Foreword: Necessary Progress in Biosecurity

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We need to strengthen U.S. biosecurity. The Obama White House's recent policy document on biosecurity, *National Strategy for Countering Biological Threats*, judged that biological attacks could place at risk the lives of hundreds of thousands of people and impose costs exceeding one trillion dollars.[1] A UN Secretary's report on terrorism stated that "[t]he most important under-addressed threat relating to terrorism, and one which acutely requires new thinking on the part of the international community, is that of terrorists using a biological weapon."[2] The U.S. anthrax attacks of 2001 showed that a tiny amount of powder in a few envelopes could cause tremendous national anxiety and disruption, in addition to illness and death.[3] Advances in the biological sciences will improve human health, expand the food supply, and provide countless other benefits. As an example of the pace of change, the cost of human genome sequencing has declined 10,000-fold in the last twenty years.[4] But these advances in science will also lower the cost of creating biological weapons.[5] Given these and many other events, assessments, and trends, it is clear that the United States and other nations must work strongly to counter the threats posed by biological terrorism.[6]

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[1] NAT'L SEC. COUNCIL, NATIONAL STRATEGY FOR COUNTERING BIOLOGICAL THREATS 1 (2009), *available at* http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf.

[2] The Secretary-General, *Report of the Secretary-General on Uniting Against Terrorism: Recommendations for a Global Counter-Terrorism Strategy*, ¶ 52, *delivered to the General Assembly*, U.N. Doc. A/60/825 (Apr. 27, 2006), *available at* http://www.un.org/unitingagainstterrorism/sg-terrorism-2may06.pdf.

[3] *See, e.g.*, Fed. Bureau of Investigation, Amerithrax Investigation, http://www.fbi.gov/anthrax/amerithraxlinks.htm (on file with the Harvard Law School Library).

[4] Rob Carlson, *The Bio-Economist*, SYNTHESIS, Sept. 9, 2009, http://www.synthesis.cc/2009/09/the-bio-economist.html (on file with the Harvard Law School Library).

[5] COMM. ON ADVANCES IN TECH. & THE PREVENTION OF THEIR APPLICATION TO NEXT GENERATION BIOTERRORISM & BIOLOGICAL WARFARE THREATS, INST. OF MED. OF THE NAT'L ACADS., AN INTERNATIONAL PERSPECTIVE ON ADVANCING TECHNOLOGIES AND STRATEGIES FOR MANAGING DUAL-USE RISKS, at vii–viii (2005), *available at* http://www.nap.edu/catalog.php?record_id=11301.

[6] *Cf.* U.S. GOVERNMENT JUDGMENTS ON THE THREAT OF BIOLOGICAL WEAPONS: OFFICIAL ASSESSMENTS, 2004–2009 (Ctr. for Biosecurity of UPMC ed., 2010), *available at* http://

Similarly, the threat posed by the H1N1 flu virus over the last year has shown how essential it is for the country to be prepared for pandemics. Last year's pandemic appeared at a time outside of the normal flu season,[7] leading some countries to suspend normal travel and business and school activities,[8] and provoking many people in our country to demand that borders be closed in a (futile) effort to keep the flu from coming to the United States;[9] it was already spreading in the United States by the time that calls to close the border were being made.[10] The 2009 H1N1 flu led to increased numbers of deaths in pregnant women and in young and middle-aged adults.[11] It also caused deaths in children two to three times that of a normal flu season.[12]

Biosecurity, as is true for national security and disaster response, needs to be a nonpartisan issue. Improving biosecurity requires long-term focus and commitment by the government and the private sector. Strengthening biosecurity is an explicit policy goal of the current Administration just as it was in the last Administration.[13] How we approach this goal and with what speed are the critical questions.

The question of how to approach biosecurity should be of compelling interest to progressive thinkers, experts, and legal scholars. As the articles in this Symposium on Public Health and Biosecurity demonstrate, there are important decisions to be made regarding how we prepare, how we invest, how we organize, and how we prioritize to improve the country's biosecurity. The articles in this Symposium examine distinct facets of biosecurity policy and programs, each article raising issues worth consideration.

Lawrence O. Gostin, in the first article in the Symposium, makes a case for a new global compact for improving global health. He sets forth a "Global Plan for Justice—a voluntary compact among states and their partners in business, philanthropy, and civil society to redress health inequali-

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www.upmc-biosecurity.org/website/focus/national_security/2010-01-19-gov_judgments_BWthreat.pdf.

[7] Ctrs. for Disease Control & Prevention, CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April 2009–February 13, 2010, at 4 (2010), *available at* http://www.cdc.gov/H1N1flu/pdf/2009_H1N1_Estimates_031210_final.pdf.

[8] *See, e.g.*, Edward Wong, *China's Tough Flu Measures Appear to be Effective*, N.Y. Times, Nov. 11, 2009, at A3.

[9] *See, e.g.*, Jeff Butera, *Franks: Close US-Mexico Border*, KPHO.com, Apr. 29, 2009, http://www.kpho.com/health/19328625/detail.html (on file with the Harvard Law School Library).

[10] *Id.*

[11] Ctrs. for Disease Control & Prevention, *supra* note 7, at 10; Denise J. Jamieson et al., *H1N1 2009 Influenza Virus Infection During Pregnancy in the USA*, 374 Lancet 451, 455 (2009).

[12] *2009–2010 Influenza Season, Week 13 ending April 3, 2010*, FluView (Influenza Div., Ctrs. for Disease Control & Prevention, Atlanta, Ga.), Apr. 2010, at 7, *available at* http://www.cdc.gov/flu/weekly/pdf/External_F1013.pdf.

[13] The White House, Homeland Security, http://www.whitehouse.gov/issues/homeland-security (on file with the Harvard Law School Library); Press Release, Office of the Press Secretary, Homeland Security Presidential Directive (Oct. 18, 2007), *available at* http://georgewbush-whitehouse.archives.gov/news/releases/2007/10/20071018-10.html.

ties."[14] He describes how socioeconomic status fundamentally affects health and how life expectancy remains starkly different around the world. Gostin offers a critique of the current funding strategy by donor countries and foundations, arguing that funders should use their investments to build health systems and human resources, rather than to respond to specific crises and short-term goals.

A pillar of Gostin's plan is the creation of a Global Health Fund that would be administered by the World Health Organization and would be able to meet the basic health needs of developing countries. Steady funding for these efforts would be needed from high-income countries. He proposes that part of this funding target the provision of essential medicines and vaccines, including a more equitable global distribution of vaccines during major epidemics, which was not the case in the H1N1 experience of the past year. Another portion of the funding would go to basic needs such as food, clean water, sanitation, and vector control. The remainder would go toward climate change adaptations—preparations for extreme events, scarcity of water, changes in epidemic disease patterns, and increased cardiovascular and pulmonary diseases caused by poor air quality. Gostin's argument should make us reflect on the core strategies of improving global health—an international element of improving biosecurity.

Sam Berger and Jonathan D. Moreno, in their Symposium article, distinguish between coercive and cooperative models of response to public health emergencies.[15] Coercive models rely on forceful measures, such as involuntary quarantines, to contain infectious diseases. They are, to some extent, a legal codification of procedures that played historical roles in containing the spread of epidemics, for example, quarantining a ship just outside Venice for forty days to make sure it was carrying no lethal infectious diseases. For the most part, though, the historical conditions that may have led coercive models to be useful in the past no longer exist.

Cooperative models, on the other hand, work to contain contagious diseases by encouraging the public to cooperate with public health guidance, but they do not force the public to comply. A major underpinning of cooperative models is the argument that no public health guidance is likely to work without cooperation from the public, and that the public is unlikely to cooperate unless it trusts public health officials. Berger and Moreno argue that in most situations cooperative models are likely to be more effective, and that they are more likely to improve the public health system over time because they focus on building systems useful for a range of public health challenges. Berger and Moreno's discussion of these issues has important implications for public health emergency planning.

In the Symposium's next article, Fazal Khan describes the legal landscape of public health preparedness, including shortcomings in legal protec-

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[14] Lawrence O. Gostin, *Redressing the Unconscionable Health Gap: A Global Plan for Justice*, 4 HARV. L. & POL'Y REV. 271, 272 (2010).

[15] Sam Berger & Jonathan D. Moreno, *Public Trust, Public Health, and Public Safety: A Progressive Response to Bioterrorism*, 4 HARV. L. & POL'Y REV. 295 (2010).

tions and unnecessary expansions of government powers.[16] He describes the genesis of the Model State Emergency Health Powers Act used by many states to change public health law after 9/11. He argues that this Act went too far in restricting liberties in response to exceptional events, but since has been improved and narrowed after debate in the legal community. In contrast, Khan argues, since 9/11 the federal government has merged its public health policies with national security policy. He sees President Obama's vows to restore accountability and transparency as steps in the right direction, but also sounds a note of serious concern regarding the balance between civil liberties and security, arguing that it is time that the Administration reexamine this issue.

In the last article in the Symposium, Serena Vinter, Dara Alpert Lieberman, and Jeffrey Levi argue that "[a] cornerstone of public health emergency preparedness is community resilience: the notion that healthy, well-connected communities are better prepared to both weather public health emergencies and recover from their aftermath."[17] Community resilience, and thus public health emergency preparedness, requires advanced technologies and a robust and well-trained workforce. It also relies upon the capacity of the health care system to care for the many sick people that could follow in the wake of an act of bioterrorism or a major epidemic. The authors also explain how public health emergency preparedness will improve with the recent passage of health care reform legislation, which contains funding for community-based prevention programs,[18] core public health infrastructure such as surveillance systems and laboratories,[19] improved access to vaccines,[20] and increased access to insurance coverage.[21] These increased funding provisions will encourage the sick to seek earlier treatment and help lessen the normal and crisis burdens on the country's emergency rooms. The $20 billion investment already provided by the American Recovery and Reinvestment Act (ARRA)[22] in 2009 is also likely to transform health information technology in ways that improve routine health care as well as emergency preparedness.

In addition to describing these reforms, the authors remind us that challenges remain even after the passage of the recent health care legislation. They urge us to continue to pursue goals such as obtaining adequate funding for hospital preparedness, developing standards for medical care during crises, reducing disparities in access to care around the country, and increasing

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[16] Fazal R. Khan, *Ensuring Government Accountability During Public Health Emergencies*, 4 HARV. L. & POL'Y REV. 319 (2010).

[17] Serena Vinter et al., *Public Health Preparedness in a Reforming Health System*, 4 HARV. L. & POL'Y REV. 339, 339–40 (2010).

[18] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 4201, 124 Stat. 119 (2010).

[19] *Id.* at § 4304.

[20] *Id.* at § 4204.

[21] *Id.* at § 1101.

[22] American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §§ 13001–4, 123 Stat. 115.

utilization of telehealth technologies to help reduce health care disparities and improve care delivery during a pandemic. The authors also raise the issue of delivering health care for the estimated twelve million undocumented workers in the country—an important problem in and of itself, but especially so when persons in that group contract and spread untreated contagious diseases. Vinter, Lieberman, and Levi's assessment of public health emergency preparedness and its potential linkages to health care reform is a valuable contribution as the country begins to implement and evaluate the recent legislation.

Taken together these Symposium articles provide a series of high-level principles and goals for biosecurity to which we can aspire over time, and near-term recommendations for improving biosecurity that are predicated on core American values and priorities. It is useful to consider those recommendations in the context of a broader U.S. biosecurity agenda—a list of prevention and response priorities that are important and necessary.

First, we need sound planning and strategy on these issues, and we need it from the top. White House prioritization of biosecurity is critically important. Regrettably, federal responsibilities for setting and implementing biosecurity policy continue to be divided around the government. Without coordination at the White House and strong leadership on these issues in the agencies, the planning process will not be coherent or strong enough to make progress. This could change, though, with new signals from the top and a stronger, dedicated effort in the White House and the agencies on these issues.

Second, we need to pursue sound prevention policies. An important Administration policy document, *Countering Biological Threats*, outlines a set of important policy goals.[23] According to the document, the United States will continue to support the Biological Weapons Convention, and it will do so with pragmatism. We will work toward improving international disease surveillance, as well as strengthening our intelligence efforts so as to improve our ability to respond. We will pursue sensible lab security measures in our own labs and hope that these measures will persuade other countries to put similar measures in place. And we will improve our forensics efforts so we are better able to attribute future biological attacks. All together, this prevention-oriented policy is sound and, to the extent it can be implemented in the months and years ahead, will move U.S. biosecurity policy in the right direction.

One particularly critical element of prevention is the country's deterrence policy for biological weapons. With nuclear weapons, the threat of a retaliatory nuclear response following the use of nuclear weapons against the United States or its allies has worked effectively as a deterrence mechanism. U.S. deterrence policy has been marked by calculated ambiguity regarding whether the United States will respond with nuclear weapons if an adversary uses biological weapons against the country. The *Nuclear Posture Review*, a

[23] *See* NAT'L SEC. COUNCIL, *supra* note 1.

legislatively mandated statement of U.S. nuclear policy, recently clarified that the United States will not use nuclear weapons in response to a chemical or biological attack by a country that is in compliance with the Nuclear Non-Proliferation Treaty.[24] But the *Review* also stated that "[g]iven the catastrophic potential of biological weapons and the rapid pace of bio-technology development, the United States reserves the right to make any adjustment in the assurance that may be warranted by the evolution and proliferation of the biological weapons threat and U.S. capacities to counter that threat."[25] Regardless of the impact of this statement on the actions of states, threatened nuclear retaliation will not deter terrorist groups whose whereabouts are uncertain, and it will not deter lone scientists determined to commit acts of bioterrorism.[26] The kind of deterrence we need to build for biosecurity against those threats is resilience. The country needs to become so resilient, so capable of containing and diminishing the consequences of a biological attack, that biological weapons are no longer appealing to our adversaries. It will always be possible to inflict some level of harm with biological weapons, but if we act wisely in the time ahead, if we transform our ability to detect and respond to biological attacks, if we are able to make and deliver medicines and vaccines so quickly that damage is minimized, it could be feasible to remove biological weapons from the category of weapons of mass destruction.

Third, we need to improve our response systems. A key part of response is biosurveillance, or the effort to provide an early warning of a new outbreak or of a bioterror event. There is broad agreement in the public health community that biosurveillance is important, but there remain obstacles to building needed surveillance systems.[27] There often is too much focus on technology and not enough on the people who would use it or on efforts to understand exactly what form of information is necessary. There are many surveillance systems domestically and internationally, and the more we can reduce redundancy and act strategically with these systems, the better the effort will be. As part of improving our surveillance efforts, we need better linkages between public health agencies and hospitals. We need better rapid diagnostic tests in hospitals and clinics. And we need to increase the epidemiologic workforce, which is currently threatened by state budget pressures around the country.

Since 9/11, the country's hospitals have become much more prepared to cope with the victims of an attack or pandemic. But as we saw last fall with H1N1, hospitals have limited emergency department and intensive care unit

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[24] Dep't of Def., Nuclear Posture Review Report 15 (2010), *available at* http://www.defense.gov/npr/docs/2010%20Nuclear%20Posture%20Review%20Report.pdf.

[25] *Id.* at viii.

[26] For example, the Department of Justice's Amerithrax investigation determined that the fall 2001 anthrax attacks were the work of one U.S. Army doctor, Dr. Bruce E. Ivins. U.S. Dep't of Justice, Amerithrax Investigative Summary 1 (2010), *available at* http://www.justice.gov/amerithrax/docs/amx-investigative-summary.pdf.

[27] *See, e.g.*, Jennifer B. Nuzzo, *Developing a National Biosurveillance Program*, 7 Biosecurity & Bioterrorism: Biodefense Strategy, Prac., & Sci. 37, 37–38 (2009).

capacities, and in possible future large-scale events they might be unable to handle higher numbers of patients. Before the next crisis, we must prepare standards of care to apply to situations of great resource scarcity. This planning effort should be conducted by planning coalitions that include hospitals, public health agencies, emergency management agencies, and other institutions that can provide outpatient care or alternative care sites. Many areas of the country have begun to develop these coalitions.[28]

Another critical part of the response to biological events is the medicine and vaccine stockpile needed to treat the sick and to protect the well from becoming infected. The country has invested substantially in preparing to make flu vaccines rapidly during a pandemic. The 2009 H1N1 experience showed that making new vaccines on scale was possible. But it also showed that vaccine preparation would take many months and, that for the majority of people in the country, the vaccine would not be available until after the peak of the pandemic. These were the outcomes despite the fact that the country is better prepared to rapidly manufacture vaccines for flu than it is for other types of drugs required in the event of any other biological threat.[29] To make progress, we need to better fund the Biomedical Advanced Research and Development Authority (BARDA), the HHS agency responsible for developing and manufacturing the medicines and vaccines needed for biosecurity.[30] Because there is no commercial market for these medicines, a strong government program is necessary, as is the engagement of the "big pharma" sector of the biopharmaceutical industry. Effective distribution mechanisms for these medicines are also crucial.

A final critically important part of the response is the public and community engagement around these efforts. Not long ago, many in the emergency response community regarded the public as something that "had to be managed" in the event of a crisis.[31] Fortunately, most professionals in the response community now recognize that the public will respond in rational ways during crises and can provide substantial help for themselves, their neighbors, and their communities.[32] These efforts should be supported and strengthened. One way to do this is to actively encourage the engagement of community and faith-based organizations in community preparedness efforts. Another is to provide legal protections for organizations that volunteer in crises. All of these efforts are valuable. They recognize that the community itself is the greatest source of help in many crises.

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[28] Eric Toner et al., Ctr. for Biosecurity of UPMC, The Next Challenge in Healthcare Preparedness: Catastrophic Health Events (2010), *available at* http://www.upmc-biosecurity.org/website/resources/publications/2010/pdf/2010-01-29-prepreport.pdf.

[29] Lauren M. Smith & Gigi Kwik Gronvall, *Influenza Vaccine Production for the U.S. Market*, 7 BIOSECURITY & BIOTERRORISM 259, 260 (2009) (describing the broad capacity of American pharmaceutical manufacturers to produce flu vaccines rapidly).

[30] Jason Matheny et al., Letter to the Editor, *Cost/Success Projections for US Biodefense Countermeasure Development*, 26 NATURE BIOTECH. 981, 982 (2008).

[31] *See* Berger & Moreno, *supra* note 15, at 298–301.

[32] *See, e.g.*, Joseph Barbera et al., *Large Scale Quarantine Following Biological Terrorism in the United States*, 286 JAMA 2711, 2716 (2001).

Strengthening biosecurity is a priority that has broad and bipartisan appeal. Most Americans think that the country should be able to respond rapidly to the next pandemic. We all agree that we should have the vaccines and medicines to defend ourselves against future bioterrorism events. Few would want our hospitals to be unprepared to respond to large crises. Containing epidemic disease will be critical. These and other top goals of biosecurity are widely supported. It is how we pursue these goals that requires continued wise planning, pragmatism, and consistency with American values and principles.