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Citation Details

Smallman, S. (2013). Biopiracy and vaccines: Indonesia and the World Health Organization's new Pandemic Influenza Plan. *Journal Of International & Global Studies*, 4(2), 20-36.

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Biopiracy and vaccines: Indonesia and the World Health Organization's new Pandemic Influenza Plan

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Abstract

Viral samples of avian influenza are essential to preparing pre-pandemic vaccines. In 2007, the conflicting interests of the developed and developing nations led Indonesia to briefly stop sharing viral samples. The result was a struggle in which the two blocs argued for different paradigms for viral sample sharing. The first paradigm, articulated by the developed world, depicted the issue as one of health security, in which international law mandated the sharing of viral samples. The second paradigm, advanced by the developing world, depicted viral sample sharing as a form of biopiracy, which violated countries' sovereign control of their biological resources. Ultimately, the second paradigm proved more politically effective, enabling developing nations to achieve many of their goals through the WHO's 2011 pandemic influenza plan. This paper examines how this plan was shaped by Indonesia's argument that the global public good required a new approach to global health governance, in order to eliminate neocolonial power relationships.

Acknowledgements

I wish to acknowledge the feedback received from my colleagues at the Influenza 2012 conference at Oxford University, as well as from Professor Birol Yesilada. Hamrawit Gebretsadik, Peter Pham, and Brittany Smith all carried out invaluable research for this project.

Introduction

Influenza poses some nearly unique issues in global health governance. The global community is haunted by the memory of 1918, when perhaps as many as 100 million people died during a major influenza pandemic. Despite the continued circulation of highly pathogenic avian influenza (HPAI), particularly in South-East Asia and Egypt, the virus directly affects only small numbers of people today. For this reason, influenza lacks the patient advocacy organizations that are a critical aspect of health policy for illnesses such as HIV/AIDS. Accordingly, the most important actors in influenza policy are often not patient groups but rather states, which collaborate with pharmaceutical organizations and international organizations such as the World Health Organization (WHO). However, the national interests of the developing and the developed nations do not always coincide, particularly with regard to the issue of viral sample sharing for pre-pandemic vaccines. Accordingly, the two blocs view this issue in terms of competing paradigms. For developed countries, international law requires developing countries to share samples in order to support global health security (Elbe, 2010, pp. 476-477; Franklin, 2009, pp. 355-372). For developing countries, viral sample sharing has at times been perceived as a form of biopiracy, which maintains neocolonial relationships and ensures the dependency of developing countries upon the developed world. This issue came to a head in 2007, when Indonesia briefly stopped sharing viral samples of influenza strains with the World Health Organization. This paper will consider the competing views of the developed and developing world during this standoff, and how the World Health Organization has sought to resolve the differences with its Pandemic Influenza Plan of 2011. In the end, the developing world won a limited victory, in part because biopiracy proved to be a more effective tool to frame the issue politically than did international law and security.

Influenza and Vaccines

The influenza virus is a very contagious agent that infects many animals, in which it can cause diverse symptoms, as well as humans, for whom it is mainly a respiratory disease. Because it is a highly mutagenic virus, periodic pandemics sweep the globe, of which the most devastating in modern history occurred in 1918 (Barry, 2005). As Alfred Crosby and Arno Karlen have argued, one of the most unusual aspects of the influenza pandemic was that for a time, it was largely forgotten amongst the general population (Crosby, 1990; Karlen, 1995, p. 145). Global health authorities, however, always remained aware of the dangers that influenza poses. In 1997, an outbreak of HPAI in Hong Kong sickened eighteen people and killed six. The government killed more than a million chickens in a few days, which stamped out the outbreak (Davis, 2005, pp. 45-54). In 2003 and 2004, bird flu again appeared in South East Asia, particularly in Vietnam, and it has since spread to countries as geographically distant as Turkey and Indonesia. While H5N1 receives the most media coverage, other strains of the virus also pose a threat. For example, in February 2004, an outbreak of a different strain of HPAI in the Fraser Valley of British Columbia caused the Canadian Food Inspection Agency to order the destruction of nearly twenty million chickens (Davis, 2005, pp. 94-95). Then, in 2009, a new form of influenza, novel H1N1 (the so-called swine flu) emerged in Mexico. While this form of the virus did not prove to have a high mortality, the outbreak led to intense planning by global health authorities as well as widespread media coverage.

As is well known, the current vaccine system for influenza suffers from multiple weaknesses (Osterholm, Kelly, Sommer, & Belangia, 2012; Youde, 2008, p. 151). The flu virus mutates rapidly, and there are many different strains, each characterized by different proteins in their outer shell. Every year, scientists scour the planet looking for different forms of the virus. They then guess which forms will likely dominate epidemics in the coming winter (for each hemisphere). They come to a consensus on three different forms. It then takes months to grow the virus in chicken eggs. One challenge is that vaccine designers sometimes guess incorrectly, and a virus strain that is not covered by that year's vaccine will circulate widely. Another risk is that a novel form of the virus will appear for which the vaccine developers are completely unprepared.

The current vaccine technology has other limitations, including its reliance upon millions of chicken eggs, which could be difficult to obtain if an avian influenza pandemic wiped out chicken farms. Contamination can also be a challenge, as proved the case in October 2004, when a plant owned by Chiron in the United Kingdom produced a vaccine contaminated by a bacteria. This one failure meant that the US health system lost tens of millions of expected doses of vaccine (Davis, 2005, 140-144). The US media asked how the country could deal with pandemic flu if it could not guarantee a vaccine supply in a normal year. For this reason, as well as to shorten the time required for vaccine preparation there is currently a major effort to create new vaccine technologies. Pharmaceutical companies are also seeking to create pre-pandemic vaccines based on viral samples from the wild in order to shorten the time needed for the preparation of a vaccine in case of a pandemic. In addition, nations are stockpiling or signing advance contracts for one of the four drugs currently used to treat influenza (Yamada, 2009; Elbe, 2010, p. 480; Vezzani, 2010, p. 681).

Even before the 2009 pandemic, efforts to fight the flu raised key moral questions. European and North American governments collectively spent billions of dollars stockpiling medications, testing vaccines, and encouraging basic research on the flu, while developing nations struggling to contain avian influenza found comparatively little aid forthcoming for tasks such as culling infected flocks. With the emergence of H1N1, developed countries re-activated pre-existing contracts with major vaccine manufacturers in order to give their countries first access to the vaccines produced. The manufacturers would not take orders from poorer but more populous countries because the manufacturers lacked the capacity to fill such orders. As Marcel Verweij (2009, pp. 207-209) has noted, nations such as Australia, Canada, and the Netherlands were able to receive vaccine, and the WHO could only ask these nations to share excess vaccine with developing countries. Nations such as Mexico resented being unable to access needed vaccines and medicines in a timely fashion. For some nations affected by HPAI (such as Cambodia, Indonesia, and Vietnam), it was difficult not to conclude that they were living in a "sacrifice zone," from which viral samples were extracted while the needs of the population were ignored. Because wealthy countries dominated the global infrastructure of vaccine factories, laboratories, and pharmaceutical companies, research did not necessarily protect much of the world's population from influenza. Rather, from the perspective of front-line states, the global health system maintained their dependence on wealthy countries, which first secured the needs of its peoples, keeping the governments of poorer states as supplicants. As such, the global health system embodied neocolonial relationships.

Indonesia

Inevitably, developing nations proved reluctant to collaborate with First World nations to develop pre-pandemic vaccines because it appeared unlikely that developing nations would benefit from such cooperation. In 2007, this issue came to a head when Indonesia learned that the World Health Organization had shared a viral sample collected in Indonesia with a pharmaceutical company, which had then modified and patented the virus. The company allegedly then offered to sell the vaccine to Indonesia for protection against the strain of virus circulating in that country (Franklin, 2009, p. 356; Stephenson, 2011, p. 623; Vezzani, 2010, pp. 677-678). This was not the only such case in which genetic sequences from viral samples collected in Indonesia and other countries such as Vietnam (Vezzani, 2010, 677) were used by pharmaceutical companies, but it added to mounting Indonesian frustration with obstacles to their nation's pandemic preparedness planning. For example, as early as 2005, Indonesia's health minister had found that she could not purchase Tamiflu because Western countries were allegedly stockpiling all production (Elbe, 2010, pp. 480-481). In response to this final incident, Indonesian health authorities decided to stop sharing viral samples with the WHO and to make proprietary arrangements to exchange viral samples for vaccine from a pharmaceutical company directly:

In January, frustrated that an Indonesian strain of the virus had been used to make a vaccine that most Indonesians would not be able to afford, the country stopped cooperating with the WHO and made a deal to send samples to Baxter Healthcare, an American company, in return for a low-cost vaccine and help in building vaccine factories in Indonesia. Some other poor countries applauded the move and debated whether to follow suit, a move that could have set back global vaccine research. Yesterday, Indonesia's health minister, Siti Fadilah Supari, told reporters in Jakarta that she would resume sending samples to the WHO "immediately." (McNeil, 2007, p. 2)

This resolution proved ephemeral, however, and Indonesia continued to insist on more sweeping changes to the global health order. In response, developed countries and the World Health Organization tried to point to international law and, in particular, the International Health Regulations. From Indonesia's perspective, the existing system did not address their concerns or national interests. Based on Indonesian interpretation of international law, the country was willing to share the virus samples only with parties that agreed to sign Material Transfer Agreements (Fidler, 2007; see Mullis, 2009, pp. 947-948; Stephenson, 2011, p. 623; Franklin, 2009, p. 357). Indonesian officials and bureaucrats pointed out that the International Health Regulations, which were revised in 2005, did not specifically state that nations had to share biological samples (Seyaningsih, Isfandari, Soendor, & Supari, 2008, p. 484; Franklin, 2009, pp. 362-363).

As Harley Feldbaum and Joshua Michaud have argued (2010), developing countries believed that the 2005 revisions of the International Health Regulations were undertaken so as to reflect the interests of the most powerful countries:

[T]he IHR were adopted because they served powerful state interests, and, accordingly, some developing countries view the IHR as an instrument of the foreign policy and national security interests of developed countries seeking protection from epidemics emanating abroad, and, therefore, as only an extension of age-old power politics. (p. 7)

In short, there remain substantial concerns within the developing world regarding both the overall structure of global health governance and the independence of the World Health Organization from the pharmaceutical companies (Cohen & Carter, 2010, p. 2912).

Indonesia and other developing countries argued that legally, pharmaceutical companies could not develop vaccines using seed stocks from developing countries without the countries' permission:

The fact that pharmaceutical companies had access to Indonesian [vaccine seed] viruses that were shared with the WHO affiliated laboratories was not only in violation [again] of the WHO guidance for virus sharing (March 2005), but [it] also—as strongly argued by Indonesia—revealed the unfairness and inequities of the global system. (Sedyaningsih, et al., 2008, p. 486)

In February 2007, the WHO sent representatives to Indonesia, which had agreed in March to resume sharing samples on a provisional basis. By May of 2007, a working group was formed to begin studying this problem (Sedyaningsih, et al., 2008, p. 486; Franklin, 2009, pp. 358-359). Still, this work had yet to overcome widely divergent interpretations of the problem in developing countries and the developed world.

Biopiracy and Viral Sovereignty

Many developing countries supported Indonesia's position. From the perspective of these countries, the WHO was not a disinterested party. Journalist Edward Hammond (2009) captured their viewpoint, asking:

How did it come to pass that the WHO's global surveillance system acts as a free virus collection and R&D department for the world's largest vaccine companies, with familiar names such as Sanofi-Pasteur, Novartis, and Astra-Zeneca, yet give very little benefit to developing countries?

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 (Hammond, 2009). From the developing countries' perspective, this was a case of biopiracy, little different from Henry Wickham's stealing rubber seedlings in Brazil for Britain in the late nineteenth century, which led to the end of Brazil's rubber boom, or Richard Spruce's successful collection of the seeds of the cinchona tree, which ended the Andean monopoly on quinine.

For people in developing countries, this was an emotional issue. After the US patent office gave a patent for turmeric to researchers at the University of Mississippi Medical Center in 2005, the Indian government had to fight to prove that Indians had long been aware of the medical benefits of turmeric. They succeeded after a decade long legal battle (Philip, 2010, p. 250). With intellectual property law permitting the patenting of life forms, people in developing countries now feared that the Trade Related Aspects of Intellectual Property (TRIPS) clause of the World Trade Organization (WTO) could be used to enforce companies' claims over viruses originally collected from developing nations. But could viruses be thought of as resources in the same manner as plants? If so, could a pathogen be considered an aspect of biodiversity under the Convention on Biological Diversity or CBD (Mullis, 2009, p. 955; Fidler, 2008, pp. 88-94; Caplan & Curry, 2007, pp. 1-2)? In this case, developing countries could argue that the Rio de Janeiro Convention on Biological Diversity (CBD) covered the genetic sequences of

viruses collected in their countries so that viruses were sovereign property (Vezzani, 2010, p. 678).

In order to justify her position, Indonesian Minister of Health, Supari created a new doctrine, which she labeled “viral sovereignty.” In this paradigm, viruses formed part of the biological patrimony of the nations in which they were found, which held exclusive rights to them. This idea attracted support amongst developing countries, such as India, in part because this argument strengthened the developing countries’ position relative to the pharmaceutical companies that provided vaccines. Other front-line states also adopted the Indonesian position. Thailand raised similar issues at WHO’s Executive Board meeting in January 2007, and its representative argued:

We are sending our virus [samples] to the rich countries to produce antivirals and vaccines. And when the pandemic occurs, they survive and we die. . . . We are not opposed to sharing of information and virus [samples, but we will share them] on the condition that every country will have equal opportunity to get access to vaccine and antivirals if such a pandemic occurs. (Fidler, 2007)

Thailand’s position was also voiced by other developing countries, including those nations not directly impacted by HPAI such as Brazil, Iran, Libya, and Nigeria (Franklin, 2009, pp. 366, 369-370; Vezzani, 2010, p. 678).

Intellectual property scholars such as Simone Vezzani (2010, pp. 678-679) have argued against Supari’s position because the original intent of the CBD treaty was to protect indigenous knowledge and encourage the conservation of nature. In this context, the interpretation of the treaty to include the preservation of viruses is problematic, he says, because viruses only become truly alive as part of human biology. Developed countries could therefore argue that the concept of “viral sovereignty” represented a misinterpretation of the CBD’s intent. The debates that took place over limiting the transfer of plant genetic resources now shaped those that took place regarding viral sample sharing, despite significant differences in their political context (Vezzani, 2010, p. 685). Still, the concept of “viral sovereignty” represented a useful tool for developing countries to argue that for the global public good, there had to be a balance between the demand for viral samples on the part of developed countries and the need for more of the benefits of the vaccine created from those samples in the poorer nations most affected by HPAI.

In May of 2007, Indonesia raised questions pertaining to this conundrum at a meeting of the World Health Assembly (Vezzani, 2010, p. 670). During this meeting, developing countries launched a critique of how the World Health Organization had shared viral seed stock samples:

In the course of these deliberations, it emerged that WHO had not abided by the terms of the 2005 WHO guidelines on sharing of viruses, which required the consent of donor countries before WHO’s collaborating centers could pass on the viruses (other than the vaccine strains) to third parties such as vaccine manufacturers. While discouraging the use of material transfer agreements (MTAs) at the point when donor countries transferred their virus samples to the WHO, WHO’s collaborating centers nonetheless resorted to MTAs when they transferred to third parties’ vaccine strains containing parts of the viruses supplied by developing countries such as Indonesia, Vietnam and China. Indeed, WHO’s collaborating centers themselves, as well as third parties, had sought patents covering parts of the source viruses used in developing vaccines and diagnostics. (Khoon, 2010)

Perhaps because of these revelations, twenty developing countries entered a resolution to the World Health Assembly “calling for a new international framework to be set up for the sharing of avian influenza viruses, to review the existing WHO research system, and to prioritize the manufacture and availability of vaccines in developing countries” (Khor, 2007). The resolution stated that any “vaccines, diagnostics, anti-virals, and other medical supplies arising from the use of the virus and parts thereof must be made available at an affordable price and in a timely manner to the developing countries, particularly to those under the most serious threat or already experiencing the pandemic threat” (Khor, 2007).

This resolution was opposed by the United States, which was particularly concerned that changes to the Material Transfer Agreements (which governed viral seed stock sharing) might undermine global collaboration to produce vaccines against pandemic strains of the vaccine. In the end, the World Health Assembly passed a resolution calling on the WHO to create a vaccine stockpile, as well as new rules regarding influenza virus sample sharing (Khoon, 2010; Fidler, 2008). Based on this vote, Indonesia returned to sharing viral samples with the WHO, as part of the Global Influenza Surveillance Network (GISN) (Irwin, 2010).

Indonesia continued to successfully push its position at a series of international forums over the coming months:

A hastily organized WHO consultation in Singapore began on 31 July 2007, only weeks after the WHA. Although the Singapore meeting was privately described by one WHO official as an attempt to “ambush” the Indonesian negotiator, the ambush backfired when Indonesia tabled a detailed proposal to restructure the WHO system, including material transfer agreements, improved access to vaccines, and new terms of reference to govern the relationships between the WHO, GISN labs, industry and developing countries. (Hammond, 2009)

By the end of the year, the US was reconsidering its opposition to material transfer agreements, while the WHO had decided to undertake a sustained effort to address the issue.

At first, the developed countries had tried to advance their position based not only on international law but also upon the argument that health was a security issue, as Stefan Elbe (2010) has argued. As Elbe noted, however, there were costs to this argument. Indonesians bitterly resented the accusation that they or their actions had undermined the security interests of the US and other developed countries. In return, US government officials publically denounced Indonesia’s position, and articles in the popular media reflected the perspective that Indonesia’s actions posed a security threat. For example, public health journalist Laurie Garrett and Richard Holbroke published an article in the *Washington Post* to denounce the notion of viral sovereignty, which they argued would undermine the kind of global cooperation required to face the next influenza pandemic. The authors called on China to use its influence with Indonesia and for the United States to exercise “muscular diplomacy.” Indonesia perceived itself to be isolated for challenging the hegemony of the powers that kept it vulnerable and was angered by the intensity of the attacks it faced from the US. Stefan Elbe (2010) has made the argument that it was precisely because avian flu was increasingly viewed in terms of security that the standoff between the West and Indonesia became so severe.

From the US perspective, the costs of this confrontation with Indonesia became excessive. In particular, the Department of Defense maintained a Naval Medical Research unit (NAMRU 2) in Jakarta, which became caught up in the standoff. The Indonesians were increasingly reluctant to renew the agreement that would enable this research center to continue operating. Indonesia’s

health minister made inflammatory comments about both the center and the developed countries, which she suggested might be creating biological weapons out of this research, even though the US had joined the Biological Weapons Convention in 1975. These comments caused a media firestorm when she published her book, *Time for the World to Change: God is Behind the Avian Influenza Virus*. Supari may have been surprised by the attention the work attracted, as “the English translation of the book was officially withdrawn by her (due to what she claims were inaccuracies in translation)” (Elbe 2010, p. 480). Many people within Indonesia were critical of Supari's comments (Foster, 2009, pp. 46-49). Even outside of Indonesia, however, there were suspicions regarding US biodefense activities, of which it was said that “...if a nation were planning to use biological weapons, this is exactly the course they would follow: developing vaccines or other prophylactic treatments to protect their own troops” (King, 2010, p. 404; Elbe, 2010, p. 482). It has also been suggested that Supari's real concern may have been that the facility in question would share viral samples with US government agencies, which would have undermined Indonesia's bargaining position both with the WHO and with the developed world. The larger issue remained after Supari ended her term as Minister of Health. The Indonesians were reluctant to give NAMRU 2's employees diplomatic immunity, as the US requested, while government officials were angered that a former NAMRU employee had harshly critiqued their response to the avian influenza threat. In the end, in 2008 the center closed, only to reopen with a new name (Indonesia-United States Center for Medical Research, or IUC) as a non-military center. Indonesia's new Health Minister, Endang Rahayu Sedyaningsih, said NAMRU 2's character as a military unit made its continued operation impossible (Maulia, 2009; Normile, 2008, pp. 598-599). For the US, the costs of the confrontation had both been high and had illustrated the risks of framing health issues in security terms.

The Role of the World Health Organization

From the start of the crisis, people had looked to the WHO to broker an agreement. For example, in February 2007, the medical journal *The Lancet* published an editorial in response to Indonesia's declaration, which said that the WHO needed to achieve an agreement that would demonstrate solidarity in preparing for the next pandemic (Khoon, 2010). The need for a successful resolution was made clear by the 2009 pandemic. During the crisis, poor nations could not access vaccines:

Despite appeals to humanitarian solidarity and to enlightened self-interest, almost all of the first billion doses of H1N1 vaccine produced in 2009 were allotted to 12 wealthy nations which had made advance orders. Sanofi Pasteur and GlaxoSmithKline pledged 120 million doses to the WHO for distribution to poor countries, but even those pledges could be fulfilled only months after the pandemic had waned. (Khoon, 2010)

In response, health journalist Laurie Garrett warned that events seemed to be proving Supari's fears to be correct (Khoon, 2010). Even while the epidemic waned, developing countries remained uncertain whether they might receive unused vaccine from wealthy countries (Verweij, 2009, pp. 207-209).

Expectations were low for a breakthrough. Most observers agreed that the reason that global health governance had not changed was because the status quo favored the interests of the most powerful nation-states (Fidler, 2010). Indonesian authors emphasized this point:

Poor countries have no bargaining position because their participation in the production of these products is not valued as they are “just” natural resources (clinical specimens, viruses, and other microbes); on the other hand, the industrialized countries’ contributions are highly valued because they are human invented technology. (Sedyaningsih et al., 2008, p. 487)

Nonetheless, an agreement was reached, which represented a bargain to reconcile the needs of the developed and developing world.

The Pandemic Influenza Plan, PIP

Four years of negotiations came to a head in April 2011, when a working group of member states agreed upon a framework that provided clear rules for the sharing of virus samples in exchange for benefit sharing. The committee itself had been chaired by the Ambassadors of Mexico and Norway and had included WHO member states, industry groups, and civic organizations. The framework (resolution WHA64.5) was then brought to the World Health Assembly on May 24 2011, where the member states voted to adopt it (WHO News Release, 2011). At its core, the agreement sought to ensure that the WHO could continue to collect and distribute viral samples to the developed world and pharmaceutical companies in exchange for providing more benefits (such as vaccines and medicines) to developing countries (WHO, “Benefit Sharing,” n.d.). But in the end, what was absent from the agreement was as interesting as what was present. An earlier suggestion to create a major endowment to ensure benefit sharing disappeared from the final report.

In April, the working group of member states on Pandemic Influenza Preparedness (PIP) had produced a report entitled “Pandemic Influenza Preparedness: options for sustainable financing of benefit sharing.” The goal of the document was to examine how to ensure the availability of funds that developing countries would need to obtain vaccines. It laid out the five year costs for pandemic influenza preparedness activities, such as disease based surveillance, laboratory strengthening, new WHO collaborating centers, increased demand for seasonal influenza vaccines in developing countries, augmenting vaccine production in developing countries, changing vaccine technology, the use of new adjuvants, and creating stocks of both vaccines and medicines. The total cost was approximately \$1.121 billion in US dollars. While significant, this was much less than the costs in the event of a pandemic, which were estimated at \$2.98 billion to cover the cost of deploying 276 million courses of vaccine, which represented “5.5% of [the] population in countries without access” to vaccine as well as the cost of providing anti-retrovirals for 66 million people or “2.25% of [the] population of countries without access [to them]” (Open Ended Working Group, 2011, pp. 7-8).

This represented a substantial investment and would have been a major step towards providing access to needed care in the developing world in the event of a pandemic. To fund this, the report suggested the creation of a PIP endowment. In addition, the report suggested that countries “could access bilateral funding through the International Monetary Fund Special Drawing Rights, similar prearranged International Monetary Fund support mechanisms, and World Bank [programs] . . . at the time of a pandemic event” (Open Ended Working Group, 2011, p. 12). The objective of the endowment was to provide stable and predictable funding to meet long term needs for pandemic preparedness. Amongst other funding mechanisms, the PIP endowment would have relied on a subscription fee to the Global Influenza Surveillance Network and in-kind contributions from industries. Companies would have contributed a

percentage of sales of vaccines to the PIP endowment in exchange for access to “candidate viruses” for vaccines (Open Ended Working Group, 2011, pp. 13-15). The result would have been a substantial fund to address the needs of developing countries in a pandemic. However, this portion of the proposal this formed no part of the final draft of the WHO report in 2011.

The final report stated instead that influenza “vaccine, diagnostic, and pharmaceutical manufacturers using the WHO GIRSRS will make an annual partnership contribution to WHO for improving global pandemic influenza preparedness and response. It was decided that the sum of the annual contributions shall be equivalent to 50% of the running costs of the WHO GIRSRS” (WHO, 2011, p. 21). This was equivalent to a figure of \$28.5 million US, a significant figure, though far less than the sum suggested in the original draft of the report, as was the scale of the benefits. Still, developing countries did get numerous concessions that were critical to their interests. The report recognized “the sovereign right of States over their biological resources. . .” (WHO, 2011, p. 4). It also created an oversight system to allow developing countries to track the viral samples that they had donated through the Influenza Virus Traceability Mechanism:

The IVTM is an electronic, internet based system that records the movement of PIP biological materials into, within, and to parties outside the WHO GIRSRS. The purpose of the system is to allow users to see where PIP biological materials have been sent. . . . It also enables users to see the results of analyses and tests carried out with them (WHO, “Influenza Virus,” n.d.)

The PIP also created Standard Material Transfer Agreements to cover all biological materials that moved within the WHO GIRSRS. The plan also stated that the WHO would help build stockpiles of anti-virals and vaccines for developing countries. This stockpile was to include 150 million doses of vaccine, with 50 million doses set aside for the location where the outbreak began, and 100 million for developing nations (WHO, 2011, p. 19). The key to creating this stockpile and other forms of benefit sharing was the Standard Material Transfer Agreement 2. This document governed viral samples transferred outside the GISRS. These terms merit quoting at length because they were central to the WHO's plan:

For manufacturers of vaccines and/or anti-virals, the recipient shall commit to at least two of the following options:

- A1. Donate at least 10% of real time pandemic vaccine production to WHO.
- A2. Reserve at least 10% of real time pandemic vaccine production at affordable prices to WHO.
- A3. Donate at least X treatment courses of needed antiviral medicine for the pandemic to WHO.
- A4. Reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices.
- A5. Grant licenses to manufacturers in developing countries on mutually agreed terms that should be fair and reasonable including in respect to affordable royalties, taking into account development levels in the country of end use of the products, on technology, know-how, products and processes for which it holds IPR for the production of (i) influenza vaccines (ii) antivirals and/or (iii) diagnostics.
- A6. Grant royalty-free licences to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licences on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants,

anti-virals products and diagnostics needed in a pandemic. The WHO may sublicense these licences to manufacturers in developing countries on appropriate terms and conditions and in accordance with sound public health principles. (WHO, 2011, p. 34)

In principle, these requirements gave developing countries access to benefits in return for viral sample sharing and embodied the exchange that Indonesia had first proposed in 2007.

From the perspective of the developed states and pharmaceutical companies, the PIP ensured the continued flow of viral samples. The PIP stated (6.3.1) that the WHO Collecting Centers would give viral samples to “influenza manufacturers on a no preference basis” (WHO, 2011, p. 16). This meant that the developed countries would continue to have access to vaccines as quickly as possible in the event of a pandemic. Significantly, however, these benefits were awarded to developing nations from the pharmaceutical industry rather than from developed nations directly, and the agreement made no mention of key international organizations (such as the World Bank or IMF). To some extent, this was perhaps to be expected, given trends in global health.

The Rise of Transnational Alliances

In the era of globalization, questions of sovereignty and health create new perspectives on international order. Niamh Stephenson (Stephenson, 2011, pp. 616-637) has argued that people look no longer solely to the nation state for “rights and representation” but rather to an array of other transnational actors. Stephenson suggested that the WHO has been a weakening political actor because of decades-long trends in which it has been challenged and underfunded. As the WHO has worked to securitize health in order to respond to international health challenges, new political actors, which she called “aggregates,” have become involved in these affairs. These aggregates are alliances between varying actors—developing countries and NGOs, the World Health Organization, and pharmaceutical companies—that mobilize around an ideology to achieve their health objectives. Stephenson argued that this international order is shaped by neoliberal objectives, in particular the need to ensure the unimpeded flow of trade goods. Accordingly, health security has become equated with unimpeded trade. In this context, Stephenson stated (2011) that nationalist rhetoric, such as that of Supari, has been employed to challenge transnational powers and the neoliberal agenda.

What the Indonesian experience suggests is that in the sphere of global health, nation-states remain significant actors and are able to challenge international organizations and transnational aggregates. From Stephenson’s perspective (2011, p. 622), in 2010, the WHO essentially played a mediating role in order to convene a new set of actors to deal with the challenge Indonesia raised. Simone Vezzani (2010, p. 681), in contrast, argued in 2009 that the Director General’s proposal generally favored the developed countries and pharmaceutical companies. In either case, the WHO did not originally seek to advocate for developing countries in order to balance their health needs with developed countries’ wishes for viral samples. Instead, Indonesia found that it had to fight for its political vision, which it did by framing a narrative around biopiracy. As Stephenson notes, from the start, Indonesia referred to the Convention on Biological Diversity and insisted that there be a comprehensive solution to virus-sharing based on the sharing of benefits (Stephenson, 2011, p. 624). Indonesia’s position focused on more than

bird flu alone. If that had not been the case, the WHO might have been able to address Indonesia's immediate concerns in 2007:

. . . Supari also felt sufficiently emboldened to hold out for more than just a few concessions made by the West and to push for a fundamental transformation of the virus-sharing mechanism. When, for example, she was approached by the WHO with offers of a laboratory upgrade and as much vaccine as they needed in February 2007, she turned these offers down. . . . Rather than simply accepting these offers of material support and resolving the dispute there and then, the Indonesian health minister instead formulated a much stronger demand that made Indonesia's resumption of virus sharing conditional upon a more fundamental reformation of the whole virus sharing mechanism. (Elbe, 2010, p. 482)

Indonesia's position remained consistent after Supari's tenure as Minister of Health because of a widespread consensus within the government that the virus sharing issue entailed broader questions of biopiracy.

As Nicolas Rose (2007, pp. 5-6) has noted, modern medicine has become increasingly focused on the "molecularization" of medical issues (i.e. the focus on life at the molecular level). The debates over viral sample sharing are a classic example of this molecular focus, as the debate takes place about the genetic code of viruses. At the same time, this debate was different from most biopolitics in that it took place at the international level. There were three factors that made this discussion distinctive. First, there were no powerful patient advocacy groups for influenza like those that support most other diseases. Second, the debate was shaped by "bioeconomics," which is the effort to extract value from the molecularization of medicine (Rose, 2007, pp. 31-39). In this instance, pharmaceutical companies were less committed actors than were states not only because the profits to be made from influenza vaccines are lower than the profits to be made from vaccines for other diseases but also because the health of populations in states affected by influenza was of greater central concern to national governments than to the pharmaceutical companies. Third, although "biocapital" is located in developing countries, particularly India (Rose, 2007, p. 36), vaccine manufacturing remains focused in the developed world. This meant that the debate was largely defined in terms of the Global North and South and that nation states were key actors in the debate.

In *Global Health Governance*, Jeremy Youde (2012, pp.158-159) has argued that since the 1980s, there has been a shift from "international health governance" to "global health governance," in which nation-states are not necessarily the critical actors. In the debate over virus sample sharing, pharmaceutical companies were powerful and critical actors, as their commitments funded benefit sharing. At the same time, nation-state actors were essential to this political contest, and they placed the struggle in the context of power relations across the developed/developing divide. Scholars such as Appadurai (1996, p. 19) have predicted over the last twenty years that the nation-state will cease to be the key unit in international affairs. This was not the case in the debate over viral sample sharing, which became enmeshed in larger issues between states, such as the allegedly neocolonial architecture of global health governance.

Neocolonialism and the WHO's credibility

The World Health Organization recognized the power of the biopiracy argument because over most of the four years it took to create the PIP, the organization did not base its arguments upon the law but rather upon the need for benefit sharing (Stephenson, 2011, p. 622). While Indonesia's argument regarding biopiracy and viral sample sharing attracted support in the developing world, it also formed a means to pressure international organizations, by depicting them as neo-imperial instruments. This was particularly important in the case of the WHO, though Stephenson's argument perhaps overstated the World Health Organization's weakness. While the organization had issues of underfunding, it was the only body capable of convening all the actors to address the competing paradigms. Because Indonesia's biopiracy argument also portrayed the WHO as an institution that reflected neo-colonial relationships, it was strongly in the WHO's interests to broker a settlement; that is, the biopiracy argument not only proved more influential than a legal/security framework during negotiations with developed countries, it also pressured the WHO to act in order to maintain its own credibility. With the rising power of the political left in Latin America, Bretton Woods¹ institutions and key international organizations have faced criticism that they act primarily to advance the economic interests of the great states. In this political context, as well as given concerns that an HPAI pandemic could break out at any moment, a comprehensive resolution to the standoff was critical for the WHO. The PIP demonstrated the institution's continued relevance, while protecting it from criticism. With this plan, the WHO could argue that it had balanced the interests of diverse nations, in order to make a proposal that best served the global public good.

Conclusion

The WHO's Pandemic Influenza Plan represented a limited victory for front-line states in the struggle to contain HPAI. There were a number of reasons for their success. Pharmaceutical companies wanted to see an agreement reached and did not oppose incurring some costs in exchange for viral samples. The WHO was able to broker a transnational alliance to address the issue and resolve a classic collective action problem (Olson, 1971) in which each participant would have been worse off following their national interests than if they cooperated. There was also the reality that the developing countries controlled the viral samples, which were a resource that the major powers wished to obtain. Developed countries also did not have to bear the costs for this plan and so had little reason to oppose it. For all of these practical reasons, an agreement was feasible.

At the same time, the creation of the WHO's PIP represented a contest between two narratives around global health that embodied the conflicting interests of the developed and developing world. As Elbe has noted, developed countries applied the language of security to the dispute and sought to justify their position based on international law. This attracted media attention in wealthy countries and, initially, some support from the WHO. But it also meant that military activities in front-line states—such as those conducted at NAMRU 2—were harmed. From this perspective, the securitization of health policy had unexpected costs for the United States, which was both the most powerful political actor and that state that had done the most to securitize influenza (Youde, 2008, pp. 154-158). In contrast, Indonesia's effort to describe the dispute in terms of biopiracy rallied the support of developing countries, particularly the front-line states, whose viral samples were most important to pandemic preparations. For developing

nations, the patenting of traditional plants, as well as the appropriation of indigenous knowledge about their medicinal usage, entailed powerful issues that shaped their perception of the dispute. While the idea of “viral sovereignty” faced scorn in the wealthy countries, it received a sympathetic hearing in Thailand, India, and other developing countries. For Indonesia, the dispute was not only central to national interest, but it was also one of principle, as the country wanted a systemic resolution to viral sample issues. By framing the issue in terms of biopiracy rather than global health inequality, Indonesia suggested that developed countries were actively doing something wrong, instead of passively failing to provide charity. The argument also placed one biological problem (i.e. the spread of disease) in the context of another (the theft of plants and knowledge) in a manner that evoked much broader support. The success of this approach will likely lead developing countries to express similar demands not only in the field of health (such as mandating the sharing of viral sequences for influenza) but also in intellectual property, particularly regarding indigenous rights over medicinal knowledge. In this respect, the benefits-sharing model integral to PIP will be viewed as a likely model for future agreements in these areas.

¹ The Bretton Woods conference (also known as the United Nations Monetary and Financial Conference), was a gathering of representatives from the forty-four Allied countries in Bretton Woods, New Hampshire in 1944, during which these nations sought to create a new architecture for the global financial system. The term “Bretton Woods institutions” refers to the World Bank, International Monetary Fund, and the World Trade Organization, which had their roots in this conference. Critics in the developing world argue that these institutions bolster the historically powerful position of Western states in the world order.

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