

Comment

## **BIOLOGICAL WARFARE: THE WEAPONIZATION OF NATURALLY- OCCURRING BIOLOGICAL DISEASES**

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## INTRODUCTION

Since the beginning of humanity's reign on Earth, warfare and the tools used to effectuate its wrath have long been the determining factors for control and power. As a propensity for violence has developed through more effective means, individuals, cultures, communities, and governments have continuously sought new methods and tools to increase their advantage in conflicts amongst each other. Bow and arrows helped ancient cultures ward off attackers from much farther away than hand-to-hand combat allowed, increasing the distance between their loved ones and the incoming dangers.<sup>1</sup> The use of gunpowder and explosives enabled armies to fire projectiles with greater speed and lethality.<sup>2</sup> Rifled barrels greatly enhanced accuracy, allowing armies to target and eliminate specific fighters and leaders.<sup>3</sup> Aircraft and fighter ships allowed a single war to cross large expanses and territories.<sup>4</sup> Increasingly powerful artillery and aircraft-delivered explosive ordnances permitted forces to eliminate significant numbers of enemy fighters with a single strike.<sup>5</sup> The progression in warfare technology culminated with the development of the nuclear bomb, with which entire cities and populations, including innocent civilians, could be wiped out instantaneously from miles away.<sup>6</sup>

Despite the persistent, exponential increases in the power of these man-made weapons, one crucial element blunting their impact was that of human control. Humans can choose which weapon to use, whom to target, and the degree of damage to inflict. More importantly, a user can choose *not* to deploy their weapons, preventing the

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<sup>1</sup> See Paul M. Bingham et al., *Social Complexity and the Bow in the Prehistoric North American Record*, 22 *EVOLUTIONARY ANTHROPOLOGY* 81, 84 (2013).

<sup>2</sup> Barry Kellman, *Of Guns and Grotius*, 7 *J. NAT'L SECURITY L. & POL'Y* 465, 467 (2014).

<sup>3</sup> GEORGE D. MOLLER, *AMERICAN MILITARY SHOULDER ARMS, VOLUME III: FLINTLOCK ALTERATIONS AND MUZZLELOADING PERCUSSION SHOULDER ARMS, 1840-1865*, at 22 (Univ. of N.M. Press 2011).

<sup>4</sup> See Nathan A. Canestaro, *Legal and Policy Constraints on the Conduct of Aerial Precision Warfare*, 37 *VAND. J. TRANSNAT'L L.* 431, 441 (2004).

<sup>5</sup> See *id.* at 472-73.

<sup>6</sup> Mary Eileen E. McGrath, *Contemporary International Legal Issues – Nuclear Weapons: The Crisis of Conscience*, 107 *MIL. L. REV.* 191, 192 (1985).

dangerous effects entirely. These aspects increase the influence of morality and ethics within the equation, possibly preventing violent attacks for want of the will to implement them.

However, one enemy humanity has always struggled to confront is nature. Natural viruses and bacterial infections have decimated populations without regard for money, power, military strength, race, religion, or political views.<sup>7</sup> Diseases spread in various manners, are often invisible to the human eye, and are, generally, undetectable until someone is already infected.<sup>8</sup> As with any potentially dangerous force, humans have attempted to tame nature and create a tactical advantage for themselves with the destructive effects of these already-available biological compounds.<sup>9</sup>

This Comment will examine the development and use of naturally-occurring diseases as biological weapons in modern global warfare and their political implications. This Comment is not meant to instill fear or exaggerate the danger of these weapons to ordinary individuals, but rather to openly discuss potential risks and how they could be mitigated before and after an attack occurs. The objective of this Comment is to demonstrate that the United States, as a primary world power, owes a duty to actively seek cures and treatments for potentially weaponizable, naturally-occurring diseases, as well as a duty to make these treatments available to ordinary citizens. It will examine the legal ramifications, both domestically and internationally, of the production and use of such weapons. Further, it will address the crucial aspect of the weaponization of naturally-occurring biologics: the responsibility that developing governments, militaries, or private entities have in ensuring that a cure or treatment is readily available for use by themselves, the citizens of their respective countries or groups, and the innocent people who lie in the zone of danger.

Part I will briefly detail the history of warfare leading to the development of modern biological weapons. Part II will address

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<sup>7</sup> See *Bioterrorism Overview*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://emergency.cdc.gov/bioterrorism/overview.asp> (last updated Feb. 12, 2007).

<sup>8</sup> See *id.*

<sup>9</sup> Flávia Falci Ercole et al., *Biological and Chemical Terrorism: A Challenge for Health Professionals*, in *BIOTERRORISM: PREVENTION, PREPAREDNESS AND PROTECTION* 139-61 (J. V. Borrelli ed., 2007).

known instances in which the various biological weapons have been used. Various agents, such as smallpox, anthrax, and bubonic plague will be detailed in order to provide a background for understanding the use of biological weapons – not just as a hypothetical possibility, but as a legitimate threat. Part III will review the federal and state statutory limitations attempting to curtail, and eventually eliminate, the use of biological weapons. It will also review global treaties and regulations that have been established in other countries, including actions by the United Nations regarding these issues. Part IV will address the new and significant role terrorism plays in the risks involved with the production and use of biological weapons. Part V will then address current and proposed legal provisions dealing with the aftermath of a biological attack. In particular, it will examine the establishment of a new right of access to preventative measures for the general public to better protect itself in the event of biological attack.

## I. HISTORICAL ANALYSIS

### A. Ancient Warfare

Human civilizations have long used natural resources to increase the lethality of their weapons. Ancient Greeks were known to coat the tips of their arrows with extracts from poisonous plants found growing in the region.<sup>10</sup> Armies in the Middle Ages are believed to have used catapults to fling human corpses infected with Bubonic Plague over their enemies' walls to drive out the inhabitants through fear of contagion.<sup>11</sup> As more civilized empires began to exert control over greater areas, however, these practices declined, in favor of formal standing armies and battle formations.<sup>12</sup> Civilized nations

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<sup>10</sup> GILBERT MURRAY, *THE RISE OF THE GREEK EPIC* 126–30 (Oxford Clarendon Press, 3d ed. 1924) (1907) (“There is no doubt whatever that the primitive inhabitants of Greece poisoned their arrow-heads.”).

<sup>11</sup> Ercole et al., *supra* note 9, at 141; *see also* Mark Wheelis, *Biological Warfare at the 1346 Siege of Caffa*, 8 *EMERGING INFECTIOUS DISEASE J.* 971, 973 (2002) (“But they ordered corpses to be placed in catapults and lobbed into the city in the hope that the intolerable stench would kill everyone inside.”).

<sup>12</sup> THOMAS S. BURNS, *ROME AND THE BARBARIANS: 100 B.C.–A.D. 400*, at 16–18 (Johns Hopkins Univ. Press 2003).

viewed military action as a prideful event, and, thus, frowned upon the barbaric tactics of the past.<sup>13</sup>

### B. World War I and Its Impact

At the turn of the twentieth century, worldwide warfare created new incentives to develop significantly more powerful and dangerous weapons to combat the increasing sizes and strengths of militaries around the world. The incredible destruction resulting from World War I induced an even greater desire to make weapons more powerful than those of one's enemies.<sup>14</sup> Seeking to tame nature's power, many countries began developing chemical and biological weapons. Germany became one of the first modern civilized nations to employ biological or chemical weapons in an officially declared war when it deployed mustard gas in World War I.<sup>15</sup>

With the use of these weapons comes a risk: an entity who uses a biological weapon against others is often just as vulnerable to infection as is the intended target.<sup>16</sup> Thus, in order to safely turn naturally-occurring biological compounds into feasible weapons, users should first develop preventative aids to adequately protect themselves against the effects *before* deployment. Mustard gas, though manufactured and not naturally-occurring, poses dangers similar to naturally-occurring weapons, such as damage to the lungs if inhaled, and is just as uncontrollable and indiscriminate against whom it affects.<sup>17</sup> In fact, mustard gas was so difficult to control that many troops were inadvertently exposed, often suffering severe injuries.<sup>18</sup>

In *U.S. v. Cole*, a U.S. serviceman who was exposed to mustard gas filed suit against the government's military insurance programs,

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<sup>13</sup> *Id.*; see also WAR, PEACE AND WORLD ORDERS IN EUROPEAN HISTORY 55 (Anja V. Hartman & Beatrice Heuser eds., Routledge 2001).

<sup>14</sup> See generally Gerald J. Fitzgerald, *Chemical Warfare and Medical Response During World War I*, 98 AM. J. PUB. HEALTH 611 (2008) (describing the origination of chemical warfare during WWI in order to better understand the chemical warfare threats of today).

<sup>15</sup> *Id.*

<sup>16</sup> *Bioterrorism Overview*, *supra* note 7.

<sup>17</sup> Fitzgerald, *supra* note 14, at 611-12.

<sup>18</sup> *Id.*

seeking restitution for damages resulting from that exposure.<sup>19</sup> The Court struggled to resolve the issue regarding the serviceman's coverage because the symptoms sustained from exposure manifested after the expiration of Cole's military insurance coverage.<sup>20</sup> The court ultimately determined that the insurance carrier was not liable, due to the delay in becoming symptomatic.<sup>21</sup> The *Cole* decision offers just a glimpse into the difficulties of addressing a weapon that can injure its operators just as easily as its intended targets. Unfortunately, the ruling created no financial incentive for militaries to limit the destructive power of their arsenals.

### C. Modern Warfare

World War II created a rush for even more powerful weapons, culminating in the development and use of the nuclear bomb.<sup>22</sup> The mere threat of such weapons became enough to deter enemies from using their own nuclear arms, leading the Union of Soviet Socialist Republics (USSR) and the United States to rush to create large stockpiles of such weapons during the Cold War.<sup>23</sup> Both countries viewed chemical and biological weapons as dangerous and destructive enough to warrant stockpiling various forms of them as an additional threat to nuclear armament.<sup>24</sup>

With the seemingly endless threat of war hanging over their heads, as well as the ever-increasing availability of incredibly dangerous weapons held in unstable areas, militaries and governing bodies were forced to develop methods to protect their own soldiers and citizens from the potential devastation that these new weapons could inflict.<sup>25</sup> While there is no defense against a nuclear explosion, the damages from biological weapons are slightly more preventable. The key aspect of 'defense' in terms of biological weapon development

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<sup>19</sup> U.S. v. Cole, 45 F.2d 339 (6th Cir. 1930).

<sup>20</sup> *Id.*

<sup>21</sup> *Id.* at 341.

<sup>22</sup> McGrath, *supra* note 6.

<sup>23</sup> *Id.*

<sup>24</sup> Ercole et al., *supra* note 9, at 142.

<sup>25</sup> 138 CONG. REC. H27-03 (daily ed. Jan. 22, 1992) (statement of Rep. Browder).

is the additional development of vaccines, toxoids, and post-exposure drug treatments.<sup>26</sup> However, before developing an antidote, one must thoroughly understand the dangers presented by biological weapons.

## II. COMMONLY KNOWN BIOLOGICAL WEAPONS

Unlike standard military firearms and chemical weapons, significantly less research and development goes into the weaponization of naturally-occurring biological diseases. While chemical and physical weapons require significant financial backing for development, production, testing, and other highly-technical aspects of manufacture, naturally-occurring diseases develop through evolution without human interaction.<sup>27</sup> This makes them particularly troubling because nature has already taken care of most of the development. Many naturally-occurring biological diseases have been employed or researched for potential weaponization.<sup>28</sup> Like non-weaponized diseases, each weaponized disease presents its own advantages and disadvantages compared to other potential agents.<sup>29</sup> In order to better understand the threats they pose, previously-used agents should be reviewed.

### A. Bubonic Plague (*Yersinia pestis*)

In the 1990s, a group of twenty-five experts analyzed the feasibility of turning bubonic plague (*Yersinia pestis* or *Y. pestis*) into a deployable biological weapon.<sup>30</sup> The possible use of weaponized bubonic plague presents a troubling scenario, given its long history of

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<sup>26</sup> ED REGIS, *THE BIOLOGY OF DOOM: THE HISTORY OF AMERICA'S SECRET GERM WARFARE PROJECT* 81 (Henry Holt 1999).

<sup>27</sup> The United States Publishing Office estimated the cost of military weapon development in 2014 to be nearly \$63 billion. *Budget FY 2015*, U.S. GOV'T PUBLISHING OFF. (Mar. 10, 2014), <http://www.gpo.gov/fdsys/search/pagedetails.action?granuleId=BUDGET-2015-TAB-5-1&packageId=BUDGET-2015-TAB&fromBrowse=true>.

<sup>28</sup> See generally Duraipandian Thavaselvam & Rajagopalan Vijayaraghavan, *Biological Warfare Agents*, 2 J. PHARM. BIOALLIED SCI. 179 (2010) (detailing numerous biological warfare agents, their mode of transmission, and the detection and prevention methods available to combat them).

<sup>29</sup> *Id.*

<sup>30</sup> Thomas V. Inglesby et al., *Plague as a Biological Weapon*, 283 JAMA 2281, 2282 (2000).

devastating illness and death throughout Europe as far back as 500 CE.<sup>31</sup> In 1970, the World Health Organization (“WHO”) released a report showing that, “in a worst case scenario, if 50 kg of *Y. pestis* were released as an aerosol over a city of 5 million, pneumonic plague could occur in as many as 150,000 persons, 36,000 of whom would be expected to die.”<sup>32</sup> This would be a disastrous death toll to any country, likely creating significant panic.<sup>33</sup> Such an environment would also be hostile to a country’s economic system.<sup>34</sup>

A vaccine for bubonic plague was developed in the 1990s, but manufacturers discontinued production despite promising (albeit unproven) results, and it is now available only for individuals in high-risk occupations, such as research laboratories.<sup>35</sup> If bubonic plague is so dangerous that a small release can cause such a large death toll, perhaps the U.S. government should increase research of the vaccine, including ways to increase its effectiveness and restore production for distribution to its citizens.

### B. Smallpox (*Variola vera*)

Another potential biological agent, smallpox (*Variola vera*), is one of the most well-known and rightly-feared viral infections ever used in warfare.<sup>36</sup> The virus, once responsible for millions of non-war related deaths each year, has since been greatly contained in naturally-

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<sup>31</sup> *Id.*

<sup>32</sup> *Id.* (citing WORLD HEALTH ORG., HEALTH ASPECTS OF CHEMICAL AND BIOLOGICAL WEAPONS 98–109 (1970), <http://apps.who.int/iris/bitstream/10665/39444/1/24039.pdf>). Pneumonic plague is caused by the same bacterium as bubonic plague, but the infection is located in a different area of the human body. *Plague – Frequently Asked Questions*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/plague/faq/#different> (last updated June 16, 2015).

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> Inglesby et al., *supra* note 30, at 2285; *Plague*, VA. DEP’T OF HEALTH, <http://www.vdh.state.va.us/oep/pdf/PlagueFactSheet.pdf> (last updated June 2013); *see also Plague*, WORLD HEALTH ORG., <http://www.who.int/ith/diseases/plague/en/> (last visited May 18, 2016).

<sup>36</sup> David A. Koplow, *That Wonderful Year: Smallpox, Genetic Engineering, and Bio-Terrorism*, 62 MD. L. REV. 417, 423 (2003).

occurring settings.<sup>37</sup> Smallpox was considered so dangerous and frightening that many states made vaccination against the disease mandatory, an action ruled constitutional by the Supreme Court in *Jacobson v. Massachusetts*.<sup>38</sup> Supported by international treaties generating an influx of financial and technical support from throughout the world, the WHO was able to develop a treatment and prevention protocol that could be easily adapted to various locales.<sup>39</sup> By 1980, smallpox had been declared officially eradicated, primarily by the use of large-scale vaccination programs.<sup>40</sup> These programs were particularly effective in poorer countries, which were more likely to be afflicted with the more-deadly strain of the disease known as *Variola major*.<sup>41</sup> This marked the first time in human history that a disease had been eradicated through human action.<sup>42</sup>

Since the active threat of smallpox had been diminished, the period of vaccination for the general public came to a close, especially in the U.S. where individuals were more likely to contract *Variola minor*, a less-deadly form of the disease.<sup>43</sup> This lower risk, as well as the perceived lack of danger, discouraged Americans from receiving the vaccination; additionally, the cost involved to produce the vaccine seemed unnecessary given the low risk involved.<sup>44</sup> Today, no smallpox vaccinations are given to the general population.<sup>45</sup> Hence, if the virus were released today, the highly virulent infection could wreak havoc on the world population. Nearly half of the world population has

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<sup>37</sup> *Id.* at 419 (quoting Lawrence K. Altman et al., *Smallpox: The Once and Future Scourge?*, N.Y. TIMES, June 15, 1999, at F1 (reporting that smallpox caused up to half a billion deaths in the twentieth century)).

<sup>38</sup> *Jacobson v. Massachusetts*, 197 U.S. 11, 38-39 (1905).

<sup>39</sup> Koplów, *supra* note 36, at 432.

<sup>40</sup> *Smallpox*, WORLD HEALTH ORG., <http://www.who.int/csr/disease/smallpox/en/> (last visited May 18, 2016).

<sup>41</sup> Poorer countries are generally assumed to have lower hygiene standards and less access to healthcare, allowing diseases to spread faster. Koplów, *supra* note 36, at 431.

<sup>42</sup> *Id.* at 419.

<sup>43</sup> *Id.* at 441-42; *see also id.* at 432 n.99.

<sup>44</sup> *Id.* at 441-42.

<sup>45</sup> Most smallpox vaccinations given today are instead given to military personnel in combination with multiple other biological weapon protections. *Id.* at 503.

never received a vaccination, and those who were inoculated in the 1960s and 1970s are unlikely to have sufficient antibodies to fight off infection.<sup>46</sup>

In 2002, researchers, prompted by the increased fear of terrorist attacks, examined the effectiveness of new vaccinations for smallpox in the general public. The authors concluded: “mass vaccination results in both far fewer deaths and much faster epidemic eradication.”<sup>47</sup> If a simple vaccine can eliminate the tactical advantage of weaponized smallpox, why would a government not actively prevent its spread among its citizens? The potential side-effects of the vaccine, including the possibilities of contracting the disease or dying from complications, are serious enough to warrant hesitation.<sup>48</sup> However, with further research and continued financing, pharmaceutical companies could develop effective vaccines or treatments that limit or eliminate dangerous side-effects.

### C. Anthrax (*Bacillus anthracis*)

Anthrax (*Bacillus anthracis*) is a bacterial infection that was initially weaponized in World War I by the British military.<sup>49</sup> Its lethality is well documented, with numerous deaths and injuries resulting from an accidental release of the bacteria from a Soviet bio-weapons facility in 1979.<sup>50</sup> As an illustration of its potency, a single kilogram of anthrax powder has the capability to kill up to 100,000 people depending on the mechanism of delivery.<sup>51</sup>

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<sup>46</sup> *Smallpox Vaccine Overview*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.emergency.cdc.gov/agent/smallpox/vaccination/facts.asp> (last updated Feb. 22, 2016).

<sup>47</sup> Edward H. Kaplan et al., *Emergency Responses to a Smallpox Attack: The Case for Mass Vaccination*, 99 PROCEEDINGS NAT'L ACAD. SCI. 10935, 10935 (Aug. 6, 2002).

<sup>48</sup> *Side-Effects of Smallpox Vaccinations*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.emergency.cdc.gov/agent/smallpox/vaccination/reactions-vacc-public.asp> (last updated Feb. 7, 2007).

<sup>49</sup> *Overview of Potential Agents of Biological Terrorism*, SIU SCH. OF MED., <http://www.siumed.edu/medicine/id/bioterrorism.htm> (last updated Oct. 6, 2015).

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* (citing Danzig R. Berkowsky, *Why Should We Be Concerned About Biological Weapons*, 278 JAMA 431, 431-32 (1997)).

As was the case with the aforementioned bubonic plague and smallpox, a preventative vaccine for anthrax was developed in 1970.<sup>52</sup> Throughout the 1990s, the vaccine was administered to military personnel involved in the Gulf War despite questions about its safety and efficacy.<sup>53</sup> In 2000, an analysis of the vaccine demonstrated that it was sufficiently effective, and presented low risks of serious side effects.<sup>54</sup> After the Amerithrax Letter Attacks (discussed in Part IV, *infra*) exposed the risk of anthrax use among the general population, the vaccine was recertified in 2002 by the U.S. Food and Drug Administration ("FDA") following changes in its manufacturing process aimed at increasing storage life and effectiveness.<sup>55</sup> With these changes, many of the fears and risks associated with the anthrax vaccine were greatly diminished or eliminated; with those issues remedied, the vaccine would seem ripe for public distribution. Yet, the primary publically available medical treatment for anthrax remains ciprofloxacin, a commonly available antibiotic given to patients *after* exposure is confirmed to treat symptoms as they begin to manifest.<sup>56</sup> Using antibiotics *before* exposure is generally frowned upon, as overuse can lead to an increase in bacterial resistance and a decrease in antibiotic effectiveness.<sup>57</sup> Thus, while the vaccine can be used as a preventative measure, ciprofloxacin is not an appropriate treatment prior to suspected exposure.

#### D. Ebola (*Ebolavirus*)

The Ebola virus causes Ebola Virus Disease (formerly known as Ebola Hemorrhagic Fever), which is highly virulent and deadly.<sup>58</sup> The

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<sup>52</sup> INST. OF MED., THE ANTHRAX VACCINE: IS IT SAFE? DOES IT WORK? 1 (Lois M. Joellenbeck et al. eds., Nat'l Acads. Press 2002).

<sup>53</sup> *Id.* at 3.

<sup>54</sup> *Id.* at 12-13.

<sup>55</sup> AMANDA J. DORY, CIVIL SECURITY: AMERICANS AND THE CHALLENGE OF HOMELAND SECURITY 78 (Ctr. for Strategic & Int'l Studies 2003).

<sup>56</sup> Taiwo A. Oriola, *Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy*, 7 U. ILL. J.L. TECH. & POL'Y 287, 301 (2007).

<sup>57</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2013, at 5 (2013), <http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf>.

<sup>58</sup> *Ebola Virus Disease*, WORLD HEALTH ORG. [hereinafter *Ebola Virus Disease Fact Sheet*],

mortality rate for Ebola is significant: between 25% and 90% of infected individuals die following infection, depending on the specific strain of the virus that is contracted.<sup>59</sup> In 2014, a major outbreak of the virus occurred in western Africa, infecting over 25,000 individuals and causing over 10,000 fatalities.<sup>60</sup>

The ease with which Ebola can spread is frightening, particularly considering the restrictive manner in which the virus moves from individual to individual. Ebola is not an airborne virus; it spreads solely via direct contact with the bodily fluids (e.g., blood, saliva, semen, or feces) of an infected individual.<sup>61</sup> Despite these biological restrictions, the disease has flourished in poor nations that do not have the infrastructure necessary to decontaminate water supplies contaminated with human waste.<sup>62</sup> Countries with strong decontamination protocols and adequate healthcare resources are better prepared to fight the virus and prevent spreading.<sup>63</sup> However, even with one of the strongest and most advanced healthcare systems in the world, two nurses treating the first individual to bring Ebola into the United States contracted the virus in the course of the patient's treatment.<sup>64</sup>

Ebola is recognized by the Centers for Disease Control and Prevention ("CDC") as a "high priority agent" that "can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, cause public panic and social disruption, and require special action for public health preparedness."<sup>65</sup> There is currently no approved cure for

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<http://www.who.int/mediacentre/factsheets/fs103/en/> (last updated Jan. 2016).

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*; see also *2014 Ebola Outbreak in West Africa – Case Counts*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html> (last updated Apr. 13, 2016).

<sup>61</sup> *Ebola Virus Disease Fact Sheet*, *supra* note 58.

<sup>62</sup> *See id.*

<sup>63</sup> *See id.*

<sup>64</sup> Manny Fernandez & Jack Healy, *With New Ebola Case Confirmed, U.S. Vows Vigilance*, N.Y. TIMES, Oct. 16, 2014, at A1.

<sup>65</sup> *Bioterrorism Agents/Diseases*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://emergency.cdc.gov/agent/agentlist.asp> (last updated Feb. 12, 2007); *Category A, B, & C Priority Pathogens*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, <http://www.niaid.nih.gov>

Ebola Virus Disease.<sup>66</sup> While several Ebola patients in the U.S. have been treated with apparent success through use of the experimental drug ZMapp, the treatment has not been officially approved for human use and supplies are limited.<sup>67</sup> Researchers at The University of Texas at Austin, working under a grant from the National Institute of Health (“NIH”), recently released promising findings of a preventative vaccine; however, the vaccine must undergo more research and human trials before it can be administered to the general public.<sup>68</sup>

With such a high risk of contagion, Ebola could be targeted by foreign militaries or terrorist organizations as the newest biological weapon. While Ebola’s actual effectiveness as a weapon may be limited by the mechanism of infection, the fear and panic likely to result from its deployment could cause major disruption to day-to-day life. With so much at stake, the U.S. government should devote significantly greater resources towards the continued research and further development of possible treatment avenues.

### III. LEGAL ASPECTS OF BIOLOGICAL WEAPONIZATION

In order to evaluate the responsibility of governing entities to protect their citizens, one must examine the relevant legal duties currently imposed upon those entities, both domestically and abroad.

#### A. General Duties of Government

The duties governments owe to their citizens to protect them from dangerous biological weapons are less than clear. A U.S. Congressman once proclaimed, “The first duty of the Government is to afford protection to its citizens.”<sup>69</sup> As Professor Steven Heyman explains, “the

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/topics/biodefenserelated/biodefense/pages/cata.aspx (last updated Jan. 25, 2016).

<sup>66</sup> *Ebola Virus Disease Fact Sheet*, *supra* note 58.

<sup>67</sup> Sanjay Gupta & Danielle Dellorto, *Experimental Drug Likely Saved Ebola Patients*, CNN (Aug. 4, 2014), <http://www.cnn.com/2014/08/04/health/experimental-ebola-serum/>.

<sup>68</sup> J.B. Bird, *Inhaled Ebola Vaccine May Offer Long-Term Protection from Virus*, UNIV. OF TEX. (Nov. 3, 2014), <http://www.utexas.edu/news/2014/11/03/ebola-vaccine/>.

<sup>69</sup> Steven J. Heyman, *The First Duty of Government: Protection, Liberty and the Fourteenth Amendment*, 41 DUKE L.J. 507, 508 (citing CONG. GLOBE, 39<sup>th</sup> Cong., 2d Sess. 101 (1867) (remarks

national government was responsible for security against foreign danger.”<sup>70</sup> If this is indeed the case, the U.S. government should have an affirmative duty to protect its citizens from the physical and mental dangers of biological attack. In the case of bubonic plague, for example, an effective way to meet this duty would be by funding the development of a safer and more effective vaccine and distributing it freely at hospitals and clinics throughout the country. Increased distribution of prophylactic treatment protocols will be discussed in depth *infra*.

## B. U.S. Statutory Provisions

### 1. Governmental Rights

The United States has several laws dealing with the legal aspects of biological weapons, including their development, production, and storage. The Secretary of Defense is permitted to develop, research, and store chemical and biological weapons in the name of “National Defense.”<sup>71</sup> In pursuing these tasks, the Secretary of Defense is required to provide Congress with a written report of the state of biological warfare, including “[t]he status of research and development programs, and acquisition programs, for required improvements in chemical and biological defense equipment and medical treatment, including an assessment of the ability of the Department of Defense and the industrial base to meet those requirements.”<sup>72</sup> The report must also include “measures taken to ensure the integration of requirements for chemical and biological defense equipment and material among the Armed Forces.”<sup>73</sup> Interestingly, these statutes do not explicitly require providing defense equipment to non-military civilians. Additionally, as a signatory to several international treaties regarding the use of biological weapons

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of Rep. Farnsworth) (debating Reconstruction Act of 1867).

<sup>70</sup> *Id.* at 525 (citation omitted).

<sup>71</sup> 50 U.S.C. § 1522 (2012).

<sup>72</sup> *Id.* § 1523(b)(2).

<sup>73</sup> *Id.* § 1523(b)(3).

(discussed *infra*), the U.S. government has promised never to conduct this sort of research or production of biological weapons.<sup>74</sup>

## 2. *Civilian Rights*

Civilians, as reasonably expected, are not permitted any involvement with biological agents without certain licenses and authorization from government and military entities. Congress has explicitly prohibited “the develop[ment], produc[tion], transfer, acqui[sition], ret[ention], or possess[ion] of any biological agent, toxin, or delivery system for use as a weapon . . .”<sup>75</sup> A violation of this statute triggers a fine and imprisonment for an indefinite number of years.<sup>76</sup> Jurisdiction is not limited to only within the borders of the United States or its territories.<sup>77</sup> Additionally, possession of “any biological agent, toxin, or delivery system . . . not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose . . .” carries an additional fine and imprisonment of not more than ten years.<sup>78</sup> As a caveat, “the terms ‘biological agent’ and ‘toxin’ do not encompass any biological agent or toxin that is in its naturally occurring environment, if the biological agent or toxin has not been cultivated, collected, or otherwise extracted from its natural source.”<sup>79</sup>

Various State legislatures have further sought to protect their citizens from the dangers of biological agents. For example, Alabama has declared: “It shall be unlawful for a person to conspire to commit an explosives or destructive device or bacteriological or biological weapons crime . . .”<sup>80</sup> New Jersey statutes impose a \$10,000 per day violation for any unregistered possession of a biological agent.<sup>81</sup>

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<sup>74</sup> See, e.g., Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, June 17, 1925, 26 U.S.T. 571 [hereinafter Geneva Protocol].

<sup>75</sup> 18 U.S.C. § 175(a) (2012).

<sup>76</sup> *Id.*

<sup>77</sup> See *id.*

<sup>78</sup> *Id.* § 175(b).

<sup>79</sup> *Id.*

<sup>80</sup> ALA. CODE § 13A-10-198(a) (West 2015).

<sup>81</sup> N.J. STAT. ANN. § 26:13-22 (West 2015).

Nevada has made it “unlawful to discharge any radiological, chemical or biological warfare agent or high-level radioactive waste into any waters of the state.”<sup>82</sup>

### C. International Action

Nations with and without global power have come together on multiple occasions, attempting to eliminate the threat of military use of chemical and biological weapons. The resulting treaties of many of these meetings offer hope that the great world militaries will curtail the dangers biological weapons present.

#### 1. Geneva Protocol

In 1925, following the use of biological agents in World War I, major world leaders met in Geneva, Switzerland, to discuss the development of a treaty in which all nations would agree to prohibit future use of such weapons.<sup>83</sup> These meetings culminated in the Geneva Protocol, the first multilateral disarmament treaty banning the development, production, and stockpiling of biological weapons, went into effect on June 17, 1925.<sup>84</sup> The provisions were short, declaring:

That the High Contracting Parties, so far as they are not already Parties to Treaties prohibiting such use, accept this prohibition, agree to extend this prohibition to the use of bacteriological methods of warfare and agree to be bound as between themselves according to the terms of this declaration.<sup>85</sup>

Like many other international treaties, the Geneva Protocol includes no incentives or punishment for failure to ratify the text, nor does it provide for penalties for violations of its measures.<sup>86</sup>

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<sup>82</sup> N.R.S. 445A.575 (West 2015).

<sup>83</sup> See *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (Geneva Protocol)*, U.S. DEP'T OF ST., <http://www.state.gov/t/isn/4784.htm> (last updated Sept. 25, 2002).

<sup>84</sup> Geneva Protocol, *supra* note 74.

<sup>85</sup> *Id.* The treaty refers to “bacteriological weapons” specifically; however, this is now generally recognized as including viral agents as well as bacterial agents.

<sup>86</sup> Geneva Protocol, *supra* note 74; see also Charles C. Flowerree, *The Biological Weapons Convention and the Researcher*, 666 ANNALS N.Y. ACAD. SCIENCES 113, 113-30 (Raymond A. Zilinskas ed., 1992).

Additionally, the U.S. did not ratify the treaty until nearly fifty years later.<sup>87</sup> Perhaps more importantly, the U.S. ratification of the Geneva Protocol was subject to an added reservation of its effectiveness:

That the said Protocol shall cease to be binding on the Government of the United States with respect to the use in war of asphyxiating, poisonous or other gases, and of all analogous liquids, materials, or devices, in regard to an enemy State if such State or any of its allies fails to respect the prohibitions laid down in the Protocol.<sup>88</sup>

The effectiveness of a biological weapons ban treaty that is only followed by other signatory nations may help in conflicts between those nations, but does little to mitigate the dangers of the use of such weapons by or against non-signatory nations or political groups.

## 2. *Biological Weapons Convention*

The United Nations, perhaps recognizing the ineffectiveness of the Geneva Protocol, further worked to eradicate more modern biological agents from the military realm. The Biological Weapons Convention (“BWC”) was opened for signature on April 10, 1972.<sup>89</sup> Over 150 state-nation members have signed the treaty, which calls for “effective progress toward general and complete disarmament, including the prohibition and elimination of all types of weapons of mass destruction, and . . . the prohibition of the development, production and stockpiling of chemical and bacteriological (biological) weapons and their elimination, through effective measures . . .”<sup>90</sup> President Gerald Ford ratified the treaty on March 26, 1975.<sup>91</sup> In doing so, the United States promised:

[N]ever in any circumstances to develop, produce, stockpile or otherwise acquire or retain: (1) Microbial or other biological agents, or

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<sup>87</sup> See Geneva Protocol, *supra* note 74.

<sup>88</sup> *Id.*

<sup>89</sup> UNODA, *Biological Weapons*, UNITED NATIONS, <http://www.un.org/disarmament/WMD/Bio/> (last updated Oct. 7, 2014).

<sup>90</sup> Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *opened for signature* Apr. 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163 [hereinafter Biological Weapons Convention].

<sup>91</sup> *Id.*

toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.<sup>92</sup>

This begs the question: is the promise the U.S. made by signing the BWC at odds with the statutory authority of the U.S. Secretary of Defense to develop biological weapons, even if the intent is to develop defenses to such weapons? In addition, would development of biological weapons for defensive purposes truly be considered “prophylactic, protective, or peaceful” in nature? These questions present significant legal problems that have yet to be addressed in a court of law. Interestingly, while the BWC seeks to ban outright the creation and storage of biological weapons, it contains no provisions banning the actual *use* of such weapons, perhaps relying on the Geneva Protocol’s handling of the issue. Further, the BWC fails to establish an international coalition to develop cures or treatments for those weapons that already exist, focusing instead on “prohibit[ing] and prevent[ing] the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.”<sup>93</sup>

If the global community is going to effectively rid the world of biological warfare, a more effective strategy is needed to attack the problem from both ends. A new international treaty declaring a requirement to actively pursue medical treatments for potential biological agents would create a global incentive to stop diseases in their tracks, encouraging the great world powers—the United States, China, Russia, the European Union, and others—to pool their resources for the greater good. Enforcement provisions requiring nation-parties to commit resources to a centralized international fund or organization could significantly increase the availability of new approaches to medical treatment. Further, centralizing research efforts could ensure that radical new approaches receive the economic and

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<sup>92</sup> *Id.* art. I.

<sup>93</sup> *Id.* art. IV.

professional attention they require. Unfortunately, these efforts were not effectuated by the Geneva Protocol or the BWC.<sup>94</sup>

The U.S. Department of State claims in its annual reports on treaty compliance that “all U.S. activities during the reporting period were consistent with the obligations set forth in the 1925 Geneva Protocol” and “all U.S. activities during the reporting period were consistent with the obligations set forth in the BWC. The United States continues to work towards full transparency of biological defense work using the BWC confidence-building measures.”<sup>95</sup> However, the general public has little, if any, access to investigate whether the military and Department of Defense (“DOD”) have truly followed the treaty to the letter, or if defense programs are used for improper purposes.<sup>96</sup>

### 3. Foreign Statutory Provisions

Many countries have instituted their own statutory restrictions on biological agents in addition to the promises made in the BWC. The United Kingdom prohibits the development, production, stockpiling, acquisition, and retention of “any biological agent or toxin of a type and in a quantity that has no justification for prophylactic, protective or other peaceful purposes.”<sup>97</sup> Germany prohibits the deployment of biological weapons in any armed conflict, whether domestically or internationally.<sup>98</sup> Even Iraq, a country known to have used biological weapons in the 1980s, has promised not to “use, develop, manufacture

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<sup>94</sup> Both treaties fail to incentivize eradication of biological agents and instead focus on prohibiting their use in warfare. *See id.*; Geneva Protocol, *supra* note 74.

<sup>95</sup> U.S. DEP'T OF ST., ADHERENCE TO AND COMPLIANCE WITH ARMS CONTROL, NONPROLIFERATION, AND DISARMAMENT AGREEMENTS AND COMMITMENTS REPORT 5-6 (July 2013), <http://www.state.gov/documents/organization/212096.pdf>.

<sup>96</sup> Ronald M. Atlas & Margaret Somerville, *Life Sciences or Death Sciences: Tipping the Balance Towards Life with Ethics, Codes and Laws*, in *A WEB OF PREVENTION: BIOLOGICAL WEAPONS, LIFE SCIENCES AND THE GOVERNANCE OF RESEARCH* 15, 16 (Brian Rappert & Cairtriona McLeish eds., 2007) (“[The ‘peaceful purposes’ provision] has allowed several countries . . . to cloak their biological weapons programmes within seemingly legitimate facilities[.]”).

<sup>97</sup> Biological Weapons Act 1974, c. 6, § 1(1) (Eng.).

<sup>98</sup> Gesetz zur Einführung des Völkerstrafrechtsgesetzbuches [Act to Introduce the Code of Crimes against International Law], June 26, 2002, Bundesgesetzblatt, Teil I [BGBl. I] at 1842, art. 1 § 12(1)(2) (Ger.) (Eng. translation available at <http://www.loc.gov/law/help/crimes-against-humanity/#germany>).

or acquire any [biological] material . . .”<sup>99</sup> However, while it is encouraging that so many nations have prohibited the use of biological weapons, the risk remains that private individuals or organizations will ignore the law, and instead seek to use these weapons of mass destruction without regard for human life.

#### IV. TERRORISM IN THE MODERN AGE

On September 11, 2001, the United States experienced the first major terrorism attack on U.S. soil to be carried out by a foreign terrorist group. Members of the terrorist group Al-Qaeda traveled to Florida, received pilot training, hijacked four airplanes, and flew them into the two World Trade Center towers in New York City and the Pentagon in Virginia.<sup>100</sup> The attacks shocked the nation and brought forth new fears about the safety of Americans within the U.S. borders. Innocent American citizens with no connections whatsoever to the military or government were attacked without any formal declaration of war upon the country. Nearly 3,000 people lost their lives in the attacks.<sup>101</sup> Cultivated by non-stop media coverage, an aura of fear overwhelmed the public, with Americans across the country believing that they could be targeted next.<sup>102</sup>

Congress responded to the September 11th attacks by passing the Authorization for Use of Military Force (“AUMF”) which authorized the President to:

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<sup>99</sup> Marie Colvin & Uzi Mahnaimi, *Saddam Tested Anthrax on Human Guinea Pigs*, LONDON SUNDAY TIMES (Jan. 18, 1998), <https://www.gpo.gov/fdsys/pkg/CREC-1998-02-25/pdf/CREC-1998-02-25-pt1-Pg5952.pdf>; see also U.N. SCOR, 46th Sess., 2994th mtg. at 6, UN Doc. S/PV.2994 (June 17, 1991).

<sup>100</sup> NAT’L COMM’N ON TERRORIST ATTACKS UPON THE U.S., THE 9/11 COMMISSION REPORT: FINAL REPORT OF THE NATIONAL COMMISSION ON TERRORIST ATTACKS UPON THE UNITED STATES 1-14, 224 (2004), <http://www.9-11commission.gov/report/911Report.pdf>. The fourth plane was intended to hit another high-value target, but was thwarted by the passengers. It crash-landed in a field in Pennsylvania. *Id.*

<sup>101</sup> *September 11th Fast Facts*, CNN, <http://www.cnn.com/2013/07/27/us/september-11-anniversary-fast-facts> (last updated Sept. 7, 2015).

<sup>102</sup> See, e.g., Mark Zdechlik, *Terror Preparations in the Heartland*, MINN. PUB. RADIO (Mar. 16, 2003), [http://news.minnesota.publicradio.org/features/2003/02/21\\_zdechlikm\\_terrorhere/?refid=0](http://news.minnesota.publicradio.org/features/2003/02/21_zdechlikm_terrorhere/?refid=0); see also Marco R. della Cava, *Preparing for What May Come*, USA TODAY (Feb. 20, 2002), <http://usatoday30.usatoday.com/life/2002/2002-02-20-terror-training.htm>.

use all necessary and appropriate force against those nations, organizations, or persons he determines planned, authorized, committed, or aided the terrorist attacks that occurred on September 11, 2001, or harbored such organizations or persons, in order to prevent any future acts of international terrorism against the United States by such nations, organizations or persons.<sup>103</sup>

The AUMF, which passed with full bipartisan support and only a single “Nay” vote in either chamber,<sup>104</sup> did not name a specific country, group, or entity, but rather divested to the President the power to identify targets.<sup>105</sup> With the country already on edge, any additional attacks seemed likely to cause mass panic; this broad authority was met with little Congressional rebuke.

### A. The Rise of Bioterrorism

Accompanying the fear of further violent attacks was an increase in fear of biological terrorism, or “bioterrorism.”<sup>106</sup> Bioterrorism is “the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants.”<sup>107</sup> Biological agents used in terrorism are often very difficult to detect, and may spread easily from person to person long before symptoms arise to alert individuals and government officials.<sup>108</sup> The threat of undetectable weapons in the hands of terrorists is obviously worrisome. Terrorists are often independent from nation-states and governments; as such, they are unlikely to restrain themselves to boundaries set by legislation or international treaties. This lack of

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<sup>103</sup> Authorization for Use of Military Force, Pub. L. No. 107-40, 115 Stat. 224 (2001) (codified at 50 U.S.C. § 1541 (2012)).

<sup>104</sup> In the House, only Representative Barbara Lee (D-CA) voted against the AUMF, while five Republicans and five Democrats did not cast a vote. Off. of the Clerk, *Final Vote Results for Roll Call 342*, U.S. HOUSE OF REPRESENTATIVES, <http://clerk.house.gov/evs/2001/roll342.xml> (last visited Oct. 9, 2015). Two Senators, both Republicans, did not vote in the Senate. *U.S. Senate Roll Call Votes 107th Congress – 1st Session*, U.S. SENATE, [http://www.senate.gov/legislative/LIS/roll\\_call\\_lists/roll\\_call\\_vote\\_cfm.cfm?congress=107&session=1&vote=00281](http://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=107&session=1&vote=00281) (last visited May 19, 2016).

<sup>105</sup> 50 U.S.C. § 1541 (2012).

<sup>106</sup> See Deborah Josefson, *US Fear of Bioterrorism Spreads as Anthrax Cases Increase*, 323 *BRIT. MED. J.* 883, 883 (2001).

<sup>107</sup> *Bioterrorism Overview*, *supra* note 7.

<sup>108</sup> *Id.*

institutional control presents numerous difficulties in preventing the intentional deployment of a biological weapon by independent actors.<sup>109</sup>

One of the primary objectives of terrorism is “to create a sense of fear in order to portray a government as either unable to prevent attacks on its citizens and representatives or losing control over events.”<sup>110</sup> With the unpredictable nature of how biological agents spread among human populations, public fear could spread faster than the disease itself. Even if the actual agent used is less than deadly, the public, often uneducated on the realities of diseases, could succumb to panic and cause accidental injuries to others.

### B. The Anthrax Letters

In the months following the September 11th attacks, the threat of a biological attack on American soil was realized when anthrax-laced letters were mailed to multiple news outlets and government officials.<sup>111</sup> Five victims died in the 2001 Anthrax mail attacks, dubbed “Amerithrax” by the FBI, with seventeen others recovering from infection.<sup>112</sup> The massive federal investigation that followed led to Dr. Bruce Ivins, an American citizen, as the likely culprit;<sup>113</sup> however, no charges were filed against Dr. Ivins, who died of apparent suicide in 2008.<sup>114</sup>

Though neither a foreign agent nor terrorist, the ease with which Dr. Ivins allegedly spread the biological agent through the postal service demonstrates the ability of bioterrorists to discharge their

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<sup>109</sup> JEFFREY SIMON, U.S. ARMED FORCES MED. INTELLIGENCE CTR., TERRORISTS AND THE POTENTIAL USE OF BIOLOGICAL WEAPONS 3 (1989), <http://www.rand.org/content/dam/rand/pubs/reports/2005/R3771.pdf>.

<sup>110</sup> *Id.* at 8.

<sup>111</sup> *Jones v. Brown*, 461 F.3d 353, 356–64 (3d Cir. 2006).

<sup>112</sup> *Amerithrax or Anthrax Investigation*, FED. BUREAU OF INVESTIGATION, <http://www.fbi.gov/about-us/history/famous-cases/anthrax-amerithrax> (last visited May 19, 2016).

<sup>113</sup> *Gilvar v. United States*, No. 09 Civ. 8941(LTS), 2011 WL 2161866, at \*3 (S.D.N.Y. May 26, 2011).

<sup>114</sup> David Willman, *Apparent Suicide in Anthrax Case*, L.A. TIMES (Aug. 1, 2008), <http://articles.latimes.com/2008/aug/01/nation/na-anthrax1>. Incredulously, Dr. Ivins was directly involved in the FBI’s investigation of the attacks as an expert in microbiology. *Id.*

weapons without keeping their fingers on a physical trigger or remaining in close proximity to their intended targets. While the physical damage was low, "it has been suggested that the geopolitical impact [of the anthrax mailings] . . . was of a similar scale to the 2002 to 2003 SARS outbreak, which caused an estimated 8098 cases and 774 deaths."<sup>115</sup> The ability of even a small release to cause such massive political and economic damage highlights the variety of dangers and impacts that bioterrorism presents.

The primary danger of an anthrax attack is the ease with which one can become infected through simple inhalation of anthrax spores.<sup>116</sup> Airborne anthrax is the most likely form to be used in a biological attack, and is the most lethal form of delivery.<sup>117</sup> A terrorist could release a concentrated powder or aerosolized mixture of anthrax spores into the air and rely on wind to carry spores over a large expanse of land.<sup>118</sup> Without the need for direct control over the spores once released, a terrorist could then leave the area before personal risk develops. Unfortunately, this type of threat is not merely hypothetical. In the summer of 2015, the terrorist organization "Islamic State of Iraq and Syria" (colloquially known as "ISIS" or "ISIL") was believed to have deployed mustard gas in small amounts against Kurdish fighters.<sup>119</sup> While the attacks were limited in size and scope, the ability of a terrorist organization to access chemical weapons and use them in the field diminishes doubt as to the dangers of such an organization utilizing naturally-occurring biological diseases in a similar manner.<sup>120</sup>

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<sup>115</sup> ROYAL SOC'Y, REPORT OF THE RS-IAP-ICSU INTERNATIONAL WORKSHOP ON SCIENCE AND TECHNOLOGY DEVELOPMENTS RELEVANT TO THE BIOLOGICAL AND TOXIN WEAPONS CONVENTION 10 (Nov. 2006), <https://fas.org/biosecurity/resource/documents/rs-iap-icsu%20report.pdf>.

<sup>116</sup> See Amesh Adalja et al., *Clinical Management of Potential Bioterrorism-Related Conditions*, 372 NEW ENG. J. MED. 954, 956 (2015).

<sup>117</sup> *Id.*

<sup>118</sup> See *id.*

<sup>119</sup> Raja Abdulrahim, *Islamic State Accused of New Chemical Weapons Attack in Syria*, WALL ST. J., <http://www.wsj.com/articles/islamic-state-accused-of-using-chemical-weapons-in-syria-1440353562> (last updated Aug. 23, 2015).

<sup>120</sup> ISIS is a designated Foreign Terrorist Organization in accordance with Section 219 of the Immigration and Nationality Act. *Foreign Terrorist Organizations*, U.S. DEP'T OF ST., <http://www.state.gov/j/ct/rls/other/des/123085.htm> (last visited May 19, 2016); 8 U.S.C. § 1189 (2012).

### C. Ease of Use by Terrorists

As the Amerithrax attacks demonstrated, a terrorist could simply place a small amount of anthrax-laced powder into a standard envelope and mail the biological weapon to anyone in the country for the cost of a postage stamp.<sup>121</sup> All a potential target would have to do is open the mail and breathe in the powder to be at an extreme risk of infection.<sup>122</sup> In response to this danger, the United States Postal Service (“USPS”) began irradiating all postal mail sent to federal buildings and offices, including the White House and Congress.<sup>123</sup> The irradiation process blasts the envelopes with electron beams or x-rays to destroy the DNA of any organisms inside, thereby eliminating any harmful threat of a biological substance.<sup>124</sup> However, these protocols are only used on federally-addressed mail and are generally unavailable for the average citizen.<sup>125</sup> As a result, most Americans remain at risk should a terrorist group attempt to recreate the 2001 attacks.

The potential threat of biological agents traveling by mail manifested itself yet again in early 2015, when live anthrax samples were inadvertently shipped across the country, and overseas, by a military research laboratory.<sup>126</sup> While no injuries occurred as a result of the mistake, the fact that such a seemingly well-secured agent could so easily make its way across the globe further demonstrates the dangers posed by biological weapons.<sup>127</sup>

Unlike most military arms or nuclear weapons, biological agents are often stored in significantly less secure research facilities.<sup>128</sup> Without the requirement for design, production, or significant

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<sup>121</sup> See *Amerithrax or Anthrax Investigation*, *supra* note 112.

<sup>122</sup> See Adalja et al., *supra* note 116.

<sup>123</sup> OFF. OF RADIATION & INDOOR AIR, ENVTL. PROT. AGENCY, MAIL IRRADIATION 1 (Aug. 2014), <http://www3.epa.gov/radtown/docs/mail-irradiation.pdf>.

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> David Alexander, *U.S. Base Shipped Live Anthrax to 19 States Plus D.C.: Pentagon*, REUTERS (June 8, 2015), <http://www.reuters.com/article/2015/06/08/us-usa-military-anthrax-id-USKBN0OO2ER20150608>.

<sup>127</sup> *Id.*

<sup>128</sup> SIMON, *supra* note 109, at 3.

financial investment, nearly any individual or group with access to a contagious disease can intentionally contract a virus or bacterial infection and travel to highly populated areas, silently spreading the disease.<sup>129</sup> While airport security has significantly increased in technological capabilities since the September 11th attacks, the inability to accurately track infectious diseases complicates any effort to confirm that individuals are healthy upon entrance through U.S. Customs and Border Protection.<sup>130</sup> The recent incidents of Ebola reaching American cities for the first time in history demonstrate this problem, as innocent civilians can unknowingly be carriers of deadly diseases.<sup>131</sup> In order to curtail the dangers posed by bioterrorism, the U.S. can no longer rely solely on prior legislative and international action to protect its citizens.

## V. POST-DEPLOYMENT LEGAL REMEDIES

In response to the growing threat of biological warfare and bioterrorism, Congress has enacted several programs aimed at reducing both the danger and the effects of a biological attack.

### A. Project Bioshield Act

In 2004, Congress enacted the Project Bioshield Act, which established a \$5.6 billion project with the goal of developing strategic reserves of therapeutics and vaccines against known biological agents in a new Strategic National Stockpile.<sup>132</sup> According to the CDC, the Strategic National Stockpile stores enough vaccines to immunize every American in the event of a biological attack.<sup>133</sup> However, a prophylactic vaccine is entirely ineffective for an individual's immune

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<sup>129</sup> See, e.g., Jamie Doward, *Top Secret Military Warning on Ebola Biological Weapon Terror Threat*, *GUARDIAN* (Feb. 21, 2015), <http://www.theguardian.com/uk-news/2015/feb/21/top-secret-ebola-biological-weapon-terror-warning-al-qaida-isis>.

<sup>130</sup> See *ALPA Issue Analysis: Aviation Security: 10 Years After the 9/11 Attacks*, AIR LINE PILOTS ASS'N, INT'L (Sept. 8, 2011), [http://www.speednews.com/speednews\\_files/data/2041.pdf](http://www.speednews.com/speednews_files/data/2041.pdf).

<sup>131</sup> Dana Ford, *First Diagnosed Case of Ebola in the U.S.*, *CNN* (Sept. 30, 2014), <http://www.cnn.com/2014/09/30/health/ebola-us/>.

<sup>132</sup> Project Bioshield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835, 842, 852 (2004).

<sup>133</sup> See, e.g., *Smallpox Vaccine Overview*, *supra* note 46.

system if it is administered after contracting the disease it is meant to prevent.<sup>134</sup> Further, vaccines are not immediately effective, as the immune system takes time to develop immunity to newly introduced foreign organisms.<sup>135</sup> Without an active vaccination program, the American public is essentially left unprotected until the danger has already hit.

The theoretical strategic advantage of large stockpiles ready to be put into action is clear, as the production time for new vaccines would no longer be an issue when the drugs have already been produced and stored for future use. "However, strains can easily mutate and become resistant to stockpiled vaccines; long-term reserves of therapeutics tend to be unstable; and large-scale manufacturing of therapeutics takes one to three years using traditional techniques."<sup>136</sup> Without a stable and trustworthy system for quick dissemination of therapeutic compounds, innocent civilians remain unprotected from the threat of biological release. The Project Bioshield Act expired in 2014 after a statutory ten-year effective period.<sup>137</sup> Congress provided extended funding in 2013 and 2014 to keep the program available; however, without a stable and lasting extension, the future of the program is unclear.<sup>138</sup>

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<sup>134</sup> *Id.*

<sup>135</sup> *Understanding How Vaccines Work*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-understand-color-office.pdf> (last visited Oct. 17, 2015); *see also Acquired Immunity*, MERCK SHARP & DOHME, <http://www.merckmanuals.com/home/immune-disorders/biology-of-the-immune-system/acquired-immunity> (last visited May 19, 2016).

<sup>136</sup> Royal Soc'y, *Science and Technology Developments Relevant to the Biological Weapons Convention*, in *A WEB OF PREVENTION: BIOLOGICAL WEAPONS, LIFE SCIENCES AND THE GOVERNANCE OF RESEARCH* 85 (Brian Rappert & Caitriona McLeish eds., Routledge 2012).

<sup>137</sup> *See* ROBERT KADLEC, CTR. FOR A NEW AM. SEC., *RENEWING THE PROJECT BIOSHIELD ACT: WHAT HAS IT BOUGHT AND WROUGHT?* 1 (2013), [http://www.cnas.org/files/documents/publications/CNAS\\_RenewingTheProjectBioShieldAct\\_Kadlec.pdf](http://www.cnas.org/files/documents/publications/CNAS_RenewingTheProjectBioShieldAct_Kadlec.pdf).

<sup>138</sup> *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013*, Pub. L. No. 113-5, 127 Stat. 161 (2013); *Consolidated Appropriations Act of 2014*, Pub. L. No. 113-76, 128 Stat. 5 (2014); *see also* Frank Gottron, *The Project Bioshield Act: Issues for the 113<sup>th</sup> Congress*, CONG. RESEARCH SERV. (June 18, 2014), <http://fas.org/sgp/crs/terror/R43607.pdf>.

## B. Military Protection Procedures

The military, given its heightened risk of exposure if biological agents are deployed by an enemy force, often requires servicemen and servicewomen to undergo prophylactic treatment against a variety of possible contagions.<sup>139</sup> However, these treatments are not always fully developed before being administered, possibly due to lack of ability to test them or lack of appropriate oversight during their development, given the legal concerns regarding defense research of known biological agents.<sup>140</sup> In *Doe v. Sullivan*, the D.C. Circuit Court resolved a question regarding the legality of administering unapproved medical drugs to military personnel for protection against chemical and biological agents.<sup>141</sup> Judge Ruth Bader Ginsburg, sitting on the Circuit Court just two years before her appointment to the Supreme Court, ruled that informed consent was not required for the DOD to administer unapproved investigational drugs to military personnel.<sup>142</sup>

The *Sullivan* ruling centered on an FDA regulation permitting the DOD to make a determination that informed consent was “not feasible in certain battlefield or combat-related situations.”<sup>143</sup> This regulation was an attempt to relieve the restrictions set by the Federal Food, Drug, and Cosmetic Act (“FDC&A”) and prior FDA regulations requiring informed consent from any recipient of an investigational drug.<sup>144</sup> The serviceman in *Sullivan* challenged the DOD’s argument that the dangers of war created a situation in which informed consent was not feasible.<sup>145</sup> He argued that the administration of the drug without his consent constituted a violation of the Due Process Clause of the Fifth Amendment.<sup>146</sup>

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<sup>139</sup> 21 U.S.C. § 360bbb-3(b)(1)(B) (2012).

<sup>140</sup> *Doe v. Sullivan*, 938 F.2d 1370 (D.C. Cir. 1991).

<sup>141</sup> *Id.* at 1381.

<sup>142</sup> *Id.*

<sup>143</sup> Informed Consent for Human Drugs and Biologics; Determination that Informed Consent is Not Feasible, 55 Fed. Reg. 52,814 (Dec. 21, 1990) (codified at 21 C.F.R. § 50.23 (2015)).

<sup>144</sup> 21 U.S.C. § 355(i) (2012); 21 C.F.R. § 50.20 (2015).

<sup>145</sup> *Sullivan*, 938 F.2d at 1374–75.

<sup>146</sup> *Id.* at 1375.

The Court, while recognizing the questionability of the new regulations, determined that the ambiguities in the language of the statute required deference to the agency's interpretation, not the court's judgment.<sup>147</sup> Furthermore, the court agreed with the agency's argument that "administering the drugs uniformly prevents unnecessary danger to troops and medical personnel from injury to, or the death of, fellow military personnel in battle."<sup>148</sup> Additionally, "the DOD [had] an interest in successfully accomplishing the goals of Operation Desert Storm."<sup>149</sup> These goals satisfied the constitutional requirements of the Fifth Amendment, thus defeating the constitutional challenge.<sup>150</sup>

The *Sullivan* ruling demonstrated the complexities in preventing the dangers of biological weapons among the military. More complex, still, is the question of how to prevent their disastrous effects from reaching the general public. As Professor James Hodge Jr. notes, "there is no central public health system in the United States. Instead, a collaborative workforce of federal, state, and local authorities work in conjunction with other inter-level agencies . . . to accomplish public health outcomes."<sup>151</sup> This vast separation of power and authority complicates the development of a single, unified plan to address the dangers of biological weapons.

### C. Protecting the Public - A New Approach

The Department of Homeland Security ("DHS"), established following the September 11th Attacks, present a prime opportunity for the federal government to take action to mitigate the dangers posed by naturally-occurring biological diseases.<sup>152</sup> Tasked with "secur[ing] the nation from the many threats we face," DHS is properly positioned to

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<sup>147</sup> *Id.* at 1381-82 (citing *Chevron U.S.A. v. NRDC*, 467 U.S. 837 (1984)).

<sup>148</sup> *Id.* at 1383 (quoting *Doe v. Sullivan*, 756 F. Supp. 12, 17 (D.D.C. 1991)).

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> James G. Hodge, Jr., *Bioterrorism Law and Policy: Critical Choices in Public Health*, 30 J.L. MED. & ETHICS 254, 257 (2002).

<sup>152</sup> *See id.* at 258.

coordinate a response to biological attacks.<sup>153</sup> By federalizing the response, the military medical and weapons research complex can become involved, with its vast supply of protective gear and protocols. Additionally, governors can declare a state of emergency in their respective states, permitting the involvement of the National Guard and its resources.<sup>154</sup> Standardized treatment protocols developed by the CDC can be required in every hospital and treatment facility, and the public's fears can be mitigated by the knowledge that there is a plan in action and known steps to follow.

Relying on and taking advantage of the federal government's vast resources would be valuable. Consolidating these research and funding responsibilities within the federal government would permit greater control over the national response to the release of biological weapons, enabling faster and more effective means of medical treatment and other time-sensitive actions to mitigate the damage. However, these issues only address steps taken *after* the release has already occurred. To greater protect the public *before* any such release, a more effective strategy might be to markedly expand the funding given to research for preventative measures.

#### D. New Legislative Options

In order to better protect citizens from the devastating effects of an intentional release of a biological agent, Congress should pass new legislation that addresses the constantly changing nature of modern warfare. Legislative action may not prevent foreign militaries or terrorist organizations from attempting an attack on the United States; however, effective response systems, if established now, will reduce the time and confusion inherent in administering needed aid in the aftermath of an attack.

##### 1. *Developing Preventatives and Treatments*

Legislative action requiring the active development of preventative measures for known biological agents would

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<sup>153</sup> *About DHS | Homeland Security*, DEP'T OF HOMELAND SECURITY, <http://www.dhs.gov/about-dhs> (last updated July 21, 2015).

<sup>154</sup> *See, e.g.*, 32 U.S.C. § 328 (2012); *see also id.* § 502(f); CAL. MIL. & VET. CODE § 324 (West 2015); TEX. GOV'T CODE ANN. § 437.005 (West 2013).

significantly increase the public's preparedness in the event of a biological release. While the DOD is permitted to research biological warfare agents to develop prophylactic measures, the results are rarely made public, and are often of little use to the average citizen.<sup>155</sup> This is not to suggest that the federal government is not actively and diligently researching preventative measures; the NIH, CDC, and other federal agencies are constantly pressing forward with new research and medical applications.<sup>156</sup> Rather, the argument is that such research should not be used solely for military defense purposes, but instead should be viewed more broadly as a public health matter.

While a strategic reserve of pharmaceutical treatments is indeed a positive step, such a system is unlikely to work well in an atmosphere of panic that is likely to set in following a release of biological weapons. Much like the mad dash of individuals rushing into various retail stores on Black Friday, the lines at various vaccine distribution centers would likely be far too large to maintain civility and control over those anxious to receive their vaccinations.<sup>157</sup> Price, method of payment, insurance payouts, priority of who should receive treatment first, and other logistical issues will have to be analyzed and resolved quickly, often by bureaucrats with little or no medical education.<sup>158</sup> Rather than having politicians and military leaders make these crucial healthcare decisions in times of crisis, Congress should greatly expand the Project Bioshield Act by establishing greater civilian access to these preventative vaccines and treatments before disaster strikes, thereby reducing the security-oriented restrictions currently in place.<sup>159</sup>

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<sup>155</sup> 50 U.S.C. § 1522 (2012).

<sup>156</sup> See, e.g., *Mission and Goals*, NAT'L INST. OF HEALTH, <https://www.nih.gov/about-nih/what-we-do/mission-goals> (last updated Apr. 9, 2015).

<sup>157</sup> See *Aylward v. Wal-Mart Stores, Inc.*, No. 10-4799, 2011 WL 2357762, at \*1 (D.N.J. June 9, 2011) (describing the mayhem that often accompanies Black Friday sales).

<sup>158</sup> Jeremy W. Peters, *Is There a Doctor in the House? Yes, 17. And 3 in the Senate.*, N.Y. TIMES (Mar. 7, 2014), <http://www.nytimes.com/2014/03/08/us/politics/doctors-confident-in-their-healing-powers-rush-for-congress.html> (Asserting that most members of the legislature are not medical doctors – only 20 out of 535 – in 2014).

<sup>159</sup> Cf. Project Bioshield Act of 2004, Pub. L. No. 108-276, § 319F-1(a)(2)(E)–(G), 118 Stat. 835, 842, 852 (2004) (codified at 42 U.S.C. § 247d-6a (2012)) (detailing the security-oriented restrictions currently in place).

## 2. *Civilian Rights of Access*

The development of a new legal right of access for the general public to obtain preventative medicines and physical protective equipment regardless of actual or current risk of exposure would allow individuals to protect themselves in a timely manner without reliance on the bureaucratic processes currently required to distribute these items. These vaccines would be treated like any other preventative vaccine. For example, just like the influenza vaccine, the smallpox or anthrax vaccine could be obtained from an individual's physician or pharmacy at that individual's discretion.<sup>160</sup> Costs of these vaccines could be determined by the open insurance market, with higher-risk individuals receiving higher compensation rates. In a time of emergency, the federal government, under the direction of the Department of Health and Human Services, could subsidize these costs to increase ease of access for underprivileged Americans. Post-infection treatments could be handled like antiviral medications used to treat influenza, which require a simple prescription from a physician and can be picked up at any local pharmacy.<sup>161</sup> This establishment of access rights would not require mandatory vaccinations, but rather would allow each individual—and their physician—to decide whether vaccination is appropriate.<sup>162</sup>

Of course, it will take time to establish safe and effective vaccines and ensure the supply is sufficient to withstand the rush for vaccinations following any sort of outbreak. However, by making the government's resources available to third-party pharmaceutical companies and distribution centers, this supply could build up quickly and be immediately available for distribution in the case of an emergency, without reliance on the Strategic National Stockpile and its bureaucratic restraints. Supply would be crucial for any elective

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<sup>160</sup> Cf. *Flu Shot FAQs*, DEAN HEALTH PLAN, <http://www.deancare.com/insurance/faqs/flu-shot-faqs/#2> (last visited May 19, 2016) (noting that a prescription is not required to obtain a flu shot).

<sup>161</sup> *Influenza (Flu) Antiviral Drugs and Related Information*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm> (last visited May 19, 2016).

<sup>162</sup> See generally *Jacobson v. Massachusetts*, 197 U.S. 11, 11 (1905) (establishing the foundations and limits of compulsory vaccinations in the U.S.).

vaccine; studies have demonstrated that more than half of Americans would be likely to seek vaccination for smallpox should one be released to the general public.<sup>163</sup> As media coverage of newer high-risk diseases continues to build, the number of civilians seeking to affirmatively protect themselves via preventative vaccination could very likely rise.

## CONCLUSION

As we press further into an age where every individual is aware of the threat of terrorism and war, the United States must continue to recognize the threat that intentionally weaponized biological organisms pose. However, recognition is not enough. If “Homeland Security” is to truly exist, and not be just another government entity, we must address the threat head-on with full faith and effort. Natural organisms, like terrorists, do not follow laws or international treaties. Worse than terrorists, however, biological agents do not follow any leader, text, or code; they cannot be guided, and they do not discriminate. If our government wishes to protect us, it must renew the once-vigilant work towards developing cures and treatments for the effects of biological weapons. This not only includes conducting research and studies, but requires real-world protections and preventative protocols as well.

The United States should renew vaccination programs for currently relevant biological threats. It should heavily increase funding for the NIH, the CDC, and other medical institutes and physicians who devote their lives to saving others. Most importantly, it should provide these life-saving vaccines, treatments, and preventative equipment to any entity in need, whether it be third-world countries or American citizens who just wish to protect themselves should the unimaginable occur. We can proactively fight these diseases. In doing so, we can prevent those who seek to turn naturally-occurring viruses and bacteria into highly destructive weapons from being successful.

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<sup>163</sup> Robert J. Blendon et al., *Research on Americans' Response to Bioterrorist Threats and Emerging Epidemics*, in *BIOTERRORISM: PREVENTION, PREPAREDNESS AND PROTECTION* 43, 51 (J.V. Borelli ed., Nova 2007).