] From a permissive perspective, the failure to regulate breeds uncertainty about NT's future and chills investment and research. From the prophylactic perspective, regulating now would allow society to "keep the genie in the bottle," shielding society from the most dangerous possibilities.

Yet many of these same factors may militate in favor of deferring action. On one view, given the nascent state of NT, regulatory debates and enactments may distract researchers and policymakers from the more pressing imperatives of funding and development.[25] Attempting to regulate in the face of great uncertainty will only chill research and innovation. Regulatory discussions conducted with little real knowledge of NT's capabilities and dangers may undercut the public's still generally positive opinion of the technology.[26] Should the assumptions of early action turn out to be incorrect, the legitimacy of experts and policy makers could be undermined.[27] Finally, regulations often reflect sub-optimal compromises, even in more certain conditions; once enacted, however, they may be difficult to amend, casting a regulatory shadow far into the future.

E. Flexible Transnational Regulation

Our tentative conclusion, explored further below, is that – assuming that some form of transnational regulation is deemed appropriate – preliminary and flexible forms of regulatory action would be most suitable under current conditions. A flexible approach is clearly compatible with transnational political realities: states and other international actors typically act in tentative or exploratory fashion when the nature of a problem or the politics or capacities of actors are uncertain.

Consistent with the governance paradigm, the most tentative approach – although not necessarily the most flexible – involves reliance on non-state actors to generate initial understandings and norms; once a polity has gained experience with these private norms, public authorities can override or ratify them as appropriate. This approach draws on the expertise and experience of the actors most directly involved in research, development and commercialization; one can also expect those actors to update norms as their knowledge advances. Researchers, and increasingly business firms, operate within a web of professional norms that exerts some discipline on rule-making. Still, the self-interestedness of private actors creates concern, and their questionable legitimacy as rule-makers can weaken public acceptance of private norms.

A public form of exploratory transnational governance, especially useful in the early stages of cooperation, involves informal arrangements for research, information sharing, dialogue and peer review among national regulators or other technical agencies. Such arrangements frequently involve private actors – such as research organizations and business associations – in many of their activities, incorporating a broader range of expertise and viewpoints. Once common positions or "best practices" are identified, they might be adopted as transnational soft law; even soft international standards help guide independent national decisions on permissive or prophylactic regulation.

Beginning with soft law – such as transnational recommendations, guidelines or standards – provides another avenue for policy flexibility (Abbott & Snidal, 2001). The use of soft law, however, presumes that states have some idea of the appropriate substantive content of regulation; it is therefore particularly useful when policy-makers are uncertain about the social or economic impact of rules or the political reactions of

interest groups or the public, rather than about the nature of a problem or potential solutions. States can establish processes that allow them to progress gradually toward more binding agreements as they gain certainty (Abbott & Snidal, 2004).

When the technical nature of a problem is uncertain – as is the case with NT – even more highly legalized transnational arrangements can take exploratory form. "Framework conventions" offer a particularly valuable approach. These are legally binding treaties that establish limited initial obligations – typically for research, information sharing, dialogue and the like – with the expectation that the parties will add more specific substantive commitments over time as they learn about the problem and potential solutions, achieve consensus and develop trust (Brunnee & Toope, 1994). In addition, framework conventions typically provide expedited procedures for adding substantive commitments in the form of "protocols" or other follow-on instruments. This approach is widely used in environmental law (e.g., the Framework Convention on Climate Change/Kyoto Protocol), and has come to be used in other areas, such as public health (e.g., the Framework Convention on Tobacco Control; Taylor, 1996).

When the interests or regulatory capacities of particular states are in question, initial agreements may be limited to small groups of states (e.g., OECD members), with the hope of adding additional parties over time as their interests and capacities become clear. Many treaties also apply the equitable principle of differentiated obligations, for example, by imposing weaker obligations on poor countries (Stone, 2004).

III. STRUCTURAL CHOICES FOR TRANSNATIONAL REGULATION

In considering possible forms of transnational NT regulation – in the broad sense of the term outlined above – a number of strategic decisions must be made. (On transnational institutional design, see, e.g., Koremenos, Lipson & Snidal, 2003; Mitchell & Kailbach 2001.) Public attention is typically focused on the shaping of substantive rules, but there are many structural and formal attributes that must be agreed upon in designing a regulatory regime. We suggest here some of the most important issues.

A. National vs. transnational action.

The threshold question is whether some form of transnational regulation aimed at promoting or controlling NT research, development and exploitation – or at constraining national regulatory choices that might produce economic costs and diplomatic friction – would be desirable, or whether society would be better served by leaving regulation entirely to individual states. Each approach has advantages and disadvantages.

National regulations can be closely tailored to the level of technical and economic advancement and the social preferences of each polity. At a systemic level, moreover, diverse national approaches allow for experimentation; others can learn what works and what does not. Ideally, national regulation will promote beneficial competition, leading states to "trade up" to socially superior outcomes (Vogel & Kagan, 2004; Vogel, 1998).

In practice, of course, competition may instead result in a "race to the bottom," as advocates allege is occurring on environmental and labor standards. Even short of a "race," national officials tend to ignore transnational impacts, since foreign citizens do not vote locally. Similarly, national regulators may yield to protectionist or alarmist demands when they can externalize the costs onto foreign researchers and producers. National officials (at least those from "have" states) acting alone are unlikely to volunteer an equitable sharing of resources or benefits with "have-nots." Inconsistent national regulation creates burdens for transnational researchers and firms. And uncoordinated regulation may be poorly suited to address potential security threats arising from NT.

Most new technologies have been subject only to national regulation. For many, this has not appeared to hinder progress, although the counterfactual is difficult to establish. Human genomic sciences and many of their applications, for example, have flourished without substantial transnational coordination. Other technologies, however, have been less fortunate: genetically modified foods ("GMOs"), notably, have faced widely varying social attitudes and laws, producing a substantial burden on researchers and producers, allegations of protectionism and trade conflicts. Without hazarding an overall conclusion on the merits of the GMO case, there can be little doubt that the technology has suffered because of disparate regulation.[28] Stem cell research is another technology where divergent national regulations are impeding orderly development.

B. Optimal Scope of Transnational Regulation

If it is determined that some form of transnational regulation is desirable, a related design choice is the scope of the regulatory regime, which can be equated to its breadth of participation. Regulation of any kind is most effective when its scope is congruent with the issue being addressed; thus for most issues there is an optimal scope, although it may be difficult to achieve in actual negotiations. Table 2 indicates the principal alternatives; it suggests that the national/transnational choice is the most significant of all.

Table 2
Scope of Regulation

Multilateral
Plurilateral
Bilateral
. . . .
Unilateral – national action

1. For some issues, broad multilateral participation may be necessary (e.g., global warming) or desirable (e.g., international trade).

2. For other issues, agreement among smaller groups of states – such as the industrialized countries – may be sufficient (e.g., control of high-technology exports). A finely-tuned plurilateral approach is difficult to achieve, however, unless negotiations can be pursued in an organizational forum whose membership matches the relevant group of states; where no such forum exists, it may be necessary to create a new institution, a

costly endeavor. Given the range of nations currently investing in NT, the lack of an appropriate forum may well be a problem in the case of this technology.

3. Bilateral agreements may even suffice for some issues (e.g., taxation).

Each form has strengths and weaknesses in addition to congruence with the underlying issue. For example, a multilateral agreement can produce greater harmonization, inclusiveness and equity (e.g., by including developing countries), but it is more costly and difficult to negotiate. The narrower the scope of each particular regulatory arrangement, the greater the latitude for experimentation and competition in the system as a whole; however, this latitude comes at the expense of harmonization, and often of equity: bilateral trade and investment agreements, for example, are often pursued by powerful countries seeking to "pick off" vulnerable partners one at a time.

Since NT poses such a host of potential issues, it would not be surprising if multiple agreements of different scope constituted the optimal response. But this raises a related structural issue: it is often easier to reach an international agreement when a number of issues are linked in negotiations, allowing trade-offs across issues. Thus there may be an optimal scope in terms of issues as well as participation. States should not hastily split off different issues into unrelated negotiations.

C. Norm-generating Actors

In traditional IL, rules were adopted by states and were applied to states; it was up to each government to apply agreed rules to actors within its jurisdiction, a principle that allowed for a great deal of "slippage." In recent decades, however, other actors have come to play an increased role in international governance, specifically in the adoption of international rules and standards. "Transgovernmental" arrangements among national regulators, discussed above, are of growing importance in fields ranging from finance to food and drug regulation. Through these informal and flexible arrangements, expert regulators share information and "best practices," harmonize rules and procedures, assist one another in enforcement proceedings and resolve disputes. Specialized regulators can easily develop distinct sets of regulatory norms for different areas of concern. This could be a highly attractive option for many aspects of NT.

Even more remarkable is the growing role non-state actors and the "transnational" normative arrangements they produce. At least three types of private regimes hold promise for the early-stage regulation of NT:

1. Transnational "epistemic communities." These are groups of individuals who share common causal understandings of some area of activity, often scientific, and may share common values as well. Community members work in national agencies, international organizations, NGOs, research labs or other institutions. Communities can be organized by professional associations, international organizations or on an ad hoc basis. Epistemic communities are especially valuable in highlighting scientific problems (e.g., damage to the ozone layer, global warming), disseminating objective information and proposing knowledgeable solutions.

2. Self-regulatory arrangement by researchers – following scientific and professional norms – and by business firms – following norms of corporate social responsibility; and

3. Public-private partnerships.

Table 3 indicates the range of actors that today are engaged in transnational "regulation," broadly defined. Virtually all of these actor groups can create transnational norms at lower cost than traditional interstate treaties, draw on expert knowledge and professional norms, operate on a decentralized and flexible basis, and lend themselves to continuous learning. Governments need not abdicate responsibility entirely when non-state actor regimes are formed; public agencies can oversee and shape all types of private regimes through techniques like those noted above (Wood, 2002-03).

Table 3

Transnational Actors

States
National regulatory agencies
Public-private partnerships
Epistemic communities
Researchers, business firms

D. Legal Form and Institutionalization

We have spoken frequently of "soft law." For agreements or regimes created by states, the principal choice in terms of legal form is between some form of soft law and "hard" IL. Yet it is important to note that this is not a binary choice: agreements can be "softened" along multiple dimensions (Goldstein, 2001; Abbott & Snidal, 2000). For example, many international agreements contain strong rules, but provide few procedures for implementation, follow-up or dispute resolution. Framework conventions provide another alternative. The initial treaty is formally a "hard," legally binding agreement, but it contains little substance. Even here states have choices: for example, they can include in the initial framework agreement only provisions for consultations and information sharing, or they can prescribe clear principles for future actions and initiate a dynamic process designed to strengthen cooperation over time.

Transgovernmental arrangements generally constitute soft law, as they are not entered into in the name of the state. Indeed, avoiding the costly national government approval processes required for legal commitments is a primary rationale for this approach. Within this constraint, many forms of interaction are possible: an agreement on information sharing, for example, will be more informal than one on legal assistance.

Private self-regulatory arrangements take diverse forms, such as recommendations and guidelines. Many professional[1] and business[2] organizations promulgate "codes of conduct," varying from brief statements of aspiration to elaborate systems of rules with external monitoring procedures. Specialized monitoring organizations, both profit-seeking and non-profit, have sprung up to service such codes. Public–private partnerships often promulgate rules that closely resemble law, in form if not in effect. An example is the UN Global Compact, which enlists business firms to voluntarily implement principles drawn from multilateral treaties.

Institutional arrangements are an important aspect of regime design, and are often closely related to the level of legalization. A formal organization has significant advantages for a regulatory regime. It allows for centralization of administration,

[1] http://onlineethics.org/codes/
[2] http://www.bsr.org/CSRResources/IssueBriefDetail.cfm?DocumentID=50303

facilitating negotiations, technical assistance and other activities. Additionally, a formal organization can be granted some independence, allowing it to produce and disseminate unbiased information, allocate resources fairly and mediate disputes. But the costs of creating and maintaining a formal organization are high. Increasingly, transnational regulation – especially when administered by government agencies, non-state actors and public-private partnerships – is structured around more or less informal networks. Networks sacrifice some of the benefits of centralization and independence, but provide increased flexibility, adaptability, and low operating costs.

Table 4
Legal/Institutional Form

Interstate regimes:
Hard law/strong institutions
Soft law/weak institutions
Interagency networks: **soft law**
Public-private partnerships: **soft law**
Non-state actors: **self-regulatory codes of conduct**

E. Substantive Content

Substantive obligations are crucial to any regulatory arrangement. Yet it is difficult to generalize as to the range of choice in these matters: transnational rules and implementation activities can be as varied as the problems they address. Referring back to Table 1 and the accompanying discussion, NT presents an extraordinarily varied set of substantive problems, at least hypothetically. Substantive rules, whether permissive or prophylactic, must be drawn with a full understanding of these risks, including their political, economic and social aspects as well as their technical underpinnings.

One way to gain analytical purchase on this question is to consider the underlying situation structure of each issue. While NT may pose a wide range of potential risks, these may be categorized into a smaller number of problem types, each of which may require particular forms of regulation.

To illustrate, consider several examples:

1. If the problem to be addressed is defined as a transboundary harm, as with many forms of pollution and the spread of infectious diseases, substantive obligations will focus on preventing or limiting passage of the harmful agent across national borders, and providing for a response if such passage takes place. In most cases regulations will not need to restrict research, commercialization, or production of the substance. Related activities might include monitoring of transboundary flows (e.g., through trade or in the atmosphere), and technical or financial assistance to states that lack capacity to prevent transboundary flows or to respond as needed. Similar provisions are characteristic of transnational denial regimes, such as export controls on dual-use technologies relevant to conventional weapons (e.g., missiles), weapons of mass destruction or terrorism.

2. If the problem is defined as the safety of researchers, workers and others exposed to nanomaterials, very different rules will be required. Here the nature of the problem is two-fold: transnational regulation is seen as appropriate in order to promote human rights, even in states that might not do so on their own, and to limit economic competition on the basis of lax national standards. Transnational labor regulation, e.g., ILO rules on wages, working conditions and occupational safety and health, responds to

such problems. Transnational rules might therefore set harmonized minimum standards for safe exposure and remediation in the workplace. Related activities might include monitoring, technical assistance, research on permissible exposures and alternate processes, and support for negotiations.

3. If the problem is defined as a risk of widespread harm to human health, or to global commons such as the atmosphere, from the release of a dangerous substance, substantive obligations would have to address the full product cycle, from R&D through production. They might set standards for the safe conduct of such activities (or in extreme cases prohibit them), require public notice in the event of a release, and provide for compensation, penalties or other incentives. Related activities might include licensing, surveillance, information disclosure, consultations, research on risks and responses, and technical/financial assistance.

4. If the problem is defined as one of international equity, like the "digital divide" in computer technology, regulation would aim to impose affirmative substantive obligations to assist less-advantaged nations through technical assistance, transfer of technology, financial aid, trade benefits or other means.

5. If a problem or its extent remains undefined, a framework convention or similar exploratory approach might be appropriate. Under the circumstances, such an agreement will contain few firm substantive obligations, although it might spell out basic principles (e.g., differentiated obligations, non-discrimination in trade) to be followed in future substantive agreements. As noted above, framework convention activities typically provide for coordinated research, information sharing, consultations, technical and financial assistance, and support for negotiations.

Because the alternatives for substantive regulation are so diverse and problem-driven, we believe that the most fruitful way to proceed is through consideration of actual regulatory regimes that address technologies with features analogous to NT. We elaborate this approach in the following section.

IV. Models of Transnational Regulation

If and when it is decided that NT regulation is justified, and *if and when* it is determined that transnational regulation is appropriate, actors can look to a broad range of regulatory regimes designed for other technologies as models. Some regimes will be relevant because they focus on substantive problems analogous to those associated with NT, such as environmental agreements aimed at transboundary harms or arms control and non-proliferation regimes. Others will be relevant because they utilize mechanisms – such as framework conventions or private codes of conduct – that appear useful for NT regulation. Given the unique characteristics of NT, it is doubtful that any existing regime would fit it precisely. Nevertheless, regulatory regimes designed for other technologies can provide valuable analogies and lessons. We summarize here pertinent aspects of several regulatory regimes that may be relevant models for NT regulation at different stages in the development of the technology.

A. Potential models for the long term

Most well-known transnational regulatory regimes are relatively strong on most of the design criteria discussed here: they are typically created by interstate agreements, take the form of binding IL, are at least moderately institutionalized, and contain fairly rigid substantive rules. (Nonetheless, even these regimes are widely criticized for their weakness, based on substantive vagueness or loopholes, weak implementation, and inadequate monitoring and enforcement.) As a result, their lessons will be most valuable in the future, when the risks of NT development have become far more clear.

1. International Agreements on Environmental Pollutants

Several multilateral agreements restrict or prohibit the production and use of specific toxic substances based on their harmful effects on important components of the global environment. In terms of the problem structures introduced in the previous section, these agents threaten widespread harm to human health or to global commons. Examples include the Stockholm Convention on Persistent Organic Pollutants[29] and the Montreal Protocol on Substances that Deplete the Ozone Layer.[30] Treaties of this sort tend to focus on a relatively small number of agents that present well-demonstrated and substantial risks. For example, the Stockholm Convention as initially adopted in 2001 banned

production and use of twelve substances (referred to as the "dirty dozen") that are highly toxic, persistent and accumulative, and can move long distances in the environment. All participating states were quite prepared to ban them, if they hadn't already.[31]

The most controversial part of the Stockholm Convention is its provision for adding additional substances in the future. (The Montreal Protocol, itself an expansion of the Vienna ozone convention, and other environmental agreements include similar provisions; in that regard all resemble framework conventions.) This critical provision – notably the criteria and procedures for designating additional pollutants – has been the focus of much disagreement amongst signatories and potential signatories;[32] it has been the primary impediment to US Senate consent to the convention.

Because they focus on a limited set of very hazardous agents, agreements like Stockholm tend to impose strict substantive restrictions, often in the form of a full or partial prohibition of production or use. This contrasts with most national environmental laws, which prescribe acceptable levels for many pollutants. The combination of limited scope and substantive stringency likely reflects the cost and difficulty of negotiating binding international agreements, which make them feasible only for particularly harmful substances that all agree should be restricted.

Indeed, agreement is often possible only once the industries that produce the target substances agree to phase out production. For example, the Montreal Protocol became feasible only after DuPont, the principal manufacturer of chlorofluorocarbons (CFCs), the primary focus of the Protocol, identified commercially feasible alternatives and agreed to stop producing CFCs. Without industry agreement, negotiations can drag on indefinitely. For example, the United Nations Environmental Program (UNEP) has for years been promoting a treaty on mercury in the environment, without success.[33]

Other international environmental agreements are designed to limit or regulate the transboundary movement of pollutants – in the air, in water or as transportable solids. Examples include the European Convention on Long-Range Transboundary Air Pollution (LRTAP)[34] and the Basel Convention on Transboundary Movements of Hazardous Wastes and Their Disposal.[35] While transboundary agreements have a narrower substantive focus, as discussed above, and need not impose bans, they are still difficult

and costly to negotiate. As a result, they too tend to focus on pollutants that are prevalent in the environment and known or strongly suspected of causing significant damage.

These characteristics suggest that international environmental agreements have limited applicability as models for NT regulation in the near term. Given the political and practical impediments to successful negotiations, states have only demonstrated the necessary commitment in dealing with a limited set of harmful substances. It is difficult to imagine states undertaking such a burdensome process to address the hypothetical risks of future NT products or processes that have yet to inflict any known environmental harm; moreover, no known NT applications pose such serious risks that a ban or severe restriction seems appropriate. If environmental risks of NT appear in the future, however, these agreements will provide important lessons.

2. Non-Proliferation Arms Control Agreements

Arms control treaties, especially those that seek to prevent the proliferation of weapons of mass destruction (WMD), provide another transnational model of potential relevance to NT. Examples include the 1968 Nuclear Non-Proliferation Treaty (NPT),[36] the 1972 Biological Weapons Convention (BWC),[37] and the 1993 Chemical Weapons Convention (CWC).[38] Several aspects of these agreements limit their applicability as models for NT.

First, non-proliferation treaties seek to control technologies (i.e., nuclear, chemical or biological weapons, or inputs to them) that are clearly dangerous, as indicated by the term "WMD." Notwithstanding some extreme scenarios, it is unlikely that current or near-term applications of NT will rise to the same level of threat. In the long term, some NT applications could present a WMD threat, but that is likely far in the future. States are unlikely to act until the risks are more concrete and immediate.

Second, existing arms control treaties only apply to states. Their impact on non-state actors is indirect at best (e.g., the CWC and BWC require state parties to prohibit activities on their territory that are prohibited directly for them). Yet non-state actors, particularly transnational terrorist networks, may present the greatest threat of turning NT to malevolent uses. Another implication of this statist focus is the requirement of state consent; states can choose not to ratify these agreements and can drop out if they join. All

three WMD treaties have experienced states, often those presenting the greatest threat, electing not to ratify the agreement, withdrawing from it, or failing to comply with its obligations.[39] If a rogue state were to seek to use NT for malevolent purposes, current "Geneva style" arms control agreements would likely be ineffective.

Nevertheless, if predictions as to the potential military applications of NT are borne out,[40] at some point in the future states may be forced to consider arms control agreements to restrain a NT arms race or the aggressive state use of NT for weapons purposes, in part because of the lack of good alternatives. In such a situation, current agreements do suggest some lessons.

One of the principal tensions in the NPT results from its two-tier membership structure, in which some states – those grandfathered as of 1968 – are permitted to possess nuclear weapons while others are prohibited. The Director of the IAEA, Mohamed ElBaradei, recently emphasized this tension by 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."[41] The lesson may be that an agreement to control NT weapons should be negotiated before any "early adopter" states actually acquire them, or alternatively that any such nations be required to relinquish their NT weapons as a condition for international agreement.

Another lesson is that the technology transfer and assistance provisions of agreements like the NPT and BWC have been a strong inducement for developing countries to participate. These provisions require developed countries to share nuclear and biological information and technologies with developing countries for use in legitimate peaceful activities. Such provisions could provide a similar incentive for developing countries to enter agreements designed to control NT weapons.

A third lesson is that arms control regimes that include a formal oversight body are on the whole more successful than more decentralized regimes. In particular, the International Atomic Energy Agency (IAEA) has played a critical role in the stability and effectiveness of the NPT (as evidenced by its receipt of the 2005 Nobel Peace Prize), and the Organization for the Prohibition of Chemical Weapons has played an equally effective, if less visible role in the CWC. In contrast, the lack of an oversight body in the

BWC has led to ineffective monitoring and leaves the UN Security Council as the only enforcer of the convention, creating a sense of instability around the treaty.[42]

A central issue in arms control is verification.[3] For example, the inability of states to agree on a verification regime for the BWC has put the continued vitality of that treaty into question. The verification challenge is particularly acute for "dual use" technologies that can be used for both peaceful and malevolent purposes.[43] For example, much genetic research has dual use potential, making verification and enforcement of the BWC problematic.[44] Rather than prohibiting certain forms 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. Yet when a technology has both permissible and proscribed uses, verification becomes difficult if not impossible, at least without highly intrusive inspections. Governments and industry are likely to resist such intrusions in order to protect proprietary research.[45] All of these tensions are likely to arise equally in the case of NT. Current attempts to address the verification problem in the BWC, including consideration of codes of conduct, will have relevance to any future agreement governing NT.

3. Global Ethics Treaties

There have been a few international agreements designed to prohibit conduct held to violate ethical standards. In the past, most such agreements have been aimed at social practices, e.g., by banning the slave trade. More recently, the focus has turned toward governing ethical aspects of new technologies. Although these efforts have led to few concrete results, they still provide useful lessons for NT regulation. A prominent example is the recent attempt to negotiate a UN convention prohibiting human cloning.

Although there was widespread agreement among states that reproductive cloning (i.e., creation of a cloned human being) should be banned, negotiations foundered over disagreement whether to include a ban on therapeutic cloning (i.e., derivation of embryonic stem cells from cloned embryos for potential therapeutic applications).[46] As this case suggests, even with broad consensus on the desirability of restricting one

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[3] Kenneth W. Abbott, "Trust but Verify:" The Production of Information in Arms Control Treaties and Other International Agreements, 26 Cornell Int'l L.J. 1 (1993)

technological application, there may be incentives for some to expand negotiations to include other applications for which no consensus exists, leading to gridlock. (The situation is even more complex, since expanding the scope of negotiations is often essential to reaching agreement, as discussed above.) 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."[47] In the end, the General Assembly adopted a non-binding resolution favoring a ban on both forms of cloning by a divided vote of 84 to 34 with 37 abstentions. With this evident lack of consensus, the resolution is unlikely to have any practical impact.[48]

The cloning precedent has obvious implications for attempts to restrict NT on ethical grounds. NT 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. When the relevant inquiry is which applications should be restricted and which should not, there is bound to be controversy.

Other problems encountered in the attempt to negotiate a cloning convention may also be relevant to NT. A second issue was whether to establish an international body to administer sanctions for non-compliance, or to leave it to each state to sanction non-compliant activities within its territory. This echoes the disputes over transnational monitoring and sanctioning in arms control agreements. A third issue was whether any prohibition should be permanent or for a limited time. Proponents of limited duration cited the rapid pace of technological progress, which might well require periodic reexamination of ethical and legal issues. Similarly, with NT any future attempt at regulation must find a way to keep the regulatory structure current and properly aligned both with technological advances and with ethical perceptions and norms.

B. A Model for the Medium Term

As is surely clear by now, framework conventions are valuable instruments in situations of technical uncertainty – that is, before the risks or threats from a technology are sufficiently concrete to justify negotiation of legally binding, highly institutionalized

regimes like those just discussed, but after society has recognized that some form of regulation, and an efficient way to implement it, may soon be needed. This point has not yet been reached in the development of NT, but with the pace of technical progress we suspect it may be reached in the relatively near future.

As already noted, framework conventions typically contain few substantive obligations of the kind found in environmental or arms control treaties. Why then are they adopted as formal, legally binding instruments? The answer appears to be that states value firm commitments as to three related matters: (i) research, sharing of information, consultation and similar matters typically addressed in these agreements, all of which promote learning and incremental progress; (ii) willingness to consider more stringent action if and when concrete risks appear; and (iii) procedures for negotiating specific substantive commitments as required. These procedures are very important given the costs and difficulty of international negotiations. The Vienna ozone convention, for example, provided not only for amendment of the treaty itself, a process comparable in difficulty to creating a new agreement, but also for the adoption of annexes, protocols, decisions and other actions through streamlined procedures. In many cases, framework conventions provide that protocols may have different memberships than the treaty itself, allowing states some freedom to select the obligations to which they will submit.

For all these reasons, a framework convention would at some point in the future be a valuable intermediate step in the regulation of NT.

C. Models for the Short Term

In the short term, it is worth considering less formal and state-based alternatives to legally binding transnational regulation. While time prevents a full discussion of possible approaches, we note here some promising models.

- In some fields of transnational environmental regulation, independent groups of experts are authorized to issue periodic reports on the state of technological development and related issues. A prominent example is the International Panel on Climate Change (IPCC). The IPCC was established by UNEP and the World Meteorological Organization to assess scientific, technical, social and economic information relevant to global warming. The secretariat of the

Framework Convention on Climate Change is directed by that agreement to cooperate with the IPCC. A body like the IPCC simultaneously draws on and strengthens relevant epistemic community(ies). So long as its independent, transnational, expert status is protected, such a body can develop great legitimacy in the public eye, and can make important contributions both to well-informed regulation and to the generation of political will to act.

- Forums for information sharing and dialogue among technically expert national regulators are less threatening than transnational action and less costly than inter-state negotiations, yet they can lay a firm foundation for harmonized national regulation and even, if appropriate, for transnational regulation. Because they are decentralized, such arrangements typically need a convenor: a respected national agency, an international organization, or an NGO or professional body. The International Dialogue on Responsible Research and Development of Nanotechnology, described above, is an excellent example, already at work in the field of NT. Such arrangements face numerous challenges, however; these include: (i) maintaining momentum in the face of conflicting demands on participants; (ii) expanding participation as new actors enter the field; (iii) dealing with differences in capacity among state agencies; and (iv) avoiding capture and otherwise maintaining legitimacy in the eyes of governments, concerned communities and the public.
- Non-state actors, from business firms to scientists, often establish codes of conduct to regulate their own conduct on a voluntary basis. Motivations for self-regulation can vary widely: actors may aim to establish appropriate norms more quickly than public institutions can act, signal their good intentions, engage in a public relations gesture, or forestall burdensome state regulation. Illustrative of business codes, Responsible Care is an initiative of the global chemical industry; it includes a code for the safe handling of chemicals throughout the product cycle, administered by national associations. Among scientific researchers, the Asilomar guidelines were a 1975 effort to set standards for responsible research in the emerging field of recombinant DNA;

the guidelines reflected the ideals of the precautionary principle. As with many other private codes, portions of the guidelines were adopted by the NIH and other public bodies. Finally, the Foresight Guidelines are designed to promote the responsible development of NT-based molecular manufacturing; they were adopted at a 1999 workshop sponsored by two private organizations, the Foresight Institute and the Institute for Molecular Manufacturing.

V. Conclusion

While we eschew strong recommendations at this stage of our research, we see reasons to think that some form of transnational regulation of NT will eventually be thought desirable. It is likely that any formal transnational regulatory regime is many years in the future, but that should not prevent analysis and discussion of the challenges to transnational regulation, the structural choices that will have to be made, and the models society might look to for analogies and lessons. That is the aim of the project on which we have embarked.

For purposes of discussion, after initial consideration of a wide variety of institutional models – ranging from informal dialogue among experts to full-blown treaties with international monitoring agencies – we suggest a phased approach to transnational regulation:

(1) in the short term, begin with informal arrangements designed to increase and share knowledge of NT, its risks, and possible forms of regulation. These might include forums for dialogue among scientists, business firms and national regulators; codes of conduct informed by professional or social responsibility norms; and – somewhat more formally – a transnationally designated body of independent experts to monitor progress in the field of NT along with its social, economic, environmental and other impacts.

(2) in the medium term, consider a framework convention (or more than one addressing different areas of concern, such as environmental and social impacts).

The aim of such an agreement would not be to establish strong mandatory regulation – on the assumption that understanding of the risks of NT or the development of the technology would not have reached a point where that was called for – but rather to continue promoting research, information sharing and consultation, now on an inter-state basis, and to establish procedures by which the international community could act quickly if a need for regulation were to arise.

(3) in the long term, consider a variety of models for more traditional forms of mandatory transnational regulation, bearing in mind not only the severe challenges those efforts have faced, but also the difficulty of translating their experiences to the unique field of NT.

The overall aim would be to establish what one of us has called "pathways" to appropriate regulation:[49] opportunities for dialogue and learning, and streamlined procedures, by which regulation can be developed, designed and strengthened as necessary to respond to the risks of NT as they appear over time – and at the same time, by which regulation that is too early, too stringent or ill-informed can be avoided.

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[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 (2004) 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 October 16, 2005).

[2] F. Salamanca-Buentello et al., "Nanotechnology and the Developing World, Policy Forum, 2 (2005): 0300-0303.

[3] R. Baum, "Nanotechnology: Drexler and Smalley Make the Case For and Against 'Molecular Assemblers,'" Chemical & Engineering News, Dec. 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 October 16, 2005). 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 October 16, 2005). 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) (last visited October 16, 2005). can regulate the creation of MSDSs for nanoparticles in addition to conditions for workers creating nanoparticles,http://www.occupationalhazards.com/safety_zones/47/article.php?id=12403 (last visited

[5] Marchant & Sylvester, 2006; Bennett, 2004; Fiedler & Reynolds, 1994; Reynolds, 2003; Miller, 2003; Marlowe, 2003; Smith 2001

[6] Thayer, 2005; Pardo-Guerro & Aguayo, 2005

[7] Lemley, 2005

[8] Slaughter, Tulumello & Wood, 1998

[9] Abbott, 2004
[10] The National Nanotechnology Initiative's website is located at http://www.nano.gov/ (last visited October 16, 2005).
[11] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)
[12] Bayh-Dole 35 USCA §§ 200 to 211
[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." BIS, Commercial Encryption Export Controls, at http://www.bxa.doc.gov/Encryption/Default.htm (last visited October 16, 2005); 15 C.F.R. Parts 730-774 (2005).
[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.fda.gov/nanotechnology/ (last visited October 16, 2005). 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 October 16, 2005).
[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 October 16, 2005).
[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 October 16, 2005).
[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 October 16, 2005).
[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] K. Proffitt, "Yellow Light for Nanotech," Science, 305 (August 6, 2004): 762-5 (quoting Julia Moore).
[22] 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://australianit.news.com.au/articles/0,7204,16802091%5E26317%5E%5Enbv%5E15306-15321,00.html (last visited October 16, 2005). ETC, as noted earlier, has made numerous calls for moratoria on the commercial production of nanoparticles. ETC, "No Small Matter," Communique, 76 (May/June 2002) available at http://www.etcgroup.org/documents/Comm_NanoMat_July02.pdf (last visited October 16, 2005).
[23]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).
[24] See Proffitt, supra note 26 at 764.
[25] 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) at http://www.forbes.com/finance/2005/04/06/cz_jw_0406soapbox_inl.html?partner=rss (last visited October 16, 2005).
[26] 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" (2005) /www2.chass.ncsu.edu/cobb/me/past%20articles%20and%20working%20papers/nano%20framing%20for%20science%20communication.pdf(last visited October 16, 2005).
[27] See Cobb, supra note 31.

[28] I. Bennett and D. Sarewitz, "Too Little, Too Late? Research Policies on the Societal Implications of Nanotechnology in the United States," at http://cspo.org/ourlibrary/documents/SciasCultSubmit.pdf (last visited October 12, 2005). 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."

[29] 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).
[30] 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 Jan. 1, 1989).
[31] M. Porta & E. Zumeta, "Implementing the Stockholm Treaty on Persistent Organic Pollutants," Occupational & Environmental Medicine, 59(2002):651-653, at 651.
[32] P.E. Hagen & M.P. Walls, "The Stockholm Convention on persistent Organic Pollutants," Natural Resources & Environment, Spring 2005, at 49-52.
[33] Lauren Miura, Mercury: Dems Attack U.S. Policy on International Treaty, 10 Greenwire (Mar. 3, 2003).
[34] 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 11 substances.
[35] 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.
[36] 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.
[37] Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, opened for signature Apr. 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163.
[38] Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, Jan. 13, 1993, 1974 U.N.T.S. 45, 32 I.L.M. 800. Some military applications of NT may be subject to the BWC or the CWC. R.D. Pinson, "Is Nanotechnology Prohibited by the Biological and Chemical Weapons Convention?," Berkeley Journal of International Law, 22 (2004) 279-309, at 281.
[39] 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.
[40] . J. Altmann & 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.
[41] Quoted in J. Johnson, "An End to Nuclear Nonproliferation?," Chemical & Engineering News, July 26, 2004, at 34, 38.
[42] J.B. Tucker, "The BWC New Process: A Preliminary Assessment," The Nonproliferation Review, Spring 2004: 1-13, at 2-3.
[43] National Research Council, Biotechnology Research in an Age Of Terrorism: Confronting the Dual Use Dilemma (Washington, D.C.: National Academies Press, 2003).
[44] See Tucker, supra note 45, at 3.
[45] 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):16-18.
[46] 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, Nov. 19, 2004, at 13A.
[47] 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.
[48] I. Arieff, "Un Backs U.S. Plea for Total Ban on Human Cloning," Reuters, Mar. 8, 2005.
[49] Abbott & Snidal, 2004.