

EBOLA, EXPERIMENTAL MEDICINE, ECONOMICS, AND ETHICS:  
AN EVALUATION OF INTERNATIONAL DISEASE OUTBREAK  
LAW

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\* J.D., University of Georgia School of Law, 2016; B.B.A., University of Georgia, 2012. I would like to thank my family for always pushing me to succeed. I would also like to thank the Executive Board of the *Georgia Journal of International and Comparative Law* for helping me achieve a dream.

## I. INTRODUCTION

As of September 28, 2014, the death toll from the Ebola outbreak in West Africa exceeded 3,000 people.<sup>1</sup> The World Health Organization (WHO) confirmed more than 6,500 people had been infected with the virus as of that date, meaning that just under fifty percent of the people who contracted the virus had died from it.<sup>2</sup> Further, the WHO estimated that as many as 1.4 million people could have contracted the virus by January 2015.<sup>3</sup> Though shocking, these statistics are indicative of an even larger problem: there is no cure, preventative vaccine, or approved anti-viral medicine currently available to counter the Ebola virus.<sup>4</sup> Instead, Ebola patients are most often treated with intravenous fluids (IVs) to restore the patient's lost electrolytes, and with medicines that counter the other infections resulting from the patient's weakened immune system.<sup>5</sup>

Still, pharmaceutical companies and scientists are diligently working to find a cure or a drug to combat this deadly virus.<sup>6</sup> The National Institutes of Health (NIH), a U.S. executive agency operating under the Department of Health and Human Services that is responsible for biomedical research on a national level, is providing substantial funding to aid pharmaceutical companies in their efforts to develop Ebola vaccines and medicines.<sup>7</sup> Specifically, the NIH and other U.S. governmental entities have aided Mapp Biopharmaceutical Inc. (Mapp) by partially funding the development of an experimental Ebola drug known as ZMapp.<sup>8</sup> This experimental drug was sent to West Africa to treat patients in July and August 2014.<sup>9</sup>

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<sup>1</sup> Justin Worland, *Ebola Death Toll Tops 3,000*, TIME (Sept. 26, 2014), <https://time.com/3433638/ebola-outbreak-death-toll/>.

<sup>2</sup> *Id.*

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

<sup>4</sup> *Ebola (Ebola Virus Disease): Treatment*, CTNS. FOR DISEASE CONTROL & PREVENTION (CDC), <http://www.cdc.gov/vhf/ebola/treatment/index.html> (last updated July 22, 2015) [hereinafter *Ebola: Treatment*].

<sup>5</sup> *Id.*

<sup>6</sup> See, e.g., Lydia Smith, *Ebola Outbreak: Thailand's Siriraj Hospital Creates 'Antibody Treatment' for Deadly Virus*, INT'L BUS. TIMES (Sept. 29, 2014), <http://www.ibtimes.co.uk/ebola-outbreak-thailands-siriraj-hospital-creates-antibody-treatment-deadly-virus-1467727> (explaining that microbiologists are continuing efforts to find treatments for Ebola, even on an international level).

<sup>7</sup> *NIAID Role in Ebola and Marburg Research*, NAT'L INST. OF HEALTH, <http://www.niaid.nih.gov/topics/ebolamarburg/research/pages/default.aspx>.

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

<sup>9</sup> Dennis Lynch, *Ebola: Three African Doctors Given Experimental ZMapp Drug*, INT'L BUS. TIMES (Aug. 16, 2014), <http://www.ibtimes.com/ebola-three-african-doctors-given-experimental-zmapp-drug-1660596>.

At the time ZMapp was sent to West Africa to treat Ebola patients, Mapp had not yet received U.S. Federal Drug Administration (FDA) approval to begin “Phase 1” clinical trials.<sup>10</sup> Because Mapp did not undergo the Phase I clinical trial process, ZMapp was never given to a human before July 2014. Further, although ZMapp had been tested on monkeys prior to being administered to Ebola patients, the results from those monkey trials had not been published.<sup>11</sup> Nevertheless, seven individuals suffering from Ebola during the West African outbreak chose to take ZMapp despite the fact the drug had not been proven effective or safe for human use.<sup>12</sup>

The use of ZMapp in this context was so controversial that the WHO convened a group of experts to discuss and issue a statement about the ethical implications involved.<sup>13</sup> The WHO panel unanimously agreed that in this specific outbreak scenario “there is an *ethical imperative* to offer the available experimental interventions that have shown promising results in the laboratory and in relevant animal models to patients and people at high risk of developing the disease” as long as other strict criteria, like full disclosure to the patient and reporting the effects of the medicine, were also met.<sup>14</sup> Though they agreed that the use of experimental medicine was ethical in this context, the WHO panel did not approach the question of whether the experimental drug use was legal.<sup>15</sup>

The legality of experimental drug use in international disease outbreak contexts involves numerous complexities. For example, a jurisdictional problem exists in the absence of an international agreement governing the use of experimental medicine.<sup>16</sup> Without such an agreement, it is difficult to

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<sup>10</sup> *Id.* During “Phase 1” clinical trials under the FDA drug approval process, the drug is first introduced to healthy humans to determine its common side effects, and to study how the human body processes the drug. *The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (FDA), <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm>.

<sup>11</sup> The monkey trial results were not published until August 29, 2014. Xiangguo Qiu et al., *Reversion of Advanced Ebola Virus Disease in Nonhuman Primates with ZMapp*, NATURE, Aug. 29, 2014, available at <http://www.nature.com/nature/journal/vnfv/ncurrent/pdf/nature13777.pdf>.

<sup>12</sup> Celine Gounder, Op-Ed., *Here’s the Current Status of New Drugs to Fight Ebola Virus and What Works Best Now*, REUTERS BLOG (Sept. 2, 2014), <http://blogs.reuters.com/great-debate/2014/09/02/status-of-new-drugs-to-fight-mutating-ebola-virus/>.

<sup>13</sup> World Health Org. [WHO], Rep. of Advisory Panel to WHO, *Ethical Considerations for Use of Unregistered Interventions for Ebola Viral Disease*, WHO/HIS/KER/GHE/14.1 (Aug. 11, 2014) [hereinafter *Ethical Considerations*].

<sup>14</sup> *Id.* at 5 (emphasis added).

<sup>15</sup> *Id.* at 5–6.

<sup>16</sup> See, e.g., Chiara Giorgetti, *International Health Emergencies in Failed and Failing States*, 44 GEO. J. INT’L L. 1347, 1353 (2013) (“[P]ublic health has become a matter of

determine which state's law governs the use of these drugs given that the patients, pharmaceutical companies, and other relevant third party actors could all potentially be from countries other than where the outbreak occurs. Further, even if an international agreement governed the use of experimental drugs, it is unclear where violators of this hypothetical agreement could be held liable. Given the uncertainty of the legal landscape, the legal, economic, and ethical ramifications of experimental drug use become the guideposts that regulators should use in deciding whether to allow these untested medicines to be administered to patients in disease outbreak contexts.

This Note endeavors to analyze the scope of international law governing the use of experimental medicine in disease outbreak contexts by answering the question of which state governs the use of experimental medicine in these scenarios, and how effective those laws are within the current Ebola outbreak context. Part II provides a current contextual background, the 2014 Ebola outbreak in West Africa, from which this Note will analyze the problems involved with experimental drug use in an international disease outbreak. It also provides an overview of the current state of the law on both a national and an international level that could potentially affect or be affected by this experimental drug use. Part III analyzes how the current state of the law shapes decisions related to experimental drug use, including how uncertainty affects pharmaceutical companies' decisions about whether to produce and provide access to these drugs. This Part further analyzes the potential effects of allowing experimental drug use in international infectious disease outbreak scenarios given legal uncertainty. This Note will argue that the serious legal, economic, and ethical concerns that led to stringent experimental drug regulation outside of the outbreak context are exacerbated in the context of international epidemics; thus there is an even greater need for regulatory intervention. Finally, this Note concludes by suggesting that the WHO should serve as an emergency regulator to address the issues specific to experimental medicines in disease outbreaks.

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international concern, one that often cannot be addressed exclusively by one State, but that requires action by the international community as a whole.”).

## II. BACKGROUND

*A. The 2014 Ebola Outbreak in West Africa*

A full understanding of a current infectious disease outbreak, like the 2014 outbreak of Ebola in West Africa, is necessary to clearly define the problems that regulators face when governing the use of experimental drugs in similar scenarios. The Ebola Virus Disease was discovered in Africa in 1976.<sup>17</sup> Scientists believe bats are the natural carriers of Ebola, but the virus also infects monkeys, chimpanzees, and gorillas.<sup>18</sup> Humans become infected through contact with fluids from infected animals.<sup>19</sup> The virus spreads between humans in multiple ways, including: “direct contact (through broken skin or mucous membranes) with the blood, secretions, organs or other bodily fluids of infected people, and with surfaces and materials (e.g. bedding, clothing) contaminated with these fluids” as well as through contact with deceased Ebola victims.<sup>20</sup> Even when someone infected with the virus recovers, they may still carry the virus for up to seven weeks after recovery.<sup>21</sup>

The symptoms of Ebola include fever, muscle pains, vomiting, diarrhea, and unexplained hemorrhaging.<sup>22</sup> These symptoms can take up to twenty-one days to appear after infection, but usually appear within eight to ten days.<sup>23</sup> After the symptoms first appear in an infected patient, the virus typically develops over a ten-day period, leading to extreme bleeding, coma, shock, and even death.<sup>24</sup> Since, no cure exists for the Ebola virus, patients that have survived generally possessed strong immune systems prior to

<sup>17</sup> *Outbreak Chronology: Ebola Virus Disease*, CDC, <http://www.cdc.gov/vhf/ebola/outbreaks/history/chronology.html>.

<sup>18</sup> *Ebola (Ebola Virus Disease): Transmission*, CDC, <http://www.cdc.gov/vhf/ebola/transmission/index.html>.

<sup>19</sup> *Ebola Virus Disease: Fact Sheet*, WHO, <http://www.who.int/mediacentre/factsheets/fs103/en/> [hereinafter *Ebola: Fact Sheet*].

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

<sup>21</sup> Pauline Oosterhoff, *Ebola Can Be Transmitted Sexually for Weeks After Recovery – Education Is Critical*, THE GUARDIAN (Apr. 22, 2015, 6:29 AM), <http://www.theguardian.com/global-development-professionals-network/2015/apr/22/sexual-health-ebola-semen-sierra-leone>.

<sup>22</sup> *Ebola (Ebola Virus Disease): Signs and Symptoms*, CDC, <http://www.cdc.gov/vhf/ebola/symptoms/index.html>.

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

<sup>24</sup> Amanda L. Chan, *What Actually Happens When a Person Is Infected with the Ebola Virus*, HUFFINGTON POST HEALTHY LIVING (Aug. 2, 2014, 9:24 AM), [http://www.huffingtonpost.com/2014/08/02/ebola-symptoms-infection-virus\\_n\\_5639456.html](http://www.huffingtonpost.com/2014/08/02/ebola-symptoms-infection-virus_n_5639456.html).

infection or were not severely exposed to the virus.<sup>25</sup> However, treatments like IVs and prevention measures have been successful in decreasing the mortality rate of Ebola in some circumstances.<sup>26</sup>

The WHO was notified of the Ebola virus infections in West Africa in March 2014.<sup>27</sup> This particular outbreak began in Guinea and spread to Liberia and Sierra Leone, where the governmental health systems are relatively weak.<sup>28</sup> Those local governments, in conjunction with foreign governments and international aid groups, have taken steps to contain the virus, including: limiting or restricting international travel to and from countries with high infection rates, making donations of monetary aid and experimental vaccines, sending medical experts to provide guidance and training to local medical aid workers,<sup>29</sup> and even sending troops to increase manpower.<sup>30</sup> However, due to poor healthcare systems, lack of governmental capacity to control the virus, and fear, the virus continues to spread.<sup>31</sup>

Due to the poor healthcare systems and lack of necessary supplies in affected countries, more than 240 doctors and aid workers have been infected with Ebola during the current outbreak.<sup>32</sup> One such doctor, Dr. Kent Brantly, was the first American diagnosed with Ebola in July 2014.<sup>33</sup> Upon learning of Dr. Brantly's infection, the NIH contacted Samaritan's Purse, the organization from whom Dr. Brantly worked, and offered to send an

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<sup>25</sup> *Id.*

<sup>26</sup> *Barriers to Rapid Containment of the Ebola Outbreak*, WHO (Aug. 11, 2014), <http://www.who.int/csr/disease/ebola/overview-august-2014/en/> [hereinafter *Barriers to Rapid Containment*].

<sup>27</sup> *Ebola: Fact Sheet*, *supra* note 19.

<sup>28</sup> *Id.*

<sup>29</sup> Lisa Schnirring, *Countries Take More Control Steps as Ebola Totals Grow*, UNIV. OF MINN. CTR. FOR INFECTIOUS DISEASE RESEARCH & POL'Y (CIDRAP) NEWS (Aug. 13, 2014), <http://www.cidrap.umn.edu/news-perspective/2014/08/countries-take-more-control-steps-ebola-totals-grow>.

<sup>30</sup> *U.S. Troops Race to Stem Ebola Outbreak in Africa*, CBS NEWS (Sept. 30, 2014), <http://www.cbsnews.com/news/us-mobile-ebola-labs-open-liberia-this-week/>.

<sup>31</sup> Because the governments in these three heavily impacted West African countries are just recovering from civil war, the healthcare systems lack the manpower, supplies, and organization necessary to contain the Ebola virus. *Barriers to Rapid Containment*, *supra* note 26.

<sup>32</sup> *Unprecedented Number of Medical Staff Infected with Ebola*, WHO (Aug. 25, 2014), <http://www.who.int/mediacentre/news/ebola/25-august-2014/en/>.

<sup>33</sup> Michaelen Doucleff, *2 Americans Catch Ebola in Liberia, as Nigeria Reports First Case*, NPR BLOGS: GOATS & SODA (July 28, 2014, 2:01 PM), <http://www.npr.org/blogs/goatsandsoda/2014/07/28/336043452/2-americans-catch-ebola-in-liberia-as-nigeria-reports-first-case>.

experimental drug known as ZMapp to Liberia.<sup>34</sup> Samaritan's Purse accepted the drug and it was administered to Dr. Brantly when his condition significantly worsened.<sup>35</sup> On August 2, 2014, Dr. Brantly was flown to the U.S. to receive further treatment at Emory University Hospital.<sup>36</sup> On August 21, 2014, Dr. Brantly was released from the hospital after what has been described as a "miraculous" recovery.<sup>37</sup>

Dr. Brantly was not the only person given doses of the experimental ZMapp drug; another U.S. aid worker received the medicine and survived.<sup>38</sup> However, out of the seven people treated with ZMapp, at least two did not survive the Ebola virus.<sup>39</sup> Further, the U.S. Center for Disease Control (CDC) has stated that the drug cannot be confirmed as an effective treatment, despite its success in aiding in the recovery of some Ebola patients, because ZMapp has not been tested in a controlled clinical trial.<sup>40</sup> The positive results in some patients who have received the drug could also be attributed to the overall health of the patient prior to infection and the level of supportive therapy the patient received.<sup>41</sup> For example, two Americans that received the ZMapp treatment and survived were transported back to the U.S. where they received a high level of supportive treatment in a clean environment.<sup>42</sup>

Although ZMapp cannot be proven to be effective in humans without further drug trials, the drug was proven 100% effective in a monkey trial

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<sup>34</sup> Sanjay Gupta & Danielle Dellorto, *Experimental Drug Likely Saved Ebola Patients*, CNN (Aug. 5, 2014), <http://www.cnn.com/2014/08/04/health/experimental-ebola-serum/>.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> See John Bacon & Karen Weintraub, *U.N. Endorses Use of Untested Ebola Medicines*, USA TODAY (Aug. 12, 2014, 11:24 AM), <http://www.usatoday.com/story/news/world/2014/08/12/priest-ebola-dies/13939545/> (explaining that a Spanish priest who received ZMapp later died); *Ebola Kills Liberia Doctor Despite ZMapp Treatment*, BBC NEWS (Aug. 25, 2014), <http://www.bbc.com/news/world-africa-28925491> (announcing the death of a Liberian doctor who was given ZMapp).

<sup>40</sup> See *Ebola Virus Disease (EVD) Information for Clinicians in U.S. Healthcare Settings*, CDC, <http://www.cdc.gov/vhf/ebola/healthcare-us/preparing/clinicians.html> (stating that the CDC cannot confirm the "safety, efficacy, or effectiveness" of any Ebola investigational medicine).

<sup>41</sup> *Ebola: Treatment*, *supra* note 4 ("Recovery from Ebola depends on good supportive care and the patient's immune response.").

<sup>42</sup> See Gupta & Dellorto, *supra* note 34 (describing the challenges of two American Ebola patients being sent back to the U.S. for treatment).

published in late August of 2014.<sup>43</sup> The drug was given to eighteen monkeys between three and five days after being infected with Ebola.<sup>44</sup> The scientific community is very optimistic about the results of the monkey trial due to the drug's high effective rate, and because the doses were given to the monkeys days later than other experimental Ebola medicines.<sup>45</sup> However, the successful monkey trial does not necessarily serve as an accurate prediction of how the drug could react in humans.<sup>46</sup> Major differences between humans infected with Ebola and the monkeys in this trial include: the way humans are infected with Ebola and the way the monkeys were infected with Ebola in a lab setting, the treatment window between humans and monkeys because Ebola can take up to twenty-one days to develop in humans, and the potential differences in side effects of the medicine.<sup>47</sup> Still, prior to the drug being given to Dr. Brantly, it had never been tested in humans.<sup>48</sup>

Along with its unknown human efficacy, the limited supply of ZMapp created another ethical dilemma. After the seven doses were distributed, Mapp declared that their supply of the drug was exhausted.<sup>49</sup> With such a limited supply of the drug available, questions of distributive justice arose.<sup>50</sup> In dealing with these concerns, the WHO recommended consideration of several factors such as the fairness of the distribution between countries and between different population groups within those countries, the social usefulness of the patient, and how advanced the disease was within a patient.<sup>51</sup>

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<sup>43</sup> Xiangguo Qiu et al., *supra* note 11; *ZMapp Cures Monkeys of Ebola Virus*, CBS NEWS (Aug. 29, 2014, 3:06 PM), <http://www.cbsnews.com/news/zmapp-cures-monkeys-of-ebola-virus/>.

<sup>44</sup> *ZMapp Cures Monkeys of Ebola Virus*, *supra* note 43.

<sup>45</sup> Since the Ebola virus had developed to the point that the majority of the monkeys involved in the trial were already showing symptoms, scientists described this particularly high level of drug efficacy in the monkeys as an "extremely impressive" result. *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* Dr. Brantly gave informed consent to be treated with ZMapp after he had been warned that the drug had never been used on humans but had been successful in the monkey trial. Gupta & Dellorto, *supra* note 34.

<sup>49</sup> *ZMapp Cures Monkey of Ebola Virus*, *supra* note 43.

<sup>50</sup> *Ethical Considerations*, *supra* note 13, at 6.

<sup>51</sup> This is not an exhaustive list of the criteria recommended by the WHO ethics panel. Further, the panel did not recommend what priority level each of the factors should receive. *Id.* Since the panel only made recommendations, the distribution of the medicine was actually left up to the countries receiving the experimental drugs. Alexandra Sifferlin, *WHO Outlines Timeline for Experimental Ebola Drugs*, TIME (Sept. 5, 2014), <http://time.com/3274636/who-timeline-ebola-drugs/>.

ZMapp is not the only experimental treatment being developed and used during this Ebola outbreak.<sup>52</sup> The governments of multiple nations are funding the development of several new drugs to help stop the virus.<sup>53</sup> Further, the WHO has recommended that these new drugs and vaccines be “fast-tracked” so that they can be put to immediate use.<sup>54</sup> As discussed later in this Note, the fact that these drugs are just beginning human testing phases means that they could be tested for the first time on Ebola patients in West Africa.<sup>55</sup> Who will regulate these tests, and under what standard will these drugs be regulated?

### *B. Experimental Drug Use and The Law*

In this age of increased globalization, when infectious diseases like Ebola can travel from Liberia to the U.S. in less than a twenty-four hour period,<sup>56</sup> much of the existing law governing experimental medicine is outdated or ineffective.<sup>57</sup> Outside of the human experimentation context, drug regulation on an international scale is effectively non-existent. Instead, current experimental drug regulation is mostly managed on a nation-by-nation basis.<sup>58</sup> This disjointed approach leaves significant regulatory gaps that are exposed during international emergency situations like the Ebola outbreak. However, understanding the need for stricter experimental drug regulation during outbreak scenarios requires an understanding of the current legal landscape surrounding experimental drugs.

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<sup>52</sup> *Ebola: The Race for Drugs and Vaccines*, BBC NEWS (Mar. 27, 2015), <http://www.bbc.com/news/health-28663217>.

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

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* (discussing many experimental drug and vaccine projects underway in West Africa).

<sup>56</sup> This time frame is based on a flight from Dallas Fort Worth Airport to Roberts International Airport. Some websites reported that the actual flight time could be as short as fourteen hours; others reported that even with three layovers, the trip could be completed in twenty-four hours. See, e.g., *Flight Time from Dallas, TX to Monrovia*, PROKERALA, <http://www.prokerala.com/travel/flight-time/from-dallas-tx/to-monrovia/> (stating that a nonstop flight from Dallas, Texas to Monrovia, Liberia would take thirteen hours and fifty-eight minutes).

<sup>57</sup> See, e.g., Benjamin Mason Meier, *International Protection of Persons Undergoing Medical Experimentation: Protecting the Right of Informed Consent*, 20 BERKELEY J. INT'L L. 513, 530–35 (2002) (arguing that experimental drug and related research regulation was ineffective to govern the ATZ trials and the resulting harmful human experimentation that took place in Africa).

<sup>58</sup> Lawrence O. Gostin & Eric A. Friedman, *Towards a Framework Convention on Global Health: A Transformative Agenda for Global Health Justice*, 13 YALE J. HEALTH POL'Y L. & ETHICS 1, 20–21 (2013).

### 1. *The Current International Legal Landscape*

The use of experimental medicine and the management of clinical trials, particularly human trials, is governed by four key internationally recognized documents: the Nuremberg Code, the Declaration of Helsinki (Declaration), the International Covenant on Civil and Political Rights (ICCPR), and the WHO-CIOMS Guidelines (Guidelines).<sup>59</sup> The world first recognized a need for the regulation of human medical experimentation when the Nuremberg Tribunal exposed the atrocities of human experimentation that took place during World War II.<sup>60</sup> In *United States v. Karl Brandt*, the Nuremberg Military Tribunal laid out ten ethical guidelines that were meant to govern the future of medical experimentation on humans.<sup>61</sup> These ten ethical standards are commonly referred to as the “Nuremberg Code.”<sup>62</sup> Notably, among its ten ethical standards, the Nuremberg Code includes requirements such as informed consent, for the experiment to be “designed and based on the results of animal experimentation and a knowledge of the natural history of the disease,” for the degree of risk of the experiment not to outweigh the benefits of the experiment, and for preparations to be made and facilities kept such that the subject is protected from “even remote possibilities of injury, disability, or death.”<sup>63</sup> In short, the principles outlined in the Nuremberg Code were aimed at protecting human rights at the expense of future research.<sup>64</sup> Though the Nuremberg Code is widely thought of as the first

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<sup>59</sup> See David M. Carr, Note, *Pfizer's Epidemic: A Need for International Regulation of Human Experimentation in Developing Countries*, 35 CASE W. RES. J. INT'L L. 15, 19 (2003) (crediting the Nuremberg Code, Declaration of Helsinki, and the WHO-CIOMS Guidelines as the “central standards” governing current experimental research); Finnuala Kelleher, Note, *The Pharmaceutical Industry's Responsibility for Protecting Human Subjects of Clinical Trials in Developing Nations*, 38 COLUM. J.L. & SOC. PROBS. 67, 71, 73 (2004) (adding the International Covenant on Civil and Political Rights to the list of influential documents to the extent that it made informed consent to human experimentation part of binding international law).

<sup>60</sup> Meier, *supra* note 57, at 521.

<sup>61</sup> UNITED STATES V. KARL BRANDT, 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW No. 10, at 181–82 (1948) [hereinafter NUREMBERG CODE], available at [http://www.loc.gov/tr/frd/Military\\_Law/pdf/NT\\_war-criminals\\_Vol-II.pdf](http://www.loc.gov/tr/frd/Military_Law/pdf/NT_war-criminals_Vol-II.pdf).

<sup>62</sup> Meier, *supra* note 57, at 523.

<sup>63</sup> NUREMBERG CODE, *supra* note 61. “Informed consent requires that the physician inform the potential patient of the nature, the aims, methods, risks and benefits, alternative treatments available, and of the patient’s ability to refuse to participate or withdraw from the research.” Carr, *supra* note 59, at 25–26.

<sup>64</sup> Kristen Farrell, Comment, *Human Experimentation in Developing Countries: Improving International Practices by Identifying Vulnerable Populations and Allocating Fair Benefits*, 9 J. HEALTH CARE L. & POL'Y 136, 141 (2006).

international regulation of medical experimentation, its practical application is extremely limited because it is not legally binding, and is viewed as “too uncompromising and too inhospitable to the advancement of science.”<sup>65</sup>

The Declaration of Helsinki was, in many respects, the international response to the Nuremberg Code by the medical community.<sup>66</sup> It is a document created, disseminated, and regularly updated by the World Medical Association (WMA), an international association of private physicians created to “work for the highest possible standards of ethical behaviour and care by physicians”<sup>67</sup> and to espouse the WMA’s position regarding “biomedical research involving human subjects.”<sup>68</sup> The Declaration includes provisions regarding informed consent, privacy and confidentiality, necessary research protocols, and the post-trial dissemination of results.<sup>69</sup> The Declaration notably recognizes that “vulnerable” populations should receive “specifically considered protection” because of their “increased likelihood of being wronged or of incurring additional harm” as a result of the medical experimentation.<sup>70</sup> Further, the Declaration specifically identifies the ethical boundaries of using an “unproven intervention” like ZMapp.<sup>71</sup> In doing so, it provides a very limited set of circumstances under which unproven interventions should be administered. The Declaration only allows this use “where proven interventions do not exist or other known interventions have been ineffective.”<sup>72</sup> Further, the Declaration requires the physician to seek expert advice and obtain the informed consent of the patient.<sup>73</sup> Finally, the Declaration provides that the unproven interventions should only be administered “if in the physician’s

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<sup>65</sup> Meier, *supra* note 57, at 524 (quoting Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now*, in *THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION* 235 (George J. Annas & Michael A. Grodin eds., 1992)).

<sup>66</sup> World Med. Ass’n, *Declaration of Helsinki: Ethical Principles for Research Involving Human Subjects* (2008) [hereinafter *Declaration of Helsinki*], available at <http://www.wma.net/en/30publications/10policies/b3/>. The Declaration was the first time doctors attempted self-regulation via an international document that allowed for more leniency than the Nuremberg Code. Meier, *supra* note 57, at 525. See also Carr, *supra* note 59, at 22–23 (describing the events leading to the creation of the Declaration).

<sup>67</sup> *About the World Medical Association*, WORLD MED. ASS’N, <http://www.wma.net/en/60about/index.html>.

<sup>68</sup> *History: Declaration of Helsinki*, WORLD MED. ASS’N, <http://www.wma.net/en/60about/70history/01declarationHelsinki/index.html>.

<sup>69</sup> *Declaration of Helsinki*, *supra* note 66.

<sup>70</sup> *Id.* paras. 19–20.

<sup>71</sup> *Id.* para. 37.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

judgment it offers hope of saving life, re-establishing health or alleviating suffering.”<sup>74</sup>

While the Declaration is more specific than the Nuremberg Code regarding the application of many ethical principles, the Declaration remains susceptible to interpretation.<sup>75</sup> Further, like the Nuremberg Code, the Declaration is not a legally binding document.<sup>76</sup> Because its ethical standards lack enforceability both legally and medically, the Declaration has “little effect on the regulation of human research.”<sup>77</sup>

The WHO and the Council of the International Organization of Medical Sciences developed the International Ethical Guidelines for Biomedical Research Involving Human Subjects to provide guidance for nations developing medical regulations.<sup>78</sup> One of the driving principles behind the Guidelines is that they require research involving human experimentation to be conducted with “respect for persons, beneficence and justice.”<sup>79</sup> While the Guidelines are currently the most expansive and specific international instrument governing experimental drug use, they, like the Nuremberg Code and the Declaration, are neither enforceable nor binding international law.<sup>80</sup>

The ICCPR is the only legally binding treaty to address the use of human experimentation.<sup>81</sup> Thus, it tangentially governs the use of experimental medicine. Article 7, the ICCPR’s only medically related article, reads: “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.”<sup>82</sup> However, because of its limited application to the experimental drug context, its applicability to state

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<sup>74</sup> *Id.*

<sup>75</sup> See Meier, *supra* note 57, at 531 (quoting M. Cheriff Bassiouni et al., *An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation*, 72 J. CRIM. L. & CRIMINOLOGY 1597, 1601 (1981)).

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

<sup>77</sup> *Id.*

<sup>78</sup> COUNCIL FOR INT’L ORGS. OF MED. SCI. (CIOMS), in collaboration with the WHO, INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Geneva 2002) [hereinafter GUIDELINES], available at [http://www.cioms.ch/publications/guidelines/guidelines\\_nov\\_2002\\_blurb.htm](http://www.cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm) (explaining that the Guidelines were meant to provide guidance to developing countries on how to apply the ethical standards from the Declaration given their “socioeconomic circumstances” and “administrative arrangements”); see also Meier, *supra* note 57, at 526–27.

<sup>79</sup> GUIDELINES, *supra* note 78, at 17.

<sup>80</sup> See Carr, *supra* note 59, at 48 (explaining that neither the Nuremberg Code, Declarations, nor Guidelines are binding on nations).

<sup>81</sup> International Covenant on Civil and Political Rights art. 7, Dec. 16, 1966, 999 U.N.T.S. 171 [hereinafter ICCPR]; Kelleher, *supra* note 59, at 73.

<sup>82</sup> ICCPR, *supra* note 81.

actors only, and its lack of self-enforcement, the ICCPR is ineffective at governing the use of experimental medicine except to the extent that it recognizes informed consent as a principle of international law.<sup>83</sup>

## 2. *The Role of the WHO*

The WHO is the primary body that oversees international health matters.<sup>84</sup> It consists of 194 member states and is governed primarily by the World Health Assembly.<sup>85</sup> The WHO is responsible for coordinating global health initiatives, providing support to countries that request aid in building stable healthcare systems, and providing support in training healthcare workers.<sup>86</sup> The WHO's primary objective is "the attainment by all peoples of the highest possible level of health."<sup>87</sup> Although the WHO has both normative and directive powers, its constitution lacks enforcement power against member states because it does not include an expulsion provision.<sup>88</sup> However, in recent years, through resolutions that serve as directives to member states, the WHO has updated and bolstered two important international regulatory instruments: the 2005 International Health Regulations (IHR) and the Global Outbreak Alert and Response Network (GOARN).<sup>89</sup>

The WHO defines the IHR as "an international legal instrument that is binding on 196 countries across the globe, including all the Member States of [the] WHO. Their aim is to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide."<sup>90</sup> The IHR serve as a "step forward in [the] WHO's ability to control and prevent health emergencies of an international

<sup>83</sup> Kelleher, *supra* note 59, at 73.

<sup>84</sup> Giorgetti, *supra* note 16, at 1359.

<sup>85</sup> *Id.*; see also CONST. OF THE WORLD HEALTH ORG. art. 10, available at [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf) (explaining the organizational structure of the WHO).

<sup>86</sup> Giorgetti, *supra* note 16, at 1360.

<sup>87</sup> CONST. OF THE WORLD HEALTH ORG. art. 1, available at [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf).

<sup>88</sup> Giorgetti, *supra* note 16, at 1359–60.

<sup>89</sup> INTERNATIONAL HEALTH REGULATIONS (2005) (2d ed. 2008) [hereinafter IHR 2005], available at [http://apps.who.int/iris/bitstream/10665/43883/1/9789241580410\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/43883/1/9789241580410_eng.pdf); WHO Dep't of Communicable Disease Surveillance and Response, *Global Outbreak Alert and Response*, WHO/CDS/CSR/2000.3, available at <http://www.who.int/csr/resources/publications/surveillance/whocdscsr2003.pdf?ua=1>.

<sup>90</sup> IHR 2005, *supra* note 89, art. 2 (stating that the goal of the IHR is to "prevent, protect against, control and provide a public health response to the international spread of disease").

nature by requiring countries to report certain disease outbreaks and public health events to [the] WHO, and defining the rights and obligations of Member States to report public health events.”<sup>91</sup> However, the emphasis of the IHR is on reporting and monitoring these “public health events” rather than regulating the measures taken to control and eliminate the infectious disease.<sup>92</sup> The IHR does not address the use of experimental drugs or vaccines.<sup>93</sup>

The IHR provides for the establishment of an “Emergency Committee” to address specific issues as they emerge in public health emergencies.<sup>94</sup> The IHR Emergency Committee has met multiple times to address the West Africa Ebola outbreak, and met twice during the height of infections during 2014.<sup>95</sup> During the first Emergency Committee meeting, the committee members and attending member states unanimously decided that the outbreak had reached the level of a “Public Health Emergency of International Concern.”<sup>96</sup> The Committee also made several suggestions to the Director-General for addressing the Ebola outbreak in accordance with the IHR regulations.<sup>97</sup> These suggestions include: the declaration of a state of emergency, the establishment of pipelines of supplies, and the establishment of strict barriers to international travel to and from states where Ebola was being transmitted; increased surveillance and monitoring of suspicious fevers and deaths, and the institution of strict guidelines if cases of Ebola are confirmed in states that border the transmission states and those with potential Ebola cases; continuance of relatively unrestricted trade and travel, and provision of relevant information to the general public for all

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<sup>91</sup> Giorgetti, *supra* note 16, at 1369.

<sup>92</sup> Compare IHR 2005, *supra* note 89, art. 15(3) (limiting the WHO to making time-constrained recommendations rather than binding regulations about health measures), with *id.* art. 5(1) (mandating that member states put assessment, notification, and report measures into effect within five years).

<sup>93</sup> The IHR makes no reference to experimental medicine. IHR 2005, *supra* note 89.

<sup>94</sup> *Id.* art. 48.

<sup>95</sup> *Statement on the 1st Meeting of the IHR Emergency Committee on the 2014 Ebola Outbreak in West Africa*, WHO (Aug. 8, 2014) [hereinafter *1st Meeting of IHR Emergency Committee*], <http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/>; *Statement on the 2nd Meeting of the IHR Emergency Committee Regarding the 2014 Ebola Outbreak in West Africa*, WHO (Sept. 22, 2014) [hereinafter *2nd Meeting of IHR Emergency Committee*], <http://www.who.int/entity/mediacentre/news/statements/2014/ebola-2nd-ihr-meeting/en/index.html>.

<sup>96</sup> *1st Meeting of IHR Emergency Committee*, *supra* note 95.

<sup>97</sup> *Id.*

other states.<sup>98</sup> The Director-General implemented this advice as “Temporary Recommendations” under IHR Article 19.<sup>99</sup>

Because the Ebola virus continued to spread during the month of September, the Emergency Committee met again, through electronic communications, to address areas of concern.<sup>100</sup> Since many states had issued international travel bans to West African countries, the Emergency Committee was concerned with the economic welfare of the area; thus, the Committee encouraged states to restore travel and trade with these areas in accordance with the IHR.<sup>101</sup> Further, the Committee encouraged greater vigilance by states to ensure that healthcare workers were adequately supplied with safety equipment and were trained for handling the virus.<sup>102</sup> The Director-General used these suggestions to further explain and extend the timeframe of the “Temporary Recommendations” that were implemented in August.<sup>103</sup>

Another key regulatory instrument of the WHO is GOARN. The WHO defines GOARN as a technical “collaboration of existing institutions and networks . . . [who] pool[] human and technical resources for rapid identification, confirmation and response to outbreaks of international importance.”<sup>104</sup> As an informational network, GOARN “contributes towards global health security” through efforts aimed at organizing planning and preparedness measures, efficiently identifying global health emergencies, and ensuring supplies and technical assistance reach the affected countries.<sup>105</sup> In an effort to standardize global epidemic response, GOARN has published its “Guiding Principles of International Outbreak Alert and Response” and accompanying protocols that provide guidance on response measures including “epidemiological, laboratory, clinical management, research, communications, logistics support, security, evacuation and communications systems.”<sup>106</sup> Though the network is one of the primary regulators of epidemic response measures, neither the “Guiding Principles” nor the

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> *2nd Meeting of IHR Emergency Committee, supra* note 95.

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Global Outbreak Alert and Response Network*, WHO, [http://www.who.int/ihr/alert\\_and\\_response/outbreak-network/en/](http://www.who.int/ihr/alert_and_response/outbreak-network/en/).

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*; see also *Guiding Principles for International Outbreak Alert and Response*, WHO, <http://www.who.int/csr/outbreaknetwork/guidingprinciples/en/> (elaborating on efforts by GOARN to standardize global epidemic response).

protocols have specifically addressed whether the use of experimental medicine should be encouraged.<sup>107</sup>

Thus, because it does not include experimental drug use in any of its binding regulatory documents,<sup>108</sup> the WHO only regulates the international use of experimental medicine through “non-binding global health instruments, or ‘soft law.’”<sup>109</sup> One way the WHO uses soft law in the experimental medicine context is through the promulgation of the Guidelines mentioned above.<sup>110</sup> The document consists of twenty-one guidelines broadly covering “(1) ethical review; (2) informed consent; (3) populations with limited resources; (4) choice of control method; (5) vulnerable groups; (6) women as research participants; (6) confidentiality; (7) compensation; (8) ethical and scientific review of research; and (9) the obligation to provide healthcare services.”<sup>111</sup>

Of particular importance to this Note are: Guideline 10, which governs human experimentation in “populations and communities of limited resources” by requiring that the researcher “make every effort to ensure that: the research is responsive to the health needs and the priorities of the population . . . and any intervention or product developed . . . will be made reasonably available for the benefit of that population”;<sup>112</sup> Guideline 12, which ensures that the “burdens and benefits of the research will be equitably distributed” amongst the communities that are invited to be subjects of the research;<sup>113</sup> Guideline 13, which provides for special protection for vulnerable groups, including those individuals with insufficient education or resources and those otherwise unable to protect their own interests;<sup>114</sup> and Guideline 19, which provides for the payment of medical expenses for individuals that are injured and for compensation to the families of those that

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<sup>107</sup> See *Global Outbreak Alert and Response Network*, *supra* note 104 (omitting any reference to the use of experimental medicine).

<sup>108</sup> The WHO Constitution and three multi-lateral treaties, the WHO Regulations No. 1 Regarding Nomenclature with Respect to Diseases and Causes of Death, the IHR, and the Frameworks Convention on Tobacco Control, serve as the binding instruments governing global health. Gostin & Friedman, *supra* note 58, at 20–21.

<sup>109</sup> *Id.* at 22.

<sup>110</sup> See Meier, *supra* note 57, at 526–27 (explaining the importance of the Guidelines in the context of informed consent).

<sup>111</sup> Amy F. Wollensack, Note, *Closing the Constant Garden: The Regulation and Responsibility of U.S. Pharmaceutical Companies Doing Research on Human Subjects in Developing Nations*, 6 WASH. U. GLOBAL STUD. L. REV. 747, 750 (2007).

<sup>112</sup> GUIDELINES, *supra* note 78, at Guideline 10.

<sup>113</sup> *Id.* at Guideline 12.

<sup>114</sup> *Id.* at Guideline 13.

died as a result of the experimentation.<sup>115</sup> Despite their relevancy, the Guidelines are limited in their practical application.<sup>116</sup>

Another way the WHO governs experimental medicine and its use is through the promulgation of medicine regulation standards in its WHO Medicines Regulatory Package.<sup>117</sup> The “package” is a collection of papers published by the WHO that addresses varying issues of drug regulation, including effective regulation guidelines, handbooks for establishing clinical trials, effective drug storage and distribution practices, and the current status of international drug regulation harmonization efforts.<sup>118</sup> The collection contains several documents related to the best practices of clinical and non-clinical trials,<sup>119</sup> a guide to good manufacturing practices for the development of experimental medicines,<sup>120</sup> and multiple guides to manufacturing drugs.<sup>121</sup> All of these instruments govern the use and development of experimental medicines in some manner.

<sup>115</sup> *Id.* at Guideline 19.

<sup>116</sup> See Tiffany A. Hetland, Note, *Abdullahi v. Pfizer & The Alien Tort Statute: Kicking Open A Door Left Slightly Ajar* by Sosa v. Alvarez-Machain, 4 ST. LOUIS U. J. HEALTH L. & POL’Y 427, 454 (2011) (explaining that the limited analysis of the Guidelines in both the majority and dissenting opinions in *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009) was justified because the Guidelines are merely “guidelines” and thus “lack probative value”); see also Meier, *supra* note 57, at 532 (discussing how the flexibility of the Guidelines led to “exploitation of developing countries” when they were applied to the African short course AZT trials that used African subjects to test a medication intended to prevent the transmission of HIV/AIDs).

<sup>117</sup> WHO, WHO MEDICINES REGULATORY PACKAGE (3d ed. 2014), available at <http://infocollections.org/medregpack/interface/home.htm>.

<sup>118</sup> *Id.*

<sup>119</sup> See, e.g., WHO, *Good Clinical Laboratory Practice* (2009), in WHO MEDICINES REGULATORY PACKAGE, *supra* note 117, available at <http://infocollections.org/medregpack/documents/d2003/d2003.pdf> (establishing practices for the analysis of the efficacy of medicines in clinical settings); WHO, *Handbook: Good Laboratory Practice (GLP): Quality Practices for Regulated Non-Clinical Research and Development* (2d ed. 2009), in WHO MEDICINES REGULATORY PACKAGE, *supra* note 117, available at <http://infocollections.org/medregpack/documents/d0067/d0067.pdf> (detailing best practices for the development of medicines in a non-clinical context).

<sup>120</sup> See WHO, *Good Manufacturing Practices: Supplementary Guidelines for the Manufacture of Investigational Pharmaceutical Products for Clinical Trials in Humans*, in WHO MEDICINES REGULATORY PACKAGE, *supra* note 117, available at <http://infocollections.org/medregpack/documents/d0079/d0079.pdf> (providing guidelines to experimental drug manufacturers to ensure consistency and quality in drugs developed for human trials).

<sup>121</sup> See, e.g., WHO, *Annex 5: Basic Elements of Good Manufacturing Practices in Pharmaceutical Production* (2002), in WHO MEDICINES REGULATORY PACKAGE, *supra* note 117, available at <http://infocollections.org/medregpack/documents/d0089/d0089.pdf> (explaining the necessity for uniform manufacturing practices for pharmaceuticals).

### *3. Least Developed Countries and the Absence of Enforceable, Practical Law*

As of 2002, only twenty percent of WHO member states had a “well developed drug regulation system,” and all of those states were industrialized nations.<sup>122</sup> Fifteen states, or thirty percent of WHO member states, had either no drug regulatory authority in place at all or had a drug regulatory authority that was functionally non-existent.<sup>123</sup> Developing countries generally have the weakest drug regulatory authorities and thus experience “safety, efficacy and quality” problems with medicines.<sup>124</sup> Because of the gap between the regulatory approaches of developed nations and developing nations, both the WHO and the FDA hold training conferences to help increase the overall effectiveness of global drug regulation.<sup>125</sup> Despite these efforts, the drug regulatory systems in developing countries, especially in Africa, are weak because the systems are newly established, subject to corruption, disorganized, or non-existent.<sup>126</sup>

## III. ANALYSIS

The Ebola outbreak provides an excellent example of the insufficiency of the current state of the law governing experimental drugs and related issues in disease outbreak contexts, and how the absence of clear regulation leads to a host of economic and ethical problems.

### *A. The Insufficiency of the Current State of the Law*

Even with the promulgation of the IHR and the international recognition of human rights in the medical experimentation context, the majority of

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<sup>122</sup> SAUWAKON RATANAWIJITRASIN & ESHETU WONDEMAGEGNEHU, EFFECTIVE DRUG REGULATION: A MULTICOUNTRY STUDY 11 (WHO, 2002), available at <http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf>.

<sup>123</sup> *Id.*

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

<sup>125</sup> See, e.g., *CDER Forum for International Drug Regulatory Authorities*, FDA, <http://www.fda.gov/Drugs/NewsEvents/ucm167011.htm> (discussing the FDA conference for international drug regulatory authorities); *International Conference of Drug Regulatory Authorities*, WHO, [http://www.who.int/medicines/areas/quality\\_safety/regulation\\_legislation/icdra/en/](http://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/en/) (discussing the WHO drug regulatory authority annual conference).

<sup>126</sup> See Meier, *supra* note 57, at 535 (contending that the need for resources pushes governments to avoid regulation); see also Giorgetti, *supra* note 16, at 1356–58 (arguing that the failed and failing states in Africa face perilous health problems because their government systems are incapable of promulgating and enforcing adequate regulation).

global health law is still far from being “global.”<sup>127</sup> Rather, “[t]oday’s global health discourse is dominated by terms such as ‘fragmentation’ and ‘duplication,’ with a proliferation of actors, pictorially represented as an incomprehensible, tangled web of agencies and programs.”<sup>128</sup> This makes regulating experimental medicine in a crisis like the Ebola outbreak a nightmare for all of the actors involved for numerous reasons.

First, the four major international health law documents detailed above do not specifically address the use of experimental medicines during disease outbreaks. Further, despite being the sole international documents governing the use of experimental medicine, three of these documents, and the standards that they promote, have not been “afforded the weight of binding international law, but carry only suggestive or persuasive weight in regulating conduct by doctors or in finding liability for individuals accused of unethical experimental research.”<sup>129</sup> The only binding document governing experimental medicine in the international arena is the ICCPR, which merely requires informed consent in the context of medical experimentation.<sup>130</sup> As a whole, this body of documents proves ineffective in guiding decision-makers faced with difficult economic and ethical decisions during disease outbreak scenarios.

Second, the WHO does not have the enforcement power necessary to govern during disease outbreak situations. At this point, no IHR provision or committee has addressed the use of experimental medicine in an epidemic context even though the IHR serves as the primary regulatory instrument of the WHO during outbreaks. More demonstrative of the WHO’s lack of power to regulate experimental medicines is the fact that, despite meeting multiple times after experimental medicine was first used to combat Ebola in West Africa, the Emergency Committee did not address this use.<sup>131</sup> Although it has promulgated many guidelines and other forms of soft law governing the use of experimental medicine, the WHO has no enforcement power over these documents.<sup>132</sup> Instead, the WHO standards and guidelines fall prey to the common shortfalls of soft law because they lack accountability measures, vary in precision, and even include some regulatory

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<sup>127</sup> See Joshua D. Reader, Note, *The Case Against China: Establishing International Liability For China’s Response to the 2002–2003 SARS Epidemic*, 19 COLUM. J. ASIAN L. 519, 531 (2006) (“[I]nternational health law holds fast to the boundaries of state sovereignty.”).

<sup>128</sup> Gostin & Friedman, *supra* note 58, at 26.

<sup>129</sup> Carr, *supra* note 59, at 48.

<sup>130</sup> Farrell, *supra* note 64, at 143.

<sup>131</sup> *1st Meeting of the IHR Committee, supra* note 95; *2nd Meeting of the IHR Committee, supra* note 95.

<sup>132</sup> Gostin & Friedman, *supra* note 58, at 22.

gaps.<sup>133</sup> Thus, the WHO does not provide effective or comprehensive international law governing the use of experimental medicine in outbreak contexts. Instead, the applicable law varies by country.

Finally, experimental drug regulation that exists in developing countries, particularly African countries, is often ineffective because these countries lack the legal systems necessary to effectuate enforcement and corresponding liability against violators of these regulations.<sup>134</sup> Moreover, many developing African nations resist the push to regulate experimental medicines. In what has been termed a race to the bottom, these countries aim to encourage pharmaceutical companies to pour money, medical research subsidies, and medical necessities into the economy by offering their citizens as human test subjects.<sup>135</sup> In doing so, they maintain the fewest restrictions or regulations on medical experimentation.<sup>136</sup> Further, developing countries devote disproportionately less of their total government spending to health care.<sup>137</sup> This problem is compounded by the “substitution effect,” whereby developing governments reduce the percentage of government spending put toward healthcare as they obtain more foreign aid to subsidize their health systems.<sup>138</sup>

Thus, the current state of the law regarding the use of experimental medicine is wholly insufficient to manage responses to disease outbreaks by all of the actors involved. Under the current scheme, regulators are stripped of any authority because the governing international instruments operate as

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<sup>133</sup> *Id.*

<sup>134</sup> Meier, *supra* note 57, at 532 n.119. The lack of aptly structured legal systems and appropriate remedies that are common features in developing countries has led to attempts by foreign citizens to seek aid from the U.S. legal system for injuries resulting from human experimentation by American pharmaceutical companies via the Alien Tort Claims Act. *See Abdullahi*, 562 F.3d 163 (2d Cir. 2009); *infra* Parts III.B.2–3.

<sup>135</sup> Meier, *supra* note 57, at 532; *see also* Wollensack, *supra* note 111, at 756 (explaining that Pfizer brought Trovan, an experimental drug that caused dangerous symptoms in animal testing trials, to Kano at the request of the government because the country had been “devastated” by cholera and measles).

<sup>136</sup> *See* Meier, *supra* note 57, at 532 n.124, for a clear example of how this race to the bottom theory plays out across African countries in the informed consent context. Zimbabwe requires written informed consent for human experimentation. *Id.* However, some countries, including Malawi, Tanzania, and Zaire, do not require informed consent. *Id.*

<sup>137</sup> Gostin & Friedman, *supra* note 58, at 43. African countries, on average, devote less than ten percent of their total government spending to healthcare, while the global average of healthcare expenditures as a portion of total government spending is greater than fourteen percent. *Id.* However, African countries are not the only ones to experience this trend; some developing Asian countries spend even less as a percentage of their total government spending. *Id.* at 43–44.

<sup>138</sup> *Id.*

non-binding soft law that is unenforceable. Moreover, the overall regulatory approach is so disjointed that national governments, drug producers, drug consumers, and hosts of other parties are faced with difficult decisions during these situations.

*B. Problems Created by the Existing Systems' Lack of Globalized Regulatory Standards*

No treaty or multilateral agreement governs the use of experimental medicine outside of the human experimentation context. As a result, infectious disease outbreaks pose many problems for both producers and consumers of these drugs. First, both parties are faced with legal uncertainty and the implications that flow from the inability to accurately predict where or to what extent the pharmaceutical companies can be held liable for producing dangerous medicines. Second, the unregulated production of medicine creates the potential for negative externalities to be felt by those who are least able to bear the additional cost. Finally, as noted by the WHO's Ethics Committee, the use of experimental medicine in an infectious disease scenario introduces numerous ethical complexities that must be addressed by some governing body.<sup>139</sup> All of these problems are compounded during a disease outbreak because of the time constraints and the high demand for a quick and effective treatment. The only way to address all of these issues is to have a readily enforceable agreement to govern the use of experimental medicines in these contexts.

*1. Legal Liability and Acting in the Shadow of Legal [Un]Certainty*

One of the problems that both potential producers and users of these experimental medicines face under the current legal system is uncertainty.<sup>140</sup> Drug producers lack clear guidance as to where and to what extent they can be held liable for harm potentially caused by their experimental medicines. As a result, producers are forced to make economic efficiency decisions about the production and provision of their drugs without the data necessary

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<sup>139</sup> *Ethical Considerations*, *supra* note 13, at 1.

<sup>140</sup> See generally Robert H. Mnookin & Lewis Kornhausert, *Bargaining in the Shadow of the Law: The Case for Divorce*, 88 YALE L.J. 950 (1979) (providing the legal background from which this Note analyzes legal uncertainty in disease outbreak contexts).

to make many important risk calculations.<sup>141</sup> Consequently, such companies run the risk of over- or under-producing medicines depending on their particular level of risk aversion.<sup>142</sup>

For the consumers of these medicines, uncertainty with respect to future legal liability likely plays less of a role in the decision-making process due to their dire medical concerns. However, legal liability becomes much more of a concern to the consumers when these medicines cause negative long-term health effects.

## 2. *Conflicting Interests and Normative Considerations in the Shadow of the Law*

The problems of legal uncertainty that plague producers and consumers of experimental medicines have been well documented.<sup>143</sup> One relatively recent example of these problems played out in Pfizer's Trovan drug trial in Kano, Nigeria, and resulted in U.S. tort litigation. In 1996, Pfizer brought Trovan, an experimental antibiotic that had not been approved for human use in the U.S., to Kano to fight a severe outbreak of bacterial meningitis.<sup>144</sup> Initially, Pfizer claimed that they had been invited by Nigerian government officials to test Trovan, and that the trial had been approved by an ethics committee from a hospital in Kano.<sup>145</sup> Under that authority, Pfizer spent "less than two months" in Kano distributing the drug and recording results.<sup>146</sup> Upon returning to the U.S., Pfizer reported the results of the trial to the FDA and received approval to begin selling the antibiotic to U.S. consumers.<sup>147</sup> In 1997, the FDA discovered that some of the documents submitted by Pfizer

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<sup>141</sup> See generally John E. Calfee & Richard Craswell, *Some Effects of Uncertainty on Compliance with Legal Standards*, 70 VA. L. REV. 965 (1984) (explaining the economic effects of legal uncertainty).

<sup>142</sup> See, e.g., Michelle M. Mello et al., *The Rise of Litigation in Human Subjects Research*, 139 ANNALS OF INTERNAL MED. 40, 44 (2003) (arguing that an increase in successful litigation against producers of experimental medicines could increase the cost of drug research, development, and production, and would thus disincentivize future production).

<sup>143</sup> See, e.g., Katherine A. Davis, *An International Drug Administration: Curing Uncertainty in International Pharmaceutical Product Liability*, 18 NW. J. INT'L L. & BUS. 685 (1998) (addressing the problem of legal uncertainty for pharmaceutical companies that operated internationally in the 1990s).

<sup>144</sup> Carr, *supra* note 59, at 28–29 n.123.

<sup>145</sup> Fazal Khan, *The Human Factor: Globalizing Ethical Standards in Drug Trials through Market Exclusion*, 57 DEPAUL L. REV. 877, 898 (2008).

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

<sup>147</sup> *Id.* at 898–99.

concerning the ethical approval of the trial were forged.<sup>148</sup> One year later, the *Washington Post* reported that Pfizer operated the drug trial unethically.<sup>149</sup> As a result of this unethical experimentation, eleven of the ninety-nine children treated with Trovan died, and many others “were left brain damaged, deaf or paralyzed.”<sup>150</sup>

The victims of the Trovan drug trial in Kano initiated a lawsuit in the U.S. under the Alien Tort Statute alleging that Pfizer breached provisions of “the [Nuremberg] Code, the Declaration, the ICCPR, and the ‘law of nations.’”<sup>151</sup> After years of contentious litigation, the district court dismissed the suit for a lack of subject matter jurisdiction and on the basis of *forum non conveniens*.<sup>152</sup> The court reasoned that although the plaintiffs’ claim of non-consensual medical experimentation correctly alleged a violation of the law of nations, it failed to create a private right of action sufficient to fall within the jurisdiction of the Alien Tort Statute.<sup>153</sup> Moreover, the court concluded dismissal to be proper under *forum non conveniens* analysis since the plaintiffs’ “generalized allegations of corruption and bias” failed to preclude a determination that Nigeria was an adequate alternative forum.<sup>154</sup>

While this case demonstrates the inaccessibility of the U.S. legal system to non-citizens subjected to medical experimentation, it also highlights the legal uncertainty that plaques both pharmaceutical companies and the subjects of medical experimentation. Without access to the court systems where these pharmaceutical companies are incorporated, the consumers of these drugs are forced to seek relief from their home nation. In many cases,

<sup>148</sup> *Id.* at 899.

<sup>149</sup> *Id.* at 899–900. In particular, the *Washington Post* report exposed a lack of informed consent by many of the patients and violations of drug trial protocols. *Id.*

<sup>150</sup> Carr, *supra* note 59, at 30.

<sup>151</sup> Khan, *supra* note 145, at 903.

<sup>152</sup> Abdullahi v. Pfizer, Inc., No. 01 CIV.8118(WHP), 2005 WL 1870811 (S.D.N.Y. Aug. 9, 2005).

<sup>153</sup> *Id.* at \*9–14.

<sup>154</sup> *Id.* at \*15. On appeal, the United States Court of Appeals for the Second Circuit reversed. *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009). Although the court concluded nonconsensual medical experimentation to be a violation of customary international law that fell within the jurisdiction of the Alien Tort Statute, it ultimately remanded the suit for further analysis under alternative choice of law principles. *Id.* at 190. Ultimately, Pfizer opted to settle the matter in 2009. Joe Stephens, *Pfizer to Pay \$75 Million to Settle Nigerian Trovan Drug-Testing Suit*, WASH. POST, July 31, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/07/30/AR2009073001847.html>. However, the U.S. Supreme Court has since sharply limited the ability for victims of atrocities that occur abroad to avail themselves of the U.S. court system via the Alien Tort Statute. *See Kiobel v. Royal Dutch Petroleum Co.*, 133 S. Ct. 1659, 1669 (2013) (concluding a presumption against extraterritoriality applies to claims under the Alien Tort Statute).

the nations where the trials would be expected to take place are less developed, rebuilding from a devastating event like a disease outbreak or civil war, suffering from severe governmental corruption, or lack sophisticated court systems.<sup>155</sup> These scenarios make it difficult, if not impossible, for both the producers and consumers to factor legal liability into their decision-making calculus.

### *3. Reassessing the Existing Regime Design and Its Consequences*

Under the current scheme, legal liability resulting from outbreak scenarios is subject to numerous factors that make it nearly impossible for pharmaceutical companies to make accurate predictions and adjust their production accordingly. At first glance, this issue seems as though it could be remedied by a regulatory body mandating that violations of ethical standards resulted in either strict liability or no liability on the part of producers. However, a system built on either of these two extremes would distort the behavior of the pharmaceutical companies at the expense of those suffering from the disease, or at the expense of obtaining the overall goal of ending or substantially curbing the effects of the disease.

By creating a no-liability system, the regulatory body would be inviting pharmaceutical companies to violate human rights by exploiting dying and diseased individuals in order to quickly find an effective drug that they could put on the market. Unaccountable for their actions, these companies would have no incentive to follow ethical norms or formal experimentation guidelines. Instead, market competition and profit motivation would encourage companies to conduct unethical experiments in an effort to produce an effective drug at the lowest possible cost. Since drug producers would have no additional incentive to follow ethical guidelines—which necessarily increase the cost and time it takes to conduct medical research—it is likely such human experimentation would violate the human rights initiatives laid out in the Declaration and ICCRP.

Strict liability produces results at the other end of the spectrum. Knowing they would be strictly liable for violations of ethical regulations—even if their violations were unintentional—pharmaceutical companies would likely be unwilling to invest in conducting research to aid in disease outbreaks. In particular, incentivizing companies to perform the costly research necessary to find a cure or preventative vaccine for Ebola is complicated by the fact

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<sup>155</sup> See Khan, *supra* note 145, at 905 (noting that one of the judges who was scheduled to hear the Pfizer case in Nigeria accepted bribes to delay the trial).

that the market for such high-price medicines often arises in undeveloped countries that are unable to shoulder such costs.<sup>156</sup> Moreover, by applying a strict liability standard, and thus increasing the cost of research, the regulator would only further discourage the development of much-needed medicines by lowering the already slim chance for profit. The same theory applies to disease outbreak scenarios that are not solely limited to undeveloped countries: a rise in the cost of research—which in the case of strict liability would be considerable—would presumably discourage the development of new drugs.

Thus, the problem of legal uncertainty, or during the extreme scenarios previously mentioned, the problem of legal certainty, has to be addressed by any regulation seeking to govern experimental medicines in disease outbreak contexts. However, legal uncertainty is only one facet of what is truly a trilemma for regulators in this scenario. Once regulators account for the uncertainty and the responses by all parties to that uncertainty, they are faced with the difficulty of economic and ethical allocation decisions.

#### 4. *Economics and Ethics*

During the current Ebola outbreak, there has been an extreme shortage of effective medicine. This problem is the result of numerous factors: little research has been conducted on the virus because it is relatively rare; Ebola has been isolated to Africa, where market conditions provide little to no incentive for producers to conduct costly research; and the drugs that have been produced, like ZMapp, have not been produced in quantities large enough to meet the extreme demand. However, the undersupply of medicine is not unique to this Ebola outbreak. Viruses and diseases are rapidly evolving and becoming resistant to the readily available drugs.<sup>157</sup> Consequently, the likelihood that this problem will occur in future disease outbreaks is high.

Pharmaceutical companies have an incentive to take advantage of this undersupply problem. This is especially true in unregulated markets, where effective drugs are not readily available, and where an outbreak occurs with a

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<sup>156</sup> Pharmaceutical companies have relied on monetary aid from government institutions of developed nations to partially fund the development of Ebola-related drugs. See, e.g., *Ebola/Marburg Research*, NIH, <http://www.niaid.nih.gov/topics/ebolamarburg/research/pages/default.aspx> (detailing U.S. efforts to aid both public and private Ebola-related medicine research).

<sup>157</sup> See *Viruses and Evolution*, THE HISTORY OF VACCINES, <http://www.historyofvaccines.org/content/articles/viruses-and-evolution> (detailing the process of virus evolution).

disease as lethal as Ebola. Lacking competition, the companies who produce these experimental medicines—if left unregulated—can effectively charge as much as they see fit. Consumer demand for medicine increases drastically in response to a demand shock such as a disease outbreak, those dying of Ebola are more willing to pay for access to experimental medicines that may potentially save their lives.<sup>158</sup> Naturally, producers exploit this high demand and willingness to pay by charging exorbitant prices for experimental medicine.<sup>159</sup>

Regardless of whether or not the potential for pharmaceutical companies to charge high prices is considered an economically efficient outcome,<sup>160</sup> the potential for price gauging raises allocation concerns. Under a purely economic system of allocation, which takes no notice of ethical concerns, the medicine would be given to those willing to pay the highest price. Theoretically, this is a rather simple system of allocation. However, it becomes more complicated when third party actors can get involved.

As seen in this Ebola outbreak, states and aid groups gained access to the experimental medicine before it was given to patients. This implies that the experimental medicine was either given to the aid groups and states by the producers, or that these groups were the highest bidders for the medicine. How those groups gained access to the limited supply of ZMapp is still unknown. The groups also did not reveal how they chose which patients to give the medicine to once they had access to it.

The WHO addressed the uncertainty that surrounded the distribution of ZMapp when the Ethics Committee issued its report concerning the use of experimental drugs in the Ebola outbreak.<sup>161</sup> The Ethics Committee put aside economic considerations and noted that the ethical allocation of the medicine should be the priority.<sup>162</sup> The panel, composed of ethics scholars,

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<sup>158</sup> An individual's *willingness* to pay for a particular drug or vaccine is a distinct concept from an individual's *ability* to pay for it. See, e.g., Eleonor C. Saulo et al., *Willingness and Ability to Pay for Artemisinin-Based Combination Therapy in Rural Tanzania*, 7 *MALARIA J.* 227 (2008), available at <http://www.malariajournal.com/content/7/1/227> (conveying the difference between the willingness and ability to pay for malaria medicine).

<sup>159</sup> This is known as "price gouging." See Geoffrey C. Rapp, *Gouging: Terrorist Attacks, Hurricanes, and the Legal and Economic Aspects of Post-Disaster Price Regulation*, 94 *KY. L.J.* 535 (2005–2006) (discussing the economic argument for price-gouging and the justifications for anti-gouging laws).

<sup>160</sup> Many economists believe that "[p]roducers who raise prices to the level consumers are willing to pay are simply performing as Adam Smith's invisible hand would direct" and that gouging is just reaching "market equilibrium." *Id.* at 536. Yet, anti-gouging laws have been defended using economic efficiency arguments as well. *Id.* at 557–59.

<sup>161</sup> *Ethical Considerations*, *supra* note 13.

<sup>162</sup> *Id.*

suggested that the criteria that should be considered when allocating these drugs should be: “distributive justice,” “reciprocity and social usefulness,” “likelihood of a positive impact on both individual and public health outcomes,” the “clinical stage of the disease,” and “the characteristics of the unregistered medical product.”<sup>163</sup>

Many of the ethical allocation problems posed by this scenario were outside the scope of the Committee’s report, and will inevitably result in problems that regulators will have to face in the future. For example, an issue arises in determining which party—state governments or private pharmaceutical producers—should be given the power to make allocation decisions based on the Committee’s recommended criteria. A similar question presents itself in deciding which party bears the cost of research, production, and distribution of these medicines. Finally, regulators will inevitably face difficulty in determining which of the recommended criteria take precedence over others.

Outside of allocation concerns, outbreak scenarios create other economic and ethical problems related to the use of experimental medicine. The first of these is the concern regarding human experimentation. The exploitation of populations suffering from disease outbreaks in Africa is well-documented.<sup>164</sup> Consequently, regulators should be wary when allowing pharmaceutical companies to use these populations and scenarios as testing grounds for new medicine. Nevertheless, regulators should also be aware of the problems that would arise if experimentation in these scenarios was completely disallowed. Forcing producers to undergo the full research process before allowing them to distribute medicine in these outbreak scenarios would significantly increase the length of time these diseases exist and keep much needed aid from reaching those affected.<sup>165</sup> Correspondingly, this would increase the number of individuals who are, or could potentially be, infected. This result is the opposite of what the WHO and other

<sup>163</sup> *Id.* at 6.

<sup>164</sup> The short course AZT vaccination trial and the Trovan trial are two examples of human rights violations that resulted from the human experimentation process conducted in Africa. See Meier, *supra* note 57, for an in-depth discussion on the short course AZT trial and its relation to the current state of the law governing human experimentations. For a discussion of the Trovan trial and its relation to the current state of the law governing human experimentation, see Khan, *supra* note 145.

<sup>165</sup> As a result of this problem, the research and approval process for Ebola-related drugs has been expedited in the U.S. by the NIH. *Questions and Answers: Phase One Clinical Trials of NIAID/GSK Investigational Ebola Vaccine*, NIH (Aug. 28, 2014), available at <http://www.niaid.nih.gov/news/QA/Pages/EbolaVaxQA.aspx>.

regulators aim for when they allow, or even fast track, experimental medicine trials in outbreak scenarios.<sup>166</sup>

Another notable concern is the potential for fake cures and sensationalism.<sup>167</sup> Due to the prevalence of social media, news about disease outbreaks and related issues spreads faster than ever before. This can be seen as both a blessing and a curse. The WHO has used social media sites, including Twitter, to disseminate important information about this Ebola outbreak.<sup>168</sup> However, some have used these same sites to spread false statements in an effort to incite fear and take advantage of others' lack of knowledge about the disease. For example, during the height of the outbreak, one Twitter user claimed that turmeric could cure Ebola.<sup>169</sup> Claims about false cures became so pervasive that both the WHO and the FDA have issued formal statements acknowledging that there are currently no known cures for the disease.<sup>170</sup>

While these are some of the most common economic and ethical concerns related to the use of experimental medicine in disease outbreak contexts, they do not begin to cover all of the potential issues that regulators face. The current state of the law governing experimental medicine is too disjointed and lacks the necessary enforcement power to adequately account for all of these economic and ethical issues. Since these situations present so many different complexities, it is imperative that some regulatory instrument is created to give guidance to all of the various actors involved and provide some enforcement power to the guidelines that currently govern the use of experimental medicine.

### *C. Is There a Feasible Solution?*

The legal uncertainty, economic inefficiency, and ethical ramifications of the current legal framework governing the use of experimental medicine in disease outbreak contexts demonstrate that it is highly insufficient. Moreover, the absence of binding international law and the array of different national standards and mechanisms used to govern experimental medicines indicate that a globalized solution may still be years away. However, the

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<sup>166</sup> *Id.*

<sup>167</sup> Alexandra Sifferlin, *Fake Cures and Ebola-Drug Sensationalism Need to Stop*, *WHO Says*, TIME (Aug. 15, 2014), <http://time.com/3117313/fake-cures-and-ebola-drug-sensationalism-need-to-stop-who-says/>.

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

success of the IHR in this particular Ebola outbreak should be considered an encouraging sign for the potential success of a harmonized agreement.<sup>171</sup> Although a universally accepted and binding international agreement should remain the ultimate goal, it likely is not a realistic expectation for the foreseeable future.<sup>172</sup> Until such an agreement can be reached, this Note argues that the WHO should enforce the widely accepted standards that already govern experimental drugs through the Guidelines and the Declaration, and should implement stop-gap measures to address the specific concerns that arise from international infectious disease outbreak scenarios such as the Ebola epidemic. This section first outlines how an ideal system in which a universally accepted multilateral and binding international agreement governing the use of experimental medicine would operate. Next, it puts forth a more realistic recommendation in which the WHO operates as the chief regulatory body that assumes authority in crisis scenarios such as international disease epidemics.

### 1. *The Ideal Solution*

Ultimately, a global, binding, and enforceable international agreement governing the use of experimental medicine would be ideal. This instrument would create a legal system that reduces uncertainty by promulgating mandatory standards and enforcing those standards through a reliable court system.<sup>173</sup> The court system, comprised of a panel of multinational ethical and pharmaceutical expert judges, would function solely on an as-needed basis to specifically address violations of the standards.<sup>174</sup> Violations of the mandatory standards would result in strict penalties, particularly monetary penalties, which could be enforced quickly and efficiently. Monetary penalties would likely be particularly effective in reducing oversupply since

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<sup>171</sup> The WHO has reported high levels of compliance with both the IHR reporting system and the recommendations provided by the IHR Emergency Committee during this Ebola outbreak. *WHO Statement on the 3rd Meeting of the IHR Emergency Committee Regarding the 2014 Ebola Outbreak in West Africa*, WHO (Oct. 23, 2014), <http://www.who.int/mediacentre/news/statements/2014/ebola-3rd-ihc-meeting/en/>; *2nd Meeting of IHR Emergency Committee*, *supra* note 95; *1st Meeting of IHR Emergency Committee*, *supra* note 95.

<sup>172</sup> One of the main impediments to the establishment of a binding international agreement is the issue of national sovereignty. Khan, *supra* note 145, at 906.

<sup>173</sup> This Note posits a purely hypothetical agreement that could address some of the legal, economic, and ethical issues raised by the Ebola outbreak.

<sup>174</sup> The hypothetical court system envisioned could in some ways be similar to U.S. “vaccine courts.” See generally *Vaccine Claims/Office of Special Masters*, U.S. COURTS, <http://www.uscfc.uscourts.gov/vaccine-program-readmore> (explaining the court system specifically developed to hear vaccine claims in the U.S.).

the offending pharmaceutical companies would finally be made to feel the full cost of their actions. In addition, compliance with these standards would ensure that the pharmaceutical companies would have access to lucrative medicine markets, like those in developed nations, and access to countries in need of experimental medicine.<sup>175</sup> Unfortunately, the ideal solution, like the hypothetical agreement posited by this Note, is rarely, if ever, the feasible or realistic one. This particular solution would likely be impeded by conflicts related to national sovereignty.<sup>176</sup>

## 2. WHO as Chief Regulator

Short of the ideal binding multinational involvement, an agreement granting power to the WHO to become the chief regulatory authority over experimental medicines in disease outbreak contexts would be sufficient to solve the majority of the problems that result from international disease epidemics. In order for the WHO to have any enforceable power, both developed and developing nations would have to submit to WHO authority during these disease outbreak scenarios. Submission to WHO authority is not an unrealistic expectation; many countries have already done so under the implementation of the IHR.<sup>177</sup> After gaining regulatory authority, the WHO would need to bar access to the court systems of developed countries for individuals harmed as a result of taking experimental medicines provided in an infectious disease epidemic. Closing off the court systems would ease the pharmaceutical companies' concerns over legal uncertainty.<sup>178</sup> Instead, the WHO could provide a legal remedy to individuals harmed by the experimental medicines or the experimental process, by setting up a panel of experts to hear cases of human rights violations. For extreme violations, the WHO would be granted the authority to enforce monetary penalties. The WHO should also be delegated power to enforce the ethical standards that

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<sup>175</sup> As long as the pharmaceutical companies complied with the regulations, developed nations would agree to allow the companies to market their drugs—even those drugs not produced to fight infectious diseases. Further, pharmaceutical companies with a record of compliance would be the first companies that the governing body would grant access to developing nations in need of experimental medicine.

<sup>176</sup> See Khan, *supra* note 145, at 906 (discussing the impediments to binding international law health agreements).

<sup>177</sup> See David P. Fidler, *Return of the Fourth Horseman: Emerging Infectious Diseases and International Law*, 81 MINN. L. REV. 771, 836–38 (1997) (explaining how the pre-2005 IHR became binding international law).

<sup>178</sup> Although this proposition seems counterintuitive, by closing the court systems that are plagued by the varying standards and jurisdictional confusion detailed above, pharmaceutical companies can better predict their level of liability.

have already been promulgated in the Declaration and the Guidelines. Along with those ethical standards, the WHO should implement regulations to address other notable concerns such as price gouging.

To increase the potency of the WHO's jurisdiction in this situation, pharmaceutical companies should be required to submit to WHO regulatory authority to obtain access to experimental subjects in affected regions during disease outbreaks. In order to further incentivize compliance, the WHO should provide a market-based benefit to the pharmaceutical companies.<sup>179</sup> To keep these drug manufacturers out of developing nations without the permission of the WHO, those developing nations would have to submit to the authority of the WHO as well. Developing nations would have a strong incentive to do so because access to foreign aid during these outbreaks would stem from a relationship with the WHO.<sup>180</sup>

Willing submission to this sort of emergency, short-term solution by all parties—developed nations, developing nations, and pharmaceutical companies—would temporarily remedy the legal uncertainty, and the economic and ethical concerns that plague international outbreak scenarios until a long-term binding agreement could be established.

## VI. CONCLUSION

Regardless of the ultimate solution, regulation is necessary to address the use of experimental medicine in disease outbreak contexts. The 2014 Ebola outbreak in West Africa has exposed many of the problems with a disjointed international health system. One of those exposed issues was the use of the experimental medicine, including medicines previously untested on human patients, to combat the disease. As the death toll rose in West Africa, so too did the demand for medical intervention. However, the response by the medical research and pharmaceutical communities occurred before the medical regulatory bodies could respond. As a result, the law governing the distribution and use of experimental medicine has yet to be tailored to address the unique circumstances posed by the Ebola outbreak.

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<sup>179</sup> Some scholars have insisted that economic incentives can have the effect of ensuring compliance with soft law. *See, e.g.*, Khan, *supra* note 145, at 909–11 (explaining one way that economic incentives can be used to enforce compliance on the part of pharmaceutical companies).

<sup>180</sup> In the current Ebola outbreak, the affected African nations have shown a willingness to collaborate with and submit to the authority of the WHO in order to expedite access to experimental drugs for their citizens. *African Regulators' Meeting Looking to Expedite Approval of Vaccines and Therapies for Ebola*, WHO, [http://www.who.int/medicines/news/AFR\\_reg\\_meet/en/](http://www.who.int/medicines/news/AFR_reg_meet/en/).

The current state of the law governing the use of experimental medicine on an international scale is almost non-existent. None of the documents governing international health adequately address the legal uncertainty, economic problems, and ethical issues involved with the use of experimental medicine in international disease outbreaks like the current Ebola outbreak. This leaves a gap that must be filled by sound governments or enterprising pharmaceutical companies. The ideal long-term solution may be to create an international binding agreement to govern the use of experimental medicine in disease outbreak contexts. However, the WHO should step in to implement stop-gap measures to provide a more immediate solution. In the absence of quickly implemented and effective regulation, the Ebola outbreak of 2014 may be forever memorialized by the travesties of the experimental Trovan and short-course AZT trials.