America's State of Readiness against Bioterrorism

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Introduction

A mere seven days after the September 11 terrorist attacks in 2001, envelopes filled with Anthrax spores were received by media companies and government offices throughout the country. These attacks would kill five people and infect seventeen more.

Investigation into the attacks never confirmed whether the envelopes were a part of the original September 11 conspiracy. Either way, this incident warned the American people that the worst was not over. The enemies of America, both within and without the country, were not sated by the destruction of the World Trade Center.

The United States has been fortunate that bioterrorism has not been more prolific since the September 11 attacks in 2001. Bioterrorism has many advantages over other forms of terror for the patient militant. The anthrax architect of 2001, for example, was never arrested; the FBI’s prime suspect, Bruce Ivins, committed suicide in 2008 and the ongoing case was closed. To this day, it is unclear whether the United States government apprehended the real terrorist.

While these attacks failed to throw the United States into an extended panic, they did force the American government to actively engage the threat of bioterrorism on an unprecedented level. However, it remains unclear whether the federal government has been successful in its attempts to stay ahead of the threat of bioterrorism. Plans to stay current have resulted in frustrated pharmaceutical companies, a confused and opaque government policy

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regarding the threat of weaponized bacterial agents, and a general lack of vigilance against biological attacks.

The lack of known bioterror events in America makes it easier to become lax in our national efforts at emergency preparedness. There are few recent outbreaks of disease that can be traced back to a purposeful attack on the United States. Yet, as the anthrax scare proved in 2001, bioterror remains a credible threat in a world marked by increasing globalization, travel, and shipping abilities. The United States must remain vigilant in order to stay ahead of both imaginable and unimaginable threats.

Critical Features of Bioterrorism and Current Threats

The first recorded use of weaponized biological agents dates to 67 B.C., when King Mithridates of Pontus infected honeycombs with grayanotoxin, a contagion that caused “…impaired consciousness, blurred vision, and other symptoms.”\(^4\) Since then, biological warfare continued to be employed as a weapon, and it was not until the United States became the first country to prohibit it during the Civil War in 1863 that a conversation about the morality of biological warfare began to take place. As the first international regulation to address biological warfare, The Hague Convention of 1899 attempted to continue this discussion on the world stage, but the use of biological agents as weapons continued into World War I. International agreements like the Geneva Protocol of 1925 and the Biological Weapons Convention of 1972 also attempted and failed to outlaw biological and chemical warfare.\(^5\)

By nature, biological warfare targets both combatants and non-combatants indiscriminately. In addition to the visceral horror of a biological attack, this lack of distinction

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\(^5\) Ibid.
between combatant and non-combatant, a key principle of *jus in bello* theory, is a major reason for the many aforementioned attempts at international regulation. Though individual states have not always considered biological weapons tools of terror, modern international law clearly does.

Biological attacks have become so taboo on the international stage that any use of weaponized contagions is considered terrorism, whether they are used by terrorists, insurgents, or states. This has led the National Academies and the U.S. Department of Homeland Security to define “biological attack” broadly as an “…intentional release of a pathogen (disease causing agent) or biotoxin (poisonous substance produced by a living organism) against humans, plants, or animals.”

Plants and animals are included in the Department of Homeland Security’s definition of “biological attack” due to the devastating consequences it could have on a nation’s food supply. So-called “agroterrorism” incidents could begin with a “point introduction”: an infected plant, animal, or an animal’s fluids could contaminate other crops or livestock. A biological assault on America’s agricultural industry could also target a nation’s population indirectly by attacking its economic vitality. In the United States, “…one in eight people works in an occupation that is directly supported by food production. Agriculture’s share of produce sold overseas is more than double that of other U.S. industries, which makes the sector a major component in the U.S. balance of trade.” American agricultural industries already lose billions of dollars annually to disease, and an agroterrorism attack would severely compound this problem.

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7 Ibid.
economy would suffer considerably in the event of a successful attack on its livestock or crop industries.

An agricultural attack could also infect the population indirectly through infected food products. While most Foreign Animal Diseases (FADs) are “non-zoonotic,” meaning they do not “…‘jump’ the animal-human species barrier,” some FADs are. In 2004, pig farmers in the Netherlands mysteriously began to show symptoms of Staphylococcus aureus, a common bacterium found in many pigs. This particular strain was an evolved form of S. aureus known as Methicillin-resistant Staphylococcus aureus, or “MRSA”, a strain of bacteria known as a “superbug.”

Simply put, superbugs are drug resistant bacteria. This resistance is the result of bacteria trading genes “…like trading cards,” and can take a myriad of forms. For example, Pseudomonas has an extra cell wall that helps repel antibiotics. Bacteria can even delete genetic material to survive: “[b]y deleting a single gene, an English-French research team announced, certain strains of the [tuberculosis] germ have protected themselves from isoniazid, currently the major weapon against this resurgent disease.”

While a superbug infection of America’s agricultural resources would prove incredibly deadly, terrorists could also use superbugs as a weapon against people directly. The anthrax scare revealed the damage a biological attack can have on a population beyond death and illness: not only did copycats perpetuate the scare with fake anthrax letters, but emergency services and

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investigators were suddenly also “…swamped with calls from citizens suddenly suspicious of their own mail.”\textsuperscript{14}

Bioterror attacks can create national panic and shut down government services—provided that an attacker can gain access to a contagion. The Department of Homeland Security lists six ways that a direct biological attack might occur: aerosol dissemination, contaminated food or water, person-to-person contagion, contact with infected animals, contact with insects, or physical distribution - as seen in the anthrax attacks of 2001.\textsuperscript{15} A superbug could be propagated anywhere in the United States by any of these means.

Besides the use of already existing superbugs, terrorists may soon be able to create a “designer virus” using “…genetic engineering to enhance the virulence of a pathogen or the targeting of a specific genetic code for use in terrorism.”\textsuperscript{16} These designer viruses would first create symptoms similar to the common cold, but would act as a “…‘molecular key’ to trigger secondary effects after encountering a certain DNA sequence.”\textsuperscript{17} This process mirrors methods scientists are currently studying to modify DNA sequences to cure diseases like cancer.\textsuperscript{18}

The creation of a “designer virus” requires two components: the expertise required to understand and splice genetic code, and access to genetic material. A terrorist without the full backing of a state would therefore have to spend years training in higher education and infiltrating a laboratory with access to genetic material and contagions in order to successfully

\textsuperscript{17} Ibid., 954.
\textsuperscript{18} Ibid., 954.
design a virus. While regulatory measures are in place to ensure the U.S. government’s ability to track viral DNA strands, however, there are alternatives available to those hoping to access DNA material below radar. Oligonucleotides, or “oligos”, are DNA building blocks composed of fifteen to one hundred base pairs that are separate when shipped commercially but can be linked to create gene sequences. It is not impossible that a designer virus or a superbug could be created using these oligos, and spread throughout the United States.

**Prevention Abilities**

It is imperative that government agencies actively work to prevent an outbreak. While there are some prevention strategies in place, not enough has been done to stay ahead of a possible biological attack.

The effectiveness of a biological attack relies on the vulnerability a population has to a given disease. This vulnerability spurred Charles Krauthammer to argue that every American citizen be vaccinated against smallpox, a disease that has been largely eradicated worldwide. The successful eradication of smallpox created a bizarre paradox: without exposure to the disease, the present population cannot build immunity to it. The entire human race is therefore vulnerable to attack from a disease that was eradicated decades ago. The last known stores of smallpox currently exist in both Russia and the United States, and some have argued that both countries should destroy them, thereby destroying the threat of smallpox forever. But as long as no one can be sure that smallpox is not also secretly in the hands of some other power or terror group, it

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19 Ibid., 954-955.
20 Ibid., 964.
would be unwise for the United States not to have a sample from which it could create a vaccine.\textsuperscript{22}  

Not everyone agrees with Krauthammer’s assessment. The anti-vaccination movement in the United States, for example, is largely based on the belief that vaccination is causing autism in children and argues for a return to holistic medicines in the fight against contagions. The anti-vaccination movement stems from a distrust of government agencies and major pharmaceutical companies and reflects a deeper disconnect between citizens and their government.  

Autism was first used in its modern context by Leo Kanner in 1943.\textsuperscript{23} Though many treat autism as a disease unto itself, autism has become a more encompassing term for abnormal behavior:

The symptoms that frequently occur in people diagnosed with autism include a lack of social skills and ability to interact easily with others, delayed development of speech, lack of imaginative play, a fixation on repetitive and ritualistic behaviors, and unusual eating habits.\textsuperscript{24}  

The broad definition of autism makes it a difficult and complex field of study. Autism can often be identified in children before the age of three, and many studies indicate that autism may be the result of genetics and/or environment. Some recent studies posit that autism is a result of certain environmental conditions over genetics, while other investigations indicate that autism is a result of genetic vulnerability to environmental factors rather than one or the other. This would include exposure to poisons, such as:

\begin{itemize}
\item \textsuperscript{22} Ibid.
\item \textsuperscript{23} Mark A. Largent, \textit{Vaccine: The Debate in Modern America} (Baltimore, MD: John Hopkins University Press, 2012), 68.
\item \textsuperscript{24} Ibid., 68-69.
\end{itemize}
Secondhand smoke, poor ventilation in the home, vinyl chloride (which is used in PVC products like some flooring and furniture), nickel, pesticides…certain heavy metals like mercury and cadmium, rubella infection during pregnancy, air pollution, prenatal exposure to medications like thalidomide and valproic acid, and a number of different solvents used as degreasers or paint thinners.\textsuperscript{25}

The possible poisoning of children, combined with the perceived rise in autism, launched the “Green Our Vaccines” movement. Led by Jenny McCarthy, a former Playboy model, author, and founder of Generation Rescue, the anti-vaccination movement is particularly concerned about the presence of thimerosal in vaccines. Thimerosal is a preservative used in vaccines that contains mercury, and while studies have proven inconclusive on thimerosal’s ability to cause harm even in trace amounts, the existence of this mercury-containing compound caused an entire industry to develop around the possibility that early childhood vaccination was causing autism.\textsuperscript{26} To this day, political action committees (PACs) devoted to this issue guide concerned parents through the process of exempting their children from vaccination.\textsuperscript{27}

Political issues addressing personal choice and freedom have further complicated the vaccination debate in the United States. In 2015, New Jersey Governor Chris Christie and Kentucky Senator Rand Paul supported parental discretion of vaccinations amidst a measles outbreak. Senator Paul called the choice “…an issue of freedom.”\textsuperscript{28} However, vaccination is most effective when most members of a community are immunized. This concept is known as “herd immunity”, which not only neutralizes the threat of an outbreak but also protects “…those who are not eligible for certain vaccines – such as infants, pregnant women, or

\textsuperscript{25} Ibid., 69-70.
immunocompromised individuals…”29 Declining immunization efforts places the United States at risk for further outbreaks of fatal diseases, putting the current generation at the highest risk. While the autism debate continues, widespread vaccination remains the first line of defense against bioterrorism.

The ability to immunize citizens against weaponized bacterial agents relies on already existing vaccines, and the research and development of these preventive drugs has been pursued primarily by the private sector. Unfortunately, federal law concerning regulations and standards for the FDA’s approval of drugs is demanding and opaque. As a result, private pharmaceutical companies have abandoned much of the necessary research and development required to identify, study, and combat new contagions.

Strict government regulation makes the hazards of drug development particularly risky due to the cost incurred by companies hoping to bring a new drug to market. In 2004, a Tufts Center survey found the cost to introduce a drug to the market was over $800 million. In order for companies to offset this expense, there must be a considerable expectation for profit. This means that pharmaceutical companies will produce drugs which guarantee sales upon release, rather than drugs for a niche, and therefore less profitable, market.30 Staying ahead of bioterrorism requires the United States not only to be ready for the known, but the unknown. Unfortunately, pharmaceutical companies will not spend precious time and money researching drugs for a niche and unlikely market in the name of safety and patriotism.

A number of proposed policies have attempted to correct this vulnerability. The first proposal is to reform FDA approval standards. The Trump administration, for example, is

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researching the effects of reforming FDA standards to focus, “…on a new drug’s safety and efficacy, the latter being defined simply as favorably impacting a biomarker of disease…”

Currently, FDA approval depends not only on the capacity of a drug to produce a positive outcome, but also whether the drug cuts to the heart of a disease entirely. In other words, it is not enough for a drug to have a positive impact on a patient’s health—such as lowering the patient’s cholesterol—in order to attain FDA approval. Rather, pharmaceutical companies must also demonstrate that a drug will have an effect on the root cause of a patient’s high cholesterol.

While well intentioned, these high standards have the potential to halt the supply of innovative drugs to the public.

The second proposed reform is the separation of the pursuit of new drugs from the profit incentive. This concept is known as “delinkage,” an abstract system in which the federal government pays pharmaceutical companies for researching drugs regardless of outcome. Theoretically, delinkage would ensure that the expense and risk of drug approval is no longer a factor to the drug companies that make them.

Delinkage arguments rely on the assumption of adequate federal funding and an effective level of coordination between departments. The federal government, however, has failed to maintain this role. These shortcomings are especially evident in policies regarding outbreak scenarios.

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33 Ibid.
Outbreak Readiness

In 2004, the United States federal government created Project BioShield, a program that attempted to streamline and encourage the development of innovative Chemical, Biological, Radiological, and Nuclear (CBRN) countermeasures. Joseph Larsen and Gary Disbrow have explained that BioShield, “…provided $5.6 billion over 10 years to develop, purchase, and stockpile medical countermeasures for use in a public health emergency, such as a CBRN terrorism event.”34

In 2006, Congress also created the Biomedical Advanced Research and Development Authority (BARDA), a department under the HHS Office of the Assistant Secretary for Preparedness and Response. This office serves “…as the U.S. government’s focal point for the advanced research and development and procurement of medical countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases.”35

Under Project BioShield, BARDA has been somewhat successful at stockpiling certain drugs for emergency distribution, but not enough to stay ahead of terror threats. In 2017, BARDA’s ten-year progress report noted that while it has a “robust pipeline of approximately 80 candidate medical counter-measures for multiple CBRN threat agents,” a mere 21 of these candidates have been stockpiled in the event of a bioterror incident. Of these, only six have been approved by the US Food and Drug Administration (FDA) for a CBRN-based indication.36

35 Ibid.
Although the program was created to streamline drug synthesis, the vetting process for drugs under Project BioShield frustrates most drug companies. While BARDA notes that developers are protected from litigation if recognized by Project BioShield, this protection has so far been limited to those companies fortunate enough to push a product through BARDA’s opaque and labyrinthine certification process.

In 2007, a Congressional hearing on Project BioShield revealed some of these many frustrations. Richard Hollis, CEO of Hollis-Eden Pharmaceuticals, Inc., complained against the Department of Health and Human Services (HHS) “…lack of transparency, missed timelines, poor communication and the inexperience of agency representatives.” Hollis-Eden, Inc. was not the only company that had problems with the project: Missouri Representative Bennie G. Thompson also noted that VaxGen, a pharmaceutical company currently in legal disputes with HHS, was not allowed to testify “…without repercussion on a recent settlement between HHS and VaxGen after the cancellation of [a] recent contract to develop the next generation anthrax vaccine.” Yet, Project BioShield continues to be America’s “fast-track” for emergency drug capability.

While Project BioShield covers pharmaceuticals that have already cleared FDA approval, the FDA does provide an emergency exception. This process is called the Emergency Use of an Investigational New Drug Rule (IND), an alternative protocol in which “…the FDA may

37 Ibid.
authorize use of an unapproved drug for specified use without submission of an IND.**40

However, this rule merely simplifies paperwork if the government needs a drug for use outside of its very specific FDA-approved use. The IND does not fast-track the research of new drugs, nor does it release successful drugs from trials for immediate distribution.

Besides the problem of drug availability, the federal government has also failed to create a unified and well-understood plan for swift distribution of life-saving drugs in the event of a bioterror attack. This may be a result of overly optimistic assumptions about the abilities of government forces in the event of an emergency, an issue Richard Hollis listed as one of the reasons for Project BioShield’s early failures in 2007. Citing a “60 Minutes” report revealing that the HHS had stockpiled a mere 100,000 lifesaving treatments for Acute Radiation Syndrome in the hope that many ARS victims would be treated in hospitals, Hollis believed that the federal government had been overestimating its own abilities to respond to a crisis.41

Due to the heightened concentrations of bacteria in admitted patients and the potential for interactions between different strains, hospitals are breeding grounds for new superbugs.42 Therefore, plans for dealing with CBRN casualties, particularly those from biological attacks, should be wary of relying too heavily on the use of hospitals. HHS has also laid a tremendous burden of cure and containment on local responders. This delegation strategy leaves undeniable gaps in the emergency operational plans constructed by HHS.

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This overestimation of the capacity of local channels is apparent in other government containment and treatment operations. The CDC still uses “ring containment,” for example—a tactic in which government agencies only administer vaccinations to communities that immediately encircle the contagion zone. Theoretically, ring containment is cost-effective because it targets the populations most vulnerable to the spread of infection, but the strategy only works if those inside the circle do not leave it. Imposing a timely quarantine in a fully developed, first world society before a bioweapon can spread would be nearly impossible, especially in densely populated cities with international airports and other transportation hubs.43

Hollis believed that policies relying on optimistic assumptions about government capabilities were mistaken.44 Hollis, as the CEO of a large pharmaceutical company, may have had ulterior motives for lobbying the government to buy more treatments and fast-track drug approval. However, his voice is not the only one to warn about the pitfalls of government dependence. Vaccinations may not stop an initial outbreak, and in the event of an attack, the federal government would need an “all hands on deck” approach far beyond the capacity of local hospitals.

While departments such as HHS have put their hope in local responders, many government protocols also treat the public as a panicked, incapable mob rather than a partner in crisis scenarios:

[Current strategy often] considers layperson response as one of a number of post-attack problems, not as a resource. Laypeople are seen, at best, as subjects for control, at worst, obstacles that reduce survival rates and impede recovery


In an article entitled, “The Public Is Likely to Respond Well in a Bioterror Attack,” Thomas A. Glass and Monica Schoch-Spana of John Hopkins University’s Bloomberg School of Public Health note that “[b]y definition…a disaster is an event that generates casualties in excess of available resources.” Glass and Schoch-Spana further posit that while most government emergency scenarios “…routinely feature rioting, looting, and vigilantism,” American citizens placed in disaster situations have frequently proven their ability to engage in emergency actions in a calm and orderly manner.\footnote{Thomas A. Glass and Monica Schoch-Spana. “The Public Is Likely to Respond Well in a Bioterror Attack,” in \textit{Fighting Bioterrorism}, ed. Lisa Yount (Farmington Hills: Greenhaven Press, 2004), link.galegroup.com/apps/doc/EJ3010258210/OVIC?u=pepp12906&xid=b548cba9.}

Glass and Schoch-Spana recommend that the government modify its current emergency policy to incorporate the public as a partner rather than a hindrance during emergencies. Providing the public with upfront, accurate information during a bioterror incident is important to quell the rising fear an attack might produce.\footnote{Ibid.} While federal and local agencies would likely be able to create and send their own messages through media networks, the government could not prevent those media networks from speculation in between official statements. Misinformation and conjecture attempting to fill knowledge gaps may cause more harm than the truth. Government emergency agencies should therefore seek to foster channels of communication with the media that would efficiently direct information to the American people in the event of a bioterror attack.
As early as 2003, The National Academy of Engineering in Washington D.C. argued that government’s poor relationship with the press would harm the media’s ability to propagate critical and actionable information to the public. In a crisis, the nation’s ability to rise above the fear of the moment would largely depend on a confidence buoyed by the public’s ability to participate in its own survival. The National Academy suggested that government agencies should cooperate with media groups and organize mock disaster scenarios of bioterror attacks to prepare reporters, who are often the first to arrive at an emergency scene. A bioterror attack may continue for some time before it is officially identified as a hazard, making reporters who are providing field coverage especially vulnerable at the onset of an outbreak. Exposure to contagions could also turn on-scene reporters into points of human-to-human contact that would further spread disease, widening the ring of containment at a critical stage of outbreak.48 As a critical conduit of information, the press should have priority status in future government emergency management plans.

**Conclusion**

The American people have been fortunate thus far that bioterror is not more common in the United States. Aside from the anthrax attack of 2001, the only other recent bioterror incident occurred in 1984, when the Rajneeshees, a Buddhist religious group from India led by a guru named Bhagwan Shree Rajneesh, contaminated ten restaurant buffets with *Salmonella* in Wasco County, infecting 751 people in a nonlethal attempt to influence a local election.49

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It would be a mistake for the United States to use the past, however, as an excuse to lower its guard against ongoing threats such as North Korea’s rogue regime. A recent report from the Belfer Center for Science and International Affairs suggested North Korea may possess weaponized biological agents. North Korea has shown a willingness to use CBRN weapons in the past; President Kim Jong-Un’s half-brother, Kim Jong Nam, was assassinated in an airport in Kuala Lumpur with a chemical agent. Nam, “…once considered the heir apparent to lead North Korea before falling out of favor with…the late Kim Jong Il,” was “…carrying 12 vials of atropine, a general-purpose antidote for nerve agents that is often issued to soldiers in case of a chemical attack.” Kim Jong Nam was ultimately unable to save his own life, but his personal stock of atropine indicates an expectation that North Korean leadership is both capable and willing to use CBRN weapons.

Therefore, the federal government must take steps to prepare for a CBRN attack on American soil. Such preparation should include reforming the FDA drug approval process, but there is more that government agencies can do in the short term. The first and most effective preparatory step is to reform government attitudes that view the public as a menace or hindrance in a crisis. The 2001 anthrax scare demonstrated that it is in the government’s best interest to communicate openly and transparently with the public. That attack overwhelmed not only the mail services, which came to a complete stop, but also local police and investigative services as worried people flooded both emergency and non-emergency lines with calls seeking information. Government agencies must therefore update their emergency contingencies to include the public.

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50 Hattie Chung, Hyun-Kyung Kim, and Elizabeth Philip, “North Korea’s Biological Weapons Program: The Known and Unknown” (Paper, Belfer Center for Science and International Affairs, October 2017), 5.
as an active force in its own survival. Transparency and active communication is fundamental to bioterror readiness in America.

Ironically, while the federal government has increasingly based its response plans on unilaterally saving the American people, the American people themselves have increasingly withdrawn their trust in the government’s ability to keep them safe. It is no accident that Jenny McCarthy’s rise as the spokesperson of the anti-vaccination movement began with a personal frustration with official voices:

McCarthy found her two-year old in his crib, limp and struggling to breathe while he had a seizure. She called 911, and an ambulance took him to the hospital where he was given a series of tests and released the next day. When he left the hospital he was unable to walk, barely spoke, and acted oddly, and health care providers could not tell her why. Her discussion of that horrible day is laced with small details that foreshadow her eventual disgust with the medical profession, from the paramedics who had casually walked up her driveway…to frustration with the glacial pace of hospitals and their bureaucracy…to the doctor she called “a young Doogie Howser neurologist,” who dismissed Evan’s seizure as an unexplainable one-time event…Unable to find solutions to — or even adequate explanations for — Evan’s seizure or the radical changes to his physical and cognitive abilities that followed, McCarthy writes that she turned to the Internet: “I decided to start doing some research— and by research, I mean Google.”52

The United States must acknowledge the initial angst that caused the anti-vaccination movement, and meet those concerns to be fully prepared for a biological attack. In a CBRN attack, survivors will be reliable and constant flows of information. If government agencies hope their voices will be heard over the panic and misinformation of the moment, it should begin to repair communication lines with pharmaceutical companies and the American people immediately.

52 Mark A. Largent, Vaccine: The Debate in Modern America (Baltimore, MD: John Hopkins University Press, 2012), 141.
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