NOTES

WHO'S VIRUS IS IT ANYWAY? HOW THE WORLD HEALTH ORGANIZATION CAN PROTECT AGAINST CLAIMS OF "VIRAL SOVEREIGNTY"

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I. INTRODUCTION

On June 11, 2009, just two months after the first cases of H1N1 (the Swine Flu) were reported, Margaret Chan, the Director-General of the World Health Organization (WHO) officially confirmed the news that many in the international health community had feared. "Ladies and gentlemen," she began, "The virus is entirely new. [It] is contagious, spreading easily from one person to another, and from one country to another . . . . The world is now at the start of the 2009 influenza pandemic." Although health experts have long predicted that the world would soon face another global health crisis, many thought H5N1 (avian influenza) was the most likely candidate. Since it was first discovered in 1997 that humans could be infected with the H5N1 virus, many industrialized nations have devoted considerable resources to developing an effective vaccine, in hopes of minimizing the adverse consequences of a future pandemic to their citizens. Now the same countries are scrambling to inoculate their citizens against the Swine Flu. Unfortunately, many developing countries do not have the same access to the Swine Flu vaccine and have in effect been left to fend for themselves.

The Swine Flu outbreak has renewed interest in the best way to protect the world’s population against pandemic influenza. The last time the issue made international headlines was when Indonesia refused the World Health Organization’s request to share samples of avian influenza strains collected from newly discovered outbreaks of the virus in 2007. Indonesia’s decision

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2 Lawrence O. Gostin & Benjamin E. Berkman, Preparing for Pandemic Influenza: Legal and Ethical Challenges, in ETHICAL AND LEGAL CONSIDERATIONS IN MITIGATING PANDEMIC DISEASE: WORKSHOP SUMMARY 78, 79 (Bd. on Global Health ed., 2007).


was a major departure from the WHO’s virus-sharing protocol, where member states share newly discovered viral strains with one another in order to assist in the development of vaccines.\(^6\) The WHO relies on viral samples donated from different member states to prepare seed strains that pharmaceutical companies use to manufacture a variety of vaccines.\(^7\) Instead of following international norms, Indonesia asserted “viral sovereignty,” property rights over the newly discovered H5N1 strains,\(^8\) and subsequently entered into contractual negotiations for the samples with Baxter Healthcare, a large United States-based pharmaceutical company.\(^9\) Under the contract with Baxter Healthcare, Indonesia agreed to allow the company access to its H5N1 samples in exchange for intellectual property rights and access to any vaccines developed from the samples.\(^10\)

Indonesia was concerned with the fact that developing countries often freely share viral samples with the WHO and receive little to nothing in return.\(^11\) 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

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\(^7\) Bryan Walsh, Indonesia’s Bird Flu Showdown, TIME, May 10, 2007, http://www.time.com/time/health/article/0,8599,1619229,00.html. A seed strain is the particular viral strain selected to form the basis of the vaccine. Gigi Kwik Gronvall & Luciana L. Borio, Removing Barriers to Global Pandemic Influenza Vaccination, 4 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE & SCI. 168, 172 (2006), available at http://www.liebertonline.com/doi/pdfplus/10.1089/bsp.2006.4.168. The effectiveness of the vaccine turns on selecting the correct seed strain. Id. The WHO Global Influenza Surveillance Network monitors emerging influenza strains across the globe, determines which strains are most likely to cause illness, and makes recommendations to vaccine manufacturers about which strains should be included in the seed strain for a particular year. Id.

\(^8\) “Viral sovereignty” is the idea that each nation has sovereign property rights over viral strains found within its borders. See, e.g., Richard Holbrooke & Laurie Garrett, ‘Sovereignty’ That Risks Global Health, WASH. POST, Aug. 10, 2008, at B7 (explaining the concept of viral sovereignty and arguing that refusing to share viral strains with international scientific community is morally reprehensible).


\(^11\) See Walsh, supra note 7 (stating that poor nations provide samples but often cannot afford to purchase vaccines, and are likely to be the last to receive vaccines during public health emergencies).
by developed countries. In addition to developed nations, the pharmaceutical industry also benefits immensely from the existing vaccine distribution system. For example, sales of the influenza vaccine alone generate revenue of approximately $2 billion per year for the pharmaceutical industry. As a result of their mutually beneficial relationship, neither developed countries nor vaccine manufacturers have much of an incentive to change the status quo.

In support of her nation’s decision to deviate from international norms, Indonesian Health Minister Siti Fadilah Supari said the Indonesian government withheld its H5N1 samples from the WHO to entice the global community to create a system that would provide benefits to countries that contribute to vaccine development.

After a months-long standoff, the WHO resolved the conflict by promising Indonesian officials that the H5N1 samples would not be given to pharmaceutical companies without the Indonesian government’s permission. As part of the settlement, Indonesia agreed to resume sharing samples collected from newly discovered H5N1 influenza outbreaks. On May 30, 2007, the World Health Assembly adopted a resolution among its member states to share viral strains. As part of this resolution, the WHO agreed to “assess and develop potential mechanisms, including Material Transfer Agreements, that could promote equitable distribution and availability of pandemic influenza vaccines developed and produced from these viruses.”

12 Id.
15 Indonesia, WHO to End Bird Flu Dispute, supra note 6.
16 Id.
Through a proposed Material Transfer Agreement, Indonesia aimed to retain sovereign rights over the donated viral strains, the right to receive the seed virus at no cost, and the right to participate in research and receive acknowledgement for its valuable contributions to the WHO’s viral sharing program.19

This Note will demonstrate why the WHO must prevent member states from following Indonesia’s lead in withholding samples of potentially catastrophic diseases. Specifically, this Note argues that the WHO must offer positive incentives so developing countries will have a compelling reason to share samples of newly discovered viruses with the international scientific and health communities.

In order to better appreciate the need for a change in the current system, Part II of this Note will provide background information on both the WHO and the International Health Regulations. Part III will provide a brief history of pandemic influenza and will discuss why health experts feared in 2007 that avian influenza would be the next deadly global pandemic. Part IV will propose solutions to prevent countries from withholding viral samples in the future, which include amending the International Health Regulations, imposing economic sanctions against non-compliant countries, or creating a system that provides developing countries with positive incentives for sharing viral samples.

II. BACKGROUND ON THE WORLD HEALTH ORGANIZATION AND THE INTERNATIONAL HEALTH REGULATIONS

A. World Health Organization

The United Nations established the WHO on April 7, 1948.20 It has 193 member states and is governed by the World Health Assembly.21 The constitution of the WHO grants the organization the power to adopt treaties.

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and regulations that can become "binding" on member states.\textsuperscript{22} However, because each member state is free to either explicitly reject the treaty or regulation or accept it with reservations,\textsuperscript{23} it has been challenging for the WHO to implement an effective set of guidelines that comprehensively deals with emerging threats to global health.\textsuperscript{24} As a result of this type of governing structure, the WHO has rarely exercised its formal legislative powers and has been criticized by leading scholars for not taking sufficient steps to prevent the spread of communicable diseases, especially in developing nations.\textsuperscript{25}

\textbf{B. International Health Regulations}

One of the rare occasions where the WHO exercised its power to promulgate rules was in 1951 when it adopted the International Sanitary Regulations.\textsuperscript{26} However, because the WHO had no enforcement capabilities at the time, many countries simply ignored its disease-reporting requirements.\textsuperscript{27} To combat these problems and provide a more formal framework, the WHO adopted the International Health Regulations in 1969 (the 1969 Regulations).\textsuperscript{28} The 1969 Regulations were the first source of international law primarily concerned with preventing the spread of communicable diseases to protect global health.\textsuperscript{29}

Compared with the International Sanitary Regulations, the 1969 Regulations were a step in the right direction toward preventing the spread of infectious diseases; they provided more guidance to member states about what measures to follow in the event of an outbreak.\textsuperscript{30} However, they were still

\begin{itemize}
  \item \textsuperscript{22} David Bishop, \textit{Note, Lessons from SARS: Why the WHO Must Provide Greater Economic Incentives for Countries to Comply with International Health Regulations}, 36 GEO. J. INT’L L. 1173, 1187 (2005).
  \item \textsuperscript{24} Id. at 376–77.
  \item \textsuperscript{25} Id. at 377–78.
  \item \textsuperscript{28} Allyn L. Taylor, \textit{Controlling the Global Spread of Infectious Diseases: Toward a Reinforced Role for the International Health Regulations}, 33 HOUS. L. REV. 1327, 1341 (1997).
  \item \textsuperscript{29} Bishop, \textit{supra} note 22, at 1188.
  \item \textsuperscript{30} See Taylor, \textit{supra} note 28, at 1343–44 (discussing the obligations placed on member states
unable to fully combat the spread of infectious diseases. For example, the 1969 Regulations only monitored six infectious diseases: smallpox, cholera, typhus, yellow fever, relapsing fever, and the plague. Moreover, developing nations often did not have sufficient financial resources to invest in the technology necessary to detect infectious-disease outbreaks, and many developed nations failed to disclose them for fear of negative economic consequences—i.e., a reduction in trade or tourism. As a result of the narrow scope of the 1969 Regulations and the detection and reporting problems, the world was left vulnerable to many diseases, including pandemic influenza.

In response to these problems, the World Health Assembly revised the International Health Regulations in 2005 to provide a more comprehensive structure for addressing global health challenges. The revised International Health Regulations seek to ensure “their relevance and applicability for many years to come even in the face of the continued evolution of diseases and of the factors determining their emergence and transmission.” A major difference between the old and new International Health Regulations is that the 2005 Regulations afford member states less discretion in determining whether to report an outbreak of a disease to the WHO.

The 2005 Regulations apply to all communicable and non-communicable public health emergencies of international concern. The 2005 Regulations define a public health emergency of international concern as “an extraordinary event which is determined ... (i) to constitute a public health threat risk to other States through the international spread of disease and (ii) to potentially

by the 1969 Regulations).

Fidler, supra note 26, at 336.


Miano, supra note 27, at 31.


Id. art. 2.
require a coordinated international response." The 2005 Regulations improved international efforts to prevent the spread of infectious diseases.\textsuperscript{37}

One way the WHO and the 2005 Regulations attempt to control the spread of viruses like H5N1 avian influenza is by requiring member states to use a "decision tree" to assess whether a disease constitutes a public health emergency.\textsuperscript{39} A "decision tree" contains three paths, and each path lays out a different course of treatment and reporting requirements for the three categories of diseases: (1) known diseases with serious outbreaks that occur without warning; (2) known diseases capable of developing into a public health emergencies; and (3) unknown or potential health threats.\textsuperscript{40} Member states must report to the WHO any disease outbreak that falls into the first category, and may need to report an outbreak that falls under the second or third categories after weighing the severity of the illness, the likelihood of the outbreak spreading to other countries, and the possible impact on travel and trade.\textsuperscript{41}

Furthermore, a provision was added to the 2005 Regulations that gives the Director-General of the WHO the authority to decide whether a "public health emergency of international concern" exists, even if the member state affected by the outbreak makes a contrary determination.\textsuperscript{42} While the new provision appears to give the WHO more supervision over the decisions of member states, the WHO suffers from a weak governance structure.\textsuperscript{43} Therefore, other than the WHO exerting political pressure, little can be done to mandate compliance with the International Health Regulations.\textsuperscript{44} Thus, it is essential that the WHO develop a system that provides positive incentives so that developing countries share samples of newly discovered infectious diseases in a timely manner.

\textsuperscript{37} Id. art. 1.
\textsuperscript{38} Silver, supra note 34, at 230.
\textsuperscript{40} Miano, supra note 27, at 37.
\textsuperscript{41} Id.
\textsuperscript{42} See Aoki, supra note 30, at 551 (discussing the increased power of the Director-General under the 2005 Regulations).
\textsuperscript{43} Bishop, supra note 22, at 1197.
\textsuperscript{44} Id.
III. BACKGROUND ON PANDEMIC INFLUENZA AND THE H5N1
AVIAN INFLUENZA VIRUS

A. Pandemic Influenza

Before the recent Swine Flu pandemic, the world has faced the consequences of three influenza pandemics since 1900 and has been threatened by numerous infectious diseases. Three conditions must exist for an influenza pandemic to occur: the virus must be capable of causing sickness in humans, the population must have little or no pre-existing immunity to the virus, and it must be capable of easily spreading among people.

The first of the deadliest influenza pandemics, called the Spanish Flu, occurred in 1918. The 1918 influenza virus likely originated in the United States, and in less than two years, it spread across the globe in three waves. It is estimated that more than one billion people worldwide were infected between 1918 and 1919, with twenty million to forty million deaths attributed to the pandemic.

The second influenza pandemic, called the Asian Flu, emerged in February of 1957. In response to the threat of a deadly outbreak, public health officials in the United States conducted vigilant surveillance and rapidly vaccinated its citizens. Although not as widespread as the 1918 Spanish Flu, the Asian Flu claimed the lives of nearly 70,000 people in the United States alone.

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48 See JOHN M. BARRY, THE GREAT INFLUENZA 1–5 (2005) (discussing the devastating consequences of the 1918 influenza pandemic). "Influenza killed more people in a year than the Black Death of the Middle Ages killed in a century; it killed more people in [its first] twenty-four weeks than AIDS has killed in twenty-four years." Id. at 5.
50 Nicosia, supra note 45, at 481.
51 Id.
52 Id.
mildest of the three pandemics, the Hong Kong Flu, occurred in 1968 and claimed the lives of approximately 33,800 people in the United States.53

Due to the increased accessibility of air travel, people and infectious diseases are able to travel more rapidly now than in years past, making it increasingly difficult to contain an outbreak.54 Before discussing the impact of a potential avian influenza pandemic, however, it is important to have a basic understanding of the history of the disease. There is a growing consensus in the scientific community that the 1918 influenza virus and current strains of the H5N1 avian influenza virus are similar in several respects.55

B. H5N1 Avian Influenza

Avian influenza is caused by a type-A strain of the influenza virus and is carried primarily by migratory birds.56 In addition, the international distribution of poultry products and an increase in foreign travel have contributed to the spread of the virus.57 As a result, avian influenza has been detected in many countries around the world, including Germany, France, Iraq, Iran, Saudi Arabia, Egypt, Nigeria, and India.58

Although avian influenza usually affects only the bird population, the first known cases of bird-to-human infection were found in Hong Kong in 1997 and involved the H5N1 strain.59 The Hong Kong government promptly ordered the

53 Id.
54 Bishop, supra note 22, at 1178.
58 Id.
slaughter of 1.5 million birds\textsuperscript{60} to protect the public from the threat of a global health crisis.

The outbreak of avian influenza in Hong Kong made authorities keenly aware of the need for an H5N1 vaccine. In 2004, WHO laboratories isolated the H5N1 virus samples obtained from two Vietnamese citizens infected with the disease, resulting in a major breakthrough in the development of an avian influenza vaccine.\textsuperscript{61} In March 2005, a branch of the National Institutes of Health began the first human trials of the vaccine prototype in the U.S.\textsuperscript{62}

Prior to 2005, almost all cases of humans infected by H5N1 influenza were thought to have resulted from direct contact with diseased birds.\textsuperscript{63} In early 2005, however, scientists suggested H5N1 had acquired the ability to be transmitted from person-to-person, not merely from bird-to-human.\textsuperscript{64} Fortunately, current strains of avian influenza have not yet demonstrated the capability of sustained transmission between humans.\textsuperscript{65} Even though H5N1 avian influenza has not yet mutated into an easily transmissible form, it has already killed at least 186 people across the globe, including seventy-seven people in Indonesia.\textsuperscript{66} If the H5N1 virus continues to evolve though adaptive mutation, it could become highly transmissible between humans, which would likely lead to a pandemic outbreak with the potential to cause widespread illness and death.\textsuperscript{67} For example, if an avian influenza pandemic were to hit the United States, the Centers for Disease Control and Prevention has estimated that more than 200,000 Americans would die and more than 700,000 would require hospitalization.\textsuperscript{68} If a H5N1 pandemic could have such a devastating effect on the population of a developed country that already has a sophisticated healthcare system in place, imagine the toll the same pandemic would likely have on the populations of some of the world’s poorest countries who do not have access to such resources.

\textsuperscript{60} O’Leary, supra note 47, at 517.
\textsuperscript{61} O’Leary, supra note 49, at 479.
\textsuperscript{62} Id.
\textsuperscript{63} Avian Influenza – Are We Prepared?, supra note 46.
\textsuperscript{65} Gostin & Berkman, supra note 57, at 124.
\textsuperscript{66} Bhattacharya, supra note 5, at 588.
\textsuperscript{67} Id.
\textsuperscript{68} Nicosia, supra note 45, at 484.
Not only would an avian influenza pandemic cause many deaths, it would also have severe economic consequences to the global economy. Recent avian influenza outbreaks have adversely affected employment and have reduced the profitability of the poultry industry as hundreds of millions of domesticated birds have been killed or died as the result of infection.\textsuperscript{69} It is estimated that the 1997 avian influenza outbreak cost Asia as much as $10 billion in direct economic losses.\textsuperscript{70} The economies in developed countries, like the United States, could see a drop in gross domestic product by as much as 5% if one of these outbreaks turns into a more widespread pandemic.\textsuperscript{71} Therefore, given the enormous potential destruction that could be caused by such a pandemic, it is critical that the WHO be allowed access to all samples of H5N1 in a timely manner.

\textbf{C. The Need to Monitor Newly Discovered H5N1 Strains}

With the real threat of an emerging avian influenza pandemic, the ability of the international scientific community to control the spread of the disease by developing an effective vaccine is heavily dependent on access to all newly discovered strains of H5N1.\textsuperscript{72} Without access to newly discovered H5N1 viral strains, scientists cannot assess whether the H5N1 virus has mutated into a form that is easily passed from person-to-person, which would signal the beginning stages of a global pandemic.\textsuperscript{73}

Furthermore, avian influenza vaccine research and development is an ongoing process, and in the event of a global health emergency, the vaccine must closely match the specific strain of H5N1 that causes the pandemic in order to be effective.\textsuperscript{74} The earlier the pandemic strain of the H5N1 virus is identified and made available for vaccine production, the sooner the populations that are most at risk can begin to receive life-saving protection from the disease.

\textsuperscript{69} \textit{Id.}

\textsuperscript{70} Gostin & Berkman, \textit{supra} note 57, at 126.

\textsuperscript{71} \textit{Id.}

\textsuperscript{72} \textit{Avian Influenza – Are We Prepared?}, \textit{supra} note 46. It takes approximately six months to produce a new flu vaccine. O'Leary, \textit{supra} note 47, at 542.

\textsuperscript{73} See Gostin & Berkman, \textit{supra} note 57, at 133 (discussing the need for easy access to newly discovered H5N1 viral strains).

\textsuperscript{74} O'Leary, \textit{supra} note 49, at 481.
Although Indonesia’s withholding of samples from the WHO was an extreme departure from established international norms, it drew attention to the inequitable viral sharing program that is the status quo: samples of infectious diseases are provided by developing countries in order to produce vaccines to protect the citizens of developed countries. Indonesia argued that because it had been repeatedly neglected by the WHO’s viral sharing program in the past, it had no choice but to enter into its own private agreement with Baxter Healthcare. Some critics of the WHO’s viral sharing program agree that “poor developing nations are often priced out of needed medicines, and they’re likely to be the last in line for vaccine during a pandemic.”

Thus, in order to ensure that the scientific community has access to newly discovered H5N1 strains, it is important for the WHO to motivate developing countries to turn over samples of diseases discovered within their borders. The best way to provide this motivation is to develop a system that provides incentives that are comparable to the benefits that developing countries would receive if they were able to enter into exclusive private agreements with vaccine manufacturers. If such a system were developed, member states would not have a valid justification for withholding viral samples from the international community. This Note argues that the WHO must take affirmative steps to prevent other countries from following Indonesia’s course of action in order to adequately protect the health of the global society. This Note will now propose and examine potential solutions to address this international dilemma.

IV. SOLUTIONS TO PREVENT DEVELOPING COUNTRIES FROM WITHHOLDING VIRAL SAMPLES

A. Revising the International Health Regulations

A potential solution for preventing developing countries from withholding viral samples would be to re-word the International Health Regulations to explicitly require member states to turn over all sample strains of highly infectious diseases, such as H5N1, to the WHO. This would help prevent countries such as Indonesia from relying on ambiguities within the Regulations to support their argument that they are not required to share samples with the
global scientific community. Furthermore, this proposed course of action could be implemented quickly, and without any great expense to the WHO.

While rewording the International Health Regulations to explicitly require member states to share viral samples might be an appropriate legal solution to the problem, it might not be a practical solution. As previously discussed, enforcement of the 2005 Regulations continues to be a problem. Under the current Regulations there is no authoritative international body to enforce the regulations, and states are unlikely to limit their sovereignty by granting the WHO more power than it currently has. Even if countries fully accept the changes to the International Health Regulations, compliance with the Regulations only continues as long as it remains beneficial to the member state.

For developing countries such as Indonesia, the benefits of complying with the International Health Regulations are often outweighed by the costs. For example, the WHO does not provide developing nations with funding to create the public health infrastructure necessary to comply with the 2005 Regulations. According to international law scholar David Fidler, "[the new IHR leave unanswered . . . how many States . . . with weak or nonexistent public health systems will comply with their core-capacity obligations. The revised Regulations contain no obligations on State Parties to provide financial or technical resources to help developing and least-developed countries [comply with the Regulations]."

Thus, amending the International Health Regulations to explicitly require member states to share samples of newly discovered viruses would likely have little effect on solving the problem. Historically, the WHO has relied on good-faith efforts by its member states and the threat of international political and economic pressure to encourage compliance. Indonesia's actions demonstrate that relying on the good-faith compliance efforts of member states is not sufficient, especially in the face of a global avian influenza pandemic.

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75 See Bishop, supra note 22, at 1196–97 (noting that under the International Health Regulations it is easy for a country to justify nondisclosure by not considering the health issue one of "international concern").
76 Id. at 1193.
77 See Mack, supra note 34, at 366 (discussing the possible collision between state sovereignty and IHR).
78 Miano, supra note 27, at 54.
79 Fidler, supra note 26, at 374.
80 Silver, supra note 34, at 244.
To prevent developing countries from following Indonesia’s course of conduct, the WHO needs to address the underlying reasons developing nations may choose to withhold samples and enter into exclusive agreements with pharmaceutical companies. Merely revising the 2005 Regulations to explicitly require member states to transfer all viral samples, without addressing the underlying issues, will have a limited impact on preventing a global pandemic. It would be more effective to provide incentives to encourage member states to share viral samples with the international community. The remainder of this Note will discuss whether the WHO should pursue this course of action.

B. Economic Sanctions

Another possible way to prevent developing countries from withholding viral samples would be to formally sanction non-compliant member states by imposing monetary penalties for violations. Such punishment would be justified because willful violations of the International Health Regulations endanger the entire global community. Economic sanctions for violations would also provide an incentive for non-compliant member states to quickly conform their conduct to the International Health Regulations in order to avoid additional penalties. Further, substantial economic sanctions could deter other member states from acting in a similar fashion.

However, imposing monetary penalties on non-compliant member states is not the best solution to this problem. First, while Indonesia’s actions may appear morally reprehensible from the standpoint that they increase the risk of an ineffective response in the event of a deadly H5N1 influenza pandemic, Indonesia was most likely acting to protect the health of its citizens because it was being neglected by the existing vaccine distribution system. From Indonesia’s perspective, it would not be fair to punish the country for taking measures to safeguard the health of its own citizens. Furthermore, imposing monetary penalties would be largely ineffective because of the inability to collect fines from impoverished nations. Without a way for the WHO to force compliance with the International Health Regulations, there is a substantial risk that developing nations would simply ignore the fines and continue to withhold samples.

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81 Bishop, supra note 22, at 1175.
Finally, imposing monetary sanctions against non-compliant member states would be a difficult policy for the WHO to implement. The WHO would have to choose whether to vest the power to impose sanctions for non-compliance in an individual, such as the Director-General, or whether this decision would be better made by a full vote of all member states. In addition, detecting subtle violations would be difficult in many cases and intrusive investigations might invade the national security interests of member states. In any event, the behavior of member states would have to be closely monitored by the WHO to make such a policy effective. Such monitoring would likely be expensive because an additional administrative body would have to be established to carry out surveillance to ensure member state compliance. Opponents of economic sanctions argue that this money would be better spent improving the healthcare systems of developing nations rather than on implementing a micromanagement program.  

Other economic sanctions that could be used to force compliance include trade and travel restrictions. However, like monetary penalties, travel and trade restrictions could have devastating effects on many countries that are already severely impoverished, and may only produce minimal results.  

Imposing economic sanctions on developing countries would likely have the greatest impact on the poorest citizens who might lose their livelihood as a result of the trade restrictions. Further, it would simply be unfair to punish the citizens of a member state that has chosen to violate the International Health Regulations; often the poor have no political influence over their government’s decisions. For these reasons, the WHO should not formulate a system of economic sanctions to encourage member states to turn over their samples.

C. Economic Incentives

In order to guard against a future influenza pandemic, the WHO must offer economic incentives so developing countries such as Indonesia will have compelling reasons to share samples of newly discovered viruses and to

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82 See Lawrence O. Gostin & Robert Archer, The Duty of States to Assist Other States in Need: Ethics, Human Rights, and International Law, 35 J.L. MED. & ETHICS 526, 530–31 (2007) (arguing that it is in the interest of developed nations to help developing countries improve their “public health infrastructures”).
83 See Bishop, supra note 22, at 1204 (arguing that placing trade sanctions on non-compliant member states would result in deadweight loss and adverse political consequences).
The WHO could possibly provide some form of intellectual property protection to developing countries in exchange for access to samples collected from infectious disease outbreaks, directly pay member states in exchange for their samples, adopt provisions that entitle compliant member states to a share of profits made by pharmaceutical companies from selling vaccines developed from their shared samples, or ensure that developing nations are allocated an equitable share of any vaccines made from donated viral samples. Each of these incentives has strengths and weaknesses that must be evaluated by the WHO before reaching a decision.

### 1. Intellectual Property Rights

Some scholars say member states that share viral samples of newly discovered pathogens should be granted intellectual property rights to the genetic structure of the disease. Providing intellectual property protection for newly discovered viral strains would likely encourage member states to invest the time, energy, and money to discover new forms of viruses, which could be used by pharmaceutical companies to make vaccines. Furthermore, adopting a system to provide intellectual property rights to the first country that files a claim with the WHO would likely give member states an incentive to turn over samples of viruses as soon as they are discovered.

If it were possible for the WHO to grant member states some form of intellectual property rights to newly discovered viral strains, a framework similar to the International Union for the Protection of New Varieties of Plants (UPOV) could be potentially adopted. UPOV was established in 1961 by the International Convention for the Protection of New Varieties in Plants (the UPOV Convention). In short, the UPOV Convention requires countries that have ratified the treaty to protect indigenous plant varieties, including those

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84 See Gostin, supra note 23, at 335 (arguing that international law must create incentives for developing nations to improve the health of their citizens).

85 See Gostin & Berkman, supra note 57, at 133 (discussing the need for international coordination to prevent countries from keeping health information secret due to intellectual property concerns).

86 See INT'L UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS [UPOV], WHAT IT IS, WHAT IT DOES (2009) [hereinafter UPOV, WHAT IT IS, WHAT IT DOES], available at http://www.upov.int/export/sites/upov/en/about/pdf/pub437.pdf. The UPOV is an intergovernmental organization established in 1961 to provide intellectual property protection to plant breeders. Id.

that have a natural source of variation.\textsuperscript{88} A plant variety is eligible for protection under the UPOV Convention only if it is new, distinct from existing varieties, homogenous or uniform, and stable.\textsuperscript{89} If a newly discovered plant variety meets these requirements, it is listed in an international register so that others will know that the plant variety is protected.\textsuperscript{90} Once the plant is protected, others wishing to market the plant commercially must obtain prior authorization from the breeder.\textsuperscript{91} In 1991, the UPOV Convention was amended to permit scientific research on protected plant varieties as long as the research is not used for commercial exploitation.\textsuperscript{92} Finally, the UPOV Convention contains a compulsory license provision which allows licenses to be granted where necessary to protect the public interest.\textsuperscript{93}

A similar system to protect newly discovered viral strains, including strains of H5N1 or H1N1, could in theory provide developing countries like Indonesia with enough of an incentive to share viral samples with the WHO. The requirements of novelty and distinctiveness could be adopted to protect certain viral strains. However, under such a system, many newly discovered strains of H5N1 might not qualify for protection. H5N1 avian influenza, like many other viruses, has the ability to rapidly mutate and might not be able to fulfill the stability or homogeneity requirements. In the event that a unique viral strain does meet the requirements for intellectual property protection, research and compulsory license exceptions should be included in the governing provisions of the program. Such a system would likely be beneficial in the context of H5N1 avian influenza because developing nations that provide samples of viruses used to produce a commercially marketable vaccine would receive compensation for their contributions, and scientists would be allowed to conduct research on evolving H5N1 strains in order to effectively monitor for signs of a pandemic. Further, in the event of a pandemic, global health should take priority over intellectual property rights, and compulsory licenses should be issued in order to protect global health.

However, there are several drawbacks to adopting such a system. First, assuming that it is even possible, a form of intellectual property protection for newly discovered viral strains would result in a complex regulatory scheme
due to the amount of new strains that are constantly emerging. Such a regulatory scheme is bound to be inefficient, which would likely deter vaccine manufacturers from making life-saving vaccines. Specifically, if pharmaceutical companies were required to pay a fee to license viral strains from the WHO, the costs of vaccines would increase. Naturally, manufacturers would pass along the increase to vaccine purchasers in the form of higher prices. As a result of the increase in prices, it would likely be even more difficult for developing countries to afford to purchase vaccines to protect their citizens from pandemic diseases. Finally, an increased number of disputes would likely arise between two or more countries that discover similar strains of H5N1, creating the potential for increased international litigation and unnecessary friction between competing countries. It appears that because the costs of some form of intellectual property protection for newly discovered viruses outweighs the benefits, a better course of action is for the WHO to utilize a different form of positive economic incentives to foster compliance with the International Health Regulations.

2. Monetary Payments

Another way the WHO could prevent countries such as Indonesia from withholding viral samples of newly discovered diseases would be to make direct payments to member states for sharing the samples with the international community. Not only would direct monetary payments provide a strong incentive for member states to meet their obligations to the international community, but such a system would offer other benefits as well. First, a system of monetary rewards would provide much-needed funding for improving the basic healthcare systems of developing nations. This type of system is desirable because the well-being of the world’s unhealthiest people will be improved with an increased investment in the health infrastructure of developing nations.

Second, providing monetary incentives to member states for sharing samples with the WHO addresses the concern of developing nations, such as Indonesia, that feel it is unfair to give up their samples and receive nothing in return. Through a system of monetary compensation for access to samples of newly discovered diseases, member states would actually receive something tangible in return for their compliance efforts. Member states could then use these payments to fund other development areas, including healthcare infrastructure advancements.
However, one can easily imagine problems that might occur if the WHO were to pay developing nations for access to samples of unique viral strains. One of the first problems that would need to be resolved would be determining who would fund such a system, and how much each country should contribute. One may assume that the burden would fall on wealthy, developed nations because they presumably have the most money to spend on pandemic preparedness measures. However, given the severe downturn in the global economy, many developed nations may not see the benefits of establishing and contributing to such a pay-for-performance system when there may be more pressing matters at hand. It would likely be easier to convince developed nations to fund such a program if they were to receive guarantees that their contributions would be spent on healthcare infrastructure in developing nations. However, it might be difficult to ensure funds given to developing nations would actually be used to improve healthcare rather than for other purposes.

Secondly, even if a payment system were established, it would likely be a formidable challenge to determine which member states are eligible to receive funds and how much they would be entitled to receive for their compliance efforts. With finite resources, the WHO may be put in the awkward position of determining which samples are worth “buying” and which ones are not. Furthermore, it would likely be difficult to determine how much compensation to provide member states for sharing samples of diseases. Thus, a pay-for-performance system that provides direct funding for access to samples of newly discovered diseases may lead to allegations by some member states of arbitrariness and favoritism in the WHO. Also, such a system might become susceptible to manipulation by rogue states or terrorist groups who could use samples of deadly pathogens to extort money from the WHO by threatening to use them in acts of biological terrorism.

Furthermore, in order to motivate member states, the monetary incentives would have to be significant; thus, the WHO would have to be prepared to pay a substantial amount for access to newly discovered viral samples. Since such a proposal is not likely to be embraced by a majority of member states, the WHO should look to other forms of economic incentives to induce member states to comply with the International Health Regulations.
3. Share of Profits

Because intellectual property protection for newly discovered H5N1 strains may be too radical of an idea for many developed member states to accept and a pay-for-performance framework may prove to be unworkable, perhaps developing nations should only be entitled to a share of profits derived from vaccine sales. In contrast to previously mentioned incentives, private pharmaceutical companies, rather than the WHO, would be responsible for paying member states for access to their samples. Such a system would directly compensate developing member states for their contributions to the international viral sharing program without placing too much of a burden on the WHO. Since the source of funding would come from the private sector rather than from the public sector, developed nations would be more likely to embrace such a proposal.

Although most member states would likely support such a proposal, there are several problems that must be addressed. First, many vaccine manufacturers would likely oppose this type of incentive. Pharmaceutical companies are already reluctant to manufacture H5N1 vaccines due to high investment costs, limited markets, and complex regulatory requirements. Pharmaceutical companies may argue by merely providing samples of viral strains, developing nations do not contribute very much to the development of the end product and should not be entitled to any profits made from vaccine sales. Developing countries, on the other hand, are likely to argue that other industries routinely pay royalties to those who help in the development of a final product and that vaccine development should be no different. In response, the pharmaceutical industry may assert that in this context, manufacturers bear all the risks of developing a particular vaccine, and therefore, should be entitled to all of the rewards.

A second problem with requiring pharmaceutical companies to pay countries a share of profits derived from vaccine sales is that such a system might encourage member states to follow Indonesia's lead and bypass the WHO altogether. Instead of turning their samples over to a centralized

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94 However, the World Health Organization would still have to ensure that the pharmaceutical companies met their obligations to member states. Therefore, some type of regulatory committee would have to be established to monitor the activities of vaccine manufacturers.

95 Silver, supra note 34, at 250–51.
international body, a member state may choose to enter into direct negotiations with vaccine manufacturers, particularly if the private pharmaceutical industry is willing to pay a premium for access to samples of a particular disease. Such an arrangement would undermine the authority of the WHO and would lead to considerable disruption of the international framework for combating the spread of disease; there would no longer be a centralized comprehensive international repository of infectious disease samples. Thus, implementing this type of incentive is also not the best solution.

4. Equitable Access to Vaccines

Rather than enacting a profit-sharing incentive system, the best way to ensure developing member states will continue to provide viral samples to the WHO is to ensure that member states receive an equitable share of any vaccines developed from such samples. In addition to being the least controversial way to provide meaningful incentives for developing nations, this solution provides multiple benefits. For example, equitable access to vaccines is of primary importance to developing countries. Developing countries, such as Indonesia, are more likely to share samples of newly discovered viruses with the global scientific community if they believe the allocation of vaccines developed from those samples will be fair.

However, like any type of incentive system, there are downsides to providing developing nations with equitable access to vaccines. First, determining exactly what constitutes an “equitable” distribution of vaccinations could cause considerable disagreement. The WHO would have to choose between establishing a bright-line rule and determining what is “equitable” on a case-by-case basis. A bright-line rule might be preferable because it would provide member states with advanced notice of how many doses of a particular vaccine they could expect to receive in return for sharing samples with the WHO. Additionally, a bright-line rule would likely reduce claims of favoritism or arbitrariness from member states. However, the WHO might encounter problems when rationing the vaccines because often there are

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96 As a condition to allowing vaccine manufacturers to have access to viral samples obtained from member states, the WHO could insist as part of its contractual agreements with pharmaceutical companies that the companies sell a certain amount of vaccines back to the WHO at a reduced price. The WHO could then sell the vaccine to the appropriate developing countries at the same reduced cost.
not enough doses of a particular vaccine to inoculate everyone who needs it.\textsuperscript{97} As a result, developed countries might object to such a system if they fear that they will not be able to purchase enough vaccines to protect their citizens. However, if the WHO was able to convince developed nations that one of the best ways to stop the spread of infectious diseases that originate in developing countries is to contain them at the source, developed countries might agree to grant developing nations greater access to certain vaccines. Since the benefits of an equitable distribution of vaccines appear to substantially outweigh the arguments against such a system, the WHO should grant developing nations that contribute viral samples equitable access to vaccines in the event of an infectious disease outbreak.

V. CONCLUSION

By taking an in-depth look at the stand-off that occurred between Indonesia and the WHO in 2007, this Note has sought to critically evaluate the World Health Organization’s current viral sharing program. While Indonesia’s actions may not have been contrary to its obligations under the current International Health Regulations, by withholding samples of H5N1, Indonesia increased the risk that scientists would not be able to develop an effective and timely vaccine to respond to an avian influenza pandemic. Thus, to prevent developing countries from following Indonesia’s lead and entering into private arrangements with vaccine manufacturers, the WHO must take action immediately.

To prevent member states from asserting “viral sovereignty” over newly discovered diseases, the WHO should amend the International Health Regulations so that member states can no longer rely on ambiguity to justify their actions. However, due to the weak governance structure of the WHO, this may not be enough to discourage other countries from acting in a similar manner.

To effectively prevent member states from asserting “viral sovereignty,” the WHO must also provide incentives for member states to share samples of newly discovered viruses with the international community. Disincentives will not be as effective as positive incentives because of detection problems and the

\textsuperscript{97} See, \textit{e.g.}, Centers for Disease Control and Prevention, Current Vaccine Shortages & Delays, \url{http://www.cdc.gov/vaccines/vac-gen/Shortages/default.htm} (last visited June 20, 2010) (charting vaccination shortages in the United States).
risk that developing member states could refuse to pay fines if sanctioned. Thus, the WHO should offer incentives to reward member states for sharing samples with the global community. Although the WHO could possibly provide member states with some form of intellectual property protection for strains of unique viruses discovered within their borders, this solution is unworkable with regard to avian influenza because the virus has the potential to mutate rapidly.

Another option is that in exchange for access to viral samples, the WHO could either make direct monetary payments to member states or ensure that pharmaceutical companies give member states a percentage of profits made from selling vaccines. The former proposal is likely to receive strong resistance from developed nations who may be unwilling to pay member states for access to newly discovered samples. On the other hand, pharmaceutical companies are likely to strongly oppose the latter proposal and may be deterred from developing vaccines altogether.

Thus, the WHO should ensure that developing nations that contribute samples have equitable access to vaccines derived from those samples. Such a proposal is the least controversial and furthers the WHO’s underlying mission of improving health around the world. Unless the WHO provides member states with equitable access to vaccines, developing member states, such as Indonesia, may be tempted to withhold viral samples of newly discovered diseases, jeopardizing the health of the global community.

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98 See WORLD HEALTH ORGANIZATION, CONSTITUTION OF THE WORLD HEALTH ORGANIZATION, at art. 1 (2006), available at http://www.who.int/governance/eb/who_constitution_en.pdf (stating the WHO’s goal “shall be the attainment by all peoples of the highest possible level of health”).