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An Exploration of Conceptual and Temporal Fallacies in International Health Law and Promotion of Global Public Health Preparedness

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Introduction

H5N1 avian influenza has reportedly claimed the lives of 186 persons worldwide, 77 of whom resided in Indonesia.[1] On February 7, 2007, the government of Indonesia announced that it would withhold strains of H5N1 avian influenza virus from the World Health Organization (WHO). On the same day, Indonesia signed a memorandum of agreement with Baxter Healthcare, a United States-based company, to purchase samples and presumably ensure access to subsequent vaccines at a discount.

In the past, the WHO received samples from afflicted nations and then provided them to vaccine manufacturers. Among the manufacturers was Australia's largest pharmaceutical company, CSL, which announced a week prior that it had developed the world's first vaccine against avian influenza. Initial trials suggested promising results, and the company claimed that it could manufacture sufficient quantities to protect the entire Australian population within six months. In response, Indonesian Health Minister Siti Failah Supari vowed that Indonesia would not share future virus samples "without a change in rules" to preclude poorer countries from becoming "commercial target[s]."[2] Indonesia's requests included a legally binding agreement that would prevent the WHO from sharing viral samples without the donor country's consent and limited use for public health risk assessment purposes.

The WHO claimed that withholding samples would prevent essential monitoring of the virus's potential evolution and oversight of key diagnostic capabilities of individual laboratories. The result was a stalemate in which WHO officials pleaded with Indonesia to resume sharing its viral samples. The decision to withhold samples came amidst fears of the pathogen evolving into a human-to-human transmissible agent and potentially causing a pandemic.

On May 30, 2007, the World Health Assembly adopted a stopgap resolution[3] among its 193 Member States (including Indonesia) to share viral strains and thereby encourage global surveillance and monitoring of intra-State diagnostic capacities. A WHO official reported that failure to do so would "put the whole world at risk."[4] Nonetheless, many questions remain unanswered. What are the legal bases to preclude States from claiming viral ownership to secure future access to medicines? Although international viral sharing has resumed, what particular avenues exist to

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promote intra-State capacity building? Is the current international legal landscape amenable to foster inter-State collaborations to secure global health?

These issues remain important for a myriad of reasons. Indonesia is currently lacking the developmental capacity to produce a vaccine (hence, its agreement with Baxter), and "cannot afford to buy" vaccines produced by other countries (e.g., Australia).[5] While the revised International Health Regulations (effective June 15, 2007) adds legal pressure for States to comply with the new resolution, the WHO has yet to identify any specific pathways to secure global health by promoting intra-State capacity building. By capacity, I mean an adequate balance of population and individually tailored interventions to protect public health, which specifically includes the use of non-pharmaceutical interventions (e.g., isolation and quarantine, health promotion) and available treatment options (e.g., provision of vaccines, health services). A failure to recognize the appropriate balance of both initiatives leaves a gaping hole in global public health preparedness.

Under the WHO resolution, States agree to provide "fair and equitable distribution of pandemic-influenza vaccines at affordable prices," but their progressive realization is undermined by failure to appreciate the underlying public health crises existent in developing- and least developed States.[6] In this article, I argue that existent health and trade agreements are necessary to control infectious diseases, but insufficient to secure global health. I focus specifically on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Revision of the International Health Regulations (IHR). While the agreements must be read in concert to ensure an effective response to disease outbreaks, they disproportionately favor post-event treatment options. This is problematic where a particular State has an unstable health infrastructure, thereby undermining global cooperation to minimize cross-border public health threats.

My analysis first explores conceptual and temporal fallacies that permeate the current international legal landscape. The conceptual fallacy is the presumption of stable health infrastructures – the most stable nation status – without which the provision of health- and public health-related services are ineffective. The temporal fallacy is that infectious disease control strategies are invoked only during circumstances that cause unstable States to remain in states of perpetual emergencies.

Against this backdrop of conceptual and temporal fallacies, I proceed to focus on State obligations to advance epidemic control and property interests in the use of biological materials (e.g., viral strains). Discordant views of express legal obligations obfuscate a State's role and responsibilities in protecting sovereign interests without jeopardizing global health. Resolving these issues is vital in order to encourage collaboration among States to control infectious disease outbreaks and promote global public health preparedness.

> While the International Health Regulations urges States to take all appropriate measures to ensure public health capacities are well-equipped to respond to potential outbreaks, it is silent on precisely how Member States should collaborate to meet this challenge.

Finally, recommendations are proffered, including the following: (1) adoption of intra-State laws facilitating implementation of non-pharmaceutical interventions; (2) incorporation of minimum protections and additional rights to protect individual liberty interests; and (3) the construction of suretyship arrangements to secure political accountability and support public health capacity building.

International Treaties and Public Health

Conceptual Fallacy of the Most Stable Nation Status

Developing and least developed States bear a disproportionate burden of dealing with potential infectious disease outbreaks. For example, Christopher Murray et al. estimated that an influenza pandemic mimicking the 1918-1919 pandemic would claim 62 million lives, with 96 percent of deaths occurring in developing countries such as Indonesia.[7] Of the 186 deaths caused by H5N1 influenza over the past four years, 41 percent have occurred in Indonesia.[8] Inadequate resources and tenuous health systems make developing countries ill equipped to respond to imminent outbreaks of infectious diseases. Also, Indonesia's decentralized health system empowers local governments as the focal point for the provision of health care services;[9] this may result in regional disparities that deter efficient public health responses to disease outbreaks in the absence of statewide surveillance and policies. Effective national capacity to meet local threats and prevent their escalation into a statewide incident is vital. Consequently, international agreements that

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attempt to protect international public health should address the disproportionate impact on certain States by identifying viable avenues to strengthen intra-State health infrastructures.

Non-pharmaceutical interventions (NPIs) are an important component of State capacity in responding to the potential spread of disease in developed and developing or least developed nations. Although treatment of infected persons is essential, there will most likely be an inadequate supply of vaccines during the initial stages of a pandemic. In the United States, for example, the Centers for Disease Control and Prevention (CDC) estimates that neither well-matched vaccines nor sufficient quantities of antiviral medications will be available at the onset of pandemic flu.[10] It is reasonable to assume a similar predicament during the onset of an H5N1 pandemic. The CDC proposes numerous NPIs to curb the spread of disease, including isolation of infected persons, voluntary quarantine of exposed individuals, school closure, and the use of other social distancing measures to reduce human-to-human contact.[11]

An Overview of the Declaration on the TRIPS Agreement and the IHR

TRIPS (including its subsequent amendments) does not adequately address the use and limitations of NPIs. TRIPS was initially enacted to compel Member States to adhere to minimum standards of intellectual property protection, which includes conferring rights and duties to the holders of patents for pharmaceutical products and medicines. Amidst criticism concerning the disproportionate impact on developing States, an exception was carved to allow for compulsory licenses in the wake of an emergency (the "Doha Declaration," discussed below).

The Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) was adopted by the World Trade Organization (WTO) in November 2001 to address the gravity of communicable diseases and other epidemics. Its purpose is to protect public health and "in particular, to promote access to medicines for all."[12] States may access medicines by granting compulsory licenses only when that particular State determines a national emergency or circumstance of extreme urgency exists.[13]

The Doha Declaration focuses solely on the emergency containment of a disease and fails to address existent public health preparedness, including the role of NPIs. This approach undermines event preparedness and continues to ignore the disproportionate impact of infectious diseases on developing and least developed nations. Further, it conflates State and global interests without recognizing existent disparities across health infrastructures. Still, no identifiable legal or economic avenues foster inter-State collaborations that promote intra-State preparedness.

The revised IHR was adopted in May 2005 to provide a global instrument for protection against the international spread of disease. The IHR complements TRIPS by recognizing the importance of NPIs in controlling the spread of infectious diseases. Its recommendations include quarantine, isolation, and treatment of persons infected or exposed to communicable disease threats.[14] Moreover, the IHR urges Member States to "collaborate actively" to ensure an effective implementation of the proposed measures.[15]

Nonetheless, it is unclear how such collaborations can be successful where development of intra-State capacity is lacking. While the IHR urges States to take all appropriate measures to ensure public health capacities are well-equipped to respond to potential outbreaks, it is silent on precisely how Member States should collaborate to meet this challenge.

The IHR does not provide any substantial guidance on individual State capacity building. Access to medicines and the implementation of NPIs is predicated on inter-State collaborations and adequate health infrastructures. From a public health perspective, such collaborations are vital to mount an effective response to disease outbreaks. For example, the global response to the SARS outbreak of 2003 illustrated the importance of collaboration among Member States to curb the spread of a communicable disease (see Focus Box 2). The recommended use of NPIs (specifically isolation and quarantine) resulted in significant post-event outbreaks. Even so, provisions enabling capacity building to implement these containment measures are simply non-existent in the agreement.

While TRIPS protects pre-event intellectual property interests and supports post-event disease containment, it does not facilitate development of stable intra-State health infrastructures. Even the IHR, despite its support of strengthening and maintaining public health capacities, "does not generate fresh financial resources to support capacity-building."[16]

Securing Global Health Interests Cannot Be Traced to the Doha Declaration or the IHR

Securing global health by identifying specific avenues of State capacity building cannot be traced to the Doha Declaration or subsequent decisions by the Council for TRIPS (Council). The Doha Declaration affords a public health exception to grant compulsory licenses, but may have a limited impact without fostering capacity building and reducing inter-State dependency.[17] Compulsory licensing allows for the production of a patented product or process without the patent

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owner's consent. Parallel importation concerns the importation of a product into a country without the approval of the patent owner. This is implicated where a patent owner may have a drug patented in multiple countries, and another company purchases the drug (presumably at a lower cost in one country) and subsequently imports it into another country where it sells it for less. The patent holder's right are said to be "exhausted" upon its initial sale. TRIPS and the Doha Declaration allow Member States to "choose to deal with the exhaustion in a way that best fits their domestic policy objectives."[18] For countries, such as Indonesia, a lack of adequate domestic research and development capacity precludes production of pharmaceutical products. This is precisely why they are dependent on other States for medicines in the event of an outbreak. Although compulsory licensing and parallel importation are useful measures, they only address one aspect of State capacity building, i.e., securing viable treatment options. Even so, as discussed earlier, acquiring a supply of medicines for everyone is not likely during an outbreak.

Subsequent decisions by the Council waived the obligations of least developed States to apply provisions of TRIPS until 2016,[19] and detailed conditions upon which compulsory licenses should be granted.[20] While recognizing "insufficient or no manufacturing capacity" within afflicted States, the decisions simply

Focus Box 1

HIV/AIDS and Access to Available Treatments: The South African Experience

Reducing access barriers fails to stymie infections amidst fragmented systems

In 1997, the South African government passed Section 33 of the Medicines and Related Substances Control Amendment Act, No. 90 of 1997 (Act) that enabled importation of low-cost generic versions of HIV/AIDS drugs. Upon enactment, 39 pharmaceutical companies brought suit challenging the constitutionality of the Act.

The complaint alleged, *inter alia*, that the Minister of Health was granted excessive authority, had sole power to determine when patent rights apply, and that patent owners would be deprived of their property interest without any provision for compensation.[22]

The cost of the drugs was estimated at $12,000-$15,000 per year for patients in the U.S. While some companies offered to sell the drugs at these costs, rival manufacturers in India offered generic versions at significantly lower prices.[23]

While a spokeswoman for the companies insisted that the "industry requires patents," she failed to contextualize the Act with respect to the ongoing public health crisis. Approximately five million people in South Africa are HIV positive, amounting to 11 percent of the country's total population.[24] Yet by mid-2005, at least 85 percent of South Africans who needed antiretroviral drugs – 900,000 people – were not receiving them.[25]

Amidst international political pressure, the lawsuit was eventually dropped. Even so, the problem persists and is attributable to factors beyond legal impediments to secure essential medicines. The WHO reports that where HIV prevention programs are not sustainable, infection rates are staying the same or increasing.[26] What is needed is a combination of treatment programs and more aggressive "life-saving prevention efforts"[27] – that is, public health capacity building to ensure focused and sustainable prevention programs.

Activists and afflicted persons encourage pharmaceutical capacity building

In 2002, AIDS activists represented by the Treatment Action Campaign (TAC) and others, along with persons afflicted with HIV and health care workers, brought a complaint against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) before the Competition Commission (Commission) alleging excessive prices on four patented antiretroviral medicines

The Commission is an independent body that investigates allegations of unfair competition under the Competition Act 89 of 1998. Upon review, it may refer the complaint to the Competition Tribunal, which formally adjudicates the charge.

The complaint specifically alleged that the prices were significantly excessive of generic prices available worldwide.[28] It also took into account estimated costs of research and development, profits, licensing fees, and the incentive to develop additional drugs.[29]

The parties later entered into a settlement agreement, revealing obligations geared towards capacity building.

Among GSK's obligations was an extension of a voluntary license to Aspen Pharmacare Holdings Ltd – Africa's largest pharmaceutical manufacturer – "in respect of the public sector to include the private sector" and permission for it to export antiretrovirals to sub-Saharan countries.[30] Particular focus on capacity building was reinforced under Section 2.2.5, which provided that licenses be strongly encouraged to manufacture drugs "in the interests of developing local pharmaceutical manufacturing capacity and job creation."

By implementing WHO's recommendations to strengthen prevention programs, a comprehensive strategy will eventually supplement these initiatives. It is unclear, however, whether the parties' obligations will offset access issues if infection rates continue to increase.

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reiterate the goal of cooperating to promote "the transfer of technology and capacity building in the pharmaceutical sector."[21] Where medicines under the Doha Declaration are market commodities, their availability in response to public health threats has a limited effect on State capacity building. Moreover, facilitating access to medicines may be premised on human rights obligations; the outcome, however, amounts to nothing more than a charitable exception if it continues to foster inter-State *reliance* – as opposed to *collaboration* – to secure public health preparedness.

The Doha Declaration essentially shields developed States from inter-State threats and encourages afflicted States to rely on inter-State aid to contain diseases within their own borders. The South African experience illustrates the conceptual fallacy and its impact on securing access to essential medicines in response to public health threats (see Focus Box 1). In 2001, a lawsuit brought on behalf of 39 pharmaceutical companies against the South African government to prohibit importation of generic HIV/AIDS antiretrovirals revealed early attempts to prevent developing countries from bypassing economic hurdles to secure population health. A subsequent suit brought by affected individuals afflicted with HIV/AIDS sought a reduction of allegedly overpriced medications under South Africa's Competition Act. The quintessential element of both lawsuits was the absence of a public health capacity that adequately balances population and individually tailored interventions to reduce rates of infection and disease transmission. Yet, despite the 2001 Doha Declaration, reliance on inter-State aid continues to be the norm for afflicted States with little guidance on capacity building. In the meantime, the incidence of HIV/AIDS continues to increase.

The IHR, like TRIPS, is silent on specific avenues to promote capacity building and simply reiterates inter-State cooperation to foster global surveillance and intra-State efforts to contain public health threats. In doing so, the IHR strengthens inter-State collaborations on a premise that States can adequately deal with localized threats. The regulations do not expressly compel States to share viral samples, but require ongoing surveillance and notification of disease outbreaks and related information. After an event[31] – the manifestation of disease or an occurrence that creates a potential for disease – States may implement quarantine, isolation, and restrictions on persons from infected areas.[32] The effect of containment strategies, however, is limited without a legal framework that balances the use of NPIs and available treatment options (discussed below).

The conceptual fallacy is an impediment to securing global health, but withholding viral strains only exacerbates the problem by requiring all States to resort to NPIs as a primary containment strategy. This will only strain existing State resources and threaten health at the individual and population levels. It may also discourage States from engaging in future collaborative efforts to share goods and services – threats to population health and safety are seldom welcome as invitations to cooperate in mutually beneficial ventures.

Temporal Fallacy of Perpetual Public Health Emergencies

The temporal fallacy stems from when TRIPS and the IHR may be triggered in response to threats of infectious diseases. These agreements may only be invoked when threats amount to an emergency. While this may facilitate post-event containment, it undermines pre-event preparedness and a sustainable intra-State public health capacity to meet localized threats. Consequently, States must resort to NPIs as a primary containment strategy, which is not a long-term solution to contain infectious diseases.

The Doha Declaration and Public Health Emergencies

Whereas Article 31(b) of TRIPS allows for use of the subject matter of a patent without the authorization of the right holder during emergencies, the Doha Declaration expressly addresses public health emergencies and recognizes Members' rights to protect public health and promote access to medicines for all.[33]

Allowing States to define what constitutes a public health emergency is hardly conciliatory for developing and least developed nations. Faced with insufficient resources, many States (such as Indonesia) cannot take advantage of compulsory licenses by merely declaring a public health emergency. Moreover, the Doha Declaration is reactionary and affords flexibility in trade only after a disease has become prevalent. This approach undermines State capacity building and compels afflicted States to rely on other States to provide necessary aid. The Doha Declaration thereby fosters continued dependency on inter-State aid under the pretense of responsible State action to protect public health. However, reliance on inter-State aid is unproductive where there are limited supplies of essential medicines. Also, NPIs are most effective during the early stages of a pandemic. Since States are in the best position to conduct intra-State surveillance, a State-wide policy allowing for an efficient implementation of NPIs is essential. State control of public health maximizes the likelihood of containing a disease outbreak before it evolves into a potential inter-State threat. Empowering States to optimize their capacity to contain potential outbreaks strengthens inter-State collaborations by decreasing the likelihood of cross-

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Focus Box 2

SARS and XDR-TB – Aggressive Implementation of NPIs May Compound Health Problems and Threaten Fundamental Human Rights

Global response to 2003 SARS outbreak reveals challenges of aggressive quarantine

In March 2003, the WHO issued a global alert after numerous cases of severe, acute respiratory syndrome (SARS) arose. Recommendations were made to isolate individuals diagnosed with SARS or persons who exhibited similar symptoms.[35] After the announcement, no country where outbreaks had occurred experienced the same magnitude of outbreaks as prior to the alert.[36]

While the recommendation was apparently successful, a review of global efforts to implement quarantine had potentially deleterious health effects. One study observed symptoms of posttraumatic stress disorder (PTSD) in 28.9 percent of 129 persons who were quarantined following the SARS outbreak in Toronto, Canada.[37] Thirty-one percent of respondents also exhibited symptoms of depression. A report by Rothstein et al. for the Centers for Disease Control and Prevention (CDC) reported that aggressive use of quarantine in Taiwan contributed to public panic and was counter-productive. They also found incidents of violation of quarantine in every country.[38]

It is imperative that States enact local laws and protocols that ensure civil liberties, cultural sensitivities, basic needs, and communication for populations isolated or quarantined during a disease outbreak. Reluctance to establish uniform procedures continues a tradition dating back to the late 19th century when Eastern European Jews were singled out for quarantine upon entering New York City ports to curb the spread of cholera.[39] A century later, lack of progress continues to stifle global preparedness for future pandemics.

U.S. handling of person with XDR-TB reveals limitations of isolation

In August 2006, Robert Daniels, a 27-year-old Russian immigrant, was isolated in Phoenix, Arizona after being diagnosed with extremely drug-resistant tuberculosis (XDR-TB). The disease is considered highly lethal and untreatable. Upon his alleged failure to comply with doctor's orders to wear a mask in public, Daniels was jailed in a local prison cell, where he currently resides indefinitely.

Although details are scarce, Daniels's claims of alleged mistreatment raises concerns as to whether local governments are capable of handling a large-scale quarantine without violating fundamental civil liberties. In an interview, Daniels claims that he was never informed of how XDR-TB was transmitted; that he is not allowed to shower, but cleans himself with wet wipes; and that he has no means of communication with others.[40] His allegations raise issues of due process and the provision of basic needs and services. The lack of uniformity in U.S. quarantine laws reiterates the need to re-examine state laws.

Given the highly lethal and easily transmissible nature of XDR-TB, the case also illustrates the limitations of implementing NPIs to contain disease outbreaks. Daniels's predicament is reminiscent of that suffered by Mary Mallon, a cook and healthy carrier of typhoid fever, who was isolated in 1909 for a total of 26 years.[41] While Mallon knowingly violated orders to refrain from cooking, an action which led to her to infect others, Daniels claims he was unaware of how the disease is transmitted. Effective communication between health officials and the public is vital in ensuring cooperation and protecting the public's health. Nonetheless, indefinite isolation is not a long-term solution to combat infectious diseases.

border threats and thereby reducing the need to rely on inter-State aid.

The current language allows developing and least developed States to remain in perpetual states of public health emergencies. Under the Doha Declaration, a public health emergency or circumstance of extreme urgency exists whenever a State determines that the general health or safety of the population may be compromised.[34] This is a low threshold for States that lack stable infrastructures, potentially allowing any threat to expand and be duly characterized as a situation of extreme urgency. Whether the threat stems from the diagnosis of a single case, or a local outbreak, States are given broad discretion in initiating a declaration of public health emergency. Without viable treatment options and sustainable public health programs, States must resort to the aggressive implementation of NPIs – a short-term solution that is only effective in early stages of a pandemic (discussed below).

NPIs Are Not a Long-Term Solution to Contain Infectious Diseases

NPIs are limited in their effect because they are optimal during the initial stages of an outbreak. However, after disease prevalence has been established, NPIs will be unable to thwart its incidence and hence be rendered ineffective. A highly lethal and easily transmissible pathogen will implicate nothing short of extreme measures to protect the population. As illustrated in the worldwide response to SARS and XDR-TB,

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aggressive implementation of NPIs may compound health problems and threaten fundamental civil liberties (see Focus Box 2).

Isolation and quarantine laws were traditionally targeted at maritime vessels and may not afford comprehensive civil liberty protections to persons or populations. Even developed nations (e.g., the United States) have antiquated quarantine laws that are neither comprehensive nor uniform. Without available medicines or vaccines, NPIs are, at best, short-term solutions. Having the capacity to develop and distribute medicines will not obviate the need for NPIs. It will, however, reduce the likelihood of the *aggressive* use of NPIs and the potential legal and ethical challenges that will inevitably stem from their implementation. Thus, reliance on NPIs as a primary containment strategy is not feasible to secure population health. Schools and businesses may be closed, and interference with trade may limit the availability of many essential goods and services.

While a goal of the IHR is to broadly harmonize the legality of NPIs, the legal obstacles to implement them within sub-State regions (e.g., states, counties, localities) in a timely manner may compromise a public health response. A recent study by the Center for Law and the Public's Health at Johns Hopkins and Georgetown Universities on the legal bases for school closure as an NPI during pandemic influenza revealed a lack of uniformity among U.S. jurisdictions. Multiple agencies were authorized to close schools for different reasons; multiple levels of government were vested with the authority to act; and few intrastate pandemic influenza plans cited express legal authority to implement closure.[42] Reliance on NPIs to curb disease outbreaks is unproven and may be stymied by a myriad of legal impediments.

State Epidemic Control and Use of Biological Materials

States optimize available resources to protect population health. In the absence of sufficient resources, States may be tempted to use whatever means necessary to acquire essential products, disregarding global public health objectives. While Indonesia's reluctance to share its viral samples invited worldwide criticism, there was little explanation as to why its claim was legally unsubstantiated. This section explores (1) whether withholding viral strains is in contravention to State obligations to advance epidemic control under the IHR and (2) the relationship between State control of biological materials and global public health imperatives.

Withholding Viral Strains is in Potential Contravention to a State's Obligations under the IHR in Taking Measures to Control Epidemics

If epidemic control is a global public good, then States would certainly collaborate to protect the health and safety of their citizenry. Although there is no consensus on a precise definition, David Woodward and Richard Smith define a global public good as a good which it is rational, from the perspective of a group of nations collectively, to produce for universal consumption, and for which it is irrational to exclude an individual nation from its consumption, irrespective of whether that nation contributes to its financing.[43]

Under this definition, epidemic control may be broadly characterized as a global public good owing to its collective benefits and the inability to eliminate the threat by excluding an individual nation from implementing measures to curb its spread. Still, the specific legal obligations must be enunciated in the context of international law and agreements.

Under the IHR, epidemic control at a national level is an integral obligation of Member States. In 2003, Johan Giesecke explained how national infection control consists of an alert function (i.e., notification to other countries when an outbreak has been discovered) and control measures to contain its spread;[44] these roles are consistent with State obligations under the revised IHR (discussed earlier). The emerging issue is then whether withholding viral strains amounts to State action that threatens epidemic control.

On its face, withholding viral strains is not per se a violation of epidemic control. Epidemic control requires an actual outbreak and failure to take measures to control its spread. In the absence of an outbreak, State action in contravention of epidemic control becomes legally impossible. Even so, this is based on a premise that withholding viral strains is immaterial to the factors that give rise to an outbreak or measures to control it. This premise, however, is debatable.

In some instances, the efficient development of control measures should not be considered too remote from the actual measures themselves. Since States are aware that the H5N1 virus evolves and that constant surveillance is necessary to develop the appropriate vaccines, withholding viral strains may jeopardize an optimal response. Waiting until an actual outbreak occurs will delay development and risk the health and lives of affected persons until a vaccine is made available. This predicament illustrates that legal impossibility is outweighed by factual possibility. While withholding strains may not be correlated to an actual outbreak, it will be associated with an inevitable delay

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in developing a vaccine (should an outbreak occur). Thus, withholding viral strains precludes taking efficient control measures (including vaccine development) and may be in contravention to a State's obligations under the IHR in controlling epidemics.

State Control of Biological Materials is an Invalid Proxy for Individual Rights and is Superseded by Public Health Imperatives

Indonesia never explicitly denied its obligation under the IHR in taking control measures to prevent the spread of an epidemic. Its primary argument in withholding samples rested on its exclusive possession and control of biological materials. This approach is flawed because, as discussed above, a State's property interest is superseded by a global public health imperative, i.e., infectious disease control. Additionally, Indonesia's claim is nothing more than a proxy for asserting an individual right that would not withstand scrutiny at the national level, and, by implication, would obviate a subsequent claim on behalf of the sovereign State to take a similar stance to preclude an overriding global interest.

While it is widely held that public health imperatives (e.g., infectious disease control) supersede property rights, Indonesia has distinguished its sovereign interest from an individual's claim to biological materials on questionable grounds. The policy rationale to preclude an individual from asserting a claim in her own biological materials against public policy was aptly summarized in the United States' case of *Moore v. Regents of the University of California*.[45] In *Moore*, the California State Supreme Court addressed the issue of whether biological materials can be equated to personal property. The court found that granting Moore an interest in his biological materials was inappropriate on two levels. First, it broadly noted that state law governing the disposal of biological materials was within the exclusive purview of the state health department. Second, Moore's particular cells constituted a potential biohazardous threat, which required the state health department to dispose of the materials pursuant to its duty to protect the public's health.

Indonesia's argument is similar to Moore's claim, but cannot be distinguished to warrant a dissimilar outcome. Since Indonesia gave its viral samples of its own volition to the WHO, its disclosure obligations are not in question. Indonesia was aware of what the samples would be used for, yet it simply claims exclusive rights to ownership and the terms upon which the samples – and any products derived thereof – may be used.

The nature and lethality of the H5N1 viral strains pose a grave threat to public health and safety. Among those infected with avian flu virus, the H5N1 strain has caused the largest number of detected cases of severe disease and death in humans.[46] Moreover, more than half of all individuals diagnosed with the virus have died.[47] Its lethality would clearly qualify it as a biologically hazardous agent subject to control by a state health agency. Additionally, if H5N1 gains the capacity to spread easily from person to person, its transmission may trigger an influenza pandemic.

Regulation of viral strains should not be subject to political and economic considerations in lieu of public health objectives that affect population health on a local, national, or global scale. An exception to this narrow rule may grant control and usage of biological materials as a function of their lethality and scope of transmission. For example, an individual may reasonably exert ownership and control over biological materials that do not pose a threat to another's health or safety. On the other hand, if the materials pose a threat to the health of another person, then the state government may exercise its control over the materials pursuant to its duty to protect the public's health. Nonetheless, Indonesia's claim is nothing more than a proxy for an individual property interest that is superseded by overriding global public health imperatives to control the spread of infectious disease. Efforts to preclude essential monitoring and diagnoses on economic grounds would belie these overriding public health considerations.

Recommendations

A developing country's fear of being "left behind" and not having access to future medicines is a legitimate concern, particularly during a state of public health emergency. This fear is compounded against a fragile legal backdrop that fails to address intra-State public health capacity building as an integral component of protecting global health.

An effective public health response to potential disease outbreaks requires a legal environment that recognizes the limitations of available resources, facilitates the implementation of NPIs (e.g., isolation and quarantine, social distancing measures), and is also amenable to affected persons and populations. These requirements are not mutually exclusive; rather, successful interventions should apply sound public health measures while securing, to the extent possible, fundamental rights and respect for human dignity.

Adoption of Intra-State Laws Facilitating Implementation of NPIs

Since it is likely that there will be insufficient vaccines available for all individuals at the outset of a pandemic – even in developed States – the implementa-

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tion of NPIs is vital to protect population health. Even so, worldwide response to the SARS outbreak and inconsistent State laws reveal a lack of uniformity in legal provisions relating to isolation and quarantine or social distancing measures. Given different political regimes and legal systems, a single inter-State treaty may be ill-equipped to address State-specific challenges. Research on intra-State laws across all States is required to identify barriers in implementing NPIs in a timely and efficient manner. Specifically, laws should identify key officials at the local, state, and national (or federal) levels that are authorized to implement NPIs and the circumstances under which such authority may be exercised. Such provisions should complement the IHR and serve as practice-based regulations that facilitate timely and effective responses. This will alleviate the conceptual fallacy by complementing the availability of treatment options with pragmatic NPIs to protect population health.

Incorporation of IHR Article 32 Minimum Protections and Additional Rights into Existent State Laws

The implementation of NPIs must also be coupled with efforts to secure the basic needs and fundamental rights of affected populations. During the 2003 SARS outbreak, aggressive implementation of NPIs may have compounded health problems and contributed to public panic (see Focus Box 2). Timely and effective implementation of NPIs relies on garnering public support and cooperation. Communication is vital and should also be accompanied by reassurances that minimize societal disruptions (e.g., work-from-home options for parents taking leave to care for ill children, distance learning for displaced students).

The protections afforded under Article 32 of the IHR are necessary, but not sufficient to secure each individual's fundamental civil liberties and basic needs. Article 32 affords minimum protections to individuals who have been isolated, quarantined, or subject to other procedures for public health purposes. Basic protections include treating travelers with courtesy and respect; taking into consideration the gender, socio-cultural, ethnic, or religious concerns of travelers; arranging for adequate food and water; accommodation and clothing; protection for baggage and other possessions; appropriate medical treatment; and necessary communication in a language they can understand.[48]

Additional protections should include the following: (1) a right to procedural due process (notice and a hearing within a reasonable period); (2) specific scientific criteria (e.g., incubation period) to determine the appropriate length of detainment; (3) means of communication with family members; (4) privacy protections for the acquisition and use of health information; and (5) clarity as to who bears the cost of examinations and other health-related procedures.

The lack of uniformity in most States as it relates to protections afforded affected populations risks multiple human rights violations. This would create a scenario reminiscent of the treatment of Eastern European Jewish immigrants in the late 19th century at the port harbors of New York City[49] to combat cholera, and of vulnerable populations such as individuals afflicted with HIV/AIDS in the mid-1980s continuing into the present day. Aggressive implementation of NPIs must be accompanied by assurances to secure the fundamental rights and basic needs of affected populations. These assurances will alleviate the burden of the conceptual fallacy by providing a check on implementing NPIs within parameters respecting fundamental individual rights; they will also alleviate the temporal fallacy by securing fundamental rights irrespective of whether an emergency has been declared, but all the more so when coercive measures are taken in deprivation of individual interests.

Suretyship Arrangements to Secure Political Accountability and Support Public Health Capacity Building

The lack of political accountability stifles inter-State cooperation and must be addressed in concert with efforts to secure global health. Indonesia's reluctance to share H5N1 samples drew attention to a fragmented global health system. Threats of non-cooperation, however, do not pose a sound model for global health policy and will only stymie future collaborations. Prospective reform should identify avenues of support for capacity building in developing and least developed States, and hold States accountable for their obligations pursuant to the IHR.

Trade in particular goods and services should remain unhindered, but highly lethal and easily transmittable infectious diseases pose a unique threat that compels State action and involvement. In 2000, the U.S. National Intelligence Council (NIC) issued a report discussing the impact of global infectious diseases on national security.[50] The report highlighted potential social fragmentation, economic decay, political polarization in the hardest hit regions, and worldwide disruptions in trade and commerce. No State is immune from the impact of a pandemic, and an effective response entails global cooperation.

Regulating intra-State research on highly lethal and easily transmittable infectious diseases to foster inter-State capacity building is essential to secure global health. Funds should be allocated to promote public

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health capacity building of States disproportionately burdened by potential disease threats. Effective collaborations will require arrangements that recognize horizontal and vertical privity among States and corporations researching highly lethal and easily transmissible infectious diseases.

Suretyships provide an apt model to secure compliance and cooperation. A surety is a person who is primarily liable for the payment of another's debt or the performance of another's obligation. Against the backdrop of States' duties to secure the health of their populations and inter-State efforts to secure global health, States should be politically and, to the extent possible, economically accountable to inter-State efforts to protect global health.

Under a suretyship model, States' governments would be a surety for an intra-State corporation's "debt" to inter-State efforts to advance global health. The debt stems from the two-fold recognition that Member States are bound by international law to promote epidemic control and that regulation of intra-State activities may (and should) entail an allocation of risk among key participants. Moreover, given the inevitable global impact of highly lethal and easily transmissible infectious diseases, such contributions would be a wise investment to minimize disruptions of global trade relations. By taking steps to develop effective control measures, corporations would be fulfilling an otherwise State function. Consequently, they may potentially avail themselves of the rights and benefits afforded State agents (e.g., limited liability protections).

Potential arrangements may entail (1) direct taxation of corporations; (2) matching funds by the State(s) to support intra-State research and development; or (3) a combination thereof. Arrangements must also take into account multinational corporations that have multiple bases in different countries.

While this model is not legally enforceable pursuant to any existent international agreements, it may be incorporated within the existing framework by complementing State efforts to promote epidemic control. Although the IHR does not expressly generate financial resources for capacity building, it does encourage intra-State regulation and inter-State collaboration. The suretyship model streamlines public- and private-sector contributions to harmonize public health objectives, and ensures minimal capacities to meet the threat of highly lethal and easily transmissible infectious diseases. It also fills a gap owing to the conceptual fallacy by reducing disparities across Member States' capacities to meet localized threats. This would also alleviate the temporal fallacy by reducing the likelihood of emergencies stemming, in large part, from a lack of minimal capacity and provision of basic healthcare services. Finally, it solidifies State governance of public health and enables communication and sharing of data or funds, thereby promoting global health surveillance.

Conclusion

The international legal landscape is fraught with loopholes that impede optimal inter-State cooperation to secure global health. While the conceptual fallacy reveals an absence of adequate efforts to secure intra-State public health capacity building, the temporal fallacy potentially leaves developing and least developed countries in perpetual states of public health emergencies.

Drawing attention away from these fallacies to protect sovereign interests at the expense of global health objectives is equally inappropriate. Highly lethal and easily transmissible infectious diseases implicate health and safety issues affecting all States. Inter-State collaborations should ensure minimal public health capacity in developing and least developed States. This objective can be accomplished by (1) a legal framework that allows for timely implementation of NPIs, which would include (2) uniform adoption of minimum protections afforded affected populations and (3) suretyship arrangements to secure political accountability and contribute to intra-State capacity building.

The appropriate roles of public- and private-sector actors are often blurred in the free market where inter-State trade acts independently of political objectives. Responding to infectious disease threats is every State's prerogative, and inter-State collaborations – with a particular focus on capacity building – are essential to secure global public health preparedness.

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