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# Operationalizing Anticipatory Governance: Steering Emerging Technologies Towards Sustainability

by

Mark Jeffrey Philbrick

A Dissertation submitted in partial satisfaction of the requirements for the degree of

Doctor of Philosophy

in

Environmental Science, Policy, and Management

in the

Graduate Division

of the

University of California, Berkeley

Committee in charge:

Professor David E. Winickoff, Chair

Professor Todd R. La Porte

Professor Katherine M. O'Neill

Professor Margaret R. Taylor

Fall 2010



## Abstract

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Professor David Winickoff, Chair

Technological innovation is a double-edged and contested arena. On one hand, it has brought us global communications and unprecedented access to information for those connected to the Internet. The last 100 years have seen the widespread deployment of household electricity, potable tap water, and a host of transportation options in the Global North. Technologies allow us to manipulate matter at the subatomic level, and to observe the far reaches of the universe. Humans have been to the moon, discovered life in the deep oceans, and nearly eradicated polio. Clearly, technologies are a powerful force in the world, and innovation is seen as key to economic prosperity in the 21<sup>st</sup> century.

On the other hand, climate change threatens the survival of many species, and the livelihoods of much of the future human population. Further, it is far from alone in terms of problems to which large-scale technological deployment has contributed. Asbestos, DES, DDT, and endocrine disruptors are among the many technologies where some, perhaps many, of the negative human and environmental consequences that have ensued could conceivably have been mitigated. Technological governance is clearly an area for possible improvement, and emerging technologies present a particularly attractive leverage point, as they have yet to develop substantial sociotechnical and institutional momentum.

The dominant approach to technological governance in the U.S. is characterized by a combination of market forces, public support for basic science and targeted initiatives, and a “science-based” approach to risk assessment and regulation. In recent years, the EU has emphasized the Precautionary Principle as an alternative governance basis, and there has been much debate about the respective merits of precaution and science. This dissertation argues that much of that discourse misses a much larger point: The prevailing approaches to the governance of emerging technologies in both the EU and the U.S. are inadequate, in that they are excessively focused on relatively narrow conceptions of risk, do not provide a coherent framework for considering risks, benefits, and distributional tradeoffs simultaneously, and tend more towards reactivity than proactivity, particularly in terms of the production of public goods.

These failings systematically produce a series of governance gaps in the context of a market economy. Specifically, the rate of innovation tends to outstrip existing capacities for risk

assessment, especially in the case of emerging fields such as nanotechnology. Second, the capacity lag in oversight tends to undermine public confidence and trust. Third, markets alone tend to underproduce public goods, a problem that is particularly acute in arenas with substantial environmental externalities. Finally, relevant existing institutions in the U.S. generally lack a systematic capability to incorporate foresight into current policy-making in a meaningful way.

This dissertation proposes a combination of the concepts of anticipatory governance and sustainability as a basis for addressing these governance gaps. A strong theme of transatlantic translation runs throughout; many of the recent developments in technology assessment have occurred in Europe, and require substantial adaptation to function effectively in the American sociopolitical environment. Anticipatory governance provides culturally appropriate philosophical underpinning and process; sustainability offers substantive direction. The goal is not to develop overarching theory, but to operationalize these ideas, to put the combination into practice with respect to the governance gaps articulated above. The empirical investigations of the first two gaps employ nanoscale technologies as cases to explore specific instances of the general question “what do we need to anticipate” with respect to risks and public perceptions, respectively. The inquiries regarding the third and fourth gaps are more exploratory. In terms of the production of public goods through innovation, how do the combination of historical patterns and market structures help demark the boundaries of a “constructive intervention space” for public investment? With respect to institutional capacities, how can the combination of anticipatory governance and sustainability assist in evaluating current programs, and designing solutions for the future?

Several conclusions with direct relevance to policy, strategy, and governance regarding emerging technologies result. First, existing decision-making paradigms need improvement in order to consider risk-benefit tradeoffs adequately, and to provide guidance to actors on the ground in the prolonged absence of scientific and regulatory certainty. Second, effective public engagement programs in the U.S. must complement and feed into existing structures of representative democracy, rather than attempting to circumvent or replace them. Third, the purported “Valley of Death” between invention and market penetration is particularly acute with respect to the production of environmental public goods, as the barriers to entry in these sectors are a poor match for private funding incentives, implying that this is a constructive area for increased levels of public intervention. Finally, the combination of anticipatory governance and sustainability provides a framework that highlights the fragmented nature of U.S. policy responses to the problem of technological governance, and does indeed provide a solid foundation for the design of future institutions, while recognizing that their implementation will be dynamic, contested, and theoretically impure.

## Table of Contents:

### Chapter One: Governance Gaps

I.	Introduction: Governing Emerging Technologies .....	1
II.	Risk Analysis and the Precautionary Principle .....	3
II.A	Precaution and the Precautionary Principle .....	3
II.A.1	The Precautionary Principle is Incoherent.....	4
II.A.2	Vorsorgeprinzip, Precaution, and Forecaring .....	5
II.A.3	Precaution, Innovation, and Risk .....	6
II.B	Risk Analysis .....	7
II.B.1	Scientific Risk Assessment .....	7
II.B.2	Risk Assessment vs. Risk Management.....	9
II.B.3	Science and Precaution .....	11
III.	Evolving Ideas of Sustainability and Technology Assessment .....	12
III.A	A Brief History of Sustainability .....	13
III.B	A Brief History of Technology Assessment .....	16
III.B.1	The U.S. Congressional Office of Technology Assessment.....	16
III.B.2	European Approaches to Technology Assessment .....	18
IV.	Governance Gaps .....	20
IV.A	Innovation Is Outstripping Risk Assessment.....	20
III.B	Public Confidence and Trust.....	21
III.C	Underprovision of Public Goods; Anticipation of Market Failures.....	21
III.D	Regulatory and Policy Uncertainty .....	22

### Chapter Two: From Governance Gaps to Research Foci

I.	Overview .....	24
II.	Emerging Developments in Technology Assessment.....	24
II.A	Strategic Niche Management.....	25
II.B	Transition Management .....	26
II.C	Anticipatory Governance (U.S.) .....	28
III.	Combining Sustainability and Anticipatory Governance .....	30
III.A	Sustainability Metrics and Goals .....	31
II.B	Bounded Objectivity .....	34
III.C	Sustainability as Boundary Object.....	36
III.D	Anticipation as Shaping .....	37
III.E	From Niches to Markets.....	39
IV.	Anticipatory Research Foci.....	41
IV.A	An Anticipatory Governance Approach to Carbon Nanotubes (Ch. 3).....	43
IV.B	Public Engagement – National Citizens Technology Forum (Ch. 4) .....	44
IV.C	Narrowing the Constructive Intervention Space (Ch. 5) .....	45

IV.D Towards Anticipatory Institutions (Chapter 6)	45
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### Chapter Three: An Anticipatory Governance Approach to Carbon Nanotubes

I. Introduction	47
II. Methodological Challenges of CNTs	49
II.A Confounded Assays	49
II.B Medium Interactions	50
II.C Surfactants	51
III. Potential hazards of CNTs	52
III.A Inflammation and Oxidative Stress	53
III.B Granulomas, Fibrosis, and Secondary Effects	55
IV. Analogies to Asbestos	56
V. Anticipatory Strategies	58

### Chapter Four: Integrating Public Engagement

I. Introduction	62
I.A Upstream Engagement	62
I.B Methodology	64
II. Proof-of-Concept: Norms	65
II.A Deliberation, Advocacy, and Normative Compatibility	65
II.B Control Mutuality and Lay Rationality	68
III. Proof-of-Concept: Outcomes	71
III.A Independent Regulation	72
III.B Public Information	73
III.C NBIC commercialization	73
IV. Recommendations	74
IV.A Timing	75
IV.B Separation	76
IV.C Political Diversity	77
V. Update and Future Prospects	77

### Chapter Five: Narrowing the Constructive Intervention Space

I. Anticipating Market Failures	80
I.A Sustainability, Public Goods, and Market Failures	80
I.B Historical Framing	81
II. Empirical Grounding	82
III. The “Valley of Death”	84
III.A Macro U.S. R&D Funding levels	84
III.C Public Responses	98
III.C.1 SBIR/STTR Description	100
III.C.2 SBIR/STTR Analysis	101
III.C.3 Advanced Technology Program (ATP)	103

III.C.4	Technology Innovation Program (TIP).....	105
IV.	Needs and Market Failures ⇔ Constructive Innovation Space.....	105
IV.1	Stage of Technological Development.....	106
IV.2	Environmental Public Goods (Topic Area).....	106

## Chapter Six: Towards Anticipatory Institutions

I.	Institutionalizing Anticipatory Governance.....	108
I.A.	Evaluative Framework.....	109
II.	Technology Innovation Program (TIP).....	111
II.A	TIP Revisited.....	111
II.B	Applying the Framework.....	112
III.B.1	Foresight with respect to Sustainability.....	113
III.B.2	Stakeholder (including public) Engagement.....	113
III.B.3	Anticipating Market Failure.....	114
III.B.4	Risk/Benefit Tradeoffs within the contexts of Sustainability.....	114
III.B.5	U.S. Political Framing.....	114
III.B.6	Institutional Capacity for Anticipatory Governance.....	115
III.	National Nanotechnology Initiative (NNI).....	115
III.A	Development of the NNI.....	116
III.B	EH&S and Societal Dimensions.....	117
III.B.1	Innovation outstrips evaluation funding.....	118
III.B.2	EH&S strategy.....	118
III.B.3	Re-authorization emphases.....	119
III.C	Application of the Framework.....	120
III.C.1	Foresight with respect to Sustainability.....	121
III.C.2	Engaging Stakeholders (including the general public).....	121
III.C.3	Anticipating Market Failures.....	121
III.C.4	Risk/Benefit Tradeoffs within the contexts of Sustainability.....	122
III.C.5	U.S. Political Framing.....	122
III.C.6	Institutional Capacity for Anticipatory Governance.....	123
IV.	National Sustainability Initiative.....	123
IV.A	Existing Programs.....	123
IV.A.1	Global Change Research Initiative.....	123
IV.A.2	Obama Initiatives.....	125
IV.B	Next Steps.....	126
IV.B.1	Foresight with respect to Sustainability.....	127
IV.B.2	Engaging Stakeholders (including the general public).....	128
IV.B.3	Anticipating Market Failures.....	129
IV.B.4	Risk/Benefit Tradeoffs within the contexts of Sustainability.....	130
IV.B.5	U.S. Political Framing.....	131
IV.B.6	Institutional Capacity for Anticipatory Governance.....	131
V.	Concluding Remarks.....	132
V.A	Findings.....	133
V.B	Questions.....	133



## List of Tables and Figures:

### Tables:

1.	Translating Governance Gaps into Research Foci	24
2.	Transatlantic Term Translations	40
3.	Comparison of S. 3274, S. 1482, and NCTF Recommendations	78
4.	Evaluation/Anticipatory Design Framework	110

### Figures:

1.	The Constructive Intervention Space in the U.S.	41
2.	U.S. R&D as a percentage of GDP, 1953-2007	85
3.	Percentages of R&D Spending by Subject Area, 1953-2007	86
4.	Allocation of Federal R&D Investments, 1955-2007	87
5.	Normalized R&D Investments by Research Stage, 1953-2007	88
6.	U.S. Venture Capital Investments, 1995-2008	91
7.	Percentages of U.S. VC Investments for Selected Industries and Years	91
8.	U.S. VC Investment by State, Selected Years	92
9.	U.S. Cleantech Investments, 2004-2008	94
10.	VC Funding by Stage, 1995-2008	96
11.	Basic R&D Investments by Source, 1953-2007	99
12.	Applied Research by Source, 1953-2007	100
13.	Evaluating/Designing Constructive Interventions	109

## List of Abbreviations/Acronyms:

AHP	Analytic Hierarchy Process
AM	Alveolar Macrophages
ARPA	Advanced Research Projects Agency (U.S.)
ARPA-E	Advanced Research Projects Agency – Energy (U.S.)
ARRA	American Reinvestment and Recovery Act
ATP	Advanced Technology Program (U.S.)
BNN	Boron-Nitride Nanotubes
CAA	Clean Air Act (U.S.)
CBA	Cost-Benefit Analysis
CBD	Convention on Biological Diversity
CEQ	President’s Council on Environmental Quality (U.S.)
CERs	Certified Emission Reductions (Kyoto Treaty)
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act, aka Superfund (U.S.)
CFCs	Chlorofluorocarbons
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
COPD	Chronic Obstructive Pulmonary Disease
CNN	Critical National Need
CNS-ASU	Center for Nanotechnology in Society, Arizona State University
CNS-UCSB	Center for Nanotechnology in Society, University of California, Santa Barbara
CNT	Carbon Nanotube(s)
Codex	Codex Alimentarius Commission
CTA	Constructive Technology Assessment
CTSI	Clean Technology and Sustainable Industries Organization
CWA	Clean Water Act (U.S.)
DARPA	Defense Advanced Research Projects Agency (U.S.)
DDT	Dichlorodiphenyltrichloroethane (a pesticide)
DES	Diethylstilbestrol (a synthetic estrogen)
DHS	Department of Homeland Security (U.S.)
DOC	Department of Commerce (U.S.)
DOD	Department of Defense (U.S.)
DOE	Department of Energy (U.S.)
DTSC	Department of Toxic Substances Control (California)
DWCNT	Double-walled Carbon Nanotubes
EC	European Commission
EDF	Environmental Defense Fund (NGO)
EH&S	Environmental Health and Safety
EPA	Environmental Protection Agency (U.S.)
ESA	Endangered Species Act (U.S.)
ESTD	Early-Stage Technology Development
ETC	Action Group on Erosion, Technology, and Concentration (NGO)
EU	European Union
FAO	Food and Agriculture Organization (U.N.)

FBS	Fetal Bovine Serum, a common, protein-rich adjuvant to in vitro experiments
FDA	Food and Drug Administration (U.S.)
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act (U.S.)
GCRP	Global Change Research Program (U.S.)
GDP	Gross Domestic Product
GHG	Greenhouse Gas(es)
GMO	Genetically Modified Organism(s)
HEPA	High Efficiency Particulate Air (used in reference to filtering mechanisms)
HiPCO	High-Pressure CO Conversion, a CNT production process
IANANO	International Association of Nanotechnology (NGO)
IP	Intellectual Property
IPCC	Intergovernmental Panel on Climate Change
IPO	Initial Public Offering
ISO	International Standards Organization
IWGN	Interagency Working Group on Nanotechnology (U.S.)
LCA	Life Cycle Analysis
MCDA	Multi-Criteria Decision Analysis
MTBE	Methyl Tertiary Butyl Ether (a gasoline additive)
MTS	3-(4,5-dimethylthiazol-2-yl)- 5-(3-carboxymethoxyphenyl)-2-(4-sulfophenyl)-2H-tetrazolium, a water-soluble chemical, similar to MTT, used in cellular viability assays
MTT	3-(4, 5-dimethylthiazol-2-yl)-2, 5-diphenyl tetrazolium bromide, a chemical used in cellular viability assays
MWCNT	Multi-Walled Carbon Nanotubes
NADP	Nicotinamide Adenine Dinucleotide Phosphate (an important component in cellular processes)
NAS	National Academy of Sciences (U.S.)
NASA	National Aeronautics and Space Administration (U.S.)
NBIC	Nanotechnology, Biotechnology, Information Technology, and Cognitive Science (and the prospective convergence of these disciplines)
NCTF	National Citizens Technology Forum (U.S.)
NEPA	National Environmental Protection Act (U.S.)
NGO	Non-Governmental Organization
NIH	National Institutes of Health (U.S.)
NIOSH	National Institute for Occupational Safety and Health (U.S.)
NIST	National Institute of Standards and Technology (U.S.)
NNCO	National Nanotechnology Coordinating Office (U.S.)
NNI	National Nanotechnology Initiative (U.S.)
NOAEL	No Observable Adverse Effects Level (metric of toxicity)
NRC	National Research Council (branch of the NAS)
NSE	Nanoscale Science and Engineering
NSET	Nanoscale Science, Engineering, and Technology subcommittee of the NSTC (U.S.)
NSF	National Science Foundation (U.S.)
NSI	National Sustainability Initiative (proposed)
NSTC	National Science and Technology Council (U.S.)

NSTI	Nano Science and Technology Institute
NVCA	National Venture Capital Association
OECD	Organization for Economic Cooperation and Development
OMB	Office of Management and Budget (U.S.)
OSTP	Office of Science and Technology Policy (U.S.)
OTA	Office of Technology Assessment (U.S.)
PCA	Program Component Area (of the NNI)
PCAST	President's Council of Advisors on Science and Technology (U.S.)
PP	Precautionary Principle
PWC	PricewaterhouseCoopers
QSAR	Quantitative Structure-Activity Relationships
RCRA	Resource Conservation and Recovery Act (U.S.)
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical Substances Regulation (EU)
RNS	Reactive Nitrogen Species
ROS	Reactive Oxygen Species
RPMI	Roswell Park Memorial Institute, used in reference to a series of cellular culture growth media commonly employed in toxicological assessments
RTTA	Real-Time Technology Assessment
R&D	Research and Development
SBA	Small Business Administration (U.S.)
SBIC	Small Business Investment Company (U.S.)
SBIR	Small Business Innovation Research program (U.S.)
SIWG	Sustainability Interagency Working Group (proposed)
SNM	Strategic Niche Management
SPS	Agreement on Sanitary and Phytosanitary Measures (WTO)
STS	Science and Technology Studies
STTR	Small Business Technology Transfer program (U.S.)
SVTC	Silicon Valley Toxics Coalition (NGO)
SWCNT	Single-Walled Carbon Nanotubes
TA	Technology Assessment
TIP	Technology Innovation Program (U.S.)
TSCA	Toxic Substance Control Act (U.S.)
UCB	University of California, Berkeley
UK	United Kingdom
UN	United Nations
UNEP	United Nations Environmental Program
UNFCCC	United Nations Framework Convention on Climate Change
VC	Venture Capital
WHO	World Health Organization (U.N.)
WST	2-(4-Iodophenyl)-3-(4-nitrophenyl)-5-(2,4-disulfohenyl)-2H-tetrazolium, a tetrazolium salt similar to MTS and MTT, used in toxicological assays.
WTO	World Trade Organization

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## I. Introduction: Governing Emerging Technologies

Technological innovation is a double-edged and contested arena. On one hand, it has brought us global communications and unprecedented access to information for those connected to the Internet. The last 100 years have seen the widespread deployment of household electricity, potable tap water, and a host of transportation options in the Global North. Technologies allow us to manipulate matter at the subatomic level, and to observe the far reaches of the universe. Humans have been to the moon, discovered life in the deep oceans, and nearly eradicated polio. Clearly, technologies are a powerful force in the world, and innovation is seen as key to economic prosperity in the 21<sup>st</sup> century.

On the other hand, climate change threatens the survival of many species, and the livelihoods of much of the future human population. Further, it is far from alone in terms of problems to which large-scale technological deployment has contributed. Some prominent examples are well summarized in an EU document titled “Late Lessons From Early Warnings” (Harremoës, Gee et al. 2001). The list is somewhat appalling, and includes asbestos, DES, DDT, and endocrine disruptors among the technologies where an improved governance approach could have ameliorated some, perhaps many, of the negative human and environmental consequences that ensued. The chief claim of this widely cited piece is that we as a global society can and should do better in terms of technological governance.

In governance terms, the early stages in the technological life cycles present a unique set of opportunities. Their forms, functions, and composition are generally more malleable, and subject to stakeholder influence (e.g. Kline and Pinch 1996). To the degree that the innovations are derived from publicly funded basic research, priorities are at least somewhat responsive to democratic influences. Perhaps most importantly, early-stage technologies have usually not yet developed significant constituencies with vested interests in their success and/or continuance. They lack the network of suppliers, customers, fixed assets, and ancillary service providers that contribute to what Hughes terms “technological momentum” (1994), and others refer to as “technological lock-in” (Carrillo-Hermosilla 2006; Konnola, Unruh et al. 2006; Genus and Coles 2008; Beddoe, Costanza et al. 2009).

This unique opportunity to influence technological trajectories does not escape the attention of a variety of interested actors. Proponents frequently advance utopian visions and predictions – power “too cheap to meter” from nuclear reactors is an infamous example. Opponents sometimes articulate equally dystopian scenarios, or call for blanket moratoria on further development (ETC 2003b). Others see the emergence of significant new technologies as opportunities to learn from past missteps (Kearnes, Grove-White et al. 2006; Kuzma 2007), or as a vehicle to highlight long-standing concerns (Davies 2007). In short, emerging technologies are loci of sociopolitical contestation, which amplifies both the challenges to and opportunities for the development of innovative governance strategies.

This dissertation targets the problem of governing emerging technologies, particularly those with significant environmental implications and/or applications. It uses nanotechnologies as a primary source of case studies, although the later chapters extend the analysis to “clean” technologies more broadly. It proposes a combination of “anticipatory governance” (detailed in

chapter two) and sustainability as a constructive foundation for action in the U.S., with the goal of improving the production of public goods. This chapter sets the stage for that argument, and the empirical investigations that follow.

Some theoretical and historical context is necessary to frame the problem properly. Theoretically, there is a long-running and often heated debate between the precautionary principle and “science-based” risk assessment as philosophical bases for regulating emerging technologies. The EU and the U.S. have been the primary contestants, particularly with regard to disputes within World Trade Organization (WTO), where these issues have been most clearly articulated. Without discounting the rest of the world, which clearly has strong stakes in the debate, section II focuses on the primary antagonists for reasons of analytical parsimony. Its chief claim is that the ongoing transatlantic debate between the precautionary principle and conventional conceptions of risk analysis misses a larger point with respect to emerging technologies, i.e. that they promise benefits as well as risks. Effective governance solutions need to balance both aspects, and also consider distributional ramifications. The notion of sustainability offers promise in this regard, but is not without problems of its own.

To this end, section III briefly traces the histories of both sustainability and technology assessment. The sustainability discussion focuses largely on the U.S., and summarizes how the idea has moved from the “green” fringe to the mainstream over the last 40 years, with some caveats. Technology assessment, on the other hand, largely started in the U.S., but the locus of creative activity shifted to the EU with the demise of the U.S. Office of Technology Assessment (OTA) in the mid-90s. Bringing the results of these European efforts back across the Atlantic poses several translation problems, a major theme of chapter two. Further, chapter one’s recounting of the histories of both sustainability and technology assessment lays the groundwork for the combination of anticipatory governance and sustainability that underpins chapters three thru six. The conjunction between the two also drives the dissertation’s focus on technologies with environmental implications and/or applications, as articulated further in chapter five. The tripartite (social, environmental, economic) formulation of sustainability provides a vehicle for consideration of the broader social implications of policies primarily driven by expected market failures at the intersection of environmental applications and early stage innovation. These issues are multifaceted; again, chapter one seeks only to set the stage for further analysis.

Section IV represents a first attempt at transforming the contexts and histories summarized in sections I through III into an actionable research program. It uses and amplifies the concept of “governance gaps” originally advanced by Roco et al. (Roco 2005; Roco and Bainbridge 2005; Roco and Renn 2007) with respect to nanotechnologies as an initial problem statement. It is important to note that Roco played an important role in the development of the NNI, so even strong proponents of the technologies have raised governance concerns at a relatively early stage in the process. That fact underscores the claim that emerging technologies, such as nanotechnologies, have become a crucial nexus, and perhaps an opportunity to effect meaningful change. Thus, the governance gaps identified in section IV are a first step in the development and execution of the results-oriented research agenda embodied by the balance of the dissertation.



## II. Risk Analysis and the Precautionary Principle

The transatlantic debate over the applicability of the Precautionary Principle to the validity of national regulations under the auspices of the World Trade Organization (WTO) was lively as recently as five years ago (e.g. Winickoff, Jasanoff et al. 2005; WTO 2006; Aslaksen and Myhr 2007). That discussion also drew on previous work regarding the appropriate role of science in international governance, much of which remains relevant to the notion of governance gaps set forth in section IV (e.g. Stillman 1974; Wirth 1994; Walker 1998; Verweij and Josling 2003). The conversation centered largely around genetically modified organisms (GMOs), the emerging technology of the time. However, the historical experience with GMOs is part of the context into which nanotechnologies are emerging. While several scholars seek to apply the lessons learned from GMOs to nanotechnologies (Macnaghten, Kearnes et al. 2005; Kearnes, Grove-White et al. 2006; Kuzma 2007), others caution that it is easy to overdraw parallels between the two (Rip 2006). What is clear is that these arguments are part of the backdrop for the discourse around nanotechnologies. This dissertation argues that nanotechnologies represent a real opportunity to move beyond some of the unproductive dichotomies that characterized the transatlantic GMO debates. In order to make this case effectively, it is important to review that which has gone before, particularly since “before” is only five to ten years in the past at the time of this writing, and several of these issues are probably sleeping, rather than dead.

### II.A Precaution and the Precautionary Principle

The Precautionary Principle (PP) has become strongly associated with the EU. This is not inappropriate, as various treaties incorporate it formally, and the EU has strongly advocated the principle as a basis for international law (e.g. EC 2000). Unfortunately, this has led to the mistaken conclusion that the EU is necessarily more precautionary than the U.S. More discerning authors (Jasanoff 2005; Sunstein 2005b; Winickoff, Jasanoff et al. 2005; Murphy, Levidow et al. 2006) understand that the transatlantic differences in precautionary action lie more in the area of substance than degree. That is, the question is less ‘how precautionary’ than ‘precautionary towards what’ (Weiner and Rogers 2002)? Certainly, the EU has taken a more precautionary stance towards GMOs and chemicals, as oft-cited examples, but the U.S. has led in restricting cigarette smoking and drunk driving, and is much less tolerant of the risks presented by certain kinds of cheese that Europe continues to relish. It is clear that the EU formally endorses the PP more strongly than the US, a difference with political undertones and ramifications. However, that official distinction does not always translate neatly into variances in action, and the understandable confusion between the two is one of the ambiguities that weakens the PP as a basis for constructive action in the U.S.

At the same time, the PP remains important in international discourse. While the literature includes much bemoaning of the existence of multiple versions with subtle differences, and the lack of a definitive statement thereof, the concept retains vitality. It has become somewhat of a rallying banner for opposition to the existing order, whether manifestation of the latter is attributed to the World Trade Organization (WTO), the introduction of genetically modified organisms (GMOs) into Europe, or the prevalence of inadequately tested chemicals in commercial use. In this sense, the PP functions as a kind of boundary object (Star and Griesemer 1989), a concept that allows disparate groups to unite in common cause while maintaining their

own distinct interpretations.<sup>1</sup> Given the power and persistence of this idea, it is important not to dismiss it summarily, but rather to evaluate the objections raised against it critically.

### *II.A.1 The Precautionary Principle is Incoherent*

The differences between the various articulations of the precautionary principle are well-analyzed elsewhere (e.g. Bruce 2002; van den Belt and Gremmen 2002; Gardiner 2006). The version included in the Rio Declaration is relatively moderate, and illustrates the basic principles:

“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation” (UNEP 1992).

There are three core elements: a threat of harm, scientific uncertainty, and preventative action<sup>2</sup>. Gardiner argues that much of the debate is over appropriate thresholds in each of these categories, and the applicability of the principle to particular situations. Some critics highlight the fact that both action and inaction entail risks, rendering it useless in situations that might involve fatal outcomes (Peterson 2006). Others emphasize the lack of semantic clarity and theoretical robustness (Turner and Hartzell 2004) from a philosophical standpoint. Sunstein (2005b) offers perhaps the most cogent criticisms, and does so from a standpoint of sympathy with proponents’ aims.

Sunstein concurs with Peterson that the strongest formulations of the PP are literally incoherent. Paralleling Gardiner, he understands that advocates of the principle generally express aversion to particular kinds of risks. Unfortunately, he characterizes this selectivity as requiring a certain level of “self-blinding”, and connects this problem with notions of public cognition to derive conclusions uncomfortably close to the “public deficit” model of risk management and communication. In so doing, he either misses or ignores the symbolic value of the PP, a topic taken up in section II.A.2.

Nevertheless, Sunstein’s claim that the PP is problematic because it offers no explicit guidance in cases of risk-risk or risk-benefit tradeoffs has merit when the principle is taken as a decision rule or legal standard. Such an interpretation is eminently realistic, as many political entities have formally incorporated the PP into their legal structures. Sunstein’s best examples involve opportunity choice and probability: for example, if the U.S. was to choose to ban phthalates entirely, the country could expect some reduction in early deaths and morbidity attributable to these substances. However, the overall economic costs of the necessary regulations, and the enforcement thereof, might well reduce the income of a substantial subpopulation, and the correlation between poverty and ill health is well established. In such cases, Sunstein argues for

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<sup>1</sup> Sustainability is also a boundary object, but much more powerful in this regard, as it offers both a brighter common future, as well as more niches for individual (and group) engagement, and less political baggage. Ch. 2 expands on this thesis.

<sup>2</sup> Many would also argue that the PP implies a shifting of the burden of proof from regulators to innovators, but the Rio version does not so state explicitly.

the virtues of cost-benefit approaches, without falling into the pitfall of viewing economic valuation as a panacea.

Sunstein’s analysis raises at least one important issue. To what extent is the PP appropriate as a binding rule, vs. a statement of aspirations (Marchant 2003)? Correspondingly, to what degree does Sunstein’s analysis take the PP out of context in an excessively anthropocentric fashion, eliding environmental considerations? More subtly, are some PP proponents equally guilty of inappropriate extension, of stretching the PP beyond the limits of its usefulness as a boundary object? Might the PP’s first two conditions of harm and uncertainty limit its applicability and effectiveness? Perhaps the PP would be more powerful as a purely symbolic instrument, if freed from its instrumental bindings?

### *II.A.2 Vorsorgeprinzip, Precaution, and Forecaring*

The question of how to approach, interpret, or treat the PP is fundamental. Is a legalistic reading, such as that adopted by Sunstein and others, the most appropriate avenue of interpretation? Proponents of the principle would argue otherwise, and claim that the PP should be viewed in context, in more aspirational terms, as guidance in the development of future efforts (Stirling 2007). Proponents would also argue that Sunstein’s conception of “blindness” denigrate the convictions that underlie their commitment to the PP. Prominent among such beliefs is the idea that humanity has done a poor job of anticipating the adverse consequences of its own technological activities, especially with respect to the environment (Harremoës, Gee et al. 2001). Some advocates would go further in arguing that narrow legalistic or economic conceptions of success are a fundamental part of the problem (Daly 1996; Hawken, Lovins et al. 1999). In any case, Sunstein’s analysis largely fails to consider the ethical valences of the PP. On the other hand, PP advocates stretch the principle well beyond widely accepted articulations thereof, using it as a proxy for a larger agenda.

Jordan and O’Riordan (1999) astutely observe that *vorsorgeprinzip*, which is usually translated as ‘precautionary principle’, literally means ‘forecaring principle’. This alternative translation captures the spirit of proponents’ arguments much more accurately. For example, Hansen et al. (2008) identify four key elements of precautionary decision-making:

1. Preventative action in the face of uncertainty;
2. Shifting the burden of proof to proponents of potentially harmful activities;
3. Exploration of a wide range of alternatives; and
4. Increasing public participation in decision-making.

While advocates of this broader interpretation of the PP make a strong case for adoption of the above practices, only the first is directly included in most statements of the PP. The Wingspread Declaration is generally considered among the strongest versions. It reads:

“When an activity raises threat of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically” (Raffensperger and Tickner 1999, p.8).

While one could infer the need to search for alternative “precautionary measures” from the quote, it is difficult to extrapolate the comprehensive exploration of alternative activities that Hansen and others advocate from this text. Further, there is neither explicit mention of burden shifting (Turner and Hartzell 2004), nor any indication of the need to increase public participation. PP proponents are clearly advocating a broader agenda.

A fair portion of the argument turns on whether one interprets the PP as ‘ethical principle’ or ‘decision rule’. As previously noted, critics claim that the PP fails as a decision rule. Proponents counter by criticizing critics’ legalistically or philosophically narrow evaluation frame, and expand in the direction of sustainability. For example, Stirling argues for a conception of “precaution as process” (2007, p. 291), as a vehicle for expanding the nature of inputs into traditional risk assessment processes, a subject to which the discussion will return in section II.B. Others respond by noting that nations that initially adopt the PP as ‘guidance’ quickly evolve toward incorporating it as a legal doctrine, and claiming it as an established basis of international law (Marchant 2003). What is clear is that the PP is contentious: opponents try to pin it down to (perhaps unreasonable) standards of clarity, and proponents seek to expand it (without strong textual support) into a broader framing device. In this sense, the PP does not appear to be succeeding as a boundary object. Rather, it represents a site of contestation, and it is not clear that either proponents or opponents truly benefit from the current state of affairs.

### *II.A.3 Precaution, Innovation, and Risk*

Even some advocates of the PP assert that while it is fine as far as it goes, it does not go far enough (Cairns 2003). Precaution, and the various articulations of the PP, are focused on avoiding harm; the notion of possibly beneficial innovation is absent. While there is an emerging trend of exploration of possible synergies between the PP and innovation (e.g. Tickner and Geiser 2004; Stirling 2007; Zweck, Bachmann et al. 2008), the PP’s established connotations make this a difficult argument. Cairns is not alone: others are also seeking ways to move beyond the PP, searching for more constructive policy/strategy foundations for the 21<sup>st</sup> century (e.g. Ashford 2005; Dewulf and Van Langenhove 2005; Garcia-Serna, Perez-Barrigon et al. 2007; Helland and Kastenholz 2008). What these articles and others like them share is an emphasis on the possibility of positive solutions. Without falling into the trap of mindless technological optimism, these authors advocate various pathways and approaches that recognize that technological development can be part of the solution, if governed properly.

Properly is of course a value-laden term, one that raises many appropriate distributional questions (e.g. proper for whom, in what contexts, and who decides?). In this light, Jasanoff’s (2005) conception of and evidence for differences in ‘civic epistemologies’ is useful. The PP, with its Northern European roots, may indeed provide an appropriate foundation for both ethical and regulatory actions and processes in Europe. Although it is vital to recognize that the EU is not a monolithic entity, and substantial differences between member states remain on any number of issues, the PP is well established in European treaties. This is not the case in the U.S., where official resistance to the PP has been strong, even though it has found support among sustainability-oriented groups and individuals. The position of emerging powers such as China, India, and Brazil towards the PP is frequently ambivalent. Jasanoff’s point is well taken; that

which works well in Berlin or Brussels does not necessarily hold sociopolitical water in Washington, Beijing, Delhi, or Rio.

In summary, while many proponents see the PP as an appropriate starting point for more comprehensive, sustainability-based approaches, it is an uphill battle. Both the language of the various statements of the principle, and the political discourses in which it has been invoked pose obstacles. Europe may be able to overcome these challenges, because of their greater commitment to and broader understanding of the principle. In the U.S., though, the PP is often seen as an excessively risk-averse approach to policy that is incompatible with the entrepreneurial spirit. The conflicts between the PP and American civic epistemology detract from the principle's appeal in the U.S., and similar dynamics may be at play in key emerging economies. Successful innovation requires a certain prudent embrace of risk as opportunity, even excitement. It is difficult to reconcile the PP with such an attitude.

Often missing from this debate is the notion that traditional risk assessment also shares this failing. Although the PP has often been contrasted with regulatory approaches based on 'sound science', the purported dichotomy is largely chimerical. Rather, both philosophies place a disproportionate emphasis on risk, as both have located themselves primarily at the downstream end of technological development and deployment processes. Neither has yet developed robust mechanisms for making risk-risk or risk-benefit tradeoffs, and distributional issues have often received short shrift. In short, the PP and traditional risk assessment share a 'meta-risk' paradigm to some degree, and this meta-paradigm may represent a more fundamental problem.

## **II.B Risk Analysis**

"Science-based" risk assessment has been a cornerstone of U.S. approaches to environmental regulation, and plays an important role in other parts of the world as well, notably within the World Trade Organization (WTO). While few would deny that science is an essential element of environmental governance, the propositions that science alone can provide definitive answers, that there are clear natural role divisions between scientists, policy-makers, stakeholders and lay public, and that science and the PP are mutually exclusive have all come under increasing criticism. It is also increasingly clear that existing paradigms and methodologies in toxicological testing are inadequate to match the pace of technological innovation, especially in the case of emerging technologies such as nanoscale science and engineering and synthetic biology. The following subsections continue the argument that neither the PP nor traditional risk assessment, nor even a combination of the two, provide a comprehensive basis for technological governance in the 21<sup>st</sup> century.

### *II.B.1 Scientific Risk Assessment*

As an early leader in environmental regulation, the U.S. played an important role in establishing risk assessment practices, many of which have now been incorporated into international standards. The classic equation states that Risk = Hazard \* Exposure (Pool 1997), where risk is generally expressed as 1/n (e.g. 1/10,000, 1/100,000, 1/1,000,000) increased chance of morbidity or mortality as a result of exposure to a certain quantity of substance x. Potential hazard is evaluated by performing a series of in vitro and in vivo tests to determine, when feasible, the

highest dose at which no adverse effects are observed in test subjects (NOAEL). Agencies such as the EPA, the National Institute for Occupational Safety and Health (NIOSH) and the FDA then add margins of safety (generally one order of magnitude for each degree of uncertainty) in order to establish recommended or maximum exposure levels in various environments (e.g. workplaces, ambient air, drinking water). These levels then serve as the basis for permitting and enforcement actions.

Obviously, the above is a gross oversimplification. The EPA and others have numerous guidelines and protocols for carrying out risk analyses (e.g. EPA 1998; EPA 2000), the National Research Council (NRC) of the National Academy of Sciences (NAS) has produced several studies that are widely cited (NRC 1983; NRC 1996), and international bodies such as the Organization for Economic Cooperation and Development (OECD) and the International Standards Organization (ISO) have developed testing and materials standards. While the process is well institutionalized, it is fraught with uncertainty, and often controversial.

Focusing on environmental applications for sake of brevity, much (albeit by no means all) of the EPA's risk assessment activity occurs under the authority of two laws. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) covers pesticides, and the Toxic Substance Control Act applies to chemicals. The EPA has administered these statutes for over 30 years, accumulating both a great deal of experience, and substantial criticism, even within the established boundaries of science (not all of the following samples apply exclusively to FIFRA and TSCA):

- Current risk assessments are biased towards avoiding type I errors (false positives – determinations of potential harm that later prove unfounded) as opposed to type II (false negatives, findings of harmlessness subsequently discovered to be wrong). While no single statistical test can do both, multiple assessments with varying weightings can give a richer picture (Fjelland 2002).
- While prospective harm to non-target organisms is part of the assessment process for pesticides, evaluations have often been limited to determination of lethal doses in a small number of not necessarily representative species. In general, only statistically significant impacts with demonstrable causality carry regulatory weight, restricting consideration to well-understood and studied risk pathways, a small subset of the possible whole (Myhr and Traavik 2002).
- Product evaluations have tended to focus on active ingredients, giving short shrift to substances classified as inert (Diamond and Durkin 1997).
- Pesticide assessments generally consider a particular chemical in isolation, failing to examine the possibility of synergistic interactions between multiple substances (Hayes, Case et al. 2006).

The last point also applies not just to pesticides, but communities exposed to multiple pollutants, as highlighted by the environmental justice movement. Also, vulnerable populations (e.g. infants and the young, the elderly, pregnant women, or those with pre-existing conditions) may experience adverse effects at lower doses than the general population. Assessment practices have improved with respect to the latter two points in recent years, but the remaining data gaps are large.

More generally, of the roughly 80,000 chemicals in commerce today, less than 5% have been thoroughly screened for toxicological effects (Greim and Snyder 2008). In response to this situation, and the fact that approximately 700 new chemicals enter the U.S. marketplace each year, the NRC produced a report titled “Toxicity Testing in the 21st Century: A Vision and a Strategy” (2007c). It observes that existing methods are too slow, and often fail to capture subtle or long-term effects. The authors proposed a new strategy based on high-throughput in vitro screening, with targeted in vivo testing for follow-up and model confirmation. The vision is to move towards reliance on in vitro and in silico (computerized) methods in the long term, since current techniques are simply overwhelmed by the scope of the task at hand.

The NRC’s vision is admirable, and has promise. To the degree that scientists can connect particular molecular characteristics with specific toxicity pathways or modes of action in humans and the environmental, it will be possible to build predictive models. In theory, these models could screen large volumes of chemical compounds for multiple toxic endpoints quickly, highlighting potential problems for additional testing. The EPA and other agencies already employ such models, often under the rubric of Quantitative Structure-Activity Relationships (QSARs), but the existing tools are relatively crude, and far from comprehensive. While toxicology has made tremendous strides in recent decades, realization of the NRC’s vision requires substantial additional theoretical development, empirical testing, and model validation. Further, the NRC acknowledges that the products of some emerging technologies, such as nanoscale materials, may prove particularly challenging to model and quantify, a problem that chapter three explores in some detail. The strategy is meant to guide research over the next two decades, not to provide instantaneous solutions.

In summary, while scientific risk assessment is essential, and holds forth promise for the future, it is simply not yet capable of providing answers at the necessary scale. Regulatory and technological decisions will continue to take place in an environment of scientific uncertainty for at least another decade, and probably much longer. Science and technology policies and strategies thus need to accept uncertainty as a given, and act accordingly. This fact has implications for risk analysis strategies, the relationship between science and policy, and public trust in science and regulatory authorities.

### *II.B.2 Risk Assessment vs. Risk Management*

Traditionally, risk analysis is divided into risk assessment, the province of science, and risk management and communication, the domains of policy makers and administrators. The NRC’s “Red Book”, widely regarded as a canonical text of traditional risk assessment, declares:

“We recommend that regulatory agencies take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies” (1983, p. 151).

More recent approaches question the wisdom of this division. The 2003 Codex guidelines for risk analysis, which acknowledging the need to separate assessment and management, also recognizes that “risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application” (2003, p.3). In so stating, Codex implies that the setting of risk assessment policy is not itself a “purely” scientific endeavor, but rather incorporates societal values and policy goals.

This evolution is consistent with that within the broader literature on risk and risk analysis, again sounding the theme of civic epistemologies. Whether in framing risks or risk assessment agendas, making implicit decisions about ‘acceptable’ levels of risk, or in evaluating claims that policy judgments are solely based on ‘sound science’, the notion that cultural factors influence science and science policy is gaining traction. Wirth, for example, avers: “the allegedly scientific process of risk assessment necessarily requires inferences, choices, and assumptions that themselves reflect policy preferences, and area sometimes known as ‘science policy’” (1994, p. 834). Jasanoff (1987) finds support for this position in the ‘Red Book’ itself, which acknowledges that analytic choices in risk assessment rest on policy considerations with respect to stances toward risk. Walker also concurs, commenting that science policies, such as those that allow “risk characterization in the face of scientific uncertainty ... are not themselves scientific in nature and are not created by risk assessors alone. Rather, they are policies that reflect the broader goals of risk regulation, such as protecting human health” (1998).

Along these lines, the EU (Millstone, Van Zwanenberg et al. 2004) conducted an analysis of risk assessment policies, a specific type of Walker’s science policies. The authors divide their findings into three categories: technocratic, decisionist, and transparent, the last of which comprises their preferred option. Advocates of technocratic approaches to risk assessment describe their regulatory regimes as being purely based in science, excluding any political or economic factors. While this belief has adherents on both sides of the Atlantic, the authors note that claims of ‘sound science’ frequently serve political purposes – attempts to appropriate the authority of science in support of a particular position. Decisionist framings, which draw a clear distinction between risk assessment, a scientific enterprise, and risk management, which includes ‘other legitimate factors’, constitute the “prevailing contemporary orthodoxy” in all subject countries. The U.S. Red Book falls into this category, while the WTO’s Agreement on Sanitary and Phytosanitary measures (SPS) as interpreted by various dispute panels is probably best located on the technocratic – decisionist boundary. The transparent model, which the authors find consistent with Codex’s risk assessment policy,

“Assumes that non-scientific considerations play a distinctive up-stream role setting the framing assumptions that shape the ways in which risk assessments are constructed and conducted. It implies that rather than leaving those assumptions implicit, and leaving risk assessors to take responsibility for non-scientific judgments, risk managers could provide their risk assessors with explicit up-stream framing guidance”.

They argue that this framework helps explain both transatlantic and intra-European conflicts over risk assessment. Not only are scientists in different jurisdictions answering different questions, with varying relative prioritizations, but cultures do not share a common conception of the appropriate relationship between science, politics, and policy.



Before moving on, it is important to emphasize that science per se is not on trial in any of this literature. Science is clearly the best vehicle for investigating possible causal mechanisms, modeling prospective adverse effects, and establishing tolerance levels for potentially risky substances, among many other contributions. Put differently, science is a necessary component of risk assessment. What the above authors do challenge, though, is the idea that science alone comprises a sufficient basis for policy decisions, and those procedural frameworks that force scientists into the distinctively unscientific role of policy arbiters.

Perhaps the limitations of scientific risk assessment can best be understood by adapting an idea of Herbert Simon's, recognizing that science operates within the constraints of 'bounded objectivity' (Simon 1997).<sup>3</sup> That is, while the physical sciences do indeed concentrate on objects and their characteristics, their objectivity is bounded by the host of framing assumptions and other considerations at play in the analysis of risks within particular cultural contexts. Science excels in expanding the frontiers of understanding, in uncovering the casual mechanisms that underlie well-identified dangers, in projecting likely exposure patterns when such mechanisms are well-understood, and in producing an overall risk characterization based on the current state of knowledge, including assessing the certainty of that knowledge, and recommending directions for future research. What scientists alone can not do, and should not be asked to do, is to decide how societies should respond to such risks, or to determine when regulatory bodies should act solely on scientific bases, and when or to what degree they should weigh other legitimate factors in their deliberations.

### *II.B.3 Science and Precaution*

Does the contention that the PP and traditional risk assessment share a meta-paradigm offer a productive avenue of investigation? The two previous subsections have demonstrated that science alone can not cope with the risk assessment challenges thrust upon it in the traditional model, and that attempts to draw 'bright lines' between science and policy may well founder when exposed to the reality of performing science under public scrutiny and political constraints. Such conditions seem to match Funtowicz and Ravetz's conception that: "the science involved in risk assessments is somehow radically different from that of classical lab practice" (1992, p. 252), suggesting that their notion of "post-normal science" might also be applicable.

In their eponymous article, Funtowicz and Ravetz articulate a two-dimensional decision space. One axis is uncertainty; the other represents the stakes involved. Situations that rate highly on both scales enter the domain of "post-normal" science, in which cases the authors propose extended definitions of both scientific facts and expertise. They argue that such instances are beyond the strict jurisdiction of science, and thus require input from a larger set of perspectives. Their claims resonate with those of PP advocates that seek to expand the principle beyond extant statements thereof, and thus bear examination.

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<sup>3</sup> Simon's idea is "bounded rationality". Chapter two develops 'bounded objectivity' further.

The notion of expanded participation is a recurring theme in precautionary discourses. While saving many of the details for chapter four, which recounts and analyzes one significant participatory exercise, it seems appropriate to introduce the concept here. Just what is it about expanded participation that would necessarily improve the decision-making process? What extant problems might participation solve, and how? As previously articulated, participation is not an explicit component of any widely accepted articulations of the precautionary principle. The fact that it is mentioned so frequently in related articles, and dovetails so well with notions of “democratizing science”, suggests an indirect connection. What is the nature of that linkage, and how might it contribute to further investigation? The point of this discussion within this chapter is not to provide answers, but to suggest that this indirect connection might constitute useful grounds for further investigation in later chapters.

The idea that the PP and risk assessment are not in fact opposed, but could in fact bolster each other might also serve as a fertile site for additional research. Weiss articulates this idea well in arguing for the virtues of “science-based precaution” (2006). Adding his voice to those who argue that the supposed barriers between science and the PP have been erected for superficial political reasons, he sees no fundamental incompatibility between the two. Rather, one could argue that a combination of the PP and evolving risk assessment and analysis practices in the U.S. and elsewhere produces a “best practices” version of risk assessment. Recent EU chemical legislation (REACH) provides a good example of such a synergy, and may well serve as an instance of maximum political feasibility in the EU at the moment. However, it is important to explore new conceptual combinations, and to recall that societal attitudes change over time, in often divergent ways. Section II has essentially criticized existing approaches in both the U.S. and the EU. Deconstruction is relatively easy; effective and durable constructions in contested political environments constitute another order of challenge. Section III does not purport to provide immediate answers, but does trace two key trends on both sides of the Atlantic that may provide both guidance and opportunities for constructive action.

### III. Evolving Ideas of Sustainability and Technology Assessment

The concept of sustainability in the U.S. has undergone substantial evolution since environmental concerns first captivated public attention in the 1960s. Notions and practices of technology assessment have undergone various permutations in a similar timeframe. While the two developmental processes have been largely independent to date, there is a nascent literature that combines the two. To date, such thoughts and practices have been largely EU-centric. This dissertation explores the policy possibilities of translating such an approach across the Atlantic, emphasizing the need for customization to the U.S. politico-cultural environment. In so doing, it argues that a proactive combination of the ideas of sustainability and anticipatory governance would provide a sound theoretical basis for U.S. policy towards emerging technologies, particularly those with environmental implications and/or applications.

This section articulates the evolution of the concept of sustainability, and the practices of technology assessment. It does so quite briefly, as these stories are well documented elsewhere. The goal is to tease out certain trends from both histories, evolutionary patterns that suggest the possibility of a unique conjunction between the two at this time. This putative marriage, though, has not been fully consecrated, especially in the U.S. The science behind sustainability is well

established, and various advocacy communities having been making the case for the necessity of radical enviroeconomic change for decades, supported by elements within academia. What has changed in the last 10-15 years is that substantial elements of the dominant business and public institutions now take the need for fundamental change as a given, and increasingly see it as a strategic opportunity, or even necessity. The remaining problem is political. The questions before us are not so much what we should strive for, or why, but how, and who should pay, in what form? Again, a brief historical review provides necessary context.

### **III.A A Brief History of Sustainability**

Although the notion of living in harmony with natural ecosystems is part of many cultures (c.f. Nader 1996), and American environmentalism has roots in the 19<sup>th</sup> century transcendentalism of Thoreau and Emerson, the publication of *Silent Spring* (Carson, Darling et al. 1962) was a watershed in the modern environmental movement. Although the term “sustainability” is not mentioned, the book does describe the ecological impacts of economic activity, and at least touches on the social. Barry Commoner continued this focus on the interaction between modern industrial economies and the environment in a series of books in the 60s and 70s (e.g. Commoner 1971), an era that also saw the first Earth Day, and the creation of the Environmental Protection Agency (EPA).

The release of *The Limits to Growth* (Meadows, Meadows et al. 1972) marked a second turning point. Relying on computing resources considered vast at the time, it projected trends of resource consumption and population growth forward into the future, as represented by the year 2000 in many of their analyses. Their models warned of impending disaster, and they called for immediate corrective action. While changes in global political dynamics, improvements in modeling, and advances in computational power have rendered their initial quantitative projections rather quaint, their qualitative points remain valid today.

Endangered species were among the first foci of protective action. Discussions on the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) began in 1963, and the treaty was ratified in 1973. While the agreement now has 175 members, and is considered a limited success, the battle over restrictions on ivory trade is an excellent example of the tensions between conservation objectives, poaching incentives, and impacts on surrounding human populations engendered by CITES (e.g. Gillson and Lindsay 2003; Stiles 2004). Similar issues arose in the US, where the Endangered Species Act (ESA) of 1973 superseded earlier efforts. The law’s strong provisions for habitat protection, citizen enforcement, and restriction of private land uses have produced multiple controversies. The cases of the snail darter, a small species of fish that halted construction of a dam on the Little Tennessee River, and the spotted owl, the object of ongoing spite in disputes over logging in the Pacific Northwest have been particularly prominent. The ESA shares CITES list-driven approach; listing and de-listing have become highly contested processes (Doremus and Pagel 2001). Together with the Environmental Impact Statements required by the National Environmental Protection Act (NEPA), the provisions of the ESA have in some ways facilitated the persistence of the notion that environmental protection and economic development are diametrically opposed. Partisans on both sides of the debate have also contributed to the continuation of this dichotomous discourse as part of their political posturing.

Unfortunately, the piecemeal approach was not isolated to the above examples, but rather characterized the early stages of U.S. environmental protection. Regulatory actions took the form of bans on specific chemicals, such as DDT, or were catalyzed by highly publicized events, such as the 1969 fire on the Cuyahoga River in Cleveland that led to the passage of the Clean Water Act (CWA). The result has been a compartmentalized series of legislative actions (including the Clean Air Act (CAA), Toxic Substances Control Act (TSCA), Safe Drinking Water Act (SDWA), and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), more commonly known as the Superfund). This patchwork of regulations produces a fertile environment for competing lawsuits as well as confusion for regulated entities, and sometimes creates more environmental problems than it solves. In short, the legal U.S. reaction in the 70s and early 80s to the problems identified by Carson, Commoner, and others tended to polarize debate, and largely failed to address ecology, economy, and society as a comprehensive whole.

Within this timeframe, or shortly thereafter, the global political community was also responding to an increasingly diverse and numerous set of alarms. 1972 witnessed the first UN Conference on the Human Environment. 1983 saw the formation of the World Commission on Environment and Development, under the leadership of Gro Harlem Brundtland, the former Prime Minister of Norway. In 1984, the Worldwatch Institute produced its first annual “State of the World” report, a publication that has come to be seen as one of the world’s most comprehensive and influential tabulations of progress (or lack thereof) towards sustainability in all of its dimensions and nuances.

The final report of the “Brundtland Commission” (UN 1987) firmly established a place for a broader conception of sustainability within global political discourse. Under the rubric of “sustainable development”, the commission gave equal weight to social, economic, and ecological issues, with a particular focus on the needs of the global south. It specifically defines sustainable development in terms of the needs of future generations, injecting a human element that had not always been present in previous articulations, while recognizing the intimate relationship between humans and all types of environments, not just wilderness.

In roughly the same timeframe, scientists found evidence of an increasing hole in the ozone layer over the Antarctic. While initially controversial, consensus soon emerged regarding both the problem itself, and the role of chlorofluorocarbons (CFCs), chemicals commonly used as refrigerants in the industrialized north, as major contributors to this problem (Edwards 2005). The Montréal Protocol on Substances that Deplete the Ozone Layer (UNEP 1987) represented a remarkably rapid response on the part of the international community, which was initially celebrated as a constructive example of global cooperation. In collective action terms, limiting CFC production and release in the global north was a relatively easy problem: A limited number of actors controlled a significant percentage of production, cost-effective alternatives were readily available to these same actors, and the problem of increased skin cancer risk due to ozone depletion rapidly gained public attention (Arce 2001). More recent scholarship questions the applicability of the Montréal model to problems such as climate change (Harris 2007; Norman, DeCanio et al. 2008), and there are questions about how developing nations will cope with their rolling responsibilities. Acknowledging these criticisms, the Montréal Protocol still stands out as

a reasonably successful effort to incorporate both environmental and economic considerations, as well as a model of prompt action.

The Rio Summit of 1992 marks the next major milestone in the evolution of the concept of sustainability within global political practice. The meeting saw the ratification of the Agenda 21 documents, which seek to provide communities worldwide with actionable criteria to develop local sustainability plans, as well as the UN Framework Convention on Climate Change (UNFCCC), which laid the groundwork for the Kyoto Protocol. It also saw the adoption of the Convention on Biological Diversity (CBD), which is notable for the emphasis it places on indigenous rights to natural resources. However, in keeping with the themes of both hope and disappointment that characterize the evolution of sustainability, the U.S. refused to sign the CBD. Rio was an inflection point that signaled changes to come.

As the 90s continued, the U.S. evolved toward a neo-liberal “Washington Consensus” model of global governance. Neo-liberal is a misleading term: the Washington Consensus owed far more to the Chicago school of economics, and a general movement towards privatization, than it did to the thinking of self-identified liberals. In any case, the EU moved towards leadership on global environmental issues in this period, no matter how haltingly. At the same time, a second wave of environmentalism was growing in the U.S. The Pollution Prevention Act of 1990 focused on source reduction rather than end-of-pipe solutions, and the 1990 amendments to the Clean Air Act shared in that spirit. Both celebrated entrepreneurs (Hawken, Lovins et al. 1999) and Harvard Business School professors (Porter and Vanderlinde 1995) saw the need to move beyond the false dichotomy of environment vs. economics, towards the idea that environmentally friendly technologies and regulations might confer competitive advantage in a highly competitive global marketplace. In short, the 90s saw the emergence of a more complete model of sustainability within elements of the business community, perhaps culminating in Elkington’s articulation of a “triple bottom line” approach to corporate accountability (1998).

Internationally, agreement on the Kyoto protocol in 1997 provided a hopeful signal that the global north had begun to take substantive action with respect to climate change. In keeping with the hope/disappointment theme, negotiations over implementation dragged on for several years, the U.S. not only never ratified the treaty, but also formally withdrew from the agreement in 2001, and very few countries are on track to meet their emissions reduction targets in the specified 2008-2012 timeframe. Back to the hopeful side, the combination of hurricane Katrina, the Fourth Assessment Report from the Intergovernmental Panel on Climate Change (IPCC 2007), and “An Inconvenient Truth” seem to have solidified the consensus in the U.S. that global warming is real, and largely anthropogenic.<sup>4</sup> A few outliers remain, and the recent e-mail controversy in the U.K. has created confusion, but agreement on the need to reduce greenhouse gas emissions along with dependence on foreign sources of fossil fuels seems solid. The political question of how and when to do so, however, remains very much open to debate.

In parallel, the notion of “green jobs” occupied a prominent place in the 2008 U.S. presidential campaign. In contrast to the environment-economy dichotomies of the 70s and 80s, “green”

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<sup>4</sup> Even Exxon/Mobil now routinely runs ads on the Op-Ed page of the New York Times touting their emissions reduction activities.

technologies such as renewable energy are now routinely portrayed as saviors for the Rust Belt, and as key to national competitiveness in the future. Climate change, for example, is no longer seen as a contested theory, but as a key export opportunity. Such a shift may not be exactly what the authors of *Natural Capitalism* (Hawken, Lovins et al. 1999) had in mind, but it does constitute a clear step in their direction.

At the same time, it is important to note that the “development” aspects of “sustainable development” continue to lag. The follow-up to the Rio Summit, held in Johannesburg in 2002, illustrated the gap between rhetoric and reality, especially in the global south. The meeting, the largest ever held of its kind, was largely seen as a disappointment, and as cause for recalibration of future expectations (e.g. Gutman 2003; Seyfang 2003). One might conclude that sustainability is relatively easy to talk about, but much more difficult to implement. The distributional elements of social equity seem particularly problematic, and likely to remain so.

The above is a rather brutal summarization; others have produced more detailed and nuanced accounts (e.g. Edwards 2005). The goal of this introduction is to show that discourse has shifted along four key axes since the 1970s:

1. From a focus on physical resources for human consumption to an emphasis on systemic sink capacities;
2. Away from its roots in the environmental movement, towards a more comprehensive conception of sustainability that includes both social and economic factors;
3. Out of the “eco-fringe” into the mainstream to the point where sustainable technologies are now seen as a key driver for profitability and national competitiveness; and
4. From being seen as the sole province of “visionaries” in the industrialized countries to a pressing global concern, especially with respect to adaptation to climate change.

Again, the above is only a cursory review of the extensive effort, research, and argument invested in these topics over the past several decades. This work has produced a global consensus that human society is on an unsustainable path, and that substantial change is required in order to preserve the life support systems of the planet for both humans and other species into the future. Unfortunately, the level of agreement to date has been largely rhetorical, and the U.S. has been among the chief obstacles to substantive collective action in recent years. However, attitudes are shifting in the U.S. as well, especially among the business communities. Without ignoring the social, the intersection of the environmental and economic pillars of sustainability represents a tangible opportunity for constructive progress, as “clean” technologies are now seen as key markets for the future. It is important to recall that not all problems are amenable to technological solutions, and technologies sometime create more problems than they solve. Governance is thus a critical issue, and so the discussion turns to the next historical theme, technology assessment.

### **III.B A Brief History of Technology Assessment**

#### *III.B.1 The U.S. Congressional Office of Technology Assessment*

Although the co-evolution of societies and technologies may have its roots in the Neolithic era (Latour 1999), if not before, the U.S. Congressional Office of Technology Assessment (OTA), established in 1972, serves as a pragmatic starting point for purposes of this dissertation. The OTA did not spring fully armored from Zeus' head, and clearly owes debts to previous legislative and scholarly activities, as detailed in Herdman and Jensen (1997). However, it was very influential in establishing the legitimacy of technology assessment within a political framework, thus laying a foundation for future efforts. Its mission was in part to ensure that

“To the fullest extent possible, the consequences of technological applications be anticipated, understood, and considered in determination of public policy on existing and emerging national problems” (Herdman and Jensen 1997, p. 131).

The oft-cited phrase “technology assessment is whatever the OTA is doing” indicates the degree to which the organization's practices defined technology assessment during its lifespan, and also underscores its commitment not to be bound by any one theoretical framework (Wood 1982).

While some academic critics found this theoretical flexibility frustrating, OTA staff viewed it as a strength (La Porte 1997). As an arm of Congress, the OTA was highly policy-oriented, focused on studying subjects of direct relevance to potential legislative action. Although its charter included a charge to provide “early indications” of the potential consequences of technological change, its institutional structure mitigated against the development of an independent agenda-setting capacity (Wood 1997). Rather, most of its reports were produced at the request of influential members of Congress, and focused on relatively specific, short-to-medium term questions. Within these constraints, the OTA garnered a strong reputation for quality and objectivity, and influenced policy or policy debates in numerous areas (Hill 1997).

The OTA also distinguished itself by taking contextual issues seriously. Eschewing a strictly engineering or quantitative cost-benefit based approach, its project selection criteria included distributional issues (i.e. who benefits and who pays or suffers) and the potential irreversibility of technological impacts (Wood 1982). In this sense, the OTA's philosophy deviated from textbook policy analysis, and echoes themes found in the broader Science and Technology Studies (STS) literature. Its reports thus tended to draw complex pictures sensitive to the dynamics of technological change, and largely avoided the pitfalls of technological determinism, especially in the later years (OTA 1995a; OTA 1995b).

The OTA viewed itself as a non-partisan research organization, and did not even make recommendations, choosing instead to present a series of options to decision-makers. In this sense, it did not take an active role in shaping technological trajectories, although actions taken by Congress or others based on its output may have done so. Driven as it was by Congressional requests, most of its reports focused on issues of national importance to the U.S., i.e. large-scale problems such as climate change and national energy strategy. Although it strove to include stakeholders, particularly from industry and academia, some criticized it for a technocratic bias (e.g. Bereano 1997), and it made only limited efforts to engage the public in its deliberations.

Taking the OTA as an eponymous example, the above suggests four axes for characterization of technology assessment efforts:

- Policy: To what degree is the practice specifically intended to feed into policy-making, and how strong is the connection between research and action?
- Scale: Does the assessment address one particular application, a related group of technologies, or an entire industry or field? Geographically, is the focus local, regional, national, or international, and if national, how large is the country in question?
- Timeframe: Is the target of analysis in the past, present, or future? If future, is the horizon relatively short (0-5 years), or more visionary?
- Role: To what degree does the assessment process intentionally seek to shape the present and future trajectories of the subject technologies?

Evaluating the OTA along these axes finds a very strong policy orientation, large national scale, a relatively short-term future timeframe, and an evaluative role. The balance of this section applies this same framework to other segments of the history of technology assessment. With the demise of the OTA in 1996, the locus of activity shifted to Europe.

### *III.B.2 European Approaches to Technology Assessment*

There is no single European approach to technology assessment (TA). Schot & Rip (1997) list awareness TA, participatory TA, strategic TA, and constructive TA, all in contrast to traditional TA, and do not claim that their list is exhaustive. Their articulation of constructive TA (CTA), augmented by others as appropriate, suffices for the purposes of this section. They see CTA as expanding the focus from impact assessment to a broadening of the processes of technological design, development and implementation. In other words, CTA sees a much more active role for participants in technology assessment and technology assessors than did the OTA, and this difference represents a profound shift.

While the OTA was certainly influential, Europe also acted independently during its tenure. The Netherlands issued seminal policy statements in 1984 and 1987 that led to the creation of an organization now known as the Rathenau Institute, and Denmark also founded a quasi-governmental entity devoted to technology assessment, defined broadly, in this period. Schot and Rip see an overarching TA philosophy behind these efforts, as well as those in Norway, Germany, and other countries:

“To reduce the human costs of trial and error learning in society’s handling of new technologies, and to do so by anticipating potential impacts and feeding these insights back into decision making, and into actors’ strategies” (1997, p. 251).

This statement of principles differs from the OTA’s mandate in several important ways. First, the explicit emphasis on human costs has no OTA parallel; many of the OTA’s reports considered environmental consequences as well as human impacts. However, as discussed in chapter two, the CTA movement has also spawned a subdiscipline that combines sustainability with technology assessment, so European practices have not been constrained by this arguably anthropocentric standpoint. Anticipation indicates an orientation towards the future, and the inclusion of other actors in the feedback loop signals an enhanced emphasis on non-



governmental activities, a broadening of the sphere of assessment. Including feedback processes as a central element also implies a much more interventionist role for technology assessment; CTA actively seeks to influence technological trajectories, thereby creeping into the domain of “governance”.

CTA also draws more directly on certain aspects of STS theory than did the OTA. In particular, it assigns more weight to the co-evolution of technology and society, building on a rich academic literature on the subject (e.g. Pinch and Bijker 1984; Law 1987; Kline and Pinch 1996). Schot observes that CTA “shifts attention to the steering of the internal development of the technology” (1992, p. 37); and also draws on evolutionary economics, applying the concepts of variation, selection, and nexuses to technological innovation and diffusion. Schot and Rip develop these ideas into strategies of technology forcing, strategic niche management, and stimulation of alignment, laying the groundwork for efforts to integrate concepts of sustainability into technology assessment. CTA scholars also tend to emphasize “demand articulation” as part of their thesis that societal and technological actors contribute symmetrically to innovation processes, while recognizing that various actors play different roles.

CTA and other European approaches also assign a great deal of importance to the notion of “social learning”. While various authors conceive this idea differently, there is a common connection to a reflexive conception of co-production, wherein a panoply of concerned actors maintains an open-minded awareness of their contributions to the development of technological trajectories. The concept is articulated primarily in contrast to “traditional” forms of TA, in terms of moving the discourse away from assessment of impacts, towards a shaping of future path dependencies (van den Ende, Mulder et al. 1998). CTA is also highly sensitive to the cultural contexts of technological development, and seems particularly attractive in Northern Europe, especially the Netherlands and Denmark (Cronberg 1996).

The issue of scale remains salient. The emphasis on social learning suggests the need for network-building activities over time. Individual actors might come and go, but learning would be difficult without a certain level of continuity, and perhaps familiarity. Schot and Rip recognize the possibility of corporatism in their model, and other authors (Genus and Coles 2005; Genus 2006) question the limitations of public involvement in CTA discourses. These criticisms tie into the larger dialogue over public engagement with science and technology in Europe. Exercises have been conducted at multiple scales, ranging from the local (Renn 2003), thru the regional, to the national (Skorupinski 2002). Public involvement also varies with respect to timeframe (Niewohner, Wiedemann et al. 2005), role (in terms of upstream versus downstream engagement) (Rogers-Hayden and Pidgeon 2007), and credibility (Stirling 2008), among other factors. CTA, defined broadly, may be the most representative articulation of a European approach to technology assessment, but it is a large tent.

The abbreviated discussion in this section primarily sets the stage for chapter two, which advocates the combination of a new form of technology assessment, anticipatory governance, and sustainability as a viable basis for U.S. policy and strategy in governing emerging technologies with environmental implications and/or applications. This moment in the evolution of sustainability in the U.S. presents a unique opportunity for substantial change, and emerging “clean” technologies, largely centered around issues of energy and water, represent a particularly

attractive niche. Chapters two, five, and six all delve more deeply into various aspects of these possibilities. Prior to those discussions, though, it is important to identify the nature of the problems that the combination of anticipatory governance and sustainability seeks to solve.

## IV. Governance Gaps

Section II argued in part that both the Precautionary Principle and “sound science” approaches to technological governance share an excessively narrow focus on risk, and thus fall short in considering both risk/benefit tradeoffs and distributional questions. In fairness, the picture is a bit more nuanced. The limitations of this argument become more apparent in recognition of the fact that these regulatory principles are embedded within a larger free-market framework, especially in the U.S. Governments not only regulate technologies, they also promote them – the National Nanotechnology Initiative (NNI) discussed in chapter six is an excellent example. Additionally, well-developed markets offer strong incentives for innovations that serve the needs, wants, or desires of affluent consumers. These competing forces combine to produce what Renn and Roco (2006) term as “governance gaps”, areas where the pace of innovation exceeds the societal capacity for governance thereof. The translation between these governance gaps and constructive research projects is somewhat tricky; chapter two tackles that problem in greater detail. To start the conversation, four governance gaps are particularly prominent with respect to emerging technologies with environmental implications and/or applications, with nanoscale innovations as a primary case.

### IV.A Innovation Is Outstripping Risk Assessment

As noted in section II, the rate of introduction of new materials outstrips our capacity to assess potential harms. This problem is particularly acute at the nanoscale. As chapter three explores in some detail, the unique properties of materials at the nanoscale present an additional series of challenges to existing risk assessment procedures and practices. Summarizing briefly for the moment, certain nanomaterials interfere with some standard toxicological assays, methods for detecting nanoparticles in ambient environments are either highly cumbersome and expensive or non-existent, and the fact that the nanoscale represents a transition zone between classical physics and quantum mechanics means that investigators must consider significantly more variables in assessing nanomaterials. In particular, the latter implies that mass may not be the most important metric of toxicity, which has profound consequences for the regulatory system, as mass is a key element of most legally binding exposure levels.

These challenges are surmountable, but for the moment, they exacerbate the governance gap in this area. The toxicity of nanomaterials is likely to remain uncertain for some time, at least in terms of precise quantifiability. This implies a need for anticipatory approaches to risk management, and for careful prioritization of scarce assessment resources. It also suggests that relevant actors will need to make decisions based on incomplete information, making precisely the kinds of risk/risk and risk/benefit tradeoffs that the dominant paradigms address inadequately. Chapter three presents one case of an anticipatory governance approach to carbon nanotubes, but the problem also has institutional ramifications for chapter six.

### **III.B Public Confidence and Trust**

Renn and Roco (2006) frame this gap in terms of their concern that public resistance could derail, or at least delay, the prospects of nanotechnologies. Early public opinion data indicates that Americans are reasonably confident that the benefits of nanotechnologies will outweigh the risks (Cobb and Macoubrie 2004), although their trust in industry and government to manage these risks is low (Macoubrie 2006). Europeans appear somewhat less optimistic about the prospects for nanotechnologies in general (Gaskell, Ten Eyck et al. 2005), and share the U.S. pessimism towards regulatory institutions. Given the capacity problems outlined in section II, these concerns may be well founded. The European backlash over genetically modified organisms (GMOs) has spooked nanotechnology proponents on both sides of the Atlantic (Roco and Bainbridge 2005), leading to calls for increased public participation as part of the development process, or “upstream engagement”.

Not all forms of participation are created equal, and the literature encompasses a lively debate over how best to structure and evaluate engagement processes (e.g. Rowe and Frewer 2000; Rowe and Frewer 2004; Bingham 2005; Genus and Coles 2005; Rowe and Frewer 2005; Fung 2006; Hamlett and Cobb 2006). The “GM Nation” exercise in the UK was particularly controversial (Rothstein 2004); and the very notion of “upstream engagement” is the subject of some debate (Rogers-Hayden and Pidgeon 2006; Rogers-Hayden and Pidgeon 2007; Stirling 2008). The real governance gap in this area is not whether to engage the public, but how, which publics, and for what purposes? Is the goal simply to gain public acceptance for existing technological trajectories, or to give citizens a real voice over R&D priorities?

Incorporating sustainability in these engagements would allow for a more comprehensive approach that could include the construction of shared visions of a desirable future (e.g. Carlsson-Kanyama, Dreborg et al. 2008; Dissel, Phaal et al. 2009; Loveridge and Saritas 2009). The three pillars (again, environmental, economic, and social) facilitate consideration of distributional issues, e.g. how will society address the needs of coal miners and oil workers as it reduces fossil fuel consumption? What roles should technologies play in the development of such futures? Are there potential applications that do not merit public support because they conflict with societal values and priorities? Chapter four explores one such experiment in detail, and produces recommendations for future endeavors. It argues that, done properly, such exercises can constitute an important element of governance, and that work remains to institutionalize public engagement effectively.

### **III.C Underprovision of Public Goods; Anticipation of Market Failures**

The fact that existing governance mechanisms are embedded within a market economy, especially in the U.S., raises the question of public goods. Economists as far back as Adam Smith (2003 [1776]) have noted the existence of goods that, while beneficial to society as a whole, do not offer sufficient opportunity for profit to justify the necessary investments in terms of ‘pure’ market logic. These public goods are traditionally defined as being “non-rival” in terms of consumption, and “non-exclusive” in terms of benefits (Kaul and Mendoza 2003). A stable climate is probably the best example of a global public good; the clean air, water, and biodiversity provided by healthy ecosystems illustrate the principle at a local level. Generally

speaking, markets alone provide inadequate incentives to invest in such goods, resulting in systemic underprovision. The problem becomes particularly acute in cases of mismatch between the scopes of the (often ecological) systems that produce the goods and the boundaries of relevant human authority structures. Although the picture has become much more complex since Smith's day, his notion that one of the roles of government is to intervene in such cases of market failure remains eminently salient.

Renn and Roco do not address this question, but the combination of anticipatory governance and sustainability points clearly to market failures in the underprovisioning of public goods as a target for integrative analysis. The Precautionary Principle and risk analysis focus on the avoidance or mitigation of public bads. While not wrong per se, as reductions in public bads do contribute to public goods, the primary emphasis is on only one side of the equation. Sustainability facilitates questions such as “what problems does society need to solve, and in which areas might emerging technologies best contribute”? Further, for which of these needs will normal market incentives suffice to provide timely solutions, and where would public intervention be most productive in spurring the development of socially beneficial technologies? Chapter five argues that environmental goods, including but not limited to renewable energy and clean water, have been historically underfunded, and represent an opportunity for public investment, particularly in the early stages of applied research. Perhaps more importantly, it demonstrates the paucity of institutional capacity for the ongoing identification of public needs within existing Federal programs, thus laying the groundwork for chapter six.

### **III.D Regulatory and Policy Uncertainty**

Nanoscale science and engineering pose a particular challenge in this area (e.g. Bowman and Hodge 2006; Bowman and Hodge 2008; Paradise, Wolf et al. 2009; Wiek, Gasser et al. 2009). How should regulatory authorities respond to a family of innovations that both highlight the limitations of existing law, while simultaneously presenting profound new challenges? Put differently, how should the EPA and sister organizations worldwide address a set of emerging technologies that calls some of their most fundamental assumptions (e.g. dose/response metrics) into question? Taking a different perspective, how might private actors (including NGOs) best position themselves under conditions of regulatory uncertainty? What are the costs and benefits of regulatory inaction, in contrast to more conventional cost/benefit analyses of proposed rules? From another angle, what is the responsibility of the National Nanotechnology Initiative (NNI), an R&D coordination effort, to contribute to the development of oversight strategies and policies for the very technologies it is chartered to promote?

One claim here is that regulatory and policy uncertainty in itself comprises a condition that influences technological development, i.e. it constitutes a governance gap. Cognizant authorities may well be faced with a “wicked problem” (Rittel and Webber 1973) in this regard. As previously observed, existing risk assessment frameworks include provisions for coping with a certain degree of uncertainty, largely via the incorporation of order of magnitude margins of safety in the establishment of exposure levels. These approaches implicitly assume that uncertainties can be safely bounded, and admirably seek to err on the side of caution.

Unfortunately, such assumptions do not apply when the fundamental metric of regulation is in question, as is the case for nanoscale technologies. Taking just one example, if aspect ratio and surface charge correlate much more strongly with cytotoxicity than mass in the case of carbon nanotubes, traditional uncertainty adjustment factors might prove meaningless, as they would be operating on the wrong variable. How should actors such as the EPA regulate in the face of such profound challenges? How should private firms govern their own technological development under conditions of sustained regulatory confusion? More generally, how does society need to adapt by creating governance structures that take uncertainty as an ongoing given, rather than a temporary situation subject to short-term correction?

This may be the largest of the four governance gaps, and the most difficult to close, as it speaks to the need for new institutional arrangements. The problem has at least two levels: the specific issues raised by nanoscale science and engineering, and the larger question of guiding emerging technologies in general. Chapter six uses the combination of anticipatory governance and sustainability to construct an evaluative framework, which it then applies to the NNI and the Technology Innovation Program (TIP), a relatively new initiative that seeks to foster the development of technologies to meet “critical national needs”. Based on the results of this analysis, chapter six also proposes a process to develop a “National Sustainability Initiative”, building on efforts already underway. The goal of these efforts is less about providing definitive answers than to articulate a viable path forward, to identify feasible next steps. Governance gaps are dynamic phenomena, subject to change over time, and can probably never be closed completely. Addressing them requires flexible and adaptive institutions that are difficult to construct and maintain within political and constitutional constraints. “Muddling through” (Lindblom 1959) may be the best we can expect, and chapter six manifests the spirit of policy experimentation, in line with an anticipatory governance approach.

## I. Chapter Two Overview

Chapter one focused largely on the past, providing both historical contexts, and identifying the governance gap problems. This chapter establishes a foundation for movement both from the past to the future, and from problems to productive avenues of inquiry for solutions. It does so by proposing the combination of anticipatory governance and sustainability as a constructive basis for policy and strategy in the U.S., in contrast to the traditional U.S. and EU approaches outlined in chapter one. Taken together, these two concepts frame the balance of the dissertation, which in turn seeks to both deliver concrete examples of the effectiveness of this combination, and prepare the ground for future constructive policy experimentation.

The notion of translation is key in two aspects. First is the translation of the governance gaps (problems) identified in chapter one into solution-oriented research endeavors. The theoretical framing provided by the combination of anticipatory governance and sustainability in the U.S. political context facilitates the transition of these governance gaps into practical projects that fall under the general rubric of “what do we need to anticipate”? Table 1 summarizes these translations, which map roughly onto chapters three through six.

**Table 1: Translating Governance Gaps into Research Foci**

Governance Gap	Research Foci
Innovation Outstrips Risk Assessment	Preliminary risk characterizations, anticipatory design & management strategies
Public Confidence and Trust	Experimentation with public input methodologies, incorporation into policy mechanisms
Underproduction of Public Goods	Development of societal needs assessment processes and metrics, anticipation of market failures, strengthening of mechanisms to support beneficial innovations
Regulatory and Policy Uncertainty	Institutional innovations to facilitate anticipatory policy development and implementation

The second critical aspect of translation is transatlantic. Chapter one was largely historical, and only hinted at the most recent developments in both sustainability science and technology assessment. Sections II and III of this chapter examine the current “state-of-the-art” in more detail, with a particular emphasis on the need to adapt the salient aspects of largely European approaches to American sociopolitical contexts. While the “strategic niche management” and “transition management” literatures, largely of European origin, contain any number of valuable insights and perspectives, the EU’s “civic epistemologies” (Jasanoff 2005) fit poorly with current American political realities. The recent concept of “anticipatory governance” exhibits promise, but it requires substantive theoretical partnership in order to gain traction in practice. This dissertation argues that, in conjunction with anticipatory governance, a nuanced conception of “sustainability”, one that acknowledges both its strategic ambiguity and dynamically contested nature, offers a viable path forward, even in a politically polarized environment.

## II. Emerging Developments in Technology Assessment

As noted in chapter one, the demise of the OTA effectively moved the locus of innovation in technology assessment to the EU. While the U.S. is beginning to recover from the loss of such a seminal institution, as exemplified by section II.C, the recent conceptual balance of trade still strongly favors the EU. At least two different strains of thought, “strategic niche management” and “transition management” merit attention due to their systematic approach to innovation, with a particular eye on opportunities for constructive transatlantic translation, and to direct technological governance towards sustainability.

## **II.A Strategic Niche Management**

Consistent with the notion of ‘anticipating market failures’, the EU has sponsored several projects that take a holistic approach to technological promotion. Rather than focusing on a particular application, e.g. photovoltaic cells, in isolation, these programs attempt to address deployment in terms of industrial ecology, viewing market development as an evolutionary process that requires infrastructural support. Operating under the general label of ‘strategic niche management’, these efforts have produced very few market successes to date, but they do offer some interesting ideas that could be useful with appropriate modification.

Strategic niche management (SNM) is closely connected with constructive technology assessment (CTA, see chapter one), and includes several of the same players. In a sense, it is an attempt to expand CTA to a larger scale, with an explicit emphasis on sustainability. As such, it stresses actor networks, user participation, and the importance of social learning. The basic concept is one of reflexive, evolutionary co-construction of technologies and their markets via the development of a pre-market niche that allows experimentation. The goal is to match innovations with societal needs through iterative interaction, thus overcoming structural barriers to entry that might otherwise preclude market success.

Proponents of SNM such as (Caniels and Romijn 2008) recognize that initial expectations for the approach were over-optimistic, but do assert that learning has occurred. SNM is best matched to technologies that benefit from iterative user interaction – information technology-based systems are a good example. They recognize that success depends on a cooperative network of producers, users, and regulators, and that crises in entrenched regimes may offer opportunities for niche creation and extension. As an example, they discuss food safety concerns as creating a window for the introduction of a more sustainably produced type of bread. Other advocates (Schot and Geels 2008) emphasize that SNM is not a technology-push strategy, and that governments do not create niches, but facilitate endogenous steering within actor networks.

The most interesting element of SNM is its evolutionary perspective. There are strong resonances with notions of evolutionary economics, in that niche management involves altering the selection environment for innovations. There are also elements of Schumpeterian “creative destruction” in displacing existing technological trajectories. The notion of constructing niches for innovations with positive social externalities along with the technologies themselves is attractive; the Prius may be a good example. However, the emphasis placed on social learning and cooperation in the SNM literature and the related notion of sustainable innovation journeys (Geels, Hekkert et al. 2008) may translate poorly into environments where competition plays a more important role.

## II.B Transition Management

Some SNM scholars see an opportunity to expand and/or combine niches in ways that support system-level innovation, and/or view niches as part of a larger industrial ecology (e.g. Gaziulusoy, Boyle et al. 2008; Geels, Hekkert et al. 2008; Nykvist and Whitmarsh 2008). This strain of the literature emphasizes the need for interconnected multi-level analysis, and claims that sustainability is a property of meta-systems, rather than individual innovations. In particular, scholars are concerned that incremental improvements will not suffice to address large-scale problems such as climate change in a timely manner. To meet the sustainability challenges of the 21<sup>st</sup> century, systems innovation and/or regime transitions will be necessary. This “transition management” literature generally takes a multi-level approach to such issues, dividing the innovation universe into the landscape, regimes, and niches.

The landscape represents the social, economic, and ecological context in which innovation systems occur. Climate change and its expected repercussions are part of the landscape. Regimes are a combination of “technologies, industry, infrastructure, policy, user behaviour and culture” (Nykvist and Whitmarsh 2008, p. 1377). Their particular article is concerned with “mobility regimes” in the UK and Sweden; the term is equally applicable to electricity generation regimes, computing regimes, and other industries. Niches occur at the lowest level, and do not necessarily conform to dominant regimes – in fact, windows of regime instability are seen as opportunities to establish new niches, and expand existing ones (Caniels and Romijn 2008).

The field expresses a great deal of concern about avoiding technological lock-in (e.g. Carrillo-Hermosilla 2006), which occurs when sub-optimal solutions secure market and regime dominance. The classic example of lock-in is the QWERTY keyboard, used in writing this dissertation. Lock-in poses two temporally different types of challenges. The first occurs with existing regimes, such as the vast networks of producers, suppliers, infrastructure, and branding centered on the internal combustion engine. The second can be characterized as a “rush-to-solution”, where narrow policies and visions prematurely fix on a particular set of technologies without adequate consideration of consequences and alternatives. MTBE in gasoline is representative of this type, corn-based ethanol may also fall into this category, and there is some danger that sequestering CO<sub>2</sub> in gaseous form may fit this pattern. In both cases, lock-in can pose significant barriers to entry for sustainability-preferable solutions, implying a role for policy.

Sustainability is critical in this discourse, as the goal is to manage the transitions from unsustainable to sustainable technological regimes. Whether under the rubric of new paradigms (Nill and Kemp 2009), sustainable innovation journeys (Geels, Hekkert et al. 2008; Schot and Geels 2008), second-order sustainability (Sartorius 2006), or sustainable technology development (Gaziulusoy, Boyle et al. 2008), there is an emerging recognition that while attention to particular technologies is probably necessary, it is not sufficient. Rather, overcoming technological lock-in by facilitating large-scale transitions, such as the development of new industries and interlocking consumer practices, demands policies that address systemic conditions. Thus, the problem of scale is vitally important, as is the appropriate role of



government. Both of these issues are particularly salient in translating these ideas across the Atlantic, a problem to which chapter six will return.

Foreshadowing the discussion regarding metrics in section III.A, the transition management literature also acknowledges the difficulty of assessing the sustainability of any particular innovation in isolation. While it is certainly possible to calculate the comparative emissions and resource use of a novel industrial process, and such assessments are essential (Partidario and Vergragt 2002), there is a sense in which sustainability is not meaningful at the level of individual technologies. Rather, it is a system level property, a function of adaptive capacity over time (Sartorius 2006). The innovation milieu is a complex adaptive system; the landscape, regimes, and niches (not to mention actors) interact in a non-linear, co-evolutionary manner (Foxon 2006). Effective policy and decision-making in such a dynamic and frequently ambiguous environment is neither easy nor simple, but it is necessary in order to encourage the evolution of niches and regimes well suited to prosper in the landscapes of the future.

Thus, determining how to formulate, select, and implement effective strategies and policies at the level of dynamic systems remains subject to interpretation. However, the evolutionary underpinnings of this literature do provide some constructive hints. Drawing from industrial ecology, Adamides and Mouzakis (2009) suggest the possibility of viewing eco-industrial parks as productive niches. Rather than depending on social networks, as was the case at Kalundborg, Denmark, the canonical example of a successful industrial ecosystem, firms might design technologies and processes to fit certain pre-existing mixtures. For example, shoreline coal generation facilities present a natural opportunity for a system that produces both cement precursors and partially desalinated water from coal plant effluents (Calera 2009). Such ‘bridging’ technologies could serve as anchor tenants for industrial systems, giving them options in marketing their products to both potential partners and municipalities.

Alternatively, Foxon (2006) advances the idea that sustainability might serve as conceptual glue in binding niches together into industrial ecosystems. Recognizing that the spontaneous occurrence of such synergies is likely to be rare, especially when the niches do not fit neatly into existing regimes, he advocates policies designed to support stable intermediate states as a practical avenue to facilitate systems transitions. Schot and Geels (2008) discuss similar possibilities in their analysis of the possibilities of multi-level evolution within the landscape, regime, and niche formulation. Nykvist and Whitmarsh (2008) observes that niches tend to evolve more quickly than regimes, and that this dynamic can create upward selection pressure.

A third strain of relevant thinking views market or systems failures as opportunity windows for niche expansion and/or systems innovation (Foxon and Pearson 2008; Nill and Kemp 2009). In some sense, this constitutes Schumpeter (1975) with a sustainability twist. Market and systems failures can take several forms, including inadequate investment in public goods, infrastructure deficiencies, and marketing asymmetries, as well as technological lock-in. Such situations may present policy windows, but given the complexity of the innovation environment, successful interventions will require careful crafting. Chapters five and six address these problems in more detail in the U.S. context.

In summary, these recent approaches offer a number of useful insights and perspectives. The trend towards utilizing technology assessment as a promoter of sustainability, and towards more of a “steering” function, is entirely compatible with the aims of this dissertation, as is the co-evolutionary view of technologies within their socioenvironmental contexts. At the same time, the geographic, economic, and cultural scale of the U.S. presents problems that are not necessarily relevant in Denmark or the Netherlands. The differences in sociopolitical culture are perhaps even more challenging, particularly with respect to default assumptions regarding the appropriate role of government. Section III.D picks up these threads, but for the moment, the discussion turns to recent theoretical developments in the U.S.

## **II.C Anticipatory Governance (U.S.)**

“Anticipatory governance” is designed to address governance gaps with respect to emerging technologies. The concept derives from Guston and Sarewitz (2002), who build on previous experiences with technology assessment in both the U.S. and Europe to articulate their vision of “Real-Time Technology Assessment” (RTTA), a strategy for addressing some of the deficiencies of previous efforts to involve both social scientists and lay publics in technological design and development. They contrast RTTA with recent flavors of “Constructive Technology Assessment” (CTA) as detailed in chapter one.

Barben et al. develop the notion of “anticipatory governance” further in a recent piece (2008). The authors identify three challenges inherent in operationalizing anticipatory governance:

1. Anticipation and assessment of technologies in the process of emerging.
2. Engagement with publics and stakeholders largely latent at present.
3. Finding constructive vehicles for the integration of broader considerations into R&D policy, funding, and activity.

They summarize these issues as foresight, engagement, and integration respectively. Foresight demands research with an explicit focus on the future. It differs from forecasting in that it does not attempt to predict the future, but rather to make the exploration of possible futures and their potential consequences an intrinsic element of the innovation process. The authors’ vision extends beyond learning from past mistakes (e.g. Harremoës, Gee et al. 2001) to encompass a more proactive, co-evolutionary shaping of technological trajectories. It is thus necessarily prescriptive as well as descriptive and analytical, and accepts uncertainty as a baseline condition.

The combination of foresight and engagement complements recent thinking regarding “upstream engagement” in technology assessment. Barben et al. argue that nanoscale technologies meet the criteria for “post-normal science” (Funtowicz and Ravetz 1992) in that both decision stakes and uncertainty are high, thus peer review should extend beyond academic boundaries. Advocates such as Roco and Bainbridge (2005) highlight the need to involve multiple stakeholders, and more generally extol the virtues of public participation in technology assessment and governance. In any case, the idea of public participation in and shaping of technological development is central to discussions of anticipatory governance.

Barben et al.'s use of the term integration is somewhat specific to the incorporation of the social sciences into upstream technological governance. They identify two areas in which the U.S. legislation that reauthorized the NNI (U.S. Congress 2003) expects social scientists to contribute to the responsible development of nanotechnologies, and observe the potential for conflict between the two. The social sciences are called on to both “provide NSE researchers with contextual awareness of the interdependencies among science, technology, and society”, and “elaborate assessments of societal impacts and interact with publics accordingly” (Barben, Fisher et al. 2008, 984). The tension lies in the requirement to simultaneously shape and predict sociotechnical outcomes. One might argue that such a balance is inherent in any project that includes a significant interventionist component, and that implied struggle is inherent in the shift from assessment to governance, especially when oriented towards the future.

The notion of anticipatory governance as articulated by Barben et al. also includes a strong flavor of distributed knowledge production, where that distribution is both spatial and methodological, and also includes diverse sets of actors. They refer to this in part as research “ensemble-ization” (2008, 990), and their focus on research in part reflects the intended audience for the volume in which the article appeared. This decentralized approach parallels the literature concerning governance (e.g. Rhodes 1996; Stoker 1998), which emphasizes the role of non-state actors, and more diffuse forms of operation than traditional top-down government. Their article emphasizes the differences between anticipation, which is rooted in the co-evolution of science and society, and predictive certainty. This distinction further separates anticipatory governance from earlier efforts at technological forecasting.

Applying the evaluative framework set forth in chapter one to anticipatory governance is an interesting exercise, as the process reveals some ways in which that framework is an oversimplification. This is not a flaw in the analysis of earlier efforts, but rather a signal that anticipatory governance is in fact subtly different from previous versions of technology assessment. Chapter one proposed a four-part set of assessment criteria: policy orientation, scale, timeframe, and role (of the assessors). Locating anticipatory governance on these axes is relatively easy in terms of scale and timeframe, so the discussion begins there.

In terms of timeframe, anticipatory governance is clearly oriented towards the future. One might say that the bulk of the focus is on 5-10 years hence, with significant minority contributions in the 2-5 year and 10+ year periods. In this sense, anticipatory governance resembles the OTA, and is perhaps more narrowly focused than many transition management efforts. A similar analogy applies in terms of scale: anticipatory governance targets nanotechnologies (and, in the future, other emerging technologies) as a whole, while of course leaving room for more granular efforts. This emphasis provides a sharp differentiation from many SNM efforts, focused as they have been on particular technological applications or local implementations (e.g. Renn 2003). At the same time, anticipatory governance lacks the explicit emphasis on sustainability within the SNM and transition management literatures, which suggests possibilities for combination.

The discussion necessarily becomes more nuanced in addressing the parameters of policy orientation and role. Anticipatory governance clearly envisions a more active role for technology assessors in allowing the “modulation of innovation paths and outcomes in response to ongoing analysis and discourse” (Guston and Sarewitz 2002). The goal, at least at this stage,

is not to advocate particular R&D directions, but rather to “lay the intellectual foundation” (Barben, Fisher et al. 2008, 992) for future policies and strategies. The article makes a number of references to incremental capacity building, so it is possible that the authors envision a more direct policy role in the future. However, they make no specific policy recommendations in this piece, nor do they explicitly call for the development of same. In this sense, the policy connection is less evident than it was for the OTA.

The question of role is also somewhat ambiguous. Barben et al. discuss “embedding” social scientists within physical science labs, and also articulate the need for technology assessors to facilitate and participate in public engagement exercises. They also stress the need for “action” or “results-oriented” research, which is often not the case for academic efforts. Their article further expounds the ability of the aforementioned ensembles to shape the connections between policy and knowledge production. What it does not do is call explicitly for technology assessors to engage directly with policy makers. Again, the manuscript was published in a book directed to a specialized academic audience, which may explain the emphasis on social scientists, and research more generally. In a different publication, one of the co-authors does tackle the challenges of innovation policy, albeit at a very high level (Guston 2008).

On the whole, anticipatory governance is a subtle and powerful idea, with a great deal of potential for future development. One of the central questions of this dissertation is how to operationalize it, using nanotechnologies as a primary source of case studies. Doing so will require the re-importation of a subset of recent European practices, translating them to fit the American civic epistemology as necessary. As hinted above, the combination of anticipatory governance and sustainability might offer a “best of both worlds” solution for the U.S. Anticipatory governance’s emphasis on a decentralized approach, and its silence on the role of government make it a better fit for U.S. political culture than the SNM and transition management literatures. Sustainability provides the content that anticipatory governance explicitly avoids, and allows the framing of tangible answers to the question “what do we need to anticipate”, which is essential in operationalizing the concept. Sustainability is by no means a panacea, and remains a highly contested idea, even acknowledging the evolution traced in chapter one. In order to forge this theoretical “coalition”, it is necessary to examine certain aspects of sustainability in more depth.

### III. Combining Sustainability and Anticipatory Governance

The Brundtland report offers the classic definition of sustainable development, and continues to frame discourse on the subject, so it is worth repeating here:

“Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs. It contains within it two key concepts:

- the concept of 'needs', in particular the essential needs of the world's poor, to which overriding priority should be given; and
- the idea of limitations imposed by the state of technology and social organization on the environment's ability to meet present and future needs (UN 1987)”.

The bullet points are often omitted in citations; including them emphasizes the degree to which even early conceptions of sustainability included both economic and social elements, and awareness of North-South issues. The emphasis is on the need to address all three pillars, economic, ecological, and social simultaneously, to overcome the false environment-prosperity and environment-development dichotomies that had been prevalent until that time.

Sustainability is not without its detractors. Similar to the precautionary principle, various articulations thereof have been criticized as vague and unactionable. Particularly in the late 90s and early 21<sup>st</sup> century, activists accused corporations and other institutions of using the term as cover for “business as usual”, i.e. greenwashing (e.g. Gutman 2003; Seyfang 2003). From the other side, prominent green engineering/architecture advocates essentially dismiss sustainability as unexciting, as failing to offer visionary positive goals (McDonough and Braungart 2005). Sustainability is somewhat like “motherhood” in the U.S.: no politician who wants to be re-elected would run on an “anti-motherhood” platform. At the same time, the sacrosanct status of motherhood gives very little guidance regarding effective measures to reduce teenage pregnancies, and offers little tangible assistance to single parents struggling to make ends meet. In order for sustainability to serve as an effective governance tool, more concrete measurements are necessary.

Recognizing these criticisms (and others), the combination of sustainability and anticipatory governance does offer some significant advantages over both the precautionary principle and traditional approaches to risk analysis for the governance of emerging technologies with environmental implications and applications. First, it inherently includes the possibility of benefits, moving beyond a sole focus on risk. Second, the “three pillars” of sustainability (economic, ecological, and social) provide a high-level framework for tradeoff analysis, supporting the inclusion of distributional considerations in technology assessment. Third, related scientific disciplines have evolved to the point that quantitative metrics of sustainability are emerging, providing the possibility of more actionable definitions in specific situations. As the next section hints, many challenges remain, especially within the social pillar, but attention to Life Cycle Analysis (LCA) and related practices has produced significant progress in the environmental arena.

### **III.A Sustainability Metrics and Goals**

Measuring progress towards sustainability has been problematic; translating the Brundtland Commission’s definition into clear evaluative criteria poses numerous difficult challenges. However, the growing consensus on climate change simplifies the search for quantifiable metrics, especially in the environmental area. Greenhouse Gas (GHG) emissions are measureable in many cases, and the science of translating gases such as methane into CO<sub>2</sub> equivalents is well established. Agreement extends to the need to reduce fossil fuel consumption, and replace it with renewable energy sources, and to reduce energy consumption per unit of production, both of which lend themselves to monitoring. The critical importance of fresh water is also widely recognized, as is the need to bring emissions of all kinds within the capacity of natural sinks, which is very limited in the case of highly toxic materials. 40 years of implementing and enforcing environmental regulations have produced a robust set of tools and

methodologies for quantifying environmental bads, and recognition that the current industrial ecosystem is unsustainable.

The challenge lies in moving from bads to goods, from mitigating damage to promoting ecological, economic, and societal health. Fortunately, there is progress in this area as well. Gasparatos et al. argue that 20 years of debate have produced a rough consensus that sustainability assessments should:

- “integrate economic, environmental, social and increasingly institutional issues as well as to consider their interdependencies;
- consider the consequences of present actions well into the future;
- acknowledge the existence of uncertainties concerning the result of our present actions and act with a precautionary bias;
- engage the public;
- include equity considerations (intergenerational and intergenerational)” (2008, p. 287).

There are strong parallels between these five elements and the statements of advocates of the precautionary principle (e.g. Hansen, von Krauss et al. 2008), although not all proponents of sustainability would agree with the “precautionary bias” in the third point. The chief differences between the two positions are that sustainability emphasizes all three pillars, focuses explicitly on equity, and considers a longer timeframe.

The authors also note the distinction between strong and weak sustainability, where the former holds that financial, human, and social capital are not necessarily substitutable for natural capital. Essentially, the claim is that some ecological systems are irreplaceable within societal timescales. Mihelcic et al. comment on the emergence of “sustainability science and engineering” as a new metadiscipline (2003). They see it as the next evolutionary step for practices such as Green Chemistry, Green Engineering, Design for Environment, Life Cycle Assessment, and Industrial Ecology. These authors argue that treating it as a metadiscipline permits the necessary combination of multiple skill sets without having to sacrifice rigor, and also lends itself to research focused on finding solutions to particular problems. They further observe that while many of these fields successfully incorporate ecological and economic factors, the additional of societal elements is essential in the construction of metrics for sustainability, as is the ability to handle multiple spatial and temporal scales of analysis. While the task is by no means impossible, the challenges in formulating indicators that are credible, comprehensible, and efficient to calculate are formidable.

The uncertainties inherent in emerging technologies such as nanotechnologies further complicate the challenges of developing workable sustainability metrics:

1. Life Cycle Assessment (LCA, as an example of the various disciplines that feed into sustainability assessment) is a very data-intensive process, and depends heavily on prior knowledge. While good economy-scale datasets are publicly available, they generally do not include extensive information on nanotechnologies. Part of the governance gap with respect to emerging technologies is that the production of data about environmental and

societal impacts tends to lag market introduction by a substantial margin. Methodological tools that depend on well-characterized summaries of existing data are of limited utility under such circumstances.

2. While researchers have developed some quantitative indicators in the social dimension, most work to date has focused at the organizational level. Although useful for Corporate Social Responsibility (CSR) purposes, the scaling problem in this regard is not linear. In particular, the links between the choices available to individual organizations and broader sociocultural impacts are poorly understood, and the path toward improved understanding thereof is itself unclear.
3. Boundary-setting is one of the biggest challenges for conventional LCA. Given the global interconnectedness of many industrial processes, care and judgment are essential in order to avoid including a significant chunk of the world's GDP in any particular case. The incorporation of social factors exacerbates this problem in ways that will require substantial additional articulation.
4. Sustainability assessment enters a policy world in which benefit-cost analysis (CBA) of potential regulation has been a powerful, if not dominant paradigm. While the hegemony of CBA has come under increasing fire in the first decade of the 21<sup>st</sup> century, its influence remains strong. Various scholars have proposed methods for integrating sustainability into CBA (e.g. Bebbington, Brown et al. 2007; Saez and Requena 2007), but these modifications have not yet gained widespread acceptance, and face resistance from both sides of the ideological fence. CBA has become a loaded term, and has often been employed as a political weapon, at least in the U.S. While sustainability metrics do not necessarily need to conform to CBA frameworks, the legacy of battles over CBA forms part of the context for implementation.

For current purposes, the points are that while sustainability science and the development of useful metrics have seen substantial progress in the last five to ten years, much work remains. Given the complexity of the concept, it is probable that no single indicator will ever suffice. Rather, approaches like that advocated by (Dewulf and Van Langenhove 2005), which emphasize the need to fit metrics to a particular purpose, may offer superior ways forward. Other authors emphasize the need to construct hierarchies of indicators, to facilitate the prioritization process (Jin and High 2004). Gasparatos et al. (2008) take a critical stance towards reductionist assessments, including CBA, while recognizing the value of numbers in decision support. Their argument raises the valuable point that the construction, adoption, and implementation of sustainability metrics are political acts.

This assertion resonates with some of the criticisms of transition management as either elitist (Loveridge and Saritas 2009), vulnerable to capture by existing interests (Hendriks 2009), and/or insufficiently sensitive to power relationships (Meadowcroft 2009; Voss, Smith et al. 2009). It also highlights the fact that defining sustainability, or particular sustainable futures, is an inescapably normative enterprise (Smith and Stirling 2010). Anticipatory governance per se in some ways seeks to sidestep these kinds of problems, although it acknowledges their importance via its emphasis on reflexivity. Adding sustainability to the mix, however, brings contestation to

the forefront, especially in the current U.S. political climate. Operationalizing the combination of anticipatory governance and sustainability may force us to reconsider our notions of metrics, and their role in American political discourse. To this end, one of the key figures in public administration theory may have some light to shed.

## **II.B Bounded Objectivity**

An extension of Herbert Simon’s seminal idea of “bounded rationality” may prove useful in the design and implementation of sustainability metrics and practices. Although his original formulation used the term only lightly, and he developed the concept further over the years, three core elements were present from the outset:

1. Human knowledge of the consequences of our choices is almost always incomplete.
2. Since these consequences lie in the future, our assessments of how we will value them at the time are only estimates. Economists put this in terms of the uncertainty of future preferences.
3. Objective rationality, which Simon argues against, requires evaluation of all possible alternatives. In practice, only a limited subset of the available alternatives receive serious consideration (Simon 1997).

Given these constraints, Simon claims that humans rarely optimize their behaviors in accordance with fixed utility functions, as neo-classical economic theories assume. Rather, especially when operating in organizational contexts, they *satisfice* (Simon 1997, p. 118). To *satisfice* is to choose a course of action that is “good enough” for present purposes and constraints, recognizing a substantial subjective component in both assessment and decision. Simon goes on to discuss the critical role of attention in *satisficing*, to which the discussion will return later.

*Satisficing* may have value not just in describing decision-making behavior, but also in the construction and deployment of decision support objects, such as sustainability metrics. In some of his later work, Simon speaks to the desirability of incorporating the tenets of bounded rationality into the design of human institutions (Simon 1985, p. 303). In that spirit, this dissertation introduces the idea of “bounded objectivity”. As rationality is bounded in practical environments, in contrast to the postulates of economic theory, so does ‘objectivity’ never attain the perfection ascribed to it by positivist accounts of science. The constraining factors are not exactly the same, but are sufficiently similar to merit further examination.

For Simon, rationality is constrained by incomplete knowledge of consequences and future preferences, and search limitations with respect to alternatives. Objectivity is constrained somewhat differently, in ways that raise more difficult philosophical questions. First, we can never be certain that our knowledge of any given object is complete. Following Hacking (1983), we may employ criteria of predictability and control to establish the ontological status of say, electrons, but we have no way of knowing whether, or the degree to which, our control encompasses all possible aspects of electrons. Secondly, correlating with preferences, we cannot know the degree to which a priori notions have influenced research priorities and direction. In vernacular terms, to what level do we find only what we are looking for, except in unusual situations? Thirdly, our search domain is constrained by our knowledge and imagination. To



what degree is our capacity to recognize novelty limited by current knowledge and abilities? These questions are beyond the scope of this dissertation, but are included here to illustrate the profound nature of the uncertainties inherent in governing emerging technologies. The challenge is to formulate frameworks for decision and action under these conditions.

This need is driving force behind this dissertation's conception of bounded objectivity. It is best put as a question: can a perspective on objectivity that draws from and resonates with bounded rationality be useful in formulating metrics, processes, and decisions that advance sustainability in technological governance? It is important to note that the phrase is not original: it was first used in a legal commentary on U.S. Supreme Court decisions that stressed the importance of interpretive communities (Fiss 1982). In terms of sustainability metrics, there is a resonance with evolutionary notions of fitness for a particular purpose. There may be value in abandoning "objective" notions of a single optimal state, of embracing instead pluralistic conceptions of objectivity that account for either an observer's standpoint (e.g. Hacking 1983; Haraway 1988; Harding 1995) and/or political realities (e.g. Lindblom 1959; March 1978; Forester 1984; Jones 2003). Perhaps the crucial variable is the expectations of objectivity held by various actors; what standards they expect decision-support objects to meet, as well as their guesses regarding the political efficacy of arguments based on traditional definitions of objectivity.

Nominally, objectivity is concerned with the objects of study. When these objects are relatively non-controversial, i.e. in a discussion of the nest-building behaviors of a certain population of ants, objectivity is generally not problematic. When the conversation shifts to objects with significant political ramifications, such as the calculation of Certified Emission Reductions (CERs) under the Clean Development Mechanism of the Kyoto Protocol, contestation is often the order of the day. CERs are clearly constructed objects, with multiple, sometimes competing interests involved. A combination of Simon's earlier work with contributions from Latour (1979) suggests one way to view this variation as a continuum. Simon started from a strong distinction between 'facts' and 'values', although his later contributions recognized the interactions between the two (1995). Latour offers the idea that scientific facts undergo various stages of stabilization, an evolution from individual submission to collectively accepted truth. Traditional notions of objectivity, of a clear separation between facts and values, might then apply to well-stabilized facts (i.e. the Earth orbits the Sun).<sup>5</sup> More relativistic or standpoint-orientated conceptions may be more appropriate for earlier stages of fact production.

In this vein, sustainability metrics are facts under construction, and may never fully stabilize; arguments will be endemic. Operationalizing either anticipatory governance or strategic anticipation thus involves taking not just uncertainty, but also conflict, as given. In this light, the flexibility of the notions of bounded rationality, and bounded objectivity may afford some space for negotiation. The recognition that full precision is unattainable might facilitate compromises, preventing perfect from being the enemy of good, and possibly making it more difficult to use "sound science" in obstructionist ways. At the same time, objects, particularly quantifiable ones, have value in political discourse as tangible bases for action. The next section focuses on boundary objects as a possible vehicle for negotiating complex political situations. In some

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<sup>5</sup> Of course, there is a temporal aspect. Copernicus and Galileo operated in societal contexts where the orbital relationship between Earth and Sun was by no means considered established fact.

sense, boundary objects exploit the boundedness of rationality and objectivity as a political asset, which could be a useful tool in pursuing more sustainable solutions.

### **III.C Sustainability as Boundary Object**

Star and Griesemer introduce the concept of boundary objects in their account of the development of the Museum of Comparative Zoology at the University of California, Berkeley (1989). Their goal is to examine how multiple disparate groups, including but not limited to scientists, university administrators, museum curators, private sponsors, government officials, amateur naturalists, and professional trappers were able to establish and maintain a successful system of cooperation. They find that this collaboration was mediated via “boundary objects”, ideas that are sufficiently “plastic” to adapt to the needs and constraints of various stakeholders, yet “robust enough to maintain a common identity” (Star and Griesemer 1989, p. 393).

The authors delineate four different kinds of boundary objects, of which three are of primary interest here. They term one of these types “coincident boundaries”, where all parties agree upon the borders of the entity, but interpret the ‘interior’ differently. Their example in this case is the State of California, which served the needs of several different parties. The university administration saw serving the state as part of its public service mission, and also wished to distinguish itself from the eastern academic establishment. The naturalists and conservation groups shared an interest in preserving and recording the unique flora and fauna of California, and a geographical framework also meshed well with the museum director’s theoretical orientations. ‘California’ thus meant different things to different stakeholders, while allowing agreement that all were in fact referring to the same object.

Sustainability works well as a boundary object in this sense. The concern is with the entire planet. More precisely, the three pillars (ecological, social, and economic) indicate that the idea’s domain includes all human interactions with the biosphere, and that humans themselves are part of that biosphere. Of course, parties diverge in the priorities they place on various aspects of these interactions. Star and Griesemer note that this kind of interpretive flexibility is essential to facilitate cooperation among diverse groups. While conflicts will certainly arise, the coherence of the shared portion of the understanding provides a framework under which to seek resolution.

Star and Griesemer articulate a second category of boundary object relevant to the discussion of sustainability metrics. They highlight the Museum’s success in developing and enforcing data collection and recording methodologies that included both note taking and the treatment of animal specimens. They label this type of object a “standardized form”; Fujimura (1988) expressed a very similar notion, but used the term “standardized packages”. Again, the idea is that while there is a consistent core, various stakeholders engage with it in ways consistent with their individual constraints. Trappers, for example, groused at the need to preserve samples in relatively pristine form (i.e. intact skulls), but grudgingly complied in order to collect their payments from the museum.

The core of the boundary object is not necessarily fixed, and subject to negotiation and evolution over time. Star and Griesemer’s article covers the period from 1907-1939, so it has the

advantage of hindsight. Sustainability metrics are still in an early stage of evolution, and the scale of operation is much larger than a single organization. As stated previously, a one-size-fits-all approach is probably not appropriate. However, it may well be possible to establish standardized forms or processes within proscribed domains – the ISO 14000 standards regarding procedures for Life Cycle Assessment are a good example. Developing agreement on sustainability metrics is likely to be contentious, especially if they are used as the basis for regulation, or allocation of substantial resources. However, a focus on standardized forms and processes may well be useful in managing political conflict, to the degree feasible.

The third kind of relevant boundary object is the “ideal type”. Star and Griesemer offer species as an example, noting the need to reify details in order to highlight a larger pattern. In this sense, sustainability may have value primarily as a normative abstraction; it would be very difficult to argue directly and credibly that the needs of future generations are not important. This is one way in which sustainability is superior to the precautionary principle as a framing device (Benford and Snow 2000). The merits of the alternative translation of *vorsorgeprinzip* as ‘forecaring principle’ notwithstanding, the precautionary principle as generally stated is much more vulnerable to attack than sustainability. Sustainability is a better boundary object, in that it transcends more boundaries than it creates. As such, sustainability provides a more constructive foundation for future efforts, both ideationally and normatively. It is not a panacea, and many challenges remain, but sidestepping some of the baggage associated with the precautionary principle should allow increased focus on present and future problems, as opposed to continuing battles from the past. Such an approach is entirely consistent with anticipatory governance’s orientation towards the future.

### **III.D Anticipation as Shaping**

Not only does anticipatory governance seek to avoid the chimera of precise prediction, it also eschews the technological determinism that underpins many traditional forecasting exercises. In this sense, it is compatible with the co-evolutionary philosophies espoused by strategic niche management and sustainable innovation policy approaches. Barben et al. briefly mention a number of foresighting methodologies as vehicles for anticipation, and the Center for Nanotechnology in Society at Arizona State University, with which the authors are affiliated, has placed a particular emphasis on developing scenarios as a platform for facilitating reflexivity within the research enterprise.

Speaking generally, Europe and Japan have embraced formal public sector involvement in innovation more enthusiastically than the U.S. (Faucheux and Hue 2001; Kameoka, Yokoo et al. 2004). That statement is somewhat of an oversimplification, as e.g. the U.S. National Aeronautics and Space Administration (NASA) and the Advanced Research Projects Agency (ARPA, now DARPA, where the D stands for defense) have clearly supported and promoted the development and deployment of new suites of technologies, with the Internet serving as a prominent example. The distinction probably lies more in the area of framing – the U.S. has tended to exhibit an aversion to labeling its activities as ‘industrial policy’, whereas other countries seem much more comfortable doing so. Japan in particular has a long history of large-scale engagement of scientific and technological expertise in support of future planning. While

their efforts in the 70s and 80s are probably better categorized as forecasting, the Japanese experience clearly provides a foundation for more recent efforts worldwide.

Faucheux and Hue (2001) provide a valuable summary of the global movement from forecasting to foresighting. They describe a gradual evolution away from purely expert processes towards various styles of participation, an increasing emphasis on societal needs as opposed to national competitiveness, and a growing integration of sustainability issues into technological deliberations. They report uneven progress amongst the different countries studied, noting that the Netherlands and Germany had evolved furthest in terms of public participation and sustainability, respectively, at the time of writing. The Strategic Niche Management and Sustainable Innovation Journey literatures invoked previously update Faucheux and Hue – the trends identified in 2001 have amplified, expanded, and extended in new directions.

Prominent among recent developments is the combination of backcasting with foresighting. Simply, backcasting starts by constructing a shared vision of a desirable future (or sets thereof) in certain respects. It then contrasts current situation(s) with these visions, and produces a set of alternatives designed to ‘get us from here to there’. There are profound philosophical differences between backcasting and forecasting, as Dreborg highlights in quoting Robinson, and by extension Lovins:

“The major distinguishing characteristic of backcasting analysis is a concern, not with what futures are likely to happen, but with *how desirable futures can be attained*. It is thus explicitly normative, involving working backwards from a particular desirable future end-point to the present in order to determine the physical feasibility of that future and what policy measures would be required to reach that point” (Dreborg 1996, p. 814, italics added).<sup>6</sup>

While anticipatory governance as articulated by Barben et al. fully recognizes that incorporating reflexivity into the research process has normative ramifications, it stops short of setting goals or objectives, or choosing particular futures. For technologies without significant sustainability ramifications, such caution is entirely appropriate. However, in cases where applications with the potential to deliver significant public goods face possible market or systems failures, an activist approach is more likely to produce societal benefits. Combining backcasting and foresighting provides a process for steering innovation in more sustainable directions (Partidario and Vergragt 2002; Dortmans 2005; Gaziulusoy, Boyle et al. 2008). This emphasis on influencing technological trajectories is a key difference between anticipatory governance alone in contrast to the combination of anticipatory governance and sustainability. In other words, the conjunction of the two constitutes an interventionist form of anticipatory governance, guided by the principles and metrics of sustainability, applied to environmental arenas. Under certain circumstances, the best way to anticipate the future is to take an active role in shaping it. This position clearly involves a normative stance, a contribution that sustainability brings to anticipatory governance. Just as SNM and transition management require translation in order to

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<sup>6</sup> The quotation is from Robinson, J. B. (1982). "Energy Backcasting: A proposed method of policy analysis." *Energy Policy* 10(4): 337-344. Robinson coins the term in discussing ‘soft energy paths’ as advocated by Amory Lovins, and credits Lovins as providing the idea behind the word.

be effective within an American sociopolitical context, anticipatory governance requires a conceptual partner in order to maximize its chances of delivering tangible policy and strategy results.

### **III.E From Niches to Markets**

As previous sections have consistently alluded, the strategic niche and transition management literatures require substantial translation in order to be viable in the U.S. political context. This requirement is entirely in keeping with Jasanoff's notion of "civic epistemologies", which emphasizes the need to consider the ensemble of "local" sociopolitical factors, tendencies, and histories in cross-cultural exercises (2005). As observed earlier, much of the existing literature in these areas, e.g. discussions of strategic niche management (Caniels and Romijn 2008; Schot and Geels 2008), systems transitions theory (Wiek, Binder et al. 2006; Gaziulusoy, Boyle et al. 2008; Nykvist and Whitmarsh 2008), and sustainable innovation journeys (Foxon and Pearson 2008; Schot and Geels 2008) has a strongly European bent. Given the resistance in Washington to anything that "smells French",<sup>7</sup> incorporation of such thinking into a foundation for U.S. policy requires a compelling narrative in the American political vernacular. There are three requisite axes of translation: scale, the extent of societal consensus on sustainability, and the range of implicit assumptions regarding the appropriate role of government in the marketplace.

Turning first to scale, the Netherlands packs a population close to that of Florida (16.6 million vs. 18.5 million) into an area roughly 2/3 the size of West Virginia, a significant percentage of which is below sea level. Denmark, another country where participatory technology assessment has received a great deal of state support, is marginally larger than the Netherlands, with a population of 5.4 million. The U.K. and Germany are obviously much bigger at approximately 61 and 82 million inhabitants, respectively, and Germany in particular is much more of an economic power as well. Taken together, these four countries, which have been at the forefront of the "new wave" of technology assessment, equal roughly half of the population of the U.S. in an area slightly larger than Texas. This huge disparity in population densities (and economic scale, especially in contrast with the Netherlands and Denmark) pose challenges in translating technology governance schemes and practices across the Atlantic.

Perhaps more profound, though, are the differences in sociopolitical culture. The EU is of course by no means monolithic; the UK and Germany, for example, have very different approaches to the interactions between science, technology, and culture (Jasanoff 2005). However, since much of the relevant literature comes primarily from the Netherlands, this discussion takes that country as its basis for identification of translational issues.

First, the strategic niche and transition management literatures implicitly assume a natural role for government as a strategic, if not leading actor, as well as a general preference for collective action. One could argue that the unique Dutch geography, which demands cooperation in keeping much of the nation above water, has contributed to the development of a corporatist culture, but such claims are beyond the scope of this dissertation. What is clear in contrast is that the appropriate role of government is much more contested in the U.S., to the degree where it is

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<sup>7</sup> This is a direct quote from a relevant U.S. government official, drawn from an October, 2009 conversation.

often a significant political flashpoint. These literatures seem to assume that national consensus is both possible and desirable, even normal; conditions that may not obtain in the U.S. at this time. This is not to assert that Dutch politics are free of dissension and argument, nor that transition management approaches have been problem-free in the Netherlands (Voss, Smith et al. 2009). There are, however, substantial differences in civic epistemologies between countries that a successful translation strategy must address, even within Europe (Heiskanen, Kivisaari et al. 2009), including the recognition that transitions to sustainability are irreducibly political processes (Meadowcroft 2009).

Secondly, the consensus regarding sustainability is more robust in the Netherlands than it is in the U.S. Chapters one outlined the trajectory of environmental consciousness in the U.S. over the last several decades, and make the point that “green jobs” have become part of mainstream conversation. Agreement is relatively strong within the scientific community, the Executive branch in the current administration takes sustainability more or less as a given “public good”, and even the business community has shifted substantially in that direction, albeit with varying degrees of sincerity and commitment. What the U.S. lacks vis-à-vis the Netherlands and several other European countries is political agreement, especially in Congress. Although the House passed significant climate change legislation in 2010, that bill’s prospects in the Senate are uncertain as of this writing. Challenges to the notion that climate change is primarily anthropogenic have gained popularity in recent discourse, even though the scientific evidence is both robust and growing. In short, sustainability is still very much contentious in the U.S. as a basis for concrete action. While this is compatible with the notion of sustainability as a boundary object advanced in section III.C, it also implies that sustainability alone will not carry substantive bills through the U.S. Congressional process.

Fortunately, many of the terms and concepts within these literatures map nicely onto existing language within U.S. political discourse. While the latter is itself problematic in that it continues to depend heavily on notions of American “exceptionalism” and “sound science”, among other questionable ideas, such are the realities of Washington at this juncture. The following table suggests translations for some of the key ideas, based on language from the America Competes

**Table 2: Transatlantic Term Translations**

<b>Transition Management</b>	<b>U.S. Political Realities</b>
Avoiding technological lock-in	Disruptive Innovation, High-Risk/High-Reward Investments
Social learning	Adaptive Management
Participatory Technology Assessment	Stakeholder Engagement
Sustainability	Energy Security and National Competitiveness
Government Leadership	Green Jobs, bridging the “Valley(s) of Death”
Transition Management	Addressing Critical National Needs

Act of 2007 (U.S. Congress 2007), which created both the Technology Innovation Program (TIP) discussed in chapter five, and the Advanced Research Projects Agency – Energy (ARPA-E) unit within the Department of Energy. The table also draws from the 2003 legislation that formally endorsed the National Nanotechnology Initiative (NNI) (U.S. Congress 2003), as well as various

reauthorization bills for this same initiative. While an oversimplification, particularly with respect to sustainability, it does provide a concise “dictionary” to aid in adapting valuable elements of European thinking and experience to American political contexts.

A couple of the translation entries merit amplification and explication. Sustainability is not present in the U.S. column because the table draws from approved legislation. This implies somewhat of a “stealth” approach to sustainability, at least as far as Congress is concerned. Sustainability is valuable as a motivating and organizing principle at the operational levels of governance, but does not yet win elections, whereas energy security has become an accepted element of the political discourse. Secondly, something does get lost in the translation. One of the strengths of the European literatures is their systematic approach to the challenges of sustainable innovation policy. Although at least one prominent advocate does call for precisely such a strategy in the U.S. (Tassey 2010), that recommendation has not yet been adopted, and will likely face an uphill battle. Given the undercurrent of ideological resistance to anything that smacks of a “planned economy”, implementing a coherent sustainable innovation policy in the U.S. will be a delicate matter. Chapter six sketches out some steps in that direction, and does so in a necessarily tentative fashion.

To summarize, policies that seek to promote the combination of anticipatory governance and sustainability in the U.S. need to focus on creating and developing markets for innovations that meet underserved public needs. The government’s role needs to be perceived as less invasive than in Europe, and more delicately targeted. Policies should strive to enable private actors to the degree feasible, to create the necessary conditions of market success for technologies that produce socially desirable outcomes. Although there are clearly areas that require public intervention, U.S. innovation policy should follow a rather minimalist strategy, serving in many cases as a signal to markets, rather than the primary driver thereof. On the demand side of the equation, the enormous purchasing power of the U.S. Government allows it to take strong action in making markets without imposing regulatory burdens. Instruments such as tax credits and loan guarantees also fill valuable niches, while raising fewer ideological hackles than direct intervention. Regulatory certainty over time is another valuable market enabler, especially for long-term investments. In short, while there will always be areas where strong regulation is the only viable option, constructive interventions in the U.S. will generally be characterized by a lighter touch than their counterparts in Europe.

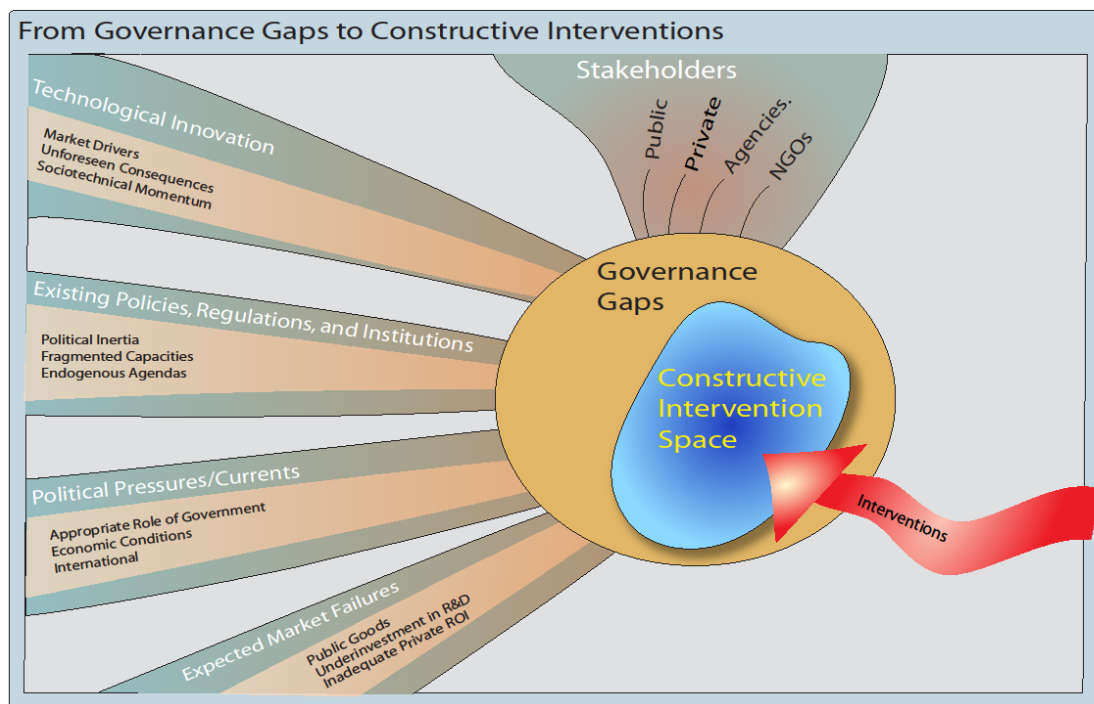
#### IV. Anticipatory Research Foci

The challenge for the balance of the dissertation is to develop the research foci in table 1 into tangible research questions. Additionally, in order to advance the objective of operationalizing anticipatory governance, the research subprojects must put the concept into practice. This fits with the idea of anticipation as shaping articulated in section III.D, and the notion of “learning by doing” that is central in much of the relevant literature. This is the first translation problem articulated in section I, and it manifests within a complex and dynamic national innovation system, which is itself embedded globally.

No single model or typology can fully capture the richness, diversity, and multiple levels of interactions of national innovation systems (Eriksson and Weber 2008; Kowalski, Stagl et al.

2009; Smith and Stirling 2010; Smith, Voss et al. 2010). Recognizing this irreducibility, figure 1 presents a stylized graphic of what it terms the “constructive intervention space” regarding the steering of emerging technologies towards more sustainable outcomes in the U.S. The two-toned “arms” represent the driving forces that interact dynamically to create the governance gaps

**Figure 1: The Constructive Intervention Space in the U.S.**



identified in chapter one. This dissertation calls on the combination of anticipatory governance and sustainability to address these gaps with respect to emerging technologies with environmental implications and applications, at least partially. In order to aid in translating the problem of governance gaps into a constructive opportunity, the diagram introduces the notion of a “constructive intervention space” for public-private strategy and policy in the U.S.

Simplistically, this constructive intervention space is derived by viewing the union of the governance gaps identified in chapter one as policy opportunities. However, it also fits with the notion of transatlantic translation, in that the constructive space is smaller than the governance gaps, reflecting the boundaries of political feasibility. Given the previous discussion, it is highly probable that these boundaries differ between Europe and the U.S., not to mention China, Brazil, and the rest of the world. Further, it resonates with the criticism of the “sound science” vs. precautionary principle debates set forth in chapter one, in that it allows for the inclusion of benefit considerations in policy deliberations, moving beyond a narrow focus on risks.

The idea also facilitates explication of the subjective and normative nature of the governance gaps, another area of transatlantic resonance. Taking the first governance gap as an example, how much risk assessment is enough? What standards of proof of safety should manufacturers be required to meet before introducing a new nanomaterial into commerce? This is far from a



purely theoretical question; there are substantial differences between European and U.S. regulatory approaches in this area (Denison 2009), and the U.S. National Nanotechnology Initiative (NNI) has been criticized for inadequate funding of and planning for Environmental Health and Safety (EH&S) research (Denison 2005; Dunphy-Guzman, Taylor et al. 2006; NRC 2008; NNCO 2009). Accepting that there is a governance gap in this area with respect to nanotechnologies (e.g. Oberdörster, Oberdörster et al. 2005; Maynard, Aitken et al. 2006; Miller and Senjen 2008; Paradise, Wolf et al. 2009), on what bases should the NNI assess the adequacy of its EH&S effort? Chapter six evaluates the NNI in greater detail; the point for the moment is that the size and nature of this particular governance gap is open to interpretation, negotiation, and contestation.

The NNI and risk assessment is just a small example. The size, nature, and indeed the very existence of governance gaps regarding emerging technologies are all subjects of political and ideological contestation in practice, paralleling the discourses about sustainability noted earlier. A full theoretical exploration of governance gaps would need to address a host of additional literatures – the ongoing debate about the evolving nature of “governance” (e.g. Rhodes 1996; Jones, Hesterly et al. 1997; Stoker 1998; Nanz and Steffek 2004; van Kersbergen and van Waarden 2004) is but one example. While chapter five delves into some of these issues in more detail with respect to public support for technological innovation in a market-oriented climate (the U.S.), on the whole, these deeper theoretical questions are of only tangential relevance to this dissertation’s focus on operationalization.

The notion of a “constructive intervention space” also aids in keeping the discussion practical, and in maintaining the focus on transatlantic translation. As section III, and particularly subsection III.E emphasize, recent European insights can have value for the U.S., but the necessary cultural adaptation is a non-trivial exercise. The European literature owes a strong debt to complexity theory, and as a result can be impenetrable at times. While acknowledging the contributions, and in some cases accuracy, of complexity theory, the purpose of proposing a “constructive intervention space” is to frame the relevant research problems in terms accessible to U.S. policy makers and private sector actors. It is a bridge that facilitates the translation from governance gaps into constructive action. In the spirit of experimentation, the following chapters each traverse that bridge in their own ways.

### **IV.A An Anticipatory Governance Approach to Carbon Nanotubes (Ch. 3)**

Chapter three undertakes what it terms as an “anticipatory risk characterization” of carbon nanotubes (CNTs). It addresses the governance gap of innovation outstripping assessment with respect to nanomaterials. Given that the scientific uncertainty about the potential toxicity of CNTs is likely to persist for some years, they pose a particularly illuminating case. Relevant private and public sector actors need to make decisions now, based on the information available, while recognizing the incompleteness of current analyses. This is clearly a problem of anticipatory governance.

More specifically, chapter three poses a number of subquestions:

1. How do CNTs problematize existing risk assessment procedures and paradigms?

- a. To what degree are these issues specific to CNTs?
  - b. Alternatively, in what ways do CNTs simply serve as a particularly harsh test that exposes weaknesses or gaps in current risk assessment techniques?
2. Given the conflicts, confusion, and ambiguity in the currently available literature, what tentative conclusions make sense?
  3. Under these conditions, what options are available to relevant actors, and what kinds of processes might be useful in minimizing the risks while maximizing the potential benefits of these and similar technologies?

Saving most of the details, the answers to question three include life cycle approaches, which direct attention to all phases of a product's existence early in the design phase, risk/benefit frameworks such as the one put forward by the Environmental Defense Fund and Du Pont, and more general "green nanotechnology" strategies. The conclusions and recommendations from this chapter stand partly on their own, and also inform some of the policy and institutional deliberations in chapter six.

#### **IV.B Public Engagement – National Citizens Technology Forum (Ch. 4)**

Chapter four relates UCB's participation in the recent National Citizens Technology Forum (NCTF) on Converging Technologies and Human Enhancement (Hamlett, Cobb et al. 2008), serving as one of six sites in this nationwide effort sponsored by the Center for Nanotechnology in Society at Arizona State University (CNS-ASU). The project, which used a modified consensus conference model, brought participants together for two face-to-face weekends at the beginning and end of March 2008, with multiple, scheduled online interactions in the intervening weeks. The online sessions included question and answer sessions with experts, and input from the conferees was important in determining which fields of expertise were made available.

Each of the six groups produced a final consensus report. The format of these documents was not specified, but groups generally listed their hopes, concerns, and governance recommendations regarding the applications in question. These reports constitute the primary data set for chapter four, which poses the following broad questions in addressing the governance gap of public confidence:

1. Is the consensus conference model viable at a national scale in the U.S.?
2. Are consensus conferences compatible with U.S. political culture?
3. How can participatory technology assessment efforts effectively feed into policy-making processes?

Briefly, the NCTF provides evidence supporting emphatic answers of yes to questions one and two. Question three is subtler, and the analysis compares the site reports with a 2008 U.S.

Senate bill<sup>8</sup> reauthorizing the National Nanotechnology Initiative (NNI). It concludes that not only did participants produce recommendations salient to policy-makers; there are also several opportunities for improving the integration of public input into formal policy-making. The insights from this project could prove valuable in designing processes for participatory foresighting and backcasting, an important element of the proposals put forward in chapter six.

#### **IV.C            Narrowing the Constructive Intervention Space (Ch. 5)**

Chapter five differs from chapters three and four, in that it does not in itself comprise a constructive intervention. Instead, it takes a triangulatory approach, interrogating multiple data sets in order to bound the constructive intervention space with respect to the environmental implications and applications of emerging technologies. In particular, it seeks to focus discussion with respect to appropriate arenas and rationales for federal support, and highlights how multiple systemic incentives for underinvestment in R&D combine to produce gaps in the development cycle for sustainable innovation in the environmental arena. Empirical interview data from nanotechnology businesses and venture capital firms provides important ground-truthing; to what degree do these actors consider risks and benefits simultaneously in making investment choices? The chapter addresses the following questions, among others:

1. To what degree have investments in the DOD, NASA, and more recently the NIH, effectively constituted U.S. innovation policy in the post-WWII period? What arenas might this de facto arrangement have systematically underprioritized?
2. Is the purported “Valley of Death” real in terms of societally beneficial innovation? Is there in fact more than one “Valley of Death” for some environmentally relevant applications?
3. Does American strength in terms of venture capital and other forms of early stage investment fully capture the possible future public goods benefits of innovation? Are there gaps in the venture capital model that merit public intervention? If so, what are their characteristics?
4. If there is a constructive intervention space for federal innovation policy in environmental arenas in the U.S., where are its boundaries? How can or should we differentiate between effective policy and corporate welfare?

Both the theoretical questions and the empirical evaluations initiated in chapter five feed directly into chapter six.

#### **IV.D            Towards Anticipatory Institutions (Chapter 6)**

As chapter one emphasized, governance gaps result from the dynamic interplay of innovation, policy, markets, culture and other forces. That is, they change over time, therefore potential solutions must include the ability to adapt. This implies the need for institutions with a significant capacity for learning. Chapter six examines two existing institutions that aim to

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<sup>8</sup> Although a similar bill passed the House, financial conditions in the fall of 2008 precluded a Senate vote. The House of the 111<sup>th</sup> Congress passed legislation almost identical to their previous version, and a revised bill was introduced in the Senate in 2009. There are significant differences between the House and Senate versions, but other priorities have precluded substantive Senate action on the matter to date.

govern emerging technologies, the Technology Innovation Program (TIP) within the National Institute of Standards and Technology (NIST) and the National Nanotechnology Initiative (NNI). It uses the combination of anticipatory governance and sustainability, plus some of the lessons drawn from chapters three thru five, to construct and apply an evaluative framework to these (successful) programs.

Based on the results of that evaluation, chapter six then proposes a process for developing a new National Sustainability Initiative, which would tie together several existing programs into a coherent whole. While the development of such an institution would take several years, and determining its final form would be part of the process, it does provide a draft illustration of how the combination of anticipatory governance and sustainability could serve as an institutional design tool.

## I. Introduction

Nanoscale science and engineering promises a new degree of control over material and biological entities. This power, though, challenges our ability to manage the deployment of nanotechnologies in ways that maximize the production of public goods while minimizing adverse impacts. This is a clear example of the governance gaps discussed in the previous two chapters; innovation rates in nanotechnologies exceed our capacity to assess the human and environmental consequences of those innovations, especially when deployed at commercial scales. It also highlights the institutional character of governance gaps, in that traditional risk characterizations, particularly as practiced in U.S. regulatory contexts, are simply too slow to address the needs of relevant decision makers in a timely fashion. Since nanotechnologies are emerging at a critical junction in the development of technological governance (Balbus 2005; Macnaghten, Kearnes et al. 2005; Kearnes, Grove-White et al. 2006; Barben, Fisher et al. 2008), they are a fertile source of case studies for the operationalization of anticipatory governance, and as such provide a focal point for both this chapter and the next.

This particular governance gap predates nanotechnologies; uncertainty and the interpretation of ambiguous or conflicting research results are endemic to risk assessment. At the same time, there is a tension between the levels of data and analysis necessary to justify and support formal regulatory or legislative actions, and the information needs of actors who must make decisions in advance of such legal determinations. Governmental bodies rightly eschew making definitive declarations of risk or hazard in the absence of evidence that meets statutory standards. However, the pace of development of promising innovations such as carbon nanotubes (CNTs) creates the need for decisions under conditions of scientific and regulatory uncertainty, situations where waiting for official declarations is not a competitive option.

CNTs are among the most remarkable products to date within the rapidly expanding field of nanoscale technologies, and as such represent a superb case of deliberately engineered nanostructures. Some variants conduct electricity and heat better than copper (Park, Oh et al. 2009; Pradhan, Duan et al. 2009), others are stronger than steel while weighing less than aluminum (Jensen, Mickelson et al. 2007), and yet others display unique photoacoustic properties in the near-infrared range (Kang, Yu et al. 2009). Their electromagnetic characteristics are also highly sensitive to the adsorption of foreign materials, rendering CNTs potentially useful in a new generation of sensors (Jeykumari and Narayanan 2009; Yuan, Chang et al. 2009). Additionally, their small scale (single-walled versions (SWCNT) are generally 1-2 nm in diameter) raises the possibility of using them for targeted drug delivery to individual cells, as well as a host of other biomedical applications (Shvedova, Kisin et al. 2009). Because of these and myriad other possibilities, CNTs have received a substantial amount of research attention in recent years.

CNTs are also an excellent example of the double-edged nature of the unique mix of properties present at the nanoscale. In their raw form, they are extremely hydrophobic, which suggests the possibility of interaction with lipids in cell membranes, and similar biological entities. Their small mass and size suggests that they may remain airborne for extended periods, and have the potential to penetrate into the deepest, most vital, and most sensitive regions of the lungs (Murr, Esquivel et al. 2004). Although they can be incinerated, and researchers have discovered at least

one enzymatic method of decomposition in the laboratory (Allen, Kichambare et al. 2008), no pathways of biodegradability under ambient conditions have yet been identified, thus raising end-of-life concerns. Also, long CNTs share a number of characteristics with asbestos fibers, a known health hazard. In short, CNTs are an exemplar of both the tremendous potential of engineered nanostructures to both provide societal benefits and pose unknown risks, and thus present a superb opportunity to apply the notion of anticipatory governance.

In the case of CNTs, there is a poor fit between the information needs of urgent decision-makers and the existing nanotoxicology literature. While there have been several valuable reviews (Donaldson, Aitken et al. 2006; Lam, James et al. 2006; Handy and Shaw 2007; Card, Zeldin et al. 2008; Lewinski, Colvin et al. 2008; Oberdörster 2010; Shvedova, Kagan et al. 2010), including recent articles focused specifically on CNTs (Shvedova, Kisin et al. 2009; Shvedova and Kagan 2010), in vitro challenges for nanomaterials (Doak, Griffiths et al. 2009; Donaldson, Borm et al. 2009; Jones and Grainger 2009; Kroll, Pillukat et al. 2009), and possible parallels between CNTs and asbestos (Jaurand, Renier et al. 2009), none of them target the individuals responsible for current choices in product design, financing, insurance, and regulation that may have long-term consequences. Unlike the excellent project led by a team at the University of Minnesota (Kuzma, Paradise et al. 2008; Paradise, Wolf et al. 2009), which invokes anticipatory governance in developing oversight strategies for nanobiotechnologies, this chapter does not propose a new formal methodology. Rather, it applies the key anticipatory governance tenet of foresight in conducting a preliminary risk characterization of CNTs, and sketching possible mitigation strategies under conditions of scientific and regulatory uncertainty. In so doing, it essays to address the immediate needs of decision-makers in the public and private sectors, recognizing that the technology and risk assessment communities are critical elements of the translation process between laboratory research and commercial and policy actions.

This chapter argues four main points:

1. Carbon nanotubes, as a case of engineered nanostructures, pose a number of challenges to existing assays. While these problems are surmountable, solutions that meet the standards necessary for evidence-based policies will require vetting and validation, thus regulatory uncertainty is likely to persist.
2. The available evidence, while conflicted or ambiguous in many cases, suggests a tentative conclusion that relevant actors should treat CNTs “as if” they are hazardous.
3. The parallels between asbestos and long carbon nanotubes strengthen this conclusion. The degree to which the effects of CNTs mimic those of asbestos is not yet clear, but the preliminary data does warrant concern.
4. In summary, the data supports a preliminary conclusion that treating CNTs “as if” they are hazardous is a prudent course of action. This implies limiting exposure throughout product life cycles, particularly to those CNTs that are long (roughly  $> 5 \mu\text{m}$ ) or possess significant metal contaminants. Various life cycle, risk-benefit, and multicriteria decision analysis approaches and tools may also help in identifying appropriate strategies under conditions of uncertainty.

The remaining sections take up each of these points in turn.

## II. Methodological Challenges of CNTs

The National Research Council (NRC) recently released a report titled “Toxicity Testing in the 21<sup>st</sup> Century: A Vision and a Statement” (NRC 2007c). The authors encourage the development of high-throughput *in vitro* and *in silico* screening techniques, supplemented by continued *in vivo* experiments where necessary. Combined with emerging evolution in computational biology and related disciplines, they envision a world where the toxicity of substances can be predicted and shaped prior to commercialization, thereby dramatically reducing adverse impacts on human populations and the environment, i.e. a structural reduction in the governance gap. The report acknowledges the long-term nature of its vision, and emphasizes the need for extensive validation of *in vitro* and *in silico* modeling against apical endpoints.

The NRC report also notes that nanoscale materials may pose some unique challenges in implementing their vision, partly because existing *in vitro* and *in silico* models may require substantial modification in order to reflect nanoscale variations. Results to date underscore their concerns. The propensity of CNTs to adsorb a variety of substances of interest, including other CNTs, and the consequences thereof, underlies much of the discussion in sections two and three. Aggregation, fate, and transport of CNTs under various environmental conditions are critical areas for further investigation. The role of impurities and purification methods in CNT cytotoxicity requires additional clarification, as does delineation of the boundaries of “long” nanotubes, and the degree to which the long-term effects of CNTs parallel those of asbestos. While the NRC’s vision is very attractive in the long term, and worthy of pursuit, it will take time, and substantial additional *in vivo* experiments, to surmount the assessment obstacles posed by engineered nanostructures.

### II.A Confounded Assays

*In vitro* procedures do not require the sacrifice of animals, are generally less expensive and more rapid than *in vivo* projects, and have proven useful in both clarifying modes of toxic action and establishing priorities for further testing. Standardized assays are a cornerstone of these efforts, several of which rely on the use of metabolically specific dyes in conjunction with various techniques of microscopy and spectroscopy.

One of the more commonly used cytotoxicity tests is the MTT viability assay. MTT, 3-(4, 5-dimethylthiazol-2-yl)-2, 5-diphenyl tetrazolium bromide, is normally yellow in solution. In metabolically active cells, mitochondrial dehydrogenase enzymes reduce the soluble tetrazolium salt into insoluble purple formazan (Lewinski, Colvin et al. 2008). Thus, the amount of formazan formed is proportional to the number of active cells in the culture, and can be quantified by measuring absorbance at 570 nm (Casey, Herzog et al. 2007). Similar tetrazolium salt-based assays also include MTS, which is soluble, and is measured at 492 nm, and WST, examined at 450 nm. Other dyes used to assess metabolic activity include Alamar Blue, which turns pink as a result of NADP activity, and Neutral Red, which accumulates in the lysosomes of active cells. *In vitro* procedures such as these are an important component of a high-throughput risk assessment process.

It is thus disturbing that recent studies indicate that carbon nanotubes interfere with all of these tests, although not always in the same direction. Belyanskaya et al. (2007) found that single-

walled carbon nanotubes (SWCNTs) adsorb to the formazan produced by cells in the MTT assay, thus giving a lowered indication of cell viability, i.e. a false toxicity positive. They noted, though, that the interference varied depending on both the surfactant used (nanotubes dispersed via PS-80 produced the least disturbance), and whether or not the SWCNTs had been purified by heating. Montiero-Rivere and Inman (2006) confirm that carbonaceous nanomaterials can give rise to false positives in the MTT assay, and further observe that carbon black nanoparticles can interact with the Neutral Red assay to produce indications of cell viability even in the complete absence of living cells. The authors also note that these materials may also adsorb to IL-8, a cytokine associated with inflammatory cellular response, further confounding the reliability of their results.

Self-observed anomalies in their earlier work (Casey, Davoren et al. 2007; Davoren, Herzog et al. 2007) led a group of researchers at the Dublin Institute of Technology to undertake a systematic assessment of the interference of carbon nanotubes with several common dye-based assays, including those mentioned above. They found significant, dose-dependent fluorescence modification in all tested cases (Commassie Blue, Alamar Blue™, Neutral Red, MTT, and WST-1). In the cases of MTT, AB, and WST-1, CNT adherence quenches fluorescence, resulting in false indications of toxicity. Conversely, CNT binding to Neutral Red enhances fluorescence, possibly yielding falsely negative results. Regardless of the direction of influence, the authors conclude that “the indicator dyes used in this study ... are not appropriate for the quantitative toxicity assessment of carbon nanotubes” (Casey, Herzog et al. 2007). A separate study confirmed their findings, and also noted that CNT agglomerates on cell plates can render cell-counting techniques difficult, if not impossible in the time available (Monteiro-Riviere, Inman et al. 2009). While many studies have employed multiple assays to address precisely these kinds of problems (Manna, Sarkar et al. 2005; Magrez, Kasas et al. 2006; Schrand, Dai et al. 2007), and others report no significant assay interference, perhaps due to different experimental procedures (Elgrabli, Abella-Gallart et al. 2007; Kaiser, Wick et al. 2008), it seems clear that *in vitro* results which rely on these assays should be interpreted with extreme caution (Worle-Knirsch, Pulskamp et al. 2006).

### **II.B Medium Interactions**

Carbon nanotubes also interact with other experimental components. Cell cultures are generally grown in a medium, such as RPMI 1640, which contains numerous proteins, vitamins, and other nutrients necessary to healthy cell development and proliferation. It is also common to supplement the medium with some variant of bovine serum (e.g. FBS), as well as antibiotics to prevent interference by microbial infection. The same Dublin team that has taken the lead in quantifying the fluorescence assay problems has also recognized the possibility that CNTs might also bind to media components in problematic ways (Casey, Davoren et al. 2007; Elgrabli, Abella-Gallart et al. 2007). They find that carbon nanotubes bind selectively and differentially with elements of both RPMI medium and supplemental serum, thus exerting indirect toxicity by reducing the availability of nutrients to the cells, and thereby decreasing proliferation and growth *in vitro*. These effects obtain even when the CNTs are removed from the medium prior to the introduction of cells (Casey, Herzog et al. 2008).



The mechanisms underlying this finding are supported by multiple other studies (Salvador-Morales, Flahaut et al. 2006; Dutta, Sundaram et al. 2007; Valenti, Fiorito et al. 2007; Wallace, Keane et al. 2007; Guo, Bussche et al. 2008; Barnes, Phillips et al. 2009). CNTs bind to a number of proteins present in both medium and serum, notably albumin and fibronectin under the conditions studied to date. Guo et al. observe that CNTs also adsorb amino acids, vitamins, and certain cytokines (e.g. IL-6, IL-8, IL-10, and TNF- $\alpha$ ). These cytokines are important biomarkers for inflammation-related cellular response pathways, so any significant binding to CNTs might result in false negative results for these endpoints. Additionally, reduced levels of key vitamins with special affinity for CNTs, such as folate, riboflavin, and thiamine, may result in downregulation of genes associated with apoptosis and cell cycling, further increasing the probability of skewed findings (Guo, Bussche et al. 2008).

The tendency of CNTs to bind with important organic compounds not only increases the difficulty of interpreting *in vitro* experiments, it also may have subtle *in vivo* ramifications as well. Salvador-Morales et al. (2006) demonstrate that the adsorption of albumin onto CNTs activates both primary and alternative immune system response pathways, a possible explanation for the formulation of granulomas discussed in section III. In a separate series of experiments, the same group shows that CNTs bind preferentially to certain key proteins present in human lung surfactant, SP-A and SP-D. These substances play an important role in normal immune response to infection, suggesting that the presence of carbon nanotubes in the lung could increase susceptibility to other forms of disease (Salvador-Morales, Townsend et al. 2007). Other work suggests that the character of the “protein corona” may evolve over time, as higher-affinity but slower-binding proteins substitute for e.g. albumin, further complicating analysis (Shvedova, Kagan et al. 2010). Extrapolating these *in vitro* results to *in vivo* situations is complex and problematic, as multiple pathways may interact synergistically, antagonistically, or independently. The anticipatory conclusion is to treat *in vitro* results to date as qualitative or suggestive at best, and to recognize the need to solve multiple interrelated problems before *in vitro* testing can serve as a reliable prediction tool for real-life consequences.

### **II.C Surfactants**

Surfactants, by definition, modify the interactivity of surfaces. SWCNTs have all of their molecules on the surface; their surface area/mass ratio (specific surface area) is thus extremely high. Multi-walled carbon nanotubes (MWCNTs), which are comprised of a series of concentric SWCNTs, have internal molecules which are generally inaccessible, but still have a large surface area compared to bulk materials, and their larger diameter (roughly 10-150 nm) presents possibilities for binding with organic substances too large to wrap themselves around SWCNTs. In the absence of surfactants, whether incidental or introduced, both types tend to aggregate over time, often forming complex bundles that can exceed 1 $\mu$ m in diameter.

In toxicity terms, it is tempting to view this propensity to aggregate as a redeeming feature, since bundles with aerodynamic diameter > 2.5  $\mu$ m are less likely to penetrate as deeply into lungs (Asgharian and Price 2007), or cross cellular boundaries. However, in terms of workplace exposure, it is important to evaluate the potential effects of CNTs as produced, prior to any aggregation that may occur within packaging. Also, aggregated materials may need dispersal in order to incorporate them effectively into products, thus raising the possibility of exposure

during later stages of production. Further, some of the nascent work on the ecological ramifications of CNTs raise the possibility that common organic materials such as those found in many rivers and lakes may act as natural surfactants (Hyung and Kim 2008). Thus, most in vitro (along with some forms of in vivo) studies to date use some combination of surfactants and sonification (ultrasound treatment) to ensure even dispersal of CNTs in the test environment.

The addition of surfactants renders CNTs more soluble in water-based solutions (such as cell growth media), inhibits the formation of aggregates, and in some cases disperses existing bundles. However, some common laboratory surfactants are toxic to cells in their own right, and thus inappropriate for viability assays (Dong, Joseph et al. 2008). Also, surfactants differ in their dispersive effectiveness (Moore, Strano et al. 2003; Sun, Nicolosi et al. 2008), and the surfactant employed can affect both the assay interference described in subsection II.A (Belyanskaya, Manser et al. 2007), and the degree of binding to medium elements referenced in subsection II.B.

In order to avoid possible surfactant interference with experimental results, several recent studies eschew the use of chemical surfactants (Bottini, Bruckner et al. 2006; Davoren, Herzog et al. 2007; Schrand, Dai et al. 2007). Others seek to turn the medium problem into an advantage by using serum elements as a dispersal vehicle (Elgrabli, Abella-Gallart et al. 2007). Alternative approaches use components of natural lung surfactants (Tabet, Bussy et al. 2009), or bronchoalveolar lavage (BAL) fluid from either laboratory animals or human volunteers. Efforts are also underway to produce less-expensive substances that mimic the effects of these natural materials (Porter, Sriram et al. 2008), and one team reports success with gum arabic (Simon-Deckers, Gouget et al. 2008). Similar to the assay and medium interaction problems, the aggregation and agglomeration issues posed by CNTs are solvable, but it will take multiple trials over time to do so, thus uncertainty is likely to persist.

In summary, while in vitro methods promise a lower-cost, higher throughput set of procedures for toxicity screening and mode-of-action elucidation for many substances, CNTs pose a number of challenges that need to be overcome before such techniques can replace in vivo studies to a significant degree. These issues do not negate the value of in vitro efforts; rather, there is a growing body of research that has produced novel findings meriting further attention (Bottini, Bruckner et al. 2006; De Nicola, Gattia et al. 2007; Grabinski, Hussain et al. 2007). For example, Ghafari et al. identify a situation where CNTs affect the metabolism of a protozoal species important in waste treatment (Ghafari, St-Denis et al. 2008). Kang et al. explore the relationship between CNT diameter and antibacterial activity, finding SWCNTs much more potent in this regard than MWCNTs (Kang, Herzberg et al. 2008), and Muller et al. undertake an in-depth examination of the possible genotoxicity of CNTs (Muller, Decordier et al. 2008). Efforts are also underway to develop new techniques to bypass the assay problems with CNTs, notably the use of Raman spectroscopy for direct interrogation of cell states (Knief, Clarke et al. 2009). In vitro experimentation permits investigation of phenomena difficult to characterize or visualize at the organism level, and clearly has an important role to play in nanotoxicology now and in the future, but it is not yet capable of providing definitive results in the case of CNTs.

### III. Potential hazards of CNTs

Although in the *in vivo* results to date also contain conflicts, ambiguities, and uncertainty, emerging patterns suffice to support preliminary conclusions. There are parallels between current evidence regarding CNTs and our existing understandings of the adverse effects of inhaling particulate matter, most notably ultrafine (< 100 nm) particles (Oberdörster, Oberdörster et al. 2005; Soto, Garza et al. 2008). Tentatively, CNTs appear to induce many of the same pathologies as e.g. diesel exhaust, including but not limited to inflammation, oxidative stress, increased susceptibility to further insult, and exacerbation of existing respiratory and cardiopulmonary pathologies. Although inhalation implies ingestion, to the degree that particles are cleared via mucosal mechanisms, and there is also concern about dermal pathways (Maynard and Kuempel 2005), the bulk of the research to date has focused on inhalation as the most likely pathway of human exposure in the short term.

### **III.A Inflammation and Oxidative Stress**

Vertebrates routinely breathe airborne foreign substances, and have evolved a multi-layer inhalation defense system, in which inflammation plays an important role. In humans, the upper respiratory tract filters out most particles larger than 10  $\mu\text{m}$  and smaller than 10nm (Oberdörster, Oberdörster et al. 2005). The tracheobronchial region includes a mechanism known as the mucociliary escalator, which captures exogenous material larger than roughly 2.5  $\mu\text{m}$  in “sticky” mucus, and moves it into the esophageal tract via the continuous motion of small, hair-like extrusions known as cilia. Particles between approximately 10 nm and 2.5  $\mu\text{m}$  in aerodynamic diameter, a class that includes many nanoparticles, are able to penetrate to the pulmonary region (Asgharian and Price 2007), wherein reside further lines of defense.

Generally, inflammation arouses the immune system, recruiting defensive cells to the site of insult. Perhaps most important in this discussion are alveolar macrophages (AM), which are unique to the lung, although neutrophils and monocytes (basically, more generic, smaller macrophages) also play a role. Macrophages seek to engulf invasive material in a process known as phagocytosis, analogous to a Pac-Man munching dots. They also release substances toxic to bacteria and viruses, including but not limited to reactive oxygen species (ROS), a phenomenon known as an oxidative or respiratory burst (Pulskamp, Worle-Knirsch et al. 2007). Additionally, under conditions of stress, macrophages secrete pro-inflammatory cytokines such as IL-1, IL-6, and TNF- $\alpha$ , as well as chemokines (IL-8), partly as a signal to recruit additional neutrophils and other leukocytes to the site of invasion.

In cases where the insult is within the system’s capacity, inflammation is short-lived. Neutrophils that have successfully phagocytized foreign matter undergo apoptosis (programmed cell death). Alveolar macrophages in turn phagocytize the apoptotic neutrophils, simultaneously releasing IL-10 as a signal to terminate the inflammation response, and are gradually cleared via the mucociliary escalator (Rubins 2003). Alternatively, in the case of organic irritants, the AM can digest the material, breaking it down to non-toxic metabolites. Poorly soluble particles, such as quartz dust, can interfere with these defense mechanisms. Since they are indigestible, they can only be cleared via the mucociliary escalator. This clearance process is slow in humans (Greim and Snyder 2008), so relatively small doses can cause persistent inflammation, even if the particles themselves are of low toxicity (Duffin, Tran et al. 2007; Monteiller, Tran et al. 2007). CNTs raise an alert in this regard, as several studies report acute inflammation

immediately post-exposure, and persistence in the lung over time (Brown, Kinloch et al. 2007; Chou, Hsiao et al. 2008; Han, Andrews et al. 2008; Liu, Sun et al. 2008; Shvedova, Kisin et al. 2008a; Shvedova, Kisin et al. 2008b).

The production of reactive oxygen species (ROS) and reactive nitrogen species (RNS) is a normal aspect of both inflammatory response and routine cellular function. Oxidative stress occurs when the external insult overwhelms the capacity of living systems to process excess ROS and RNS. This is believed to be one of the modes of action of airborne particulates, notably diesel exhaust (Risom, Moller et al. 2005), which uncoincidentally contains nanoparticles (Dobbins 2007), as well as of cigarette smoke. Oxidative stress can induce DNA damage (genotoxicity), the first step in carcinogenicity, damage cell membranes via lipid peroxidation, and exacerbate existing conditions such as asthma (Cienciewicki, Trivedi et al. 2008). The problem can be compounded under the conditions of “frustrated phagocytosis” described below, leading to the release of additional ROS and RNS into the intracellular environment.

In this light, evidence that CNTs cause oxidative stress is disturbing. *In vivo*, Chou (2008), Han (2008), Mercer (2008), Muller (2008), Murray (Murray, Kisin et al. 2009), and Shvedova (Shvedova, Kisin et al. 2008a; Shvedova, Kisin et al. 2008b) all report significant increases in ROS. In a related paper, Shvedova et al. note the possible contribution of vitamin E deficiency to oxidative stress responses (Shvedova, Kisin et al. 2007). The degree to which metal and amorphous carbon impurities are responsible for these results remains unclear. Several of the most common CNT production processes rely on other metals as a catalyst, most notably iron and nickel. The HiPCO process in particular yields raw nanotubes containing as much as 20% iron (Kagan, Tyurina et al. 2006), and Liu et al. report nickel contamination levels as high as 24% in SWCNT produced via arc synthesis (Liu, Gurel et al. 2007). Some forms of both of these metals can catalyze oxidation reactions, producing ROS directly (in addition to those secreted by macrophages).

The contribution of these impurities to oxidative stress depends on their bioavailability, the degree to which they are accessible for interactions with living entities. If the metals are firmly encased within the CNT structure, and cannot react with cells or bodily fluids, their presence may be irrelevant. Ironically, it appears that some acid treatments used to “purify” CNTs may actually increase the bioavailability of these metals, even as they reduce gross percentage levels of contamination (Liu, Gurel et al. 2007). In at least two *in vitro* cases, refined MWCNTs and SWCNTs proved more toxic than raw materials (Magrez, Kasas et al. 2006; Tian, Cui et al. 2006), although both of these studies rely partly on the MTT assay. Carbon atoms not firmly bound to the nanotube structure may also play a role (Pulskamp, Diabate et al. 2007; Pulskamp, Worle-Knirsch et al. 2007), and Muller et al. (Muller, Huaux et al. 2008) argue that structural defects play an important part in determining MWCNT toxicity.

In contrast, some teams report either no oxidative stress (Mitchell, Gao et al. 2007), note that the use of serum as a dispersant appears to diminish oxidative stress *in vitro* (Herzog, Byrne et al. 2009), or even antioxidant activity from certain CNTs (Muller, Delos et al. 2009). The latter case is interesting, building on previous evidence that annealing CNTs at 2400°C in an inert gas removes both impurities and structural defects (Muller, Huaux et al. 2008), findings recently

echoed elsewhere (Koyama, Kim et al. 2009). In short, while there is a fair degree of evidence that some CNTs induce oxidative stress, and that transition metal impurities contribute to these effects, a definitive understanding of all relevant variables (and thus the evaluation of possible prophylactic measures) must await additional study.

### **III.B Granulomas, Fibrosis, and Secondary Effects**

Several groups have also investigated the longer-term effects of CNTs. The formation of granulomas was one of the earliest effects reported (Lam, James et al. 2004; Warheit, Laurence et al. 2004), although Warheit did not find a dose-dependent relationship, and questioned whether the phenomenon might be an artifact of experimental technique. NIOSH has been prominent, but not alone, in developing this line of research, and has identified two distinct mechanisms of longer-term impact, namely granuloma formation centered on larger aggregates, and increased alveolar fibrosis induced by more dispersed SWCNTs (Shvedova, Kisin et al. 2005; Grubek-Jaworska, Nejman et al. 2006; Chou, Hsiao et al. 2008; Han, Andrews et al. 2008; Liu, Sun et al. 2008; Mercer, Scabilloni et al. 2008; Muller, Huaux et al. 2008; Shvedova, Kisin et al. 2008a).

CNT-induced granulomas are generally comprised of a core of aggregated CNTs partially surrounded by macrophages and other leukocytes. Their formation appears related to the phenomenon of “frustrated phagocytosis” (Brown, Kinloch et al. 2007), wherein a single macrophage is unable to engulf a long fiber or bundle of nanotubes. In such cases, the macrophages appear to “band together” to surround the CNTs or CNT bundles, constructing an agglomerate that lodges itself within the alveolar matrix. Chou et al. suggest that SWCNTs may also frustrate phagocytosis by inducing oxidative stress within the macrophages, stimulating the release of pro-inflammatory cytokines that recruit additional neutrophils to the site of injury, leading to the formation of granulomas (Chou, Hsiao et al. 2008).

Sustained aggravation of intracellular signaling mechanisms, such as occurs with poorly phagocytized substances, can also induce overdevelopment of the physical infrastructure that supports the cells active in gas exchange, immune response, and surfactant generation, a condition known as fibrosis (Greim and Snyder 2008). The NIOSH team has demonstrated that such conditions obtain for well-dispersed SWCNTs (Shvedova, Kisin et al. 2005; Mercer, Scabilloni et al. 2008), and their most recent research has pinpointed the contribution of distributed SWCNTs to collagen deposition and interstitial fibrosis (Shvedova, Kisin et al. 2008a; Wang, Mercer et al. 2010). Cumulative fibrosis is a characteristic symptom of a number of pulmonary disorders, especially those catalyzed by exposure to inhaled inorganic particles. Again, it appears that as-produced CNTs share pathways of injury with known hazards such as quartz dust, cigarette smoke, and diesel exhaust, although many of the critical variables require additional investigation (Xia, Li et al. 2009).

Particulate matter of various sizes also induce secondary effects, exacerbating existing conditions such as asthma and arteriosclerosis (Lundborg, Dahlen et al. 2006; Helfenstein, Miragoli et al. 2008), and impairing lung defenses against further insult (Moller, Hofer et al. 2002; Lundborg, Dahlen et al. 2006). CNTs appear to share these characteristics. Li et al. found an increase in arterial plaque formation after exposure to SWCNTs in ApoE knockout mice, a strain engineered

to model individuals with high cholesterol levels (Li, Hulderman et al. 2007). Using a similar mouse model, Jacobsen et al. report pulmonary injury from SWCNTs and other nanoparticles (Jacobsen, Moller et al. 2009), underscoring the notion that vulnerable populations may be more susceptible to nanoparticle toxicity.

Further, exposure to fine or ultrafine particulates can dampen the immune system, increasing the probability of bronchitis, pneumonia, and other infectious diseases (Moller, Hofer et al. 2002; Lundborg, Dahlen et al. 2006). Again, CNTs seem to fit this pattern. Mitchell et al. (Mitchell, Gao et al. 2007) performed a whole-body inhalation study using MWCNTs in mice that found no acute inflammatory effects, but did note degradation in adaptive immune system response to subsequent insult. As cited previously, Salvador-Morales et al. report that lung surfactant proteins SP-A and SP-D bind selectively to double-walled CNTs (DWCNTs), thus increasing vulnerability to subsequent infection (Salvador-Morales, Townsend et al. 2007). In a separate study, the same team shows that SWCNTs and DWCNTs differentially activate both the classical and alternative pathways of adaptive immune system invocation, suggesting unknown future consequences (Salvador-Morales, Flahaut et al. 2006). Similarly, Park et al. suggest that MWCNTs may induce allergenic responses (as well as oxidative stress) (Park, Cho et al. 2009), and Nygaard et al. report that CNTs, particularly MWCNTs, exacerbate allergenic responses (Nygaard, Hansen et al. 2009).

In summary, while the data is incomplete, and generally insufficient for precise quantification, the current evidence trends toward a conclusion that the effects of CNTs parallel those of several known inhalation hazards (Shvedova and Kagan 2010). This suggests that actors should treat CNTs “as if” they are hazardous, and thus take steps to limit exposures throughout the product life cycle (Oberdörster 2010). Before moving to consideration of alternatives, though, it is important to review the possible parallels between CNTs and asbestos.

#### IV. Analogies to Asbestos

Asbestos is frequently cited as an example of “late lessons from early warnings” (Harremoës, Gee et al. 2001). Although good epidemiological data was available as early as 1930 (Greenberg 1994; Egilman and Reinert 1996), the U.S. did not take substantive regulatory action until decades later. The substance occurs naturally, and its capacity to induce negative human health outcomes was known in Roman times (Gochfeld 2005). In commercial terms, crocidolite (blue), amosite (brown), and chrysotile (white) asbestos are the most prominent. Asbestos fibers have a high aspect ratio (length/width), with diameters in the high nanoscale (50-300 nm). The most potent versions (crocidolite and amosite) tend to persist in the lungs, and present high levels of iron and other metallic impurities to the alveolar environment. Oxidative stress is thought to play an important role in asbestos toxicity and carcinogenicity (Panduri, Surapureddi et al. 2006). In short, asbestos fibers share a number of characteristics with CNTs, at least superficially.

Exposure to asbestos can cause several lung ailments. Non-cancerous outcomes such as asbestosis fall under the general category of Chronic Obstructive Pulmonary Disease (COPD), and are similar to conditions resulting from exposure to airborne particulates. “Normal” lung cancer (carcinoma) is also a common outcome, as is the case for cigarette smokers. The data regarding asbestos-exposed smokers is somewhat conflicted, but does tend to suggest a

synergistic effect (Reid, de Klerk et al. 2006; Schneider, Sporn et al. 2008). The “signature” affliction of asbestos, though, is mesothelioma, cancer of the mesothelial lining which surrounds the *outside* of the lung. This disease has a 30-40 year latency period; the process of translocation from *inside* the lung, where inhaled particles contact living tissue, to the mesothelium, is a slow one, and the biopersistence of the most potent forms is thought to play a critical role (Miserochi, Sancini et al. 2008).

In this light, two relevant studies published in 2008 have attracted a great deal of attention. Both employed intraperitoneal injection in mice (insertion of CNTs directly into the body cavity via needle), so neither establishes the inside-out translocation so critical to the development of mesothelioma under real-world conditions. However, both do demonstrate significant adverse effects when the mesothelial layer is exposed to relatively long CNTs *in vivo*. It is important to emphasize that neither of these two studies prove that inhalation of long CNTs causes mesothelioma; certain critical links are still missing. However, the findings are sobering, and clearly indicate the need for further, targeted research.

Poland et al. conducted a short-term study, examining the responses of C57BL/6 mice at 24 hours and seven days post-exposure. The research used both long and short amosite asbestos fibers as positive and negative controls, respectively, comparing asbestos to various MWCNT samples intentionally prepared to test the hypothesis that long (> 15  $\mu\text{m}$ , in this case) fibrous materials are more toxic to mesothelial cells than shorter ones. Long MWCNTs produced adverse effects comparable to those induced by the positive asbestos controls under the specified experimental conditions. The researchers found significant inflammatory responses and granuloma formations entirely consistent with the *in vivo* results discussed in previous sections, including evidence of frustrated phagocytosis (Poland, Duffin et al. 2008). The negative results from a more recent long-term experiment that employed shorter MWCNTs support their conclusion that length is a significant variable in mesothelial toxicity (Muller, Delos et al. 2009).

Takagi et al. mounted a 180-day experiment, and also used C57BL/6 mice. However, in this case, the animals were produced from a breeding stock intentionally selected for susceptibility to genotoxic and ROS-related carcinogens. Specifically, the mice were p53-heterozygous, or knockout, meaning that they possess only one effective copy of the p53 gene, rather than the normal two. The p53 gene plays a central role in apoptosis, or programmed cell death, which serves partly as last line of defense against cancer. These knockout mice are thus highly vulnerable to mesothelioma and other forms of cancer (Venkatachalam, Shi et al. 1998), so they serve as a sensitive experimental model.

This second study used blue, rather than brown, asbestos as a positive control. Blue asbestos contains higher amounts of iron impurities than brown, implying an elevated capacity to produce ROS. The MWCNT dosage was almost two orders of magnitude higher than that administered by Poland et al., (3 mg vs. 50  $\mu\text{g}$ /mouse), but the iron content of the CNTs was low (0.35%). 27.5% of the CNTs were longer than 5  $\mu\text{m}$ . Some of the mice were sacrificed at day 10 to observe early responses, but the experiment continued until all of the mice in the MWCNT group died. Both the MWCNT and blue asbestos groups showed frustrated phagocytosis, granuloma formation, and fibrosis, consistent with the previous sections. 87.5% of the MWCNT mice also developed malignant mesothelioma, as compared with 77.8% of the animals receiving

crocidolite. In short, CNTs administered in an artificial fashion were at least as effective in inducing mesothelioma and related ailments as the most potent form of asbestos in highly vulnerable mice (Takagi, Hirose et al. 2008).

The stigma associated with asbestos renders interpretation of these results risky. Takagi et al.'s findings that CNTs induce mesothelioma at levels statistically comparable to crocidolite are disturbing. The fact that their results are essentially supported by Poland's article, and additional in vitro work (Pacurari, Yin et al. 2008) lends credence to their claims. At the same time, the intraperitoneal methods leave significant questions unanswered. Under what inhalation conditions do CNTs, whether SWCNT or MWCNT, actually penetrate to the alveolar regions? Mesothelioma has a very long latency period, which seems to depend on the ability of asbestos fibers not only to persist, but also to translocate from inner to outer lung linings (Miserocchi, Sancini et al. 2008). Do CNTs share this capacity? The answer at the moment is unknown, but there is cause for concern, a need for additional robust data, and the recognition that the existing social perception of asbestos renders any findings of similarity highly vulnerable to social amplification (Slovic 2000).

An anticipatory governance approach requires provisional conclusions under conditions of substantial uncertainty, in order to meet the needs of individuals whose circumstances require them to make decisions about emerging technologies prior to the development of scientific or regulatory consensus. The degree to which CNTs confound in vitro assays establishes the prevalence of scientific uncertainty. The weight of the toxicological evidence to date suggests that inhaling CNTs may induce injury, and the analogies with asbestos counsel an additional level of caution. Recognizing the substantial need for additional research, this article argues that the data supports treating CNTs "as if" they are hazardous.

This finding closely parallels a recent DOE report, which recommends that its laboratories manage nanomaterials "as if" they are both acutely and chronically toxic (2008). However, the DOE standards apply to all nanomaterials, based on the fact that they are of unknown toxicity, a description that does not apply exactly to CNTs. Rather, CNTs might be characterized as having unquantified toxicity, with significant uncertainty regarding the specific properties that mediate adverse effects. The use of the term "hazardous" is intended to reflect the fact that the evidence summarized above does in fact support a conclusion, no matter how tentative. It also suggests, again in keeping with the DOE guidelines, that some CNTs *may* eventually be categorized as hazardous wastes under the Resource Conservation and Recovery Act (RCRA) (EPA 2009). Such materials are subject to much more stringent requirements in shipping, handling, engineering controls, personal protective equipment, and disposal than substances of unknown toxicity. While CNTs do not yet meet the legal definition of hazardous waste, designating them "as if hazardous" sends a cautionary signal. Most importantly, though, the word is part of the classic equation: Risk = Hazard \* Exposure. Thus, treating CNTs as "as if" they are hazardous implies limiting exposure throughout the product life cycle.

## V. Anticipatory Strategies

An anticipatory governance approach is not an excuse for methodological sloppiness, exaggerated claims, or a relaxation of standards of scientific rigor. Rather, it *recognizes that*



*pivotal actors must make decisions in the absence of scientific certainty, and that such choices are an important element of the governance of emerging technologies.* Preliminary risk assessment has a vital role to play, in the form of “best available conclusions” derivable from the extant data. The anticipatory element enters the picture as these actors evaluate and select risk management, product design, and technology implementation strategies based on these “best available conclusions”. Such an approach requires flexibility, and willingness to change course based on new information, and in that sense is very similar to “adaptive management” strategies in the fields of natural resources (Medema, McIntosh et al. 2008; Armitage, Plummer et al. 2009).

Environmental Defense Fund (EDF) and Du Pont have issued one of several useful frameworks available to guide such anticipatory decision-making. One of their tenets is to use “reasonable worst-case” scenarios as temporary fillers for data gaps (Medley and Walsh 2007). In the case of CNTs, a reasonable worst-case assumption would be that their hazard profile parallels that of crocidolite or amosite, i.e. the more potent forms of asbestos. Doing so implies the question: “how would we treat asbestos differently if we had it to do over again, given what we know today”? Fortunately, there are conceptual tools available that allow us to avoid many of the negative consequences seen with asbestos, even with materials *assumed* to be equally hazardous for *tentative planning purposes*.

The combination of life-cycle thinking and risk analysis comprises one such toolset (Sweet and Strohm 2006; Bauer, Buchgeister et al. 2008; Shatkin 2008). While full-scale life cycle assessments require datasets that do not yet exist for many nanomaterials, the underlying theoretical framework retains utility in anticipatory circumstances. A life cycle approach facilitates consideration of possible release pathways and vulnerabilities in advance, and thus the identification of mitigation strategies prior to actual exposure. In the case of CNTs, the evidence to date suggests that engineering controls can be effective in controlling workplace concentrations, and both NIOSH (2009) and the DOE (2008) have issued helpful guidelines in this regard. Had HEPA filters been available and deployed in the heyday of asbestos manufacturing and usage, the epidemiological history might be quite different. *It is also worthwhile to note that engineered CNTs are not mined, but produced under (more or less) controlled conditions in (reasonably) closed systems, simplifying the containment problem.* Useful information is also emerging regarding the release characteristics of various production methodologies (Yeganeh, Kull et al. 2008), and modes of hood design and usage to minimize worker exposure (Tsai, Hofmann et al. 2009).

Life cycle approaches can also facilitate consideration of process alternatives with implications beyond workplace safety. For example, Bayer has developed a MWCNT production process that creates largely non-respirable aggregates as its primary output. While this method implies the need for disaggregation steps in secondary manufacturing processes, it does reduce both primary workplace exposure and transportation risks (Bayer 2009). Alternative chemical formulations may also have potential: one recent article suggests that boron-nitride nanotubes (BNN) could be superior to CNTs for drug delivery applications (Chen, Wu et al. 2009). While much more research on the potential toxicity of BNN is needed, such a substitution might be entirely in keeping with the NIOSH hierarchy of exposure controls (NIOSH 2009).

Functionalization of CNTs is also an option, although there is somewhat of a gap between the biomedical and risk assessment literatures in this regard. In particular, while a number of experiments report benefits from coating CNTs with various ligands in drug delivery and photothermal applications (Erbaş, Gorgulu et al. 2009; Taylor, Lipert et al. 2009; Tripisciano, Kraemer et al. 2009; Wang, Huang et al. 2009), examinations of the environmental fate and transport of such materials remain rare. Questions remain in this regard: to what degree can functionalization improve the toxicity profile of CNTs without interfering with the very surface properties that make them valuable in many cases, and how robust are such modifications throughout product lifetimes? In this sense, life cycle approaches are valuable as a focusing device, raising questions that might not otherwise come to the fore, especially in the early stages of product development, where design modifications are relatively inexpensive.

Operating from the assumption that CNTs should be treated “as if” hazardous also has implications for later stages of the product life cycle. A “reasonable worst-case” postulation of CNTs as equally hazardous as crocidolite or amosite suggests eliminating, or at the very least minimizing, the probability of release during the use phase. *This constraint largely rules out the possibility of using CNTs in dispersive applications, e.g. as pesticides, as ingredients of household cleaning products, or unbound water treatment agents, to name a few.* It also suggests that CNTs may not be appropriate in situations where normal wear and tear will lead to release, such as vehicle brake linings, or tires. In these kinds of situations, risk/benefit analyses, such as implied by the EDF/Du Pont framework, or more explicitly called for by the IRGC (Renn and Roco 2006), might be useful decision-making tools. Additionally, recent literature suggests the applicability of Multi-Criteria Decision Analysis (MCDA) methods (Linkov, Satterstrom et al. 2007; Linkov, Steevens et al. 2009), whether alone or in combination with LCA approaches (Seager and Linkov 2008).

Finally, an anticipatory approach (of which LCA is an example) must include end-of-life considerations. On this subject, the literature is discouragingly thin. What methods are available to recycle CNTs? In the case of incorporating CNTs in consumer electronic devices, are the issues likely to be similar to current e-waste problems? While use-phase risks may be low, what effects are likely to ensue when cell phones or other PDAs containing nanomaterials are “recycled” in China, India, or elsewhere with the primary goal of recovering valuable gold, etc., under conditions of minimal enforcement of environmental regulations? Alternatively, do manufacturers have recovery strategies for CNT-impregnated polymers for anti-static applications, such as automobile fuel lines? Such processes might be feasible, as polymers tend to melt at temperatures well below 600°C, the point at which some CNTs begin to break down in air, but the peer-reviewed literature is disturbingly silent on such subjects. Perhaps an anticipatory governance approach can help spur activity in these areas in academia, relevant regulatory agencies, and the private sector. The evidence to date, while undeniably preliminary, suggests that the answer to the question “Are CNTs the next asbestos” lies less in the intrinsic hazard of the materials than in the adoption of prudent risk management strategies.

Among the governance gaps identified in chapters one and two, the problems in the “risk” arena are perhaps the easiest to perceive, and the most clearly articulated. Various actors have criticized existing governance efforts for their perceived inadequacy in this area (ETC 2003b; Miller and Senjen 2008; SVTC 2008), and the National Nanotechnology Initiative (NNI) in the

U.S. has received fire for alleged flaws in its accounting and planning processes (Dunphy-Guzman, Taylor et al. 2006; NRC 2008). While many of these critiques raise valid points, it is not clear that the NNI should be held accountable for the structural conditions of its own birth, a question to which chapter six returns. This chapter has outlined a strategy for coping with one class of nanomaterials under conditions of scientific uncertainty, i.e. how relevant actors might address this particular aspect of the overall governance gap. In that sense, it instantiates anticipatory governance with respect to foresight. At the same time, it does not propose a solution for the underlying causes, and so does not comprise a complete answer. This is very much in keeping with the notion of this dissertation as one small part of a larger, distributed effort – it strives to provide partial contributions to larger issues, rather than definitive answers to small questions. Chapter four also falls in this vein, but with respect to the tenet of engagement.

## I. Introduction

Chapter three addressed the first of the four governance gaps identified and articulated in chapters one and two, which dovetails nicely with the anticipatory governance tenet of foresight. This chapter focuses on the second gap, the solutions to which center around possibilities for public engagement. It concurs with those (e.g. Macnaghten, Kearnes et al. 2005; Kearnes, Grove-White et al. 2006; Rip 2006) that see the advent of nanotechnologies as an opportunity to develop new mechanisms for technological governance, one requiring that the social and policy sciences co-evolve along with the physical disciplines. The National Citizens' Technology Forum (NCTF), a consensus conference conducted in 2008 at six geographically diverse sites in the U.S., represents a constructive step towards seizing that opportunity, and was itself an instantiation of anticipatory governance.

The NCTF was the first nationwide consensus conference in the U.S., and served as a proof-of-concept for this mode of public participation in the governance of emerging technologies domestically. It demonstrated the feasibility of conducting such exercises across three time zones, and illustrated the compatibility of the consensus conference model with American political norms. It provides evidence that, given a structured, constructive environment for deliberation, with appropriate access to information and expertise, lay citizens can and do produce policy-relevant recommendations in highly technical arenas. Finally, the lessons learned from the exercise point out opportunities for future improvements in integrating input from the public, stakeholders, and experts into the policy-making process.

### I.A Upstream Engagement

Recalling the discussion of anticipatory governance from chapter two, the combination of foresight and engagement complements recent thinking regarding “upstream engagement” in technology assessment. Barben et al. argue that nanoscale technologies meet the criteria for “post-normal science” (Funtowicz and Ravetz 1992) in that both decision stakes and uncertainty are high, thus peer review should extend beyond academic boundaries. Advocates such as Roco and Bainbridge (2005) highlight the need to involve multiple stakeholders, and more generally extol the virtues of public participation in technology assessment and governance. However, not all forms of participation are created equal, and the literature encompasses a lively debate over how best to structure and evaluate engagement processes (e.g. Rowe and Frewer 2000; Rowe and Frewer 2004; Bingham 2005; Genus and Coles 2005; Rowe and Frewer 2005; Fung 2006; Hamlett and Cobb 2006). The “GM Nation” exercise in the UK was particularly controversial (Rothstein 2004); and the very notion of “upstream engagement” is the subject of some debate (Rogers-Hayden and Pidgeon 2006; Rogers-Hayden and Pidgeon 2007; Stirling 2008). In any case, the idea of public participation in and shaping of technological development is central to the notion of anticipatory governance (as well as some conceptions of sustainability).

Integrating participatory technology assessment with specific cultural norms and policy processes is perhaps the most challenging aspect of Barben et al.'s formulation, an endeavor that the authors refer to as “ensemble-ization” (2008, 990). As chapters one and two established as the case for technology assessment in general, much of the recent activity in this domain has taken place in Europe (e.g. Schot 2001; Kearnes, Grove-White et al. 2006; Quist and Vergragt

2006). The notion of transatlantic translation is particularly salient with respect to public participation, as each society draws on its own system of values, cultural norms, and sociotechnical history, which Jasanoff (2005) terms “civic epistemologies”. Thus, participatory techniques suitable in e.g. Denmark or the Netherlands are not automatically viable in the U.S.; the hypothesis that they are requires testing.

Dryzek and Tucker (2008) address this issue directly in their comparison of consensus conferences in Denmark, France, and the U.S. They find that such efforts mesh perfectly with the “actively inclusive” vision of democracy prevalent in Denmark, without necessarily claiming that all Danish actors share this view. In contrast, based on the two U.S. cases studied (one of which was an early Citizens’ Technology Forum led by the coordinators of one of the NCTF sites), they concluded that the legitimacy of both conferences was distorted by the “advocacy” culture of political involvement in the U.S. Nielsen et al. (2007) voice similar concerns in evaluating consensus conferences in France, Norway, and Denmark, using a Habermasian framework to consider cross-national differences in conceptions of legitimate participation in governance. Their chief claim is that the consensus conference model does not necessarily “travel well” across cultural contexts in theoretical terms.

The anticipatory governance tenet of engagement also forces consideration of the outcomes of public engagement exercises. Common criticisms of participatory governance efforts include the ideas that they have little to no impact on policy (e.g. Guston 1999), are subject to group dysfunction (Sunstein 2005a), and that citizens need help in order to contribute effectively (Olsen 2004). Upstream engagement might be seen as posing a particular problem in this regard, as it requires citizens to evaluate future technologies about which they know little (Gaskell, Ten Eyck et al. 2005; Macoubrie 2006). Operationalizing anticipatory governance thus raises questions of both substance and process, particularly in the U.S., a diverse nation of 300-plus million that spans five time zones.

Without claiming to provide definitive theoretical answers to the above questions, this chapter argues that the NCTF offers strong empirical evidence on three fronts:

1. The consensus conference model is indeed compatible with American democratic norms in practice, and is thus not limited to a Northern European context;
2. The NCTF panels produced highly policy-relevant recommendations. This outcome demonstrates the capacity of lay populations to deliver germane advice on highly technical subjects. Further, differences between the NCTF results and an important Senate bill from 2008 highlight the potential substantive value of citizen contributions to the policy process; and
3. The NCTF experience suggests several process modifications that could improve integration of public participation exercises with the U.S. policy process, specifically in the context of the National Nanotechnology Initiative (NNI).

The core claim is that the NCTF serves as a strong proof-of-concept for the incorporation of consensus conferences into U.S. policy process. In contrast to Dryzek and Tucker (2008), this chapter argues that with proper design, public input can be successfully incorporated into an “advocacy” culture, while acknowledging the need for procedural alterations in order to

operationalize this goal (Renn 1999). It also concludes that the NCTF largely solved the scale problem inherent in conducting nationwide efforts in the U.S., and provides evidence for the existence of a “lay rationality” that can underlie policy-relevant recommendations even in highly technical cases. It further asserts that the NCTF is a step in carving out a space for substantive, as opposed to solely normative or instrumental (Stirling 2008), goals for citizen participation in technology assessment.

Sections II and III focus on the NCTF as proof-of-concept in terms of norms and outcomes, respectively. While this approach does not conform precisely to the evaluative framework laid out by Rowe and Frewer (2000), it does concur with the idea that norm compatibility is critical in assessing the transferability of the consensus conference model from Europe to the U.S. In terms of outcomes, the discussion is geared towards demonstrating both that the NCTF produced recommendations compatible with active legislative drafts, and that participant discussions transcended current legislative language in important ways, thus underscoring the value of public engagement. Finally, section IV enumerates several recommendations for improved integration of future public engagement exercises into the NNI governance process.

## **I.B Methodology**

Hamlett et al. (2008) have produced a succinct summary of the NCTF exercise:

“In March 2008, the Center for Nanotechnology in Society at Arizona State University (CNS-ASU) and its collaborators at North Carolina State University held the nation’s first “National Citizens’ Technology Forum” (NCTF), on the topic of nanotechnology and human enhancement. Organizers selected from a broad pool of applicants a diverse and roughly representative group of seventy-four citizens to participate at six geographically distinct sites across the country. Participants received a sixty-one page background document – vetted by experts – to read prior to deliberating. They also completed a pre-test questionnaire to record their initial attitudes and understandings of the topic. They deliberated face-to-face in their respective geographic groups for one weekend at the beginning of the month, and they deliberated electronically across their geographic groups in nine, two-hour sessions during the rest of the month. Electronic deliberations included question-and-answer sessions with a diverse group of topical experts. The NCTF concluded with a second face-to-face deliberation at each site. Participants drafted reports that represented the consensus of their local groups, and they completed a post-test questionnaire to record their perspectives on the NCTF and any changes in their attitudes and understandings.”

For purposes of this chapter, the primary data set is the final reports produced by all six NCTF sites. The project team chose the final reports, rather than the online transcripts, or the videotapes of the proceedings, because they represent the consensus arrived at by each group. This selection contrasts with the approach taken by our colleagues Delborne et al. (2009, personal communication), who focus on the transcripts from the online sessions. These choices appropriately reflect differences in emphasis; Delborne et al. focus on process, whereas the UCB group targeted outcomes, insofar as they exist to date. The two efforts represent complementary

interpretive approaches to the same underlying project, and perhaps should be read together to yield more holistic insights.

The UCB researchers coded the site reports independently using nVivo, making at least three passes through the materials, alternating the order in which locations were treated. They then took the categories derived from the participant reports, and applied them in coding both the background materials supplied to the participants, and the text of the 2008 legislation reauthorizing the NNI, as introduced into the Senate as S. 3274. While the 110<sup>th</sup> Congress did not pass S. 3274, and there are differences between the version coded and the bill passed by the House in 2009 as H.R. 554 (111<sup>th</sup> Congress), S. 3274 is a better point of comparison, since it addresses participatory mechanisms more specifically.

The research team also served as co-facilitators of the California NCTF site, and were present for both the in-person California deliberations and the nationwide online sessions. In order to minimize the possibility of facilitator bias, the analysis treated all sites equally, and also draws on the pre- and post questionnaires (which were administered by other members of the larger NCTF team) for supporting evidence (again, see Hamlett et al. (2008) for details).

## II. Proof-of-Concept: Norms

This section has two parts. The first focuses on how participants' normative statements demonstrate the viability of the consensus conference model in a U.S. setting. It argues against previous articles that find this model incompatible with democracy as practiced in the U.S. (Nielsen, Lassen et al. 2007; Dryzek and Tucker 2008), highlighting the prevalence of both individual rights and common good stances among the participants. Data from the NCTF indicates that there is substantial space for deliberation in an “advocacy” culture such as the U.S., given sufficiently upstream engagement.

The second subsection problematizes the notion of “control mutuality” with respect to exercises like the NCTF. Specifically, deliberation exercises that operate in the shadow of Congressional and executive branch mandates are unlikely to attain full “control mutuality” as articulated in Powell and Colin (2008). At the same time, if participation is to have meaning, it can not simply ratify existing trajectories, or risk being seen as such (Rogers-Hayden and Pidgeon 2006). Data from the NCTF site reports suggest an intermediate conclusion. Following Renn (1999) and others, the patterns of participant responses support a claim of “lay rationality”, wherein citizens display a capacity for prioritization in situations of uncertainty, and a certain skeptical distance in formulating policy recommendations based in part on expert testimony. As a proof-of-concept exercise, the NCTF appropriately approximated the constraints likely to obtain in participatory endeavors tightly coupled with substantive policy processes. In this light, the degree to which participants exercised independence is promising, and suggests the practical promise of future endeavors.

### II.A Deliberation, Advocacy, and Normative Compatibility

The consensus conferences that Dryzek and Tucker (2008) examined focused on genetically modified (GM) food, which may partly explain their finding that the U.S. events were distorted

by advocacy. Even though GM foods are not as controversial in the U.S. as they have been in Europe, by 2001 and 2003 when the conferences were held, the debate had been ongoing for several years, and positions had hardened. In contrast, nanotechnologies are still relatively unknown: 82% of the NCTF participants had heard either nothing or “just a little” about nanotechnologies in consumer products prior to the conferences. While several actors, including nanoscientists, have raised concerns about possible risks from nanomaterials, and some NGOs have been actively assertive in the area (e.g. ETC 2003a; Miller 2006; ETC 2007; Miller and Senjen 2008), nanotechnologies are not yet as controversial as GM foods. In large part, this reflects the fact that the NCTF focused largely on future applications, and thus constitutes more of an “upstream” engagement than the GMO projects, a point to which subsequent sections will return.

Further, the NCTF recruitment process excluded applicants who worked for nanotechnology firms or had other conflicts of interest. All of the experts were academics actively engaged in research relevant to the conference subject – questions about which “side” any of them were on did not arise. The review board for the background materials was non-partisan, and participants did not know their identities. Thus, very few of the conditions that Dryzek and Tucker cite as contributing to an environment of advocacy obtain for the NCTF.

Additionally, many of the sentiments expressed in the final site reports underscore participants’ commitment to American ideals, demonstrating the appropriateness of the consensus conference model to common conceptions of U.S. democracy, at least in this instance. Participants approached deliberation from an individual rights-based perspective, resonating with traditional U.S. political and legal culture. This perspective, however, also proved compatible with a range of ‘common good’ or social concerns. The deliberation about and consensus reached on concerns that span from the individual to the collective indicate that deliberative participation is neither limited to European political cultures, nor essentially “un-American”. The following paragraphs provide some examples.

One theme that arose nationwide is the importance of maintaining the integrity of the individual, as illustrated by this quote from one of the site reports:

“We believe in an overriding sense of both individuality and personal identity, and an environment that nurtures free will, in which each person has the right to use or refuse enhancement. It is important to safeguard the ideal that every individual is in fact a unique and sovereign entity in his or her own right. We should also strive to protect and respect the sanctity of the idea of an individual, unique, soul”.

Participants also referenced foundational rights explicitly:

“However, in presenting and adopting these new developments we should aim to maintain the ideals that allow the individual to become who she/he strives to be, and safeguard the values of liberty and free will, and the pursuit of happiness”.

And, from a different site:



“However, no matter how far this technology advances it is never acceptable for our government to use such advances to usurp civil liberties and freedoms that are guaranteed to U.S. citizens under our Constitution”.

In both cases, the opening “however” signals that these statements occur within the context of broader considerations. In general, participants articulated their rights-based concerns within an overall framework of guarded optimism about the potential contributions of NBIC technologies. The nuance inherent in their views suggests a sophisticated understanding of the political, economic, sociological, and environmental milieus into which these developments will emerge, and with which they will interact. In other words, these quotes (which represent others) serve as evidence that the NCTF process succeeded in eliciting elements of “lay rationality”, a point to which the discussion will return.

The endorsement of individual values is perhaps unsurprising in a U.S. context. However, the final reports also included a number of statements directed towards the collective good, and emphasizing the value of public engagement. The final statements of all six sites asserted the inherent value of common goods, and hinted at the idea that unregulated markets do not necessarily optimize the production thereof. They also expressed a strong preference towards prioritizing benefits to groups over those that accrue solely to individuals, at least in terms of public policy. The following statement is representative of participants’ concerns in this regard:

“We encourage the development of beneficial applications, but believe that public safety, individual rights and privacy should be a higher priority than profitability.”

Regarding public representation of the common good, some sites linked the formulation of public concerns to the need for public information and engagement:

“We believe that an informed public can alter the course of this technology, so as to avoid the possible disastrous outcomes of a technology, which runs rampant without proper regulation, and to ensure that nanotech is used for the greatest good for the greatest number.”

Participants also demonstrated awareness of the difficulties and tradeoffs inherent in the policy process, underscoring the sophistication of “lay rationality”. Their recommendations clearly sought to promote NBIC technologies that address practical social problems:

“The future of NBIC technologies should rest with the needs of advancing humanity past the scourges of the human condition. These include poverty, disease, and manual labor. The direction should be bound by the concerns of the public.”

These quotes, from different sites and representative of other material in the reports, show that in this instance, deliberation produced a strong consensus around the need to protect and promote social needs and rights over special interest groups, including industry and government. Participant recommendations regarding the relative prioritization of human remediation over enhancement provide germane supplemental evidence. The background materials given to participants were framed around the question of prioritizing research on NBIC technologies for

remediation (cure, restore) of human incapacities and illness versus enhancements beyond current capacities. Five of the six sites concluded that remediation should be a higher priority than enhancement. Opinions in favor of remediation over enhancement are grounded in concern over the common good, as seen in these quotes from different sites:

“The goals of these technologies should be prevention, treatment and cures over enhancement, and prioritizing humanitarian gain over special interest gain.”

“To focus NBIC technologies on lowering inequalities, reparative applications should lead in funding rather than research on enhancements.”

Finally, the (pre and post) questionnaires provide additional support for the claim that the deliberative processes of the NCTF were not unduly tainted by advocacy. As Hamlett et al. (2008) report:

“The panelists demonstrated high levels of support for the specific provisions of each group’s final report and high levels of congruence between their individual preferences and the contents of those reports. Overall, 89.9% of participants agreed or strongly agreed that their group’s consensus report accurately reflected their individual preferences. Similarly, 81.2% said that they personally endorse almost every major point in their group’s Final Report, while an additional 15.9% said that they personally objected to a few of the major points, and only 2.9% personally objected to many of the major points in the Final Report”.

In addition, there was a battery of six questions about dealing with disagreement, listening to others, and forming consensus. Respondents scored themselves on a scale of one to six, where one represents the adversarial extreme, and six indicates that the individual is highly oriented towards cooperation. For five of these six questions, the average score was at or above 4.5 in both pre and post tests, indicating a fairly cooperative group. While it may be that cooperative individuals self-select into these kinds of endeavors, the available data indicates the NCTF was primarily a deliberative experience for the participants, in keeping with reports from earlier U.S. consensus conferences that did not center on GM foods (Guston 1999; Kleinman, Powell et al. 2007). As discussed in section IV, the situation may change in the future, should citizen participation enter the mainstream of public priority setting and policymaking, but the available evidence indicates that the NCTF discussions closely approximated deliberative norms of democratic discourse.

## **II.B Control Mutuality and Lay Rationality**

In their critical evaluation of citizen engagement with science and technology, including their own experiences with consensus conferences concerning nanoscale technologies, Powell and Colin (2008) emphasize the importance of “control mutuality”. The concept refers to the degree to which all parties recognize each others’ right to influence the course of deliberation, including the setting of agendas. In cases like the NCTF, full control mutuality is not feasible, as the

subject areas were established by Congressional mandate.<sup>9</sup> Powell and Colin's efforts represent a "purer form" of participation than did the NCTF, which operated at the intersection between representative and participatory democracy. In the spirit of Rowe and Frewer (2004), this chapter thus evaluates the effectiveness of the NCTF using a weaker, or more relaxed, interpretation of control mutuality, maintaining the spirit while adapting to the given constraints.

This distinction highlights the differences between bottom-up and top-down approaches to participation. In the latter, there is a danger of using public engagement to ratify existing technological trajectories, or to gain public acceptance without serious consideration of alternatives (e.g. Rogers-Hayden and Pidgeon 2007; Stirling 2008). To assess the performance of the NCTF in this regard, the team coded both the background materials and the final site reports with respect to benefits vs. concerns, further dividing the latter category into health and ethical subcategories. This analysis highlights several areas of difference in emphasis and content between the two datasets, thus buttressing the claim that the participants were not unduly influenced by the information provided. The independence demonstrated by participants is particularly important in light of the "upstream" nature of the NCTF. Given that the subjects reported little previous exposure to information regarding nanotechnologies, it was possible that the background materials would shape opinions inappropriately. The team's analysis of the data supports a rejection of this hypothesis.

The first difference between the background materials and the site reports is in the balance between the potential benefits of NBIC technologies for human enhancement on one hand, and safety and ethical concerns on the other. According to the team's coding, the background materials were quite balanced in this regard – the percentage coverage of benefits and concerns were substantially equivalent. This is not the case for the site reports, which devote significantly more attention to human and environmental health issues and, in five of six cases, to ethical considerations, than to benefits. The combination of the two concern categories greatly exceeds the bandwidth devoted to benefits in all cases, a stark contrast with the background materials.

This finding is not an indication that participants see no benefits to NBIC technologies. To the contrary, post-deliberation, approximately 59% of participants reported being either very or somewhat certain that "the benefits of enhancing human capabilities will exceed the risks" and, as Hamlett et al. (2008) note, 98% of participants described themselves as "hopeful" regarding NBIC technologies. Their concerns focused more on issues of governance and oversight, on ensuring that the development of these technologies serves the public good. They express concern about the capacity and trustworthiness of, and resources available to, the relevant oversight agencies, with some reports even calling for a new regulatory agency to oversee NBIC technologies. In this context, while their personal responses reflect hopefulness, their policy recommendations emphasize concerns over benefits.

Another locus of differentiation between the site reports and the background materials lies in the

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<sup>9</sup> Public Law 108-153, the Congressional reauthorization of the NNI operative during the NCTF, explicitly calls for both public input, and for "ensuring that ethical, legal, environmental, and other appropriate societal concerns, including the potential use of nanotechnology in enhancing human intelligence and in developing artificial intelligence which exceeds human capacity, are considered during the development of nanotechnology" U.S. Congress (2003). "21st Century Nanotechnology Research and Development Act." *Statues at Large* **117**: 1923-1932.

emphasis that several of the sites placed on alternatives to NBIC trajectories. In addition to the near-unanimous support for prioritizing remedial applications over enhancements, four of the six sites discussed alternatives to NBIC technologies, an option not seriously considered in the background materials. One site in particular was vocal in this regard, stating that:

“For every dollar of public money invested in NBIC technologies for disease remediation, a proportionate amount must be allocated towards research in, the promotion of, or increasing the accessibility of preventative medicine ...

We recommend that, for each family of enhancement applications, we assess the availability of lower-risk and/or more cost-effective alternatives to NBIC technologies prior to allocating significant funding ...

Patients seeking or eligible for NBIC-based treatments and human enhancement options should be informed by their physicians of alternatives. Complete information should be available and accessible to the public in both printed and electronic form”.

The other sites were not as specific, but did express concerns about the health care system in general, the need to emphasize prevention and general wellness, and the fact that public investments in NBIC technologies might reduce the resources available for other needs.

Environmental considerations constitute the final distinction between the background materials and the participant reports for purposes of this article. The background document contains one phrase regarding environmental applications of converging technologies as part of a much larger quote, and two other paragraphs that one can interpret as referring indirectly to ecological systems. In contrast, five of the six sites mention either environmental applications, concerns, or both. Several comments urge the development of environmental applications, for example:

“NBIC technologies should be used to find new environmental solutions to both new and old environmental problems, e.g., medical and biological waste”.

Concern about possible waste production and the lack of knowledge regarding potential consequences was also widely shared, and issues of trust also enter the equation:

“How do we ensure that there is a careful analysis of the long-term side effects (i.e. on people, plants, animals and the environment) of these emerging technologies?”, and (different site):

“We are concerned about who can be trusted, where reliable information can be found, and who is going to assure human and environmental safety now and in the future ...

For example, atomic energy sites and old military bases are now “Superfund” sites because of the environmental cleanup costs – the government created a problem and is now responsible for toxic environmental cleanup ...

In addition, we are concerned that we don't have adequate knowledge about, or means of disposal of, "waste" produced by NBIC technologies".

Participants also expressed concerns about the natural resource consumption consequences of longer life spans via NBIC technologies, the importance of product testing and recycling, and two sites articulated environmental justice and community right-to-know issues with respect to the siting of NBIC facilities.

The preceding discussion is not a criticism of the background materials; the analysis supports Hamlett et al.'s (2008) conclusion of balance in that document. Rather, it seeks to demonstrate that the NCTF process did evince a fair amount of participant independence, even under top-down conditions. Further, the inclusion of several tangible scenarios aided in the process of translating speculative future applications into contexts familiar to the subjects, allowing them to bring relevant experiences to bear. The NCTF deliberations were characterized more by "opening up" than "closing down" (Stirling 2008) – the panelists introduced new considerations and framings drawn from their own perspectives, rather than being constricted by the background materials, or focusing only on the alternatives presented to them.

The fact that the final reports included substantive elements not present in the background materials also supports the claim of "lay rationality". That is, citizens possess perspectives drawn from their life experiences that can enrich policy discussions, even in areas where they lack technical expertise. Individuals routinely make decisions under conditions of incomplete knowledge, or that involve evaluating the advice of professionals whose expertise exceeds their own. In the U.S., such situations arise in terms of vehicle maintenance, health care choices, and roofing repair, to name a few. In this sense, this chapter stands firmly in the camp of those who believe that upstream public participation has the potential to deliver substantive results, as opposed to purely normative or instrumental value (e.g. Wynne 1991; NRC 1996; Wynne 1996; Renn 1999; Kenyon 2001; Genus 2006; Guston 2008). One of the key questions in this regard is the degree to which public participation influences policy, thus the discussion now turns to outcomes.

### III. Proof-of-Concept: Outcomes

The article upon which this chapter is based (Philbrick and Barandiaran 2009) started this section with a negative assertion: "The NCTF had had no discernible influence on policy to date". Ensuing events have eroded the solidity of that claim, as detailed in section V, which also notes that significant uncertainty still remains. In any case, the NCTF was designed and executed as a proof-of-concept of the consensus conference model in the United States, and timing considerations precluded the incorporation of NCTF input into the legislative activities of the 110<sup>th</sup> Congress. However, comparison of the panel reports with the language of S. 3274, the more extensive of the two NNI reauthorization bills from that session, supports two conclusions that dovetail with earlier arguments:

1. The parallels between the site reports and the draft legislation provide strong evidence that lay citizens can produce policy-relevant recommendations; and

2. The differences between S. 3274 and the opinions voiced via the NCTF process illustrate how public engagement can make substantive contributions to policy.

The NNI is the primary vehicle for coordination of public funding and research efforts at the nanoscale in the U.S. It was scheduled for renewal in 2008, and S. 3274 was introduced into the Senate for this purpose, but was never brought to a vote. At the time of this writing, the issue is now before the 111<sup>th</sup> Congress, where the House has re-passed its version as H.R. 554, and the Senate has yet to act substantively on S. 1482, a modification of S. 3274 from the previous session, given other priorities. Even in the absence of formal reauthorization, the NNI budget for FY 2011 includes roughly \$1.8 billion in research funding (NNCO 2010b), and its probable approval will constitute a de facto statement of U.S. policy towards nanoscale research that is likely to garner worldwide attention. There is no guarantee that the language of S. 3274 and its successors will become law, but it was the best comprehensive statement of possible legislative intent available at the time. Section V addresses developments subsequent to the research upon which this chapter primarily draws.

In comparing S. 3274 and the NCTF reports, it is vital to recall that the two have fundamentally different scopes. The NCTF examined converging (NBIC) technologies for human enhancement over an indefinite timescale. S. 3274 addresses only U.S. federal research activities involving nanoscale technologies within a five-year timeframe. These differences render the correspondences between the two more striking. Specifically, the participants' calls for an independent regulatory body, increased provision of public information, and an intensification of the focus on Environmental Health and Safety (EH&S) issues all resonate with particular provisions of S. 3274.

### **III.A Independent Regulation**

Although the sites varied in the specificity of their calls for a new regulatory body to oversee the development and deployment of NBIC technologies for human enhancement, they strongly agreed on the need to increase proactive oversight. Our results here support Hamlett et al.'s (2008) prioritization of this conclusion. In contrast, the background materials refer to this issue only obliquely within a quote questioning the FDA's assessment of its own regulatory capacity, another piece of evidence in support of "weak" control mutuality.

S. 3274 creates several new governance entities for the NNI. First, it requires that the Advisory Council be an independent body, rather than allowing the President's Council of Advisors on Science and Technology (PCAST) to fulfill this role. Second, it establishes a new subpanel for "societal, ethical, legal, environmental, and workforce concerns". Finally, it mandates a new associate director position within the Office of Science and Technology Policy (OSTP) charged with oversight of the "societal dimensions of nanotechnology". All three units must provide annual reports to Congress, and are subject to the triennial NAS review process. There are specific oversight requirements to ensure that input from the advisory bodies receives due consideration, and to review the adequacy of "societal dimensions" funding. EH&S issues, broadly defined, are prominent within the text, echoing the spirit of views expressed by the NCTF participants. In this sense, the NCTF constitutes validation for the NNI renewal process to date, an important citizen "check and balance".

### **III.B Public Information**

If there is one area of agreement among NCTF participants nationwide, it is the need for governmental agencies to provide better information to the public. S. 3274 responds to this need in multiple ways. First, it requires the National Nanotechnology Coordinating Office (NNCO), which administers the NNI, to compile a database of all funded projects in certain program areas (emphasizing the societal dimensions arena). It specifies how these projects should be grouped, probably in response to criticisms of previous characterizations of EH&S effort (e.g. Dunphy-Guzman, Taylor et al. 2006), and that the database should be made available to the public. The legislation also calls for the widespread dissemination of research results regarding the “ethical, legal, environmental, and other appropriate societal concerns related to nanotechnology”, as well as the overall program budget.

While these provisions are welcome, the participants push further. Various sites call on the Federal government to:

“Create a federally managed online clearinghouse that consolidates all current resources and information on nanotech. These resources should be advertised in a variety of popular media”; and,

To publicize lists of “all companies involved in manufacture and maintenance of NBIC technologies including the processes they use”, as well as “all NBIC products and components in development and commercially available”.

Additionally, panelists desired much more specific data on risk, and risk/benefit tradeoffs:

“In order to ensure that the risk/benefit ratio is properly assessed prior to using such products, we recommend that FDA provide effective communication of possible/expected side effects and long term effects of using any nanotech products, not just medicine and food-related, in easy language that is understood by the common people”; and,

“All test results affecting public safety and welfare must be fully disclosed in a timely manner upon discovery. It is in the public’s interest to have all information concerning health and safety readily available so that an informed decision can be made by each individual as well as by society as a whole”.

Calls for information about insurance coverage of specific NBIC technologies and procedures were also common. More generally, the sites looked to the Federal government to play the role of primary information broker with respect to these technologies and their potential consequences. While S. 3274 makes some positive steps in that direction, the NCTF results suggest the need for additional action in this area.

### **III.C NBIC commercialization**

Perhaps one of the most significant differences between participants' reports and S. 3274 lies in the area of commercialization. While the U.S. Senate bill focuses on how to promote U.S. productivity and industrial competitiveness and facilitate the transfer of technology from lab to market, participants raise some concerns about the existence of adequate controls and testing procedures. For example:

“Perhaps an intermediate waiting period in addition to existing requirements should be instated before a given technology is released to the public, to allow independent evaluation regarding possible positive and negative implications to society.”

This statement is echoed in others that call for “prevention rather than cure” in so far as preventing human health risks from exposure to new substances and devices and “global websites” that maintain information commercial developments, doctors' performance, ‘ask the expert’ features, among other things. The NCTF panelists are not Luddites; they expect significant benefits from NBIC technologies. They are, however, concerned about the capability of existing regulatory systems and institutions to ensure that the trajectory of technological development actually serves the public good. Echoing earlier sections, participant concerns regarding commercialization focus less on the technologies themselves than the adequacy of oversight authorities and capacities. To this end, section IV focuses on specific policy recommendations for the implementation of the impending NNI reauthorization.

#### IV. Recommendations

S.3274 extends the scope and specificity of the public and stakeholder input provisions of its predecessor (U.S. Congress 2003). In particular, it adds new sections titled “Societal Dimensions of Nanotechnology” and “Public Outreach”, as well as effectively amending the existing requirements for public engagement. The “Public Outreach” section calls on the Director of the NNCO to “convene a national discussion to engage the people of the United States and increase their awareness of nanotechnology”. The bill calls for this discussion to take place within one year of its enactment, and requires that it take place via “not less than 2 large-scale deliberative forums”. The Director must ensure diverse public participation, and incorporate the views of stakeholders such as academic, NGOs, and industry. Substantively, the charge is to:

“Identify the collective priorities and concerns of the general public and stakeholder groups that relate to –

- (1) Nanotechnology products;
- (2) Research and development; and
- (3) Regulatory policy”.

This section also authorizes \$2 million to carry out this national discussion, and makes it clear that such funds are intended as a supplemental appropriation in addition to the amounts provided for general NNCO support under other sections.

Superficially, those that advocate increased public participation in the policy-making process (e.g. Schot 2001; Jasanoff 2003; Ravetz 2005, among many others) might critically welcome the



provisions of this new section, with an emphasis on “critically”. This chapter argues that the NCTF results suggest three arenas of possible improvement to either the legislation itself, or its implementation procedures:

1. Public engagement efforts should be timed to correspond with the triennial NAS review. In this way, both the NNCO and the Congressional oversight committees can simultaneously consider public, stakeholder, and scientific input in updating the NNI strategic plan, and in debating future reauthorizations of the program;
2. General public input and known stakeholder engagement should be separate processes, at least in the early stages; and
3. There is probably some room for improvement in recruiting procedures for future public participation efforts. In particular, while the NCTF did quite well by certain measurements, future efforts might benefit from an enhanced focus on the political aspects of diversity.

The following subsections address each of these three points in turn.

#### **IV.A Timing**

Barben et al. (2008) focus on “integration” between the natural and social sciences as a central tenet of anticipatory governance. In this context, a broader definition, one that includes agency representatives, private stakeholders, independent scientific bodies, and the public, is more appropriate. In order to incorporate all of these viewpoints, timing is critical: in order for public/stakeholder engagement to influence policy, it must be effectively integrated with the policy making process. S. 3274 institutionalizes ongoing oversight: the triennial NAS review feeds into the triennial strategic plan update one year later, so that the revised strategic plan is available to the relevant oversight committees in time to develop the expected reauthorization legislation. The process provides evaluative information to Congress in the early stages of bill drafting, facilitating the incorporation of lessons learned and input offered into the next round of governance.

This structure presents a perfect opportunity to incorporate citizen and stakeholder input into the policy process. Public engagement is not a panacea, and should not be viewed as a replacement for expertise. Rather, the challenge lies in combining lay rationality, interest group advocacy, scientific knowledge, and political judgment into a coherent whole. Harmonizing engagement efforts with the NAS review cycle will present lay and expert opinions to policy makers simultaneously, allowing them to evaluate both contributions in the context of the other. Such a strategy is entirely in keeping with the idea of “analytic-deliberative” governance (Renn 1999), which seeks to marry the virtues of public participation with the knowledge of experts. Translating Renn’s insights to NCTF-like processes, public engagement exercises might look to elicit value responses, perhaps including relative priorities, and then to apply such broad guidance in evaluating specific decision options. A recent NRC analysis of public participation in environmental decision making concurs, stressing the importance of viewing engagement as more than a statutory requirement (Dietz and Stern 2008). This theme also closely follows the Danish model of incorporating consensus conferences into national policy making (e.g. Nielsen, Lassen et al. 2007). The NCTF results demonstrate the practicality of such an approach in the

U.S., and also point to the fact that scaling the Danish model to the U.S. requires more time for preparation.

However, building the kind of network necessary to implement a successful nationwide consensus conference takes years. Given the need to harmonize with the NAS cycle, the NNCO (or the NSF, should the NNCO choose to delegate the details of grant solicitation and administration) would need to issue a call for proposals shortly after the legislation becomes law. Such an approach would also allow for continued experimentation with other forms of public participation, and/or variations within the consensus conference model.

#### **IV.B Separation**

The NCTF experience also demonstrates the value of a separate pathway for public input. Stakeholders by definition have an interest in the issue at hand, and so may be more likely to advocate for a particular course of action. Stakeholders will generally have more knowledge about the subject, creating a power imbalance between them and participants drawn from the general public. While S. 3274 calls for input from both groups, it does not specify separate processes. At least a portion of the public engagement process should stand alone, to reproduce the relatively level playing field enjoyed by NCTF participants. The NNCO will clearly need to combine the two streams, and might even ask stakeholders to comment on the results of the public deliberations. Details should probably be left to implementation, but the public needs a protected space, such as provided by the NCTF, to maximize the quality of their deliberations within an overall environment of advocacy.

The NCTF also points to another possibility for improved separation. While the site reports did display substantial independence from the initial background materials, the discussions of control mutuality and lay rationality in earlier sections suggest that participants might have benefited from a less restrictive project framing. In particular, future efforts might seek to build on the independence demonstrated by NCTF subjects by focusing more explicitly on relative investment priorities and value tradeoffs in a broader context, especially with respect to the future of the NNI. In moving to a more general discussion, it is essential to retain the specificity provided by the NCTF scenarios, as that tangibility was vital in grounding the discussion. In short, there is room for experimentation in project framing, and a process explicitly targeted to the NNI might well produce better results.

The NCTF had the relative luxury of operating within an upstream space, in that participants generally did not enter the process with hardened positions. As previously noted, the relatively speculative nature of the technological applications under discussion did not prevent participants from introducing and considering salient issues. Such conditions will not necessarily obtain in the future, as awareness of and investment in nanoscale technologies increases. While Dryzek and Tucker's (2008) claims about the "advocacy" nature of U.S. political culture may not have obtained within the NCTF, their observations remain valid, and may regain salience in the future. There is thus a certain urgency to these procedural recommendations; it would be ideal to institutionalize participation processes before the issues become controversial.

### IV.C Political Diversity

For purposes of the national discussion, S. 3274 calls for diversity in age, geography, income, and education. The NCTF did a good job in meeting the first two requirements, and also achieved balance close to national averages for gender and race. However, the participants self-identified as liberals at significantly higher rates than the general population (41% vs. 25%), and Republicans were underrepresented (9% of the panelists vs. 27% nationally). It is not clear whether this tilt represents self-selection bias, or other factors. Further, the evidence does not suggest any systematic political tilt on the part of NCTF participants in terms of their political orientations towards emerging technologies. However, it does seem worthwhile for future projects to make extra efforts to reach out to the more conservative segments of the population.

Several possibilities suggest themselves in this regard. First, all of the NCTF sites were located on the campus of major universities. One strategy would be to hold the forums off-campus, in communities whose population is perhaps more representative of regional political balance. A second would be to use random selection to construct the sample frame, although this would entail a significant cost increase. A third might be to subcontract a portion of the forums to a professional market research firm, and hold the events at their facilities. Given financial constraints, none of these options may prove feasible, but it does seem important to invest energy in producing more politically balanced panels, especially as the public engagement process becomes more tightly interwoven with policy making.

## V. Update and Future Prospects

In a theoretically ideal world, the NCTF would have taken place in time to inform the initial drafting of NNI reauthorization legislation in 2008. However, the translation between theory and practice is often uneven and non-linear, and often produces results in ways that theory would not have predicted; such conditions obtained for the NCTF. While both H. 554 and S. 3274 had strong bipartisan support, the financial crisis in the fall of 2008 drew Congressional attention elsewhere. The failure of the NNI reauthorization to pass in the 110<sup>th</sup> Congress for exogenous reasons created an opportunity for input from the NCTF to exert more influence than it otherwise might have. At the same time, relying on serendipity is not a robust strategy; the recommendations put forward in section IV.A leave much less to chance.

As part of their ongoing engagement strategy, Arizona State organized a briefing with the U.S. Congressional Nanotechnology Caucus in March 2009. While the NCTF was a small part of the overall meeting, it garnered enough interest to merit delivery of an executive summary of the findings contained in this chapter to the counsel of one of the co-sponsors of S. 3274. This summary extracted four themes from the participant reports for Congressional consideration:

1. Strong, coordinated Federal oversight of nanotechnology research, development, and deployment, including international cooperation;
2. Increased public communication and engagement;
3. An emphasis on environmental and human health and safety; and
4. Priority for applications with clear public benefit, with special attention to distributional issues, in the allocation of public research dollars.

The document went further in identifying specific problems and recommendations with respect to translating input from the NCTF into the NNI renewal. Being careful not to over claim, this summary may well have influenced ensuing legislative action.

A revised version of S. 3274 was introduced in the 111<sup>th</sup> Congress as S. 1482. Table 3 summarizes some of the key differences between the two bills, and highlights the correspondence with the recommendations put forward from the NCTF project. The textual citations are primarily drawn from section 11 of S. 1482, which corresponds to section 12 of S. 3274:

**Table 3: Comparison of S. 3274, S. 1482, and NCTF Recommendations**

S. 1482 (2009)	S. 3274 (2008)	Recommendation Relevance
“Deliberative Public Input in Decision-Making Processes”	“Public Outreach”	These are the titles of the respective sections. While the executive summary made no explicit recommendation in this regard, the shift is clearly consonant with the aims of the NCTF.
(a) “convene the first in a series of national discussions to engage the people of the United States, increase their awareness of nanotechnology, and give them a continuing voice in the evolution of nanotechnology”.	(a) “convene a national discussion to engage the people of the United States and increase their awareness of nanotechnology”. This discussion was to be completed within one year.	The executive summary explicitly mentioned the need to extend the proposed comment period beyond one year, and noted that the NCTF participants sought a norm of ongoing engagement, rather than a one-off exercise.
(b) “not fewer than two deliberative forums in the first 18 months, including one large-scale forum and one small-scale forum, and, in each subsequent years, at least one deliberative forum”	(b) “not less than 2 large-scale deliberative forums”.	The NCTF demonstrated the quality of deliberation attainable from a series of relatively small groups. Quoting from the recommendation, “Large-scale forums may also have a role to play, but that should not come at the expense of a now-proven methodology”.
(d) “Broad participation and incorporation of stakeholder views”	(d) “Incorporation of views”	These subsection titles reflect the increased emphasis on public participation. S. 1482 also adds “citizens from the general public” as an explicit stakeholder group, and requires that each group be included ongoing deliberations.
(e) “identify the collective	(e) “identify the collective	The extensions manifested in

<p>priorities and concerns of the general public and other stakeholder groups that relate to:                  (1) nanotechnology products;                  (2) research and development;                  (3) regulatory policy;                  (4) other concerns as identified by the group; and                  (5) the means by which citizens can learn about and participate in policies affecting the design and use of nanotechnology on an ongoing basis”.</p>	<p>priorities and concerns of the general public and other stakeholder groups that relate to:                  (1) nanotechnology products;                  (2) research and development; and                  (3) regulatory policy”.</p>	<p>sections (4) and (5) of S. 1482 are indicative of the expanded conception of public participation embodied within this bill. Such a view is entirely consistent with a recognition of the validity of “lay rationality” as articulated above, as well as an endorsement of the value of enhanced “control mutuality” in future engagement exercises.</p>
<p>(f) “report ... summarizing the results of the forums and a report issued and approved by the participants of the small-scale forum”.</p>	<p>(f) “report summarizing the national discussion”</p>	<p>The recommendations explicitly characterized the NCTF as a small-scale forum in problem two, emphasizing the value of smaller groups in producing quality deliberation.</p>

While table 3 does present some strong evidence, it is important not to overstate the NCTF’s influence in this regard; correlation does not necessarily imply causality. There is no ‘smoking gun’ that directly connects the NCTF-derived recommendations with the differences between S. 1482 and S. 3274. However, table 3 does support a conclusion that the NCTF produced output compatible with the policy process, and as such represents an instance of anticipatory governance. It also buttresses the larger claim that public participation efforts can make a constructive contribution to the governance of emerging technologies, even in highly technical subject areas.

In terms of the larger context, chapters three and four fit rather straightforwardly into the various frameworks set forth in chapter two. Both connect directly with one of the four governance gaps identified in chapter one, explore the “constructive intervention space” via a trial intervention, and as such constitute instances of operationalizing anticipatory governance. Chapter five takes a slightly different approach. In itself, it is not an intervention. Rather, it strives to understand and delineate the constructive intervention space at the intersection of market failures with respect to innovation in general, and environmental public goods in particular.

## I. Anticipating Market Failures

### I.A Sustainability, Public Goods, and Market Failures

The literature regarding the collective action challenges of delivering public goods is well developed at a general level (e.g. Ostrom 1998; Dietz, Ostrom et al. 2003; Kaul and Mendoza 2003). However, operationalizing the combination of anticipatory governance and sustainability requires a more specific, and perhaps pointed, set of questions. In terms of a particular set of emerging technologies, which public goods are most salient? The notion that societies can achieve sustainability through purely technological means flies in the face of previous experience, as detailed earlier. However, as sustainability becomes an increasingly mainstream concept, particularly within the framing of “green jobs” and national competitiveness identified in chapter one, the possibility that emerging technologies do have a significant role to play in certain environmental areas merits serious consideration. To the degree that win-win options do exist, they could help establish momentum, and perhaps reduce the need for more painful behavioral adaptations.

So, where might these win-win alternatives be found? Sustainability science is sufficiently advanced to identify energy and water as two crucial global issues for the next century, and there are probably others, especially at national, regional, and local scales. However, this assertion raises the question of how societies should go about identifying future needs in order to inform R&D policies. The problem is particularly acute in the U.S., where there is a standing resource of resistance to anything that resembles the government picking “winners and losers”, and a strong ideological preference for market-based solutions. The combination of anticipatory governance and sustainability is useful in this situation. Without prejudicing choices of specific technologies, the conjunction of the two ideas suggests a focus on future societal needs as a basis for policies intended to promote innovation. Recognizing that market approaches dominate political discourse in the U.S., the next step is to anticipate which needs markets will meet without assistance, and where systematic barriers to entry indicate opportunities for policy action.

This anticipatory process can be viewed as an effort to map and narrow the constructive intervention space for federal support of beneficial technologies. The respondents to the interview project detailed in section two tend to use the term “space” in reference to particular market segments, but they rarely describe the contours of these spaces in any detail. Without attempting to identify specific technologies at this time, is it possible to specify certain combinations of characteristics that help to focus future needs assessments? In other words, if there is such a space, what are its axes? This mapping exercise requires answers to a series of historical questions in order to understand the strengths and weaknesses of previous efforts in this area. First, how have patterns of government funding of R&D changed in the post-WWII era? Are there shifts and/or gaps in investments at various stages of the technological life cycle, or in topical areas? Is the purported “Valley of Death” for technological innovation real?

Second, to what degree do private sector investments address the potential governance gap with respect to the production of public goods? Are there areas where the incentives for e.g. venture capital investors are poorly aligned with societal needs? If so, what are the key issues that define the boundaries of these areas? Under what circumstances might public funding be counterproductive, or constitute “corporate welfare”? Does the recent trend towards investment in “clean” technologies fully address the problem, or are there significant portions of the “intervention space” that do not make financial sense for the private sector in the absence of explicitly supportive public policies?

Third, how effective are existing federal programs in addressing the putative governance gap in this regard? Do they include processes for the assessment of societal needs, and if so, how do those assessments inform funding priorities? In those programs that lack institutionalized needs assessment, how are priorities established, and what criteria determine which projects receive dollars? In this area, this chapter does not seek to perform a comprehensive analysis, but rather extracts a subset of the available lessons in order to inform chapter six. That discussion relies on an analytical framework produced by examining the empirical findings of this chapter through the lenses of anticipatory governance and sustainability. This is in keeping with the notion of anticipatory governance as adaptive management; results from earlier stages inform subsequent research.

## **I.B Historical Framing**

Exploration of the questions above will produce three arguments. The first claim is that the purported “Valley of Death” for innovation, the existence of a gap between the conception of an idea and market success, is in fact real, particularly in the absence of a coherent strategy for identifying and prioritizing national needs in light of probable market failures. This gap is especially pronounced in the early stages of applied research, although there may be a second “valley” in moving capital-intensive applications, such as energy generation, to scale. Second, the provision of environmental public goods, which tend to have large externalities, substantial sunk costs, high barriers to entry, long decision times, and high vulnerability to political delay, are a particularly poor fit for existing private sector funding models. Third, the case for public investment in targeted solutions to salient public problems is indeed strong, as there are indeed significant obstacles to high-risk, high-reward research that governments are in a unique position to ameliorate.

The notion of a “Valley of Death” between invention and innovation is an important theme in this investigation, but that term has only gained currency in the last 15 years or so. A longer-term perspective is necessary in order to understand the origins of the current terms of debate, so section III extends the analysis back to 1953, relying primarily on NSF data, supplemented by other sources. An element of the historical story that this data tells is the degree to which the Department of Defense (DoD) and the National Aeronautics and Space Administration (NASA) effectively constituted U.S. “industrial policy” through the 1980s, and provided an essential springboard for subsequent public and private developments. While the data clearly support such a de facto interpretation, acknowledgement of this reality has often seemed ideologically inconvenient, while also providing arguments for advocates (Wehrenberg 1983; Perry 1991; O'Mara 2006; Block 2008) of investment in those areas. In part, the data suggest a U.S. pattern

of needs analysis by assertion, a theme relevant to the evaluation and governance of future initiatives.

Section III.A presents Federal R&D data, demonstrating that current overall investment levels in R&D are not significantly below postwar averages, and have in fact increased in recent years. Section III.B examines private investment trends, and observes the limitations of VC and Angel investment models in areas of national need, in contrast to the vocal minority that argues that public investment in innovation is a form of corporate welfare, and simply crowds out private funding. Section III.C explores several relevant public programs of varying degrees of longevity and success, and includes a more detailed treatment of the theoretical arguments for and against public intervention in innovation markets. Section II sets the stage for these analyses by establishing an empirical foundation drawn from the nanotechnology business and investment communities.

## II. Empirical Grounding

In order to frame and ground-truth the claims of this chapter, I conducted approximately 25 semi-structured interviews with nano-businesses and venture capital firms, mostly in 2008. The sample frame was drawn from attendees at relevant conferences, most notably those sponsored annually by the Nano Science and Technology Institute (NSTI) and the International Association of Nanotechnology (IANANO), as well as periodic workshops offered by the California Department of Toxic Substances Control (DTSC). The NSTI conferences are joint efforts with the Clean Technology and Sustainable Industries Organization (CTSI), and participants include industry, government, academic, and NGO representatives, with the plurality slightly skewed towards the private sector.

The interviews were semi-structured, and the questions were divided into four sections: general nano, benefits, risks, and regulations. Usually, the interviews followed that sequence, but in several cases, the conversation flowed naturally in a different order. Most took place over the phone, but approximately 25% were conducted in person. Respondents were concentrated in the San Francisco Bay Area, but included individuals located in other parts of the U.S. as well. Only organizations either using nanomaterials (in the case of businesses) or actively pursuing equity investments in nanoscale technologies (venture capital, or VCs) were invited to participate. Businesses represented 60% of the sample (16/25); venture capitalists, 40% (9/25).

These formal data collection activities were augmented by quasi-formal and informal interactions at a number of relevant professional gatherings. These events included the annual conference sponsored by NSTI from 2006-2010, where the latest instantiation boasted more than 5,000 attendees. These meetings were co-sponsored by the Clean Technologies and Sustainable Industries Organization (CTSI), which amplified their salience to public goods issues. The International Association for Nanotechnology (IANANO) provided additional conversational opportunities by hosting international conferences in 2006-8, as well as several smaller convocations at their San Jose offices. Finally, the California Department of Toxic Substances Control (DTSC) has put on several workshops related to their data call-in regarding carbon nanotubes under the authority of AB-289. While more directly relevant to chapter three, these sessions did result in a number of productive discussions that also inform both chapters five and



six. In short, while the formal n of this project is perhaps suboptimal, its findings are bolstered by a rich set of informal interactions, which both underscore the preliminary conclusions, and have helped target subsequent data collection efforts.

The project sought to develop an understanding of how these individuals (as members of their respective organizations) perceived the possible benefits, risks, and potential regulation of nanoscale technologies. The goal was not to produce statistically significant results – the sample frame was not random, and undoubtedly suffers from self-selection bias at multiple levels. Rather, the goal was to develop a basic understanding of the relevant governance gaps, and thus the possible constructive intervention space, from a private sector perspective. The results of this project then shaped further research directions and priorities, as reported in the balance of this chapter, and chapter six. This strategy is very much in keeping with the idea that this dissertation strives to enact its object of study, in that it is itself an instance of anticipatory governance in the adaptive sense, where each phase helps to shape subsequent research directions.

The most significant finding from these interviews is that a very small percentage of firms and venture capitalists consider product risks and benefits simultaneously. Small firms tend to view the prospective benefits of their innovations as their *raison d'être*; they are comfortable articulating them, but assign them an entirely different ontological status than potential risks. Somewhat surprisingly, VCs paid little attention to product (as opposed to financial) risks in evaluating possible investments. At least within this limited sample set, product risks fell outside of the VC timeframe, and so received minimal consideration. This conclusion suggests that the constructive intervention spaces for benefits and risks, i.e. maximizing public goods and minimizing public bads may be quite different – this is particularly relevant to the institutional design issues tackled in chapter six.

The only respondents that were comfortable addressing risk/benefit tradeoffs in the product development process were large multinationals. Again, the subsample size (4 of 16) is too small to support any definitive claims, but does suggest that product line diversity allows for greater analytical distance in making go/no go decisions. In other words, tools such as the EDF/Du Pont Nano Risk Framework (Medley and Walsh 2007) may be useful primarily to Fortune 1000-type operations. Indeed, several of the large firm participants voiced concern about the ability of small-to-medium size enterprises (SMEs) to cope with risk assessment challenges, underscoring the importance of this issue for future policies.

With respect to the promotion of public goods, the clearest message from the interviewees is that the purported “Valley of Death” for early stage investments is real, particularly for innovations whose public benefit might significantly exceed the private returns appropriable within a relative short (five year) timeframe. From the business perspective, while federal assistance available via vehicles such as Small Business Innovation Research (SBIR) grants can be helpful, the award limits are constraining, and the program does not cover the full extent of the funding gap, particularly for agencies that are not the primary customer for the supported innovations. Also, venture capital is not suitable for all startups. Respondents expressed concern about the time, dollar, and energy investments required in order to secure VC funding, as well as the loss of control and equity dilution inherent in accepting such funds. From the other side, VCs noted the

constraints inherent in their business model. In order to provide the level of returns their investors expect, they have to look for “home runs”, opportunities that might yield ten or more times their initial investment (10x). Since many venture investments fail entirely, and many more are at best marginally profitable for the VCs, the “home runs” have to pay for the entire portfolio (Gompers and Lerner 2001).

These preliminary findings strongly suggest that the “Valley of Death” is part of the governance gap with respect to the underproduction of public goods in the area of emerging technologies. The small n and semi-structured methodology of this data collection effort preclude definitive conclusions. However, the interview results function as an empirical framing device, and as a pointer to a rich literature vein. The wisdom of public intervention into markets for emerging technologies is a contested topic, one that fits nicely with the idea that a certain amount of transatlantic translation is necessary in order for the combination of anticipatory governance and sustainability to serve as a politically feasible foundation for U.S. policy and strategy. Following figure 1, section III examines the “Valley of Death” and U.S. public and private responses thereto, in support of a more precise articulation of the domestic constructive intervention space with respect to emerging technologies and public goods.

### III. The “Valley of Death”

The notion of a gap in translating basic research into commercial success, particularly in terms of securing early stage funding, is by no means new, especially for smaller enterprises. The U.S. Congress recognized some portion of the problem by providing low-cost capital via Small Business Investment Companies (SBICs) in 1958 (Brewer and Genay 1995), and significantly expanded the program to include equity investments in 1991 (Dahlstrom 2009). Support for NASA and DOD research in the 20<sup>th</sup> century was often justified partly by citing the spinoff benefits of such investments (Wehrenberg 1983; Perry 1991; Rouse, Winfield et al. 1991). Regardless of the validity of such claims, the argument that Federal funding was instrumental in facilitating the development of innovation clusters in Silicon Valley and the Route 128 beltway in Massachusetts is fairly compelling (Harrison 1994; O'Mara 2006; Wonglimpiyarat 2006; Etzkowitz and Dzisah 2008). Independent data also points to the social capital advantages that these two regions continue to enjoy, even as Federal funding has diminished relative to private investment (Lerner 1999).

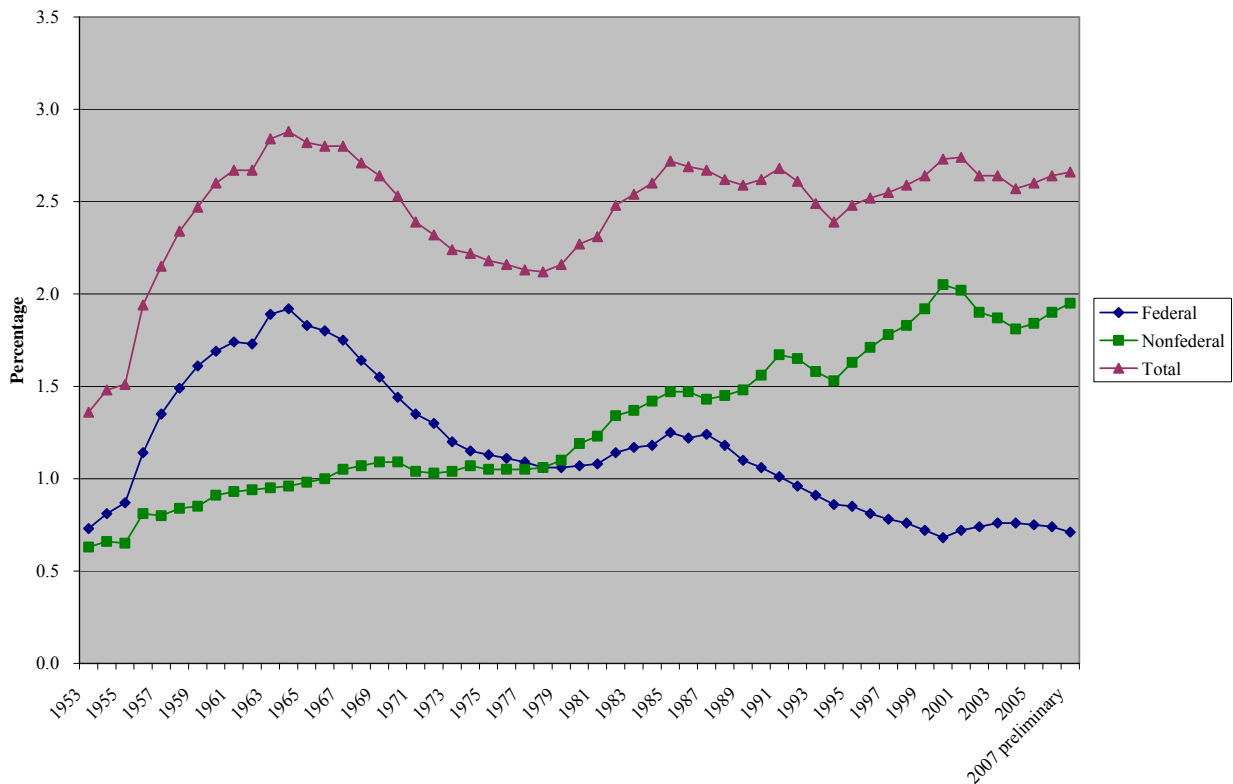
One of the central questions in debates regarding the purported “Valley of Death”, and industrial policy more generally, is how much of a role the Federal government should play in supporting innovation, and under what conditions is public involvement most productive? In other words, what is the nature and extent of the constructive intervention space with respect to emerging technologies, and what kinds of programs, policies, and strategies might best address whatever governance gaps might exist in these areas? These are not easy questions; it seems prudent to begin the analysis by scoping the dimensions of the problem.

#### III.A Macro U.S. R&D Funding levels

Figure two depicts Federal funding of R&D as a percentage of GDP relative to private investment for 1953-2007 (NSF 2008b). Both Federal and total R&D investment peaked on this

scale in 1964, led by defense and space spending (NSF 2008a). As the Apollo program and the Vietnam War wound down, federal investment declined sharply in the 1970s, followed by a mild spike during the Reagan administration, again largely driven by increases at the DOD. In this same period, non-federal (which includes states and universities) funding levels surpassed those of the U.S. government, and the gap between federal and non-federal spending has continued to grow in the 21<sup>st</sup> century. The Obama administration has committed to increased support for certain critical research areas, but the general trend is likely to continue. This chart does not in itself suffice to delineate the Valley of Death, but it does suggest the possibility of underinvestment with respect to public goods. It is also important to recall that the two may not match perfectly, i.e. that the public goods governance gap may comprise more than problems in commercializing beneficial technologies. Adjustment of research priorities and national needs assessments with an explicit focus on sustainability may also be necessary components of constructive solutions.

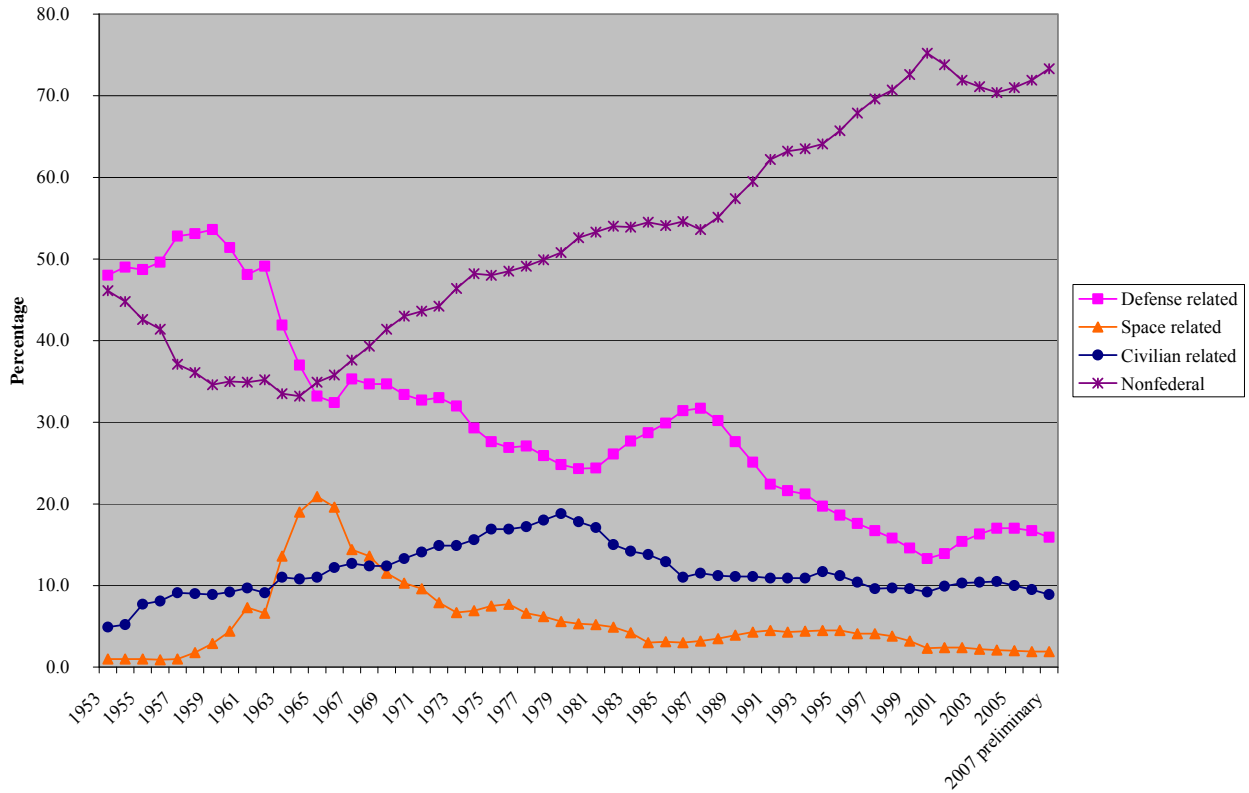
**Figure 2: U.S. R&D as a percentage of GDP, 1953-2007**



Data Source: NSF

The next graph shows percentages of total R&D funding, and divides the federal portion into defense, space, and “civilian” (all other) sectors. In addition to the previously noted patterns in defense and space, federal support for civilian research as a percentage of overall R&D has been declining since 1979, and has dropped below 10% of the total investment.

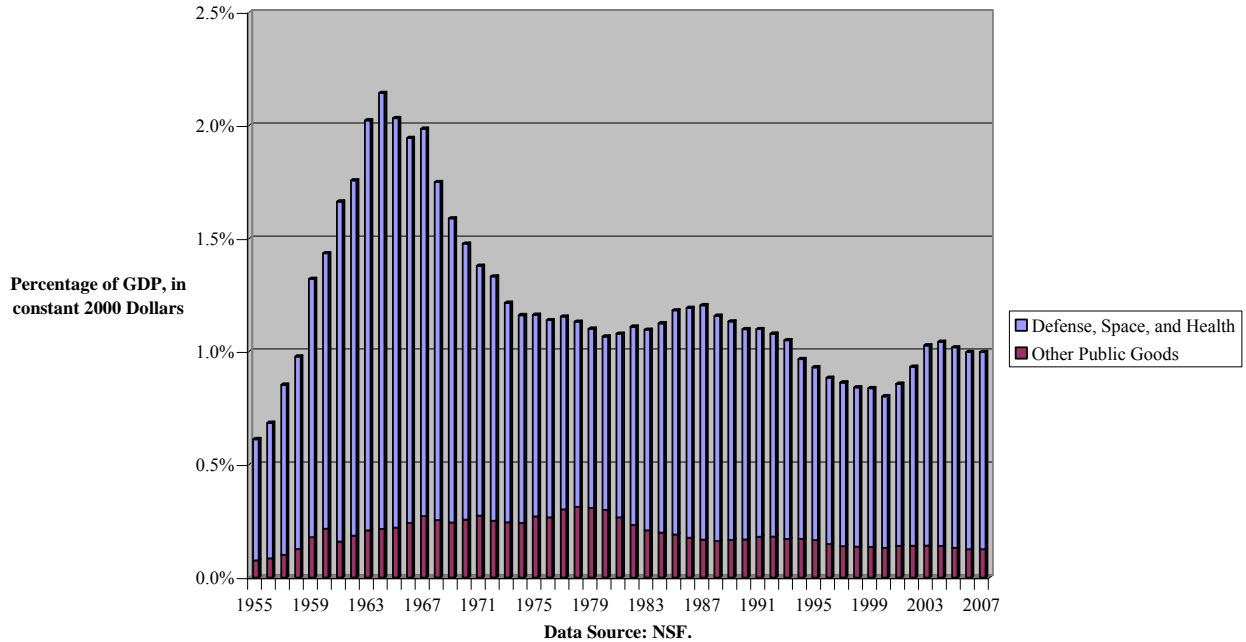
Figure 3: Percentages of R&D Spending by Subject Area, 1953-2007



Data Source: NSF

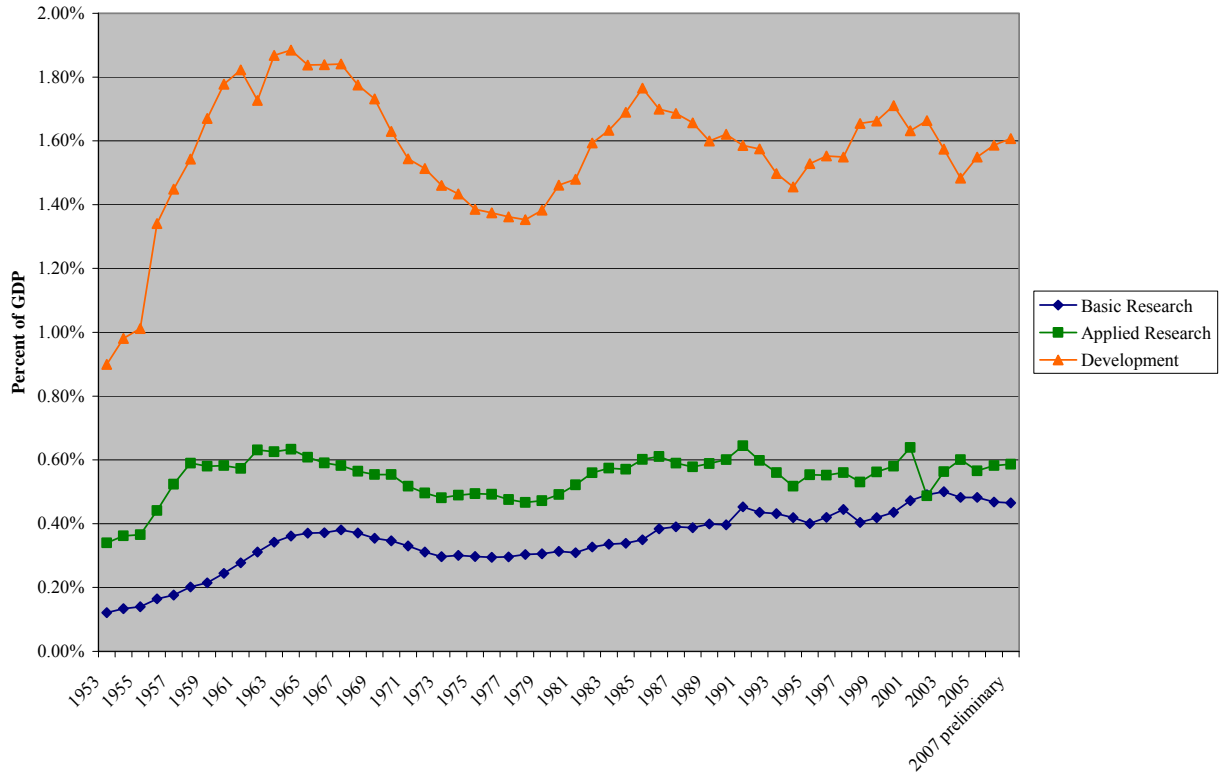
To hone in further, figure four uses similar categories as figure three, but only includes Federal funding, and presents the data as a percentage of GDP in inflation-adjusted dollars. The “other public goods” category comprises the entire Federal government, except for the DOD, NASA, the NIH, and certain DOE and DHS expenditures classified as defense-related (NSF 2008a). This presentation underscores that public R&D funding has been declining relative to the overall economy for all but a few areas since the Carter administration. Again, the 2010 budget calls for doubling funding for the NSF, the DOE’s Office of Science, and the National Institute for Standards and Technology (NIST) over the next five years (OSTP 2009). All of these agencies fall into the category of “other public goods”, so the magenta area of the graph should expand somewhat in the near future. At the same time, it is not clear whether slight increases on a GDP basis will be adequate to address critical needs. What does seem likely, though, is that subject area is a good candidate for one axis of the constructive intervention space, which further suggests that sustainability approaches could be useful in crafting possible solutions.

**Figure 4: Allocation of Federal R&D Investments, 1955-2007**



The same NSF data that underlies the previous three charts can also be sliced in terms of developmental stage. They report three categories: basic research, applied research, and development. Without necessarily adopting a linear model of innovation, this perspective does help to further scope the relevant governance gap. Figure 5 reports total U.S. R&D expenditures from all sources, and shows the same spikes in the 1960s and mid-1980s evident in the previous graphs. What is new about this cut on the data is the degree to which those humps are associated primarily with development expenses, not basic or applied research. As indicated in figure 2, non-federal investments passed federal funding in the late 1970s, so the oscillations in the late 90s and first few years of the 21<sup>st</sup> century are driven more by market conditions, specifically the dot com explosion and collapse.

**Figure 5: Normalized R&D Investments by Research Stage, 1953-2007**



Data Source: NSF. All values in constant 2000 dollars

Interestingly, the level of investment in basic research as a percentage of GDP is somewhat immune from these fluctuations. While there are two periods of gradual decline, one in the late 1960s-early seventies, and a lesser decrease following the bubble burst in 2001, the overall trend is gradually up, and the 2007 numbers are still higher than the previous peaks in the 60s and the 80s, in contrast to the previous figures. Not only has basic research enjoyed a relatively consistent, if modest, pattern of growth relative to GDP, the share funded by non-industry sources (including federal, state, university, and NGOs) was close to its historical high in 2007, as non-federal participants have significantly increased their contribution in recent years.

Figures 2 through 5 are all drawn from the same NSF dataset, so any conclusions drawn there from are necessarily tentative, and require additional validation and triangulation. However, for purposes of this dissertation, it is useful to derive four hypotheses/questions as a possible basis for further investigation:

1. This evidence does not conclusively indicate that the U.S. suffers from gross underinvestment in R&D. The level of total funding as a percentage of GDP is well within post-WWII normal ranges. It is certainly possible that history is a poor guide to the globally competitive environment of the 21<sup>st</sup> century, and more data collection and analysis are indicated, but the numbers about overall investment levels do not raise immediate alarms.

2. Much of the decline in the federal share of R&D funding is attributable to a reduction in development activities at two agencies, the DOD and NASA. This can be interpreted in multiple ways, but from a governance gap angle, it raises the question of whether there are unmet sustainability needs that might benefit from the kind of concentrated, substantial, and long-term investments that the U.S. has previously made in national defense and space, i.e. are there constructive interventions that might be revealed by a sustainability-driven systematic approach?
3. The data also shows that federal R&D in areas other than defense, space, and health has declined relative to the overall economy since the late 1970s, i.e. energy, water, transportation, agriculture, and everything else that falls within the environmental pillar. While the new administration has initiated substantial initiatives in these areas, it is not clear how to assess the adequacy of these efforts in meeting national needs. This suggests that sustainability, and sustainability metrics, could contribute to the identification and evaluation of constructive interventions.
4. The “Valley of Death” does not span the entire public goods governance gap. Rather, it is a specific set of problems regarding technology commercialization that occurs within a larger framework. This suggests that more than one set of policy responses may be appropriate.

Question one is beyond the scope of this dissertation, although others are pursuing it in interesting ways (Tassey 2010). Point two falls primarily in the institutional realm, and so are properly reserved for chapter six. Items three and four, though, are on point for this chapter, and so guide the remainder of the discussion, which continues with an inquiry into private sector responses to the “Valley of Death”.

### **III.B Private R&D Investment**

Venture capital (VC) has received a great deal of attention in recent years, particularly during the Internet boom. The first venture capital firm, American Research and Development, was founded in 1946 in Boston (Hsu and Kenney 2005), and the Massachusetts Bay Area remains second in concentration of VC activity in the U.S. However, many people equate VC with Silicon Valley in northern California, and more specifically Sand Hill Road in Palo Alto, where many of the most celebrated funds are located. The industry has developed a somewhat iconic status, given the spectacular successes of VC-backed firms such as Apple, FedEx, Google, Intel, and Microsoft. Monies invested in VCs grew from \$2.1 billion in 1980 to \$92.9 billion in 2000, with over 60% of the total coming from large institutional investors such as endowments, foundations, and pension funds (Census Bureau 2002)

It is important to recall, though, that the VC realm remains relatively small relative to the overall economy, constituting 0.2% of GDP in 2008 (NVCA 2009b). However, according to the National Venture Capital Association, the preeminent industry trade group, firms that had received VC backing at some point in their history earned revenues of \$2.9 trillion, or roughly 21% of the U.S. economy in 2008. This data is consistent with the VC strategy described earlier of seeking home runs, firms that provide returns 10x, 100x, or even 1000x of the original investment. Of course, there are many more failures than Googles, but the basic VC business model is for a few big winners to pay for all of the losers and also-rans.

This model is necessary in order to deliver the superior annual returns that investors expect. Even after a prolonged downturn, the industry average from 1999-2008 is 17% (NVCA 2009a). Institutions include VC funds in their portfolio to raise their overall returns, so VCs are under pressure to outperform other types of investments, notably stocks. Interview respondents generally reported that, when investing in 10 firms, they expected three or four complete losses and four to five marginal performers, meaning that most of their rewards come from one or two successes. While there is debate about the optimal portfolio mix (Bernile, Cumming et al. 2007), VCs consistently search for rapid growth opportunities, and disruptive innovations.<sup>10</sup> In other words, the “market” for VC investments is rather narrow; only a small percentage of businesses meet the return criteria dictated by this investment structure.

This requirement partly explains the phenomenon of “too much money chasing too few deals”, a problem of particular salience in the first decade of the 21<sup>st</sup> century. The success of the information technology industry in general, and the Internet boom in particular, attracted huge amounts of capital to the VC realm in the late 90s (Census Bureau 2002). Software and web-based innovations were particularly suited to the VC model, as they required relatively small initial capital investments, were entering an exponentially growing market, and also benefited from a highly favorable initial public offering (IPO) climate. The last factor is particularly important, as VC investments are primarily an equity play. In a bubble environment, investee revenues and profits are less important than market valuation in terms of VC exits.

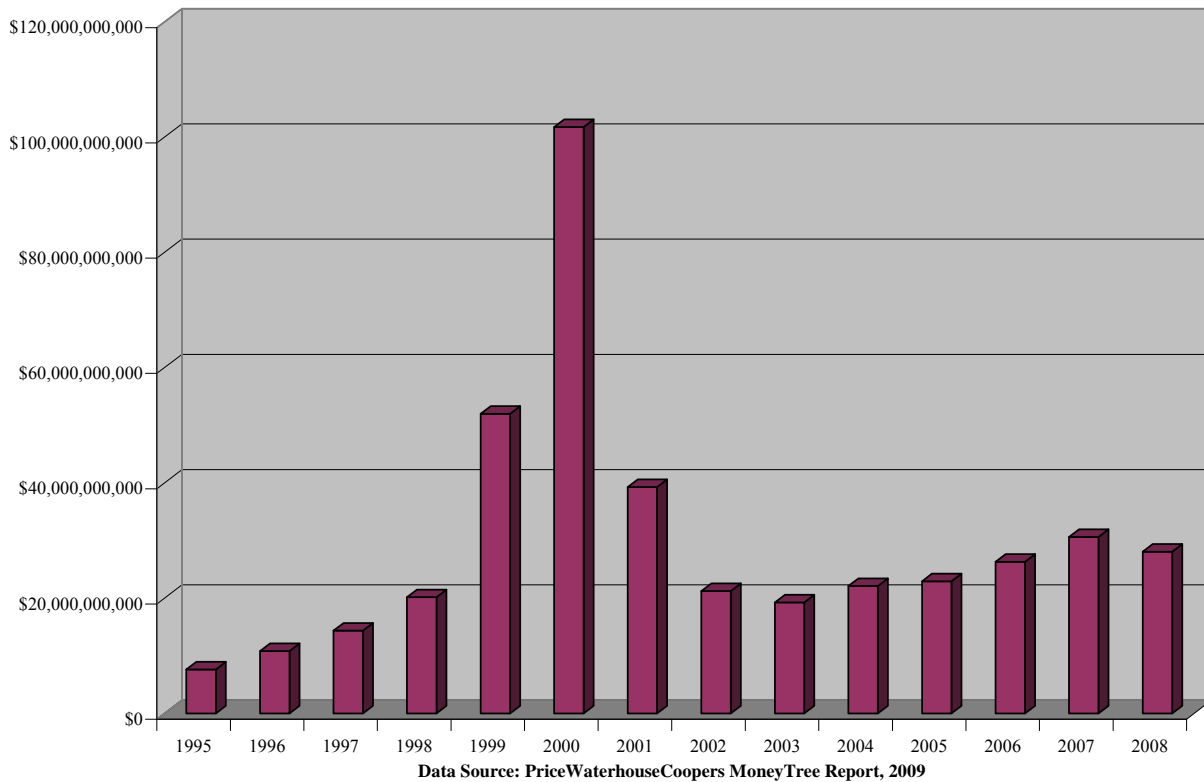
Figure six depicts this phenomenon graphically. There was a huge spike in VC investment between 1999-2001, with a dramatic peak in 2000. In any case, levels of investment gradually recovered from 2003-7, until falling again during the financial crisis that began in 2008. The aggregate numbers from 2008 are still higher than those in 1998, which suggests somewhat of a return to normalcy, although it is important to note that these figures are not in constant dollars, and thus do not account for inflation.

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<sup>10</sup> One respondent emphasized that “the novel is normal” in their world.



**Figure 6: U.S. Venture Capital Investments 1995-2008**



These aggregate funding levels do not represent the entire picture. Historically, venture capital investments have been highly concentrated in a few industries, and largely in two states (CA and MA). Figure seven shows a quick snapshot by industry, picking 1996 as the beginning of the Internet boom, 1998 as the last year before the 1999-2001 explosion, and 2003 as the post-bubble nadir of investment. Two industries clearly dominated; somewhat surprisingly, IT’s

**Figure 7: Percentages of U.S. VC Investments for Selected Industries and Years**

	1996	1998	2003
Information Technologies	47.63%	52.01%	56.02%
Medical/Biotechnologies	22.67%	17.49%	28.15%
<b>IT + Biotech</b>	<b>70.30%</b>	<b>69.50%</b>	<b>84.17%</b>

Data Source: 2009 National Venture Capital Association (NVCA) Yearbook

share continued to grow even after the dot-com bust.<sup>11</sup> The 2003 figures may represent a retrenchment towards the known under duress, a phenomenon that finds some resonance in the

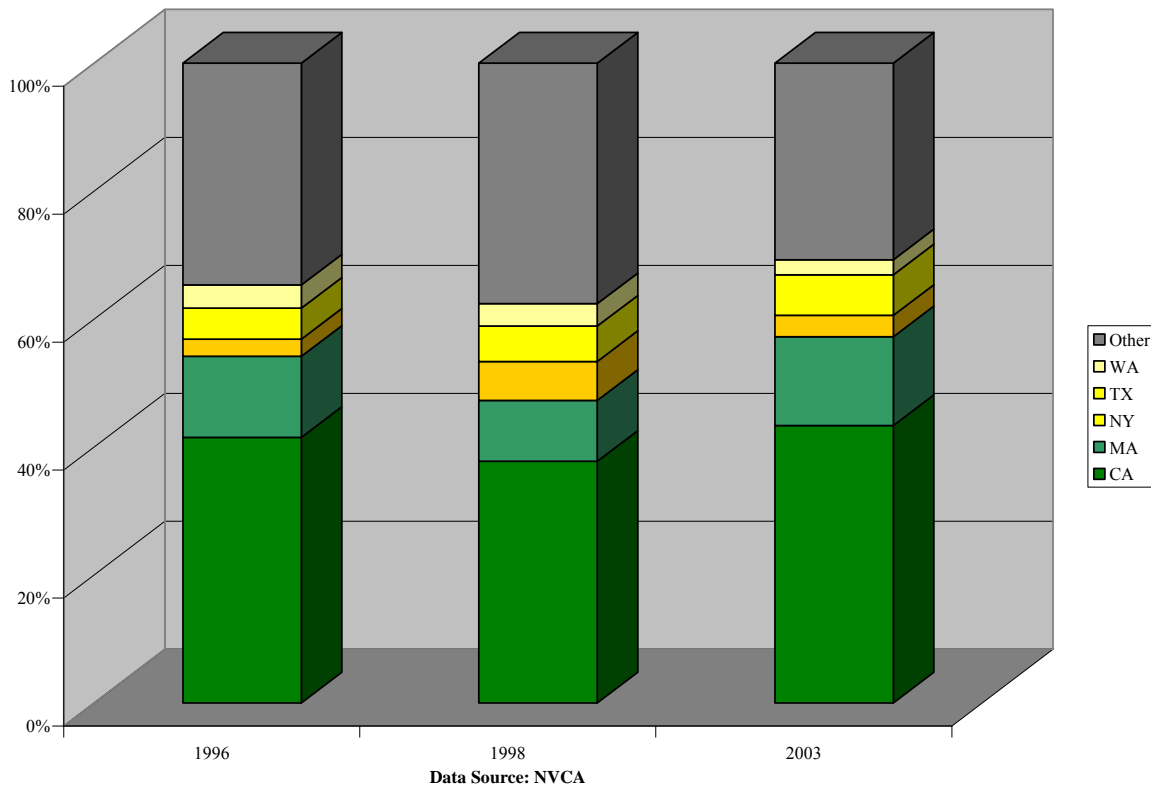
<sup>11</sup> IT is defined as the sum of the software, telecommunications, networking and equipment, computing and peripherals, semiconductors, and IT services categories from the NVCA data. Biotech is summarized as biotechnology, medical devices and equipment, and healthcare services. If anything, this grouping understates IT, as portions of several other categories are probably also IT-related.

state data (figure eight). In any case, these figures provide further support for the notion introduced earlier in section three, i.e. that the investment gap with respect to public goods may not occur so much at the overall level, but instead be more sector specific. Thus, subject or content area remains a strong candidate for one axis of the constructive intervention space.

Geographical variation is a candidate for a second axis, although there are embeddedness constraints that preclude simplistic application. The continued success of Silicon Valley, for example, is attributable to a complex network of factors working in conjunction (Harrison 1994; O'Mara 2006; Wonglimpiyarat 2006; Ferrary and Granovetter 2009); successful replication of this model would require substantial amounts of time, money, and perhaps guidance from an ecological conception of innovation cluster (Porter 1998) evolution, similar to those found within the strategic niche management and sustainable innovation journey literatures (e.g. Nill and Kemp 2009).

However, these nuances do not prevent presentation of some rather glaring imbalances in U.S. VC investment by state. Figure eight provides a brief summary, using the same three comparison years as figure seven. It shows that VC investments in the selected years flowed

**Figure 8: U.S. VC Investment by State, Selected Years**



primarily to five states: California, Massachusetts, New York, Texas, and Washington. While there are variations in details by year, the dominance of California, and secondarily Massachusetts (the green areas of the graph) is striking. Together, these two states, which

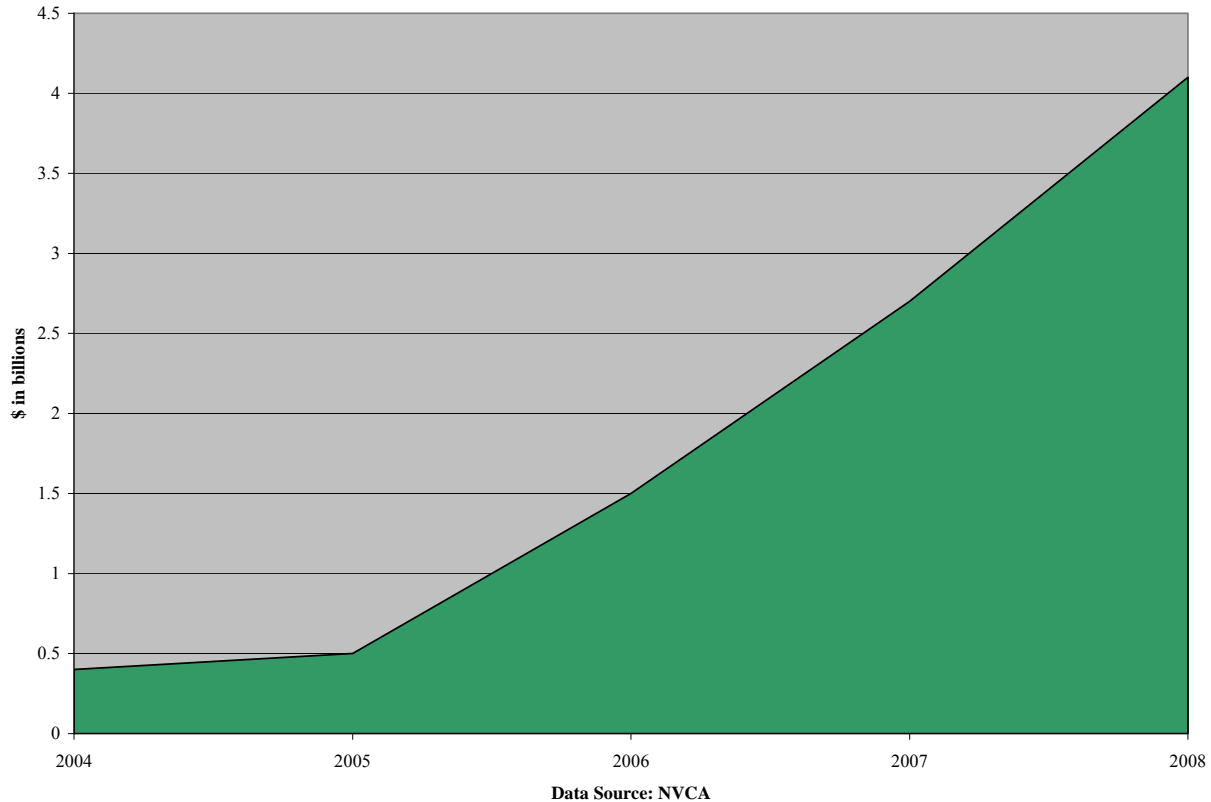
constitute roughly 12.5% of the U.S. population,<sup>12</sup> consistently garner more than 50% of venture capital investment. This conclusion is fairly robust throughout the 1980-2008 period (NVCA 2009a). This data should not be interpreted as evidence of geographical bias, but rather as recognition of the strength of the innovation clusters, of which VC firms are an important element (Ferrary and Granovetter 2009), in these two areas. The relationship between geography and the production of public goods is not at all clear, but the dominance of certain regions does provide an important backdrop for policy design, and is salient to the overall mapping effort.

Recognizing this lack of a proven connection between geography and sustainability, data from the VC sector offers two additional lines of attack that might prove more productive. The first acknowledges a new trend that has emerged in the recent past, which is a surge of dollars to “cleantech” investments. Precise definitions of the term remain elusive, but generally include both “sustainable technologies”, primarily centered around renewable energy and water issues, and “footprint reduction”, i.e. minimizing the adverse impacts of existing technologies and systems (CTSI 2009). Some advocates are careful to delineate between cleantech, which they articulate as “new technology and related business models that offer competitive returns for investors and customers while providing solutions to global challenges”, and greentech, which “has represented “end-of-pipe” technology of the past (for instance, smokestack scrubbers) with limited opportunity for attractive returns” (Cleantech Group 2009). This characterization clearly relies more on market opportunity than environmental benefit as a differentiating factor, basically claiming that cleantech has much more profit potential than greentech.

Without necessarily endorsing a clear division between cleantech and greentech, such arguments do provide support for the idea that sustainability has become mainstream, as chapters one and two advocate. It is entirely possible that the primary difference between cleantech and greentech is two decades of societal evolution, but the question is not central. It is also worth recalling that the semiconductor and electronics industries were originally advertised as “clean” technologies, in contrast to the “smokestack” activities of the “Rust Belt”. In reality, Silicon Valley’s history with respect to sustainability has been mixed, given its high concentration of Superfund sites, and there is some concern that the manufacture of photovoltaic cells could lead to similar issues (SVTC 2008). A certain amount of caution thus seems in order in evaluating “cleantech” claims.

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<sup>12</sup> As of the 2008 election, California had 55 electoral votes, Massachusetts 12. The combination yields 67/538 total.

**Figure 9: U.S. Cleantech Investments, 2004-2008**

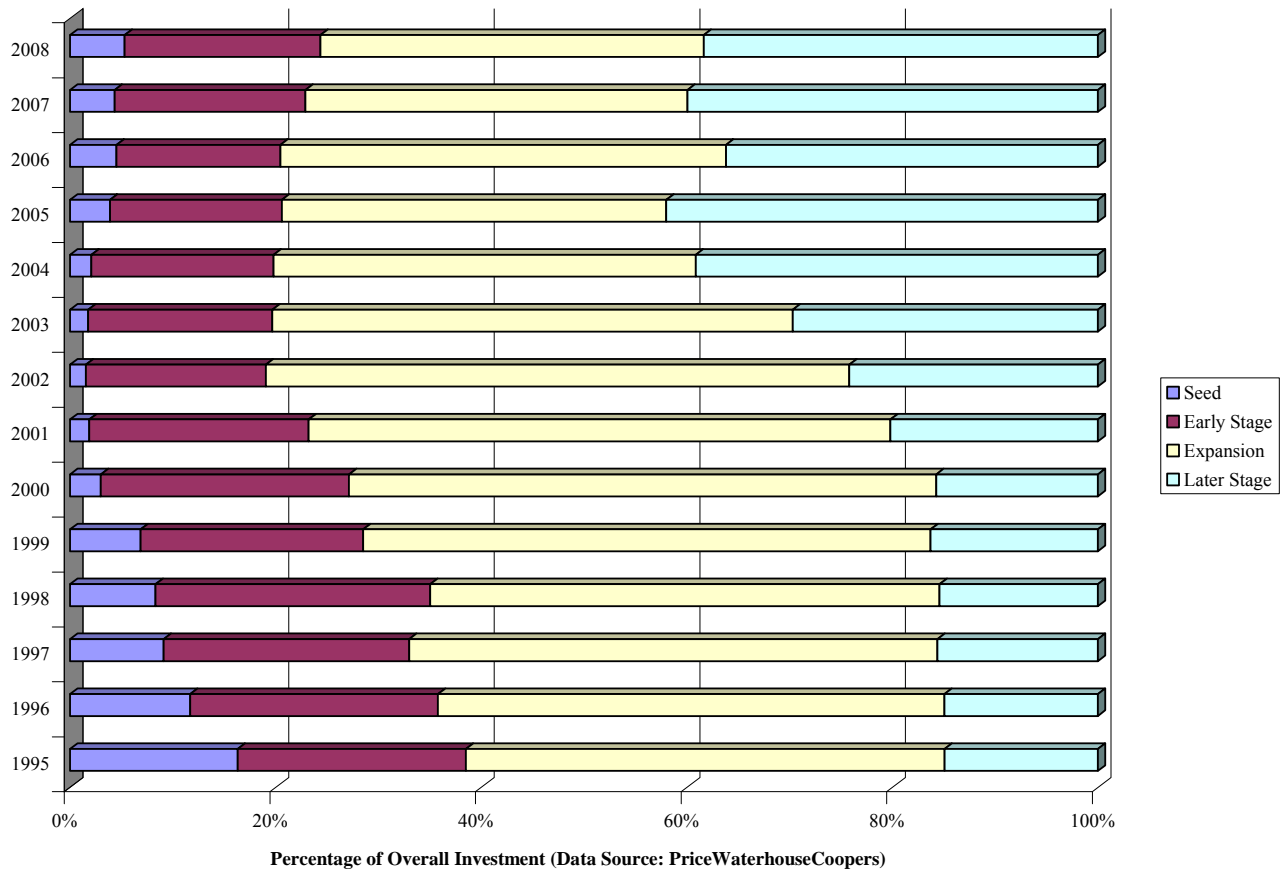
What is evident is the explosive growth in investment in this space over the last several years. The NVCA reports cleantech as the fastest growing sector of venture capital, as represented in figure 9. Although the overall level of VC funding declined precipitously as part of the global financial crisis that began in the fall of 2008, cleantech has recovered more quickly than other sectors in 2009 (Ernst & Young 2009). The American Reinvestment and Recovery Act (ARRA), better known as the “stimulus package”, includes substantial funding in this area, and the current administration clearly sees green jobs as an ongoing priority (OSTP 2009). The private sector appears to be responding positively to these governmental signals, which might indicate a narrowing of the funding gap. However, the venture capital model, dependent as it is upon profitable equity exits, may not span even the “valley of death” region of the constructive intervention space with respect to cleantech.

Especially during the boom years, Internet, and IT-related investments more generally, enjoyed an extremely favorable exit environment. Google, for example, staged a successful IPO within one year of initial VC funding (NVCA 2009b). The “irrational exuberance” of the markets in that period was not sustainable, but did prove very profitable for many individuals and organizations, VCs among them. The cleantech market is very different. In many cases, the ultimate customers are highly regulated and risk-averse utilities subject to political scrutiny. Such organizations often resist adopting new technologies, in some cases for good reasons, as they are responsible for the reliable operation of critical infrastructures, such as energy and

water. To wit, if a new social networking web site fails because the firm behind it goes bankrupt, the negative impacts are largely limited to user disappointment. If, on the other hand, California suffers serious brownouts or blackouts due to the introduction of e.g. large quantities of wind energy to the electrical generation mix, the consequences are far more serious.

In VC investment terms, this translates into longer time to exit, which basically raises the bar for home runs. As the average holding time grows, so must the gross equity gain, in order to maintain competitive rates of return over time. Put crudely, 10x (10 times original investment) is no longer adequate; 50 or even 100x become necessary in order for the classic VC model to work. Such winners are few and far between, which partially explains the recent retrenchment in seed/early stage investment pictured in figure 10. Although cleantech is growing as a category, it is paralleled by a trend toward investment in the later stages, where risks are lower, and payoffs more likely. Exogenous market factors are driving some of this shift, but the interview data also suggest that VCs are coming to recognize that cleantech does not necessarily follow the IT model, and are adjusting their strategies accordingly.

Most of the discussion so far has focused on one proposed axis of evaluation, i.e. sector/application focus. The second line of attack involves timing, i.e. the stage of development at which VCs and other private sector actors, including “angel” investors, are most comfortable committing funds. Figure 10 portrays variations on this front over time, drawing on data from

**Figure 10: VC Funding by Stage, 1995-2008**

PricewaterhouseCoopers (PWC 2009). One observation that this graph enables is the general decline in seed stage funding since 1995. Even in the boom year of 2000, the percentage of investments in this phase dropped substantially versus 1999. While the levels have recovered somewhat since then, the percentage of dollars flowing to startup ventures has not yet returned to 1998 levels. This is not necessarily negative, and may indicate that the Internet boom period of the late '90s represents an anomaly, unsuitable for usage as a benchmark. In any case, the relatively low percentage of VC funds currently flowing to seed-stage companies fits well with theoretical predictions of capital market imperfections (Peneder 2008).

There are a number of reasons to expect suboptimal levels of seed or early-stage funding. First is the problem of information asymmetry (Hall and Lerner 2009). Startup firms are generally small, and by definition have a limited track record of financial success. Thus, potential investors have very little information about the company, a concern of particular importance in light of the moral hazard possibilities inherent in the situation (Wang and Zhou 2004). VCs perform extensive due diligence in order to alleviate such concerns, but such exercises consume precious time and attention, and they may be hesitant to undertake the investigative expense, much less provide capital to relative unknowns. The problem works in both directions: the companies may lack expertise in fundraising, or positioning within an appropriate innovation network (Ferrary and Granovetter 2009). Serial entrepreneurs or individuals with experience at

well-embedded organizations may mitigate these problems via pre-established relationships, but the basic issue remains. Hall and Lerner (2009) argue that information asymmetries and project uncertainties lead to a higher cost of capital for early-stage R&D, contributing to underinvestment.

Additionally, new ventures typically lack the capacity to appropriate the benefits of their innovations (Martin and Scott 2000). This problem applies both to patented procedures, where small organizations often lack the resources necessary to protect their intellectual property, and more tacit forms of knowledge, which tend to reside with critical employees with high employment mobility. In general, the social rate of return to R&D frequently exceeds the private rate available to the innovating firm, leading to systematic underinvestment in research, especially in cases of substantial public goods spinoff possibilities (Tassey 2004). Further, young organizations often lack tangible assets and/or revenue streams to serve as debt collateral, meaning that such financing mechanisms are expensive, when available at all.

So, it seems that the stage of development is a candidate for a second axis of the constructive intervention space, especially with respect to the VC industry. Angel investors (individuals apart from friends and family) may make up some of the gap, but macro data on this class is scarce, since it is diffuse, and not subject to strict reporting requirements. Also, it is not clear whether angels have the same capacity as VCs to overcome the information asymmetry and moral hazard problems (Lerner 1998), so the case for public encouragement of this vehicle is unclear. A recent study sponsored by the Small Business Administration (SBA) suggests that successful angel investments strongly resemble those made by traditional VCs, and that as much as 40% of angel funding is provided in the form of debt (Shane 2008). While additional research is clearly needed, the evidence to date does not yet support a conclusion that angels close the gap between VCs and an optimal level of private investment in R&D, especially when public goods or sustainability criteria are incorporated in the equation.

Branscomb and Auerswald (2002) examine this early-stage funding question in more detail, albeit without focusing on public goods. It is important to note that their definition of “early-stage” is much more expansive than that represented in the PWC data, and includes corporate VC data, which the PWC figures do not. Their study, which combines data from multiple sources, including workshops and interviews, concludes that while VCs play an important role, they do not provide the majority of funding for the stage “between invention and innovation”. They confirm that VCs are in the equity business, and prefer to support technologies at later stages of maturity. They also argue, in keeping with the literature cited above, that “markets for allocating risk capital to early stage technology ventures are not efficient” (Branscomb and Auerswald 2002, p. 5). They further note that new institutional forms are arising in response to this gap, underscore the continued importance of geographically based networks, and observe significant variation by industry in support for early-stage technology development (ESTD).

Branscomb and Auerswald also make a number of points relevant to public sector participation in ESTD, to which the discussion will return shortly in section III.C. Before moving on, though, it is important to summarize preliminary findings. The data presented in section III.A suggests that U.S. underinvestment in R&D may be sector-specific, and that declines in the Federal share thereof are largely attributable to reductions in development expenditures for defense and space

programs. Section III.B built on these propositions, providing further evidence that VC investment has been highly concentrated in a narrow range of industries and geographical areas, and also observing that the VC model is limited to a narrow range of opportunities. VC investment criteria do not necessarily optimize public goods, suggesting that the classical “valley of death” is a subset of the broader “constructive intervention space” that this chapter seeks to characterize.

In terms of narrowing the constructive intervention space, the analysis so far suggest two strong candidates for “axes” of evaluation: application sector, and stage of investment. Geographic region is a third possibility, but the literature and data articulating the benefits of innovation clustering argue against the inclusion of this criterion in the absence of additional evidence. Rather, the recent shift towards “cleantech” applications prompts inquiry into the intersection between the first two candidates, i.e. do early-stage “cleantech” opportunities represent a unique set of challenges not apparent in examining either factor in isolation? Additionally, to what degree do VC tendencies towards specialization (Gompers, Kovner et al. 2009) exacerbate funding gaps with respect to cross-cutting innovation, and to what degree are any such blindnesses amplified or mitigated by governmental structures?

So, having examined private venture capital responses to the “Valley of Death” in the context of narrowing the constructive intervention space, with nods to both angel investors and corporate venture investments, the discussion now moves to the public sector. The arguments for public intervention in R&D are by no means new, and the U.S. has a long and rich history in this regard, even in light of strong ideological opposition to government interference in markets. The purpose of this examination is to test the validity and applicability of the candidate axes of evaluation, amplifying and modifying them where necessary, as well as to explore additional possibilities. The overall goal of this dissertation is to assist in the process of translating governance gaps into feasible U.S. policy possibilities, in full recognition of the anticipatory nature of the project. This chapter seeks to trace the connections between the governance gap in investment in public goods, the anticipation of market failures, and the most promising arenas for constructive intervention.

### **III.C Public Responses**

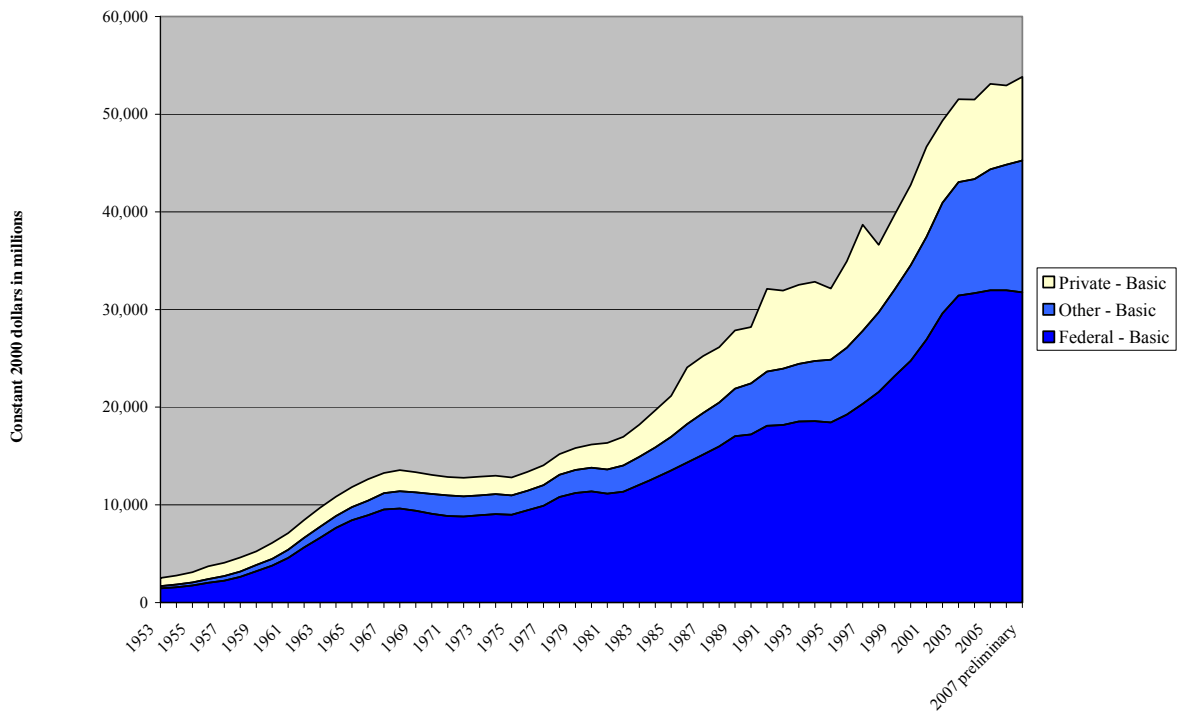
In keeping with the chapter’s title and overarching goals, this subsection focuses on Federal policies specifically designed to bridge the valley of death, reserving broader contextual considerations for chapter six. The preceding analyses have established two proposed axes for description of the constructive intervention space, namely topic area, especially with respect to agency jurisdiction, and stage of technological development. The following discussion explores the most prominent Federal programs in these areas, with a particular emphasis on the intersection between the two axes. The goal is to delineate this aspect of the governance gap with sufficient specificity to construct targeted institutional solutions in chapter six.

Prior to delving into program details, it is important to elevate the granularity of assessment one notch further. Figure five demonstrated that overall funding for basic research in the U.S. has not only kept pace with GDP growth, but actually shows a gradual relative upward trend. Figure 11 (NSF 2008b) breaks this category down by funding source, where “other” includes state and



local governments, NGOs, and universities. Obviously, not all universities are public, and it is likely that a substantial percentage of this funding derives from non-governmental sources, but the dataset does not provide this level of detailed separation.<sup>13</sup> With that caveat, figure 11 shows that the percentage of basic R&D funded by the private sector has declined substantially from a peak of nearly 35% in 1956 to approximately 16% in 2007. While the federal share has also fallen from a maximum of almost 72% in 1968 to 59% in 2007, that trend is likely to reverse direction in 2009-10, and is more than countered by the substantial increase in the “other” category. Evidently, states, NGOs (including foundations), and universities have picked up where large corporate labs and the federal government have left off since the heydays of Bell Labs, Xerox PARC, and NASA. To the degree that public goods are at least as much of a driver for funders in the “other” category as they were for federal investments in the earlier post-WWII period, the percentage of basic R&D devoted to the public good has not declined, and may even have increased. Again, more data and analysis are required in order to establish such a conclusion firmly, but the available evidence continues to indicate that basic R&D is not the problem.

**Figure 11: Basic R&D Investments by Source, 1953-2007**



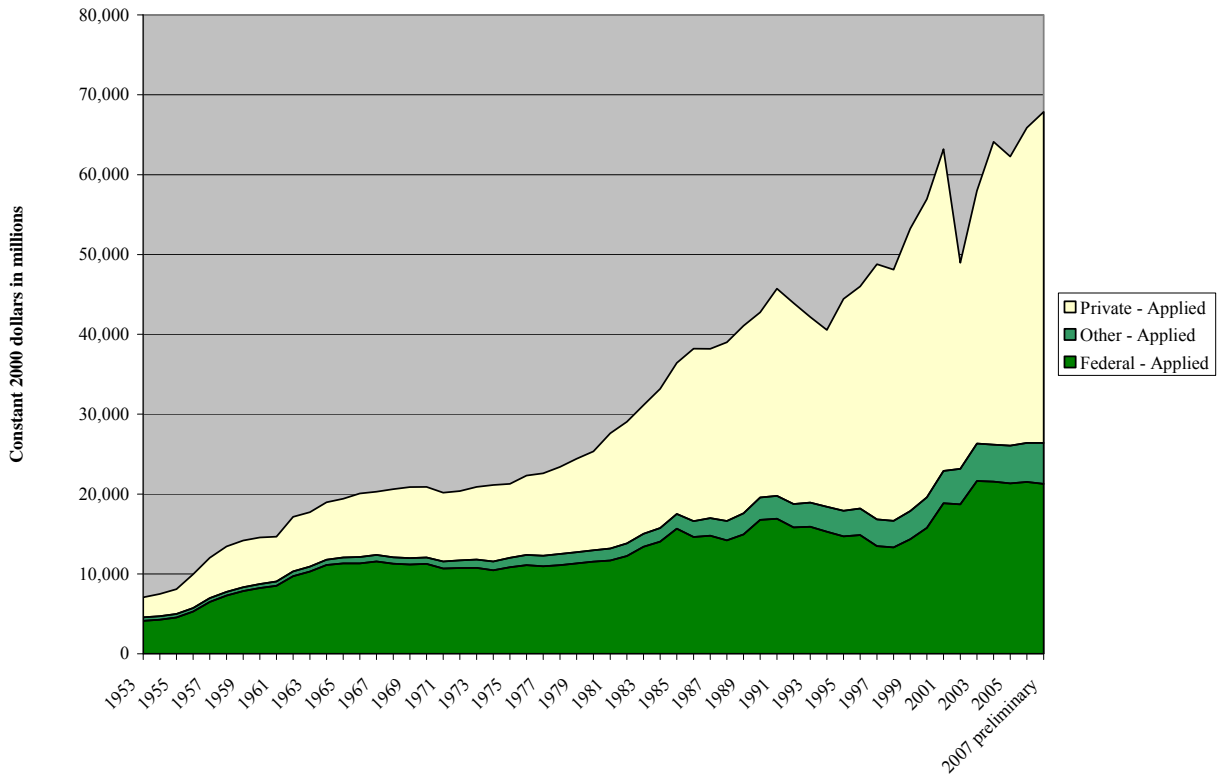
Data Source: NSF National Patterns of R&D Resources: 2007 Data Update

Applied R&D is another story. Figure five depicts relatively flat levels of total applied R&D

<sup>13</sup> The dataset does show steady increases in the amount of industry-funded research performed by universities and colleges, but does not subdivide the figures by research stage. However, even if all of the industry-financed research performed by universities (approx. \$2.3B in 2007) were basic, reallocating those monies to the private sector would not materially affect the graph, or the overall argument.

investment as a percentage of GDP since roughly 1960. It is not clear whether a constant percentage is appropriate, given the increasing expense of innovation in progressively more complex technical environments (Auerswald, Branscomb et al. 2005; Tasse 2010), but stable relative levels of investment are not in themselves an indication of degradation. However, as figure 12 illustrates, the non-private segment of applied R&D spending has dropped from peaks of 65% in 1953 and 62% in 1965 to just under 39% in 2007. Some portion of this phenomenon undoubtedly tracks the precipitous drop offs in development spending by NASA and the DOD documented in section III.A, and as such, may not be cause for concern. However, it is not clear that the end of the cold war and the success of the Apollo missions justify all of the relative decreases in public investment in applied R&D. Rather, the differences between public contributions to basic and applied research may support the “funding gap” hypothesis. In aggregate terms, both overall basic R&D, and private development are increasing as a percentage of GDP. Applied R&D is not, particularly outside of the private sector. Taken together, these figures underscore the claim that public programs designed to “bridge the Valley of Death” comprise an important segment of the constructive intervention space. Thus, this subsection examines the major Federal efforts in this area.

**Figure 12: Applied Research by Source, 1953-2007**



*III.C.1 SBIR/STTR Description*

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are intended in part to guarantee that small businesses, as defined by the Small Business Administration (SBA), benefit from federal R&D contracts. The Small Business Innovation Development Act, enacted in 1982, mandated that all federal agencies with annual extramural research budgets of more than \$100M set aside 1.25% of these funds for small businesses under the SBIR program (Lerner 1999). Subsequent reauthorizations have increased this level to 2.5% (Cooper 2003), and renewal proposals currently under Congressional consideration would continue this trend, gradually raising the allocation to 3.5% by 2020 (Landrieu 2009). 11 federal agencies currently participate, and overall SBIR funding now exceeds \$2B per year, with the DOD accounting for slightly more than half of this total (OSTP 2009).

Both programs delineate a three-stage process, with the third phase ineligible for SBIR funding (to date). Phase I involves a proof-of-concept, with funding generally capped at \$100k over one year under current legislation. Only successful phase I projects are eligible for phase II awards, which are theoretically limited to \$750k, although there have been larger exceptions (Wessner 2008). Allocation of SBIR/STTR funds to phase III projects, the commercialization stage, is generally prohibited, although agencies are free to make grants from other budget lines. Pending legislation would raise these levels to \$150k and \$1M respectively, and also loosens the Phase III rules, especially for the DOD and DOE (details below). “Small” businesses are defined as those with less than 500 employees, regardless of age, which points to a certain ambiguity along the business stage axis hypothesized in previous sections.

Although SBIR has sometimes been characterized as public venture capital, the government does not take an equity position, therefore there is no exit requirement, unlike private VCs. Rather, the awarding agency receives certain rights in inventions generated via the grant, subject to time-limited disclosure restrictions. The specific terms vary by granting agency, but the general theme of exchanging funds for constrained public intellectual property, useful particularly in cases of grantee business failure, is consistent across Federal departments. On the whole, the program is primarily focused on the early stages of technology development (Branscomb and Auerswald 2002), and represents a substantive public intervention into the “Valley of Death” problem that frames much of this chapter.

STTR extends the SBIR effort to consortiums that involve universities. Although earlier iterations required private sector actors as lead entities, subsequent reauthorizations have expanded the permitted role of universities in both project management and intellectual property terms. Universities are now allowed to take project leadership, and retain patent rights developed under the program (SBA 2009). Funding set-asides are a fraction of those for the SBIR, but would increase under pending legislation (Landrieu 2009). The STTR is essentially a supplement to the SBIR that permits substantive involvement by universities and federal laboratories – the basic parameters and constraints are largely similar.

### *III.C.2 SBIR/STTR Analysis*

While the SBIR/STTR programs are widely viewed as successful, and enjoy bipartisan Congressional support, the analytical axes developed in previous sections illuminate at least two

areas of inadequacy. First, the lack of a clear funding source for Phase III highlights the “Valley of Death” problem – even government efforts specifically designed to support the transition from invention to innovation fail to adequately support the crucial transition from proven prototype to sustainable commercial success. Invoking the second axis, this problem is particularly pronounced for agencies that are not the primary customer for the outputs of their own SBIR/STTR projects. The program works very well for the DoD (Audretsch, Link et al. 2002), and to a lesser degree NASA, which are in a position to tailor their solicitations to meet internal procurement needs (Wessner 2008). For agencies that lack either budget capacity, such as the EPA, or clear acquisition mandates, e.g. the NSF, it is not clear that the SBIR/STTR programs are as effective in producing public goods, although they do contribute economically.

Examining the DOD in somewhat more detail, the scope of their SBIR participation justifies supplemental efforts to maximize the value of public investment. The Department has had a pilot phase III program in place for several years, and pending legislation (Landrieu 2009) would formalize and direct additional funds to this effort. The Navy is seen as a leader in this area, as they have implemented multiple programs to facilitate engagement between SBIR applicants and primary contractors, organized multiple forums to encourage interaction and spin-off commercialization, and generally taken steps to encourage phase III funding for promising phase II awardees (NRC 2007b). More generally, the capacity of various branches of the DOD (as well as NASA) to offer phase III contracts, often under single-sourcing exceptions to federal acquisition regulations, positions them handsomely in facilitating the transition from applied research to viable products.

To its credit, the NSF has developed a creative approach to the phase III problem, even in the absence of a procurement budget. They have established a phase IIB program, wherein particularly promising phase II awardees are eligible for an additional \$500k of funding over two year, provided that they match each SBIR dollar with two dollars of external funding. This is a promising idea, and pending legislation authorize other agencies to create such experiments (Landrieu 2009). In contrast with the balance of their grants, the NSF SBIR/STTR program also targets market needs, and strongly encourages commercialization (NRC 2007a). However, while results to date appear positive, the NSF is the only non-procuring SBIR/STTR entity that has taken such steps to date, which suggests the existence of gaps in other program areas, particularly those that are less well endowed.

There have also been complaints that the SBIR/STTR set-asides constitute a “tax” on research budgets (Cooper 2003). The restriction that SBIR funds may not be spent on program administration exacerbates this problem, and in some ways constitutes an “unfunded mandate”. More profoundly, although the SBIR/STTR program is widely viewed as an overall success both directly (Lerner 1999), and indirectly in terms of positive signaling effects (Toole and Turvey 2009), it is of only marginal utility in narrowing the constructive intervention space. It is useful in focusing consideration along the “stage-of-development” axis on SBIR phase III, especially for agencies that lack substantial procurement budgets. However, since the SBIR/STTR funding allocations are a simple percentage of existing Federal R&D budgets, further analysis is unlikely to reveal anything not depicted in previous graphs. In other words, SBIR investment mirrors the dominance of the DOD, the NIH, and to a lesser degree, NASA in

Federal R&D. Rather than rehash this point, the discussion turns next to a very different kind of Federal effort, the Advanced Technology Program.

### *III.C.3 Advanced Technology Program (ATP)*

The Advanced Technology Program was created in 1988 within the National Institute for Standards and Technology (NIST), a division of the Department of Commerce, and made its first grants in 1990 (Darby, Zucker et al. 2004). Unlike the SBIR programs, the ATP had an independent budget, although it oscillated greatly over the years (Wessner 2001). It explicitly targeted “high-risk, high-reward” efforts with the potential to create large societal benefits, especially in economic terms. It funded both single companies, and joint venture projects that often included universities, and required substantial cost sharing from participants. Although there were no limits on firm size, a substantial percentage of the awards went to small businesses. Like most early-stage efforts, a small number of projects produced an inordinate proportion of the benefits (Feldman and Kelley 2003). However, the ATP was known for the rigor of its internal and external evaluations; a variety of methodologies and reviewers concluded that the ATP did in fact contribute strongly to U.S. economic development (e.g. Jaffe 1996; NRC 2001; Branscomb and Auerswald 2002; Pelsoci 2007; Campbell, Shipp et al. 2009)

The ATP conducted both open and “focused” competitions, and relied heavily on industry to shape its priorities. In this sense, it was very much a market-driven program, and not an exercise in “industrial policy”. Funding skyrocketed during the Clinton years, reaching a peak of \$431M in 1995 (AIP 2000). However, these increases drew Congressional attention, and opposition to the program, on grounds of “corporate welfare”, and the belief that government should not be in the business of picking “winners and losers”, gained strength with the 1994 transition of the House into Republican hands, and persisted into the 21<sup>st</sup> century. The Senate was less hostile, and overcame House initiatives to eliminate the program throughout the 1990s. However, the change of administration in 2001 altered the political landscape, and no competitions were conducted in 2003, 2005, or 2006. The ATP was finally repealed and replaced by the Technology Innovation Program (TIP), the subject of subsection III.C.3 (U.S. Congress 2007).

The resistance to the ATP was not diluted by the substantial body of evaluations indicating that the program succeeded in fostering innovation. Assessments by both the ATP and outside bodies indicated that awardees enjoyed increases in revenues, employment, and patenting activities (NRC 2001; Darby, Zucker et al. 2004). NIST maintains an extensive survey database of both awardees and rejected applicants, and has taken concrete steps to make this information available to outside researchers (Campbell, Shipp et al. 2009). The evidence contained therein indicates that a majority of the projects either would not have been undertaken, reduced in scope, or significantly delayed in the absence of ATP funding (Link and Scott 2001; Feldman and Kelley 2003). Similar to the SBIR, ATP projects often benefit from a “halo” effect: winning an ATP award “certifies” the applicant, and increases their chances of securing subsequent private funding (Feldman and Kelley 2003). The ATP also conducted numerous case studies demonstrating substantial social benefit from particular grants (e.g. Pelsoci 2007).

The theoretical underpinning for the ATP (and similar programs) has several pillars. The first is the difficulty for any given firm to appropriate all of the benefits from R&D, due to the presence

of “spillovers”. Jaffe (1996) identifies three different kinds of spillovers: knowledge, market, and network, in an effort to aid the ATP in selecting high-spillover projects. Knowledge and market spillovers are a particular problem for small firms, which lack the resources necessary to develop additional applications of their core technologies with appropriate speed. The ATP practice of encouraging collaborations between large and small firms addresses this problem, in much the same way that the DOD is facilitating linkages between prime contractors and SBIR phase III projects. Network spillovers, which occur in situations where each individual actor depends on the success of a large number of others, seem particularly well suited to the ATP joint venture model – implementation of a “smart grid” to support a decentralized, renewable-driven electricity distribution is a good example. To the degree that these spillovers are material to the required investment, the social rate of return will be much higher than the private rate, leading to underinvestment in R&D.

The second problem is one that ATP-like policies share with the private sector, that of capital market failure. As noted in section III.B, information asymmetries between investors and entrepreneurs can lead to suboptimal levels of funding. The certification function of the ATP and SBIR program is particularly relevant; an award from either of these (generally) well-regarded Federal programs sends a strong signal to private financial markets, creating possibilities for constructive leveraging of taxpayer dollars.

The combination of the above factors decreases firm’s willingness to invest in high-risk projects where many of the benefits are likely to flow to other companies, often competitors. ATP’s focus on “enabling technologies” tackles this problem directly. Enabling technologies can be thought of as solutions to Hughes’ technological salients (Hughes 1994) – key issues that hold up the development of entire industries.<sup>14</sup> By providing a validated neutral ground for interested parties, the ATP facilitates the kind of cooperation necessary for effective collective action.

As observed earlier, the ATP did not lack for critics, and it did suffer from certain weaknesses. Large corporations such as IBM, Dow, and General Electric received Federal funding under the program, which at least rendered the ATP vulnerable to charges of “corporate welfare” (Moore 1997). Less ideologically driven commentators endorse the value of allowing large firms to participate in ATP-like joint ventures (NRC 2001) on a pay-as-they-go basis. In short, engagement by large firms may add value, but such organizations do not need taxpayer contributions. Others argued that awards tended to be too close to the applied research/development boundary, and so were suboptimal in addressing the “Valley(s) of Death” problem articulated in previous sections (Fong 2001). The ATP also required that private-sector partners retain all intellectual property (IP) rights, a serious problem for potential university and Federal laboratory partners. Finally, the ATP’s focus on economic benefits created possible areas of overlap with private sector funding, and did not explicitly target non-economic public goods, an issue that becomes more prominent when viewed through a sustainability lens.

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<sup>14</sup> The utility-scale power storage capacity required to incorporate intermittent renewable generation sources such as wind and solar into the U.S. electricity grid is a good example, one which NIST is considering as a target for future TIP solicitations.

### III.C.4 *Technology Innovation Program (TIP)*

The “America Competes” Act (U.S. Congress 2007) abolished the ATP, replacing it with the Technology Innovation Program (TIP). Although TIP retains the ATP’s basic structure,<sup>15</sup> there are a number of substantive alterations. First, TIP is explicitly focused on “critical national needs”. The statute does not define these needs, a question to which chapter six will return, but does elevate the importance of non-economic goals. Secondly, intellectual property rights are subject to agreement between the partners in joint ventures, a significant step forward versus the ATP for universities, NGOs, and Federal laboratories. Large firms are still allowed to participate in joint ventures, but may not receive any funding, in acknowledgment of the “corporate welfare” issue. Finally, awards are capped at \$3M over three years for single firms, and \$9M over five years for joint ventures.

TIP seeks “to support, promote, and accelerate innovation in the United States through high-risk, high-reward research in areas of critical national need” (U.S. Congress 2007). The program will sponsor a series of competitions targeted to particular social challenges, seeking to fund transformative research that generates “substantial benefits to the Nation that extend significantly beyond the direct return to the proposer” (NIST 2008). The first two competitions took place in 2008 and 2009, and TIP anticipates issuing one or more solicitations annually. Total new awards so far are in the range of \$10-20M/year, an order of magnitude less than peak ATP levels, and the size and number of future competitions is subject to Congressional appropriation.

Evaluating “critical national needs” poses a new challenge for TIP on several levels. NIST has identified six critical national priorities as part of its overall strategic planning efforts: Energy, Environment, Health Care, Information Technology, Manufacturing, and Physical Infrastructure (NIST 2009b). Within this framework, TIP has posted four white papers for comment to date in order to “further develop and refine the areas of critical national need” (NIST 2009a).

Translating these priorities into specific solicitations is a non-trivial problem; how can TIP best focus its announcements and decision criteria in order to maximize the probability that the outcomes of any particular competition will actually contribute to the designated national need? Additionally, how might TIP compare the success of multiple competitions over time, given that each is likely to address different public goods, given the diversity of challenges facing the nation? Finally, where is sustainability in this picture? How can TIP know whether the NIST strategic planning process is an appropriate baseline? In other words, how might the competencies and constraints of the DOC inappropriately influence NIST’s construal of critical national needs?

## IV. Needs and Market Failures ⇔ Constructive Innovation Space

Chapters one and two proposed the combination of anticipatory governance and sustainability as a superior theoretical foundation for the governance of emerging technologies. They also acknowledged both the necessity and the difficulties of translating recent European thinking into policies culturally and politically appropriate for the U.S. Within those frameworks, this chapter has explored the intersection between private and public R&D markets, with particular attention

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<sup>15</sup> And many of its personnel.

to both the empirically derived “Valley of Death” and the theoretically driven “Constructive Intervention Space”. While it may be tempting to view these two phenomena as opposite sides of the same coin, they are not, because the “Valley of Death” is only one aspect of the larger systems failure when viewed through an anticipatory governance/sustainability lens. However, the “Valley(s) of Death” have served as a useful focusing device in exploring both the nature of the problem, and the private and public sector responses thereto.

This chapter has proposed various axes of characterization for the constructive intervention space, in order to help narrow the problem into actionable terms. Before moving on to chapter six, which will explore possible institutional responses and next steps, it seems appropriate to summarize the findings so far. Although the discussion raised other alternatives, the two primary themes of the analysis were stage of technological development and topic area, with an emerging understanding that the intersection between the two proposed axes may be critical:

### **IV.1 Stage of Technological Development**

The evidence presented in this chapter strongly supports the conventional wisdom that the “Valley of Death” is in fact real, particularly in the case of public goods. The problem does not lie in overall levels of R&D funding, or in a decrease of support for basic research, but rather in the region of applied research. Somewhat uniquely, this chapter argues that the decline in the Federal share of applied R&D as a percentage of GDP is not necessarily bad news, but rather reflects an appropriate move away from Defense and Space expenditures as de facto industrial policy. However, with the possible exception of the NIH, it is not clear that the combination of Federal, private, and “other” sources has adequately filled the void left by the end of the cold war, the completion of the Apollo program, and the demise of the unique profitability conditions that allowed certain large U.S. corporations to maintain basic R&D facilities such as Bell Labs in the post-WWII period. Venture capital, defined broadly, has become a critical driver of innovation in the last 25 years, but its “home-run” based business model necessarily excludes many otherwise promising initiatives.

### **IV.2 Environmental Public Goods (Topic Area)**

The public and private sectors offer different, but related challenges in this area. In the public sector, funding levels correlate strongly with areas of attainable political consensus. In Federal terms, this translates into consistent support for the DOD, increasing commitments to the NIH in the last decade, and lingering constituencies for NASA, the Department of Agriculture, and a few other departments. In other words, reading the data presented in this chapter through a sustainability/anticipatory governance lens suggests that the environmental pillar has received short shrift. The Obama administration, to its credit, is building on previous Congressional commitments to double research budgets for the NSF, the DOE Office of Science, and NIST. Coupled with the climate change bills currently up for Congressional consideration, these initiatives constitute significant positive steps, as well as a reversal of trends prevalent in the previous administration. At the same time, these efforts do not constitute a coherent program from an anticipatory governance/sustainability standpoint. In particular, there is very little emphasis on a comprehensive evaluation of societal needs, desires, and visions as a basis for



policy. While the current administration is moving in the right direction, it is doing so in a piecemeal fashion, and there is significant room for improvement.

Additionally, it is not reasonable to expect the private sector alone to fill this gap. The above sections describe the rate of return parameters that constrain venture capitalists. Although it is difficult to pinpoint precisely, the high-risk/high reward model shared by both the venture capital community and the ATP/TIP programs seems to undervalue certain public goods, even though TIP is explicitly designed to produce same. The market orientation of all of these efforts limits their effectiveness to areas of moderate market failure, i.e. where the market only needs a nudge in order to bring private and social rates of return into reasonable correspondence. It is not clear that this level of response will suffice to address serious collective action problems, especially those with international dimensions. Climate change is the obvious example here, though its current prominence may mask other issues.

To summarize, the historical mapping exercise in this chapter leads to several tentative conclusions. First, the decline in both public and private investment in the early stages of the technological life cycle supports the contention that the “Valley of Death” with respect to emerging technologies is real. Further, the evidence suggests that environmental technologies may face a second “valley”, as the barriers to entry in the energy, water, and other infrastructure sectors are much higher than those in the Internet realm, where much of the private capital community learned its trade. Second, historical trends in Federal R&D levels suggest, but do not definitively establish, a pattern of underinvestment in the environmental pillar. Recent developments in the “cleantech” area support this claim, as the private sector is seeing opportunity in this space. At the same time, private sector funding models do not explicitly consider public goods, and thus shy away from innovations with long-term economic payoffs, regardless of their larger societal benefits. This problem is particularly pronounced for technologies that address environmental externalities, as the current economic system does not reflect their full value. The combination of sustainability and anticipatory governance is useful in addressing this problem, as it provides a different starting point for analysis, one not necessarily constrained by existing private sector parameters.

Finally, from the standpoint of anticipatory governance and sustainability, existing Federal programs in support of innovation are sorely lacking in terms of a systematic connection between societal needs and public investment. Chapter six explores this problem in greater detail. For the moment, though, it suffices to conclude that the constructive intervention space with respect to public goods is much larger than that addressed by existing efforts in both the public and private sectors. Remaining sensitive to the market orientation of the U.S., there is in fact productive room for more public intervention in the early stages of application development for technologies with significant environmental benefits, and perhaps in assisting such innovations to attain economies of scale as well. Chapter six examines two programs that ostensibly strive to meet such goals, TIP and the NNI, through the lens of anticipatory governance and sustainability, identifying their successes and shortfalls in order to inform future institutional development efforts, such as the efforts towards development of a National Sustainability Initiative proposed in section IV thereof.

## I. Institutionalizing Anticipatory Governance

Chapter two posited the combination of anticipatory governance and sustainability as a theoretical framework for U.S. policy with respect to emerging technologies. That blend suggested the question of “what do we need to anticipate” in order to narrow the various governance gaps identified in chapter one. The theoretical goal was to identify and articulate a “constructive intervention space” for nanotechnologies as a case of emerging technologies. In keeping with this dissertation’s philosophy of enacting its premises, chapters three and four entailed example anticipatory characterizations of risks and public perceptions in specific contexts. Within the same rubric, chapter five approached the problem somewhat differently; it sought to sharpen understanding of the nature of the governance gaps with respect to the production of public goods, particularly with respect to funding mechanisms. In some sense, chapters three thru five sought to narrow the constructive intervention space from diverse perspectives.

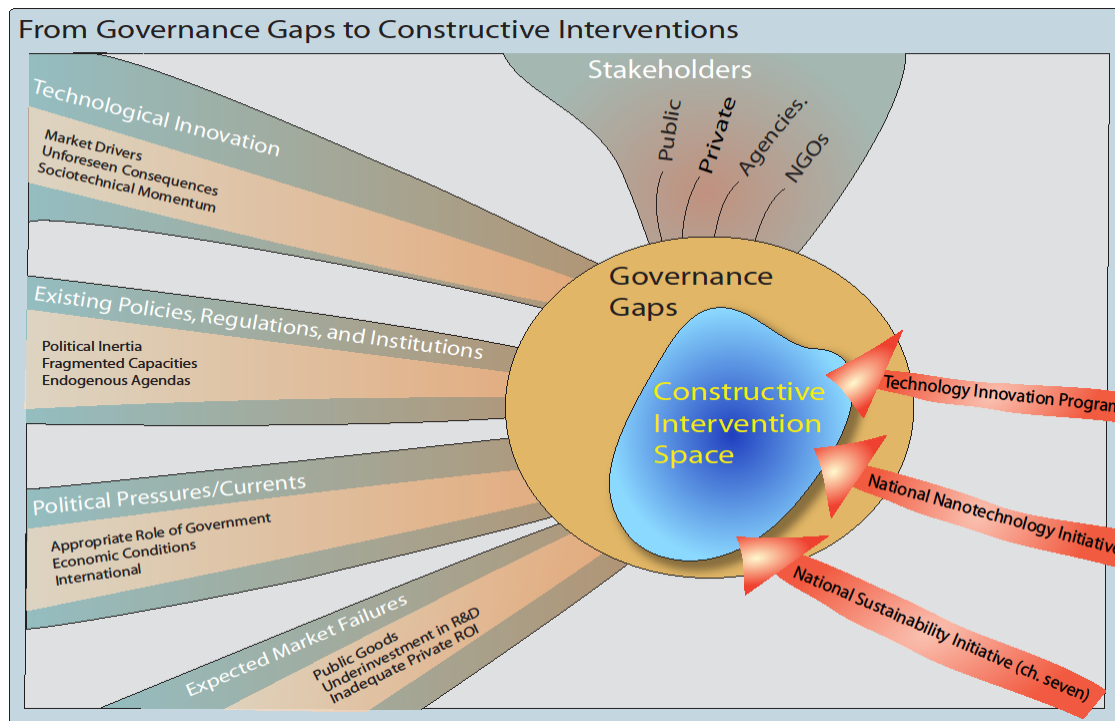
In keeping with the notion of anticipatory governance as a distributed capacity (Barben, Fisher et al. 2008), this dissertation seeks to contribute one portion of a larger collective effort. Previous chapters have sought to identify, articulate, and narrow the “constructive intervention space”. In contrast and conclusion, this chapter explores specific feasible interventions, using two existing federal programs as cases. Building on these examples, it further posits the idea of a National Sustainability Initiative (NSI) as a scenario, and evaluates that possibility in terms of the combination of anticipatory governance and sustainability. In short, having scoped and narrowed the constructive intervention space, the final two chapters explore three specific constructive intervention options, ranging from the immediately tangible to the speculative.

To frame this discussion, it is useful to return to the graphic initially presented in chapter two. The diagram sketches some of the influences that comprise the context for potentially constructive policy or strategy interventions. Previous chapters have explored various graphical “tentacles”, and this chapter continues to draw on those themes, as well as some of the theoretical influences outlined in chapter two. However, if one were to ask, “what was wrong with that picture”, it is that it represents possible interventions with a single red arrow, possibly implying a “one size fits all” approach. Such a conclusion is compatible with neither the theoretical frameworks articulated in chapters one and two, nor the empirical evidence with a policy twist discussed in chapters three through five.

Thus, this chapter adopts a progressive case study approach in synthesizing the empirical results and theoretical approaches articulated in the balance of this dissertation. The three cases increase in both scope, and the degree to which they apply the combination of anticipatory governance and sustainability in developing tangible alternative pathways. They also follow a continuum of growing emphasis on constructing institutions, rather than just policies or processes, although the latter retain importance throughout. This emphasis is in keeping with the notion that governance gaps are dynamic phenomena that require ongoing solutions. For that matter, the concepts of sustainability and anticipatory governance themselves need to evolve continually in order to maintain relevance (Eriksson and Weber 2008; Gaziulusoy, Boyle et al. 2008). Concepts do not evolve in the absence of active human attention, which suggests the need for institutions with both the capacity for and commitment to adaptive learning. That is,

part of the answer to the question “How do we operationalize anticipatory governance” may lie in how we institutionalize it.

**Figure 13: Evaluating/Designing Constructive Interventions**



So, in graphical terms, figure 13 splits the earlier single arrow into three specific constructive interventions (the bright orange arrows in the lower right). They are the Technology Innovation Program (TIP) touched on in chapter five, the National Nanotechnology Initiative (NNI), and a proposed National Sustainability Initiative (NSI). Evaluating the first two via the framework articulated in the next section provides a basis for the design of the process to produce the third.

### I.A. Evaluative Framework

Three themes from previous chapters further inform the current analysis. The first is the desirability of incorporating stakeholders in establishing public investment priorities, and the need to do so in an effective manner. This echoes the empirical work reported in chapter four, and also connects with the idea of public goods explored in chapter five. Questions of “who decides” are standard within the STS literature; concrete proposals for effective vehicles for incorporating citizen and stakeholder participation into policy-making processes are less common. The second challenge is how to include risk/benefit tradeoffs within a larger sustainability framework. This line of inquiry is partly driven by empirical interview results, and also by deficiencies in the existing U.S. regulatory and market structures. Finally, the addition of sustainability to the anticipatory governance equation forces consideration of the necessary characteristics of institutions focused on the future.

Pulling these influences together, this chapter interrogates its cases with the following questions:

**Table 4: Evaluation/Anticipatory Design Framework**

Keyword(s)	Question(s)
Foresight, Sustainability	How effectively do they implement foresight, with a particular eye towards sustainability considerations? Put differently, how well do their goals and objectives help to articulate, and/or fit within, emerging frameworks of sustainability?
Effective Engagement	To what degree do they succeed in engaging stakeholders, including the general public, and how effective are the feedback mechanisms to incorporate these inputs into the policy process?
Market Failures	How well do they anticipate and address potential market failures, particularly with respect to the production of public goods?
Risk/Benefit, Sustainability	How do they handle risk/benefit tradeoffs within the context of sustainability, if at all?
U.S. Political Framing	How successful are they in framing problems for the American political environment, and in creating possibilities for enduring societal consensus, as measured by reasonably consistent funding?
Anticipatory Capacity	To what degree do they build institutional capacity for anticipatory governance?

Table 4 is about putting the combination of anticipatory governance and sustainability into practice. It uses the empirical data and analysis from chapters three through five to translate the theoretical notions of “governance gaps” and the “constructive intervention space” into tangible evaluative tools. As noted in chapter two, anticipatory governance by itself is too process-oriented to be effective alone; it needs pairing with something more substantive to provide a foundation for practical action. Sustainability, for all of its ambiguity and contested nature, provides such a productive coupling. It facilitates more comprehensive assessments of future societal needs, and its tripartite formulation (economic, environmental, and social) supports the anticipatory governance tenet of public and stakeholder engagement in the governance of technologies with environmental implications and/or applications. More basically, it helps provide answers to the question “what do we need to anticipate”, answers to which are essential in operationalizing anticipatory governance.

Some of these points merit further explication, as they fall into the general category of “wicked problems” (Rittel and Webber 1973), which unfortunately are likely to comprise the norm rather than the exception with respect to sustainability (Batie 2008). For example, as chapter four suggests, the question is not whether to engage the public and stakeholders, but how to do so productively. The key issue is to articulate an appropriate series of intersections between deliberative and representative democracy that allow citizens and stakeholders to influence policy without negating the virtues of the system set forth in the U.S. constitution. This meta-question implies several subinquiries, all of which need to be addressed via a multiplicity of experiments:

- a. What mix of engagement mechanisms should we employ in various sociotechnical contexts, given funding and participation constraints?

- b. Values, priorities, and needs seem to provide the richest opportunities for citizen involvement. How do we determine:
  - i. When to solicit input in terms of the R&D cycle?
  - ii. What balance to strike between specific technological applications, and broader enabling technologies, or technological trends?
  - iii. How best to integrate citizen input into the policy cycle?
- c. How should we determine the relative importance of citizen input into technology governance issues versus other sociopolitical priorities, such as elections?

The risk/benefit question is also crucial, as it forces consideration of the core issues in the governance of emerging technologies: How should societies decide which paths to pursue? What criteria should we develop and deploy? Who needs to be involved? At what point in the development trajectory is public intervention appropriate? The answers to all of these questions are, unfortunately, it depends. Thus, this dissertation focuses on the needs/market failure angle, in order to provide a portion of the necessary context for specific decisions. Knowing what is at stake in terms of public goods for particular areas of national need will help in developing appropriate answers to the above questions for particular arenas and applications. This knowledge will not solve all of our problems, but it could give us at least one leg to stand on in muddling through complex decisions.

Informed by chapters three through five, Table 4 also has a strong practical orientation. In keeping with the theme of translation espoused in chapter two, it seeks both to put theory into practice, and to import valuable lessons from Europe into the U.S. political environment. To this end, the real test of table 4 lies in its application to existing programs in the U.S., and the degree to which the framework is useful in informing the design of possible future initiatives, such as the one articulated in section IV. The detailed discussion begins with a return to the Technology Innovation Program (TIP), housed within the National Institute for Standards and Technology (NIST).

## II. Technology Innovation Program (TIP)

### II.A TIP Revisited

As noted in chapter five, TIP replaced the Advanced Technology Program (ATP), which contended with ideological opposition throughout its lifetime. While TIP is focused on “critical national needs”, and the funding levels are much smaller than those enjoyed by the ATP at its peak, it will likely face similar challenges in justifying its existence and securing funding. These struggles will probably be more pronounced for a related program created by the same legislation, the “America Competes” Act (U.S. Congress 2007), the Advanced Research Project Agency – Energy (ARPA-E). While Congress appropriated \$300M for ARPA-E in FY 2008, the Bush administration took no action, and the program stayed dormant until the new administration took office, and secured passage of the American Reinvestment and Recovery Act (ARRA), which provided \$400M in initial funding (U.S. Congress 2009). The lesson for TIP, ARPA-E, and indeed any attempt to incorporate sustainability into technological governance in the U.S. is

that such efforts are likely to be painted as “industrial policy”, an epithet with connotations of “socialism” in certain quarters. Thus, domestic policy suggestions in these areas need to be particularly robust, and prepared to defend themselves to a much greater degree than their European counterparts.

Returning to TIP, the America Competes Act does not provide a definition of “critical national needs” (CNNs). While the incoming administration did establish priorities for science and technology, and set forth a plan for doubling the R&D budgets of three key agencies (NSF, DOE’s Office of Science, and NIST) over time (OSTP 2009), it did not provide specific guidance to TIP. As previously mentioned, this left TIP to rely on NIST’s six research priorities: Energy, Environment, Health Care, Information Technology, Manufacturing, and Physical Infrastructure (NIST 2009b) in determining CNNs in structuring its competitions. It is important to note that in establishing these priorities as part of its strategic planning process, NIST considered its “organizational competencies”. In other words, these are areas where NIST feels that it has a contribution to make, which do not necessarily correspond with actual national needs. While organizationally appropriate, and perhaps an efficient allocation of resources, this process does illustrate how phrases like “critical national needs” are filtered through agency priorities. As such, it is a good example of how the often theoretical “transition management” literature needs to pay greater attention to existing agencies, actors, and practices (Voss, Smith et al. 2009). Such pragmatic considerations are particularly important in translating European approaches to the U.S.

Given the political realities of Washington, how should TIP go about translating “critical national needs” into constructive solicitations? Competitions need to elicit proposals with not only the potential to address targeted CNNs, but also do so in ways that enable subsequent markets, and emphasize areas where existing public and private investment mechanisms are inadequate. This is a problem of identifying critical innovation roadblocks, or “technological salients” (Hughes 1994), within selected CNN domains. TIP has already proven its ability to identify and clarify such opportunities in a white paper (2009) that focuses on the need for utility-scale energy storage solutions to permit the smooth integration of intermittent renewal sources such as solar and wind into an overall “smart grid”. Building on TIP’s previous experience, a more systematic approach to designing specific solicitations within particular domains of national need could prove beneficial. Space precludes full discussion of a possible detailed methodology to address these issues, but the application of Multicriteria Decision Analysis (MCDA) techniques, particularly the Analytic Hierarchy Process (AHP) (Saaty 1994) with broad stakeholder participation holds promise both for TIP, and other programs that seek to anticipate market failures within the framework of sustainability. The combination of anticipatory governance and sustainability is capable of producing rigorous methodologies, but their articulation must await other publication opportunities. For purposes of this discussion, the next step is to apply the evaluative framework set forth in table 4 to TIP.

## **II.B Applying the Framework**

The authorizing legislation for TIP mentions neither sustainability nor anticipatory governance, so in some sense the application of an evaluative framework derived from the combination of those two ideas is unfair. However, the introduction of a new framework is very much the point.

If the ideas incorporated therein have merit, they should produce new insights with respect to TIP and other existing public efforts to facilitate constructive innovations.

### *III.B.1 Foresight with respect to Sustainability*

From a theoretical standpoint, the tendency is to award TIP a poor grade in this regard. While four of NIST's six priorities are relevant to sustainability, TIP has made no attempt to develop a comprehensive vision of a sustainable society from which critical national needs could be derived. However, as previously noted, transition management theory does a poor job of acknowledging existing political realities. The America Competes Act (U.S. Congress 2007) is not about sustainability, and in fact does not mention the term once (zero hits on a textual search). It targets innovation and the commercialization of R&D, in order to bolster U.S. competitiveness. Given these goals, and the history of hostility to the ATP from the incumbent administration, working within existing parameters in terms of identifying solicitations within previously defined Critical National Needs (CNNs) made eminent sense. In this sense, TIP serves as an important empirical reality check, and as an aid in transatlantic translation. Managing transitions to sustainability only makes sense when sustainability is a clearly articulated goal of the effort, a condition that does not obtain in this case. Thus, TIP's focus on "high-risk, high-reward research in areas of critical national need" scores more highly with regard to this criterion, given its political contexts.

### *III.B.2 Stakeholder (including public) Engagement*

In anticipatory governance terms, NIST's response to the America Competes Act appears to score poorly in terms of both participation and engagement. However, it is very difficult to fault the agency, which was scrambling to promulgate new regulations, and retain as many experienced staff as possible through the transition from ATP to TIP. ATP, and now TIP, do have a solid track record of engaging with industry stakeholders, in part to fend off potential criticisms of conducting "industrial policy". However, they have very little history of incorporating input from the general public. There is clearly a tension between the participatory tenets of anticipatory governance and political realities in Washington, one that will probably never be fully resolved. However, there are constructive possibilities, as the NNI discussion in section III will highlight.

Part of the challenge of operationalizing anticipatory governance lies in integrating participatory and representative democracy in a coherent fashion. Too often, advocates of citizen participation in science and policy either give slight attention to existing processes, or implicitly position participatory engagement as an alternative to current practice (Schot 2001; Genus 2006; Powell and Kleinman 2008). More pragmatically minded practitioners emphasize the importance of appropriate citizen involvement (Renn 2003; Robinson 2003; Rogers-Hayden and Pidgeon 2007), with a reflexive understanding that "appropriate" may be a contested term. The NCTF project reported in chapter four constitutes an example of "appropriate" engagement, and section III will explore the necessary conditions for "appropriateness" in more detail in the context of the NNI. In contrast, it would not have been appropriate for NIST to delay its rulemaking with respect to TIP in order to conduct such a consensus conference. Not only did NIST lack a formal mandate or funding to solicit citizen input, the political vulnerabilities inherited from ATP

required a rapid response in order to retain Congressional support. Applying the combination of anticipatory governance and sustainability to specific examples produces lessons about the limitations of the conceptual approach, as well as new possibilities.

### *III.B.3 Anticipating Market Failures*

TIP scores relatively highly on this criterion. The program is premised on the notion that there are categories of projects that are unlikely to garner private sector funding, for the reasons detailed in chapter five. It specifically targets such situations, and the review process includes a rigorous assessment of the reasons why applicants have experienced difficulty in securing private financing. It also takes prospective markets into account – the critical national need area of infrastructure is particularly salient. For example, while the potential market for non-destructive techniques for evaluating structural health, the subject of a recent TIP solicitation, could be substantial over time, it offers nowhere near the growth potential of an iPad. Thus, efforts in this area are less likely to attract VC funding, because the prospective returns fall short of their requirements. In other words, needs of this nature fall squarely into the constructive intervention space articulated in chapter five, and TIP's efforts to meet them constitute constructive interventions. The primary criticisms of TIP in this regard is that it is not funded at levels commensurate with the scale of the needs, and, echoing criterion one, that it lacks a mandate for comprehensive evaluation.

### *III.B.4 Risk/Benefit Tradeoffs within the contexts of Sustainability*

TIP flunks in this category. In addition to the previously noted lack of an overarching vision, TIP's forms, web site, and practices to date are almost completely devoid of any consideration of potential environmental and social risks posed by the projects they support. In keeping with the bifurcation between technology regulation and promotion identified in chapter one, risks other than technology and market failure are simply not on TIP's radar screen. This is not to say that NIST is not concerned about the environment, but rather to note that the America Competes Act provides strong empirical backing for the theoretical arguments advanced in chapter one. Existing practice tends to treat risks and benefits as existing within different universes. This is a deficiency that the combination of anticipatory governance and sustainability could aid in addressing; section IV will sketch some (hopefully) politically feasible moves in that direction.

### *III.B.5 U.S. Political Framing*

Almost by definition, TIP largely excels in this area. Although it was only passed after the Democrats regained control of Congress, the America Competes Act was signed by an administration that strongly questioned its predecessor, the ATP, and had targeted the earlier program for elimination. The legitimacy of government intervention in markets, even in clear cases of market failure, remains highly contested in the U.S. The fact that this legislation passed with strong bipartisan support attests to the effectiveness of its framing, with the strong caveat that ARPA-E, which the act also authorized at much higher funding levels, did not materialize until a change of administrations, and the unique financing opportunity manifested in ARRA. Both TIP and ARPA-E will likely face future challenges, but for the moment, the very existence of TIP has to be judged a success in terms of this criterion. Again, funding levels are inadequate



to needs, but the fact that the ATP essentially survived in reduced form has to be counted as a plus here.

### *III.B.6 Institutional Capacity for Anticipatory Governance*

Results here are mixed. Should TIP successfully implement a coherent program for identifying and prioritizing “critical national needs” based on a participatory backcasting type of process, it would be a significant step forward for the operationalization of anticipatory governance, and lay a foundation for future expansion. Absent such a move, their responses to new challenges will likely be ad-hoc, and continue to lack coherence in sustainability terms. While some TIP personnel have signaled strong interest in participatory/anticipatory approaches, it remains unclear whether NIST as a whole will view it as enough of a priority to allocate scarce resources. At the moment, the outlook for substantive improvement is bleak, forcing the assignment of a C-/D+ grade in this area.

In summary, TIP as a case nicely illustrates both the potential and the limitations of an “anticipatory governance & sustainability” approach to U.S. political realities. The theoretical framework helps to highlight certain inadequacies in TIP’s approach, particularly with respect to the lack of processes for developing a comprehensive conception of sustainability, and the utter absence of risk/benefit tradeoffs within larger societal concepts. At the same time, the application of theory to practice also points out the inadequacy of existing theory as a practical tool to cope with existing political realities in the U.S. There is a need for context-specific methodologies to identify and prioritize “critical national needs”, however they are framed, within U.S. political constraints. This is a difficult problem, and TIP serves as somewhat of a negative control, the case most constrained by political baggage. The National Nanotechnology Initiative (NNI) is an animal with entirely different stripes, and the subject of the next section.

## III. National Nanotechnology Initiative (NNI)

The National Nanotechnology Initiative (NNI) is the coordinating vehicle for all federally sponsored nanoscale R&D in the U.S. Total investment has grown from roughly \$500M in FY 2001, when the initiative was formally launched, to the approximately \$1.8B requested for FY 2011. Participation has also mushroomed from 7 agencies at the outset to 25 in FY 2011, 15 of which have specific budgets for nanotechnology (NNCO 2010b). The program is largely considered a success, and is viewed as instrumental in maintaining the U.S.’s competitive position globally (PCAST 2010). To underscore the point regarding transatlantic translation, note that the 2010 PCAST document mentions sustainability precisely once, on p. 18, but searching on a combination of “competitiveness” and “U.S. leadership” yields nine hits. The emphasis is clearly different than that found in the European technology assessment literature.

Returning to the topic at hand, the NNI states an ambitious vision of “a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society”. It defines nanotechnology as “the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length

scale” (NNCO 2010b). It is important to emphasize the criticality of scale. Nanotechnology, or more properly nanotechnologies, is not a single set of scientific disciplines, technological innovations, or application areas. Rather, numerous avenues of R&D seem to be converging in these dimensions, where physics, chemistry, biology and a variety of other fields intersect (Roco 2005), with probable economic, social, and environmental consequences. In this sense, nanotechnology is a superb case for the study of emerging technologies, because it is not a technology per se, but rather an organizing framework for a vast range of scientific and technological developments, a meta-technology. Solutions that work for nanotechnologies should generalize well to other cases for precisely that reason, but such solutions will not arrive easily.

### **III.A Development of the NNI**

The NNI’s history and structure gives it a relatively unique authority position, which has both advantages and disadvantages. In formal terms, pre-activities began with the designation of an Interagency Working Group on Nanotechnology (IWGN) under the National Science and Technology Council (NSTC) in 1998 (NNI 2010). The NSTC describes itself as a “Cabinet-level Council” which “is the principal means within the executive branch to coordinate science and technology policy across the diverse entities that make up the Federal research and development enterprise. Chaired by the President, the membership of the NSTC is made up of the Vice President, the Director of the Office of Science and Technology Policy, Cabinet Secretaries and Agency Heads with significant science and technology responsibilities, and other White House officials” (OSTP 2010). While impressive in theory, in practice, much of the actual work of the NSTC is carried out through its committees and subcommittees.

Based in part on the IWGN’s work, President Clinton elevated Federal support for nanoscale R&D to the level of a national initiative (the NNI) in his FY 2001 budget. With Congressional approval, the IWGN was transformed into the Nanoscale Science, Engineering, and Technology (NSET) subcommittee of the NSTC’s Committee on Technology, and the National Nanotechnology Coordination Office (NNCO) was founded as the secretariat to NSET (NRC 2008). NSET coordinates the “budget crosscut” process, where participating agencies designate appropriate segments of their budgets for inclusion in the NNI, in order to produce a coherent funding picture for the NNI. Note, however, that the NNI and the NNCO have no formal budget authority; individual agencies negotiate their requests with the Office of Management and Budget (OMB), subject to further modification by Congress. This limits the NNCO’s ability to set priorities or hold agencies accountable, which has become an issue with respect to Environmental Health and Safety (EH&S) strategy (NRC 2008).

The NNI is divided into eight Program Component Areas (PCAs):

1. Fundamental nanoscale phenomena and processes;
2. Nanomaterials;
3. Nanoscale devices and systems;
4. Instrumentation research, metrology, and standards for nanotechnology;
5. Nanomanufacturing;
6. Major research facilities and instrumentation acquisition;

7. Environmental, health, and safety; and
8. Education and ethical, legal, and other societal dimensions.

In the NNI's first decade, PCAs 1, 2, 3 and 6 have received the vast majority of funding (NNCO 2010a). However, as the initiative matures, the emphasis on both commercialization and EH&S is increasing, thus investments in PCAs 5 and 7 are expected to exhibit the fastest growth in the near future. Additionally, the FY 2011 budget introduces three “nanotechnology signature initiatives”, focused on “nanotechnology applications for solar energy”, “sustainable nanomanufacturing”, and “nanoelectronics for 2020 and beyond” (NNCO 2010b). The NNI expects to launch more such initiatives in the future, partially in response to the most recent PCAST (2010) review, and also in keeping with an evolving understanding of the appropriate balance between “curiosity” and “opportunity” driven research, aka basic and applied science. This dovetails with the findings of chapter five, namely that government has a constructive role to play not just in funding basic research, but also in facilitating the deployment of technologies that provide public goods.

The NNI's most recent strategic plan (2007) also articulates four overarching goals:

1. Advance a world-class nanotechnology research and development program;
2. Foster the transfer of new technologies into products for commercial and public benefit;
3. Develop and sustain educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology; and
4. Support responsible development of nanotechnology.

For purposes of this dissertation, goal four is the most salient, with an honorable mention to goal two. The NNI's plan explicitly references “maximizing benefits” and understanding and managing potential risks with respect to goal four in the same sentence (2007, p. 3), but includes no mechanisms for considering both simultaneously. The NNI's treatment of environmental health and safety (EH&S) issues has been among its most controversial aspects, and so merits further investigation.

### **III.B EH&S and Societal Dimensions**

Much of the controversy over nanotechnologies to date may have less to do with nanotechnologies per se than the contexts into which they are emerging. In particular, memories of the debate over genetically modified organisms (GMOs), as well as previous examples of “late lessons from early warnings” (Harremoës, Gee et al. 2001), informed much of the early conversation around the societal dimensions of nanotechnologies (e.g. ETC 2003b; Balbus 2005; Roco and Bainbridge 2005; Scheufele and Lewenstein 2005; Macoubrie 2006). Early is a relative term with respect to emerging technologies; as nanotechnology matures, and GMOs fade in discursive prominence, it is becoming clearer that the differences between the two cases exceed their similarities. As noted in chapter two, this dissertation sides with those that see nanotechnologies as an opportunity to do things differently (e.g. Macnaghten, Kearnes et al. 2005; Kearnes, Grove-White et al. 2006; Renn and Roco 2006). At the same time, nanotechnologies are not so unique as to render the discussion of governance gaps from chapter

one irrelevant, recalling that the idea is partly drawn from experiences with previous technologies, a library that extends well beyond GMOs.

### *III.B.1 Innovation outstrips evaluation funding*

The Erosion, Technology, and Control (ETC) NGO claimed the early media high ground with their call for a moratorium on deployment of nanotechnologies in commercial products, pending regulatory review (ETC 2003a). Although they did not use the term, their argument, that the pace of innovation was outstripping societal capacities for the evaluation of possible consequences, fits the governance gap framework nicely. Additionally, the fact that their grey literature publication was widely cited within the nanotechnology community (NNI 2004; Roco 2005; IRGC 2006) suggests both a heightened sensitivity to public criticism, and the value of ETC's proclamation as a discursive device. The GMO debate primed both advocates and opponents of nanotechnologies for a media fight. As time has gone on, nanotechnologies seem to have passed through the hype/hate cycle, although that conclusion may merely reflect a snapshot at this particular moment.

The ETC's statements may have included a certain element of political posturing, but a number of other actors from various sectors did assert the need for increased emphasis on the EH&S aspects of nanotechnology development at a relatively early stage (Denison 2005; Morgan 2005; Oberdörster, Oberdörster et al. 2005; IRGC 2006). Additionally, questions were raised about the categorization of EH&S investments (Dunphy-Guzman, Taylor et al. 2006), and the NNI now pursues a much more conservative approach (NNCO 2010b). Without necessarily asserting a causal connection, the budget for PCA 7, which corresponds strongly to EH&S, has increased from \$37.7M in FY 2006 (NNCO 2010a) to a request for \$116.9M in FY 2011 (NNCO 2010b).

While this funding increase is welcomed, and appropriate, it does raise the question of how much EH&S research is enough, and on what grounds should participating agencies make that determination? Further, the EH&S figures do not include more "societally" oriented research – how should those funding levels be set, and by whom? The NNI is arguably breaking new ground in these regards, thus posing difficult practical questions for the operationalization of anticipatory governance, as well as hinting towards sustainability issues. Moving beyond dollars, the debate over the NNI's EH&S strategy offers additional evidence for consideration within these frameworks.

### *III.B.2 EH&S strategy*

As previously noted, early criticisms of the NNI highlighted the relative lack of attention to EH&S issues. In response, the NNI initiated a number of workshops and other engagement exercises, which culminated in the publication of a document that highlighted EH&S research needs (NNI 2006). Recognizing that this was only a first step, the NNI engaged in further consultations and deliberations in order to produce an initial strategy for nanotechnology-related EH&S research (NNI 2008). While in some ways a monumental achievement in terms of interagency coordination, the fact that the document is lacking in a number of ways hints at the organizational limitations of the NNI structure.

In keeping with the spirit of constructive oversight embodied in its endorsing legislation (U.S. Congress 2003), the NNI commissioned an independent review of its EH&S strategy by the National Research Council (NRC) of the National Academies of Science (NAS). Their report was rather scathing in “inside the Beltway” terms, engendered a rather stern response from the NNCO, and also seems to have influenced the reauthorization legislation discussed in subsection III.B.3.

The most striking point of disagreement between the NRC and the NNCO is over the meaning of the word ‘strategy’. The NRC set forth a definition, identified nine critical elements of a risk research strategy, and found the NNI’s 2008 plan wanting in a number of these critical areas. In particular, the NRC found that the NNI strategy “falls short of ensuring that the results of strategic research are useful and applicable to decision-making that will reduce the potential environmental and health effects of nanotechnology” (NRC 2008). Additionally, the NRC argues that the NNI relied excessively on existing research trajectories in the various participating agencies, and failed to conduct the comprehensive needs analysis necessary to inform an appropriately strategic approach.

The NNCO issued a strongly worded response that objected to many of the NRC’s key findings (NNCO 2009). They argued that the NRC assessed the document as a “strategic plan”, rather than a “strategy”, and ignored the organizational realities of the NNI structure. The response also noted that the NRC took a narrow view of both the stakeholder engagement and scientific review activities that fed into the final plan. In the latter areas, the NNCO’s protests have merit, and there is a certain political valence to the NRC’s assessment that suggests a criticism of the Bush Administration as a whole, rather than the NNCO in particular.

The key issues, though, are what the NNI’s EH&S strategy ‘should’ do, and whether the NNI organizational structure suffices to meet future needs. The most recent PCAST review (PCAST 2010), the first under the Obama administration, tends to side with the NRC in demanding additional accountability from the NNCO, but also recognizes the NNCO’s need for substantial additional resources in order to effectively discharge their mandate. PCAST essentially agreed with the NRC in calling for significant strengthening of the NNCO’s authority vis-à-vis the participating agencies, and an amplification of emphasis on EH&S issues. Their report was issued after the FY 2011 budget submission, so what actions will transpire in the short term remain to be seen. It does seem clear, though, that the NRC raised some important organizational questions about the NNI that are salient to the larger discussion.

### *III.B.3 Re-authorization emphases*

Given its executive branch origins, the NNI does not technically need legislative reauthorization in order to continue. Obviously, it does rely on continued appropriations, but there are no explicit sunset clauses in its validating legislation (U.S. Congress 2003). At the same time, reauthorization bills have been introduced into both houses in both the 109<sup>th</sup> and 100<sup>th</sup> Congresses, and have passed the House in both sessions. As is par for the course at the moment, the Senate has failed to bring the matter to a vote, so many of the reforms proposed by draft legislation remain in legal limbo. However, it is still useful to analyze the most recent Senate

bill, S. 1482 (2009a), as it contains a number of provisions of interest to the argument, and represents the most comprehensive indication of congressional intent to date.

Chapter four focused primarily on S. 3274, the 2008 version, with brief allusions to S. 1482 (introduced in 2009, and representative of the current state of deliberation in the Senate) in support of its argument for the possible legislative influence of the NCTF process. This subsection addresses S. 1482 in more detail, in light of the both the findings from chapter five and the larger objectives of this chapter. There are several key themes in this bill that are relevant to the overall discussion:

1. EH&S, and societal dimensions issues more generally, are gaining in prominence, oversight scrutiny, and funding. The bill calls for the appointment of a Coordinator for Societal Dimensions within OSTP, specifically requires a separate strategic plan, and establishes a new advisory subpanel for this area;
2. A clear recognition of the need to strengthen central authority within the NNI in order to augment the initiative's coherence;
3. An increasing emphasis on commercialization and technology transfer; and,
4. Direction of research into areas of “national importance”, i.e. towards “opportunity-driven” (as opposed to “curiosity driven”) projects.

While some of the enhanced emphasis on job creation is a reflection of current economic conditions, much of the discussion predated the financial crisis. Themes three and four above were also included in the 2008 legislation, and there is increasing convergence between the NNI and the America Competes Act. In fact, the House in 2010 is considering combining the renewal of both into a single bill. All of these developments indicate that a consensus is growing around the conclusions of chapter five, i.e. that there are strong rationales for public investments in applied research to produce public goods. Further, there is an understanding that the NNI needs to be more than a research program in order to yield significant societal benefits, an important lesson for future efforts, such as the one proposed in section IV.

### **III.C Application of the Framework**

This evaluation is based on a projection of what the NNI will look like by FY 2012. That projection is drawn from the NNI's FY 2011 annual report (NNCO 2010b), the recent PCAST assessment of the NNI (PCAST 2010), S. 1482 (2009a), and H.R. 554 (2009b), the House counterpart to S. 1482 which passed by voice vote. Although S. 1482 has fallen victim to the general backlog in the Senate, and its fate in the 111<sup>th</sup> Congress is uncertain, there are enough commonalities between the two bills and the PCAST report to draw some conclusions. Additionally, the Executive branch has the authority to move on PCAST's recommendations without Congressional action, and officials in OSTP and the NNI have indicated a willingness to do so.<sup>16</sup> The NNI reauthorization bills have strong bipartisan support in both Houses; the question is not whether they will pass, but when, and in what precise form. The current analysis assumes that the final legislation will include most of the provisions of S. 1482, and employs the same framework used in section II.

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<sup>16</sup> Based on informal conversations at an NNI event on March 30, 2010.

### *III.C.1 Foresight with respect to Sustainability*

With some exceptions, the NNI scores rather poorly on this criterion. Its goals do not mention sustainability, and to date it has been oriented primarily towards science and technology push strategies. FY 2011 did see the introduction of three “signature initiatives” in support of the President’s priorities, two of which are relevant to sustainability (“Nanotechnology Applications for Solar Energy” and “Sustainable Nanomanufacturing”). While these initiatives are welcome, and underscore the shift towards “opportunity-driven” research, paralleling TIP and ARPA-E, they represent less than .5% of the total NNI budget, and there is no formal process for identifying and prioritizing future needs.

Perhaps the best hope in this regard is the overall strategic plan for societal dimensions research called for in both S. 1482 and the PCAST report. Applying the combination of anticipatory governance and sustainability to the development of this plan could yield significant improvements in the targeting of future signature initiatives, and map a path towards greater integration of sustainability into the NNI in general, in keeping with the notion of “anticipation as steering” articulated in chapter two. However, there is no guarantee that this will occur; it is merely an opportunity at this point. S. 1482 also includes some specific requirements with respect to “Green Nanotechnologies” for existing nanotechnology centers. While laudable in theory, significant progress in this area is unlikely in the absence of additional funding, as many of the centers probably lack expertise in these areas. On the whole, the NNI rates poorly in this area at this time, although some possibilities for improvement are in motion.

### *III.C.2 Engaging Stakeholders (including the general public)*

The NNI has done moderately well in this regard. The NCTF project detailed in chapter four arose from workshops sponsored by the NNI, and the NNCO has engaged in substantial outreach around both EH&S and commercialization issues (NNCO 2009; NNCO 2010b; PCAST 2010). The NNCO has been reasonably receptive to input from NGOs and academic stakeholders, and is generally viewed as an honest broker.

However, as argued in chapter four, there is still substantial room for improvement. If S. 1482 passes, it will be an imperfect step in the right direction. It includes meaningful funding for participatory efforts, establishes a new advisory subpanel for societal dimensions, and requires direct reporting to the relevant Congressional oversight committees of the results from public deliberation efforts, all of which is good. However, these efforts lack coordination with the triennial review processes. More importantly, it lacks a comprehensive vision of how to meld deliberative and representative democracy within NNI governance structures. Perhaps this is another opportunity for the societal dimensions research plan to tackle.

### *III.C.3 Anticipating Market Failures*

This kind of thinking, which characterizes chapter five, is fairly alien to the NNI. In contrast to TIP, which has been playing in these spheres for decades, thanks to its predecessor program, the ATP, the NNI seems to view commercialization from an “if you build (and promote) it they will

come” perspective. TIP (and ARPA-E) display a good understanding of potential future markets. S. 1482 and H.R. 554 do not demonstrate a similar level of sophistication. They focus on “government-push” out from R&D types of activities, which are not necessarily bad, but also do not necessarily square with success in deployment of solutions that advance the public good.

The various NNI proposals pay almost no attention to market realities, or to the intersection between public interventions and private markets that chapter five explores. The largest gap is the absence of any kind of comprehensive needs analysis. In private terms, this is market research. The public sphere is more complicated, but still requires some level of strategy development and gap analysis in order to target limited resources effectively. Within an anticipatory governance plus sustainability framework, there is need for a series of ongoing needs identification, analysis, and prioritization processes that include appropriate stakeholder input. While the signature initiatives are a step in the right direction, on the whole, the NNI merits a failing grade in this area, a fact that informs section IV.

#### *III.C.4 Risk/Benefit Tradeoffs within the contexts of Sustainability*

Again, this criterion points to areas of future improvement. Since the NNI does not meaningfully prioritize sustainability, it almost automatically fails on this measure. However, a simple pass/fail grade would obscure possible insights, so the question deserves additional consideration. The traditional bifurcation between promotion and regulation of emerging technologies raised in chapter one helps to shape a refined question: how can future initiatives better incorporate risk/benefit tradeoffs, including distributional ramifications, in their governance structures?

The NNI scores poorly here, albeit almost through no fault of its own. While sustainability offers useful theoretical assistance, including an implicit emphasis on distributional considerations, the NNI as currently structured is simply not in a position to address these kinds of issues simultaneously; it has no regulatory power. Additionally, combining power over risks and benefits in a single entity raises “foxes guarding the henhouse” issues. This dilemma points to the need for a new kind of organizational structure, one that allows comprehensive deliberations without undue vulnerability to regulatory capture. A decentralized structure, where the NNCO contracts out certification of private decision-making processes, similar to the ISO 14000 series of standards, might be a step in the right direction. While a concrete solution to this problem may well lie beyond the scope of this dissertation, it is clearly an area that requires additional attention in order to operationalize anticipatory governance successfully.

#### *III.C.5 U.S. Political Framing*

The NNI clearly rates highly in this area. It has enjoyed strong bipartisan support throughout its lifetime, which now spans three administrations. The failure to pass reauthorization legislation has much more to do with other priorities, and the overall political climate, than anything specific to the NNI. As noted previously, there are areas for improvement, but there is a reasonable consensus about what needs to be done – the primary question is whether funds can be found amongst competing priorities, and when. The NNI is a good example of how to make things happen in a polarized environment. In terms of anticipatory governance and



sustainability, it does not go far enough, but it is a good example of the “art of the possible”, and might provide a practical reality check for future proposals.

### *III.C.6 Institutional Capacity for Anticipatory Governance*

This has largely been covered in the other points, which might suggest that the framework could benefit from some condensation. However, one aspect that merits brief further amplification is the lack of a formal NNI mechanism to anticipate future needs. The program is making progress on with the ongoing development of a strategic plan for EH&S, which will hopefully be extended to societal dimensions writ more largely. The Signature initiatives are also a step in the right direction, but a systematic approach for identifying and prioritizing possible initiatives seems lacking. Many of the points raised under criterion four are relevant here as well. The NNI seems to be organizationally constrained, in that the NNCO has limited ability to act, and create structures for future action, on its own initiative. NNCO personnel are not at fault here, the problem lies with the delicate balancing act required of crosscutting initiatives, at least as operationalized to date.

The challenge for future institutional design is to create a structure that is sufficiently centralized and autonomous to help anticipate and shape future directions without sparking a turf war among existing agencies. As the discussion of the Global Change Research Initiative in section IV indicates, this is a “wicked” problem (Rittel and Webber 1973), especially since cross-cutting initiatives only make sense in addressing problems that exceed the capabilities of any agency acting alone. However, even though seeking definitive solutions to wicked problems is probably quixotic, one can still identify “better” or “worse” policy/strategy options, (Batie 2008). Uncertainty and complexity do not necessarily imply paralysis, but taking them as baseline assumptions does have significant ramifications for policy framing, design, and evaluation.

## **IV. National Sustainability Initiative**

This concluding section proposes a National Sustainability Initiative, not necessarily as a recommended course of immediate action, but as a scenario, in order to place the insights from previous sections and chapters into a plausible framework. In keeping with the theme of “operationalization”, it does articulate specific paths forward, and takes existing institutions into account. Consonant with the notion of anticipatory governance as a distributed capacity (Barben, Fisher et al. 2008), it also recognizes that the problem at hand is beyond the scope of any individual dissertation. More pointedly, both the tenet of engagement and political reality demand that any enterprise of this scope and significance involve multiple players over time. What this section does do is use the example of a National Sustainability Initiative to demonstrate how the questions summarized in table 4 can serve as viable institutional design parameters. The discussion begins with a review of two key existing federal initiatives regarding sustainability.

### **IV.A Existing Programs**

#### *IV.A.1 Global Change Research Initiative*

The Global Change Research Program (GCRP) originated in the Reagan administration, born of a happy conjunction of multi-agency synergy, the exogenous political pressure exerted by reports about the decline of the ozone layer, and early warnings about climate change, and administrative desire to defer legislation. Lambright (1997) provides an illuminative account of the dance of machinations and interests that led to the introduction of the GRCP as the “first” Presidential research initiative, and its subsequent ratification by Congress. Among other things, Lambright highlights the strategic use of research funding as an alternative to more direct policy action, and the critical role of authority relationships between the Office of Management and Budget (OMB), the Office of Science and Technology Policy (OSTP), and the panoply of involved agencies. The organizational considerations remain relevant with respect to both the NNI, and any future initiatives.

In many ways, the GCRP has been a resounding success. Its budget has grown from \$133M in FY 1989 to roughly \$1.8B in FY 2009, not to mention the fact that it has actually survived for two decades. It has produced a well-respected series of reports on the possible impacts of climate change at a variety of levels, and been a major contributor to the assessments of the Intergovernmental Panel on Climate Change (IPCC), which is widely seen as the authoritative source of information on the subject, albeit not without controversy. The U.S. is clearly among the world leaders in climate science, and much of that work has taken place under the auspices of the GCRP (NRC 2009).

At least for a time, the GCRP was also seen as a model of interagency collaboration, and its coordinating committee was a precursor to what is now the National Science and Technology Council (NSTC), which coordinates all Federal R&D under the auspices of OSTP. Although the GCRP may have initially suffered from the expansion of executive oversight under the Clinton administration (Lambright 1997), the NSTC now serves as a well-established framework for cross-cutting initiatives, such as the NNI. In that sense, the GCRP played an important role in developing the federal infrastructure for coordinated R&D, which facilitates the development of future initiatives.

At the same time, the GCRP was not, and is not without its problems. From its inception, there has been a tension between a focus on basic research, with an emphasis on the development of predictive models, and a mandate “to produce information readily usable by policymakers” (Brunner 1996). The GRCP has in some ways been a conjunction of high-level desires to substitute research for action and agencies seeking to insulate their “scientific” agendas by eschewing policy-related inquiry (Brunner 1996; Jones, Fischhoff et al. 1999; Pielke 2000a). Although the program continues to produce valuable research, these problems have persisted into the Obama administration, leading to a recent call for radical restructuring from the NAS (NRC 2009).

For purposes of this discussion, the GRCP highlights three key issues. First, crosscutting initiatives are subject to dynamic political pressures, especially in terms of bureaucratic infighting. Good institutional design can only go so far in the absence of appropriate champions in key agencies. Second, anything like a National Sustainability Initiative would need to work with the GRCP, the NNI, and other existing entities, and this cooperation will involve political struggle. Third, and perhaps most importantly, any initiative that seeks to treat innovation as a

national ecosystem, apropos parameter one, will encounter some deep-seated ideological obstacles.

The conflicts over the GRCP, ATP, the America Competes Act and so forth illustrate that the thinking of Vannevar Bush (Bush 1945) remains relevant to this day, albeit as a subject of contestation, rather than as received wisdom. Notions of a clear separation between science and society and linear models of scientific input into policy decisions retain significant rhetorical power, as do conceptions of “pure” science and objectivity. Pielke addresses these questions with respect to the GRCP in a series of articles (Pielke 2000a; Pielke 2000b), and also raises broader questions in collaboration with others (Pielke and Byerly 1998; Sarewitz and Pielke 2007). However one draws the boundaries, e.g. basic vs. applied science, various stages of research and development, public vs. private goods, etc., the fundamental tension remains. Future initiatives will have to address the perceived conflict between “curiosity” and “opportunity” driven science in ways that better match the “supply” of science to societal needs and demands (Sarewitz and Pielke 2007; NRC 2009).

#### IV.A.2 *Obama Initiatives*

The Obama administration has taken a number of actions that fall under the general rubric of sustainability. Building on momentum from the America Competes Act, the American Recovery and Reinvestment Act (ARRA) funded ARPA-E for the first time, provides significant increases for renewable energy and related projects in the DOE’s Office of Science, and also supports the development of “green” manufacturing approaches through NIST (U.S. Congress 2009). The climate change legislation pending before the Senate includes a host of additional measures, as well as a cap-and-trade system for carbon. While its future is uncertain, the recent oil spill in the Gulf of Mexico has put the topic back to the top of the Congressional agenda.

Less visible, but perhaps equally important is an executive order on Federal Leadership in Environmental, Energy, and Economic Performance. It is a superb example of locating sustainability firmly in the U.S. political context, recognizing both opportunities and constraints. Section 1 reads in part:

“In order to create a clean energy economy that will increase our Nation’s prosperity, promote energy security, protect the interests of taxpayers, and safeguard the health of our environment... Federal agencies shall increase energy efficiency; measure, report, and reduce their greenhouse gas emissions from direct and indirect activities; conserve and protect water resources through efficiency, reuse, and storm water management; eliminate waste, recycle, and prevent pollution...” (Obama 2009, 52117).

The framing is important. Even though the notion of sustainability pervades the details of this order, the word itself only appears late in section 1, and is not an overt selling point. However, the order does specify that “agencies shall prioritize actions based on a full accounting of both economic and social benefits and costs”, and clearly endorses the tripartite conception of sustainability. This approach fits with the idea that sustainability has a great deal to offer the U.S. as a practical organizing and measurement principle, even in the absence of full political consensus.

The order expands an initiative started in the 90's, as amended by the previous administration (Bush 2007). Significantly, the new policy requires agencies to set absolute greenhouse gas (GHG) reduction targets for continuous improvement, rather than relative energy intensity goals. It also includes firm objectives for recycling, water use, fossil fuel consumption of federal vehicle fleets, and the carbon neutrality of future federal facilities. Further, it mandates that agencies consider not just their own direct and indirect emissions, but also those of their supply chains. The emphasis on federal procurement is intended to help make markets for environmentally preferable technologies in addition to achieving direct sustainability goals. Put bluntly, this is an example of niche creation and transition management, American style.

The Obama version is also much stronger organizationally than previous versions. It requires agencies to develop sustainability plans as part of the larger strategic planning process legislated in the early years of the Clinton administration (U.S. Congress 1993). Additionally, it grants the OMB director and the chair of the President's Council on Environmental Quality (CEQ) joint authority over these plans, and explicitly incorporates the review thereof into the annual budget process. It also establishes a Steering Committee on Federal Sustainability, comprised of newly designated Senior Sustainability Officers from each agency, and co-led by the OMB director and CEQ chair. While these assignments, committees, and acronyms may seem opaque, the bottom line is that this executive order establishes a much stronger power basis than that enjoyed by TIP, the NNI, and the GCRP, because planning and performance under this order are tied directly to the regular agency budgeting process. As such, it could serve as a useful springboard for future organizational designs.

In essence, this order constitutes a sustainability initiative for the Federal Government. In contrast to previous examples, it does not include research, or invest in the development of new technologies. Rather, it focuses on the government's capacity to make markets through its direct purchasing power, and indirect ability to demand contractor compliance with tangible sustainability targets. As such, it is a valuable complement to R&D oriented strategies, and the combination thereof points the way towards more integrated efforts. It is worth noting, though, that regulation is still omitted from the overall equation, which suggests the need for additional development.

#### **IV.B Next Steps**

As hinted in section IV.A, actualization of something resembling a National Sustainability Initiative (NSI) would require intensive interactions in Washington over a period of years, from a position of authority not available to this dissertation. However, it is feasible to sketch a process to develop an institutional solution to the needs that an NSI would be intended to address. The appropriate form of this putative program is unclear, and it is possible that a separate initiative in this area would actually be counterproductive. The primary aim of this subsection is again to demonstrate the applicability of the combination on anticipatory governance and sustainability to institutional design, as mediated through the framework articulated in table 4. The secondary claim is that the time is appropriate to investigate the possibility of establishing an NSI. Much work remains prior to the presentation of a formal plan for Presidential, and ultimately

Congressional approval. However, the preparatory work could and should start now, in order to have something ready for the FY 2013 budget submission.

Following the examples of both the GCRP and the NNI, the time is ripe to establish a new interagency working group (IWG) within the NSTC. Co-chairs should come from the Committees on Environment and Natural Resources and Technology, with strong input from the Committee on Science. Representation from the GCRP and the SCFS will be critical, as it is entirely possible that the NSI would subsume both of these programs in time. The precise name is not critical; the Sustainability IWG (SIWG) will suffice for purposes of this discussion.

SIWG would be charged with developing an NSI proposal. The precise form, timing, and even the name, should not be fixed a priori. Rather, this group's task would be to articulate a practical plan for moving the country towards sustainability, recognizing that establishing ongoing participatory processes for defining and redefining sustainability is an essential element of the project. Selecting which agencies, and which programs within agencies, might participate at the outset, and which others might join over time, is also part of the charge, informed by the experiences of the GCRP and the NNI. The exact authority structure is another key matter to be determined, again drawing from the advantages and disadvantages of previous models.

The framework articulated in Table 4 serves as a basis for this preliminary design. None of the factors should be considered in isolation, as they are tightly interwoven, but some separation is necessary for expository purposes. It might be helpful to view this section as a first draft of a future executive order or OSTP memo establishing the SIWG. Whether or not this proposal comes to pass, it is a useful vehicle for demonstrating how the research program set forth in this dissertation could translate into practical action, i.e., as an instance of operationalizing anticipatory governance in the contexts of sustainability.

#### *IV.B.1 Foresight with respect to Sustainability*

Transforming the U.S. into a sustainable society is a huge undertaking, of which the governance of emerging technologies is only a small part. However, it may be only of the more tractable pieces, as it lends itself to the construction of tangible scenarios around specific possible applications. The SIWG should give serious consideration to institutionalizing a backcasting (Robinson 2003; Swart, Raskin et al. 2004; Quist and Vergragt 2006; Carlsson-Kanyama, Dreborg et al. 2008) function in the NSI. One of the early goals would be to identify a broad range of possible societal needs and desires, and then to prioritize those where technological innovation is most likely to make a positive contribution. This dissertation has argued that at the moment, the intersection between the environmental and economic pillars of sustainability offers the most promising area of opportunity, but the SIWG should not assume that those conditions will obtain in the future.

Obviously, such exercises will need to be iterative, and involve a wide group of stakeholders. It might be prudent to begin with bounded topic areas, e.g. the sustainable provision of potable water within the southwestern U.S., in order to gain experience. Again, the U.S. poses scale problems not generally found in Northern Europe where many of these exercises have taken place to date, so starting at the regional level might simplify the translation challenges. The

SIWG should also consider ways to cumulate the results of multiple iterations. The Multi-Criteria Decision Analysis approaches mentioned briefly in section II.A might be useful in this regard. These techniques, particularly the Analytic Hierarchy Process (AHP) (Saaty 1994), are well-suited for the evaluation of nominally incommensurable criteria, and handle uncertainty and incomplete information well. They also allow the incorporation of both objective and subjective results in a comparable framework, which would be invaluable in this instance.

Of course, the questions of which topic areas to pick first, and who to include in initial discussions would be problematic. Practically, the conversation would probably need to begin with the SIWG, and then expand to a larger set of Federal and external stakeholders. Over time, it would be essential to involve the public in the conversation, the subject of the next section. There is also the question of how to involve Congress, the duly elected representatives of their constituents. Participatory foresighting and/or backcasting raises thorny issues at the intersection between expertise, and representative and deliberative visions of democracy. Answers would need to be developed in practice over time.

#### *IV.B.2 Engaging Stakeholders (including the general public)*

The inescapably normative nature of visualizing “desirable” futures makes this an excellent locus for public participation, and a superb venue for discussion of the various meanings of sustainability. There are clearly practical issues to overcome in the integration of public and expert input, and in connecting both with policy (Kowalski, Stagl et al. 2009; Mahmoud, Liu et al. 2009; Meadowcroft 2009). For example, chapter four identifies some very practical modifications to the NNI reauthorization legislation that would enable constructive experiments, and improve integration of public input with established review mechanisms. If the NNI adopts some of these recommendations, those exercises would provide valuable guidance in expanding to a higher level of capacity with the NSI.

The SIWG should take the lessons from the NNI into account, and design public and stakeholder input into the process from the ground up. Renn’s analytic-deliberative framework (Renn 1999) provides a superb theoretical outline for doing so that is well-grounded in experience. The key question is: where do citizens have both competence and standing to engage constructively in policy debates? The answer lies in the realm of values, priorities, and societal needs. Technical expertise clearly matters: the average citizen has little knowledge of the life-cycle viability of various CO<sub>2</sub> sequestration strategies, or the adequacy of disaster planning for deep-water oil spills. However, regular folks in the U.S. are quite familiar with evaluating expert counsel in terms of their cars, houses, personal health, etc., and balancing that advice with their own preferences and priorities. In other words, interested citizens bring their own expertise, and a unique perspective, to the governance of the science/technology/policy interfaces.

At the same time, it is important to note that public participation is not a panacea. Poorly designed or timed participation can exacerbate pre-existing problems, especially when it is seen as a mechanism to justify prior decisions (Macnaghten, Kearnes et al. 2005; Genus 2006; Rogers-Hayden and Pidgeon 2007; Stirling 2008). SIWG’s challenge is again one of translation; integrative models have worked well at local and regional scales, but operationalizing such efforts across the U.S. in a global context raises the stakes by one or more orders of magnitude.

While chapter four details one success at this level, it is a limited example, and the breadth of issues encompassed by sustainability raises the bar. Experimentation at multiple scales, methods, and foci is in order. We in the U.S are faced with a new set of problems, and we won't know what works in which situations until we try it. The combination of anticipatory governance and sustainability implies a hypothesis approach to policy, and the SIWG needs to adopt such a stance, recognizing that it poses risks to established Washington funding practices. The NSI needs to provide a certain level of “air cover” for policy innovation, accepting that some percentage of experiments will fail. There is room for a “venture capital” conception of governance, with the key difference being the lack of a need to provide extraordinary private returns in producing public goods.

### *IV.B.3 Anticipating Market Failures*

Both chapter five and several earlier sections in this chapter have touched on the relationship between sustainability-driven needs assessment and the identification of prospective market failures. To recap briefly, the process is to identify societal problems to which there might be promising technological solutions, and then to pinpoint specific areas where the kinds of barriers to entry and deployment detailed in chapter five justify public intervention. As articulated so far, though, this line of analysis has not fully considered the perspective of innovators. Viewing the forces and elements that shape the constructive intervention space as a “national innovation ecosystem” may be helpful to the SIWG in this regard.

Chapter five highlighted some of the diverse programs that the U.S. has adopted in order to help innovations bridge the “Valley of Death”, and also pointed out that there may be more than one such valley. While some enterprising entrepreneurs have been successful in stitching together a variety of public and private funding sources available at various stages, no U.S. initiatives to date have yet addressed the full innovation cycle in a coherent fashion. Viewing the problem in systems terms might help the SIWG to develop more comprehensive solutions throughout the innovation life cycle. While a systems approach is inherent in much of the transition management literature, its application to the U.S. has been rare, and needs further development (Tassey 2010).

Tassey's model of a national innovation ecosystem might be useful to the SIWG in several ways. First, his holistic view might aid in pinpointing the contours of future governance caps, market failures, and constructive intervention opportunities. Second, this perspective might help elide the increasingly artificial distinction between basic and applied research (Pielke and Byerly 1998). TIP and ARPA-E both exemplify movement in this direction, as do the recent “Signature Initiatives” from the NNI. A key question for SIWG is how to pacify, or at least dampen, resistance from those with a perceived stake in maintaining the purported firewalls between science and society, policy, and outcomes. Vannevar Bush's vision has worked extremely well for a certain segment of the scientific community, and the NSF's recent emphasis on “broader impacts” as well as “intellectual merit” has perversely rewarded those individuals gifted at scientific storytelling, without necessarily producing improved results with respect to public goods.

Third, and perhaps most importantly, the vision of a national innovation ecosystem could help render some of the arguments about the government picking “winners and losers”, or crowding out private investment that were so fatal to the ATP less relevant (see chapter five for details). Tasse’s depiction shows the government interacting naturally with the private sector, NGOs, and universities as part of a larger whole. The SIWG should explore extensions to and applications of these ideas, as such efforts could help change the debate from “whether” the government should intervene in terms of innovation to “when”, “where”, and “how”. Chapter five presents strong evidence for the existence of a governance gap/constructive intervention opportunity in the arena of environmental public goods. The SIWG would need to both further articulate the boundaries of constructive intervention, and propose specific programs that would actually make a difference.

#### *IV.B.4 Risk/Benefit Tradeoffs within the contexts of Sustainability*

The question of metrics is critical to this criterion. Chapter two establishes the value of viewing sustainability as a boundary object, which implies the need for a multiplicity of context-specific metric sets. The question then becomes: which metrics should we develop and employ in which contexts, and how should we go about doing so? This is closely connected to the notion of identifying critical national needs set forth in section IV.A, as evaluative metrics will play a key role in shaping the implementation of programs designed to address such needs. In theory, evaluative metrics should also shape subsequent solicitations, need prioritizations, and future program design. It would probably be best for the SIWG to address this question from the bottom-up, outlining metric categories, development procedures, and evaluation processes as a further charge to specific subsequent programs, rather than attempting a “one-size-fits-all” approach. In other words, practical implementation of sustainability needs to take regional and local variables into account; a one-size-fits-all approach is likely a prescription for failure (NRC 2009).

Another key question is how to integrate regulation into the overall picture? Any initiative that seeks to address the full (often non-linear) path from invention to innovation to public goods success needs to incorporate prospective regulatory developments. Although the NNI has made some attempts in this direction in terms of stakeholder outreach, none of its initiatives to date have produced tangible results. SIWG would face a challenge in this regard; how can we best reconcile promotional and regulatory responsibilities? One of the theoretical promises of the tripartite conception of sustainability is that it offers the possibility of a comprehensive framework for risk/benefit tradeoffs that incorporates distributional considerations by definition. In order to operationalize this notion, though, we need a better understanding of where critical decisions regarding technological deployment are made now, and what factors influence those choices.

The empirical interview data from chapter five is sobering in this regard, as it indicates that smaller firms and venture capital outfits find a comprehensive risk/benefit framework alien, without even considering distributional consequences. Even in medium and larger size enterprises, the precise location and valences of product development decision points in interaction with existing and expected regulations and societal perceptions remains fuzzy. The SIWG will probably not have the resources or the luxury of time to fund comprehensive studies



of these issues. Rather, they should focus their efforts on known leverage points, such as those offered by programs like TIP and ARPA-E, and to a lesser degree the NNI, while remaining receptive to independent input.

#### *IV.B.5 U.S. Political Framing*

In some ways, this is the most difficult challenge of all, especially over time. The transition to sustainability, if it occurs, will take decades or more. Ultimately, sustainability needs to be seen as a public good on a par with national defense in order to enjoy the necessary levels of public support over time. While the concept has gained a great deal of currency over the last several decades, it has not yet attained that level of consensus in the U.S. In the interim, the notion of transatlantic translation has an important role to play.

Two themes seem to have consistent resonance in post-war America: national security and national competitiveness. The two clearly come together in discussions of energy policy, although there is still a great deal of resistance to any kind of carbon pricing scheme on economic grounds. As noted in chapter one, the idea of “green jobs” appears to have some appeal, although it is unclear how long that will last, especially if results fail to live up to promises. A third factor is that advances in environmental regulation tend to be crisis-driven; the Deepwater Horizon spill in the Gulf of Mexico may prove to be such an event, but it is too soon to tell.

The notion of a “new contract” for science and technology (Pielke and Byerly 1998; Sarewitz and Pielke 2007) has some potential. However, it needs a framing that captures the national imagination, as the Apollo program did, but under more difficult circumstances. Putting a “Man on the Moon” appealed to the U.S. “frontier” ideology, visions of technological progress, and competition with the Soviets, and also delivered visually compelling images. Sustainability will require much more international cooperation, is not entirely amenable to technological solutions, and is as much about mitigating catastrophe as it is an opportunity for unambiguous collective triumph. This is a political problem that the combination of anticipatory governance and sustainability does not solve. However, operationalizing the two together can help in identifying victories along the way, and in improving the delivery of public goods.

#### *IV.B.6 Institutional Capacity for Anticipatory Governance*

The existing initiatives and programs reviewed above are extremely weak in this area, and it is a serious challenge for the SIWG. The obvious need is for something like the OTA, without the OTA’s constraints. Some advocates of anticipatory governance argue for the development of a distributed capacity in this regard, involving a quasi-formal network of universities, NGOs, and interested others (Sclove 2010). While that model has value, and could contribute to an overall whole, it lacks the compelling political power evidenced in Executive Order 13514. The SIWG has work to do; how should we best combine centralized legitimacy and authority with decentralized locality and relevance?

The concept of national needs has some integrative potential at the political level, although it will and does engender resistance from elements of the scientific community. TIP and ARPA-E are perhaps the most advanced in this regard, although their methodologies could use substantial

improvement, particularly in terms of public participation. Although the idea of institutionalizing foresight collides with orthodox free-market ideologies in a number of ways, the notion of anticipating market failures offers a path forward. The idea that pure market incentives systemically lead to socially suboptimal levels of investment in public goods is well articulated (e.g. Ostrom 1998; Martin and Scott 2000; Branscomb and Auerswald 2002; Beard, Ford et al. 2009). What is missing is a systematic investigation of where such failures are likely to harm the public interest, especially on an ongoing basis.

A restructured GCRP could provide a natural home for such capacities. The recent NAS review calls for an overhaul of the program, reorganizing it by areas of expected future need, rather than academic discipline. It also recommends significant enhancement in the integration of social and natural science data in evaluating possible mitigation and adaptation strategies (NRC 2009). Given the Herculean nature of the climate change challenge, it is almost certain that markets alone will not suffice, so identifying probable areas of market failure as points for public intervention is necessarily part of the effort. Although the GCRP does focus more on prediction than a “pure” anticipatory governance approach, the IPCC and others have employed scenarios extensively, and the GCRP will need to do so as it moves to a regional focus. Mitigation and adaptation scenarios will also require substantial socialization in order to secure public acceptance, pointing to an important role for engagement. In other words, the GCRP would be a good test for the combination of anticipatory governance and sustainability, assuming that the administration adopts the bulk of the NAS recommendations.

The SIWG will need to carefully consider possible interactions between the NSI and the GCRP. Although there is substantial overlap, and in the long term, the NSI might subsume the GCRP, it may make sense to keep the two separate at the outset. The GCRP’s problems are of long standing (Brunner 1996; Jones, Fischhoff et al. 1999; Pielke 2000a), and climate change is of sufficient importance, that it may be prudent to give the GCRP time to get its house in order before adding complexity. As previously noted, the NSI might need to start out as the National Sustainable Technologies Initiative, or something similar, in order to carve out a distinct arena. Even if the two are separate, they clearly need to interact, and the SIWG should clearly articulate practical mechanisms for them to do so as part of its proposal.

Another possibility for institutionalized anticipation would be for TIP and ARPA-E to join forces in needs identification. This could occur under the auspices of SIWG, and the EPA, other branches of NIST and DOE, and the NSF could also contribute. Such a joint solicitation selection effort could reduce duplication, and advance progress towards the innovation ecosystems theme outlined in subsection one. It would also be useful for this group to expand on their existing contacts with the private investment community, in order both to identify areas of public goods that are unattractive to VCs and others, and to minimize public “crowding out” of private funding.

## V. Concluding Remarks

This dissertation argues that the combination of anticipatory governance and sustainability provides a foundation for policy and strategy in the U.S. that is superior to existing approaches. The conjunction transcends the dichotomy between risk regulation, free-market principles, and

technology boosterism that has characterized post-war U.S. policy, and avoids the baggage associated with the Precautionary Principle in U.S. sociopolitical contexts. Anticipatory governance provides a future orientation, and a philosophy that questions the validity of overly positivist conceptions of science, including the received wisdom regarding the separations between science and policy, and between basic and applied science. Sustainability provides direction in determining what to anticipate, focuses technological governance on meeting tangible societal needs, and provides a framework for making risk/benefit tradeoffs with an eye towards distributional consequences.

Within that theoretical framework, the chief practical question has been “how best to operationalize the combination of anticipatory governance and sustainability”. Chapters three and four in particular sought to instantiate the practice with respect to risks and societal engagement, respectively. The chief lesson of chapter three relates to decision-making under conditions of prolonged uncertainty, the need to make concrete choices in the absence of conclusive data. In this practical sense, anticipatory governance is more about attitudes towards uncertainty than it is about differentiating between foresight and prediction. Chapter four is an example of engagement that benefitted from a fortuitous opportunity to contribute to the policy process. This happy accident points a way towards constructive integration of public and expert inputs into the legislative cycle, and should inform future designs.

The contributions of chapters five and six, while no less significant, are somewhat less clear cut, and are therefore best summarized in bullet form under the headings of “findings” and “questions”, the latter suggesting research and policy trajectories for the future:

#### **V.A Findings**

- Taking uncertainty as a given can aid in formulating decisions with respect to “wicked problems”.
- With proper design, citizen input can play a constructive role in policy formulation, even in highly technical cases.
- The purported “Valley of Death” is real, particularly with respect to public goods
- Well-targeted public interventions can and have achieved tangible results in bridging this “Valley”, and an explicit focus on public needs analysis would yield additional benefits.
- Only large multinational firms seem comfortable with explicit risk-benefit tradeoffs with respect to particular product lines.
- Several recent U.S. Congressional and Presidential actions point the way towards successful transatlantic translation of recent European approaches to technology assessment.
- The U.S. continues to lack a coherent capacity for technological foresight, but there are a number of possibilities to build on existing initiatives.

#### **V.B Questions**

- What will it take to displace or overcome the still politically powerful mythology of the separation of science from policy and society, and the artificial division between basic and applied research?
- Recognizing that sustainability, while it has made substantial progress in the last three decades, still lacks political consensus in the U.S., how can a “stealth sustainability” approach productively inform policy and implementation?
- Given continued ideological resistance, what are the best strategies for developing an explicitly public goods driven model of technological research and development?
- What kinds of framing devices might be most effective in engendering support for a market-failure based targeting approach to public intervention within the larger context of a market-valuing culture?

Further, the combination of anticipatory governance and sustainability, while not offering a panacea, does suggest two additional avenues for future research and experimentation. The first is organizational: What characteristics do we need our public institutions to exhibit in order to make societally efficacious decisions on contentious matters under conditions of poor generalizability, ongoing uncertainty, and distributed authority? How should we go about developing such capacities in both individuals and organizations? The second is normative: given the dynamics of governance gaps, formal policy and regulation is likely to continue to lag innovation in the case of emerging technologies. In such cases, decision-making power is likely to reside with individual actors, which implies that “soft” vehicles such as norms are among the only means for society to influence these choices in a timely manner. What does this mean for policy development and legislation, and for our strategies of governance more generally? Should norm promulgation become a prominent policy instrument? If so, how, and how do we decide which norms to endorse and promote? In practice, while there is no single answer to the question: How should we best operationalize anticipatory governance in order to steer emerging technologies towards sustainability, it is clear that the problem is inescapably political. In some sense, the questions of this dissertation can be boiled down to one phrase: “How can we make democracy better with respect to the governance of emerging technologies”, and the answers are “via inspired experimentation”. This dissertation humbly hopes to be an example thereof.

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