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BIOSECURITY UNDER THE RULE OF LAW^{*}

Lawrence O. Gostin[†] & David P. Fidler[‡]

I. INTRODUCTION

In the first five years of the twenty-first century, the United States and the rest of the world have experienced shocks, crises, and fears captured in the haunting images, words, and events that define our turbulent times: September 11th, Al Qaeda, anthrax, weapons of mass destruction, smallpox, axis of evil, SARS, quarantine, enemy combatants, USA PATRIOT Act, HIV/AIDS, Guantanamo Bay, Abu Ghraib. The troubling lexicon of the early twenty-first century captures the 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 that have few, if any, precedents. This article 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 newly emerged on national and international political agendas may initially be greeted with skepticism because biological warfare and infectious diseases were international issues for most of the twentieth century.¹ The Geneva Protocol, for example, banned the use of bacteriological agents in warfare in

^{*} This article draws on DAVID P. FIDLER & LAWRENCE O. GOSTIN, *BIOSECURITY IN THE GLOBAL AGE: BIOLOGICAL WEAPONS, PUBLIC HEALTH, AND THE RULE OF LAW* (2007) (forthcoming). Dean Gostin gave the keynote address on Biosecurity Under the Rule of Law at the Symposium on The Fifth Plague: A Unique Counterterrorism Simulation, at the Case Western Reserve School of Law on March 31, 2006. The authors acknowledge the research and editorial assistance of Benjamin Berkman, Fellow, Georgetown University Law Center; and Deborah Rubbens, Research Assistant, Georgetown University Law Center.

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¹ See generally *MEDICINE AT THE BORDER: DISEASE, GLOBALIZATION AND SECURITY, 1850 TO THE PRESENT* (Alison Bashford ed., 2006) (describing issues of border control and infectious diseases in the nineteenth, twentieth, and twenty-first centuries).

1925.² States established international health organizations tasked with international control of infectious diseases in the first decade of the twentieth century.³ In addition, international cooperation on infectious diseases dates back to at least the mid-nineteenth century.⁴

The emergence of biosecurity as a policy concern connects to historical efforts with respect to 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 bioterrorism and infectious diseases that synthesis presents a daunting challenge. This article takes up the challenge and explores the emergence of biosecurity as a critical area of policy in the early twenty-first century, paying particular attention to biosecurity's relationship with the rule of law.

II. BIOSECURITY BASICS: DEFINITION AND DIFFICULTIES

A. *Defining Biosecurity*

We define "biosecurity" as society's collective responsibility to safeguard the population from dangers presented by pathogenic microbes—whether naturally occurring or intentionally released. Traditionally, experts have used the term to describe efforts to defend against biological weapons and biological terrorism. However, our concept of biosecurity is broader, recognizing not only the dangers of biological weapons but also of naturally occurring infectious diseases. 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.

This interdependency does not mean that all outbreaks are biosecurity problems. Many disease outbreaks remain localized and low impact events that societies take in stride. The biosecurity concern is with natural or

² Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, *opened for signature*, June 17, 1925, 26 U.S.T. 571, 1015 U.N.T.S. 163.

³ The following international health organizations were established in the first twenty-five years of the twentieth century: Pan-American Sanitary Bureau (1902), Office International d'Hygiène Publique (1907), and Health Organization of the League of Nations (1923). See generally INTERNATIONAL HEALTH ORGANIZATIONS AND MOVEMENTS, 1918–1939 (Paul Weindling ed., 1995).

⁴ See generally Norman Howard-Jones, *Origins of International Health Work*, 1 BRIT. MED. J. 1032 (1950); NEVILLE M. GOODMAN, INTERNATIONAL HEALTH ORGANIZATIONS AND THEIR WORK (2d ed. 1971); NORMAN HOWARD-JONES, THE SCIENTIFIC BACKGROUND OF THE INTERNATIONAL SANITARY CONFERENCES 1851–1938 (1975); Alexandra Minna Stern and Howard Markel, *International Efforts to Control Infectious Diseases, 1851 to Present*, 292 JAMA 1474 (2004).

intentional epidemics that have the potential to 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 have a particularly powerful effect on the human psyche that extends beyond morbidity and mortality statistics.⁵ Even harms that are comparatively small statistically can have profoundly destabilizing effects. The social, economic, and political disruptions to societies caused by the anthrax attacks in 2001 and the outbreaks of severe acute respiratory syndrome (SARS) in 2003 illustrate the dangerous disruptive potential of even comparatively low mortality events.⁶ The acute devastation caused by HIV/AIDS in the developing world,⁷ the smallpox vaccination campaign in 2003–2004,⁸ and the mobilization of resources to prevent and control highly pathogenic influenza,⁹ also illustrate the social, political, and economic dimensions of disease threats.

⁵ See, e.g., Hector W.H. Tsang et al., *Psychosocial Impact of SARS*, 7 EMERGING INFECTIOUS DISEASES 1326 (2004) (noting the “social and psychological problems” associated with SARS).

⁶ Opening Remarks by Dr Richard Nesbit, WHO Acting Regional Director for the Western Pacific during the First Meeting of the Asian Pacific Technical Advisory Group on Emerging Infectious Diseases, July 18, 2006, available at http://www.wpro.who.int/regional_director/speeches/speech_20060718.htm (“SARS was unique in the panic and fear that it caused, buckling economies and crippling international trade and travel. The economic costs were estimated at perhaps up to US\$100 billion.”); Elin Gursky, Thomas V. Inglesby, and Tara O’Toole, *Anthrax 2001: Observations on the Medical and Public Health Response*, 1 BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE AND SCIENCE 97 (2003).

⁷ See, e.g., Joint United Nations Programme on HIV/AIDS [UNAIDS], *2006 Report on the Global AIDS Epidemic*, available at http://www.unaids.org/en/HIV_data/2006GlobalReport/default.asp.

⁸ COMMITTEE ON SMALLPOX VACCINATION PROGRAM IMPLEMENTATION, *THE SMALLPOX VACCINATION PROGRAM: PUBLIC HEALTH IN AN AGE OF TERRORISM* (2005); Edward P. Richards, Katharine C. Rathbun & Jay Gold, *The Smallpox Vaccination Campaign of 2003: Why Did it Fail and What Are the Lessons for Bioterrorism Preparedness?*, 64 LA. L. REV. 851 (2003).

⁹ Congress recently appropriated \$3.8 billion dollars to address pandemic influenza. Department of Defense, *Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006*, Pub. L. No. 109–148, 119 Stat. 2680, 2782–87 (2005). To meet the costs estimated by the World Bank to contain avian influenza, donor countries recently pledged \$1.9 billion. World Bank, *Avian and Human Influenza: Financing Needs and Gaps* (2005), available at <http://siteresources.worldbank.org/PROJECTS/2015336-1135192689095/20766293/AHIFinancingGAPSFINAL12-21.pdf>; International Pledging Conference on Avian and Human Pandemic Influenza, *Beijing Declaration* (2006), available at <http://siteresources.worldbank.org/PROJECTS/Resources/40940-1136754783560/beijingdeclaration.pdf>.

B. *Difficulties with Assessing Biosecurity Threat and Risk*

Biological threats pose fundamental challenges to governments and populations in every region of the globe. These challenges explain why the United Nations (UN) Secretary-General argued that, in reforming the United Nations for the twenty-first century, “[w]e need to pay much closer attention to biological security.”¹⁰ This task is, however, complicated by the difficulty of assessing the risk associated with events that have a low probability of occurring but can lead to potentially enormous adverse consequences.¹¹

Frightening analyses of what might happen abound. Government modeling or “tabletop” exercises simulating biological attacks in the United States—such as Dark Winter (smallpox) and TOPOFF (plague)—revealed serious weaknesses in public health preparedness that could contribute to potentially devastating harm.¹² Both exercises predicted large-scale morbidity and fatalities from a biological attack. The World Health Organization (WHO) concluded that the aerosolized release of *Yersinia pestis* over a large city would cause 150,000 cases of pneumonic plague.¹³ A Congressional analysis found that a similar release of one hundred kilograms of aerosolized anthrax would result in up to three million deaths.¹⁴ Pandemic influ-

¹⁰ THE SECRETARY-GENERAL, A MORE SECURE WORLD: OUR SHARED RESPONSIBILITY—REPORT OF THE SECRETARY-GENERAL’S HIGH-LEVEL PANEL ON THREATS, CHALLENGES, AND CHANGE viii (2004), available at <http://www.un.org/secureworld/>.

¹¹ See Lawrence O. Gostin, *When Terrorism Threatens Health: How Far are Limitations on Personal and Economic Liberties Justified?*, 52 FLA. L. REV. 1105 (2003).

¹² In one exercise conducted in 2001, code-named “Dark Winter,” smallpox were released in shopping malls in Oklahoma City, Philadelphia, and Atlanta. Three thousand people were supposed to have been initially infected. About two weeks after the attacks, it was estimated that sixteen thousand cases of smallpox would have been reported in twenty-five different states, with ten other countries reporting cases. Tara O’Toole et al., *Shining Light on “Dark Winter,”* 34 CLINICAL INFECTIOUS DISEASES 972, 979 (2002). Similarly, in another exercise, code-named “Top Official,” or “TOPOFF,” the federal government and the states modeled the effects of an intentional dispersal of plague. The scenario involved the release of an aerosol of *Yersinia pestis* in Denver, Colorado. By six days after the release of the plague, estimates of those with pneumonic plague ranged from 3,700 to more than 4,000, and between 950 and 2000 deaths were estimated. Thomas V. Inglesby et al., *A Plague on Your City: Observations from TOPOFF*, 32 CLINICAL INFECTIOUS DISEASES 436 (2001).

¹³ Thomas V. Inglesby, *Plague as a Biological Weapon: Medical and Public Health Management*, 283 JAMA 2281 (2000) (“The World Health Organization concluded that, worst-case scenario, if fifty kilograms of *Yersinia pestis* (the organism that causes the plague) were released as an aerosol over a city of five million people, 150,000 could develop pneumonic plague, and 36,000 of those may die.”).

¹⁴ U.S. CONG., OFF. OF TECH. ASSESSMENT, *Proliferation of Weapons of Mass Destruction: Assessing the Risks*, OTA-ISC-559, at 54 (U.S. Gov’t Printing Off., 1993), available at http://govinfo.library.unt.edu/ota/OTA_1/DATA/1993/9341.PDF.

enza estimates of morbidity and mortality have been similarly unimaginable.

Immediately underneath these scary numbers lurk difficult questions that defy easy answers. Which biological agents are readily available to terrorists? How hard is it for a terrorist to “weaponize” such agents and disseminate them effectively? Will the avian influenza virus (H5N1) mutate into a virulent strain capable of sustained human-to-human transmission? These highly contingent questions are answered only with great difficulty or not at all. Scholars and policy makers, accustomed to policy analysis derived from risk-benefit ratios, are being forced to make decisions at a time when such ratios cannot easily be calculated. In addition, far-reaching changes in ecological, technological, economic, and political dimensions at the national and international levels have reshaped risk perceptions with respect to potential biological threats.¹⁵

The difficulties of risk assessment are particularly acute with respect to bioterrorism. An effective bioterrorist attack with a contagious agent could have a major impact on public health, health care systems, economic well-being, and politics. Morbidity and mortality could be significant, the economy would suffer, the health care system would be stressed by the need for medicines, medical equipment, personnel, hospitals, and quarantine facilities. Those who are ill or quarantined would be unable to work, take care of their children, or participate in normal daily life. Confidence in political leaders and the political system might plummet, perhaps creating conditions conducive for civil unrest. Although very low probability events, acts of bioterrorism contain the potential for such adverse consequences that policy makers ignore them at their peril.

The actual and potential burden of naturally occurring infectious diseases is better understood, but this knowledge has not necessarily translated into better security against such diseases. Communicable diseases still represent one of the greatest burdens of morbidity and mortality globally, especially in the developing world.¹⁶ Malaria, tuberculosis, and HIV/AIDS alone account for six million deaths every year.¹⁷ Endemic diseases have re-

¹⁵ See INSTITUTE OF MEDICINE COMMITTEE ON MICROBIAL THREATS TO HEALTH IN THE 21ST CENTURY, *MICROBIAL THREATS TO HEALTH: EMERGENCE, DETECTION, AND RESPONSE* 19 (Mark S. Smolinski, Margaret A. Hamburg, & Joshua Lederberg, eds.) (2003) (“The increasingly interconnected and fast-paced world of transcontinental commerce and international travel has made any nation susceptible to the infectious diseases that occur incessantly outside its borders. Infectious diseases today ignore geographic and political boundaries, and thus constitute a global threat that puts every nation and every person at risk.”) [hereinafter *MICROBIAL THREATS TO HEALTH*].

¹⁶ See *id.* at 21.

¹⁷ U.S. GOV'T ACCOUNTABILITY OFFICE, *GLOBAL HEALTH: THE GLOBAL FUND TO FIGHT AIDS, TB, AND MALARIA IS RESPONDING TO CHALLENGES BUT NEEDS BETTER INFORMATION AND DOCUMENTATION FOR PERFORMANCE-BASED FUNDING* 5–6 (2005).

emerged in more virulent, multi-drug resistant forms (e.g., HIV/AIDS, malaria, and tuberculosis).¹⁸ Diseases once endemic only in the Third World have arrived in the First World (e.g., West Nile virus and monkeypox). Emerging infections have been newly identified in humans (e.g., viral hemorrhagic fevers, HIV/AIDS, and SARS) and animals (e.g., bovine spongiform encephalopathy), some with devastating consequences for world health, world trade, and tourism. Diseases have even jumped species, causing loss both in animal and human populations (e.g., avian influenza).¹⁹

The emergence and re-emergence of naturally occurring infectious diseases in the last twenty to thirty years are directly linked to the complex web of ecological, technological, economic, and political changes that have characterized world politics in the recent past.²⁰ The scale, scope, and complexity of the problem, combined with high levels of unpredictability (e.g., when will pandemic influenza strike again?), make governance of naturally occurring infectious diseases difficult on both a national and global scale.

In these difficult policy environments, there is a great temptation to believe that past, current, and future progress on biotechnology and modern medicine better prepares societies for biosecurity threats. Although such progress is important, science alone will not deliver better biosecurity for countries and peoples. The factors driving increased concern about bioterrorism and the emergence and spread of infectious diseases are not amenable to medicalization.

Indeed, even modern advances in biotechnology are not unequivocally helpful. As the scientific community better understands the biology of pathogens and methods of manipulating microbial life forms, this knowledge can fall into the wrong hands and help facilitate the ability of governments and terrorist groups to explore pathogens and their malevolent use.²¹ Individual nations and the international community must, therefore, wrestle with hard problems related to the management of scientific advances.

III. RETHINKING BIOSECURITY POLICY: FOUR THEMES

The upheaval caused by biological hazards has revealed that individual states and the international community are not well prepared to prevent such hazards and, if necessary, effectively respond. Societies are now

¹⁸ World Health Organization, *Drug Resistance*, <http://www.who.int/drugresistance/en/> (last visited Feb. 20, 2006) (noting that many diseases, including malaria, tuberculosis, and HIV/AIDS have developed strains which have proven resistant to first-line medications).

¹⁹ See John H. Beigel et al., *Avian Influenza A (H5N1) Infection in Humans*, 353 *NEW ENG. J. MED.* 1374, 1378 (2005).

²⁰ MICROBIAL THREATS TO HEALTH, *supra* note 15, at *passim*.

²¹ See generally COMM. ON ADVANCES IN TECH. AND THE PREVENTION OF THEIR APPLICATION TO NEXT GENERATION BIOWARFARE THREATS, GLOBALIZATION, BIOSECURITY, AND THE FUTURE OF THE LIFE SCIENCES (2006).

caught between the stale assumptions and policy inertia of past approaches and the uncertainties inherent in dramatically changing policy strategies. The seriousness and complexity of the biosecurity challenge requires fundamentally rethinking the manner in which the dangers of biological weapons and naturally occurring diseases should be approached. In our forthcoming book, *Biosecurity in the Global Age: Biological Weapons, Public Health, and the Rule of Law*, we identify four themes that we believe characterize the policy challenges biosecurity presents now and in the foreseeable future.

First, the policy revolution that biosecurity represents requires the integration of two policy realms previously separate from each other—security and public health. Integrating security and public health requires changing entrenched perspectives and practices in both areas and building new, sustainable governance approaches to the threats posed by pathogenic microbes.

Second, the nature of the biosecurity challenge requires supervision of the biological sciences as part of the integration of security and public health. The need for heightened supervision of science flows from the worries about malevolent actors transforming scientific advances into weapons of mass terror and destruction. The dynamics of such supervision cannot, however, sacrifice science's critical role in improving humanity's health on the altar of narrowly construed notions of national security.

Third, the integration of security and public health and the supervision of science must occur within the context of globalization, which requires globalizing governance for biosecurity. As with many policy areas penetrated and transformed by globalization, security and public health can no longer view the world through the state-centric lens of national governments and intergovernmental coordination.

Fourth, we argue that moving towards the integration of security and public health, the supervision of science, and globalized forms of governance must be informed by, and take place within, the rule of law. In the highly uncertain and contingent context of biosecurity, we assert 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.

Our book analyzes each of these themes in detail, and demonstrates the importance of viewing them as interdependent policy tasks. Here, we briefly outline the first three themes in more detail before turning, in the last part of the article, to the challenge of ensuring that biosecurity policy is embedded in the rule of law.

A. *The Integration of Security and Public Health: From Silos to Synergies*

The development of the policy area known as biosecurity flows from the collision of two policy spheres—public health and security—previously not connected or related. The distance between security policy and public health activities is reflected in foreign policy conceptualizations of security as representing “high politics” and of international health as falling within the category of “low politics.”²² Even within the realm of “low politics,” public health was at the margins because it was largely considered a technical, non-political, and humanitarian endeavor. The gap that existed between public health and the theory and practice of national and international security was enormous.²³

The manner in which states traditionally approached the threat of biological weapons demonstrated no serious consideration of the theory and practice of public health. States addressed biological weapons through classical arms control mechanisms,²⁴ but ignored public health considerations and strategies should arms control fail to prevent the use of biological weapons. If public health factored at all in biological arms control, it was as a source of friction. International legal prohibitions on biological weapons development could not outlaw peaceful research on, and uses of, biological agents because such activities were necessary for health purposes, namely basic scientific research on pathogens and applied research on drugs and vaccines.²⁵

Similarly, national and international public health systems operated without serious reference to security concerns about biological weapons. States never applied the main international legal regime for infectious disease control—the International Health Regulations—in ways supportive of the control of biological weapons. Nor were national and international public health systems and resources designed or applied with the threat of biological weapons in mind.

²² See David P. Fidler, *Health as Foreign Policy: Between Principle and Power*, 6 WHITEHEAD J. DIPL. & INT'L REL. 179, 180–82 (2005).

²³ DAVID P. FIDLER, HEALTH AND FOREIGN POLICY: A CONCEPTUAL OVERVIEW (2005).

²⁴ See generally Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous, or Other Gases and of Bacteriological Methods of Warfare, *supra* note 2; Convention on the Prohibition of the Development, Production, Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, G.A. Res. 2826 (XXVI), U.N. Doc. A/RES/2826 (Feb. 25, 1972).

²⁵ See Convention on the Prohibition of the Development, Production, Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, art. I(1) (allowing the development and production of microbial or other biological agents or toxins in types and quantities that have justification for prophylactic, protective, or other peaceful purposes).

National security and public health, then, have operated in two parallel worlds—security was highly politicized and generously funded, while public health was politically neglected and starved of resources. This separation is no longer tenable. The scientific, political, and moral restraints that made state use of biological weapons during the Cold War unlikely 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 on the development and use of biological weapons.²⁶ For rogue states and non-state actors, the scientific challenges of producing biological weapons are receding with rapid advancements in microbiology and their global dissemination.

At the same time, the resurgence of naturally occurring infectious diseases is creating new understandings about how to think about security. The HIV/AIDS pandemic made the international community face the reality of microbial-related destruction of populations, economies, development prospects, and military power. These came to be seen as having not just public health, but national security implications.²⁷ More recently, the political and socioeconomic consequences of SARS and avian influenza opened the eyes of political leaders to the security implications of infectious diseases. In its latest *National Security Strategy*, the Bush administration, for example, declared that it recognized “[p]ublic health challenges like pandemics (HIV/AIDS, avian influenza) that recognize no borders” as a national security problem related to globalization.²⁸

What does it mean to suggest that public health and national security must be transformed from separate policy silos to governance synergy? It means fundamental changes in both security and public health systems, as well as new connections between them. Expanding the concept of security to include infectious disease threats requires substantial strengthening of the public health infrastructure within and among countries. It makes little sense to invest significantly in national and international security concerning biological threats without scaling up investments in public health systems. Investments in laboratories, surveillance, data systems, and public health workforce often produce dual use capabilities that permit us to shield

²⁶ See *Reducing the Threat of Chemical and Biological Weapons: Hearing Before the S. Comm. on Foreign Relations*, 107th Cong. 54–56 (2002) (prepared statement of Amy Sands, Deputy Director, Center for Nonproliferation Studies, Monterey Institute of International Studies) (discussing the potential threat of bioterrorism from non-state actors).

²⁷ See, e.g., LAURIE GARRETT, COUNCIL ON FOREIGN REL. REP., *HIV and National Security: Where are the Links?*, at 55 (2005); Harvey Feldbaum, Kelley Lee & Preeti Patel, *The National Security Implications of HIV/AIDS*, 3 PLOS MEDICINE 774, 774–75 (2006).

²⁸ THE WHITE HOUSE, *THE NATIONAL SECURITY STRATEGY OF THE UNITED STATES OF AMERICA* 47 (2006), available at <http://www.whitehouse.gov/ncs/nss/2006/nss2006.pdf>.

against bioterrorism and naturally occurring infectious diseases.²⁹ Security and public health both must move sustainably to the realm of high resources and high politics. Public health, for its part, can no longer maintain the stance of separation from security policy and power politics. What public health does matters politically to states and the international community. It deserves to be on the agenda of political leaders at the national and global level.

The integration of security and public health means that policies and practices have to flow more seamlessly. Governance and financing structures must be harmonized. When planning and operating biosecurity policy, all relevant agencies have to be well represented: national security, law enforcement, emergency management, and public health. These agencies at the national and international level have to find ways to share data, pool resources, and make decisions cooperatively. Shorn of the weight of history and protection of bureaucratic turf, biosecurity policy should blend the strengths of security and public health endeavors into a strong force united for the common good.

B. The Supervision of Science: The Conundrum of Biosecurity and Scientific Freedom

The scientific enterprise generally, and in public health specifically, has embraced a number of inter-related principles: the importance of scientific innovation, the need for scientific freedom, and the value of open dissemination of scientific ideas. The first principle holds that scientific innovation should be encouraged. Such encouragement means not only funding scientific research, but also welcoming the rich diversity of ideas that may lead to discoveries. Society benefits from a full spectrum of scientific knowledge, even if it was often unsure where such knowledge would lead. In this way, a thriving marketplace of ideas develops, where the best concepts flourish for the public good.

But, it has always been known that even the most benevolently intended scientific research could lead to dreadful, fearsome results. Think about the dual uses for nuclear research, which bring not only peaceful energy but also the tools (and temptation) to develop weapons of mass destruction. The current standoff between the UN Security Council and Iran over Iran's nuclear activities powerfully illustrates this tension.³⁰ Beyond

²⁹ See Christopher Chyba, *Toward Biological Security*, 81(3) FOREIGN AFF. May-June 2002, at 122-24 (noting the U.S. response to anthrax attacks included strategies such as stockpiling vaccines and improving local and national disease surveillance).

³⁰ See generally Press Release, United Nations Security Council, Security Council Demands Iran Suspend Uranium Enrichment by 31 August, or Face Possible Economic, Diplomatic Sanctions, U.N. Doc SC/8792 (July 31, 2006), available at <http://www.un.org/News/Press/docs/2006/sc8792.doc.htm>.

nuclear research, society continues to struggle with the conundrums created by the pull of scientific investigation and the prospect of such investigation producing horrific consequences. The controversy over the destruction of the only known specimens of the smallpox virus in the United States and Russia highlights the dilemma—which is more important, the search for knowledge of the variola virus' secrets or the potential for dangerous misuse of the virus?³¹

Today, the science/security problem arises in the context of research relating to a wide array of pathogens and biotechnologies. Scientific investigations are needed to continue the flow of creative ideas that inform the basic understanding of the microbial world and the development of potentially life-saving vaccines and pharmaceuticals. At the same time, this research can fall into the wrong hands, providing a tool for threats to our health and security. This double-edged problem raises the need for heightened supervision of the biological sciences as an aspect of biosecurity.

The second principle is scientific freedom. Related to scientific innovation, many societies have tried to nurture an environment of scientific inquiry and exploration. We have generally been loath to overly regulate the biological sciences because such oversight can deter creativity and chill the scientific spirit. So powerful is the idea of scientific freedom that it has been embraced as an important form of freedom of expression, constitutionally protected in the United States, valued in most liberal democracies, and expressed in international human rights norms. Scientific freedom appears to give researchers full permission to delve into any area of exploration, regardless of the motivation of the scientist or the potential uses of discoveries by others. The need for supervision of the biological sciences as an element of biosecurity policy changes the traditional dynamic supported by the principle of scientific freedom.

The third principle is open dissemination of scientific ideas. Under this practice, scientists are not only free to think and innovate, but they are also free to discuss and publish. The idea of open dissemination is given life through presentation of research at scientific gatherings, publication in peer reviewed journals, private communications with individuals, organizations, or even governments, or posting data on a website or distributing it widely through electronic means.

Open dissemination is vital for science. It allows for the propagation of the ideas and means by which scientists replicate, improve on, or repudiate existing research. It is also a means by which scientists can (inadvertently or intentionally) convey vital information to those who would use

³¹ See generally DAVID A. KOPLOW, *SMALLPOX: THE FIGHT TO ERADICATE A GLOBAL SCOURGE* (2003) (analyzing the controversy over what to do with the last remaining research stocks of the smallpox virus).

the knowledge to harm others. If all scientific knowledge is truly open, then it becomes much easier for terrorists and rogue states to acquire the information needed to pursue malevolent objectives. The rise of biosecurity concerns has made many people, including those who conduct scientific research, rethink the implications of the principle of open dissemination of scientific research. This rethinking feeds into the perceived need for heightened supervision of the biological sciences.

Finding the right balance between scientific innovation, freedom, and openness, on the one hand, and biosecurity supervision, on the other, is fraught with difficulty. It is a conundrum that has no obvious or clear answer. Yet, the realities of modern society require a careful calibration of science and security that allows for a reasonable measure of security while still not trampling on the freedoms and traditions of scientists, which have contributed much to human well-being.

Appropriate supervision will involve many facets, including improved security for pathogen handling and transfer, laboratory safety and security, scrutiny of types of research considered particularly dangerous, and sometimes restraint in publishing research findings. It will require looking for helpful models in other policy areas that also attempt to balance security and the achievement of other social goals. These models might include attributes such as transparency, non-discrimination, fairness, and accountability. In addition, the supervision of the biological sciences should be guided by the principle that any restrictions on scientific activity should be no more restrictive than necessary to achieve the objective of ensuring biosecurity.

C. *The Globalization of Biosecurity*

1. From Sovereignty to Globalized Governance

We argue that a third challenge is achieving globalized governance against biosecurity threats. The threats of biological weapons proliferation, biological attack, and infectious disease outbreaks exist in a world dominated by sovereign states and political borders. However, the global governance challenge arises because humanity must confront the borderless nature of terrorism, scientific advance, and pathogenic microbes.

Our emphasis on the need for globalized governance in biosecurity does not, of course, mean that the worlds of security and public health are strangers to the effects of globalization. The "globalization of public health" is, for example, not new, especially with respect to infectious diseases. Classic public health mantras include "germs don't recognize borders" and "germs don't carry passports." Public health has long understood the role that international mobility of people and goods plays in spreading pathogenic microbes around the planet and that the division of humanity into

territorial sovereign states rarely, if ever, materially slows infectious disease spread.³²

Unfortunately, national sovereignty and borders do matter when it comes to the governance functions public health must undertake (e.g., surveillance, intervention). Governance of health threats arising in the borderless microbial world takes place in a border-filled political world that fragments jurisdiction over virtually all essential public health activities. For the integration of security and public health and the supervision of science, this fragmentation poses difficulties.

Such fragmented governance could only be ameliorated through international cooperation and, to be sure, the international community has tried to cooperate on matters of security and public health. We mentioned earlier the traditional approach of arms control agreements with respect to the threat of biological weapons. The origins of international collaboration on naturally occurring infectious diseases date back to the first International Sanitary Conference, held in Paris in 1851.³³ These efforts included several international sanitary conventions in the latter half of the 19th century, together with the formation of regional and international institutions in the early 20th century to oversee these conventions.³⁴ The formation of the World Health Organization (WHO) in 1948³⁵ and the promulgation of the International Sanitary Regulations in 1951³⁶—which later were renamed the International Health Regulations in 1969 (IHR 1969)³⁷—were seminal in consolidating international governance mechanisms on public health.

Even though states have engaged in international cooperation on biological weapons and infectious diseases, the results have been disappointing. The BWC is often considered the weakest of the arms control treaties addressing weapons of mass destruction. The IHR covered only a handful of infectious diseases. For example, after the eradication of smallpox in the late 1970s, the IHR 1969 only applied to cholera, plague, and yellow fever—the same diseases originally discussed at the first International Sanitary Conference in 1851. Even within this narrow reach, the IHR 1969

³² See INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, *THE IMPACT OF GLOBALIZATION ON INFECTIOUS DISEASE EMERGENCY AND CONTROL: EXPLORING THE CONSEQUENCES AND OPPORTUNITIES* 2–4 (Stacey Knobler et al. eds., 2002).

³³ See, e.g., Stern & Markel, *supra* note 4, at 1475.

³⁴ See generally DAVID P. FIDLER, *INTERNATIONAL LAW AND INFECTIOUS DISEASES* 26–47 (1999) (surveying these international legal efforts).

³⁵ Constitution of the WHO, July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185 (entered into force Apr. 7, 1948).

³⁶ Int'l Sanitary Regulations—WHO Regulations No. 2, *adopted* May 25, 1951, 175 UNTS 215 (entered into force Oct. 1, 1952).

³⁷ Int'l Health Regulations, *adopted* July 25, 1969, 21 U.S.T. 3003, 764 U.N.T.S. 3 (entered into force Jan. 1, 1971) [hereinafter Int'l Health Regulations].

failed to achieve its objectives because states parties violated its rules with impunity.³⁸

The need for, and importance of, globalized forms of governance for biosecurity purposes are reflected in the revised IHR, adopted by the World Health Assembly in May 2005 (IHR 2005).³⁹ The IHR 2005 radically departs from past approaches by expanding the scope of the Regulations to cover pathogenic threats whatever their origin, integrating non-state actors into global surveillance, incorporating human rights principles, imposing significant obligations concerning surveillance and response, and establishing new powers for WHO.⁴⁰ Many obstacles need to be overcome before the global governance mechanisms present in the IHR 2005 are effective, especially given the lack of resources currently available to assist developing countries in improving and sustaining the public health surveillance and intervention capacities required by the IHR 2005.

Efforts to strengthen the BWC have not, however, advanced as well as the revision of the IHR did. The attempt to create a verification mechanism in the form of a BWC Protocol failed in 2001 when the Bush administration rejected the proposed draft negotiating text.⁴¹ This failure, combined with concerns about biological weapons development or acquisition by terrorist groups, has led to controversy about the future of the BWC's arms control approach.

Emerging out of this controversy are four policy trends that characterize the new world of biological weapons governance: (1) efforts to criminalize in international law the development and use of biological weapons; (2) increased regulation of the biological sciences; (3) renewed interest, particularly in the United States, in reinvigorated biological defense research; and (4) the realization that public health infrastructures are national and homeland security assets and must be improved in case biological attacks occur. As we explore in more detail in our book, each of these trends

³⁸ See FIDLER, *supra* note 34, at 65–70 (analyzing the IHR's flaws).

³⁹ Fifty-Eighth World Health Assembly, *Revision of the International Health Regulations*, WHA58.3 (May 23, 2005).

⁴⁰ See David P. Fidler, *From International Sanitary Conventions to Global Health Security: The New International Health Regulations*, 4 CHINESE J. INT'L LAW 325 (2005); see also David P. Fidler & Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 34 J.L. MED. & ETHICS 85 (2006).

⁴¹ Kenneth D. Ward, *The BWC Protocol: Mandate for Failure*, 11 THE NONPROLIFERATION REVIEW 183, 183 (2004); see also Press Release, U.S. Mission to Geneva, Statement of the Honorable John R. Bolton Under Secretary of State for Arms Control and International Security, United States Department of State to the Fifth Review Conference of the Biological Weapons Convention (2001), available at <http://geneva.usmission.gov/press2001/1911bolton.htm> (stating the reasons the Bush Administration rejected the draft protocol).

is marked by the forces of globalization and calls for policy responses that address the truly global nature of the new world of biological weapons governance.

Resistance to globalized forms of governance in the biosecurity realm arises from outmoded notions of how sovereignty relates to security and public health. Although often criticized, sovereignty remains an influential idea in international relations. Assertions of sovereignty, of course, are not always detrimental to biosecurity, such as when a state imposes scientifically-based health regulations that are more stringent than internationally recognized standards. When used to preserve a poorly regulated status quo, however, assertions of sovereignty can severely harm national and global interests in biosecurity.

First, state power to control internal affairs enables political leaders to set low standards for public health surveillance and regulation. Given the cross-boundary effects of health threats, a state's failure to identify and respond promptly to domestic health threats poses substantial risks to both its own citizens and the populations of other nations. Second, the state's control over borders allows governments to ignore international health standards in regulating the flow of goods and people across their borders and in managing the health of their domestic populations. Finally, a state's assertion of non-interference in its domestic affairs provides an ostensible justification for failing to cooperate effectively with state and non-state actors and comply with international health norms. A country may delay notifying the WHO of an emerging pathogenic threat, prevent its scientists from sharing information, or refuse to cooperate with international agencies. Each of these acts of "sovereignty" threatens biosecurity in this global day and age.⁴²

There have always been strong reasons for international cooperation on biological weapons and naturally occurring infectious diseases, but the need for globalized forms of governance concerning biosecurity goes beyond traditional rationale for international cooperation. The relationship between globalization and the worlds of biological weapons and public health governance is very different than it was in the nineteenth and twentieth centuries. First, the prominence of security in public health and *vice versa* makes today's governance context unique. Calibrating and integrating national and international governance strategies against biosecurity threats are challenges for which no precedent exists.

Second, globalization is a more formidable governance challenge today than it has ever been. Trade and travel (and the technologies that sus-

⁴² See Lawrence O. Gostin, *World Health Law: Toward a New Conception of Global Health Governance for the 21st Century*, 5 *YALE J. HEALTH POL'Y L. & ETHICS* 413, 417–18 (2005); see also David P. Fidler, *SARS: Political Pathology of the First Post-Westphalian Pathogen*, 31 *J.L. MED. & ETHICS* 485, 486–88 (2003).

tain them) remain vectors of infectious disease spread, just as they were during the course of the past two hundred years. However, the geographical reach of these vectors, and the speeds and volumes at which they move about the planet today, are historically unprecedented. Advances in transportation and other types of technologies have transformed the historical relationship between public health, science, and globalization into something simultaneously astonishing and frightening.

Third, the accelerated nature of globalization's impact on public health and security has not been matched by transformations in public health and security governance at the national and international levels. Notwithstanding the radical nature of the IHR 2005, public health governance at the national and international levels remains weak and fragmented. States have routinely failed to invest in public health systems, update public health laws, or stimulate innovative public health research. States' public health systems are also highly uneven in quality, even though pathogens readily traverse borders and pose the same epidemiological threat to human health. States have not recognized the single most important idea in public health—that the health and safety of their citizens depend on the capacities of all countries to conduct efficient surveillance and response for infectious disease. The biosecurity challenge requires rethinking national and international governance because of the profound effect contemporary globalization has on the security, health, and well-being of populations in every region.

2. From Power Politics to Global Justice: The Particularly Difficult Task of Equitable Distribution of Authority and Resources

The global biosecurity threat raises a second overarching question: What would be the fairest and most cost-effective method of governance and resource allocation to ensure biosecurity in a globalized world? For most of modern history, governance and resource allocation has been largely determined through entrenched power structures. Economically and politically powerful countries, principally in Europe and North America, have had a disproportionate influence on the global security and health agendas. This geopolitical imbalance has caused multiple problems for the world politics affecting biosecurity.

First, geopolitical centers of power have acted as if it were possible to protect themselves from the endemic diseases of the developing world. The international sanitary conventions adopted mainly by 19th century European countries were an attempt to protect the Western European frontier from the importation of cholera, yellow fever, and plague from Africa and Asia. Border and immigration policies designed to fend off diseases, such as hemorrhagic fever, tuberculosis, and HIV/AIDS, may reflect similar motivations.

Second, the developed world has an abiding interest in continuing its economic vitality through free trade and investment policies and agreements. The importance of commerce is reflected in the IHR 2005's sensitivity to trade concerns as well as health.⁴³ Yet, the SARS outbreaks demonstrated the need for decisive public health action, sometimes directly at the expense of commerce and trade.⁴⁴ Economic interests of powerful countries and multinational companies can, thus, complicate the context in which public health must act to prevent and promote population health.

Third, developed countries have resisted systematic action to provide technical and financial assistance for adequate health protection in poorer countries. To be sure, developed countries have historically provided development assistance for health purposes; and recently the amount of financial resources being devoted to global health has increased tremendously.⁴⁵ But the neglect and complacency of previous decades cannot be transcended overnight. This failure to allocate resources equitably has powerful ramifications for the future prospects of achieving better global biosecurity.

Transforming governance and shifting resource allocations from the model of power politics to one more akin to global justice would have remarkably positive effects on global biosecurity. Skepticism arises, of course, through questions that ask why powerful countries should change their ways significantly in the areas of concern for biosecurity policy. One could observe that the biosecurity threats present in our globalized world actually make self-help the most attractive and effective strategy for powerful states. And, indeed, governments in North America and Europe have spared themselves from the same disease-related devastation that has enveloped poor regions in Africa, Asia, the Caribbean, and Latin America because they invested in national public health capabilities for their own populations.

It might be comforting to continue the policy of erecting a metaphorical wall between the developed and developing world—strong national public health capacities, niggardly international aid, and restrictive policies on immigrants, refugees, and travelers. Yet, ultimately this game of “beggar thy neighbor” politics will backfire. The determinations by national security

⁴³ The purpose of the IHR 2005 is “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.” Int'l Health Regulations, *supra* note 37, art. 2.

⁴⁴ See, e.g., Jong-Wha Lee & Warwick J. McKibbin, *Globalization and Disease: The Case of SARS*, 3 ASIAN ECONOMIC PAPERS 113, 123–30 (2004); Wayne Kondro, *Canadians Still Stung by WHO's SARS Travel Advisory*, 361 LANCET 1624 (2003).

⁴⁵ See generally Jon Cohen, *The New World of Global Health*, 311 SCI. 162 (2006) (discussing amounts of assistance developing countries have devoted to global health).

policy makers in the United States and in other developed countries that HIV/AIDS in the developing world and the spread of avian influenza are security threats underscores this point. Naturally occurring disease threats are too ubiquitous, terrorists are too dangerous, and globalization too powerful to prevent the spread of biosecurity threats to the northern and western regions of the globe. The lessons of history all warn against *cordon sanitaire* policies that assume the feasibility of erecting walls to keep biosecurity threats out of one's own territory.

One need only recall the great influenza pandemic of 1918, which caused tens of millions of deaths in a world less than one-third the size of the current global population. Modern epidemiologists now estimate that over fifty million people died. If this estimate of the death toll is true, the virus may have killed as many as eight to ten percent of all young adults then living.⁴⁶ Lest we think that this could not happen again, it is well to remember that highly pathogenic influenza pandemics have occurred roughly two to three times per century, and that three prerequisites for a pandemic have emerged as the H5N1 has spread in Asia and beyond: (1) the identification of a novel viral subtype in animal populations; (2) viral replication causing disease and death in humans; and (3) some indications of sporadic human-to-human transmission.⁴⁷

There are good reasons, then, based on pure utility to transform governance mechanisms and re-allocate some resources more evenly across regions, irrespective of political and economic power. By allowing a larger group to participate in governance, countries can become more accountable and also move the agenda to the major disease threats around the globe. At the same time, by distributing resources more equitably, it will be possible to detect, prevent, and respond to disease threats more rapidly and effectively.

It would be naïve to believe that powerful countries will buy into policies of large redistribution. Particularly in a health emergency, countries with manufacturing capacities and political/economic clout will be unlikely to give up some of their precious stockpiles of vaccines and medications for the sake of poorer countries.⁴⁸ The commitment to provide technical and

⁴⁶ Jeffery K. Taubenberger & David M. Morens, *1918 Influenza: The Mother of All Pandemics*, 12 EMERGING INFECTIOUS DISEASES 15, 15, 19 (2006); Lone Simonsen et al., *Pandemic Influenza and Mortality: Past Evidence and Projections for the Future*, in THE THREAT OF PANDEMIC INFLUENZA: ARE WE READY? (Stacey Knobler et al. eds., 2005); Homeland Security, "Pandemic Influenza," http://www.globalsecurity.org/security/ops/hsc-scen-3_pandemic-influenza.htm.

⁴⁷ See generally Laurie Garrett, *The Next Pandemic?*, FOREIGN AFF. 3, July/Aug. (2005), at 3–23.

⁴⁸ It is quite likely that in the face of a new pandemic, governments will not export any of their nationally produced vaccines until domestic demand is satisfied. See David S. Fedson &

financial assistance for health system improvement in developing countries need not be open-ended; nor would it necessarily be sufficient to meaningfully reduce global health disparities. However, at a minimum, the developed world should help assure that all nations have core public health capacities for surveillance and containment of emerging health threats of global importance. This kind of commitment not only allows progressive development of higher standards of health in resource-poor countries, but is also in the interests of the industrialized world.

IV. BIOSECURITY AND THE RULE OF LAW

A. *Why the Rule of Law?*

The fourth major theme emerging from our analysis of the biosecurity policy revolution concerns the importance of embedding biosecurity in the rule of law. We find the rule of law salient for debates about biosecurity policy for four basic reasons. First, the rule of law is essentially a philosophy of governance that is particularly important to consider in an area that is undergoing unprecedented governance changes. Second, biosecurity involves security considerations, and friction between the exigencies of security and the rule of law has existed in the United States and many countries for much of their respective histories. This friction accompanies the development of biosecurity.

Third, many rule of law controversies have already arisen in the biosecurity context. Some of the most heated political discussions about biosecurity policy concern whether legal rules should restrain the discretion of public officials. To what extent should government be permitted to conduct intensive surveillance, regulate scientific pursuits, detain subjects for extended periods without charge, use extreme interrogation measures, or order compulsory vaccinations or quarantines? These activities, and other possible examples of controversial measures, are not intended as gratuitous deprivations of individual rights, or worse, a subterfuge for discrimination. Rather, most government officials who implement such measures genuinely believe their actions are needed to protect the public.

Fourth, the normative aspects of the rule of law philosophy of governance are important for biosecurity because they force us to ask what kind of biosecurity we want. The rule of law contains various notions of justice that connect to conceptions of what constitutes the good society. Taking the rule of law into account ensures that we think about what kind of biosecurity we want to develop and maintain.

This section offers a justification for embedding biosecurity in the rule of law based primarily on normative reasoning. We explain the benefits to individuals in having a sphere of autonomy, privacy, and liberty even in an environment of heightened biosecurity concerns. We also explain the benefits of clear rules and fair processes to a democracy confronted by biosecurity threats. The intent of bioterrorism is to destabilize society, spread fear, and provoke political over-reaction. The war metaphor often used in anti-terrorism discourse conveys the importance of fighting for a certain way of life that prizes personal and political freedom. If the reaction to terrorism diminishes personal liberty, then individuals and society suffer the very harms that terrorism is intended to inflict.

We understand hard tradeoffs between collective security and individual rights must be made. Sometimes people must forego some autonomy, privacy, or liberty for the common good. Yet, we do not accept that the rule of law inevitably makes society less safe. No philosophy of governance that produced insecure societies would be worth embracing and replicating elsewhere. We demonstrate why the rule of law can actually make society safer by building into public policy standards for planning, response, and accountability. It also gives members of the political community a stake in the society in which they live. By instilling trust in government, the rule of law facilitates public cooperation. Voluntary action, as opposed to government coercion, can be a powerful force for good in a public health emergency.

Biosecurity under the rule of law has instrumental, as well as normative, value. We explain and justify this position, but before analyzing the normative and instrumental benefits, we explain what we mean by biosecurity under the rule of law.

B. Understanding the Rule of Law

The rule of law is a complex ideal, without a consistent usage in jurisprudence or public discourse. It is a fluid idea, frequently invoked on both sides of any important political debate.⁴⁹ The rule of law traditionally refers to the supremacy of legal rules—the rule of law, not men. Our thesis is that formal law (not unaccountable exercises of political power) should, to the extent possible, guide biosecurity policy. At the national level, this happens by relying upon constitutions, statutes, regulations, and court cases to authorize the exercise of power and restrain that power. At the transnational level, the rule of law is more complex and involves governance regimes that shape the behavior of actors (e.g., states, corporations, individu-

⁴⁹ See RONALD A. CASS, *THE RULE OF LAW IN AMERICA* xii, xii–xiii (2001) (explaining how both sides used the rule of law in arguing whether President Clinton should be impeached).

als) in ways that promote biosecurity while respecting important values (e.g., human rights, trade, scientific integrity).

The idea of restraint is at the core of a rule of law system, which stresses the importance of limits on government power. The fear is that government officials cannot be trusted to place the greater good before their own personal or political interests. “The essence of government is power,” wrote James Madison, and “power, lodged as it must be in human hands, will ever be liable to abuse.”⁵⁰ Legal rules authorize, and limit, power and enshrine a sphere of individual freedom. Government officials are restrained by these rules, forced to adhere to specific standards and procedures, even if doing so negatively impacts their agenda as they perceive it. This restraining force prevents government officials from engaging in unjustified, or even insidious, infringement upon individual liberties.

Restraint of government action is a key aspect of biosecurity under the rule of law. Restraint comes from the creation of clearly articulated, previously announced legal standards to guide decision-making, thus assuring that government actors cannot overstep their legally circumscribed authority. Restraint similarly comes from the insistence on rigorous processes in advance of a coercive action. Clear standards for action and fair procedures are at the heart of the rule of law. When constrained by standards and process, government action will be more predictable, even-handed, and consistent, thus avoiding the potential for abuse inherent in unfettered power. Rational rules and procedural systems help prevent arbitrary or invidious government action in the midst of a crisis. Similarly, individuals and groups cannot be singled out for adverse treatment if biosecurity policy contains rules that are racially, ethnically, and socio-economically neutral, both as written and as applied.

A rule of law system, to be sure, will not prevent all abuses of power. Nor will it necessarily protect individual rights in all circumstances. Much depends on the form and content of the law. It may have objective standards, but does the rule adopt a sufficiently rigorous standard of scientific risk assessment? It may purport to be race or class neutral, but does it truly treat everyone fairly irrespective of his or her social and economic vulnerabilities? It may provide fair procedures, but are judicial reviews of executive actions impartial and prompt? These, and many other questions, are critical to the effectiveness and fairness of rule of law systems.

Although the traditional idea of rules as a constraining force is important, we also approach the objective of biosecurity under the rule of law from a slightly different perspective. Restricting government action is vital, but not only because of fear that the individuals wielding it will abuse power. Rather, the rule of law advances normative values that are deeply

⁵⁰ JAMES MADISON, 4 LETTERS AND OTHER WRITINGS OF JAMES MADISON 51 (1884).

rooted in democratic governance: protection of individual rights and liberties, the pursuit of individual and social justice, and transparent and accountable government.

C. *Protection of Individual Rights and Liberties*

Among a government's primary obligations are to assure a certain level of health and security for the population. Absent health and security, individuals cannot enjoy political, social, and other forms of freedom that are so important to personal wellbeing and thriving societies. Yet, government should also assure a sphere of freedom that requires structural restraints on political power, designed to safeguard individual rights and personal dignity. For nations sharing the central values of the rule of law, safeguards of individual rights should bound government action.

Individual rights, of course, need not be absolute. Personal interests in privacy, bodily integrity, and liberty must sometimes be sacrificed for the greater good. Even the most cursory examination of traditional public health powers reveals the burdens achieving population health can place on individuals. Surveillance, such as reporting and monitoring health records, entails government acquisition, storage, and use of sensitive information, implicating privacy.⁵¹ Compulsory vaccination, physical examination and treatment invade bodily integrity by forcing people to submit to medical intervention.⁵² Isolation and quarantine affect the right to free association and liberty itself.⁵³ Individuals and groups who are singled out by the government express legitimate concerns about stigma, embarrassment, and discrimination.⁵⁴

Public health powers, of course, also burden economic interests. Licensing affects professional freedoms; inspections affect free enterprise; and nuisance abatement affects the freedom of contract and right to use private property. Biosecurity policies, in particular, may adversely affect economic interests including those of vaccine and pharmaceutical manufacturers and health care institutions. Consider the economic effects of decisions to cull significant numbers of animals to contain the spread of diseases such as

⁵¹ LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 115 (2000); Ronald Bayer & Amy Fairchild, *The Limits of Privacy: Surveillance and the Control of Disease*, 10 *HEALTH CARE ANALYSIS* 19 (2002).

⁵² GOSTIN, *supra* note 51, at 180, 188; Lawrence O. Gostin, *Jacobson v. Massachusetts at 100 Years: Police Power and Civil Liberties in Tension*, 95 *AM. J. PUB. HEALTH* 576, 577 (2005); Brendon Kohrs, *Bioterrorism Defense: Are State Mandated Compulsory Vaccination Programs an Infringement Upon a Citizen's Constitutional Rights?*, 17 *J. L. & HEALTH* 241 (2002).

⁵³ GOSTIN, *supra* note 51, at 203; Nola M. Ries, *Public Health Law and Ethics: Lessons from SARS and Quarantine*, 13 *HEALTH L. REV.* 3, 4–5 (2004).

⁵⁴ GOSTIN, *supra* note 51, at 76.

such as avian influenza, bovine spongiform encephalopathy, and foot and mouth disease.⁵⁵ Or consider the significant adverse effects of travel advisories on trade and tourism during the SARS outbreaks.⁵⁶ International trade rules may allow diminution of economic interests in a public health emergency, such as compulsory licensing of anti-retrovirals for HIV/AIDS or Tamiflu for highly pathogenic influenza.⁵⁷

While ensuring communal health necessarily entails some sacrifice of individual liberties, there are reasons for deep concern about government over-reaction in a public health emergency, especially one associated with security implications. Governments, understandably, view security of the population as their highest calling, particularly when the source of harm is foreign and the acts are aggressive. Terrorist acts by their nature are brutal and disturbing, often occurring without advance warning. Researchers inform us that highly visible, unusual, and violent acts engender the greatest public fear.⁵⁸ Government, then, is likely to act boldly, and perhaps repressively, in the face of a terrorist threat, trampling the liberties that they purport to defend.

In response to the terrorist threat, the U.S. federal government has engaged in a number of actions that many believe represent over-reactions and infringements on the rule of law. These actions include the USA PATRIOT Act, the detention of illegal enemy combatants in the United States and at Guantanamo Bay, and conducting domestic surveillance within the United States without federal court authorization as required by the Foreign Intelligence Surveillance Act.

Much the same concerns arise with respect to government responses to naturally occurring diseases and disasters, particularly those that are unusual or frightening. Psychological research shows that people have a tendency to overestimate their individual risk when faced with an unfamiliar or dramatic threat, such as a frightening infectious disease or a catastrophic natural disaster.⁵⁹ Governments, in an attempt to protect their populations,

⁵⁵ See generally World Bank, Sub-Comm. On Global Program for Avian Influences and Human Pandemic: *Economic Impact of Avian Flu* (2005), available at <http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/EASTASIAPACIFICEXT/EXT/APREGTOPHEANUT/0,contentMDK:20713527~pagePK:34004173~piPK:34003707~theSitePK:503048,00.html> (last visited Nov. 17, 2006).

⁵⁶ THE WORLD BANK, EAST ASIA UPDATE: COUNTERING GLOBAL SHOCKS 13 (2005), available at <http://siteresources.worldbank.org/INTEAPHALFYEARLYUPDATE/Resources/EAP-Brief-final.pdf>.

⁵⁷ See, e.g., David Fidler, *The Continuing Global Spread of Avian Influenza A (H5N1) and Its Implications for International Law*, American Society of International Law, Nov. 7, 2005, available at <http://www.asil.org/insights/2005/11/insights051107.html>.

⁵⁸ See generally Howard Kunreuther, *Risk Analysis and Risk Management in an Uncertain World*, 22 RISK ANALYSIS 655 (2002) (examining different events and the public's concerns).

⁵⁹ See *id.* at 657–59.

may overreact with unnecessarily repressive or discriminatory measures. During the SARS outbreaks, for example, mass quarantine was initiated in parts of Asia and North America.⁶⁰ Similarly, in response to the threat of pandemic influenza, President Bush said he would use the military to enforce quarantines,⁶¹ a statement from which his administration later backtracked because of its legal and policy implications.

The rule of law, through its use of objective standards, requires government officials to justify infringements of individual rights and liberties. An infringement on individual rights might be unjustified for three reasons. First, the threat might not rise to a level of severity or probability of occurrence sufficient to implicate the use of coercive measures (threshold justification). Second, the proposed intervention might be ineffective against the threat (efficacy justification). Finally, even if effective, the intervention could be unnecessarily restrictive or intrusive (least restrictive option analysis). We will deal with each of these issues in turn, demonstrating how the rule of law, through its use of objective standards, can help prevent unjustified restrictions on individual rights and liberties.

Biosecurity under the rule of law should deal with the threshold justification problem by only authorizing action in the face of a demonstrable risk, as measured by an objective standard. Emergency health legislation can, for example, be used to authorize the use of broad coercive powers. However, the legislation can be structured so that these powers are not activated unless the risk meets a certain, predefined level of certainty and seriousness. Evidence of an existing danger to the community that is both probable and severe is an essential prerequisite to coercive action. In this way, the rule of law can serve as a justificatory hurdle, restraining coercive government actions until the biosecurity risk warrants their use.

For example, the Model State Emergency Health Powers Act (Model Act), drafted by the Center for Law and the Public's Health, requires that a governor declare a "public health emergency"⁶² before being granted special, more robust, powers, such as compulsory medical examination, vaccination, treatment, quarantine. The governor must satisfy three

⁶⁰ MARK A. ROTHSTEIN ET AL., QUARANTINE AND ISOLATION: LESSONS LEARNED FROM SARS 23–25 (2003), available at <http://www.louisville.edu/medschool/ibhpl/images/pdf/SARS%20REPORT.pdf> (report presented to the Centers for Disease Control and Prevention).

⁶¹ Deidre Walsh, *Bush: Military May Have to Help If Bird Flu Breaks Out*, CNN.COM, Oct. 5, 2005, <http://www.cnn.com/2005/POLITICS/10/04/bush.avianflu/>.

⁶² MODEL STATE EMERGENCY HEALTH POWERS ACT, art. IV (Draft Prepared by the Center For Law and the Public's Health at Georgetown and Johns Hopkins Universities for the Centers for Disease Control and Prevention 2001), <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf> [hereinafter MODEL ACT]. For an overview of the Model Act, see Lawrence O. Gostin et al., *The Model State Emergency Health Powers Act: Planning for and Response to Bioterrorism and Naturally Occurring Infectious Diseases*, 288 JAMA 622 (2002).

demanding conditions before declaring a public health emergency: “(1) an occurrence or imminent threat of an illness or health condition, that (2) is caused by bioterrorism or a new or reemerging infectious agent or biological toxin previously controlled and that (3) also poses a high probability of a large number of deaths, a large number of serious or long-term disabilities, or widespread exposure to an infectious or toxic agent that poses a significant risk of substantial harm to a large number of persons.”⁶³

Furthermore, the Model Act requires that the governor specify minimum information in the emergency declaration, in support of the existence of these conditions.⁶⁴ As a check against arbitrary action, the legislature may vote to discontinue a declared emergency.⁶⁵ Similarly, the courts can review whether the governor has demonstrated the existence of the conditions listed above.⁶⁶ The Model Act was specifically designed to give states the robust powers necessary for confronting a public health emergency, but the legislation was designed to only allow those potentially coercive powers when absolutely necessary. A governor’s power is limited by the extent to which he or she can demonstrate the existence of a real threat.

Assuming the “risk” threshold has been adequately met, the next issue involves justifying the particular intervention. Biosecurity under the rule of law requires an assessment of the likely efficacy of the intervention. Government officials must show that the technique they wish to use will actually diminish the risk or ameliorate the harm. Abrogation of individual rights and liberties can only be justified if the intervention is necessary and effective to achieve an important objective. Furthermore, governments must use the least restrictive intervention necessary to reduce the risk or ameliorate the harm. Usually, multiple effective strategies will be available, varying in their liberty-restricting coerciveness. The law should require government officials to select the most effective option that imposes the least restriction on individual rights.

The law can incorporate the principles of the most effective and least restrictive interventions necessary to abate the risk. Under the Model State Emergency Health Powers Act, isolation and quarantine may only be used pursuant to a court order based on evidence that the intervention will prevent transmission of an infectious disease, is necessary to protect the community’s health, and no other less restrictive option is available.⁶⁷ The court order must be obtained before acting, except in urgent situations. Even

⁶³ Gostin et al., *supra* note 62, at 625.

⁶⁴ MODEL ACT, art. IV, §§ 401–02.

⁶⁵ *Id.* § 405.

⁶⁶ *Id.*

⁶⁷ *Id.* art. VI, §§ 604–05.

when immediate action is required, a court order must be obtained as quickly as possible.⁶⁸

The Model Act similarly requires strong procedural due process protections. Individuals subject to restrictive action must receive written copies of the court order, accompanied by an explanation of their rights.⁶⁹ They have a right to a hearing during which they can challenge the order's validity, or the specific terms contained therein.⁷⁰

By requiring justificatory evidence at every step, the rule of law ensures that government will have the power to protect the community's health, but that this power is used only where necessary to reduce a serious health threat. With clearly articulated, objectively based legal standards and fair processes, the rule of law helps ensure that government will not unjustifiably infringe individual rights and liberties.

D. The Importance of Justice: Non-Discrimination, Natural Justice, and Distributive Justice

Justice is a complex and subtle concept with multiple meanings, but we focus on three that have special relevance to biosecurity policy: (1) *non-discrimination*—treating people equitably based on their individual characteristics (respect for difference); *natural justice*—affording individuals procedural fairness when imposing a burden or withholding a benefit (due process); and *distributive justice*—fair disbursement of common advantages and sharing of common burdens (fair allocation of risks, burdens, and benefits). For each of these meanings of justice, we explain how the rule of law advances their integration into biosecurity policy.

1. Justice as Fair Treatment: The Principle of Non-Discrimination

Just as political philosophers have focused on protection of individual interests, they have also stressed the responsibility of governments to treat individuals fairly. Justice requires “fair, equitable, and appropriate treatment in light of what is due or owed” to individuals and groups.⁷¹ Justice does not require universally equal treatment, but does require that similarly situated people be treated equally. Aristotle expressed the ideal of justice as the equal treatment of equals and the unequal treatment of unequals.⁷²

⁶⁸ *Id.* § 605.

⁶⁹ *Id.*

⁷⁰ MODEL ACT, art. VI, § 605.

⁷¹ TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 327 (1994).

⁷² ARISTOTLE, THE NICOMACHEAN ETHICS, BOOK V (H. Rackham trans., rev. ed. 1990).

Perhaps the most important aspect of justice as fair treatment is encapsulated in the principle of non-discrimination. The principle is more subtle than it may at first glance appear. At the simplest level, non-discrimination is the unfair treatment of a person because of his or her membership in a socially distinct group or category, such as race, ethnicity, sex, religion, age, or disability. Non-discrimination, therefore, requires that people be treated according to their individual characteristics and not their membership or association with a group. It cautions against judgments based on prejudice, irrational fear, or stereotype. Consequently, non-discrimination seeks equality of treatment among those who are similarly situated. For example, if a coercive action is needed to avert a risk, it should be fairly distributed among those who pose a real risk of transmitting infection.

Justice as fair treatment of individuals and groups is of particular concern in biosecurity policy because the histories of national security and public health have constant reminders of the unfair treatment of individuals and groups. One of the darkest marks in U.S. constitutional jurisprudence is the Supreme Court's decision in *Korematsu v. United States* (1944), in which the Court let stand, under the banner of national security, a blatantly racist detention program that stigmatized Japanese-Americans.⁷³ Disease epidemics, through a combination of fear and preexisting prejudices, have had a way of bringing out the worst in people. Societies have tended to blame outsiders for traumatic health events, often vilifying them in the process. It is difficult to exaggerate the dread caused by disease epidemics and the destabilizing effects on people and their communities. Persons suffering from, or exposed to, disease may be viewed as public menaces, or worse, loathed and blamed for their own condition.

Compulsory public health measures have been applied in ways that are better explained by discriminatory animus than by scientific reason. Several campaigns of restraint in 19th and 20th century America demonstrate the influence of prejudice: isolation of persons with yellow fever, despite its mode of transmission by mosquitoes;⁷⁴ arrests of alcoholics, especially poor Irishmen, in the false belief that cholera arose from intemper-

⁷³ *Korematsu v. United States*, 323 U.S. 214 (1944).

⁷⁴ David Musto, *Quarantine and the Problem of AIDS*, 64 MILBANK Q. 97, 102 (1986).

ance,⁷⁵ mass confinement of prostitutes suspected of having syphilis;⁷⁶ and forced removal of children thought to have poliomyelitis.⁷⁷

In one case, a federal court found that public health authorities were acting "with an evil eye and an unequal hand" by visiting a quarantine almost exclusively on Chinese Americans in a district of San Francisco.⁷⁸ Even in contemporary times, the hand of discrimination has been at work in, for example, the HIV/AIDS pandemic, particularly in policies targeting vulnerable groups such as injection drug users, sex workers, and gay men.⁷⁹ During the SARS outbreaks, hurtful stereotypes were rampant in the West about persons of Asian descent, implying they were unhygienic and vectors of infection.⁸⁰ This unfortunate trend continues, even in our supposedly more enlightened times.

Beyond the problem of overt prejudice and discrimination is the problem of neglect of the vulnerable. In the aftermath of the anthrax attacks in Washington, D.C. in October 2001, the government lavished great attention on Senate staffers while virtually ignoring postal workers.⁸¹ And the images of poor, mostly African American survivors of Hurricane Katrina in 2005 were seared onto the memory of television audiences throughout the world. Natural disasters are color-blind, and the relief efforts were not designed to be discriminatory. Yet government knows, or ought to know, that it is the poor who are congregated together in substandard conditions, that they cannot afford to evacuate, and that they would be most vulnerable to harm in a public health emergency. Hurricane Katrina taught this deeply important and unfortunate lesson about the profound harm that results from discrimination caused by a complacent eye and neglectful hand.

The rule of law can be a tool to protect against discrimination in biosecurity crises. Non-discrimination can be accomplished principally through the use of neutral rules, fairly enforced, and based on objective sci-

⁷⁵ Guenter B. Risse, *Epidemics and History: Ecological Perspectives and Social Responses*, in AIDS: THE BURDENS OF HISTORY 33, 45-46 (Elizabeth Fee & Daniel M. Fox eds., 1988).

⁷⁶ ALLAN M. BRANDT, NO MAGIC BULLET: A SOCIAL HISTORY OF VENEREAL DISEASE IN THE UNITED STATES SINCE 1880 (1985).

⁷⁷ Guenter B. Risse, *Revolt Against Quarantine: Community Responses to the 1916 Polio Epidemic, Oyster Bay, New York*, 14 TRANSACTIONS AND STUDIES OF THE COLLEGE OF PHYSICIANS OF PHILADELPHIA 23 (1992).

⁷⁸ *Jew Ho v. Williamson*, 103 F. 10, 24 (C.C.N.D. Cal. 1900).

⁷⁹ See generally LAWRENCE O. GOSTIN, THE AIDS PANDEMIC: COMPLACENCY, INJUSTICE, AND UNFULFILLED EXPECTATIONS (2004).

⁸⁰ Iris Chang, Op-Ed., *Fear of SARS, Fear of Strangers*, N.Y. TIMES, May 21, 2003, at A31.

⁸¹ See Eric Lipton & Kirk Johnson, *Tracking Bioterror's Tangled Course*, N.Y. TIMES, Dec. 26, 2001, at B5.

entific evidence.⁸² In contrast, discrimination is based on irrational, non-scientific biases. The biosecurity context manifests this discrimination as the unreasonable conflation of racial, cultural, and socioeconomic attributes with the etiology of disease.⁸³ It is harder to draw social or racial distinctions when the law requires action based on objective standards based on scientific risk assessments. Beyond neutral standards, the law can explicitly create sanctions for actions based on race, disability, or socioeconomic status. If non-discrimination statutes are well drafted and vigorously enforced, they can demonstrate a commitment to fair treatment of the poor and minorities, which can be particularly important in times of a health crisis.

2. Natural Justice: Procedural Due Process

Fair processes are critically important to sound, balanced decision-making under the rule of law. Procedural fairness is so fundamental to ideals of justice that Europeans frame it as “natural justice,” while North Americans frame it as “due process.” The conduct of legal proceedings according to established rules ensures the fundamental fairness that lies at the heart of due process. The elements of due process include notice, trial rights including representation by an attorney, and a fair hearing before a neutral tribunal with the power to decide the case.

The normative value of due process is well grounded in constitutional and human rights law. For example, Article 9 of the International Covenant on Civil and Political Rights guarantees the right to liberty and security of person and freedom from arbitrary arrest or detention: “No one shall be deprived of his liberty except on such grounds and in accordance with such procedure as are established by law. . . . Anyone who is deprived of his liberty by arrest or detention shall be entitled to take proceedings before a court, in order that court may decide without delay on the lawfulness of his detention and order his release if the detention is not lawful.”⁸⁴

These words have meaning and importance in the context of biosecurity policy. Governments can go a long way toward ensuring natural justice by subjecting their national security and public health decisions to rigorous independent review by a court or tribunal. Natural justice requires government to afford individuals a fair hearing in conjunction with the ex-

⁸² Procedural due process protections are also important, but will be discussed in the subsequent section. See *infra* Part IV.D.2.

⁸³ See David P. Eisenman et al., *Will Public Health's Response to Terrorism be Fair? Racial/Ethnic Variations in Perceived Fairness During a Bioterrorist Event*, 2 *BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, AND SCIENCE* 146 (2004) (discussing the importance of perceived fairness to the effectiveness of the public health departments' response during catastrophic bioterrorism).

⁸⁴ International Covenant on Civil and Political Rights, G.A. Res. 2200A, art. 9, U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316 (Dec. 19, 1966).

ercise of compulsory powers. Due process should be afforded before the individual is deprived of his rights, but could occur soon thereafter in an emergency.

The new worlds of biological weapons and public health governance will, in all likelihood, involve governments taking compulsory measures against individuals and thus infringing on their rights. Government powers exercised with respect to the criminalization of biological weapons development and use, regulation of the biological sciences, conduct of bio-defense activities, and responses to biological attacks or infectious disease outbreaks may well be coercive with respect to individuals, creating the need for procedural due process.

Fair processes protect a sphere of liberty by enabling people to contest potentially arbitrary, excessive, or wrongful biosecurity interventions. An orderly, systematic process can also promote more informed decision-making, which better serves the public interest. Due process is an important means of forestalling or correcting errors and allowing individuals to be made whole in instances of abuse. Perhaps most importantly, fair processes are inherently preferable as they affirm human dignity. Individuals gain a sense of respect for themselves and the legal system when they have a meaningful opportunity to present their case in an open forum. Fair processes facilitate public trust,⁸⁵ which is essential for orderly and safe behavior in a biosecurity emergency.

3. Distributive Justice: Racial and Economic Fairness

The final aspect of justice that is important in biosecurity policy is distributive justice, which we have already discussed in connection with the need for globalized biosecurity governance.⁸⁶ This form of justice requires that the risks, benefits, and burdens of biosecurity actions be fairly distributed, thus precluding the unjustified targeting of already socially vulnerable populations. Distributive justice is the fair distribution of benefits and burdens in a cooperative society.⁸⁷

In the context of public health, the principle requires that officials act to limit the extent to which the burden of disease falls unfairly upon the

⁸⁵ PRINCIPLES OF THE ETHICAL PRACTICE OF PUBLIC HEALTH (Public Health Leadership Society, 2002), available at <http://www.apha.org/codeofethics/ethicsbrochure.pdf>.

⁸⁶ See *supra* Part III.C.2.

⁸⁷ See generally Dan E. Beauchamp, *Public Health as Social Justice*, in NEW ETHICS FOR THE PUBLIC'S HEALTH 101, 105 (Dan E. Beauchamp & Bonnie Steinbock eds., 1999) (discussing an ideal "public health ethic" which includes "organized collective action . . . shared equally" among citizens); James F. Childress et al., *Public Health Ethics: Mapping the Terrain*, 30 J.L. MED. & ETHICS 170, 176-77 (2002) ("[S]ome evidence suggests that societies that embody more egalitarian conceptions of socioeconomic justice have higher levels of health than ones that do not.").

least advantaged and to ensure that the burden of interventions themselves are distributed equitably.⁸⁸ Thus, in the exercise of compulsory powers, distributive justice requires a fair allocation so as not to unduly burden particularly vulnerable populations. Distributive justice has been viewed as so central to the mission of public health that it has been described as its core value: “[T]he historic dream of public health . . . is a dream of social justice.”⁸⁹

Distributive justice does not merely require a fair allocation of risks and burdens. It also recognizes that public health often distributes benefits such as vaccines, treatment, disease protection devices (e.g., mosquito bed nets), access to health information, or other products or services. Problems of fair benefits allocation arise under conditions of scarcity, where there is a competition for resources. Such competition might occur, for example, with a scarcity of vaccines or treatment in the midst of a public health crisis, such as pandemic influenza. Therapeutic services can confer considerable benefit to the individual and ultimately to a population. Pandemic influenza would likely result in a paucity of vaccines and antiviral medications, raising the hard problem of fair allocation of scarce resources, nationally and internationally.⁹⁰

Advancing distributive justice is not an easy task because it forces decisions about rationing scarce resources. What values should guide rationing decisions: private need (treatment of the sick); public need (prevention among vulnerable populations); maintenance of essential services (protection of health care workers and “first responders”); or political influence (priority for those with political power and connections)? As indicated earlier, the *de facto* allocation principle in world politics has been political power.

The concept of distributive justice requires that public health interventions be undertaken in order to benefit the most people possible, regardless of their power or influence. This requirement drives policy to use private and public need to guide decisions involving resource allocations. Private need elevates the importance of increasing the resources utilized for

⁸⁸ See generally Susan Hurley, *The ‘What’ and the ‘How’ of Distributive Justice and Health*, in *EGALITARIANISM. NEW ESSAYS ON THE NATURE AND VALUE OF EQUALITY* (Nils Holtug & Kasper Lippert-Rasmussen, eds. 2007).

⁸⁹ Beauchamp, *supra* note 87, at 105.

⁹⁰ See Lawrence O. Gostin & Madison Powers, *What Does Justice Require for the Public’s Health?*, 25 *HEALTH AFF.* 1053, 1059 (2006); see generally *CITIZEN VOICES ON PANDEMIC FLU CHOICES, PUBLIC ENGAGEMENT PILOT PROJECT ON PANDEMIC INFLUENZA* (2005), available at http://ppc.unl.edu/publications/documents/PEPPPI_FINALREPORT_DEC_2005.pdf; John D. Arras, *Ethical Issues in the Distribution of Influenza Vaccines*, *YALE J. BIOLOGY & MED.* (forthcoming 2006); Kelley Lee & David P. Fidler, *Avian and Pandemic Influenza: Progress and Problems with Global Health Governance*, *GLOBAL PUB. HEALTH* (forthcoming 2007).

countries and populations experiencing the greatest burden of disease. Public need would allocate resources where they would do the most good for global health. This objective might mean rapidly allocating resources to a country experiencing an early outbreak of a novel disease in order to keep the outbreak from spreading. Public health interventions would, therefore, be used primarily for prevention and targeted at those who face the greatest risk of transmission. In other contexts, distributive justice may support priority allocations to essential workers who maintain public services critical to the functioning of modern societies.

The rule of law can contribute to this task of just rationing by creating allocation standards that require decision makers to consider a population's ability to cope with burdens and their need for extra access to benefits. This approach can take the form of distributive rules that account for the reality that certain populations are more vulnerable to disease and illness.

Of course, this requires that officials treat groups differently, seemingly violating the principle of neutrally written, scientifically based decision making standards. By incorporating the principle of distributive justice into biosecurity policy, certain populations will be treated differently from others. However, this approach is ethically justified because distribution is based on need and vulnerability.⁹¹ Unlike discrimination, which is based on irrational biases and stereotypes, distributive justice requires policy makers to face the scientific fact that certain populations require more help, and can bear fewer burdens, than others. All citizens deserve the protection of an effective biosecurity policy; it is naïve to assume that everyone has the same level of economic and social resources.

Unless policy makers recognize and internalize the reality that certain populations are more vulnerable than others because of their economic status, unjust health consequences will result. This became evident in the aftermath of the Hurricane Katrina disaster, where poor, often minority, populations did not possess the resources to evacuate. The government response plan did not account for this fact, leaving the burden of evacuation almost solely as the responsibility of individual citizens, with tragic consequences. Even though officials knew about this problem,⁹² nothing was

⁹¹ For example, American society has accepted "need" as the singular principle for allocation of seasonal (interpandemic) influenza vaccine. Consequently, priority is given to the elderly and health care workers. See U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HHS PANDEMIC INFLUENZA PLAN, app. D at D13–D15 (2005), available at <http://www.hhs.gov/pandemicflu/plan/appendixd.html>; James G. Hodge, Jr. & Jessica P. O'Connell, *The Legal Environment Underlying Influenza Vaccine Allocation and Distribution Strategies*, 12 J. PUB. HEALTH MGMT. PRAC. 340, 341 (2006).

⁹² See generally WHO ARE KATRINA'S VICTIMS? (Center for American Progress, 2006), available at <http://www.americanprogress.org/atf/cf/%7BE9245FE4-9A2B-43C7-A521-5D6FF2E06E03%7D/KATRINAVICTIMS.PDF> (presenting census data indicating that large

done. In July 2004, FEMA staged an exercise simulating a hurricane disaster scenario in New Orleans. Officials acknowledged that tens of thousands of residents would not have the means to evacuate with government assistance. Rather than address this concern, they based their response plan on the assumption that one-third of the city's residents would not be able to evacuate.⁹³ Had distributive justice been a guiding principle, officials could have avoided much of the death and illness disproportionately borne by minority populations.

Social justice demands more than fair distribution of resources in circumstances of extreme health emergency. The interests of vulnerable populations are undermined well beyond the detriments to their health. A failure to act expeditiously and with equal concern for all citizens, including the poor and less powerful, predictably harms the whole community by eroding public trust and undermining social cohesion. It signals to those affected and to everyone else that the basic human needs of some matter less than those of others, and it thereby fails to show the respect due to all members of the community. Social justice thus encompasses not only a core commitment to a fair distribution of resources, but it also calls for policies of action that are consistent with the preservation of human dignity and the showing of equal respect for the interests of all members of the community.⁹⁴

E. Transparent and Accountable Governance

Thus far, we have discussed how biosecurity under the rule of law protects individual rights and ensures that government acts fairly. The rule of law has a third normative benefit: the facilitation of open and accountable government.⁹⁵ Open government, or transparency, requires government officials to make decisions in full public view. The relevant public groups (e.g., stakeholders and the more generally interested public) should understand the factors that go into making a decision or rule: the facts and evidence, the goals, the steps taken to safeguard individual rights, the reasons for the decision, and the procedures for appealing. Open governance may be accomplished in many ways, including open forums with advance notification to the public, publication of regulatory proposals in a public register, and the right of citizens to make verbal and written comments. The hall-

numbers of impoverished and minority persons resided in Louisiana and other states affected by Hurricane Katrina).

⁹³ See Susan B. Glasser & Michael Grunwald, *The Steady Buildup to a City's Chaos: Confusion Reigns At Every Level Of Government*, WASH. POST, Sept. 11, 2005, at A1.

⁹⁴ Gostin & Powers, *supra* note 90, at 1059.

⁹⁵ For a systematic discussion, see LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* (2d ed. forthcoming 2007).

marks of open governance, then, are free flows of information and civic participation.

Accountability refers to the idea that good governance requires more than appropriate policy; government must be held responsible for executing policies fairly and efficiently. Transparent government is accountable to its citizens. This accountability certainly occurs through a democratic process as the public considers policies at the ballot box. However, public accountability goes beyond elections. It comes from checks and balances among the three branches of government. Thus, security and public health officials are politically accountable to the chief executive, must act within the scope of legislative authority, and are subject to judicial oversight. Public accountability also comes from having to justify governmental decisions to the public generally and to affected communities in particular. Finally, public accountability comes from protection of “whistleblowers”—people within agencies who speak out about illegal, improper, or secretive conduct. Since the public cannot know when public officials are concealing important information, it is imperative to encourage insiders to reveal matters of public concern.⁹⁶

Openness and accountability are important to biosecurity governance because of their intrinsic value and capacity to improve decision-making. Citizens gain a sense of satisfaction by participating in policy making and having their voices heard. Even if government decides that individual interests must yield to common needs, those who participated sense that their civic importance and personal values have been acknowledged and taken into account.

Transparency also has instrumental value because it provides a feedback mechanism—a way of informing public policy and arriving at more considered judgments. Open forms of governance engender and sustain public trust, which benefits the biosecurity enterprise more generally. Without public support, and the voluntary cooperation of those at risk, coercive biosecurity interventions would be difficult to achieve. The populace must be able to trust that its government is acting in its best interests.

When a government takes action to protect or enhance biosecurity, how can the public know whether that action was appropriate? How can citizens ensure that the government is acting in their best interests? Biosecurity under the rule of law not only limits government power, but it also affords a means of accountability. The law can identify the powers available to government, and when those powers can be used (delineation of powers).

⁹⁶ In *Garcetti et al. v. Ceballos*, the Supreme Court scaled back protections for government workers who blow the whistle on official misconduct. In a victory for the Bush administration, justices said the twenty million public employees do not have full free speech protections when making “statements pursuant to . . . official duties.” *Garcetti v. Ceballos*, No. 04-473, slip op. at 5, 9 (U.S. May 30, 2006).

It can require that the use of a power be justified through the imposition of objective, neutral legal standards that guide decision-making procedures (substantive justification). Finally, the law can put procedural protections in place to ensure that any decision is subject to judicial or legislative oversight (procedural checks and balances). Each of these rule of law characteristics provides a means through which a population can hold their government accountable in the new world of biosecurity governance.

Delineation of powers serves a defining function. A statute that articulates what is, and is not, authorized can be a helpful device. The electorate can use the statute to scrutinize government action. If law does not authorize the action, the government will be exposed as having overstepped its bounds. Officials will be aware that their constituents could notice any deviation from the rule of law. As a result, government officials will have an incentive to conform to rule of law's pre-articulated delineation of powers, or risk potential negative political repercussions.

The justification requirement takes accountability one step further. Even if a power has been authorized, it still must be used only when necessary. Specifically, as we argued above, a power must be used in the least restrictive way possible, and the benefits/burdens of that action must be distributed justly. International tribunals have applied the least restrictive measure necessary principle to actions purported to protect public health.⁹⁷ In order for a population to ensure that their government is using an authorized power appropriately, they need access to the decision-making process. Why was a specific intervention chosen? What others were discarded? How is the decision going to be implemented? And most importantly, on what evidence has the decision been based?

By requiring that governments comply with neutral, objective standards, the rule of law forces governments to articulate explicitly and publicly the rationale behind their decisions. This dynamic gives the public a tool by which they can evaluate whether an authorized power has been used in their best interests. Stated another way, the principle of transparency is a mechanism by which government can be held accountable for its decision-making procedures. Transparency is premised on the principle that individuals should understand the facts and reasons justifying biosecurity interventions, the goals of intervention, and the steps taken to safeguard individual rights. Furthermore, because all information and decision making is

⁹⁷ See, e.g., *Enhorn v. Sweden*, 34 Eur. Ct. H.R. 2005, 30 E.H.R.R. 2005 (finding a violation of art. 5(1) of the European Convention of Human Rights because the government had not sought "less severe measures" before isolating a person living with HIV/AIDS), available at <http://www.echr.coe.int/Eng/Press/2005/Jan/ChamberjudgmentEnhornvSweden250105.htm>. See also Robyn Martin, *The Exercise of Public Health Powers in Cases of Infectious Disease: Human Rights Implications*, 14 MEDICAL L. REV. 132 (2006).

accessible, it encourages civic deliberation and public participation in the biosecurity policy making process.

Finally, accountability is meaningless without an effective enforcement mechanism. Knowing that the government has acted inappropriately is valueless unless there is a procedure for overturning that decision. The law can ensure enforcement in multiple ways. It can establish procedural protections that serve as a check on governmental action. Often, these protections take the form of judicial hearings where individuals can challenge the justification or implementation of a government action. Similarly, the law can impose legislative oversight, giving an elected body the power to overturn executive decisions. Such a structure exists in the Model Act, where a governor's declaration of a health emergency can be reversed by the state legislature.⁹⁸

Despite its undoubted value, transparency may be hard to achieve in the real world of politics. How do we know when public officials are simply feigning transparency by making it look as if they are open and fair? The reasons given for their decisions may simply be "spin," which is becoming ubiquitous in our democracy. And, although officials may hold open meetings, how do we know they are not unduly influenced by economically powerful special interests acting behind the scenes, such as large industries making profits from selling oil, tobacco, firearms, or even pharmaceuticals? Citizens should not become complacent about transparency, but should insist that officials engaged in all aspects of biosecurity adhere to the literal meaning of the term—truth and openness.

F. Practical Benefits of Biosecurity under the Rule of Law

We have argued that creating biosecurity policy under the rule of law is vital because it protects individual rights, promotes justice, and encourages open and accountable government. Yet, many would argue that biosecurity crises are so variable, complex, unpredictable, and time-sensitive that government needs the freedom to act quickly, using its best judgment to react to the particular situation at hand. The rule of law, by definition, restricts government's ability to be responsive to urgent health threats. Requiring compliance with neutral standards and the presentation of scientific evidence to justify an action limits the range of actions available to government and occupies precious time. Even with the normative benefits offered by a rule of law system, perhaps practical issues could make it prohibitively difficult, undermining the need to strengthen the country's biosecurity.

Although this argument is not without merit, we believe that it overstates the practical shortcomings of biosecurity under the rule of law. In

⁹⁸ MODEL ACT, art. IV, § 405.

fact, the rule of law can produce a number of consequential benefits that would make biosecurity policy more effective and efficient. In this section, we explore these practical benefits, focusing on two areas: preparation for and response to a biosecurity emergency. Preparation involves the creation of systems that minimize the risk of an event occurring and that facilitate the mitigation of harm should an event occur. However, the best laid plans for an emergency are empty unless they lead to an effective response. Response is the set of actions designed to stop, contain, or reduce disease once an outbreak has occurred.

1. Preparation for a Biosecurity Emergency

Having a systematic plan for preparing for biosecurity emergencies has been a salient topic of discussion following the Gulf Coast hurricanes (where relevant federal, state, and local agencies appeared ill-prepared) and avian and pandemic influenza (where multiple layers of government issued multiple plans for action that would prove difficult to integrate). Three important problems relate to sound preparation: resource allocations between security, biomedicine, and public health; high versus low probability events; and transnational cooperation.

Allocation of Resources. All societies have limited resources. Certainly poorer countries have more extreme scarcity, but even well developed countries have resource limitations when catastrophes strike. Societies face the hard problem of allocating resources (e.g., vaccines, pharmaceuticals, hospital beds) in a way that creates the highest level of biosecurity for the population. One important manifestation of this resource allocation problem is choosing among security measures, biotechnology, and public health. Security systems are designed to prevent a biological threat from occurring. Security might mean increasing law enforcement to find and arrest a potential terrorist. Biotechnology entails scientific research; stockpiling and delivery of vaccines or pharmaceuticals; and access to health care services. Public health systems have the goal of early detection and response to biological threats, which entails surveillance and interventions, such as contact tracing, directly observed therapy, and isolation of the infected.

Each of these needs is important. Security is crucial for preventing the unauthorized release of dangerous laboratory specimens, detecting plots to intentionally release infectious agents, and bringing perpetrators to justice. Biotechnology is essential for ensuring that medical prevention and treatment is readily available to the population. Adequate vaccination programs can help prevent outbreaks, while treatment can be ameliorative and also preventative by reducing infectiousness. Strong public health infrastructures are similarly important. Having state-of-the-art laboratories, data systems, and a well trained and well paid public health workforce can allow for early detection and containment of disease outbreaks.

Although all three of these variables are fundamental to sound biosecurity policy, many developed countries, and particularly the United States, have focused far too strongly on the first two aspects, leaving public health systems in “disarray.”⁹⁹ In the context of biological weapons, countries have focused on domestic security and international arms control, attempting to keep any event from occurring. In the United States, for example, many core public health functions have been assigned to the Department of Homeland Security at the expense of the Centers for Disease Control and Prevention.¹⁰⁰ The reality is that no amount of traditionally conceived security efforts can keep disease out of a country, whatever the origin of the pathogens. Even if the threat of bioterrorism could be completely eradicated (an unrealistic proposition), the globe must still confront the constant threat of naturally occurring pandemics and natural disasters.

The most well developed countries have also focused heavily on biotechnology. The Department of Homeland Security’s budget has devoted the vast majority of health-related funds to research, development, and stockpiling of new vaccines and pharmaceuticals.¹⁰¹ Substantial resources, for example, went into development of better vaccines for smallpox and influenza in light of recent events. Similarly, resources were devoted to stockpiling Tamiflu in response to the threat of pandemic influenza.¹⁰²

There is nothing wrong with these expenditures *per se*, but such expenditures have been at the expense of the daily needs of public health agencies for surveillance and response to all threats. Indeed, public health

⁹⁹ The Institute of Medicine’s landmark report on *The Future of Public Health* in 1988 observed that the governmental public health infrastructure was in “disarray.” INST. OF MED., *THE FUTURE OF PUBLIC HEALTH* 19 (1988). The Institute of Medicine’s 2003 report stated that in many ways it was “still in disarray.” INST. OF MED., *THE FUTURE OF THE PUBLIC’S HEALTH IN THE TWENTY FIRST CENTURY* 98 (2003). Similarly, the Centers for Disease Control and Prevention concluded that, despite recent improvements, the public health infrastructure “is still structurally weak in nearly every area.” DEP’T OF HEALTH & HUMAN SERVS., *PUBLIC HEALTH’S INFRASTRUCTURE: A STATUS REPORT* iii (2001) prepared for the Appropriations Committee of the United States Senate, 2001.

¹⁰⁰ Michele Late, *Homeland Department Plan May Undermine Public Health: Some HHS Duties Proposed to Shift*, THE NATION’S HEALTH, Aug. 2002, available at <http://www.apha.org/tnh/index.cfm?fa=Adetail&id=1464>.

¹⁰¹ The Department of Homeland Security Appropriations Act of 2005 provides \$2.5 billion for Project Bioshield for the development and pre-purchase of necessary medical countermeasures against weapons of mass destruction, and improved bio-surveillance by expanding air monitoring for biological agents in high-threat cities and high-value targets such as stadiums and transit systems. Press Release, Department of Homeland Security, Fact Sheet: Department of Homeland Security Appropriations Act of 2005, (Oct. 18, 2004), available at http://www.dhs.gov/xnews/releases/press_release_0541.shtm.

¹⁰² President George W. Bush requested \$1.029 billion to stockpile antiviral medications. Press Release, The White House, Fact Sheet: Safeguarding America Against Pandemic Influenza (Nov. 1, 2005), available at <http://www.whitehouse.gov/news/releases/2005/11/20051101.html>.

agencies have argued that this biotechnology focus on a few health threats has undermined preparedness for the broad range of threats, particularly from naturally occurring infectious diseases and disasters.¹⁰³

Unfortunately, the disproportionate focus on security and biotechnology has left little room for improving the public health systems designed to mitigate harm in the inevitable event of a biosecurity emergency. Current approaches may not, therefore, be achieving the integration of security and public health so vital to biosecurity in the global age.

This argument meshes with the importance of the rule of law to biosecurity policy. Biosecurity under the rule of law has the practical benefit of shifting society's emphasis on traditional security thinking by focusing on the full range of security, medicine, and public health problems. This objective connects to the rule of law's requirement that governance norms and rules be prospectively articulated. Prospective biosecurity laws should be debated, enacted, and implemented in times of relative calm, well before a crisis occurs.

During this window of rationality, public health advocates can demonstrate the need for more attention to be focused on strengthening public health infrastructure. Granted, this task is difficult given that public health initiatives are inherently preventive. If they work, disease threats and prevalence decline, which encourages politicians to believe that the problem has been solved. As a result, gaining sustained political support for public health initiatives can be a daunting challenge absent an obvious crisis, like the frenzy caused by the threat of pandemic influenza. We do not suggest that biosecurity under the rule of law is a magic bullet that can completely solve this problem. Rather, the rule of law provides a rational framework, insulated from emergency situations, that makes it easier to argue for allocation decisions that integrate security, biotechnology, and public health.

Surveillance of High and Low Probability Events. Once resources are allocated, the next step is to watch for potential biosecurity risks, so as to better respond should they emerge. Here, the problem is one of orientation. Society has a tendency to focus on high consequence, low probability events. When faced with a tangible, dramatic threat, people want actions that will most directly and concretely address the threat. This dynamic can prompt government action, even if the probability of occurrence is low. For example, preparation for bioterrorist attacks consumes a disproportionate share of attention and resources, even though they are much less likely to occur than naturally occurring infectious disease outbreaks. A classic illus-

¹⁰³ See, e.g., *Concerning the Public Health Budget for Fiscal Year 2006: Hearing Before the H. Appropriations Subcommittee on the Departments of Labor, Health, and Human Services, Education, and Related Agencies*, 109th Cong. 684 (2006) (statement of the American Public Health Association), available at <http://www.apha.org/legislative/testimonies/APHAAppropriationsTestimony.doc>.

tration of this problem was the panicked attention given to anthrax and smallpox after September 11, 2001.

We have argued that an effective biosecurity policy requires an orientation towards both high and low probability events, but with an emphasis on the most probable situations. An unwavering attention to unlikely bioterrorist attacks is irresponsible if it precludes confronting the near certainty of serious naturally occurring diseases and disasters. The rule of law, if constructed with careful risk assessments, has the consequential benefit of helping society achieve an appropriate orientation towards both high and low probability biosecurity events.

This benefit results from a mechanism similar to the one discussed in the previous section. Prospectively promulgated rules, insulated from the stress of an immediate crisis, create a more effective biosecurity policy by allowing for a focus on policy initiatives that deal with events that are most probable. By prospectively creating a rational biosecurity plan, isolated from the political influence of popular fears, society is not limited by a focus on establishing security systems to prevent the most dramatic (and least likely) events. The rule of law helps create a rational framework that requires evidence and justification for policy decisions. This approach allows policy makers to focus on measurable probabilities, rather than unsubstantiated fears.

Facilitating Global Cooperation. Global cooperation and governance is vital to a being well-prepared for the range of biosecurity risks. Diseases can originate anywhere and can quickly spread in an age of rapid global transportation and commerce. We have argued that globalized governance structures are vital aspects of an effective biosecurity policy. The rule of law can facilitate the creation and implementation of cooperative global biosecurity policies.

As we have noted, the only true protection against biological threats, both naturally occurring and intentionally inflicted, comes through cooperative arrangements among countries and non-state actors. These arrangements may or may not be legally binding in terms of formal international law, but they are designed to provide the kind of rationally crafted collective action that will facilitate effective responses to biosecurity threats. The effective global governance utilized to address the SARS outbreaks in 2003 was not authorized by the IHR 1969 or any other formal international legal agreement, yet states and non-state actors participated in a response that changed the paradigm for infectious disease governance for the twenty-first century.

2. Responding to a Health Emergency

Perhaps the two most important problems associated with responding to a biosecurity emergency are timely decision-making and coordination of action. Hurricane Katrina, again, offers a lesson. During the response and

rescue phase of that natural disaster, it became evident that key questions were left unanswered: Who is in charge and accountable? How can the various public services be coordinated (e.g., police, emergency management, health care, public health)? What is the respective role of federal, state, and local agencies?¹⁰⁴ Similar questions have arisen in various tabletop exercises designed to simulate biosecurity crises, such as the use of biological weapons by terrorists.

Improved Decision-Making. Decision-making poses a problem in the stressful, time-limited context of a biosecurity crisis. Whenever a decision has to be made, information must be gathered and analyzed, then a decision must be reached. In a crisis, these tasks could take significant time, during which the situation can worsen. It is also possible that, under crisis conditions, the government could make an inappropriate choice based on disorganized or missing information. Biosecurity under the rule of law can facilitate decision-making processes by improving the gathering and flow of information, and by clearly articulating the parameters and factors that go into a given decision. The law can pre-determine such things as who is “in charge” and accountable, which level of government and agency takes the lead, and how the various services can coordinate their response.

The rule of law combats these potential problems by prospectively establishing information gathering and analysis systems. Surveillance systems can be established to systematically collect, organize, and distribute vital health information in a rational and efficient manner. In a crisis situation, it will be much easier to make difficult decisions involving, for example, quarantine, evacuation, or rescue if the information is readily available and lines of communication are clear, tested, and resilient.

Furthermore, this information can be used to continuously update biosecurity plans as circumstances change. For example, as population distribution in a region changes, evacuation thresholds and protocols can be altered. Should an emergency arise, government officials will have the most accurate data and decision-making tools available. In this context, information systems created and organized within the rule of law can serve as a reflective updating mechanism. Biomedical knowledge is always changing. New threats emerge, and new treatments are developed. With the use of

¹⁰⁴ See generally *Hurricane Katrina: Recommendations for Reform Hearing Before the S. Comm. On Homeland Security and Governmental Affairs*, 109th Cong. (2006) (statement of David M. Walker, Comptroller gen. of the U.S.), available at http://hsgac.senate.gov/_files?030806Walker.pdf; *Hurricane Katrina: Preparedness and Response by the Department of Defense, the Coast Guard, and the National Guard of Louisiana, Mississippi, and Alabama Before the Select Bipartisan Comm. to Investigate the Preparation for and Response to Hurricane Katrina*, 109th Cong. (2005), available at <http://www.ngaus.org/ngaus/files/ccLibrary-Files/File/000000000656/House%20Select%20Katrina%20Response%20Investigation%20Committee%20Holds%20Hearing%20on%20Hurricane%20Katrina%20Preparedness%20and%20Response.pdf>.

prospectively established information gathering systems, policy-makers can incorporate the most recent knowledge into the established plans and structures. This strategy avoids creating a stagnant response system.

Coordination of Action. Coordination of actions poses a similar set of issues. First, as indicated above, it is important to define prospectively who is responsible for which set of activities. Biosecurity emergencies require immediate responses. Struggling over which level of government, which agency, or which official is responsible only wastes time, allowing the emergency to spread, or its effects to worsen.

Second, responding to a biosecurity emergency is a complicated endeavor, requiring the coordination of different levels of government (local, state, federal, and even international). It is vital to define the responsibilities of each tier, so none of the necessary responses are neglected. This approach also ensures that actions by the various levels of government are not at odds with each other and fit together as an integrated security and public health response to the threat.

V. CONCLUSION

This article attempts to convey some of the profound changes that have transformed biosecurity governance. Space constraints have prevented us from a detailed exploration of all biosecurity policy issues. We have outlined some themes analyzed in our forthcoming book and focused on the importance of embedding biosecurity policy in the rule of law.

This article and our book explain the analytical reasons for our position, but we have personal motivations as well. From our scholarly and professional pursuits in different aspects of security and public health before September 11 and the anthrax attacks, we recall the complacency about the terrorist and bioterrorist threats that existed before those terrible months in the autumn of 2001. Crises replaced complacency, and out of the crises has come an opportunity to re-conceptualize biosecurity policy. This challenge has to be translated into action through new strategies and policies. Part of that commitment, we believe, must include the importance of having the rule of law stimulate both the imagination and the practice of biosecurity efforts in the twenty-first century.