

TESTIMONY BY
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TO THE HOUSE OF REPRESENTATIVES
FOREIGN AFFAIRS SUBCOMMITTEE ON TERRORISM, NONPROLIFERATION AND TRADE
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Chairman Sherman and distinguished members of the subcommittee, thank you for the opportunity to discuss the international security dimensions of preventing and preparing for violent infliction of disease.

Mr. Chairman, with your permission, I would like to formally submit for the record a report prepared by the International Security & Biopolity Institute at the request of you and this subcommittee's staff: *United States Foreign Policies and Programs To Reduce Bio-Dangers*. This report provides an overview of relevant policies and describes the various USG agencies and offices that manage programs to counter biothreats internationally. I would like to thank the many Executive branch officials who assisted us in this study as well as my principal co-authors, Michael Kraft, Zachary Clopton and Orley Lindgren. The report's full text can be found at <http://www.biopolity.org/sites/default/files/documents/ISBI%20Congressional%20Report%20Final.pdf>. We hope this report will be useful as you consider possible legislation for strengthening the United States' capacity for countering biothreats.

Today, I would like to focus on five major points:

1. The United States is not secure from catastrophic bioterrorism if our foreign allies and partners are unprepared for bio-attacks. Unfortunately, most nations are unprepared.
2. The highest policy priority is to prevent biothreats through global biopreparedness – building capacity to treat bio-attack victims and contain the spread of disease.
3. Engaging the international community in biopreparedness could have significant benefits, advancing public health and promoting a mutual and integrated global security system.
4. Global biopreparedness is impeded by legal problems that: disincentivize private sector engagement; obstruct implementation of an efficient regional stockpiling system for medical countermeasures (MCMs); undermine MCM delivery planning; and hinder dispensation of MCMs to victims.
5. These legal challenges should be addressed now, before a bio-attack. Congress should authorize a study of these legal challenges and their solutions in order to enable the State Department to identify optimal international biopreparedness policies.

OVERVIEW OF THE THREAT

A strategically executed series of anthrax attacks in major cities could kill tens of thousands, perhaps far more, and sow panic of unprecedented proportions. No one in Congress need be reminded that, following 9/11, a relatively small release of anthrax caused widespread disruption. Use of a contagious virus for which none of us carry immunity would have vastly worst consequences.

The emergence of synthetic genomics opens new opportunities to modify existing diseases, re-create maladies from our past, or create altogether novel ailments. How many might succumb to a release of synthesized smallpox or other genetically modified disease? What if other orthopox viruses—monkeypox or camelpox—can be manipulated to be resistant to the vaccines and therapeutics that are stockpiled against smallpox?

According to the National Academies of Science, “The threat spectrum is broad and evolving—in some ways predictably, in other ways unexpectedly. . . . In the future, genetic engineering and other technologies may lead to the development of pathogenic organisms with unique, unpredictable characteristics.”¹ Every passing day it will be slightly easier to commit a violent catastrophe than it was yesterday. As far as can be seen is the prospect of bioscience for life inseparably intertwined with bioscience for violence.

Nor, amid such a catastrophe, could any one know where the next attack might happen. Multiple unseen disease attacks with ceaseless nightmares about where and when the next attack might occur could well serve terrorists’ interests. Disease agents are available, cheap, easy to move and to release, undetectable, and could have widespread, long-lasting, and devastating effects. If a terrorist’s ambition is to rattle the pillars of modern civilization and perhaps cause it to collapse, violent infliction of disease is the way to go.

NEED FOR AN INTERNATIONAL PERSPECTIVE

All this leads to the question that is raised by this hearing: are we secure even if U.S. domestic resilience capacities are optimal? The answer is No.

America is not secure if our allies and trading partners are vulnerable. As President Obama recently asserted, “a biological incident that results in mass casualties anywhere in the world increases the risk to all nations from biological threats.”² More than any other threat of violence, the inherent nature of intentionally inflicted disease is international.

¹ NATIONAL RESEARCH COUNCIL, GLOBALIZATION, BIOSECURITY, AND THE FUTURE OF THE LIFE SCIENCES 49 (2006).

² NATIONAL SECURITY COUNCIL, NATIONAL STRATEGY FOR COUNTERING BIOLOGICAL THREATS, p. 3, Nov. 2009.

Even if our labs and culture collections are secure, a terrorist can likely get lethal agents overseas. Even if our law enforcement communities are trained and equipped to interrupt bioterror plots, law enforcers in most foreign nations lack comparable capacities. Even if the best bio-sensors can detect a release in major hubs and venues, a contagious disease could be spread in an overseas airport and build into a firestorm before anyone knows of the attack.

Most important, even if Americans could be immunized against every bioviolence agent, no one should think that America will be just fine. A series of bio-attacks against our allies and partners could readily cripple the international economy. Important to remember in this context is the unique capacity for repeated attacks that biological agents afford to a potential attacker. Bio-attacks that devastate allies, transform developing societies into chaos, cancel transport and trade, and sow worldwide panic would beget a profoundly catastrophic environment. If only for the potential magnitude of loss, perhaps counted in millions of lives and trillions of dollars, Americans would be gravely wounded by a foreign bioviolence attack.

THE PRIORITY OF GLOBAL BIOPREPAREDNESS

Threats of violently inflicted disease call for an array of international policies, many that the United States is currently promoting, a few of which should be substantially accelerated. Among the high priorities are: strengthening law enforcement globally, promoting secure bioscience, and enhancing situational awareness and diagnosis of disease. There is no single cure-all in this context, nor do palliatives about enhancing international conventions (as important as these conventions are) offer a potent recipe for security.

Mr. Chairman, I want to emphasize the single highest priority: *global biopreparedness* by building capacity worldwide to treat victims and contain the spread of disease and clarifying legal rules that apply to that endeavor. In the past eight years, the United States has made considerable progress toward domestic preparedness. However, vast shortfalls among our allies and partners expose substantial vulnerabilities. Put simply, the Achilles Heel of U.S. policies for confronting biothreats is the rest of the world.

Today, there is an appalling inadequacy of medical countermeasures (MCMs) to meet bio-attacks. Consider smallpox, arguably among the gravest of potential bioviolence agents. Global stockpiles of smallpox vaccine are less than 800 million doses – enough, at best, for 12% of the world’s population if ideally distributed. Over 80% of these doses are stockpiled in six countries. Ten countries have appreciable stockpiles of vaccine (relative to their population size). Nearly all other countries have little or no vaccine.

Responsibility for saving lives following bio-attacks will fall on the United States and a few allies. Time is critical. Envision, for example, release of weaponized anthrax in a foreign sports arena, infecting thousands of victims. The white powder must be collected and sent to a

diagnostic facility for analysis. Once confirmed as anthrax, stockpiled vaccines and antibiotics must be allotted; those MCMs must then be transported to a cargo plane that will take them perhaps thousands of miles to the target site where they must be dispensed to victims. All this must happen within less than 72 hours (likely less). Outside perhaps two dozen countries in the world, meeting this medical deadline is little more than a fantasy. This situation must be improved now, before a crisis demonstrates the consequences of being unprepared.

Biopreparedness policies have obvious benefits, including deterrence. If medical countermeasures (MCMs) are available, the victims can be treated and the consequences of an attack can be contained. By reducing damage and containing losses, we can deter attacks. A culprit who seeks to inflict mass violence and panic will be less inclined to use disease in the face of organized and efficient measures to limit the consequences.

Importantly, engaging the international community on biopreparedness could have powerfully beneficial effects. It is in everyone's interest to ensure MCM availability because an effective plan for MCM stockpiling and distribution could be dual-use – it could be a major tool of public health for addressing natural pandemics as well as bioviolence. Engagement of international organizations, the private sector, along with many States could thus be transformative of this entire policy arena, designing an integrated global system where benefits are shared, responsibilities are common, and security is mutual.

The good news here is that the challenge of global preparedness is not centrally about devoting enormous resources to new medicines, although better medicines to treat emerging diseases will be useful long-term. For now, we should increase stockpiles of available medicines and link those stockpiles to logistical capacities for rapid deployment.

Policies to advance multilateral coordination with key allies should focus on three key dimensions.

1. Facilitate use of MCMs by: exchanging information about threats and relevant vaccines/treatments; promoting harmonized licensing standards for mutual approval of useful MCMs; and ensuring that intellectual property protections for developers of new MCMs are effective.
2. Implement a stockpiling strategy that: provides guidance for MCM stockpile location and contents; assesses MCM procurement and surge capacities; sustains MCM stockpile surety and security; and ensures rapid deployment of MCMs as necessary in response to outbreaks.
3. Encourage MCM delivery planning that focuses on: command and control responsibilities for triggering and supervising MCM delivery, logistics for fast and efficient distribution, and public health readiness and training to receive and dispense MCMs.

In this year's State of the Union, the President announced a new and very significant initiative for responding faster and more effectively to bioterrorism at home and abroad. This initiative will expand on the Administration's newly announced *Strategy for Countering Biothreats*. This is an auspicious initiative for enhancing preparedness against global biothreats by enhancing capacities for rapid delivery of MCMs.

Yet, there are reasons to be less than optimistic about prospects for progress. *Global biopreparedness* requires a vital commitment, not only by Executive Branch officials but by Congress as well.

LEGAL CHALLENGES CONFRONTING GLOBAL BIOPREPAREDNESS

Among the challenges that Congress should confront, perhaps the most significant with the most long-lasting implications, are those associated with gaps and inconsistencies of law. The United States can propel progress in this domain. By exercising leadership in addressing these legal challenges, we would reinforce our stature as the global flag-bearer of the rule of law.

Very briefly, there are legal problems that:

- Disincentive the private sector from developing medical countermeasures

It is widely appreciated that private sector entities are important for developing and producing relevant medical countermeasures. There are substantial obstacles, however, that discourage their engagement. Because nations have inconsistent licensing standards, a producer of medicines must run a gauntlet of testing procedures for a drug that might never be used. If an emergency evokes a sudden need for their products, they could lose protection of their intellectual property rights; their return on investment might evaporate. Moreover, if their product causes any injury, even if it saves many more lives, could give rise to ruinous liability.

- Impede implementation of regional stockpiling of medical countermeasures (MCMs)

It is imperative that MCMs be forward deployed to ensure that they can get to an attacked target rapidly when necessary. It is prohibitively expensive for each nation to have its own stockpile, but a more efficient regional stockpiling system will require extensive legal arrangements to ensure that victimized nations will have access to such stockpiles as necessary. For this system to work, legal arrangements must stipulate command and control authority that keeps those stockpiles secure. Moreover, harmonized standards for emergency use of MCMs must ensure that, when needed, they can actually be put to use.

- Undermine planning for the efficient delivery of stockpiled MCMs

To distribute stockpiled MCMs efficiently to perhaps many thousands of victims requires advance planning. Packaging standards and delivery logistics must be harmonized among nations. All delivery components, including air and ground transport systems, must be networked. Again, command and control authorities must be clear and must have appropriate

capacity to coordinate with their counterparts in neighboring nations. Critical decisions must be made in advance to rationalize domestic authorities for ensuring distribution to victims. Planners must also develop contingent plans for estimating which public and private assets and personnel will participate.

- Will likely obstruct dispensation of MCMs to victims of a bio-attack during conditions of extraordinary panic when the last thing that should be done is consulting with lawyers to determine what is legal and what is not.

On the ground, law enforcers will struggle to maintain order while thousands of people, facing quarantines or other restrictions, try to get life-saving treatment. Plans should also provide guidance on preparation of medical personnel for mass countermeasure administration, specifying the appropriate number of staff at each dispensation site. It will be necessary to track adverse consequences, implicating victims' privacy rights. During an outbreak, authorities will have little time to discuss the issue, much less engage in a protracted legal process to authorize mandatory administration of MCMs. The fact that various nations resolve these questions differently can impede a multinational response.

ADDRESS PREPAREDNESS CHALLENGES

The time to address these legal challenges is now. In the United States, most of these issues have received attention, albeit unevenly. It is important to acknowledge the enormous strides that have been and continue to be made by dedicated people throughout our government. It is simply wrong – to say nothing of insulting to the many hard-working government officials dedicated to keeping us safe – to suggest that these policies are a failure. But it would be equally wrong to not identify remaining gaps, to deny that we can and should be doing more.

Mr. Chairman, as I earlier indicated, global biopreparedness is not about generosity, it is about the national security of the United States. With regard to biothreats, there is no security in isolation. Taking an international perspective means exercising leadership in the way that America does best and has earned us global respect, by promoting the rule of law. By advancing global biopreparedness, we would significantly assist all nations that share concerns about bio-threats; we would advance public health readiness; and we would accelerate the development of bioscience and technology with positive implications for our economic recovery. And, we would establish a security framework upon which additional positive initiatives can be built – a framework that can build capacity for meeting constantly evolving threats.

Mr. Chairman, Congress can take two important steps to advance global biopreparedness, two steps that carry negligible cost. First, authorized officials would be hard pressed to find serious analyses of the legal and other issues that must be the prerequisite of effective discussions about global biopreparedness with our allies and in global institutions. Congress can

usefully instruct the State Department to identify effective legal modalities to resolve preparedness challenges. Second, Congress should consider calling on the President to convene a *Global Biological Terrorism Summit*, modeled on the upcoming *Global Nuclear Terrorism Summit*. The reality here is that while the United States can and should exercise leadership in this domain, biothreats compel engagement of foreign nations at the highest level. Solutions will be more successful if our allies comparably appreciate why biopreparedness should be a high priority and how collectively we can reduce risks. A Global Summit would be a valuable step in the right direction.

Allow me to conclude on a sour note. From President Obama to this subcommittee to everyone in this government, there can be no serious question that catastrophic bio-attacks will relegate every other policy priority to insignificance. Amid a disease cataclysm that demonstrates the horrific implications of procrastination, mustering the commitment and energy to build a preparedness infrastructure for security against a second such cataclysm will be easy. In view of the potential magnitude of harm that the first attack of bioviolence could cause, we should not wait for it before preparing for the second attack.

Thank you, and I am happy to respond to any questions.