

# 1 INTRODUCTION

## The Challenge of Biosecurity in the Twenty-First Century

### I. THE UNFOLDING POLICY REVOLUTION OF BIOSECURITY

In the first years of the twenty-first century, the United States and the rest of the world have endured shocks, crises, and fears captured in the haunting images, words, and events that define our turbulent times—September 11th, Al Qaeda, weapons of mass destruction, USA PATRIOT, axis of evil, SARS, quarantine, HIV/AIDS, Guantanamo Bay, Abu Ghraib, Darfur, bird flu. This troubling lexicon captures pressing dangers individuals, countries, and the international system face today.

Some of these dangers are not new, such as war, tyranny, and torture. They represent recent manifestations of age-old threats to human dignity, national security, and international peace. Other dangers combine, however, to create new threats to individuals, countries, and the global community with few, if any, precedents. This book focuses on one of these new dangers—the threat infectious diseases pose to human life, the security of states, and international political and economic stability. In short, the world confronts a serious biosecurity threat.

The argument that something called *biosecurity* has emerged as a new issue in national and international politics may be greeted with skepticism because states addressed challenges posed by biological weapons and naturally occurring infectious diseases for most of the twentieth century. The Geneva Protocol banned, for example, the use of bacteriological agents in warfare in 1925 (Geneva Protocol 1925). States established international health organizations tasked with cooperation on infectious diseases in the first decade

of the twentieth century (Rome Agreement 1907; Weindling 1995). In addition, international cooperation on infectious diseases dates back to at least the mid-nineteenth century (Goodman 1971; Howard-Jones 1950; Howard-Jones 1975).

The emergence of biosecurity as a policy concern connects, thus, to historical efforts made to address biological weapons and infectious disease epidemics. What has transpired recently, however, represents a policy revolution, the implications of which are still unfolding and are not yet fully understood. So much of such importance has happened so rapidly with respect to the challenges of biological weapons and infectious diseases that synthesis presents a daunting challenge. This book takes up the challenge and explores the emergence of biosecurity as a critical policy area in the first decades of the twenty-first century.

## II. MAIN ARGUMENTS OF THE BOOK

We argue that biosecurity encompasses threats from both biological weapons and naturally occurring infectious diseases. The policy revolution that biosecurity represents requires integrating two policy realms previously separate from one another—security and public health. We stress the importance and difficulty of this integration strategy throughout this book. Integrating security and public health requires changing entrenched perspectives and practices and building new, sustainable governance approaches to threats posed by pathogenic microbes.

As discussed more later, our argument about integration touches on one of the many controversies that surround biosecurity. Traditionalists in both security and public health resist weaving these new areas together. The integrative task is, however, critical. Approaching this task forthrightly forces both security and public health leaders to re-think their approaches to the challenges of governance convergence. One of the most important of these challenges involves the role of the biological sciences in the pursuit of biosecurity. We argue that the development of the biosecurity challenge requires supervision of the biological sciences as part of the integration of security and public health.

The policy thrust for such supervision comes from worries that malevolent actors may transform scientific advances into weapons of mass terror and destruction. We acknowledge the prudence of these worries and accept the need for oversight to prevent or deter misappropriation of scientific progress for evil ends. The dynamics of oversight cannot, however, sacrifice science's

critical function in improving humanity's health on the altar of narrowly construed notions of national security.

As illustrated by the novel challenge of balancing scientific freedom and security fears, the integration of security and public health requires policy makers to engage in complex decisions often characterized by a lack of complete information. We argue that, in such an environment, embedding biosecurity policy in the rule of law becomes critical. Whether the issue is the supervision of science for security and public health or another of the myriad challenges biosecurity presents, the governance framework provided by the rule of law approach serves as a lodestar for biosecurity policy.

Our belief in the rule of law does not mean we claim that this approach always provides the "right" response. The choices biosecurity threats force policy makers to confront are too complex and contingent for any approach to be foolproof. We do assert, however, that the rule of law philosophy of governance provides a tested methodology for policy formulation and execution that allows material interests to be pursued without losing sight of core normative values.

The integration of security and public health within the rule of law raises the problem of achieving these ends in a world increasingly characterized by globalization. We argue that effective biosecurity policy has to involve globalized forms of governance. As with many policy areas transformed by globalization, security and public health can no longer view the world through the state-centric lenses of national governments and intergovernmental coordination. Governance mechanisms have to reflect the malevolent and benevolent roles non-state actors play in world politics.

Crafting effective globalized governance for biosecurity is, however, difficult. The enormity of the challenge often tempts people to revert to traditional governance approaches, especially retrenchment into narrow conceptions of a nation's self-interests in security and health. As the book explores, these backward-looking reversions have a powerful logic that flows from the sheer difficulty of making globalized governance work coherently. We acknowledge this difficulty but maintain that biosecurity, even narrowly defined, cannot be achieved and maintained in a sustainable way without robust globalized governance efforts.

The book develops these arguments in greater detail, but, before launching into systematic analysis, more introductory context for the biosecurity policy revolution would prove useful to readers. We have designed this book

to be useful to different academic and policy disciplines, so establishing some baseline understanding with our readers on key themes is useful. The next sections of this chapter accomplish this objective by exploring the concept, controversies, and key challenges of biosecurity policy in the early twenty-first century.

### III. THE CONCEPT OF BIOSECURITY

We generally define *biosecurity* to mean society's collective responsibility to safeguard the population from dangers presented by pathogenic microbes—whether intentionally released or naturally occurring. With respect to the malevolent use of microbes, our use of the term *biosecurity* is not novel because many experts have used it to describe efforts to defend against threats from biological weapons and biological terrorism. These threats are indeed primary subject matter for biosecurity policy, and Part I of this book addresses the threat of violence perpetrated through biological means, or what Kellman has called the perpetration of bioviolence (Kellman 2006b).

Our approach to biosecurity includes, however, more than the development and use of biological weapons. Biosecurity concerns two intertwining strands of pathogenic threats that include biological weapons and naturally occurring infectious diseases. Biosecurity is as much about public health as arms control because of the dangers infectious diseases pose to human societies in the twenty-first century. We agree, “Biological security . . . must address both the challenge of biological weapons and that of infectious disease” (Chyba 2001, 2349), and “We need to pay much closer attention to biological security” to build “an effective global defence against bio-terrorism and overwhelming natural outbreaks of deadly infectious disease” (UN Secretary-General 2004, viii). Understanding the threats of naturally occurring infectious diseases and biological weapons “is critical to formulating an effective biosecurity policy” (Grotto and Tucker 2006, 1). The threats presented by biological weapons and natural disease epidemics weave together to form an interdependent policy challenge the likes of which we have never seen before.

Acknowledging interdependencies in policies on biological weapons and infectious diseases does not mean that all infectious disease outbreaks are biosecurity problems. Many infectious disease events remain localized, low-impact outbreaks. To include these infectious disease issues within the scope of biosecurity wrongly equates this concept with public health generally. The biosecurity concern is with infectious disease outbreaks and problems, what-

ever their source or origin, that could potentially disrupt the normal functioning of societies.

Societal disruption is not, of course, a concept capable of precise measurement or prediction because too many factors are involved. Infectious disease outbreaks can powerfully affect the human psyche in ways that extend beyond statistics on death and illness. Even harms that are small statistically can generate destabilizing effects within and among societies. The social, economic, and political disruptions caused by the anthrax attacks in 2001 and the outbreak of severe acute respiratory syndrome (SARS) in 2003 illustrate the disruptive potential of even low morbidity and mortality events.

Our approach to biosecurity deviates from traditional policy perspectives on what “security” means. Security has historically been concerned predominantly with threats of military violence by one state against another state. In our view, the least pressing biosecurity concern involves the possible use of biological weapons by one state against another state. Although our concept of biosecurity includes the potential for inter-state use of biological weapons, we recognize as security concerns possible biological attacks perpetrated by non-state actors—bioterrorists—and the transnational threat presented by naturally occurring disease epidemics.

Expanding the notion of security beyond its conventional paradigm has proved controversial, whether the focus of the expansion involves pathogenic threats, environmental degradation, or other candidates for new security challenges (see more later). Threats of military conflict by one state against another remain security concerns, as worries in the United States about China’s growing military power, North Korea’s claimed possession of nuclear weapons, and Iran’s alleged pursuit of nuclear weapons suggest. Conventional wisdom about security does not, however, provide sufficient guidance when we consider the spectrum of serious threats posed by infectious diseases.

The frequency and intensity with which bioterrorism and the specter of contagious pandemics have appeared on U.S. national and homeland security agendas indicate that significant real world developments inform our analysis (White House 2002; Office of Homeland Security 2002). In its latest *National Security Strategy*, issued in March 2006, President George W. Bush’s administration again conceived of “public health challenges like pandemics (HIV/AIDS, avian influenza) that recognize no borders” as a national security problem related to globalization (White House 2006a, 47). The Bush administration argued that the risks to social order from naturally occurring

disease epidemics can be “so great that public health approaches may be inadequate, necessitating new strategies and responses” (White House 2006a, 47). One of these new strategies and responses is to conceive of naturally occurring infectious diseases as security threats, as we do in our definition of biosecurity.

As subsequent chapters discuss, the real challenge is not justifying the shift away from conventional wisdom on what security means. Rather, the task involves how best to balance the need to protect against the proliferation of biological weapons and the perpetration of biological attacks by terrorists and the need to address threats presented by naturally occurring infectious diseases. Calibrating these aspects of biosecurity constitutes a policy challenge wholly unlike previous security tasks, such as how much political détente and how much nuclear deterrence the United States needed to address the Soviet threat during the Cold War. This unprecedented task also affects traditional understandings of public health, as the position of the Bush administration in its latest *National Security Strategy* demonstrates.

#### **IV. THE CONTROVERSIES OF BIOSECURITY**

The emergence of biosecurity has generated significant controversies at virtually every level and step of analysis. For that reason, the terrain of biosecurity policy is a conceptual and practical minefield, making it a very politically charged arena of debate. The disagreements begin with attempts to define security in ways that include more than inter-state military violence. Efforts to include naturally occurring infectious diseases within security thinking form part of a larger controversy about redefining security, especially national security, away from its traditional state-centric, military-biased perspective. This conventional perspective has been particularly strong in the United States because “traditional definitions of U.S. national security have focused almost exclusively on the potential of violent attack by other countries on the United States, its citizens, and its vital overseas interests” (Bergen and Garrett 2005, 1).

Many security experts are leery of expanding the traditional concept of security to include new types of threats from non-state actors or transnational phenomena. In some respects, this wariness is warranted because discourse on new security threats often threatens to collapse notions of security with notions of governance (e.g., as happens with the concept of human security). In other respects, security traditionalists are fighting a losing battle. The

terrorist attacks of September 11th laid to rest the debate whether non-state actors really represented national security threats to the United States. With the traditional state-centric framework penetrated, policy space has opened for considering the potentially disruptive effects of transnational, nonmilitary phenomena. The Bush administration's willingness to include threats from naturally occurring infectious diseases repeatedly in its national and homeland security strategies suggests that a sea change, however controversial, has indeed occurred. Leading nongovernmental analyses also reflect this sea change (Grotto and Tucker 2006; Ikenberry and Slaughter 2006).

In addition to disagreements about what threats security policy should address, many other controversies have accompanied biosecurity's emergence as a new policy endeavor. Debates rage, for example, about what type of security threat bioterrorism really presents to countries today. Some, such as former Senator Bill Frist, have argued that bioterrorism constitutes one of the most serious existential threats to U.S. national security in the early twenty-first century (Hirschler 2005). Other analysts challenge this assessment and assert that bioterrorism is not one of the most pressing issues facing the United States or the world today (Leitenberg 2004, 2005).

This controversy contains many issues on which experts diverge. Are terrorists really interested in developing biological weapons and engaging in biological attacks? How easy is it for terrorists to weaponize pathogenic microbes and use biological weapons effectively? Should scientific freedoms be curtailed to ensure that peaceful research and development do not inadvertently facilitate the malevolent use of microbes? How much can policies pursued to defend against biological weapons also be productively exploited in addressing threats from naturally occurring infectious diseases? What is the right way to govern events that are characterized by low probability but potentially extreme consequences? These questions and others force policy makers and scholars to confront hard choices in an environment permeated by uncertainty concerning risks and benefits.

Controversies also appear when biosecurity policy turns to infectious disease epidemics. Many public health practitioners and experts have viewed with skepticism and concern the "securitization" of public health. Such attitudes suggest that conceiving of public health as a security issue poses dangers for public health's mission of protecting and promoting population health. A key danger is that a security focus will force public health to concentrate resources and personnel on rare events (e.g., a bioterrorist

attack or highly contagious pandemic) at the expense of tackling health problems that cause the great death and illness in populations daily. For example, some public health experts have expressed concern that initiatives focusing on communicable diseases divert attention away from the growing global toll that non-communicable diseases cause (Yach, Leeder, Bell, and Kistmasamy 2005).

Throughout the book, we take up many of the most serious controversies that make biosecurity policy important, intriguing, and unsettling. Our approach will not make everything fall magically into place and thus transform the controversies of biosecurity into the mere teething pains of a nascent transition to a new policy consensus. Having experienced the rough terrain of biosecurity in our professional work, we are mindful of the limitations of our analysis. We do aim, however, for this book to help biosecurity policy move beyond the disaggregated, disjointed, and dysfunctional jumble of controversies that now overshadows this emerging area of governance.

## **V. THE CHALLENGES OF BIOSECURITY**

The deeper we delved into the controversies of biosecurity, the more aware we became that behind the sound and fury of disagreements lurked deeper issues—what we identified as the central challenges of biosecurity. These challenges drive the structure and substance of our arguments in this book because they make transparent the foundations on which effective and sustainable biosecurity policy and governance must be built. Too often in our work on this book we have sensed ourselves unable to see the forest of biosecurity for all the trees—the proliferation of proposals, projects, policy wonks, and polemics on how to make the United States and the world safe from biological harm. The more frenzied the biosecurity debate became, the more convinced we were that these challenges give the frenzy underlying focus and direction. Identifying and unpacking these challenges may, for many readers, be more valuable than the recommendations we make on pursuing them.

The main arguments of this book briefly described earlier capture these four central policy challenges. Effective biosecurity policy and governance requires, nationally and globally, the integration of security and public health, supervision of science for security and public health, embedding biosecurity policy in the rule of law, and globalizing governance for biosecurity. This section explains these challenges in more detail and emphasizes not only their importance but also the difficulty of achieving these objectives.



### **A. Integrating Security and Public Health**

We argue that biosecurity will not be achieved within and among countries without effective integration of the policy worlds of security and public health. Whether the threat comes from biological weapons or naturally occurring disease epidemics, biosecurity policy confronts the task of integrating security and public health. As indicated earlier, skepticism and concern about such integration exists in both the security and public health worlds. The worry is perhaps greatest in public health, given the imbalance of power and resources between security bureaucracies and public health agencies. We understand these public health fears, which, as later chapters explore, are not unfounded. We maintain, however, that integration of security and public health is not only practically but also normatively necessary in seeking better biosecurity.

In many respects, the emergence of biosecurity flows from the collision of two policy spheres—security and public health—previously not connected or related. The distance between conventional security thinking and traditional public health activities is reflected in foreign policy conceptualizations of security as representing the “high politics” of international relations and of public health falling within the category of “low politics” (Fidler 2005a). Even within “low politics,” public health was at the margins—really low politics—because it was largely considered a technical, nonpolitical, and humanitarian endeavor (Fidler 2005b). The gap between public health and the theory and practice of national and international security has historically been enormous.

Even in the area of biological weapons, policy demonstrated no serious consideration of public health. Security approaches to biological weapons involved either deterrence (e.g., having biological weapons capabilities to respond in kind to biological attacks) or arms control (e.g., prohibiting development and use of biological weapons). If public health arose in these contexts, it caused problems. For example, international legal prohibitions on biological weapons development contained in the Biological Weapons Convention of 1972 (BWC) could not ban all research on, and uses of, biological agents because peaceful research activities were necessary for health purposes, namely basic research on pathogens and applied research on antimicrobial drugs. Similarly, national and international public health systems operated without serious reference to security concerns about the proliferation and use of biological weapons.

The biosecurity challenge of integrating security and public health is colored by the historical reality that these policy endeavors operated in distinct worlds of unequal significance. Security activities were highly political and generously funded, but public health was politically impotent and starved of resources. The emergence of biosecurity as a policy concern suggests that this separation no longer exists and is no longer tenable.

The restraints that prevented use of biological weapons during the Cold War do not necessarily have the same strength in the post-Cold War era. Non-state actors, moreover, seem even less likely to abide by international rules and norms restraining development and use of biological weapons. For rogue states and non-state actors, the scientific challenges of producing biological weapons are receding with rapid advancements in microbiology and biotechnology and the global dissemination of these advances.

At the same time, the resurgence of naturally occurring infectious diseases has stimulated new understandings about how states and populations should perceive their security. The HIV/AIDS pandemic, for example, made the international community face the reality of microbial-related destruction of populations, economies, development prospects, and military power and preparedness. Such destruction came to be seen as having not only public health but also international and national security importance (Feldbaum, Lee, and Patel 2006; Garrett 2005a; Security Council 2000). The global political and economic shock of SARS and the portents of avian influenza and an influenza pandemic have further opened the eyes of political leaders to the nexus between security and public health. For example, the UN Secretary-General's High-level Panel on Threats, Challenges and Change (2004) prominently featured the need to improve public health as part of its vision for comprehensive collective security.

The collision of security and public health has destroyed the policy silos in which governments engaged in these endeavors and produced the need to create synergies in the new relationship between security and public health. The challenge of integrating security and public health arises from this synergy requirement. Integrating security and public health requires fundamental conceptual and practical changes in both areas to strengthen connections between them. Expanding the concept of security to include infectious disease threats requires substantial improvements in public health infrastructures. Investments in national and international biosecurity make little sense without upgrading public health systems. Investments in laboratories, sur-

veillance, data systems, and public health workforce capabilities frequently aim to create “dual use” capacities for defense against biological weapons and against disease epidemics. Biosecurity means having both security and public health firmly planted in the realm of the “high politics” of foreign policy and international relations.

For its part, public health can no longer remain separated, by desire or design, from security policy and its attendant power politics. What public health does has always mattered to individuals, states, and the international community, but biosecurity has heightened the political importance of the public health endeavor. Being on the agenda of national and international leaders involves, however, political questions, pressures, and dynamics that public health rarely faced historically.

Moving security and public health from silos to synergies has not proved easy, and the integration challenge will remain a constant feature of biosecurity. Integrating security and public health involves overcoming the weight of distinct policy histories and the ever-present jealous guarding of traditional bureaucratic turfs and funding streams. Security communities may fear the loss of resources and control as public health emerges as politically important. Public health practitioners and experts may develop anxieties about the securitization of policies for protecting population health. Beyond such fears and anxieties await problems generated by a lack of shared experiences and a common culture between those responsible for security and those overseeing public health.

The difficulty intensifies because the low probability of both biological weapons attacks and socially disruptive epidemics may lull politicians into complacency that biosecurity was yesterday’s problem or the responsibility of some future government. The integration of security and public health has to be sustainable over decades and thus needs to be grooved deeply into the structures, interests, and practices of governments at the highest levels nationally and internationally.

### **B. Supervising Science for Security and Public Health**

The second central challenge of biosecurity involves the need to supervise science in the new relationship between security and public health. We argue that such supervision should be part of biosecurity policy nationally and globally. The supervision of science becomes critical when policy moves in the direction of integrating security and public health. The supervision issue

arises from security's concern about the dangers created by the rapid development and dissemination of ever more powerful scientific knowledge and capabilities. Ignoring these dangers would be imprudent from a public health perspective, let alone a security one. How such supervision unfolds is more critical than whether it should, if one accepts the need to integrate security and public health.

The policy challenge of supervision revolves around choices that have to be made with respect to three principles: scientific innovation, scientific freedom, and the open dissemination of scientific research. The collision of the policy worlds of security and public health includes a clash of cultures with respect to the enterprise of science. Biosecurity has to sort out this clash in a way that facilitates the sustainable integration of security and public health.

Traditionally, security policy has attempted to harness and control scientific research and development. The basic strategy was to allow science to innovate in ways that would increase the power of the state vis-à-vis rival states (e.g., through government-funded research) and to deny such rivals access to new technological capabilities (e.g., through export controls). National security policy on nuclear technology illustrates this approach. The United States encouraged advances in nuclear weapons technology as part of deterrence against the Soviet Union, but it also tried to prevent such technology from reaching the Soviets or other countries that presented a potential threat to the United States. As a result, the United States imposed strict regulations and oversight on nuclear technologies under scientific investigation in the United States. In short, security policy conventionally viewed the principles of scientific innovation, freedom, and open dissemination in the nuclear realm as part of the larger zero-sum game of international power politics.

By contrast, public health operated under an entirely different perspective on the pursuit of science. Advancing the cause of population health has traditionally supported maximizing scientific innovation, freedom, and open dissemination of research. The objective was the proverbial "marketplace of ideas" through which the best concepts, approaches, and technologies would emerge for the betterment of health. The scientific communities feeding research into public health developed deep commitments to the principles of encouraging scientific innovation, expanding scientific freedom, and broadly sharing the fruits of scientific endeavors. These commitments have found support too in the larger principle of the freedom of expression, which consti-

tutional law in many countries and international law recognize as a civil and political human right.

The coming together of security and public health as policy endeavors forces both areas to look again at their respective traditional approaches to the scientific enterprise. The zero-sum instincts of security policy have to confront the reality that the biological sciences are not like nuclear research and thus cannot be regulated as nuclear technologies have been. Preventing the malevolent use of scientific advances requires more complex and sophisticated thinking than the “command and control” used for nuclear technologies.

Similarly, public health’s assumption that scientific innovation, freedom, and dissemination are unquestionably public goods has confronted the specter of potentially devastating externalities arising from uncontrolled, cavalier, or misappropriated scientific exploration. Is every experiment really a good idea, regardless of its potential to be exploited for evil ends or to cause damage through unintentional release of dangerous by-products of the research? Does it make sense to deny or discount the contributions scientific openness could make to governments or terrorists potentially interested in acquiring biological weapons or engaging in biological attack? At the very least, these and similar questions have made the public health community realize that its devotion to the scientific enterprise now operates in a very different, and perhaps more dangerous, environment.

The challenge for biosecurity policy is to achieve a regime for supervising science that contributes to security without hobbling science’s potential to improve human health. Finding this balance is fraught with difficulties to which no one has easy answers. As this book explores, the scientific and political realities of today’s world require careful calibration of security and public health objectives with respect to scientific innovation, freedom, and open dissemination of research.

### **C. Embedding Biosecurity Governance in the Rule of Law**

The third challenge of biosecurity involves ensuring that integrating security and public health and supervising science occur within the framework of the rule of law. We believe that this framework is critical, especially with respect to dramatic policy changes connected with security fears and interests. The rule of law in the United States and other countries often has an uneasy relationship with the exigencies of national security. Security claims require substantive and procedural scrutiny to prevent executive discretion from eroding

political and philosophical commitments to the values grounded in the concept of the rule of law.

As lawyers, we understand that the phrase “rule of law” is often used as a ritual incantation that those chanting rarely explain. The concept of the rule of law is indeed abstract, complex, and laden with normative values. Traditionally, the rule of law refers to a philosophy of governance: Formal legal rules, rather than the arbitrary whims of politicians and leaders, govern the exercise of political power in societies. Hence, Americans are fond of asserting that they live under “the rule of law, not the rule of men.”

As a philosophy of governance, the rule of law focuses on four objectives: (1) ensuring that governance actors are properly empowered through law to take actions necessary for the defense and welfare of populations, (2) protecting individual rights and liberties in the exercise of government authority, (3) pursuing natural and distributive justice in public policy, and (4) creating transparent and accountable forms of governance.

We believe that the rule of law philosophy of governance should inform biosecurity policy. As Chapter 6 explains, the rule of law approach facilitates adequate empowerment of government actors to address biosecurity threats and disciplines the exercise of government power to ensure the protection of individual rights. The rule of law approach also ensures that principles of nondiscrimination, procedural due process, distributive justice, and transparency and accountability remain pertinent to biosecurity discourse.

This stance places our analysis right in the middle of a central challenge for biosecurity policy: How to maximize governance by formal law of the integration of security and public health and the supervision of science in a politically fragmented, globalized context. This challenge has a number of layers.

To begin, the rule of law gains most of its currency as a governance philosophy within states. When the rule of law mantra leaves the hierarchical, unitary governance context of a state and enters the anarchical, divided world of international relations, its strength wanes. Historically, international law has not governed the behavior of states in the sense projected by the rule of law philosophy of governance. International politics has most often been characterized by dominance of the great powers rather than by states’ adherence to the supremacy of formal rules of international law. We understand all too well that biosecurity governance, especially given its globalized nature, could fall into traditional patterns of great power machinations, which historically have not been characterized by the rule of law.

Within domestic and international law, the rule of law has had its greatest struggles in the context of states pursuing their security. When governments are determined to take certain actions to protect their national security, they often ignore rules of law that obstruct or complicate such actions, or manipulate such rules to provide legal cover. The post-September 11th war on terrorism has provided many examples of tension between national security imperatives and rules of domestic and international law. The rule of law challenge in biosecurity policy requires confronting these tensions rather than pretending they do not exist.

Although law and public health have had a long and critical relationship, the notion of the rule of law is not commonly associated with public health activities. The contributions of domestic and international law to public health achievements are often underappreciated (Fidler 2000; Goodman et al. 2006; Gostin 2000). Thinking about embedding biosecurity policy in the rule of law requires elucidating how and why law is critical to the public health functions required to meet the threats posed by pathogenic microbes.

The rule of law is not merely concerned with the supremacy of formal law in governance activities. This philosophy of governance also connects to the desire and need for justice. The rule of law seeks not just procedural but also substantive justice. When biosecurity policies are designed and implemented, a rule of law approach encourages that attention be paid to questions of whose security and whose public health are being protected. Biosecurity governance can become the plaything of the great powers, and it can be a source of unfair and unjust resource allocations that weaken security and public health for many populations over generations. Biosecurity governance creates questions of distributive justice, the answers to which will have profound implications for security and health around the world.

#### **D. Globalizing Governance for Biosecurity**

The fourth challenge of biosecurity policy concerns organizing governance of transnational threats through a political structure dominated by sovereign states. We argue that effective biosecurity policy requires globalized governance of biosecurity threats. Globalized governance involves activities at national, international, and global governance levels. Although definitions of “global governance” vary, what distinguishes global governance from international governance is the involvement of non-state actors. In other words, international governance is governance by and among states.

Global governance involves not only states but also non-state actors, such as nongovernmental organizations, multinational corporations, philanthropic foundations (e.g., Rockefeller and Gates Foundations), and public-private partnerships (e.g., Global Fund to Fight AIDS, Tuberculosis, and Malaria).

Our emphasis on globalized governance concerning biosecurity reflects our sense that governing the integration of security and public health has to involve the efforts of state and non-state actors. The challenge of supervising science illustrates this point. Many experts on the relationship of developments in the biological sciences and the potential proliferation and use of biological weapons acknowledge that a critical governance actor is the individual scientist, who probably does not work for, or on behalf of, any government. Raising awareness of potential dangers of biological research among the community of scientific researchers treats this community as a front-line governance actor and resource.

As noted earlier, the political structure of sovereign states affects the challenge of embedding biosecurity governance in the rule of law, but the effect of this political framework on biosecurity is more comprehensive. Integrating security and public health, supervising science for biosecurity, and embedding governance in the rule of law require governance structures and processes. The threats of biological weapons proliferation, biological attack, and infectious disease epidemics are largely transnational problems. The global governance challenge arises because humanity largely confronts the borderless nature of terrorism, scientific advance, and pathogenic microbes through a border-filled political world that fragments jurisdiction over virtually all essential security and public health functions.

The challenge of responding to transnational threats through sovereign states is not, of course, new. For public health, globalization is not a novel phenomenon. Classic public health mantras include “germs don’t recognize borders” and “germs don’t carry passports.” Public health experts have long understood that the international mobility of people, animals, and products makes pathogenic microbes a transnational threat. A message in the mantras is that humanity’s division into sovereign states rarely, if ever, materially slows the spread of infectious diseases. Governance responses have to be built, however, on the fragmented foundation provided by a system of independent, sovereign states where borders still matter politically and legally.

The answer most often given to the mismatch between the nature of transnational problems and the political structure of international relations is to



encourage better, deeper, and stronger international cooperation between states. This approach essentially attempts to supplement national governance responses with international governance, or governance by and among states. Such cooperation is, of course, necessary, and our book identifies instances where international cooperation should be pursued, however difficult it might be. Although international governance is necessary, we do not believe that it is sufficient for effectively meeting the biosecurity challenge. We accept the need to build globalized governance mechanisms to achieve sustainable biosecurity in the twenty-first century.

Contributing to the challenge of globalized governance for biosecurity are the disparate historical experiences of security and public health with national and international governance. For differing reasons, security and public health have predominantly been national governance functions. Certainly, international cooperation has been a part of these policy areas, but such cooperation has historically been weak. The unwillingness of states to relinquish sovereignty over policies connected to their basic survival and power has long plagued international cooperation on security matters. National security was too important, for example, to leave to the United Nations or to arms control agreements. International cooperation on health has long been plagued by the opposite problem, namely the status of public health as a mere humanitarian endeavor of little consequence to the balance of power and security of states.

The biosecurity challenge involves, thus, moving two policy areas toward globalized governance in a context characterized by weak international cooperation and weak international institutions. The daunting nature of this task may create incentives for policy makers to prefer what appears to be the easier route—concentrating on the state and its individual resilience in the face of biosecurity threats. Why “forward deploy” resources and assets for globalized biosecurity governance when the weakness of international institutions and international cooperation make such investments unlikely to produce sustainable results? This question implies that the prudent strategy is to “harden the target” of one’s state rather than build globalized governance castles in the air.

Although we recognize the difficulty of globalized governance for biosecurity, we are convinced that such governance plays a role in the strategies to pursue in achieving biosecurity. At relevant points, the book analyzes the most prominent challenges of globalized governance and attempts to provide our understanding of how globalized biosecurity governance should be constructed and sustained.

**E. Summary of the Concept, Controversies, and Challenges of Biosecurity**

We have introduced the reader to important aspects of the debate about biosecurity and attempted to shed light on our main arguments about this emerging area of policy and governance. Defining the parameters of biosecurity constitutes an analytical first step, and we outlined how we define and conceptualize biosecurity as involving threats from both biological weapons and naturally occurring infectious diseases. Our approach does not settle the larger controversies about how broadly “security” should be stretched conceptually. We focus, instead, on the interdependent policy tasks that arise when contemplating governance of pathogenic threats. The historical separation of security and public health, even in the context of biological weapons, is simply no longer tenable as a basis for policy choices.

Nor do we pretend that our approach neatly resolves all the politically charged and acrimonious controversies that afflict biosecurity deliberations. Indeed, we do not believe that some of these controversies can be resolved because of the lack of certainty involved with anticipating low probability/high consequence events involving microbial agents. The controversies are, however, indicators of the complexities and difficulties attending the central challenges of biosecurity policy, which we have identified as integrating security and public health, supervising science for security and public health, embedding biosecurity policy in the rule of law, and globalizing governance for biosecurity.

The normative arguments we make produce a daunting agenda for biosecurity policy and governance, one that has made us pause at times to consider whether we are too ambitious in our approach. We have tried to calibrate our ambition in such a way that produces a biosecurity regime that makes us more secure in ways that are consistent with our values. The unprecedented policy revolution biosecurity represents calls for ambition in policy and governance, even if the nature of our ambition proves unpersuasive to the reader.

**VI. STRUCTURE OF THE BOOK**

We organize our analysis in three parts. In Part I, we focus on the biosecurity threat posed by biological weapons. Chapter 2 provides an overview of the historical and contemporary problems biological weapons represent, and it includes analysis of the techniques and technologies of biological weapons and of past experiences with arms control efforts on biological weapons. Chapter 3 then examines strategies for preventing and responding to the development and use of biological weapons that go beyond the traditional

arms control approach. Chapter 3 also focuses on biodefense as a response to contemporary threats from biological weapons, including the implications biodefense creates for the relationship between security and the principles of scientific innovation, freedom, and open dissemination.

Part II looks at the biosecurity threat that naturally occurring infectious diseases pose. Chapter 4 explores the collision that has occurred between the worlds of security and public health because this collision has significantly changed both policy areas. Chapter 4 also delves more deeply into the theory and practice of public health to enrich analysis of the manner in which security and public health policies are becoming intertwined. Chapter 5 then focuses on the implications of the convergence of security and public health and on the requirements for effectively integrating them in biosecurity policy.

Part III examines the complex relationships between biosecurity policy, the rule of law, and globalized governance. Chapter 6 considers the challenge of embedding biosecurity in the rule of law. The chapter explains what we mean by the rule of law and why the rule of law is important for biosecurity policy. The chapter then delves into the specific elements of the rule of law philosophy of governance and how they relate to the governance challenges presented by biosecurity. Chapter 7 explores the relationship between biosecurity and globalized governance. It looks at how comprehensively the globalized governance challenge affects biosecurity, and the chapter digs conceptually into why it proves such a difficult task. Chapter 7 also examines the proliferation of new governance initiatives that have appeared in the biosecurity context and tries to identify patterns at the national, international, and global governance levels. These patterns, we argue, provide some signposts for the creation of a mechanism for globalized governance for biosecurity.

The final chapter reviews the book's analysis in terms of the concept, controversies, challenges, and choices presented by biosecurity's emergence. We acknowledge that our vision for biosecurity imposes significant burdens on private and public actors around the world, but the burdens are commensurate with the nature of the pathogenic threats facing world politics. Although the burdens should not be ignored, they should not overshadow the opportunity that biosecurity governance represents for twenty-first century humanity. We see in biosecurity a glimpse of how governance of the world's problems in the twenty-first century might unfold—a glimpse that presents us with momentous choices that may well mark how history remembers this century.