

E-MERS-GENCY: AN APPLICATION AND EVALUATION OF THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK TO THE OUTBREAK OF MERS-COV

*By: Andrew E. Bollinger**

I. INTRODUCTION

The global community is facing a new deadly threat: a respiratory illness dubbed Middle East Respiratory Syndrome Coronavirus (MERS-CoV).¹ While claims of new pandemic-level super-viruses seem to arise often and yet seldom live up to the hype, this newly discovered virus may nip that trend. Dr. Margaret Chan, Director-General of the World Health Organization (WHO), expressed concern at the 2013 World Health Assembly (WHA) about the new SARS-like virus that originated in Saudi Arabia.² Dr. Chan warned: “My greatest concern right now is the novel coronavirus We do not know where the virus hides in nature. We do not know how people are getting infected. Until we answer these questions, we are empty-handed when it comes to prevention.”³ As a result of the virus’s novelty, no cure, rapid diagnostic test, or vaccine has been developed.⁴

Thus far, there have been 132 confirmed cases of MERS-CoV globally, resulting in fifty-eight deaths.⁵ MERS-CoV, which was first discovered in Saudi Arabia, now has been identified in several countries, including Qatar, Jordan, the United Arab Emirates, Tunisia, Italy, France, and the United Kingdom.⁶ Further compounding the problem, roughly two million Muslims around the world make an annual pilgrimage to Mecca in Saudi Arabia for the Hajj.⁷ The WHO publicly

* J.D. Candidate, Temple University James E. Beasley School of Law, 2016; B.A., Temple University, 2007. I want to thank my mom, Rebecca, who passed away during editing after a brief fight with uterine cancer. Mom was, and always will be, an inspiration. I want to thank my dad, Garry, brother, Nick, and future sister-in-law, Morgan, for their encouragement. I want to thank my advisor, Scott Burris, for his knowledge and guidance. Finally, I want to thank my best friend, Samantha, for her love, strength, and support.

1. For a comprehensive primer on the disease, see *Middle East Respiratory Syndrome (MERS)*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/coronavirus/mers/> (last updated Feb. 12, 2015).

2. Laurie Garrett, *Why a Saudi Virus is Spreading Alarm*, COUNCIL ON FOREIGN REL. (May 29, 2013), <http://www.cfr.org/public-health-threats-and-pandemics/why-saudi-virus-spreading-alarm/p30799> [hereinafter Garrett, *Why a Saudi Virus is Spreading Alarm*].

3. *Id.*

4. *Id.*

5. GLOBAL ALERT & RESPONSE, *Middle East Respiratory Syndrome Coronavirus (MERS-CoV) – update*, WORLD HEALTH ORG. (Sept. 19, 2013), http://www.who.int/csr/don/2013_09_19/en/index.html.

6. Conference Report, Joint Kingdom of Saudi Arabia & WHO Mission, Middle East respiratory syndrome coronavirus (June 4–9, 2013), http://www.who.int/csr/disease/coronavirus_infections/MERSCov_WHO_KSA_Mission_Jun13u.pdf?ua=1

7. See generally INFO. OFFICE OF THE ROYAL EMBASSY OF SAUDI ARABIA, *Hajj*,

voiced its concern about the potential spread of MERS-CoV as a result of this pilgrimage.⁸ In response, the Saudi government undertook the unprecedented move of restricting travel visas to the country in the fall of 2013.⁹

MERS-CoV presents a unique problem to the global health regime, one that parallels the H5N1 avian influenza—commonly referred to as the “bird flu”—controversy in 2007.¹⁰ That year, Siti Fadilah Supari, Indonesia’s Minister of Health, informed the WHO that Indonesia would not submit samples of locally discovered bird flu viruses for international research, in contrast to a long-held custom of free virus sharing.¹¹ Indonesia claimed a right of “viral sovereignty,”¹²—a sovereign right to exclusively control viral strains within its boundaries.¹³ In response, the WHO passed a non-binding resolution, the Pandemic Influenza Preparedness Framework (PIP), in order to reform prior legal paradigms, promote cooperation among countries, and prevent future obstruction to global health research.¹⁴ PIP augments current International Health Regulations (IHR), creating a series of understandings that are flu-specific and address sample sharing, patents, and profits from products derived from viral discovery.¹⁵

<http://www.saudiembassy.net/issues/hajj/> (last visited Jan. 11, 2015). The Hajj is an Islamic pilgrimage to Mecca and is one of the largest gatherings of Muslims in the world annually. *Id.* The Hajj consists of a series of rituals and lasts for one week. *Id.* The Hajj is considered one of the five pillars of Islam, as well as a religious duty that must be carried out by every Muslim at some point in his or her life. *Id.*

8. See, e.g., Eryn Brown, *WHO Raises Concern About Possible Spread of MERS Among Hajj Pilgrims*, LA TIMES (Sept. 25, 2013), <http://articles.latimes.com/2013/sep/25/science/la-sci-sn-who-mers-hajj-20130925> (explaining how the Hajj poses a particular worry for public health workers because Saudi Arabia has had more cases of the disease than any other nation).

9. See SAPA, *Saudi to Restrict Visas Over MERS Fears*, IOL SCITECH (July 17, 2013), <http://www.iol.co.za/scitech/science/news/saudi-to-restrict-visas-over-mers-fears-1.1547979#UkxnaBZU2ZY> (discussing travel restrictions and the issuance of visas for the Hajj).

10. See Richard Holbrooke & Laurie Garrett, ‘Sovereignty’ That Risks Global Health, WASH. POST (Aug. 10, 2008), http://articles.washingtonpost.com/2008-08-10/opinions/36864341_1_flu-outbreaks-bird-flu-siti-fadilah-supari (discussing the 2007 bird flu outbreak).

11. See Kenan Mullis, *Playing Chicken with Bird Flu: “Viral Sovereignty,” the Right to Exploit Natural Genetic Resources, and the Potential Human Rights Ramifications*, 24 AM. U. INT’L L. REV. 943, 944–55 (2009) (providing a historic background on the international community’s practice of sharing virus data for the purposes of global health and discussing Dr. Supari’s justification for withholding bird flu specimens).

12. See Holbrooke & Garrett, *supra* note 10, which discusses the term “viral sovereignty” and argues that political leaders should not only pay attention to it but also take action to prevent it.

13. See Mullis, *supra* note 11, at 949 (explaining how Indonesia asserted a claim of ownership over domestic viruses); see also Laurie Garrett, *The Survival of “Global Health”- Part Seven: Patents and Potential Pandemics*, LAURIE GARRETT BLOG (May 25, 2013), <http://lauregarrett.com/blog/2013/5/25/8iyqyp9vznz18ruxrgjnryppav6a87> [hereinafter Garrett, *The Survival of Global Health*] (describing Indonesia’s belief that a virus found first in any given country was the sovereign possession of that nation).

14. See generally *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, GLOBAL HEALTH WATCH (Dec. 4, 2011), <http://www.ghwatch.org/who-watch/topics/pip>.

15. Garrett, *Survival of Global Health*, *supra* note 13.

The MERS-CoV outbreak was the first global health threat to test the robustness of PIP's legal framework since it was passed in May 2011.¹⁶ Predictably, a controversy is brewing from the outbreak. On one side of the controversy, a Dutch research lab has asserted a right of control over the genetic basis of MERS-CoV based on intellectual property law.¹⁷ In response, some fear that the Saudi Arabian government will follow in the footsteps of Indonesia's Dr. Supari and invoke a right of viral sovereignty.¹⁸ As a result, the conflict between intellectual property law and a right of viral sovereignty may threaten to impede a global response to a serious health threat.¹⁹

This comment analyzes the legal issues surrounding these viral sovereignty controversies, as well as critiques the WHO's response. Part II begins by discussing the historical lead up to the PIP framework through an analysis of the bird flu crisis. Part III introduces the nature of the MERS-CoV virus and explains the current controversies surrounding the patenting of MERS-CoV. Part IV discusses the legal bases for asserting viral sovereignty. Parts V and VI study what impact the recent passage of PIP has on these controversies as well as the robustness of PIP and whether it provides an adequate framework for the prevention of future viral sovereignty controversies. Finally, Part VII proposes amendments to PIP to advance its ultimate goal of effectively fighting new viruses through unimpeded global scientific cooperation.

II. LEARNING FROM HISTORY: SYNOPSIS OF THE BIRD FLU CRISIS

In early 2007, the Indonesian Minister of Health, Dr. Siti Fadilah Supari, withheld Indonesia's bird flu samples from foreign researchers in order to gain bargaining leverage for vaccinations and bird flu treatment.²⁰ Dr. Supari reasoned that the global virus-sharing system, as currently constructed, was highly inequitable to developing nations such as Indonesia, because it put them at a severe disadvantage compared to wealthier nations.²¹ Dr. Supari asserted that poor nations have a history of providing viral samples, but often cannot afford to purchase the

16. Affan Shaikh & Scott McNabb, *Global Public Health Surveillance, Governance, and Viral Sovereignty*, Webinar, INT'L SOC'Y FOR DISEASE SURVEILLANCE (Aug. 14, 2013), <http://vimeo.com/72373448>.

17. See Garrett, *Why a Saudi Virus is Spreading Alarm*, *supra* note 2 (acknowledging the Dutch laboratory's claim to all rights associated with the MERS-CoV sequence).

18. See Garrett, *The Survival of Global Health*, *supra* note 13 (discussing the WHO's concern that Saudi Arabia may claim "viral sovereignty" rights similar to Indonesia).

19. See *id.* (noting how the WHO's General Director called for support in ending intellectual property blocks when it comes to endemic research).

20. See Jason Carter, *WHO's Virus Is It Anyway? How the World Health Organization Can Protect Against Claims of "Viral Sovereignty"*, 38 GA. J. INT'L & COMP. L. 717, 719–20 (2010) (suggesting Indonesia's purpose behind its action was to encourage the protection of those countries that contribute to vaccine development but fail to benefit from its use).

21. See *id.* (illustrating the inequitable nature of the global viral sharing structure); see also Mullis, *supra* note 11, at 948–49 (suggesting that vaccinations created by donated samples from developing nations were priced too high for those same nations to obtain them for their own use).

resulting vaccines, or the resulting vaccines are only readily available in wealthy nations.²² In part, this was a response to earlier Indonesian frustration. In 2005, Dr. Supari could not purchase Tamiflu, an antiviral medication, because Western countries purchased all of the medication for stockpiling.²³ Dr. Supari stated that the “sweeping out of the Tamiflu stock by developed countries that had no cases of [bird flu] . . . really made a deep wound in my heart.”²⁴ In response, Dr. Supari and the Indonesian government threatened to close down U.S. Naval Medical Research Unit Two (NAMRU-2), a public health laboratory staffed by Indonesian and U.S. military scientists.²⁵

Citing provisions in the Convention of Biological Diversity (CBD),²⁶ Dr. Supari asserted that Indonesia has a sovereign right to biological resources that originate within its borders.²⁷ Essentially, Dr. Supari aimed at exercising leverage for more equitable access to vaccines in pandemic situations.²⁸ Likely, she sought to prevent another 2009 where, during the bird flu breakout, only twelve wealthy nations, which had placed advanced orders, received almost all of the first billion doses of the bird flu vaccine produced.²⁹ Regardless of the actual catalyst behind Dr. Supari’s actions, her goal was clear—provide the Indonesian people with adequate health supplies.

Dr. Supari’s actions shocked the international community.³⁰ Members of the

22. See Carter, *supra* note 20, at 719–20 (“Instead of rewarding developing nations for their valuable contributions to global health initiatives, the WHO contracts with private pharmaceutical companies to make vaccines later purchased almost exclusively by developed countries.”).

23. Shawn Smallman, *Biopiracy and Vaccines: Indonesia and the World Health Organization’s New Pandemic Influenza Plan*, 4 J. OF INT’L & GLOBAL STUD. 20, 23 (2013).

24. See Adam Kamradt-Scott & Kelley Lee, *The 2011 Pandemic Influenza Preparedness Framework: Global Health Secured or a Missed Opportunity?* 59 POL. STUD. 831, 834 (2011) (quoting Siti Fadilah Supari, *It’s Time for the World to Change: In the Spirit of Dignity, Equity, and Transparency: Divine Hand Behind Avian Influenza 5* (Sulaksana Watinsa Indonesia, 3d ed. 2008)).

25. Holbrooke & Garrett, *supra* note 10. NAMRU-2 is one of the world’s largest disease surveillance facilities and provides international health officials with critical virus-related information. *Id.*

26. Mullis, *supra* note 11, at 948–49; see also PEOPLE’S HEALTH MOVEMENT ET AL., *Pandemic Influenza Preparedness: In Search of a Global Health Ethos*, in GLOBAL HEALTH WATCH 3: AN ALTERNATIVE WORLD HEALTH REPORT 146, 146 (2011).

27. See Mullis, *supra* note 11, at 948–49 (explaining how the CBD seeks biodiversity conservation, sustainable use, and just benefit sharing among its member states, but emphasizes the importance of state control over local biodiversity); see also PEOPLE’S HEALTH MOVEMENT ET AL., *Pandemic Influenza Preparedness: In Search of a Global Health Ethos*, in GLOBAL HEALTH WATCH 3: AN ALTERNATIVE WORLD HEALTH REPORT 146, 146 (2011) (offering reactions to Indonesia’s decision to invoke CBD provisions pertaining to sovereign rights over biological resources).

28. See Carter, *supra* note 20, at 719–20 (suggesting the Dr. Supari and the Indonesian government withheld virus samples with the hope of encouraging a new system that would benefit the countries that assist in vaccine development).

29. See generally PEOPLE’S HEALTH MOVEMENT ET AL., *supra* note 26, at 146–48. Interestingly, GlaxoSmithKline pledged 120 million doses to the WHO for poorer nations, but these samples were not completed until months after the bird flu pandemic started to wane. *Id.*

30. See Holbrooke & Garrett, *supra* note 10 (recognizing how Dr. Supari’s views were

WHO have an obligation to comply with its regulations, which strongly encourage sharing of virus samples with no strings attached.³¹ However, in 2009, no international regulation mandated virus sharing among member states, even though sharing customarily occurs on a good faith basis.³² Therefore, some experts described Dr. Supari's assertion of viral sovereignty as an "anti-Western" and "morally reprehensible" act.³³ Further, they argued that if her actions had been applied to AIDS twenty-five years ago, for example, our capability to fight HIV today would be dramatically less.³⁴ Furthermore, some experts argued that "[i]t is even more ludicrous to extend the sovereignty notion to viruses that, like flu, can be carried across international borders by migratory birds."³⁵ In an age of globalization, these experts argued that failing to make viral samples open-source risks allowing the emergence of a new strain of influenza to go unnoticed by the international community until it exacts a human toll similar to the 1918 flu pandemic.³⁶

However, not all reactions to Dr. Supari's ban were as severe. Many experts argued that Dr. Supari had a rational basis for her position. For example, *The Lancet: Infectious Diseases* explained that:

To protect the global population, 6.2 billion doses of pandemic vaccine will be needed, but current manufacturing capacity can only produce 500 million doses. . . . In November 2004, a WHO consultation reached the depressing conclusion that more developing countries would have no access to vaccine during the first wave of a pandemic and possibly throughout its duration³⁷

Furthermore, many developing countries supported Indonesia's position.³⁸ These countries believed the 2005 IHR only reflected interests of powerful WHO member countries and argued that the 2005 IHR were merely an extension of developed countries' foreign policy.³⁹ Moreover, Edward Hammond, a journalist

initially personal, but eventually transitioned to a worldwide movement).

31. See Carter, *supra* note 20, at 718–19 (explaining how the WHO relies on viral samples donated by its member states as part of its virus-sharing protocol); see also Mullis, *supra* note 11, at 966–67 (advocating that Indonesia begin to share samples of virus strains again not only because it complies with international law and is customary among WHO member states, but because the stakes are too serious to justify not doing so).

32. See Mullis, *supra* note 11, at 966–67 (discussing virus-sharing customs). See also Shaikh & McNabb, *supra* note 16 for further information on the responsibilities of public health surveillance on a global scale.

33. See generally Holbrooke & Garrett, *supra* note 10.

34. *Id.*

35. *Id.*

36. *Id.*

37. See PEOPLE'S HEALTH MOVEMENT ET AL., *supra* note 26, at 146 (republishing part of an article published in *The Lancet* calling for the WHO to enter agreements ensuring that developing countries have affordable access to pandemic vaccines).

38. See Smallman, *supra* note 23, at 24–25 (discussing support from India, Vietnam, China, Brazil, Iran, Libya, and Nigeria).

39. See *id.* at 23 (offering an argument as to why the WHO implemented the IHR).

for *Grain*, asserted, “the WHO’s global surveillance system acts as a free virus collection and [research and development] department for the world’s largest vaccine companies . . . such as Sanofi-Pasteur, Novartis, and Astra-Zeneca, yet [they] give very little benefit to developing countries[.]”⁴⁰ Shawn Smallman further stated, “developing countries were particularly infuriated when pharmaceutical companies patented viral strains that had been obtained without permission from the countries in which they were created.”⁴¹

These arguments boiled down to two sides. On the one hand, the global community has an interest in preventing and stopping global health threats. On the other hand, Dr. Supari’s primary obligation was to help citizens of Indonesia; her obligation to help the international community came secondary. Some say Dr. Supari’s position was, therefore, a rational position to take in response to a disadvantageous international virus-sharing structure.⁴² In addition, by arguing that foreign countries violated Indonesia’s right of viral sovereignty and unjustly pirated its resources, Dr. Supari suggested developed countries were actively doing something wrong, as opposed to merely perpetuating a system of inequality and failing to provide charity.⁴³

Both arguments have merit. Poorer states, such as Indonesia, believe they do not benefit from international scientific research because medicines are seldom available to their people. In response, these countries have turned to legal instruments to gain leverage at the bargaining table. This is an understandable position, as countries have an inherent obligation to do what is in the best interest of their people. In this case, Indonesia decided it was in their peoples’ best interest to leverage access to harmful viruses in order to gain medicines and treatment.⁴⁴ Thus, the issue is whether PIP has done enough to decrease the disparity of bargaining power between wealthy and poor nations.

Indonesian and WHO health ministers eventually reached an interim agreement for Indonesia to resume sending flu virus samples to the WHO.⁴⁵ Nevertheless, the message to the international community was clear: without a more equitable virus-sharing structure, poorer nations may inevitably follow Indonesia’s path, which would put the international community at risk. Ultimately,

40. *Id.* at 24 (quoting Edward Hammond, *Indonesia fights to change WHO rules on flu vaccines*, GRAIN (Apr. 18, 2009), <http://www.grain.org/article/entries/761-indonesia-fights-to-change-who-rules-on-flu-vaccines>).

41. *Id.* (citing Edward Hammond, *Indonesia fights to change WHO rules on flu vaccines*, GRAIN (Apr. 18, 2009), <http://www.grain.org/article/entries/761-indonesia-fights-to-change-who-rules-on-flu-vaccines>).

42. Shaikh & McNabb, *supra* note 16.

43. *See* Smallman, *supra* note 23, at 33 (explaining that framing the argument as one of piracy rather than inequality makes it appear as though developed countries were active in creating the gap in access to resources).

44. *See* PEOPLE’S HEALTH MOVEMENT ET AL., *supra* note 26, at 147 (acknowledging that viral sovereignty is an “exercise of sovereign leverage for more equitable access to lifesaving vaccines in a pandemic situation”).

45. *See id.* at 146 (discussing the agreement reached on March 29, 2007 between Indonesia and the WHO).

the WHO member states enacted PIP as a means to prevent a similar situation.

III. MERS-CoV: WHAT CONTROVERSY, EXACTLY?

After the passage of PIP, there was no viral sovereignty situation like the bird flu controversy until the outbreak of MERS-CoV. There are two distinct viewpoints underlying the MERS-CoV controversy. On the one side, a nation with a relatively poor population, Saudi Arabia, is claiming rights to the fruit produced by international scientific research on the MERS-CoV strain based on legal principles of biodiversity. On the other side, a research institution from a wealthier nation, the Netherlands, is asserting a legal right to the fruit of scientific research based on intellectual property rights. Both claims can harm a rapid global response to a health threat.

A. Summary of MERS-CoV

MERS-CoV is a member of the coronavirus family.⁴⁶ Coronaviruses commonly cause respiratory illnesses in mammals, including humans.⁴⁷ MERS-CoV attacks the respiratory system leading to symptoms including cough, fever, pneumonia, and renal failure.⁴⁸ In 2012, MERS-CoV began infecting people in the Middle East.⁴⁹ The disease was first identified when a man in Saudi Arabia experienced “SARS-like” symptoms.⁵⁰ He later died in June of 2012.⁵¹ Of those infected with bird flu, over 60% die.⁵² By comparison, SARS had an initial fatality rate estimated at around 7-17%.⁵³ Like SARS, MERS-CoV is unknown to human immune systems, so an infection could trigger a “cytokine storm,” which is an over-response by the body’s immune system that hits the virus “with all its [sic]

46. See generally *Middle Eastern Respiratory Syndrome (MERS)*, CENTERS FOR DISEASE CONTROL & PREVENTION, (last updated Jan. 26, 2015), <http://www.cdc.gov/coronavirus/MERS/>.

47. See *Coronavirus*, CENTERS FOR DISEASE CONTROL & PREVENTION, (last updated Oct. 7, 2014), <http://www.cdc.gov/coronavirus/index.html> (explaining the different types of coronaviruses and the targets they typically affect).

48. Shaikh & McNabb, *supra* note 16.

49. *Id.*

50. *Rapid Risk Assessment: Severe Respiratory Disease Associated with a Novel Coronavirus*, EUROPEAN CENTRE FOR DISEASE PREVENTION & CONTROL (European Centre for Disease Prevention and Control, Stockholm, Sweden), Feb. 19, 2013, at 3, available at <http://www.ecdc.europa.eu/en/publications/Publications/novel-coronavirus-rapid-risk-assessment-update.pdf>; see generally *What is MERS-CoV? What are the symptoms of MERS-CoV?*, MEDICAL NEWS TODAY, (last updated Sept. 26, 2014), <http://www.medicalnewstoday.com/articles/262538.php> (“Most confirmed cases of MERS-CoV have displayed symptoms of severe acute respiratory illness.”).

51. *Rapid Risk Assessment: Severe Respiratory Disease Associated with a Novel Coronavirus*, *supra* note 50.

52. *FAQs: H5N1 influenza*, WORLD HEALTH ORG., (last visited Jan. 29, 2015), http://www.who.int/influenza/human_animal_interface/avian_influenza/h5n1_research/faqs/en/.

53. Chung Ming-Chu et al., *Initial Viral Load and the Outcomes of SARS*, 171 CAN. MED. ASS’N. J. 1349, 1349 (2004).

got, creating collateral damage all over the body.”⁵⁴ In May 2014, the first two reported cases of MERS-CoV were confirmed in the United States.⁵⁵

Epidemiologically, MERS-CoV is very similar to SARS, as both are easily spread by close contact and can be transmitted through the air.⁵⁶ The etiology of MERS-CoV, however, is still unknown.⁵⁷ Rapid response tests for MERS-CoV are still being developed, which could put health responders at risk if they are unable to discern between the early stages of MERS-CoV and regular pneumonia in patients.⁵⁸ This distinction is important because MERS-CoV should be handled with maximum quarantine and protective gear, while regular pneumonia does not require such protocol.⁵⁹ Thus, until medical research and technology advance, medical responders are at a particular disadvantage, putting themselves in harm’s way.⁶⁰

B. The Controversy

In June of 2012, Dr. Ali Mohamed Zaki, an Egyptian doctor working at the Dr. Soliman Fakeeh Hospital in Jeddah, Saudi Arabia, sent samples of the then-unknown MERS-CoV virus to Dr. Ron Fouchier, a Dutch virologist at Erasmus Medical Centre (Erasmus) in Rotterdam.⁶¹ Dr. Zaki sent the samples without the Saudi government’s permission.⁶² Researchers at Erasmus, including Dr. Fouchier, identified the unknown sample as a novel coronavirus.⁶³ The researchers at Erasmus then applied for a patent on the genetic strain of the novel coronavirus,⁶⁴ or more specifically, a patent on the “use of the sequence and host receptor data.”⁶⁵ One researcher at Erasmus justified the patent as necessary for incentivizing companies to invest in creating diagnostics, vaccines, or antiviral medication.⁶⁶ In addition, before Erasmus would send the genetic strain to any new researchers, it required recipients to sign a material transfer agreement (MTA).⁶⁷

Erasmus’s patent application and MTA were controversial, as many thought

54. Garrett, *The Survival of Global Health*, *supra* note 13.

55. Gerber, Susan, *Be on the Lookout for MERS-CoV*, Medscape (June 23, 2014),

56. Garrett, *The Survival of Global Health*, *supra* note 13.

57. See, e.g., Richard Knox, *Even as MERS Epidemic Grows, The Source Eludes Scientists*, NPR (Sept. 20, 2013), <http://www.npr.org/blogs/health/2013/09/19/224073023/even-as-mers-epidemic-grows-the-source-eludes-scientists>.

58. Garrett, *The Survival of Global Health*, *supra* note 13.

59. *Id.*

60. *Id.*

61. Shaikh & McNabb, *supra* note 16.

62. Garrett, *Why a Saudi Virus is Spreading Alarm*, *supra* note 2.

63. Shaikh & McNabb, *supra* note 16.

64. *Id.*

65. Kai Kupferschmidt, *As Outbreak Continues, Confusion Reigns Over Virus Patents*, SCIENCE (May 28, 2013), <http://news.sciencemag.org/people-events/2013/05/outbreak-continues-confusion-reigns-over-virus-patents>.

66. *Id.*

67. *Id.*

both stifled a global health response to MERS-CoV.⁶⁸ Ziad Memish, Saudi Arabia's then-Deputy Minister of Public Health, claimed: "The virus was sent out of the country and it was patented, contracts were signed with vaccine companies and anti-viral drug companies, and that's why [Erasmus has] a MTA . . . to be signed by anybody who can utilize that virus, and that should not happen."⁶⁹ Memish appeared to suggest that the MTA, which prohibited sample recipients from developing products or sharing the samples without permission from Erasmus, impaired other countries' ability to adequately respond to outbreaks.⁷⁰ Memish asserted that "[Saudi Arabia] [is] still struggling with diagnostics and the reason is that the virus was patented by scientists and is not allowed to be used for investigations by other scientists."⁷¹ He also complained that a contract was required every time a new laboratory wanted to use the virus.⁷²

Afterward, Dr. Chan seemed to endorse Memish's concerns, rhetorically asking at the 2013 WHA, "Why would [Saudi Arabian] scientists send specimens out to other laboratories on a bilateral manner and allow other people to take intellectual property right on new disease [sic]?"⁷³ Referring specifically to Saudi Arabia, Dr. Chan stated, "No [intellectual property] should stand in the way of you, the countries of the world, to protect your people."⁷⁴ Furthermore, the MTA created legal delays for laboratories wishing to obtain a sample of the virus.⁷⁵ Memish claimed that the Saudi government's failure to share samples of MERS-CoV with other countries directly resulted from Erasmus's MTA as well as Dr. Zaki's transfer of the viral samples to Erasmus.⁷⁶

Erasmus denies that it is impeding the global health response to MERS-CoV. In a press release, Erasmus stated, "Rumours that the Viroscience department of Erasmus MC would hamper research into the MERS coronavirus are clearly wrong and not based on facts"⁷⁷ and said it would send the viral samples to researchers who wanted it at no charge.⁷⁸ Virologist Ab Osterhaus, who heads the Viroscience Department at Erasmus, stated, "We have given this virus to virtually any lab that has asked for it."⁷⁹

68. See generally *id.* (explaining the controversy surrounding Erasmus's patent application and MTA).

69. Garrett, *The Survival of Global Health*, *supra* note 13.

70. See *id.* (addressing Memish's comments about the Saudi government's failure to share samples of the MERS-CoV virus with other countries).

71. Kupferschmidt, *supra* note 65.

72. *Id.*

73. *Id.*

74. *Id.*

75. Shaikh & McNabb, *supra* note 16.

76. Garrett, *The Survival of Global Health*, *supra* note 13.

77. Press Release, Erasmus MC, No Restrictions for Public Health Research into MERS Coronavirus (May 24, 2013), available at <http://www.erasmusmc.nl/perskamer/archief/2013/4164294/?lang=en> [hereinafter Erasmus MC].

78. Shaikh & McNabb, *supra* note 16.

79. Kupferschmidt, *supra* note 65.

Erasmus is right insofar that it is not impeding global research of the virus. Other research facilities have already gained access to the MERS-CoV genome for the purpose of research.⁸⁰ Furthermore, an MTA is a routine procedure for the transfer of cells, samples, or pathogens between biomedical laboratories, and Erasmus's MTA was not unusual.⁸¹ However, from the Saudi Arabian government's perspective, the issue is not whether Erasmus is preventing an effective global health response; it is whether Erasmus is preventing Saudi Arabia from gaining leverage in obtaining valuable medication and vaccines.⁸² To that extent, Erasmus is absolutely interfering with clear Saudi Arabian domestic interests.

The situation is still ongoing. However, any claim by Saudi Arabia to viral sovereignty is essentially moot because Erasmus already possesses the MERS-CoV genome. Thus, unlike Indonesia in 2007, Saudi Arabia has no leverage to boost its position. To that end, the world community dodged a bullet. Regardless, the situation with MERS-CoV provides a perfect opportunity to analyze the extent to which the WHO's recent passage of PIP changes the dynamic between wealthy and poor nations in regard to access to viral resources.

IV. LEGAL BASIS FOR ASSERTING VIRAL SOVEREIGNTY

When Dr. Supari decided to withhold bird flu samples from foreign researchers, she primarily based this assertion on two sources of law: IHR and the CBD.⁸³ Accordingly, this section briefly explains both sources of law. First, it examines the IHR ranging from 1969 to the early 2000s and their effect on international health obligations. Next, it describes the CBD and the ensuing tension between resource sharing and sovereignty interests.

A. *International Health Regulations*

The WHO has the power to adopt regulations that become binding on member states.⁸⁴ One set of such regulations is the IHR that were adopted in 1969.⁸⁵ The

80. See, e.g., *id.* (stating that a researcher at the University of Maryland ordered the virus from Erasmus immediately upon hearing about it and has since developed a diagnostic test); News Release, National Institutes of Health, Media Availability: NIH Study Supports Camels as Primary Source of MERS-CoV Transmission (Sept. 24, 2014), available at <http://www.niaid.nih.gov/news/newsreleases/2014/pages/camelmers-cov.aspx>; see also Erasmus MC, *supra* note 77 ("Virologists of the Viroscience Department of Erasmus MC are sending MERS coronavirus free of charge and without restrictions to all research institutions that work to benefit public health.").

81. See Kupferschmidt, *supra* note 65 ("At issue now is the MTA, a document that most biomedical laboratories routinely use when they exchange cells, samples, or pathogens.").

82. See generally Garrett, *Why a Saudi Virus Is Spreading Alarm*, *supra* note 2 (providing an overview of the tensions between the Saudi government and Erasmus).

83. See generally PEOPLE'S HEALTH MOVEMENT ET AL., *supra* note 26; David P. Fidler, *Influenza Virus Samples, International Law, and Global Health Diplomacy*, 14 EMERGING INFECTIOUS DISEASES 88 (2008), available at <http://wwwnc.cdc.gov/eid/content/14/1/pdfs/v14-n1.pdf>.

84. See, e.g., Carter, *supra* note 20, at 721–22.

85. *Id.* at 722.

1969 IHR were the first set of WHO guidelines designed to combat the spread of communicable diseases and to protect global health.⁸⁶ The 1969 IHR, however, were not without fault, and by the end of the 20th century, new global challenges necessitated revisions to the increasingly antiquated 1969 IHR.⁸⁷

Two developments made a new direction in the IHR necessary: (1) a phenomenon of new infectious diseases;⁸⁸ and (2) a new concern for bioterrorism.⁸⁹ The world had become more interconnected and political borders could not contain biological threats.⁹⁰ Global powers had become increasingly susceptible to infectious diseases because of increased trade and travel as well as inadequacies in the previous generation of IHR.⁹¹ In response to new global realities, the issue of infectious disease security was no longer a “here and there, or a you and I, or a developing world versus developed world issue, it was an ‘us’ issue, everyone had a stake.”⁹² A need to revise the 1969 IHR stemmed from the “understanding that this was now a global health security issue, and needed a global health governance approach to solve the challenges.”⁹³

New and reemerging diseases were popping up all over the world, such as SARS, E. coli, Anthrax, Hepatitis C, Lyme disease, and HIV/AIDS.⁹⁴ The HIV/AIDS pandemic, in particular, appeared to catch the WHO by surprise, which led to criticism that the WHO was no longer effective and needed a new direction.⁹⁵ In 2003, the outbreak of SARS served as a “tipping-point” and accelerated the urgency to adopt new reforms.⁹⁶ After roughly a decade of negotiations, the WHO revised the 1969 IHR, adopting the 2005 IHR on May 14, 2005.⁹⁷

The new IHR consisted of legally binding regulations aimed at helping countries to work together to save lives from the spread of infectious diseases and supporting the development of public health capabilities to increase global health

86. *Id.* at 722–23.

87. Shaikh & McNabb, *supra* note 16.

88. The U.S. Institute of Medicine issued a report in 1992 about the mounting microbial threats to health in the United States. David P. Fidler, *Caught Between Paradise and Power: Public Health, Pathogenic Threats, and the Axis of Illness*, 35 MCGEORGE L. REV. 45, 76 (2004). Donna Shalala, Secretary of Health and Human Services, described the Clinton administration as waging a war on infectious diseases. *Id.* The United States placed the threat of emerging infectious diseases on its diplomatic agendas, such as bilateral diplomacy with Russia and South Africa, GY summit meetings, and the Asia Pacific Economic Cooperation forum. *Id.*

89. *See id.* at 73–74 (discussing the emergence of bioterrorism as a concern to public health).

90. Shaikh & McNabb, *supra* note 16.

91. Fidler, *supra* note 87, at 74.

92. Shaikh & McNabb, *supra* note 16.

93. *Id.*

94. *Id.*

95. Fidler, *supra* note 87, at 73.

96. Shaikh & McNabb, *supra* note 16.

97. *Id.*

security.⁹⁸ The newly adopted IHR gave the WHO new authority, including the power to make public health recommendations to member states and travel companies.⁹⁹ Furthermore, the IHR allowed the WHO to obtain resources and information beyond that which was provided to them by member states—done primarily through new information technology—in order to hold member states accountable.¹⁰⁰

Under the 2005 IHR, member states also have new obligations. First, member states must notify the WHO of any event constituting a health emergency.¹⁰¹ Second, each member state must develop and maintain public health capabilities for surveillance of and response to events, including maintaining health and sanitary facilities at international airports and ground crossings.¹⁰² Third, member states must consult the WHO regarding any events within their territory that may, even if not officially declared, be health emergencies.¹⁰³ Finally, member states must share information during unexpected or unusual public health events.¹⁰⁴

The 2005 IHR aimed at creating a global health regime suitable for the modern global community. However, as illustrated by the actions of Indonesia in 2007, these regulations still had flaws, as they did little to address the need for equitable distribution of vaccines and medications to poorer nations.¹⁰⁵

B. Convention of Biological Diversity

During the bird flu crisis in 2007, in conjunction with current IHR, Dr. Supari based her claim of viral sovereignty on the CBD.¹⁰⁶ The CBD establishes three main objectives: (1) biodiversity conservation; (2) sustainable use; and (3) equitable and fair benefit sharing.¹⁰⁷ The CBD provides each member state a sovereign right to exploit its own resources pursuant to its own environmental policies, so long as a state's activities do not cause damage to the environment of another member state or an area beyond the state's national jurisdiction.¹⁰⁸ The concept of equitable reciprocity among member states and contracting parties is

98. *Id.*

99. *Id.*

100. *Id.*

101. WORLD HEALTH ORG., INTERNATIONAL HEALTH REGULATIONS art. 6, § 1 (2d ed. 2005) [hereinafter WORLD HEALTH ORG., INTERNATIONAL HEALTH REGULATIONS].

102. *Id.* art. 5, § 1, annex I (b)(1); Shaikh & McNabb, *supra* note 16.

103. WORLD HEALTH ORG., INTERNATIONAL HEALTH REGULATIONS, *supra* note 101, art. 8 (stating that when events do not require notification under Article Six, like situations where there is not enough information to complete the decision instrument, a member may consult with WHO and keep WHO advised of the situation).

104. *Id.* art. 7.

105. Shaikh & McNabb, *supra* note 16.

106. *Id.*; see also Catherine Tinker, A "New Breed" of Treaty: The United Nations Convention on Biological Diversity, 12 PACE ENVTL. L. REV. 191, 191 (1995) (describing the CBD, which was enacted on December 29, 1993).

107. Mullis, *supra* note 11, at 949.

108. Convention on Biological Diversity, art. 3, Jun. 5, 1992, 1760 U.N.T.S. 79, available at <http://www.cbd.int/convention/articles/default.shtml?a=cbd-03> (last visited on Oct. 23, 2013).

echoed throughout the CBD.¹⁰⁹ However, Article 15 of the CBD affirms a state's sovereign right over its natural resources, stating, "the authority to determine access to genetic resources rests with the national governments and is subject to national legislation."¹¹⁰ Furthermore, the CBD provides that access to genetic resources is subject to the "prior informed consent" of the member party providing the biological resources.¹¹¹

Thus, the CBD produces tension between two competing goals: equitable and fair sharing of resources on the one hand and respecting a state's sovereign right over its biological resources on the other. Ultimately, this tension contributed to the bird flu controversy.¹¹² The relevant question for this analysis is whether PIP, passed subsequent to the bird flu controversy, provides a sufficient framework to avoid another such controversy.

V. LEGAL ANALYSIS OF PIP

PIP is the starting point in analyzing whether WHO guidelines are sufficient to prevent another viral sovereignty crisis as, arguably, its sole purpose is to prevent another such incident. Accordingly, PIP offers a framework of principles and practices that can be applied to the MERS-CoV outbreak. Specifically, one can analyze whether PIP sufficiently solves problems caused by conflicting patent and viral sovereignty claims.

A. Background of PIP

Immediately following the agreement that Indonesia would resume sending bird flu samples to the WHO, health ministers of eighteen Asian-Pacific countries passed the Jakarta Declaration,¹¹³ demanding that the WHO:

[C]onvene the necessary meetings, initiate the critical processes and obtain the essential commitment of all stakeholders to establish the mechanisms for more open virus and information sharing and accessibility to avian influenza and other potential pandemic influenza vaccines for developing countries.¹¹⁴

These countries were concerned about the state of IHR, specifically the guidelines for and benefits of virus sharing.¹¹⁵

Any advancement, though, was tabled at the Sixtieth WHA after considerable

109. See generally *id.* art. 14, § 1(c) (establishing that member states must cooperate with other member states to respond to any activities or events that present a grave and imminent danger to biological diversity).

110. *Id.* art. 15, § 1.

111. *Id.* art. 15, § 5.

112. See Mullis, *supra* note 11, at 948–49 (stating that Dr. Supari used the CBD as a precedent in deciding that Indonesia would not share virus samples).

113. PEOPLE'S HEALTH MOVEMENT ET AL., *supra* note 26, at 146.

114. Jakarta Declaration on Responsible Practices for Sharing Avian Influenza Viruses and Resulting Benefits ¶ 7, Mar. 28, 2007.

115. PEOPLE'S HEALTH MOVEMENT ET AL., *supra* note 26, at 146–47.

disagreements among WHO member states.¹¹⁶ There were three sticking points to passing PIP: (1) how biological materials were to be transferred between WHO research facilities and pharmaceutical manufacturers; (2) how benefits could be shared among interested parties; and (3) how to balance respective intellectual property rights with affordable access to medications.¹¹⁷ Gaining a consensus on these issues proved difficult. In fact, in 2009, Dr. Supari instructed her staff that a deadlock was better than compromising.¹¹⁸ However, in light of the outbreak of bird flu in 2009, WHO member states established the Pandemic Influenza Preparedness Open-Ended Working Group, a special committee to finalize a bill.¹¹⁹ Even after Dr. Supari was replaced as Minister of Health by Endang Rahayu Sedyaningsih in 2009, gaining a consensus still proved difficult.¹²⁰

B. Problems PIP Aimed to Resolve

The difficulty of passing comprehensive vaccine distribution reforms highlights the basic dichotomy between developed and developing nations. Dr. Supari took issue with current international structure and norms.¹²¹ She primarily took issue with an existing market-based approach to vaccine distribution.¹²² Many developing nations lack resources, which in turn limits demand for seasonal influenza vaccines, resulting in limited production by manufacturers.¹²³ The lack of demand stems from a simple calculation—there are more pressing health issues in need of resources and attention.¹²⁴ Thus, the major purchasers of seasonal influenza vaccines are usually high-income countries, such as the United States, the United Kingdom, Australia, Japan, France, and Canada.¹²⁵ Even though seasonal flu outbreaks can obviously affect poorer nations, monetary constraints and limited resources often mean that vaccine manufacturers target sales to high-income countries.¹²⁶

This preference has produced residual effects. Due to their preference for high-income customers, vaccine manufacturers tend to locate their infrastructure and expertise in developed countries.¹²⁷ In 2006, for example, most of the world's

116. *Id.*

117. Kamradt-Scott & Lee, *supra* note 24, at 835.

118. *Id.*

119. *Id.* at 836.

120. *Id.*; Laurie Garrett, *The Man-made H5N1 Controversy Heats Up: What Next? (Part One)*, Feb. 15, 2015, <http://lauriegarrett.com/blog/2013/1/30/the-man-made-h5n1-controversy-heats-up-what-next-part-one>.

121. See Kamradt-Scott & Lee, *supra* note 24, at 834 (explaining that Dr. Supari wanted to restructure existing governance mechanisms specifically to help developing countries).

122. See *id.* (explaining how vaccine distribution prevented low-income countries from obtaining the necessary vaccines while other developed countries could obtain and stockpile vaccines for later use).

123. *Id.* at 836.

124. *Id.*

125. *Id.*

126. *Id.*

127. Kamradt-Scott & Lee, *supra* note 24, at 837.

vaccine manufacturing plants were located in wealthy nations.¹²⁸ Furthermore, wealthy nations often entered into agreements with vaccine manufacturers to secure access to vaccines should a pandemic or viral emergency arise.¹²⁹ These arrangements result in limited access to an already limited stock of vaccines for developing countries.

The bird flu crisis essentially served as the tipping point for change. The old market-based model of vaccine distribution needed to change, as developing countries had very limited access to necessary medications and vaccines.¹³⁰ As highlighted earlier, in a global, interconnected world, limiting the vulnerable, poorer nations' access to vaccines poses serious health threats to the global community. After four years of negotiations following the bird flu controversy,¹³¹ on May 24, 2011 the WHO adopted PIP.¹³²

C. Purpose of PIP

PIP has been hailed as a “milestone in global governance for health.”¹³³ According to the WHO, the objective of PIP “is to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system, . . . with the objective of a fair, transparent, equitable, efficient, effective system . . .”¹³⁴ Section 1 of PIP establishes several underlying principles, including:

[N]ote the continuing risk of an influenza pandemic with potentially devastating health, economic and social impacts, particularly for developing countries, which suffer a higher disease burden and are more vulnerable;

[R]ecognize that Member States have a commitment to share on an equal footing H5N1 and other influenza viruses of human pandemic potential and the benefits, considering these as equally important parts of the collective action for global public health;

[T]his Framework will be guided by the goal of its universal application

128. *See id.* (“[B]y 2006 the bulk of the world’s manufacturing capacity for influenza vaccines was focused in only nine industrialised countries.”).

129. *Id.*

130. *See id.* at 831 (stating that Indonesia’s decision not to share samples of the bird flu virus with other countries cast doubt over the general framework and highlighted the fact that many countries lacked access to vaccines but were still expected to contribute samples).

131. Shaikh & McNabb, *supra* note 16.

132. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS pmbL (2011), available at <http://www.who.int/influenza/pip/en/> [hereinafter WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK].

133. David P. Fidler & Lawrence O. Gostin, *The WHO Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health*, 306 J. AM. MED. ASS’N 200, 200 (2011).

134. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132, § 2.

for the protection of all people of the world from the international spread of disease;

[R]ecall the need for rapid, systematic and timely sharing of H5N1 and other influenza viruses with human pandemic potential with WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories as a contribution to assessment of pandemic risk, development of pandemic vaccines, updating of diagnostic reagents and test kits, and surveillance for resistance to antiviral medicines; . . .

[R]ecognize the need for a fair, transparent, equitable and efficient framework for the sharing of H5N1 and other influenza viruses with human pandemic potential and for the sharing of benefits, including access to and distribution of affordable diagnostics and treatments, including vaccines, to those in need, especially in developing countries, in a timely manner; . . .

[R]ecognize the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks; . . .

[R]ecognize that the commitment to share on an equal footing H5N1 and other influenza viruses of human pandemic potential and the benefits enables WHO Member States and the Director-General to assess the global risk of an influenza pandemic and allows WHO Member States and the Director-General to take actions to reduce the risk of the emergence of a pandemic and to facilitate the development and production of vaccines, diagnostic materials and other pharmaceuticals that can assist in rapidly responding to and containing an emerging pandemic; . . .

[A]cknowledge with serious concern that the distribution of influenza vaccine manufacturing facilities is inadequate particularly in developing countries and that some Member States can neither develop, produce, afford nor access the vaccines and other benefits; . . .

[R]ecognize the need for financing mechanisms that would promote affordability and equitable access to quality influenza vaccines, medicines and technologies by developing countries.¹³⁵

As these principles illustrate, the key goals of PIP are to improve and strengthen the global sharing of influenza viruses with human pandemic potential, as well as to increase developing countries' access to vaccines and other pandemic related supplies.¹³⁶ The specific language used to construct these principles is of particular importance. As will be discussed below, the language used ultimately limits the applicability of PIP. Specifically, all but two of the nine principles above expressly state that PIP only applies to influenza.

D. Benefits of PIP

First and foremost, PIP is intended to be a "benefit-sharing system" and calls upon "relevant institutions, organizations, and entities, influenza vaccines,

135. *Id.* § 1(2)–(5), 9, 11, 14, 16, 19.

136. *Id.* § 2.

diagnostics and pharmaceutical manufacturers and public health researchers” to make appropriate monetary contributions to the system.¹³⁷ PIP facilitates industry access to biological materials covered by it, encourages laboratories not to seek intellectual property rights on PIP biological material, supports the increase of transparency of virus transfers through a virus tracking system and a standard MTA,¹³⁸ and requires monetary contributions from pharmaceutical manufacturers that use the WHO Global Influenza Surveillance and Response System (GISRS).¹³⁹

PIP encourages WHO member states to share “PIP biological materials,”¹⁴⁰ which it defines as “human clinical specimens, virus isolates of wild type human H5N1 and other influenza viruses with human pandemic potential, and modified viruses prepared from H5N1 and/or other influenza viruses with human pandemic potential.”¹⁴¹ When member states provide biological materials, they consent to the transfer and use of the materials subject to the applicable standard MTA—established in PIP—for moving PIP biological materials within and outside of the GISRS.¹⁴² PIP facilitates the sharing of viruses and genetic sequence data through the use of two standard MTA. The first standard MTA, which governs transfers within the GISRS, requires laboratories recognized or designated by WHO to comply with national biosafety standards.¹⁴³ In addition, the first agreement discourages laboratories from seeking intellectual property rights over PIP biological materials.¹⁴⁴ The second standard MTA governs transfers from WHO to entities outside GISRS.¹⁴⁵ Together these transfer agreements create transparency to ensure that transfer of viruses conform to PIP provisions.¹⁴⁶

Section 6.1 of PIP designates the WHO to coordinate pandemic preparedness and response in accordance with applicable IHR provisions in addition to PIP.¹⁴⁷ In coordinating emergency response, the WHO has an obligation to pay attention to “policies and practices that promote the fair, equitable and transparent allocation of scarce medical resources (including, but not limited to, vaccines, antivirals and diagnostic materials) during pandemics based on public health risk and needs, including the epidemiology of the pandemic.”¹⁴⁸ Section 6.2 of PIP establishes risk

137. *Id.* § 6.0.1.

138. Shaikh & McNabb, *supra* note 16.

139. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132, at § 6.14.3.

140. *Id.* at 200.

141. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132, § 4.1.

142. *See generally* Fidler & Gostin, *supra* note 133 (outlining PIP as well as its legal status and protocol for the virus-sharing system).

143. *Id.*

144. *Id.*

145. *Id.*

146. *Id.* at 200–01.

147. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132, at § 6.1.

148. *Id.*

assessment and response procedures to pandemics.¹⁴⁹

Essential to PIP is the requirement that appropriate industries pay half of the GISRS's annual operating costs.¹⁵⁰ In return for these contributions, private industries can access PIP biological materials.¹⁵¹ Contributions from private sector companies benefit developing nations by increasing access to technologies and resources.¹⁵² However, despite requiring private industries to fund the GISRS, PIP does not require developed WHO member states to provide direct equity-sharing benefits to developing member states.¹⁵³

E. Limitations of PIP

Despite its many benefits, PIP also has limitations. First, PIP is not legally binding.¹⁵⁴ In passing PIP, the WHO opted not to exercise its constitutional authority to adopt international law.¹⁵⁵ Further, PIP mainly uses passive language and invokes no express power over pharmaceutical companies and member states.¹⁵⁶ For example, PIP does not expressly require pharmaceutical companies to share or transfer vaccines or other medical treatment to developing countries.¹⁵⁷ PIP does not require developed nations to contribute resources directly to developing nations.¹⁵⁸ There are no express obligations for pharmaceutical companies to make a certain percentage of their vaccine stock available for developing countries.¹⁵⁹

Furthermore, PIP does not ensure that pharmaceutical companies will offer vaccine stock to developing countries at a discount, which would facilitate access to needed medications for these poorer nations.¹⁶⁰ For example, Principle 8 of PIP states that viruses “should be shared” with WHO member states.¹⁶¹ In fact, we see the same passive language throughout PIP.¹⁶² PIP does, however, use standard contract agreements for laboratories and manufacturers participating in the GISRS, which creates some legal consequences for the contracting laboratories and

149. *Id.* at § 6.2.

150. *See* Fidler & Gostin, *supra* note 133, at 201 (discussing the benefit-sharing system and its requirements for compliance).

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.* at 200.

155. *Id.*

156. Fidler & Gostin, *supra* note 133, at 200.

157. *See* Kamradt-Scott & Lee, *supra* note 24, at 839 (stating that member states and pharmaceutical companies are not legally required to adhere to certain behaviors or principles, but are merely encouraged to do so).

158. *See* Fidler & Gostin, *supra* note 133, at 201 (discussing PIP's failure to demand developed nations to provide specific benefits, such as vaccines, for developing nations).

159. *See* Kamradt-Scott & Lee, *supra* note 24, at 839.

160. *Id.*

161. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132, at § 1(8).

162. *See, e.g., id.* at §§ 5.1.1, 6.0, 6.1, 6.7.1, 6.7.2, 6.9.3, 6.10.1(i), 6.10.1(ii), 6.11.1, 6.12, 6.13.2, 6.13.3, 6.13.5, 6.14.5, 7.2.5 (showing passive language that does not explicitly require member states to adhere to PIP).

manufacturers.¹⁶³

The lack of express language is hardly surprising given the virus-sharing structure existing prior to PIP's passage. The passive nature of PIP likely resulted from the voluntary system preceding it.¹⁶⁴ As explained above, before PIP was enacted, pharmaceutical companies primarily operated in response to global market forces.¹⁶⁵ They did not necessarily act in the best interests of developing countries, as demonstrated by Indonesia during the bird flu outbreak. The WHO may have been afraid that pharmaceutical companies would not participate in the marketplace if restrictive or overly burdensome regulations made it difficult to continue operations.¹⁶⁶ Furthermore, the lengthy and difficult negotiating realities of gaining support for the enacting of PIP may have contributed to its passive nature.¹⁶⁷ Finally, the respect for state sovereignty, which naturally constrains the WHO, also contributed to the passive nature of PIP.¹⁶⁸

Some experts assert that the lack of express assistance for developing nations is the biggest flaw of PIP.¹⁶⁹ Due to its "weak" passive language,¹⁷⁰ developing countries have been unable to obtain resources from pharmaceutical manufacturers that are not members of GISRS.¹⁷¹ After PIP was enacted, developing countries have gained very little with regard to improved access to vaccines and medical resources.¹⁷² Accordingly, PIP has made nominal changes to the old market-based structure.¹⁷³

However, one of the largest problems with PIP is that it only expressly applies to influenza viruses.¹⁷⁴ Sections 1, 2, and 3 of PIP make it clear that the framework applies only to influenza viruses.¹⁷⁵ The WHO's focus solely on influenza was

163. See Fidler & Gostin, *supra* note 133, at 200 (discussing how, even though PIP does not legally bind member states, it does contain contractual agreements for certain laboratories and manufacturers that participate in the GISRS for which the members of the contract are to be held legally responsible).

164. See Kamradt-Scott & Lee, *supra* note 24, at 839 (examining why PIP is a voluntary system that does not explicitly require action by the member states and the consequences of having such a passive system).

165. *Id.*

166. *Id.*

167. See *id.* (stating that overcoming the diplomatic impasse was not only challenging, but also time consuming, having taken over four years to do so).

168. *Id.*

169. *Id.*

170. See Kamradt-Scott & Lee, *supra* note 24, at 839 (examining the effect of PIP's passive language on its objectives).

171. *Id.*

172. *Id.*

173. *Id.*

174. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132, §§ 1–4.

175. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132, §§ 1–4. Section 1 of PIP provides, "In relation to pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits . . ." *Id.* § 1. Looking at

likely a calculated decision in response to the bird flu crisis.¹⁷⁶ One could also argue that given the lengthy PIP negotiations—it took four years for PIP to finally pass in its current form—many countries were content with the previous international virus-sharing structure.¹⁷⁷ Many developing countries may have simply lacked the requisite bargaining power needed for more comprehensive change.¹⁷⁸

In the past few years, PIP simply has not applied to many global outbreaks because it only applies to influenza.¹⁷⁹ For example, in April 2011, three countries in Europe reported over 6,500 cases of measles.¹⁸⁰ Measles is a highly contagious, potentially fatal viral disease¹⁸¹ that normally grows in cells that line the back of the throat and lungs.¹⁸² However, measles is epidemiologically distinct from influenza and therefore is not covered by PIP. Another example of a virus not covered by PIP is polio, which is a potentially deadly, infectious virus that spreads from person to person by infecting the brain and spinal cord and often results in paralysis.¹⁸³

PIP has, however, represented a shift in international norms. PIP represents one of the first modern reforms shifting away from the old market-based system to a progressive structure aimed at assisting poorer countries. This has some inherent, normative value, regardless of its express and structural limitations.

Section 1 more closely, thirteen of the nineteen principles underlying PIP expressly apply to influenza. *Id.* § 1(1)–1(19). Section 2 of PIP establishes the framework’s overall objectives. *Id.* § 2. Section 2 states:

The objective of the Pandemic Influenza Preparedness Framework is to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system (“WHO GISRS”), with the objective of . . . (i) the sharing of H5N1 and other influenza viruses with human pandemic potential[.]

Id. § 2–2(1). Section 3 of PIP establishes the scope of the framework and states: “This Framework applies to the sharing of H5N1 and other influenza viruses with human pandemic potential and the sharing of benefits.” *Id.* § 3.1 Section 3 continues, “This Framework does not apply to seasonal influenza viruses or other non-influenza pathogens or biological substances that may be contained in clinical specimens shared under this Framework.” *Id.* § 3.2.

176. See Kamradt-Scott & Lee, *supra* note 24, at 839 (discussing possible explanations for why the WHO chose to focus exclusively on the influenza virus).

177. *Id.*

178. *Id.*

179. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132, at §§ 1–4.

180. Global Alert & Response, *Measles outbreaks in Europe*, WORLD HEALTH ORG. (Apr. 21, 2011), http://www.who.int/csr/don/2011_04_21/en/.

181. Dep’t of Health, *Measles (rubeola, hard measles, red measles)*, NEW YORK STATE (Jan. 2012), http://www.health.ny.gov/diseases/communicable/measles/fact_sheet.htm.

182. *Overview of Measles Disease*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Sept. 13, 2013), <http://www.cdc.gov/measles/about/index.html>.

183. *What is Polio?*, CENTERS FOR DISEASE CONTROL & PREVENTION (Oct. 15, 2013), <http://www.cdc.gov/polio/about/>.

VI. APPLYING IHR TO MERCoV

Upon analyzing applicable health regulations, the MERS-CoV outbreak presents two issues: first, how the outbreak applies to the current framework; and second, whether current regulations are sufficient to prevent another viral sovereignty crisis.

When looking at PIP, MERS-CoV is clearly outside of its scope.¹⁸⁴ Since MERS-CoV is a coronavirus, it does not fall within Section 1 of PIP,¹⁸⁵ which establishes PIP's underlying principles.¹⁸⁶ Section 1 only applies to influenza—not coronaviruses. Likewise, coronaviruses also fall outside of Section 2¹⁸⁷ as well as Section 3.¹⁸⁸ Undoubtedly, PIP does not apply to outbreaks such as MERS-CoV.

Because no changes were made to IHR after the bird flu crisis except the implementation of PIP, some feared Saudi Arabia would follow in Dr. Supari's footsteps.¹⁸⁹ Memish expressed frustration that viral samples of MERS-CoV were sent outside of Saudi Arabia without formal permission.¹⁹⁰ Memish was specifically concerned that Erasmus applied for a patent of the genetic basis of MERS-CoV and required third-party entities to sign an MTA in order to receive viral samples.¹⁹¹ Simply put, besides the practical fact that samples were sent to Erasmus without permission, there has been nothing stopping Memish from making arguments similar to Dr. Supari and invoking a claim of viral sovereignty.¹⁹²

Dr. Chan echoed Memish's concerns, stating at the most recent WHA that Saudi Arabia has a responsibility to protect its citizens.¹⁹³ While Dr. Chan was responding to questions about the effect of the Erasmus patent on Saudi Arabia's capacity to respond to a MERS-CoV outbreak, Dr. Chan's remarks spoke to the concern that Memish could have taken matters into his own hands and forced foreign entities to sign an agreement that would have ensured Saudi Arabia benefitted from any research conducted on MERS-CoV samples originating within the country.¹⁹⁴

However, even if PIP applied to MERS-CoV, there are questions as to whether Saudi Arabia would have adhered to it. This results from PIP's lack of

184. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132, §§ 1–4.

185. *Id.* § 1.

186. For example, Section 1 starts, “In relation to pandemic influenza preparedness: sharing of influenza viruses . . .,” then lists the reasons for which PIP was passed. *Id.* § 1.

187. *Id.* § 2 (stating that the objective of PIP is to improve influenza response).

188. *Id.* (expressly stating that PIP applies to the sharing of H5N1 and other influenza viruses with human pandemic potential, excluding non-influenza types of illnesses).

189. Shaikh & McNabb, *supra* note 16.

190. Garrett, *Why a Saudi Virus is Spreading Alarm*, *supra* note 2.

191. Kupferschmidt, *supra* note 65.

192. *See, e.g.*, Tinker, *supra* note 106, at 191 (reinforcing a country's normative, sovereign right to exploit its own resources).

193. Kupferschmidt, *supra* note 65.

194. *Id.*

teeth.¹⁹⁵ As noted earlier, PIP is riddled with provisions written in a weak, conditional language.¹⁹⁶ Since PIP is not mandatory, it amounts to nothing more than an advisory text.¹⁹⁷ Without mandatory provisions, PIP would not stop Saudi Arabia from invoking a claim of viral sovereignty.

Fortunately, the above issues are moot because Erasmus received samples of MERS-CoV and its genetic code was mapped.¹⁹⁸ Thus, there was no opportunity for Memish to gain leverage to expel foreign researchers. But, theoretically, if viral samples had not been sent out of the country, then there could have been a serious threat similar to the bird flu crisis.

Regardless, ensuring Saudi Arabian access to any MERS-CoV vaccines and medications is critical. If the MERS-CoV outbreak worsens and Saudi Arabia is unable to access necessary medical supplies, a strong message will be sent to developing countries—that following Dr. Supari's approach may be a better option than relying on the WHO for assistance. If the outbreak worsens and Saudi Arabia cannot obtain medical supplies, then other developing countries may close their borders to prevent viral samples from leaving the country in order to maintain negotiating leverage.

Again, however, it is worth noting the normative significance of PIP. Even though PIP has little practical effect, because it does not apply to coronaviruses, it reflects an important normative shift regarding international priorities in pandemic response. Generally speaking, PIP is a sound normative approach to global health cooperation, but needs alteration to provide more force and broader applicability.

VII. RECOMMENDATIONS

Experts have already proposed several improvements to both PIP and other areas of global pandemic response.¹⁹⁹ One proposed structural improvement is to increase the size of global vaccine stockpiles and the overall global manufacturing capacity of seasonal influenza vaccines.²⁰⁰ The premise of this proposal is simple—more vaccines and greater manufacturing capacity for seasonal vaccines results in an increased capacity to create lesser used but essential medications needed for pandemic response.²⁰¹ Promoting seasonal influenza production is important because there is an intrinsic link between seasonal and pandemic capacities.²⁰² Increasing the capabilities of seasonal influenza response improves the structural

195. Kamradt-Scott & Lee, *supra* note 24, at 839 (highlighting PIP's extensive use of passive voice in its provisions).

196. *Id.* (highlighting PIP's extensive use of weak language, such as “should” instead of “shall,” in its provisions).

197. *E.g.* WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132, at § 1(1)–(19).

198. *Id.*

199. *See, e.g.*, Kamradt-Scott & Lee, *supra* note 24, at 840–44 (proposing several improvements to global pandemic response).

200. *See, e.g., id.* (discussing the advent and implementation of the Global Pandemic Influenza Action Plan).

201. *Id.*

202. *Id.*

ability to respond to pandemics. Additionally, increasing market demand for seasonal vaccines through government or private entity purchases would stimulate the market for vaccines generally.²⁰³ Stimulating the market would create a natural market solution to improve and increase the global manufacturing capacity.²⁰⁴

Proposals such as this have been widely popular among both developing and developed countries.²⁰⁵ For example, developing countries like Brazil, Thailand, and Mexico, as well as developed countries like the United States, the United Kingdom, France, and Singapore, have expressed support for increasing global production of seasonal vaccines²⁰⁶ and have supported similar initiatives in the past.²⁰⁷ However, previous initiatives have failed to gain sufficient financial backing necessary to sustain operations.²⁰⁸ Past initiatives failed because poorer countries did not have the resources needed to increase local production and manufacturing of medications.²⁰⁹ Whether or not private industry contributions required under PIP are sufficient to increase necessary production capabilities remains to be seen.²¹⁰ However, as has been seen in the past, increasing equitable access to vaccines will be difficult without direct financial assistance to developing countries.²¹¹

Looking at the MERS-CoV outbreak, another pressing need for improvement is to broaden the scope of PIP's influenza-specific language. As previously explained in detail, PIP expressly focuses on influenza, so the guidelines do not apply to coronaviruses like MERS-CoV.²¹² Similarly, PIP does not apply to the infinite types of other potential outbreaks.²¹³ Accordingly, Sections 1 through 4 of PIP, which limit PIP to influenza, need to be expanded to include other types of potential outbreaks. Further, in order to avoid future problems, any such change should avoid providing an express, exhaustive list of viruses to which it applies. Novel viruses frequently appear. For example, there were few reported cases of coronaviruses until the SARS outbreak in 2002, and the MERS-CoV strain had never been seen before 2012.²¹⁴

203. *Id.*

204. *Id.*

205. Kamradt-Scott & Lee, *supra* note 24, at 840–41.

206. *Id.*

207. *Id.* at 841.

208. *Id.*

209. *Id.* at 842.

210. WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, *supra* note 132 (requiring industry contributions for access to PIP biological materials).

211. *Id.* at § 6 (requiring industry contributions for access to PIP biological materials).

212. Lawrence O. Gostin, Alexandra Phelan, Michael A. Stoto, John D. Kraemer, & K. Srinath Reddy, *Virus Sharing, Genetic Sequencing, and Global Health Security*, 345 SCIENCE 1295 (September 2014), available at <http://www.sciencemag.org/content/345/6202/1295.short>.

213. *Id.*

214. See Fidler & Gostin, *supra* note 133, at 201 (noting that implementing innovative global governance strategies is often frustrating, underfunded, and inadequate).

VIII. CONCLUSION

MERS-CoV presents a unique opportunity for analysis of recent WHO regulations and claims of viral sovereignty. The bird flu crisis shocked the international community²¹⁵ and was the impetus for new WHO health regulations, specifically PIP.²¹⁶ The extent to which PIP will prevent another bird flu crisis is unknown.

However, after analyzing PIP, that unknown appears bleak. First, PIP does not apply to coronaviruses such as MERS-CoV. Thus, the equity-driven goals of PIP do not benefit Saudi Arabia in responding to the outbreak of MERS-CoV. Furthermore, even if PIP applied to the MERS-CoV outbreak, PIP has many structural deficiencies, such as its conditional provisions and lack of financial commitments from developed nations to ensure equitable access to vaccines.²¹⁷ Thus, PIP would likely not prove helpful even if it expressly applied to the MERS-CoV outbreak.²¹⁸

Overall, however, PIP represents an important shift away from the old market-based system of vaccine sharing. Due to globalization, infectious diseases are no longer an isolated threat.²¹⁹ A viral outbreak in one country can cause serious consequences halfway across the globe. Clearly, additional action needs to be taken. However, despite its shortcomings, PIP is still a step in the right direction for promoting equitable access to vaccines and medication.

215. Holbrooke & Garrett, *supra* note 10 (highlighting reaction to Dr. Supari's claim of viral sovereignty).

216. *See, e.g.*, Kamradt-Scott & Lee, *supra* note 24, at 841 (explaining that PIP was passed in response to the bird flu crisis).

217. *See, e.g., id.* at 838.

218. Shaikh & McNabb, *supra* note 16.

219. *Id.*