

Global Health Governance

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THE JOURNAL PROVIDES INTERDISCIPLINARY ANALYSES AND A VIGOROUS EXCHANGE OF PERSPECTIVES THAT ARE ESSENTIAL TO THE UNDERSTANDING OF THE NATURE OF GLOBAL HEALTH CHALLENGES AND THE STRATEGIES AIMED AT THEIR SOLUTION. THE JOURNAL IS PARTICULARLY INTERESTED IN ADDRESSING THE POLITICAL, ECONOMIC, SOCIAL, MILITARY AND STRATEGIC ASPECTS OF GLOBAL HEALTH ISSUES.

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DRIVERS AND BARRIERS TO PATHOGEN- AND BENEFIT-SHARING (PBS): AN EMPIRICAL STUDY OF GLOBAL PERCEPTIONS AND PRACTICES AND CASE STUDIES FROM EBOLA IN LIBERIA AND ZIKA IN BRAZIL

Anthony Rizk, Anna Bezruki, Mosoka P. Fallah, Joseph Sieka, Tolbert Nyenswah, Gustavo Matta, Ester Paiva, Gian Luca Burci, and Suerie Moon

Though ensuring the fair, reliable, and rapid international sharing of pathogen samples and related benefits is necessary to control infectious disease outbreaks, it has proven difficult. We gathered data from two country cases, influenza sample movements, interviews, and contracts to understand current practices and perceptions. We found that countries shared pathogens for instrumental, political, security, economic and scientific reasons; and that benefits were sought for the global public interest, academic recognition, strengthening national capacities, and economic returns. During outbreaks, barriers arose due to disparities in technology and capacity, biosecurity concerns, commercial interests, and the absence of clear rules. We found consensus on the urgency of improving the global governance of PBS, but not on how to do so. We discuss the options proposed for PBS governance and the need for more focused political leadership to achieve global health security, with equity.

INTRODUCTION

A perennially thorny issue hampering the global health community's ability to manage infectious disease outbreaks is the fair, reliable and rapid international sharing of pathogen samples and related benefits – what we refer to here as pathogen- and benefit-sharing (PBS). When outbreaks of infectious diseases occur, healthcare workers and researchers often take samples of biological materials, such as blood, saliva, and/or tissue, from infected persons for both medical and research purposes. Access to pathogen samples and related genomic sequencing data (GSD) is critical for identifying and understanding pathogens, enhancing the epidemiological response, and for the development of medical countermeasures, including diagnostics, drugs, and vaccines. In the early days of the emergence of SARS-CoV-2 in January 2020, Chinese researchers publicly shared GSD on the novel pathogen, but physical samples were difficult to obtain for researchers internationally.¹ Delays in sharing samples soon became moot as the virus itself spread worldwide. And as the outbreak became a pandemic, researchers voluntarily shared large volumes of GSD on publicly-accessible platforms like GISAID, making it possible to track and understand novel variants such as Delta and Omicron. Nevertheless, the absence of clear international rules and agreements on sample and GSD-sharing leaves the world vulnerable in future outbreaks.

At the same time, the ability of pathogen-sending countries to access countermeasures – including but not limited to those developed from shared samples – is critical for outbreak control and prevention. For many countries, securing access to countermeasures in pandemics is often an uphill battle, especially when governments compete over scarce supply, as demonstrated by the highly unequal rollout of Covid-19 vaccines globally. In the meantime, pathogen-sending countries are also increasingly

concerned about access to other benefits in return for granting access to their resources. Furthermore, pathogens and the countermeasures developed from their use are often controlled by different parties, in different countries, with different degrees of scientific, industrial, and economic resources. Ensuring the fair and equitable sharing of such resources and other benefits has proven difficult and remains far from a well-functioning international system.

The literature on PBS has focused on a relatively small number of cases in which pathogen sharing was controversial, such as the 2007 H5N1 influenza or 2013 Middle East Respiratory Syndrome (MERS) outbreaks.² At present, there remains little clarity on PBS practices for other pathogens of pandemic potential, or pathogens more broadly. In terms of the governance of pathogen sharing, the literature has largely focused on the relevant international legal norms,³ namely the 2005 International Health Regulations (IHR),⁴ the 2011 Pandemic Influenza Preparedness (PIP) Framework,⁵ and the 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (hereafter, the Nagoya Protocol) to the Convention on Biological Diversity (CBD).⁶ Presently, there is no publicly available and centralized data source tracking the international movement of pathogen samples or related benefits – with the important exception of influenza viruses of pandemic potential (IVPP) – and, as such, we do not have a clear picture of who shares which pathogens with whom, how quickly, under what terms and conditions, what benefits (if any) apply to those exchanges, or which are the most frequent hurdles preventing or delaying PBS. The research reported here was, therefore, motivated by the need to clarify current practices in PBS and identify workable solutions for their improvement, especially in light of the scarcity of empirical data to inform the negotiation of such solutions.

We reviewed the literature on PBS and interviewed a range of respondents across low-, middle- and high-income countries and professional backgrounds, including experts involved in PBS policy or practice across laboratories, research organizations, universities, governments, the World Health Organization (WHO), civil society, and industry. In total, we conducted 86 in-depth interviews between November 2018 and October 2020, including with 53 individuals involved in international policymaking or scientific practice around PBS, 20 individuals engaged with Ebola PBS in Liberia during the 2014-16 Ebola Virus Disease (EVD) epidemic and 13 individuals engaged with Zika PBS in Brazil during 2015-16. Throughout this article, each interview is assigned a number and is cited parenthetically (e.g., #1, 2, 3, etc.) where appropriate. We also searched for publicly available documents and solicited documents from interviewees, particularly material transfer agreements (MTAs), applicable legislation, and organizational policy documents, collecting 26 MTAs throughout the study period. Altogether, we triangulated among these data sources to generate the findings and conclusions presented in this paper. Ethical approval was granted by the Institutional Review Boards of the Graduate Institute of Geneva (IHEID), the University of Liberia (UL-PIRE) and the National Commission for Research Ethics (CONEP) in Brazil. More information on research methodology can be found in a comprehensive report on the project, which was published as Global Health Centre Working Paper #23.⁷

This study has a number of limitations. There is little quantitative or qualitative data in the public domain on the sharing of pathogens or related benefits. Additionally, key documents such as executed MTAs – the contractual documents that are commonly used between providers and receivers of biological resources – and other contracts are

usually confidential. Therefore, we sought to reconstruct from interviews a necessarily impressionistic picture of current practices and drivers. Despite our efforts to cover a broad range of interlocutors, the number and breadth of interviewees does not capture all countries or stakeholder groups. Moreover, while interviewees generously shared their time and knowledge, the political sensitivity of the topic is likely to have limited the kinds of information and documents shared with us. Finally, two important issues were outside the scope of our research: PBS for animal, environmental and plant pathogens where practices may differ from those for human pathogens, and the sharing of genomic sequence data (GSD) that is sometimes replacing the sharing of physical samples. Both PBS for non-human pathogens and the governance of GSD merit further in-depth research. The results should be interpreted with these limitations in mind. Despite these limitations, we believe this study represents the largest collection of publicly-available empirical data to date on PBS for emerging infectious diseases and has important implications for global health policy.

A BRIEF OVERVIEW OF GLOBAL HEALTH POLICY AROUND PBS

Over the past two decades, health emergencies have been accompanied by high-profile cases of countries refusing or delaying the sharing of pathogen samples important for rapid and effective global health preparedness and response. Most prominent was Indonesia's decision, in 2007, to withhold international sharing of samples of human H5N1 influenza, citing sovereignty over genetic resources and concerns that it would not get access to vaccines developed from sample-sharing. Since then, pathogen sharing controversies have routinely emerged along with new outbreaks, including with MERS sample-sharing between Saudi Arabia and Erasmus University in the Netherlands in 2013,⁸ delayed sharing of Zika samples from Brazil during the Zika outbreak of 2015-6,⁹ and reports of the mass exodus of Ebola samples during West Africa's outbreak of EVD 2014-6.¹⁰

In response to Indonesia's position in 2007, WHO, its Member States and related non-state actors (e.g. vaccine developers, manufacturers, and non-governmental organizations) participated in negotiations that culminated in the adoption by the World Health Assembly (WHA) of the PIP Framework in 2011. The PIP Framework established a system based on reciprocity: countries with pandemic influenza samples would share them with the laboratory network coordinated by WHO as well as research institutions and pharmaceutical companies outside the network; in exchange, companies producing medical countermeasures (e.g. vaccines, drugs and diagnostics) from these samples would commit to provide WHO with a range of benefits negotiated case by case with WHO to contribute to national capacities for preparedness or outbreak response. The PIP Framework has been hailed as a "milestone in global health governance."¹¹ It remains, however, the only multilateral framework designed to govern PBS to date. Periodic calls have been made by global health experts to strengthen the governance of PBS,¹² but it remains an under-governed area of global health.

PBS falls within the realms of two global regimes that have previously operated quite separately from each other: the IHR (2005),¹³ the purpose of which is to govern global preparedness and response to outbreaks of infectious disease (among other hazards); and the CBD (1992)¹⁴ and its associated Nagoya Protocol (2011), which aim at conservation and sustainable use of biodiversity and ensure both access to genetic

resources as well as fair allocation of benefits deriving from their utilization. The CBD confirmed the principle of national sovereignty over genetic resources and that sharing of such resources must be based on the prior informed consent (PIC) of the source country and under mutually agreed terms (MAT). The CBD provisions on benefit sharing are general and relatively vague, however, and the Nagoya Protocol was negotiated to articulate them more precisely and render their implementation easier. In 2011, the Nagoya Protocol was adopted as a supplementary protocol to the CBD, expanding its existing provisions on access and benefit sharing (ABS) with the objective of promoting “fair and equitable sharing of the benefits arising from the utilization of genetic resources.”¹⁵ PBS can be seen as relevant to the goals of both regimes, but also falling into an under-governed gap between them. Although the PIP Framework (2011)¹⁶ reflects the objectives of both sets of rules, it remains exclusive to pandemic influenza. As such, a climate of uncertainty continues to surround PBS.

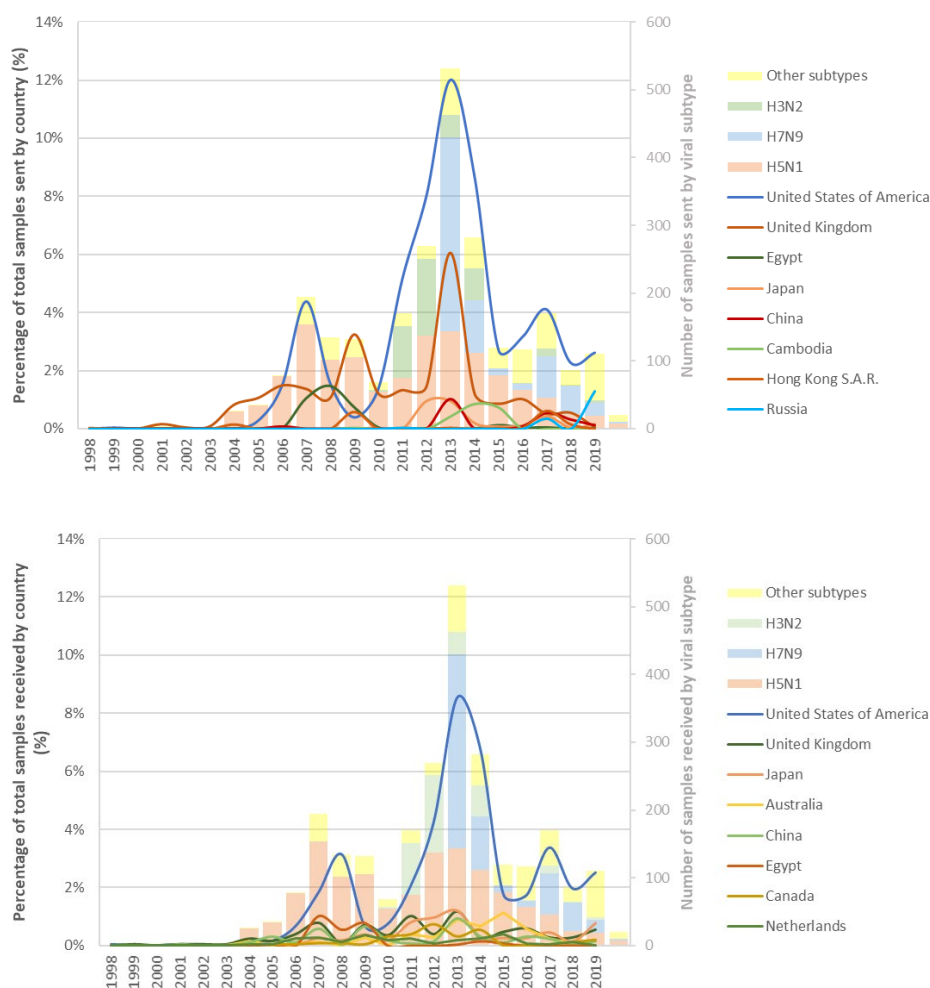
The interviews we conducted with policymakers and practitioners working on PBS reflected this uncertainty, revealing a shifting and uncertain policy and legal landscape for PBS. In Europe, changes in privacy and data protection laws and the implementation of the Nagoya Protocol are expected to have a “tremendous effect on what we can and cannot do (#45),” including anticipated difficulties in linking pathogen samples to clinical data and, for viruses other than influenza, impacting long-standing collaborations. In pathogen-sending countries, an interview respondent from a government-affiliated laboratory described situations where “nobody knows exactly what to do ... whether they have a right to share, with whom, and which framework (#39).” Industry representatives have expressed concern that the growing difficulties with pathogen sharing is “generat[ing] instability in commercial practice,” such that small- and medium-sized pharmaceutical companies may find themselves at a comparative disadvantage to large companies when attempting to navigate an emerging “mosaic” of international and national legal regimes (#46). Perceptions of the changing landscape varied from viewing it as “a threat” to long-standing and established systems of sharing (#20), to “business as usual” for those who routinely navigate complex legal systems in their everyday practice (#18), to an opportunity to redress historical inequalities between countries through PBS (#38). Left unattended, such a climate of uncertainty is expected to continue to grow, and there are calls to move towards increased coherence and clarity in the governance of PBS.

WHAT DO WE (NOT) KNOW ABOUT PATHOGEN-SHARING?

Presently, publicly available and centralized information on global movements of pathogen-samples and the benefits associated with their sharing are scarce, with the important exception of influenza viruses of pandemic potential (IVPPs). As such, we do not have a clear global picture of which countries are most centrally involved in sending and receiving pathogens, under what terms and conditions, what benefits (if any) apply to those exchanges, and which are the most frequent hurdles preventing rapid, reliable, and fair PBS. To develop some granularity on these questions, we first examine what is and is not publicly known about pathogen sharing through existing data on the global movement of IVPPs and our respondents’ identification of drivers and barriers to pathogen sharing.

The WHO's Influenza Virus Tracking Mechanism (IVTM) is the only publicly-available data repository we found that tracks global pathogen movement—in this case the global sharing of IVPPs. We analyzed data on the global movement of IVPP samples from the IVTM,¹⁷ studying patterns in a total of 2,601 IVPPs recorded between January 1998 and 2019 (latest data retrieval date: May 7th 2020). While this data source only covers IVPPs and therefore cannot be taken as representative of the sharing of pathogens more broadly, it does offer a significant level of otherwise unavailable detail regarding sending and receiving countries, participating organizations, and key developments across time in the actual international sharing of influenza pathogens.

Figure 1: Top 8 IVPP-sending (top) and IVPP-receiving (bottom) countries by time and frequency of IVPP subtypes shared



Note: The line graph represents percentage of total samples sent by country (left y-axis) and the bar graph represents number of samples sent by viral subtype (right y-axis).

Throughout the recorded period, a relatively small number of countries – about 15 – have been actively engaged in IVPP-sharing, with the United States and the United Kingdom acting as central hubs (Figure 1). Between 1998 and 2019, the United States

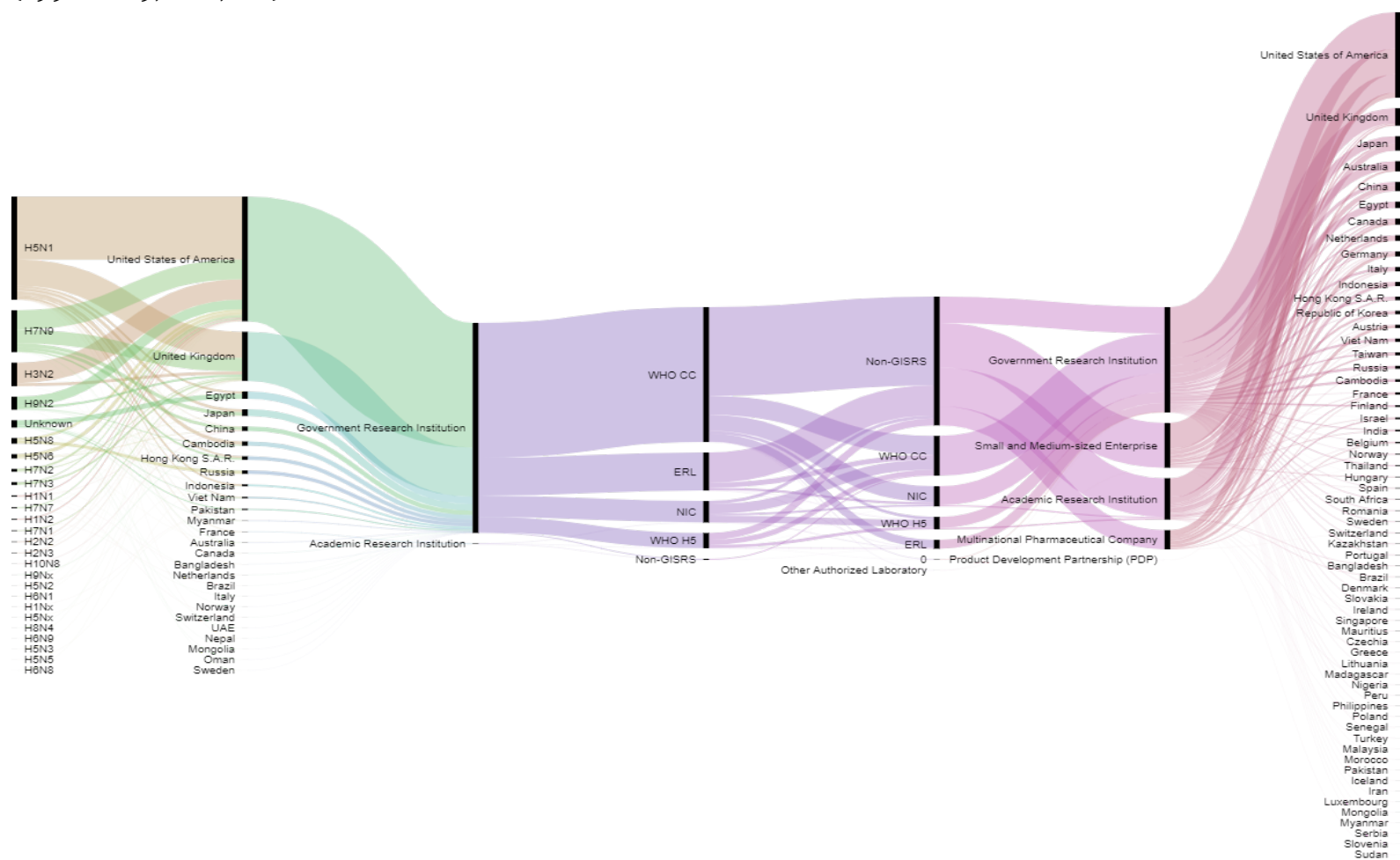
alone sent 59% and received 41% of all IVPP samples logged by the IVTM, followed by the United Kingdom (24% sent and 8% received) and, to a far lesser extent, Japan, Egypt and China (each sending between 2-4% and receiving between 3-7%). Whereas IVPP-sending institutions have almost exclusively been government-affiliated (99%) and part of the Global Influenza Surveillance and Response System (GISRS) (99%), IVPP-receiving institutions have been more variable, including both GISRS (39%) and non-GISRS (61%) affiliated institutions, indicating that samples are shared widely beyond the WHO network of GISRS-affiliated laboratories alone. IVPP-receiving non-GISRS institutions included, by order of density, small- and medium-sized enterprises (SMEs) (21%), academic institutions (20%) and multinational pharmaceutical companies (9%) (Figure 2). SMEs were the main recipients of the GISRS network from 2005-2009 and again from 2010-2015; however, from 2016-2019, there was decreased sharing with SMEs and increased sharing with academic institutions. In terms of bilateral sharing relationships, IVPP-sharing from the US and the UK has largely been with other high-income countries (HICs) – with the exception of high sharing density between the UK and China.

Our interviews with study participants across scientific and policy spheres focused on two areas of interest: drivers for sharing pathogens and the differences in practice between “ordinary” and “outbreak” contexts. While the picture is necessarily incomplete, the interview data begins to lay the groundwork for understanding drivers and barriers.

For the most part, respondents agreed that pathogen sharing practices differ between outbreaks and ordinary circumstances. In ordinary circumstances, the ability to access pathogens seems to be contingent on a number of factors, including: participation in international collaborative pathogen sharing networks, an institution’s size and geographic location – with a few major institutions having a far wider reach than most others – and an institution’s capacity to navigate a mosaic of national and international laws, regulations, and permit requirements. Outbreak contexts, however, are characterized by panic and confusion, where normal processes for pathogen sharing, if regulated, are often suspended in favor of expedited processes. Participants from many countries report that their ability to negotiate favorable terms and conditions are inhibited by the immediacy of needing access to collaborations and medical countermeasures during outbreaks. In emerging infectious disease outbreaks, pathogens “become hot items to acquire” (#17) and highly valued internationally, which may either lead to more flexible and unrestricted sharing for the rapid development of medical countermeasures or to reservations around sample-sharing, often to retain negotiating power over potential benefits. When the latter has occurred, it can be rendered ineffective by wide cross-border disease spread, where “over a very short span of time, they become accessible to the rest of the research community, so it was a matter of just waiting” (#18). Regardless, ensuring access to pathogen samples—rapidly, in adequate volumes and at acceptable quality—also remains instrumental for epidemic response, particularly, but not only, in the earliest period of an outbreak (#28).

With the absence of clear, coherent international frameworks and regulations, trust in international collaboration plays a defining role in the success or failure of effective PBS. The absence of trusted long-term collaborations has often led to slow, inefficient, and potentially detrimental barriers to access to pathogens or benefits, which may be difficult to overcome quickly in times of crisis. As PBS practices seem to be qualitatively different between ordinary and outbreak contexts, different approaches to their governance may need to be considered.

Figure 2: Global flow of IVPP samples from sending countries (far left) to receiving countries (far right) (1998-2019, n=2,601)



Notes: Sending countries (left) are not necessarily the originating countries of IVPP samples. IVTM-classified designations for laboratories are WHO Collaborating Centres (WHO CC), National Influenza Centres (NICs), Essential Regulatory Laboratories (ERLs), WHO H5 Reference Laboratories (WHO H5) for GISRS-affiliated laboratories and non-GISRS for all other laboratories. Affiliations were manually designated by the research team as either: Government institutions, academic institutions, SMEs, or multinational pharmaceutical companies. Websites of sending and receiving institutions were consulted in designating affiliations. Government-funded academic research centers (such as those in public universities) were considered academic institutions.

WHAT DO WE (NOT) KNOW ABOUT BENEFIT-SHARING?

Outside of benefit sharing as it is codified in the PIP Framework, there is little clarity or agreement about what constitutes a benefit in relation to pathogen sharing, how benefits are negotiated and implemented in practice, or how such decisions are made. To this end, this section explores what “benefits” can mean in two ways. First, we show the breadth of understandings of “benefits” as discussed with interview respondents and, second, we explore how benefits have been codified in everyday scientific practice through a collection of both publicly available and privately shared MTAs.

There appears to be growing recognition among interviewees, from both the policy and scientific spheres, of the need for reasonable, fair, and equitable benefits to be on equal footing with pathogen sharing. However, there is little consensus on what constitutes fair, equitable and reasonable benefits and there is large variation in views and practices among different groups and across global divides. Respondents’ perspectives on benefit sharing appear to be organized around four non-mutually exclusive understandings of benefits, each with certain implications for developing governance systems for PBS. First, that pathogen sharing generates benefits as a *global good* for global public health (as in the PIP Framework). Second, benefits understood as *access to countermeasures* and *increasing local preparedness and response capacities* envision PBS as a vehicle through which local capacities increase, future dependency on external parties decreases, and disparities may be reduced. Third, benefits may be understood as *scientific and intellectual recognition* in academic spheres (e.g., credit, authorship, acknowledgement, impact rating for academic publications), where the International Committee of Medical Journal Editors (ICMJE) guidelines¹⁸ may provide normative clarity. And fourthly, benefits may be defined as *economic and financial benefits* – such as intellectual property rights or royalties – for pathogen-sending countries or specific institutions within them.

Furthermore, two main areas of contention appear when discussing benefit-sharing for pathogen samples. The first area is in a *bifurcation between academic and economic benefits* in understandings of benefit-sharing. Some respondents argued that academic benefits are becoming disproportionately represented in benefit sharing discussions, at the expense of economic benefits (#32). Others, however, believed that benefits cannot be seen in purely economic terms, as “a pot of gold at the end of the pathogen rainbow” (#27) or as “something in the bank account” where “information itself is a benefit” (#30). Though financial benefits for developing countries are encouraged in general terms under the CBD, there is an absence of clear norms on what constitutes equitable distribution of economic benefits, especially with respect to IP ownership or distribution of royalties. The second key area of contention revolves around *valuation of pathogen samples*. With little to no international guidance, respondents noted that it is difficult to “value” pathogens and identify what is a reasonable and fair associated benefit when their future value is uncertain at the time of sharing (#26). Some responded that pathogens are only valuable in aggregate, especially in the development of diagnostic tests, or in relation to thousands of other pathogens, such as with the selection of candidates for the influenza vaccine. The explicit monetization of pathogens, whether by sending or receiving entities such as pharmaceutical companies, however, seems to be disapproved of by many, with one respondent noting that: “benefit sharing, if that equals to money ... I think it’s only greediness and it’s not really respecting even the principles of the CBD” (#35). Overall, it

is not straightforward to reach common understandings of benefit sharing or, more concretely, to assign clear values to pathogen samples.

To gain some insight on how benefit sharing is codified in everyday scientific agreements, we collected 26 Material Transfer Agreements (MTAs). MTAs are legal contracts that govern the transfer of research materials and associated data between parties and are regularly used to set out the terms and conditions for PBS. There are numerous standardized or model MTAs that have been prepared by organizations to handle PBS, with variations by pathogen, organization, and country, a main example of which is the Standard Material Agreements 2 (SMTA2s)¹ of the PIP Framework.^{19,20} Only four of the collected MTAs were executed MTAs; 22 were model or template agreements. Most of the MTAs collected from interviewees were from organizations and governments of HICs, and only 8 of the 26 (including 3 of the 4 executed MTAs) originated in or involved parties based in LMICs.

The majority of MTAs studied include provisions on ownership of samples and associated IP rights as well as limitations on third party transfers of materials, with 14 stating that ownership and associated rights rest with the provider of the material. All examined MTAs contained at least one benefit; however, there were significant variations in benefit provisions. The benefit provisions included: *acknowledgement in publications*, (17/26 MTAs) where acknowledging providers of samples was required, with 4 MTAs explicitly including co-authorship as a possibility, and *cost recovery*, (11/26 MTAs) where provisions were included on the costs of transfer, with 10 MTAs stating coverage or possible coverage of costs of transfer by the receiving party. *Capacity building and training* (2/26 MTAs) was rarely included through specific provisions, despite anecdotal evidence of capacity building and training as benefits associated with pathogen sharing. *Access to research outcomes* was present in 15/26 MTAs to pathogen providers, including informational outcomes and material benefits, where 11 MTAs were primarily concerned with the sharing of a scientific report on research outcomes. Four MTAs incorporated more complex arrangements regarding access to research outcomes, including access to more material benefits such as the payment of a fixed percentage of sales to third parties, that products be made available to providers for internal research purposes, and provisions on the donation of products or their sale at affordable prices. In 14 SMTA2s between WHO and commercial entities examined, all companies selected the benefits that involved donations of products and reserving products for pandemics to be sold at affordable prices to WHO, rather than benefits involving granting licenses to or ownership of intellectual property rights.

While MTAs provide a way to codify benefit-sharing into pathogen sharing arrangements, it is worth noting that enforcing an MTA in case of suspected violation of the terms is not straightforward, automatic, or easy. The likelihood of judicial enforcement can be remote, especially when the parties are separated by geographical distance, technological capacity, or other power disparities.

¹ SMTA2s have been developed as part of the PIP Framework. The SMTA2s examined were identical except for the choice of benefits companies selected from a list of preset options, which can be found on the WHO's webpage on the SMTA2: [https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-\(smta2\)](https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-(smta2))

WHAT IS (NOT) WORKING WITH PBS?

What did respondents identify as working and not working well in current PBS practices? As empirical evidence remains scarce, preliminary findings were collected here from the perspectives of stakeholders involved in both the policy and practice of PBS.

What is working? Respondents, especially scientists and researchers, described a system that works in many ways. Some researchers reported that “people tend to get what they want” (#12) – that is, that researchers are generally able to get desired pathogens under certain conditions and in normal (non-emergency) situations. When significant challenges or unsuccessful attempts were reported, they tended to be singular events rather than ongoing problems. However, respondents reported that they often do not try to acquire pathogens from certain countries or institutions that are outside the scope of existing partnerships or where they expect challenges. Networks of trusted collaborators and longstanding relationships and projects between researchers were described by multiple respondents as determinative (#18,19), over and above other policy-level considerations, and as embedded in scientific conventions. Several noted a positive feedback loop: collaborations that result in shared benefits are more likely to build further trust and willingness to share. For example, one respondent noted that over time, “the partnerships have, if anything, strengthened and become more fruitful” because the collaborating partners are “able to look retrospectively and see tangible benefits in terms of skills and capabilities and knowledge that they’ve accrued” (#19). However, when trust has been violated between collaborators, several interviewees noted that more restrictive policies tend to be put in place (#21, 36).

Another area that appears to be a bright spot in PBS is the evolution of informal norms of scientific collaboration to include recognition of all partners. This recognition takes the form of formal acknowledgement in, or co-authorship of, scientific publications. As one interviewee expressed it: “There is much, much more sharing, not only of microbes themselves, but a realization that you really have to share credit, you have to share intellectual academic credit” (#10). Through the interviews, acknowledgement was repeatedly mentioned as the right thing to do and as a necessary (if insufficient) component of benefit sharing. It was also identified as something that has now become more or less routine. While some research organizations struggle with navigating new legal terrain, others, especially those with long-standing international collaborations, have reported established practices of “putting ethics first” above and beyond international and national legal requirements in regard to sharing benefits for access to pathogens. Such measures have been enshrined in organizational policies, many of which are now codifying provisions on PBS, with publicly available sample MTAs and draft MTAs used for opening negotiations around PBS becoming more frequent, especially among institutions in HICs.

What is not working? Respondents identified numerous areas where PBS arrangements fall short; the reasons for these shortcomings can be grouped into five main categories:

Disparities in technology and capacity: Respondents described a wide range of disparities across income levels in technology and capacity, including a lack of access to equipment needed for laboratory isolation of pathogens from samples (#13), lack of in-country diagnostic capacity (#53), lack of robust surveillance systems in humans and animals for many pathogens (#7,13), a relatively higher cost of conducting scientific

research in low-resource environments (#38), and insufficient national infrastructure (e.g. electricity) for laboratory capacities (#67). These disparities shape the benefits that are sought in PBS arrangements. Many respondents agreed that capacity building and technology transfer should be part of PBS. Respondents mentioned a range of ways this could occur, including capacity building arrangements; sharing of laboratory equipment and technology, including genomic sequencing technology (#2); sharing of laboratory material, including reagents to perform tests (#20,40); and education (via targeted trainings or degree programs) (#53,67). In addition, providing back up laboratory capacity during emergencies was also identified as a valuable benefit for countries (#73).

Complications due to biosecurity and biosafety concerns: Where biosecurity is concerned, sharing may be restricted (such as with Ebola, for example) or pathogen samples may be destroyed if countries lack the laboratory capacity necessary for their safe storage and upkeep. As such, countries with limited laboratory capacity that experience outbreaks of pathogens requiring high-level containment, such as Liberia's experience with Ebola, may be requested to share such pathogens with better-equipped countries due to biosafety and biosecurity concerns. Respondents discussed this as a politically charged process, where sending countries may feel considerable pressure to share such pathogens for biosecurity reasons. Some respondents argued that samples have and can be kept in-country when secure laboratory capacity is available (#40) or can be created (#39).

Complications due to commercial interests: Complications due to the involvement of commercial interests include diverging views on balancing commercial interests against other interests, challenges in assigning value to pathogens, and mutual distrust. Several respondents argued that commercial interests negatively affected both the speed at which pathogens were shared and the potential for benefits to be secured, albeit in two conflicting ways. On the one hand, some interviewees were concerned that once IP issues entered the conversation, the sharing of pathogens critical to an effective outbreak response would be significantly slowed. One interviewee noted that, when it comes to addressing IP, "it's one thing to work it out over a year or something and it's another to begin a process like that in an emergency" (#23). In contrast, other respondents were concerned that when tangible commercial benefits were at stake, particularly during wide scale emergencies, pathogen sharing would hasten, but attempts to secure adequate benefits would be steamrolled.

Limited awareness of changing rules and their usability for researchers: Institutions and researchers report varying ability to respond to growing and changing legislation around PBS, often contingent on the availability of experienced legal offices and a sensitization of researchers to changing rules. International scientific institutions and collaborative networks report needing significant legal resources to "follow protocols...[we] have been able to request the appropriate permissions and we've gone through all the steps to get letters of authorization, MTAs, and export permits for every sample that does leave the country" (#31). The increasing complexity of rules surrounding PBS raises challenges for researchers. There is a recognition that significant steps need to be taken to sensitize researchers to emerging legislation, with some institutions needing to strengthen legal offices within their universities to ensure that researchers comply with policies, (#48) which is sometimes perceived as "one more administrative step" (#49).

Lack of clear or responsive arrangements or regulations: With the coming into force of the Nagoya Protocol in 2014, many respondents expected that the involvement of national bureaucracies and multiple agencies would run the risk of complicating pathogen

sharing on both practical and normative levels, incurring delays and/or reductions in sharing. Many respondents expressed concerns that governing PBS through the Nagoya Protocol would potentially introduce too much red tape into the sharing process and lead to an increased need for researchers to convince government officials of the importance of pathogen sharing. Importantly, an increase in bureaucratic red tape combined with a decreased prioritization of sharing was noted as having not only the potential to lead to a decline in overall sharing of pathogens, but as creating a particular risk during outbreaks, where timely and widespread sharing is of critical importance. While respondents expressed a desire for greater regulation of PBS, many also expressed concern that Nagoya was being inadequately implemented or weakened during implementation, limiting its ability to produce more equitable benefit sharing. Others advanced a related criticism: that the Nagoya Protocol was too flexible in how it could be implemented by countries and, therefore, that the resultant patchwork of laws and approaches was itself daunting for researchers and companies looking to access pathogens.

Generally, revisiting normative frameworks around PBS was largely considered to be a priority issue, especially in terms of the governance of benefit sharing. One respondent explained that “there’s a great deal of importance in having an international norm and having something in writing” because that can provide countries with enough certainty and confidence to share (#7). Despite this desire, there was a reticence expressed by many of the same respondents for entering into the lengthy negotiations necessary to develop that type of framework; in short, that “everybody knows this needs to be done, but nobody really wants to do it” (#7).

CASE STUDIES: PBS IN OUTBREAK RESPONSE

There has been little empirical research on how PBS occurs in practice during outbreaks. We conducted two case studies to better understand these practices, the first on PBS during Liberia’s EVD epidemic (2014-2016) and the second on PBS during Brazil’s Zika epidemic (2015-2016). While the two countries and their related outbreaks differ substantially (Table 2), they both experienced outbreaks that escalated to public health emergencies of international concern (PHEICs) under the IHR (2005) after the coming into force of the Nagoya Protocol in 2014. Each case offers distinct insights, with additional analytical value arising by considering them side by side.

Table 2: Development and health indicators for Brazil and Liberia (2018)²¹

Indicators	Liberia	Brazil
GDP (current US\$) (billions)	3.3	1,885.5
GNI per capita, PPP (current international \$)	1,330.0	14,520.0
Current health expenditure (%GDP) ²	8.2	9.5
Life expectancy at birth, total (years)	63.7	75.7
Mortality rate, infant (per 1,000 live births)	63.3	12.8
Mortality rate, under-5 (per 1,000 live births)	86.4	14.4

² Data only available for 2017.

Case studies were conducted using in-depth key informant interviews with scientists, policymakers, and government officials at national and international levels, including at relevant ministries, laboratories, research programs and non-governmental organizations in both Liberia and Brazil. Fieldwork in Liberia was conducted in-person between November 11-17, 2019 and included 20 in-depth interviews (83% response rate, total interview requests = 24), while, due to the COVID-19 pandemic, interviews in Brazil were conducted virtually between July and October 2020 and included 11 in-depth interviews and 2 informal discussions (37% response rate, total interview requests = 43) (**Annex 1**). External factors contributed to the low response rate for interviews in Brazil: many respondents were occupied with the COVID-19 pandemic, respondents who had previously agreed to an in-person interview declined to participate in an online interview, and the topic itself was sensitive for Brazilian scientists, made more-so by the political climate in Brazil.

Case Study 1: PBS during Liberia's EVD Epidemic (2014-2016)

On August 8, 2014, the WHO officially declared an outbreak of EVD in Liberia, Sierra Leone, and Guinea a PHEIC under the IHR (2005). At the onset of the outbreak earlier that year, Liberia's healthcare system was still recovering from over 15 years of civil war. Although Liberia's economy was one of the fastest growing prior to the epidemic, there remained high levels of poverty with an average per capita income of 690 USD in 2014, poor road infrastructure, unreliable power and communications networks, and limited access to safe water supply. Liberia's healthcare system was beset with severe shortages in health workers, health facilities, pharmaceuticals, funding for health, and other necessary materials.²² The EVD response deployed more than 40 organizations and 58 foreign medical teams, including from China, Cuba, the UK and the USA, and thousands of international and national staff.²³ In total, the epidemic caused an estimated 28,600 cases and 11,325 deaths.²⁴ While the response to the West African epidemic attracted criticism for being late and expensive,²⁵ the combination of community, national and international efforts succeeded in averting the US CDC's projection of 550,000 cases in both Liberia and Sierra Leone.²⁶ Table 3 details a timeline of PBS practices during the EVD outbreak and the next section details the key findings of the case study.

Table 3: Timeline of Ebola pathogen- and benefit- sharing during Liberia's EVD epidemic

<i>Before March 28, 2014: Pre-EVD outbreak</i>		
<i>Outbreak Context</i>	<i>Governing framework</i>	<i>Pathogen- and Benefit- Sharing</i>
EVD outbreak declared in southeastern Guinea on March 23, 2014. No cases yet identified in Liberia.	No governing frameworks in place for PBS. UL-PIRE's IRB procedures and MTAs are in place for sample-sharing in collaborative research studies (#66).	In-country diagnostic and research capacity are limited. Priority samples for yellow fever, measles and cholera are tested at the newly established National Reference Laboratory (NRL) with the support of the Global Fund while samples for Lassa

		fever and polio are routinely sent abroad with limited traceability (#62). MTAs for research samples are standard inter-laboratory agreements without benefit sharing stipulations (#66).
March 28-April 2014: Emergency mode		
<i>Outbreak Context</i>	<i>Governing framework</i>	<i>Pathogen- and Benefit- Sharing</i>
Two cases reported in the Foya District of Lofa County in Liberia, bordering Guinea, on March 28th, 2014, one of whom passes through Monrovia and dies in Margibi County on April 7, 2014. Total of six cases reported across Liberia by April 12th, 2014, with a case fatality rate of 100%.	No policy framework existed for PBS and no legally binding contracts were signed between the Government of Liberia and regional or international testing centers for Ebola.	The initial response was “confused (#55)” and a “crisis mode” prevailed for EVD testing (#57); samples were sent to Guinea, Senegal, France, among others (#54,57,62,68). Negotiating benefits was not a priority at the outset of the outbreak (#57). Sample movement was not tracked or regulated and Liberians “did not have much control at the time” (#56).
May-August 2014: The scramble for Ebola samples		
<i>Outbreak Context</i>	<i>Governing framework</i>	<i>Pathogen- and Benefit- Sharing</i>
EVD reaches Monrovia. By August 2014, monthly case incidence is 1,049 in Liberia and a PHEIC is declared by the WHO.	Beginning of case-by-case negotiation of MTAs (#54). The National Research Ethics Board (NREB) released 14 provisions for MTAs (#66).	Proliferation of mobile laboratories and testing centers in collaboration with international partners. Samples were also being tested at the Liberia Institute of Biomedical Research (LIBR) through a joint effort with the US NIH and the US Department of Defense (DoD). The Liberian government responds to the exodus of samples by empowering the NREB (#66) and a proposed HIV/AIDS lab at the NRL, funded by Global Fund, is converted to the Ebola testing laboratory. A blanket MTA is signed between the governments of the US and Liberia where “samples belong to the Government of Liberia who

		retained ownership by default” (#54).
September 2014-December 2015: Samples centralized at the National Reference Laboratory		
<i>Outbreak Context</i>	<i>Governing framework</i>	<i>Pathogen- and Benefit- Sharing</i>
EVD cases peak in September and October 2014 and begin to decline by late October to November 2014. Liberia first declared Ebola-free on May 9th, 2015 and a second declaration is made in September 2015.	Though no national policy framework is introduced, sample movement is more strongly regulated, and MTAs begin to be negotiated and signed for diagnostic samples.	All EVD sample testing and storage was centralized at the newly established NRL in Monrovia (#62,69). Riders for Health became operational in April 2015 to establish secure sample transportation (#60,61). A batch of EVD samples leave Liberia for the US due to biosecurity concerns (#63): “[it was] a political decision, high-level, signed on the grounds that we did not have storage capacity” (#68). Liberian scientists begin discussing the need for a national biobank to keep EVD samples in-country.
January 2016 onwards: Building capacity for the future		
<i>Outbreak Context</i>	<i>Regulatory System</i>	<i>Pathogen- and Benefit- Sharing</i>
Liberia declared Ebola-free in January 2016 and for the final time in June 2016.	The National Public Health Institute of Liberia (NPHIL) is established. It is mandated with establishing national guidelines for PBS and undertaking case-by-case negotiations of MTAs with international partners (#55).	Laboratory capacity in-country remains limited due to absence of genomic sequencing equipment and expertise (#56,70) and EVD samples kept in Liberia are considered a biosecurity risk (#54,57). All remaining EVD samples are sent to the US with a signed MTA that retains Liberian ownership of samples alongside continued capacity-building and infrastructure-development support to Liberia (#54,56,57). Liberian scientists continue to explore options for a national or regional biobank (#68).

PBS under the pressure of the EVD epidemic. International actors played a major role in supporting the outbreak response, with US government agencies and mobile laboratories supported by international scientific collaborators playing a particularly

prominent role. With the absence of clear rules governing PBS, there was a large exodus of EVD samples from Liberia during the outbreak²⁷:

“When you are in crisis, when you're drowning, even if someone gave you a hot iron you will hold it before you burn. In 2014, the crisis, we were looking for anything...the goal was, get the things under control. As it subsided, everybody checked back and said look, we have to do things differently (#73).”

While the WHO played a key role in providing technical assistance during the outbreak, WHO was not actively involved in providing substantive guidance to Liberian scientists and officials on negotiating PBS agreements (#64). Liberian scientists and the Liberian Ministry of Health (MoH) were involved in negotiating MTAs for the international movement of EVD samples with some negotiating leverage (#64) due to biosecurity concerns (#58), resulting in retaining Liberian ownership of EVD samples sent to the United States.

Benefit sharing in practice for Ebola samples. The interviews reflected a broad understanding of benefits. Interviewees discussed benefits as including education and training for students in the US (#58), technical capacity building for Liberian scientists and healthcare workers and technology transfer to Liberian laboratories (#63), among others. Authorship and scientific credit were mentioned as necessary, but insufficient, benefits from pathogen sharing. Intellectual property (IP) rights were reportedly a “rare benefit (#70)” that often was not explicitly codified in legal agreements (#70), and at least one agreement with a commercial enterprise reportedly fell through due to disagreement about IP (#58). Access to countermeasures was highlighted as a key benefit arising from the utilization of samples, more desirable than financial benefits – with one interviewee stating that: “I’m not thinking in terms of financial benefit, it’s more of mitigating action for prevention and control (#69).” This has become particularly relevant in light of the recent regulatory approval of an Ebola vaccine (#62). Although the large Phase-2 clinical trial for this vaccine was first initiated in Liberia, legal provisions for access to the vaccine were not included in existing PBS or other arrangements (#64). Liberia is engaging in the processes to be included in an in-country or regional stockpile (#58, 66). Previous experiences with access to countermeasures have not been encouraging, and have raised doubts among Liberian scientists about whether fair agreements are possible between host countries and commercial firms, especially given that access to countermeasures is often left to goodwill rather than legally binding agreements (#70).

Effect of PBS on Liberian laboratory and scientific capacities. Liberian laboratory capacities experienced rapid growth during and after the outbreak, especially through the strengthening of the national reference laboratory. Laboratory infrastructure, however, remained inadequate (#66), reportedly both a precipitating factor and an outcome of the decision to move EVD samples out of the country due to biosecurity concerns (#58). Liberian scientists expressed a deep interest in the need to retain EVD samples in-country. Scientists explained that samples retained in-country draw researchers and funding and would contribute to the growth of Liberian science (#56), especially with diagnostic samples routinely repurposed for research (#62). Another explained:

“If you compare to other countries that did not send their samples, they still have a lot of bargaining chips regarding research collaboration, funding, because they

still have the samples stored in-country and some have biobanks. [...] Some capacity will be held back from the country [if we don't have the samples]. Why shouldn't we have the sequencing capacity here in order to sequence our samples? [...] When you have the pathogen that you want to study, it should provide for all of those resources and capacity (#67)."

Keeping the EVD samples in-country, however, was contingent on building the needed capacity for their safe and secure storage. Liberian scientists stressed the need to leverage access to pathogens for laboratory capacity building and infrastructure development projects in Liberia, in order to build sustainability and reduce dependency on external capacities going forward (#63,67):

"We were giving the samples when we had the Ebola outbreak at its peak and then we had a change in leadership and...there was time now, because the outbreak was also over, to actually sit down and discuss and negotiate things better. So, the negotiation was that we wanted to have our own biobank, we wanted to do our own research, we wanted improvement in our laboratories (#64)."

To this end, the possibility of a Liberian or a jointly governed West African biobank has been repeatedly discussed as a possibility (#58,63), but concrete steps towards this end have yet to be taken.

The need for PBS governance. Clearer and stronger governing frameworks for PBS were identified as an imperative by interviewees. With the EVD outbreak experience, PBS governance in Liberia has rapidly transitioned from a situation of no governing framework to a case-by-case system under the purview of the National Public Health Institute of Liberia (NPHIL). Liberia is a party to the CBD and Nagoya Protocol. As elsewhere, a disconnect exists between governmental bodies focused on the implementation of Nagoya (mainly the Environmental Protection Agency, EPA) and health agencies (such as the MoH, and NPHIL) (#54). A draft law on Access and Benefit-Sharing has been developed but had not yet been finalized as of this writing²⁸ and amendments to address biosafety and biosecurity in Liberia's Title 33 Public Health Law are before the national legislature. Up to the time of our study, there were no policies or regulations specific to PBS, and legal resources were unequal when negotiating contracts with larger, more experienced, international research institutions. As has been seen in other countries, sharing of pathogen samples and related benefits depends heavily on personal relationships and long-term collaborations that engender trust (#58). Nevertheless, the use of contractual agreements such as MTAs has become established practice since the outbreak, and some benefits are included in these agreements. There are also substantial, multi-year scientific collaborations, aid flows, and political relationships between the Liberian and the US governments, which are important contextual factors in the background of any specific MTA negotiation. There is a growing and concrete interest in developing normative frameworks and governance mechanisms for PBS, both nationally and regionally, and among both scientists and policymakers.

Case Study 2: PBS during Brazil's Zika Outbreak (2015-2016)

In October 2015, the Brazilian MoH was notified of a sudden increase in cases of newborns with microcephaly and other neurological impairments in Northern Brazil. Soon linked to the spread of the Zika virus by Brazilian scientists in Recife, the Zika epidemic was officially announced an Emergency in Public Health of National Importance on November 11th 2015 and a WHO PHEIC declaration followed on the 1st of February 2016 as the Zika virus spread across the Americas and beyond. By the time the Zika outbreak subsided in 2016, there were more than 500,000 suspected and 173,000 confirmed cases, including more than 3,474 cases of confirmed congenital syndrome associated with Zika virus infection.²⁹ Zika exposed the social and health inequalities in accessing specialized healthcare in Brazil as, until the end of 2019, only 33% of children received early intervention and 50% had access to financial aid from the Brazilian Government.²⁸ As efforts to respond to the Zika epidemic were rapidly launched, international researchers faced difficulties securing samples of the Zika virus from Brazil, the epicenter of the outbreak. Table 4 details a timeline of PBS practices during the Zika outbreak and the next section details the key findings of the case study.

Table 4: Timeline of Zika pathogen- and benefit- sharing during the Zika epidemic (2015-2016)

Before November 2015: Pre-Zika Outbreak		
<i>Outbreak Context</i>	<i>Governing framework</i>	<i>Pathogen- and Benefit- Sharing</i>
In March 2015, the Brazilian MoH identified Zika infections in Brazil. By October 2015, the MoH was notified of unusual increases in cases of microcephaly in infants.	The Provisional Act 2, 186-16, of August 2001 regulated access to genetic resources, not including pathogens. The new Biodiversity Law (Law 13, 123) is adopted in May 2015, which includes “microbial species” within the remit of its definition of genetic heritage (Art 1, IV).	Before Law 13, 123, sharing of pathogen samples was less restricted and primarily at the discretion of scientists without the need for prior approval or reporting: • “The rules existed but weren’t so strong (#74).” • “We sent [dengue] samples abroad without any problems (#75).” • “[10-15 years ago] we were just sharing samples and not having any kind of benefit at all (#76).”
November 2015-July 2016: Zika-sharing interrupted		
<i>Outbreak Context</i>	<i>Governing framework</i>	<i>Pathogen- and Benefit- Sharing</i>
In November 2015, the MoH recognized the link between Zika infection and microcephaly and declared an	On November 17th, 2015, the Biodiversity Law came into force, establishing the rules for access to genetic resources and benefit	“The whole world wanted Zika samples (#77),” but international sharing of Zika samples was officially halted (#75,76,77) until an online registration system was established

Emergency in Public Health of National Importance. The WHO announced a PHEIC on February 1st, 2016. Zika outbreak response efforts were underway until the closure of the Public Health Emergence of National Importance in July 2016.	sharing. The regulatory system to enforce the law was delayed. In July 2016, the executive secretariat of the Genetic Heritage Management Council (CGen) was established.	that allows scientists to comply with the law (#79): • “With Zika, we started to have a different behavior. If the government knew that we had shipped samples to other countries without following all the rules, we could be prosecuted. So, we decided not to ship samples (#75).” • “It was in the heart of the Zika epidemic that we were delayed one or two months until we cleared internally with our legal teams (#76).” • “There was lots of discussion, they [governmental officials] were trying to find alternatives for sharing despite the fact that we were not officially allowed, I think that everyone really agreed that things should be done differently, but at the same time with the urgency of Zika it was just taking too long... (#77).”
July 2016 onwards: Post-Zika, a New Normal		
<i>Outbreak Context</i>	<i>Governing framework</i>	<i>Pathogen- and Benefit- Sharing</i>
Zika outbreak had ended.	The National System of Genetic Resource Management (SisGen) became available in November 2017. The use of MTAs was formalized.	Regulation of international sample-sharing was clarified and regularized once the SisGen was in place. The system for compliance with the Biodiversity Law has reportedly improved to accommodate the needs of scientists (#79) and negotiating benefit sharing agreements through MTAs has become a common practice: • “We started to share samples from the end of 2016 ... it just took time at the beginning but nowadays is very quick because I think everyone is more mature in terms of understanding that we are protecting our institutions and

		the receiving institution (#78).” • “I think that scientists in Brazil have learned that we have some power in terms of determining what our terms are, what changed is the fact that we can tell them what is interesting for us and then officially we can go through all the bureaucracy of sample sharing...it's still not that easy...the process takes too long [sometimes] so the international groups tend to look for other options and not really wait for us (#77).”
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The new Biodiversity Law. The Zika outbreak coincided with a period of changes to Brazil's biodiversity laws. The Provisional Act 2, 186-16, of August 2001 was the first legal framework in Brazil to regulate access to genetic resources and associated traditional knowledge for purposes of scientific research, bioprospecting, and technological development. Fourteen years later, the new Biodiversity Law (Law 13, 123 of May 20th, 2015) was adopted, establishing new rules for access to genetic resources and benefit sharing. Brazil was not a party to the Nagoya Protocol during the Zika outbreak, but ratified it in 2021. Nevertheless, Brazil has long been an active voice in international debates on sovereignty over natural resources and the importance of fair benefit sharing. Benefit sharing in the Brazilian legislation includes both monetary and non-monetary benefits, either of which will only become applicable once a product derived from the use of genetic resources is marketed.³⁰ While the new Biodiversity Law entered into force on November 17, 2015, only weeks before the Zika epidemic was announced in Brazil, its online registration system, the National System of Genetic Resource Management and Associated Traditional Knowledge (SisGen) (under Decree No. 8772 of May 11, 2016), was unavailable until November 2017, months after the Brazilian government had declared the Zika epidemic to have subsided (#79). As a result, throughout the Zika epidemic, PBS was strongly influenced by this legislative change. Although the new Biodiversity law posed barriers the during Zika outbreak, it is important to mention that until 2016 there was no clear regulation on biodiversity, including genetic materials and benefits sharing, and how to improve equity and protect Brazilian scientists and research institutions against predatorial agreements.³¹

Motivations for Zika sample sharing and non-sharing. The coming into force of Law 13,123 marked the beginning of a period of transformation in Brazilian scientific practice that coincided with the urgency of the Zika epidemic, reportedly impacting Brazilian scientists' ability to share Zika samples and related benefits throughout the outbreak. While previous legislation exempted basic research, such as microbiology, from the Provisional Act 2, 186-16 (August 2001), the new definition of “genetic heritage” in Law 13, 123 included pathogens within its scope (#79). One key improvement of the law was allowing Brazilian scientists prior authorization to use genetic resources, with the

main obligation being reporting to relevant authorities before publication, commercialization, patenting, or international sharing (#79). The law, however, created a regulatory vacuum between the time of its coming into force on November 17th, 2015 and the creation of the online registration system to enforce it, the SisGen, in November 2017 (#79). This vacuum coincided with the entire period of the Zika outbreak:

“The problem was that our previous legislation was revoked and then only in November 2017 we had the SISGEN...we had one year without regulation...and we had two years without the instruments we needed to comply with the legislation. So, during this period, we were forbidden from doing any shipment of biological material (#79).”

The Biodiversity Law was, however, not the only reason for hesitancy in Zika sample-sharing. At a time when “the whole world wanted Zika samples (#77)” hesitancy to share Zika samples was also informed by previous experiences of inadequate benefit sharing (#75,76,77,79,80) and a belief in the importance of using national capacities, fostering equitable international collaborations and securing official benefit sharing arrangements (#76,77,80,86). As one Brazilian scientist put it, “we don't have to be just sample providers [anymore], we can do a lot more than that nowadays (#77).” At the time of the Zika outbreak, Brazil had the technological capacities and materials to isolate the Zika virus, develop and validate diagnostic tests, conduct cohort and case-control studies and clinical trials, and begin vaccine development (#76). Zika sample-sharing was, therefore, motivated either by studies that required expertise or technologies that exceeded Brazil's existing capacities or when in-country studies would be prohibitively expensive (#76,77). While many Brazilian scientists interviewed believed in scientific collaboration and partnership as fundamental to knowledge production (#74), difficulties with Zika sample-sharing were jointly attributed to regulatory delay as well as the desire to have legal protections in place for PBS. “On one hand, the law introduced complexities to pathogen sharing for the global health response to the Zika epidemic (#75-77). On the other hand, scientists interviewed in Brazil foregrounded the need for “legal instruments that would guarantee that if we share samples, we will have benefits from diagnostic tests and vaccines (#75)” and for strengthening national capacities, arguing that “it's important for a developing country like Brazil ... to put our feet in there and say, okay, we can do some of it, let us take care of what we can do and let us do other things in collaboration (#77).”

Benefit sharing in practice for Zika samples. Though the Biodiversity Law stipulates that benefits only kick in once a product developed through the use of pathogens reaches commercialization, Brazilian scientists interviewed had a wider understanding of benefit sharing in practice. These included both monetary benefits, in the form of sharing grants that fund laboratory activities (#77), and non-monetary benefits in the form of co-authorship in high-impact publications, capacity building through scholarships, trainee-ships and scientific exchanges, and the transfer of equipment and technologies (#76). Benefits to patients were also emphasized, with one participant noting, “I was pissed off with this because everyone wanted to have access to our biorepository and no one wanted to help the mothers...I told them, ‘look, I will lock the biorepository if you won't help these mothers’ (#74).” Long-term collaboration had a significant impact beyond the sharing of samples:

“[In international collaborations], we share much more than the sample, we share knowledge, databases, people that come in and go abroad. Zika, it was amazing, the number of researchers and students that came in from the United States, from Europe, to stay with us ... now we are doing COVID studies with the same people with whom we were doing the Zika studies (#78).”

At the height of the outbreak, significant delays were incurred as Brazilian institutions set up legal instruments to ensure compliance with new legislation (#74-77,79,80). These delays impacted, at the time, the ability of scientists to share in the benefits of research on Zika:

“[I was asked] if I can send samples of Zika and they offered me equipment...they proposed to pay for some fellowships because I explained that I was in the middle of a big outbreak...they also sent a document that says that any publication, we will have an important position in the paper, so on ... it was just in the moment that [we] couldn’t ship samples abroad because there was a law that prohibits it... I could not send the samples and it was really terrible, a very difficult situation... (#75).”

Adaptations to the Biodiversity Law. As the Zika epidemic in Brazil subsided, the SisGen became available to Brazilian scientists and researchers in November 2017 the online registration system for the Biodiversity Law under the auspices of the CGen. Throughout this period, scientists adapted to new regulations and shifts in standard scientific practice. It is unclear, from our interviews, when Zika sample-sharing became authorized under the new Biodiversity Law, in what form, and to what extent Zika samples were sent abroad during this period. We received conflicting information in the interviews as to whether any samples had been exported at all prior to the establishment of SisGen; it is possible that some sample-sharing did take place, either via an exception for Zika samples under the new Biodiversity Law or outside of a clear regulatory framework.

These adaptations included an increased focus on data-sharing in lieu of sample-sharing (#81,83,85) and the formalization and standardization of the use of MTAs (#76,78). In addition, scientists reported a shift in conventional scientific practice from sending samples out—which remains a difficult process—to receiving test kits, equipment and researchers for in-country diagnostic testing and research studies (#74-77,81). The online registration system has also undergone revisions to better accommodate scientists in basic research. One example is changes to the standardized MTA to allow umbrella MTAs for several sample shipments valid over a 10-year period in lieu of individual MTAs per shipment. (#79) Interviewees also reported that the online registration system of the SISGEN was not designed with basic research scientists in mind (#76,80); such scientists are currently exempt from registering samples, pending a new version of the system (#79). Nevertheless, many scientists reported that sample sharing was “not yet ideal (#77)”; it remains a slow process and requires a wide range of institutional authorizations and government permissions for shipping (#74,75,85). Presently, the main barriers reported are continued dysfunctions in the regulatory system for PBS (#74,75,77), “enormous paperwork” and long bureaucratic delays with shipments, sometimes leading

to the spoiling of samples stuck in ports (#75,79) and a lack of funding and capacity to store and curate pathogen collections in-country in Brazil (#78). Some scientists expressed concern that opportunities for knowledge generation, publishing and grant-raising had been lost due to these continuing barriers (#78).

PBS in Outbreak Response

Despite stark differences between Liberia's EVD and Brazil's Zika outbreaks – including different national research capacities and governance frameworks – our case studies found a number of characteristics common to both cases of PBS: First, outbreak pathogens became highly sought-after and valuable resources at the outset of the epidemics. Second, previous experiences with benefit sharing perceived as unfair informed the decisions of governments and scientists in these specific outbreaks. Third, the absence of previously negotiated benefit sharing arrangements resulted in intense negotiations around PBS, some of which impacted either rapid pathogen sharing or fair and equitable benefit-sharing. Fourth, access to pathogens has been leveraged for certain benefits in both outbreaks. Last, both countries experienced post-outbreak formalization of PBS processes through the institutionalization of standardized MTAs and legislative or regulatory change – in other words, crises drove change.

Findings show that outbreak pathogens became valuable resources in both contexts, both nationally and internationally. The benefits that outbreak pathogens were leveraged for were, for the most part, focused on building local and national capacity for outbreak response, present and future. EVD samples in Liberia, though ultimately shared internationally, were instrumental in capacity-building negotiations, underscoring the need for strengthening national laboratory capacity and precipitating interest in national or regional biobanks for their safe and secure storage. Zika samples in Brazil – the sharing of which was delayed and partially restricted by the new Biodiversity Law – led to some benefits flowing into Brazil (e.g. access to testing kits, reagents, visiting scientists) but could also have limited the possibility of other benefits that might have been negotiated in relation to exported samples (e.g. co-authorship of publications, grants, collaborations). It is unclear, from our findings, what impact these restrictions had on the development or deployment of countermeasures to control Zika. Although no vaccine or treatment for Zika has been developed to date in Brazil and abroad, so access to countermeasures has been perhaps of limited relevance, there is some evidence that restrictions on Zika sample sharing has weakened diagnostic capacity for Zika and contributed to barriers in the global response to the Zika epidemic.³²

Evidence from these case studies support the conclusion that national governance of PBS is an emerging reality that global health actors will have to contend with. Though progress on national governance of PBS has been made in both Brazil and Liberia, national governing frameworks for PBS that are consistent with both global health need and Nagoya-related considerations have yet to be fully developed. In Liberia, PBS is still negotiated on a case-by-case basis by a public agency—the NPHIL—and, in Brazil, the system in place does not yet guarantee rapid pathogen sharing when needed for outbreak response. It is not certain, as a result, that PBS will be timely or equitable in either country in future epidemics, leaving many of the original problems unresolved.

Furthermore, it is likely that such situations will recur in future infectious disease outbreaks in countries beyond Liberia and Brazil. This is especially the case as many

countries remain either without clear national governing frameworks for PBS—as with Liberia before the EVD pandemic—or with ABS governance that affects pathogen sharing—as with Brazil during the Zika pandemic. With growing ABS legislation worldwide, rapid, unregulated, and unfettered pathogen sharing may be slowly becoming a thing of the past. Fair and equitable PBS systems should be in place ahead of outbreaks of pathogens of pandemic potential at both national and international levels, to ensure more reliable sharing of both pathogen samples and benefits in the future. This remains a significant policy challenge, as the next section discusses. Real-world experiences and perspectives from Liberia and Brazil can and should inform debates and negotiations that aim to develop global frameworks for PBS that are fair, acceptable, and functional.

GOVERNING PBS: WHAT ARE THE OPTIONS?

What do the data suggest regarding workable solutions for the key issues identified in PBS? Overall, we found that even though there are many policy options, each with their proponents, there was no one clear policy direction that was strongly supported or advocated by a critical mass of respondents. As such, there is little consensus on a clear direction going forward. We first present the many options that have been raised for governing PBS, placing them within a spectrum of approaches that cut across different levels of formality and scope, and then identify key debates in the interaction of existing rules for PBS.

Many interviewees highlighted as problematic the absence of clear international rules to govern PBS, notwithstanding the increased participation in the Nagoya Protocol. At the same time, several respondents recalled the four years required to reach agreement on a set of rules for pandemic influenza alone (the PIP Framework) and expressed reservations about the time required and difficulty of reaching agreement on a broader framework covering multiple pathogens. For this reason, it may be useful to consider a broad set of normative instruments, ranging from less to more formal, from few countries to all, and from select pathogens to all:

Informal rules, or Codified non-binding rules: At one end of the spectrum are codified non-binding rules, such as a set of principles agreed upon by a group of stakeholders for the governance of an issue of common concern. Such rules would not have binding force but would establish some norms in this under-governed area. Potential examples for PBS include developing non-binding though codified PBS principles, codes of conducts or guidelines, similar to their use in related fields such as the Declaration of Helsinki on ethical principles for medical research involving human subjects³³ and the Council for International Organizations of Medical Sciences' (CIOMS) "International Ethical Guidelines for Health-Related Research Involving Human Subjects" (2017).³⁴

Non-binding formal rules backed by an inter-governmental entity: One step towards more formal rules would be non-binding formal rules that are backed by an intergovernmental authority such as WHO. By "formal" we mean that they are negotiated and agreed upon by governments through a structured process. Examples of non-binding formal rules include the PIP Framework and the WHO Codes of Conduct on health worker recruitment and the marketing of breastmilk substitute. Nagoya parties may also adopt codes of conduct specific to PBS, though this has not been actively discussed at this point by the parties. Non-binding formal rules are likely to require more time to negotiate, but, in principle, would have greater normative weight than informal rules alone, and could

generate buy-in from key stakeholders. Potential examples for PBS could include, for example, the expanded use of standardized MTAs or the use of a traceability mechanism for PBS (fulfilling the role of the IVTM for pandemic influenza sharing, for example).

Binding formal norms backed by an inter-governmental entity: Binding formal norms include international legal instruments such as the WHO IHR (2005) and treaties such as the CBD and the Nagoya Protocol. While treaties have the advantage of carrying, in principle, greater normative weight than non-binding or less formal instruments, they may take longer to negotiate and enter into force, and are usually difficult to amend or adapt – posing challenges given that PBS is an issue area characterized by rapid technological change. Finally, formal treaties do not necessarily have a greater impact on policy or practice than less formal or non-binding rules. No interviewee suggested a formal treaty would be the appropriate instrument to improve PBS practices, although at least one interviewee noted that making the PIP Framework binding international law would have been preferable but was not supported by key stakeholders.

Table 1: Perspectives on Formality and Scope of Policy Options

Informal rules, or Codified non-binding rules	• “...if you have a long cumbersome process that could just have people run away from it, I think you can get some sort of norm, like an agreement... (#10).” • “It's very hard to find universal governance instruments and legal instruments that everyone will sign up to...[with] the pathogen community, you could get some global norms in terms of principles that people would adhere to and then you could create some rules and some implementation strategies...I think it's the right time to stand back and look where the self-regulation works and where it could be supported by other types of mechanisms...(#26).”
PBS Principles, Guidelines or Codes of Conduct	• “It's a very fine balance because you don't want to turn academics or product developers into [slowed down] bureaucratic enterprises, but if we can define timely sharing and what's a reasonable framework for negotiations around benefits [that would be good] (#23).” • “If it doesn't come out of WHO, I think there's a role for academics [and] think tanks to play and put forward templates—like Chatham House did with the data sharing—as models for potential ways of making sure that...sharing is on a common platform (#11).”
Non-binding formal rules, or Codified non-binding norms backed	• “There's a great deal of importance in having an international norm and something in writing...if you play by the rules, you also get the benefits...you have

by an inter-governmental entity	to believe that the system works well enough for your population not to be forgotten about (#7).” • “Then the question is, okay, if it's done bilaterally, then maybe that is not the best way to address in times of pandemic, so you might want something more internationally (#14).” • “We have treaties in other areas than public health to try and have some norms in place that keep us from going off the rails...the challenge is, it's one thing to work it out over a year and it's another to begin a process like that in an emergency...the time to be prepared is now (#23).”
Expanded use of Standardized MTAs	• “You can have standardized terms where the template would be adjustable for [specific] purposes...[and] have those pegged as part of the common approach...so you can make sure that the access and the benefit sharing remain somewhat on an equal footing (#11).” • “That's all about hav[ing] the right agreements and enforcing them, so you need good negotiating capacity, if you fail in drafting, then there is no way of doing it (#24).”
Traceability Mechanism	• “[A traceability mechanism is]...helps everyone understand at least part of that bargain, so we have reporting about what's been promised and the money that comes in on the benefit side, and ...the traceability mechanism...lets us see what's being shared with who and on what basis so that we can look at the adequacy and the timeliness of the sharing and evaluate that (#11).”
“Netflix” model	• “Another possibility would be that all benefits are translated into a financial benefit, which goes into a fund and you can have therefore a subscription... and it goes into a fund (#39).”
Binding formal norms, or Codified binding norms backed by an inter-governmental entity	• “Worldwide, I think, you may have expected reluctance from some countries in particular developed countries to enter into a binding agreement. As you know in WHO there is only one binding agreement, tobacco. So, that's the only one. So, in WHO it is not a common practice to give binding agreement. And, I imagine, as far as I follow the process and that some countries were not prepared at all to enter into a binding scheme (#24).”

The above possibilities need to be understood in the context of existing rules and frameworks.

IHR (2005). The IHR (2005) does not explicitly require sharing pathogen samples, raising two questions: The first is whether state parties may nonetheless be under an obligation to share pathogens if this is necessary for surveillance and response, as arguably it is with influenza. An argument in this sense was made during the PIP Framework negotiations, but that obligation would be too inchoate to be of practical relevance and could create conflicts with the Nagoya Protocol. Secondly, Article 6 of the IHR (2005) requires parties to communicate to WHO a broad range of information on notifiable health events and it was argued that this could be interpreted to include at least GSD; this interpretation was never discussed in WHO and this was certainly not the intention of the negotiators of the IHR (2005). It is noteworthy that the IHR (2005) were hardly ever mentioned in our interviews and that their feasibility as a possible regulatory instrument for PBS was questioned in view of their perceived ineffectiveness despite their formal binding legal status.

PIP Framework (2011). Referred to by many interviewees as a successful model for PBS, the PIP Framework is an innovative instrument involving not only states but also industry, civil society, and scientific institutions. It was adopted by the WHA as a non-legally binding instrument under Article 23 of the WHO Constitution. It is credited for injecting principles of equity and distributive justice that are missing from the IHR (2005) (#11). The possibility of extending the PIP Framework to seasonal flu, which has been informally discussed in WHO, or to expand the PIP Framework into a broader framework applicable to non-flu pathogens did not receive much support from interviewees. Influenza is seen as a unique case both because of the existence of GISRS (on which the PIP Framework is built) and because the need to produce annual vaccines requires institutionalized cooperation. Some of the key principles agreed in the PIP Framework – especially putting access and benefit sharing on equal footing, and multilateral sharing of both samples and benefits – and the mechanisms to implement those principles (e.g., use of standardized MTAs, pre-negotiation of benefits, financing options) could be built upon or adapted for other pathogens.

CBD (1992) and Nagoya Protocol (2011). The CBD (adopted in 1992) and its Nagoya Protocol negotiated in parallel to the PIP Framework (adopted in 2011 and in force for 132 parties as of September 2021) dominated the interviews as the legal instruments that are changing the global outlook on PBS. At the same time, there is a limited awareness of the implications of the Nagoya Protocol and even of its existence among scientists, and it is creating confusion and uncertainties because of its lack of universality and the uneven way in which it is being implemented across and within countries. There were remarkably different positions on the implications for pathogen sharing and what could be done to improve the current situation. Pathogen sharing for public health purposes, with its arguably special needs, in particular with regard to disease outbreaks, was clearly not on the mind of the CBD's drafters. Several interviewees were adamant that the bilateral and transactional approach to ABS enshrined in the CBD and Nagoya Protocol were not fit for public health, which requires unfettered and quick multilateral sharing (#45). For some respondents, the CBD and Nagoya Protocol have formalized and politicized scientific cooperation unnecessarily and raised bureaucratic hurdles that create delays and make cooperation difficult and unpredictable. Even though most interviewees seemed to consider pathogens as falling within the scope of the

CBD/Nagoya as genetic resources, some interviewees still questioned this (#24). Other interviewees felt equally strongly that the CBD/Nagoya broke with “neo-colonialist” behavior by developed countries and their industries, gave more leverage to source countries and enshrined fundamental notions of equity in international law (#15).

The Nagoya Protocol took into account the concerns raised by the PIP Framework negotiation and introduced a number of flexibilities that have been referred to in the academic literature,³⁵ and are being discussed in WHO and CBD governance. There are three main flexibilities. First, the recognition in Article 4.4 that the Nagoya regime shall not apply to the parties to specialized international ABS instruments (SII) consistent with the Protocol. Second, the requirement in Article 8(b) that parties, in developing their ABS legislation, “pay due regard” to present or imminent emergencies and consider the need for quick access to genetic resources and related benefits, including access to countermeasures (e.g., drugs, diagnostics, vaccines). Third, Articles 19 and 20 encourage the development of model contractual clauses (Article 19) as well as voluntary codes of conduct, guidelines, and best practices (Article 20) to harmonize and smooth the terms of ABS. Despite some disagreement on the inclusion of pathogens within the remit of the Nagoya Protocol, its implications for pathogens have drawn growing attention.

Despite the uncertainties surrounding the implications of the Nagoya Protocol for pathogen sharing and the parallel discussions within WHO and the CBD governance to clarify the terms of pathogen sharing, some interviewees argued there is no inherent conflict between the Nagoya Protocol and public health needs; and that the Nagoya Protocol provides clarity as a general regime and more time should be given to its implementation (#32).

In addition to the form of any governing instrument and its relationship to existing law, the question of scope arises across three dimensions: which countries, which pathogens, and for what uses and benefits.

Geographical scope: “Club models” of governance have increasingly been used to address global governance challenges when global approaches seemed elusive. Regional models could also be explored. Smaller groups of states, and/or non-state actors such as research institutes, could agree on mutually acceptable norms, principles, and PBS arrangements. For the sake of both effectiveness and political acceptability, it would be critical that such groupings include key countries and/or institutions where emerging or re-emerging infectious diseases are likely to be found and key countries/institutions where scientific research and health technology research and development (R&D) capacity are concentrated. Our analysis of IVTM data found that influenza sample-sharing is highly concentrated among about 15 sending and receiving countries; to the extent this pattern holds for other pathogens, a small group of countries or research institutes could kick-start a negotiation process.

Scope of pathogens: The scope of rules could also vary, from a narrower list of priority pathogens to a broader set. Our research found that challenges with reliable PBS arose under two main conditions – when national security concerns or commercial interests were at stake. Otherwise, pathogen sharing and at least some benefit sharing appeared to be regular and reasonably reliable within research networks for non-commercial purposes. A key question is the feasibility of determining such a list of pathogens *ex ante*, and how to determine whether a novel pathogen would fall within scope, especially in the earliest days after such a pathogen is identified. It will also be critical to include consideration of GSD from the start, rather than physical samples alone.

Scope of use and benefits: Finally, the scope of any normative framework could vary with respect to types of use permitted with a shared pathogen, or types of benefits included. In particular, it may be easier to reach agreement on PBS for non-commercial use – e.g., for research and surveillance purposes – which could be governed under specific standardized terms, whereas economic benefits would remain to be negotiated on a case-by-case basis or within a broad set of principles.

In identifying potential solutions to the challenge of PBS, key variables include the choice of normative instrument, its relationship to existing international treaties, its degree of formality and the scope of actors negotiating it, the pathogens to be included, and scope of use and benefits. While keeping these options in mind, overall, it is critical to reach a minimum level of agreement on the ultimate purpose of such an instrument – that is, form should follow function. If key stakeholders agree that there is a shared global public interest in ensuring reliable, rapid pathogen sharing and fair, equitable benefit sharing, the question of form could be more easily addressed.

CONCLUSIONS: A WAY FORWARD?

The ongoing COVID-19 pandemic underscores the urgent need to find governance solutions for PBS, and the political appetite for multilateral instruments for PBS may be changing as a result. Although additional research into PBS is needed, a few conclusions can be advanced at this time. First, there is a need for traceability of PBS beyond pandemic influenza – and the development of a traceability mechanism could act as a first step in the development of a comprehensive negotiated framework. Second, given preliminary findings on the relatively small number of countries involved in PBS, a small albeit representative group of stakeholders could begin to create clearer international normative frameworks for PBS governance. Third, there is agreement to build upon, with widespread acceptance of the importance of benefit-sharing to be on equal footing with pathogen-sharing. However, ongoing disagreements about what benefits should entail will need to be addressed. Fourth, as the case studies of Ebola and Zika underscored, PBS arrangements need to be in place ahead of outbreaks, at both national and international levels, to ensure fair and reliable sharing of both pathogens and benefits in the future. Finally, while the interaction of existing rules for health and biodiversity are complex, it is possible to develop specific rules for PBS while remaining consistent with the objectives of both regimes. Given the general agreement about the need for clarity, predictability, and equity in PBS, there are many possibilities for a way forward – if political leadership emerges.

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CORPORATE LOBBYING ON US POSITIONS TOWARD THE WORLD HEALTH ORGANIZATION: EVIDENCE OF INTENSIFICATION AND CROSS-INDUSTRY COORDINATION

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This is the first comprehensive study of expenditures on lobbying of the US federal government linked to discussions seeking to shape US policy toward, funding of, and participation in the World Health Organization (WHO). We link corporate lobbying expenditures and coinciding public statements to legislative proposals and other actions to restrict funding to, censure, and undermine confidence in the WHO. We uncover evidence of an intensifying and coordinated effort within a newly organized alliance across producers of commercial milk formulas, other ultra-processed foods, alcoholic beverages, biotechnology and pharmaceuticals, chemicals, plastics, and electronic gaming. Lobbying by the coalition occurs simultaneously with tobacco interests. Targets include WHO global health initiatives to address non-communicable diseases and access to medicines, as well as WHO protocols limiting private sector participation to mitigate conflicts of interest in health policy-making processes. The coalition characterizes its activities in terms of ‘advocacy for WHO reform’ or similar. In 2021, it argued such reforms are necessary for future pandemic response, indicating use of the Covid-19 crisis as leverage. Overall, these findings indicate corporate lobbying not only targets specific WHO processes that conflict with commercial interests, but also works to cast doubt on the integrity and narrow the operational capacities of the global health governance system itself.

INTRODUCTION

The World Health Organization (WHO) was established in 1948 as the lead United Nations (UN) authority on international health, envisioned as a bastion for international cooperation, and operating in the more technocratic ‘low politics’ of international relations. Yet the Organization has often become embroiled in the geo-political struggles and conflicting foreign policy objectives of its member states.¹ This was starkly apparent when on May 29 2020, as the Covid-19 pandemic was wreaking havoc across the world, the President of the United States (US) announced that the US would cease financial contributions to and withdraw from the WHO.²

On July 6, the Trump administration officially notified the United Nations Secretary-General of its intention to withdraw US membership from WHO,³ stating that this was because of WHO’s delay in identifying threats related to Covid-19.⁴ The President also linked complaints that China neglected reporting obligations when it first discovered the virus spreading domestically with allegations that WHO covered up this neglect and refused to make unspecified reforms demanded by the US.⁵

While linked to the pandemic, the Trump administration’s conflict with WHO occurred during a time of ongoing debate over how much engagement private sector actors should be allowed to have in health policy processes, and how to formalize protocols used to screen and mitigate conflicts of interest (COI) when engaging with

WHO.⁶ It came amid increasing tensions over the role that WHO should play in establishing international norms for public health measures that may impede trade.⁷ Furthermore, although the Biden administration quickly revoked the previous Administration's notification of withdrawal from WHO, it has called for unspecified reforms in the wake of the pandemic.⁸ Understanding competing interests at play during this time of elevated tension in US and global health policy is key to protecting the integrity of public interest institutions such as WHO.

To this end, we examine recent corporate lobbying to gain insight into the stance of commercial actors toward WHO in their communications with the US government, and the nature of their efforts to influence US participation in global health governance. We begin by using routinely collected data on lobbying of the US federal government to identify actors, quantify a subset of expenditures on advocacy via lobbying, observe variation in these expenditures over time, and identify portions of the subject area and nature of this lobbying activity. We use these data to guide a documentary search and public records request. Our findings show that the announced US withdrawal from WHO occurred in the midst of a wave of corporate lobbying aimed at shaping not just particular policies of WHO, but also its funding, the scope of its mission, and its processes for screening COI among private sector actors, with the Framework for Engagement with Non-State Actors (FENSA)—the firewall between global health governance and commercial interests—a special target for dismantling.

Previous research has highlighted coordination within industries lobbying to influence WHO policy related to consumption of ultra-processed foods⁹, and initiatives to reduce the use of tobacco or alcohol.¹⁰ In this paper, we present publicly disclosed data on all corporate lobbying of US federal agencies and elected officials where WHO or its governing body, the World Health Assembly (WHA), is mentioned. The disclosure data allow us to study lobbying related to WHO by a broader universe of actors, allowing us to observe *cross-industry coordination* through a new coalition of industry associations aimed at shaping the policy decisions, operational policies, and funding of WHO itself. While lobbying by individual industries still takes place, we show that in the years leading up to the recent conflict between the US and WHO, a new coordinated push to coalesce and amplify the efforts of individual industry associations to influence US actions toward the WHO. We conclude by considering the conditions under which the US relationship with the WHO can change, given this ongoing pressure.

BACKGROUND

The turmoil in 2020 was not the first time that WHO processes and policies have been a source of conflict with its most powerful member state. Some of these instances have intersected with related conflicts involving corporate actors who have opposed public health policy recommendations perceived to impede market access or profit.¹¹ A rich literature on the *commercial determinants* of health (CDoH) highlights a series of battles over WHO policy and funding over at least half a century.¹²

In 1985, for example, the Reagan administration not only decided to withhold US assessed contributions to WHO, but also four-fifths of its contributions to the UN as a whole, in protest to revisions made to the WHO's Essential Medicines List (EML) deemed to be harmful to the interests of the US pharmaceutical industry.¹³ Such contributions are essential to the fulfillment of the Organization's mandate. Assessed contributions not only

provide predictability for planning and alignment of resources with WHO's planned program of work, but also enables democratic priority-setting by all member states. Led by pressure from the United States, the WHO was subjected to a real (growth pegged to inflation) cap to its regular budget in the 1980s, progressing to a more stringent cap in nominal terms (absolute zero growth) during the Clinton administration.¹⁴

Conflicts related to CDoH have also involved efforts by corporate actors aimed at weakening the legal, scientific and human rights grounds for public health measures related to tobacco control, food safety and nutrition, and alcohol consumption among other issues. Often, corporate interest groups have acted in concert with powerful national governments to curb public health measures at the international level.¹⁵ This includes several instances of the US government supporting corporate objections to WHO proposals and policy recommendations for member countries to constrain inappropriate marketing of infant formula, reduce the consumption of sugar, and broaden access to essential medicines.¹⁶ Thus, we take a cross-industry approach to our analysis.

METHODS

We adopted a mixed-methods explanatory sequential design. We began with a quantitative analysis of lobbying expenditures involving discussion of WHO, then used documentary searches to get more detailed information on the positions of the parties lobbying. We elaborate on these steps here.

First, we obtained data from the US Senate Lobbying Disclosure Act Reports as aggregated in the LobbyView database.¹⁷ The Act requires all entities lobbying a federal agency to disclose expenditures on lobbying activity and the issue being discussed. LobbyView is maintained by a political scientist at the Massachusetts Institute of Technology in partnership with a team of data scientists. They have made disclosures through the second quarter of 2020 available in bulk downloads of raw data, also known as "flat files." The disclosures in the database cover lobbying of US federal government agencies, the White House, and Congress. Parties funding the lobbying are called "clients." We updated the data manually through the end of 2020 using the US Senate's online Lobbying Disclosure Act Reports.¹⁸ We used this database to get a full picture of all disclosed lobbying of the US federal government.

Using Stata 13, we searched flat files extracted from LobbyView for disclosures containing the keywords "World Health Organization", "WHO", "World Health Assembly", and "WHA", with and without capital letters. This defined our broad sample. We found it necessary to clean the data. In the database, sometimes both a client and a lobbyist independently report the same lobbying activity in separate filings. We sorted out the overlapping filings to avoid double-counting by programming an appropriate algorithm. When tallying expenditures, we excluded lobbying by the US Chamber of Commerce (USCC), which expends a great deal on lobbying every quarter and mentions WHO without detail amid many issues in an unvarying way over many quarters, obscuring when the issue is most salient.

Second, we synthesized the data from the federal filings in two forms. We tallied inflation-adjusted annual expenditures on lobbying related to our keywords to create a time series chart. We then compiled tables with names of clients who paid for the lobbying, the exact issues lobbyists disclosed, and the quarter in which the disclosures

occurred. Disclosures varied in their level of detail and left us in need of more explanatory data.

Therefore as a third step, to better understand the public positions of parties engaged in the reported lobbying activity, we also searched grey materials. These encompassed the websites of reported clients, position statements filed for public consultations held by WHO, online legislative archives of the US Congress, news media reporting on positions of clients or their industry representatives, and academic research articles on related lobbying or industry positions. For each lobbying disclosure containing our keywords, we performed web searches of additional words and phrases from the disclosures to identify related press releases by the clients and other public documents. For any proposed legislation or resolution mentioned in the disclosures, we searched for the text of the bill in online archives of the US Library of Congress.¹⁹

When conducting this search for explanatory data in public sources, we found that many clients named in the lobbying disclosures were linked to an industry group calling itself a new coalition, Engaging America's Global Leadership (EAGL). Therefore, we repeated the third step with respect to this coalition. We reviewed disclosures for concurrent or adjacent lobbying expenditures on overlapping issues. We reviewed data from our documentary searches for overlap in issues and positions. After completing the search for explanatory data in public sources, we found that more specificity was needed to characterize the precise nature of lobbying positions by two participating industries that were particularly active (dairy and beverage alcohol producers). We also wished to understand more concretely the position and scope of lobbying activity by the National Association of Manufacturers (NAM), which referred to itself as a leader in the EAGL coalition as we document below.

Consequently, as a fourth step we submitted a FOIA request (No. FY21-87) to the Office of the United States Trade Representative (USTR) for correspondence containing our keywords between the following parties and the USTR between 2016 and 2021: EAGL, NAM, National Milk Producers Federation (NMPF), US Dairy Export Council (USDEC), International Dairy Foods Association (IDFA), Distilled Spirits Council (DISCUS), Beer Institute, and Grocery Manufacturer's Association (GMA)/Consumer Brands Association (CBA). We received 298 pages of emails and attachments from the USTR FOIA Program Manager, in a pdf file, with small redactions to protect personal email addresses or communication covered by nondisclosure agreement. We post the file as a supplemental document in its entirety on the Zenodo repository (DOI 10.5281/zenodo.6525568) with Bates numbers added to the top right corner of each page. We use the Bates numbers as citations within the text below with the prefix "FOIA-USTR-FY21-87-", followed by a 3-digit page number. The documents have been donated to the University of California San Francisco Industry Documents Repository for curation, to enhance discoverability.

The final step was to synthesize the quantitative and documentary data to report the results, organizing them first in terms of the timing of expenditures, then the list of actors, and finally the common issues the lobbying addressed and the specific positions industry groups took on these issues.

RESULTS

We begin presenting summary statistics on lobbying expenditures related to WHO and WHA in all years since 2006, from LobbyView. All figures are in 2020 (PCE-adjusted) US

dollars. We show which actors are financing the lobbying and describe their positions to the degree possible from the federal filings alone. We then present data from our documentary search and FOIA request.

Lobbying disclosures: expenditures and actors

Between 2006 and 2015, expenditure on lobbying of US federal government officials with disclosures citing WHO or WHA as a focal issue averaged about US\$12.5 million annually, driven by a spike in expenditure of US\$32.6 million in 2008. This spike in 2008 was linked to issue disclosures mentioning WHO initiatives to expand access to medicines with accompanying concerns about intellectual property (IP) protections, and to initiatives aimed at prevention and control of noncommunicable diseases (NCDs), which included policy recommendations for member states to promote healthier diets and reduce harmful alcohol and tobacco use.²⁰

Expenditures on WHO-related lobbying averaged US\$14.2 million per year between 2016 and 2019. While expenditures fluctuate, this 2016-2019 average is nearly fifteen percent higher than the annual average during the previous 10 years and two and a half times higher than the previous four years. Thus, one could classify WHO-related lobbying expenditures 2016-2019 as both elevated compared to the average over the prior decade and surging after a relative lull. These lobbying expenditures rose to US\$46 million in 2020, which for comparison is roughly 15 percent of average total annual US planned (pre-pandemic) contributions to WHO for 2020-2021.²¹

Private sector actors engaged in WHO-related lobbying

Table 1 lists the names of corporate clients with WHO-related lobbying disclosures 2016-2019 and the text from their disclosures that identified the filing as relevant for this study. This includes all business entities, defined as individual firms and associations of firms listed as clients in the lobbying disclosures. Most associations of firms listed as clients in the lobbying disclosures are made up of firms within the same industry—for instance, NMPF or Biotechnology Innovation Organization (BIO). This category also contains umbrella groups whose members are firms and industry associations from more than one sector, like the USCC or the Emergency Committee on American Trade (ECAT). The table does not match dollar amounts with the issue disclosures because it is impossible to determine what portion of expenditures were devoted to lobbying on WHO-related issues versus other issues disclosed in the same filing, which sometimes are many and varied. However, since 2016, parties associated with production or marketing of breastmilk substitutes (BMS), alcohol, and biotechnology and pharmaceuticals have consistently been among the top-ten sources of lobbying expenditures disclosing WHO as a topic of discussion.

The EAGL coalition: identification, structure, and operations

In 2016, when relevant lobbying expenditures nearly tripled from the previous year, we found while searching for detail on the positions behind this surge (discussed in the next section) that all parties engaged in disclosed lobbying pertaining to WHO were

linked with EAGL. We define “linked” as being an industry association who eventually became a

Table 1: WHO-related lobbying activity by business entities and associations, 2016-2019

Firm or Group Name	WHO-related issue disclosed (verbatim except in brackets)	Year/Qtr	EAGL Link
Abbott Laboratories	• WHO Guidance on Promotion of Food for Infants and Children • Issues related to WHO Prequalification of medicinal products • Issues related to WHO Guidance on diagnostics	2016/Q1,Q2,Q3 2016/Q4 2017/Q1,Q2,Q4 2019/Q2	US Dairy Export Council, IDFA
Advanced Medical Technologies Assn (AdvaMed)	• Issues related to WHO administration of diagnostics access program	2016/Q2,Q3,Q4	Member
Alere Medical	• World Health Organization prequalification program financing • World Health Organization influenza preparedness program financing	2016/Q2,Q3,Q4 2017/Q1,Q2	AdvaMed
BD (via the Livingston Group)	• WHO Prequalification program	2016/Q2,Q3	AdvaMed
Biotechnology Innovation Organization (BIO)	• World Health Organization (WHO) Cancer Resolution--Pricing and IP Language • UN High-Level Commission on Access to Medicines--IP Proposals • Access to Medicines/World Health Organization	2017/Q2 2017/Q2 2018/Q1,Q2 2018/Q1,Q2,Q4 2019/Q1,Q2,Q3	Member
Emergency Committee for American Trade	• World Health Organization	2016/Q1,Q2,Q3,Q4	Overlapping membership
Entertainment Software Association	• Issues related to WHO proposed classification of video games	2018/Q1,Q2	Member
Genentech, Inc.	• WHO PQ Process for Diagnostics	2016/Q4	BIO

Grocery Manufacturers Assoc. (now CBA)	World Health Organization - Infant Nutrition	2016/Q1,Q2,Q3,Q4	Member
Heineken	General education on the World Health Organization's global alcohol strategy	2016/Q1,Q2,Q3,Q4 2017/Q1	Beer Institute
Infant Nutrition Council of America	- Trade, Formula Restrictions / Proposed Codes, WHO Guidance - WHO Guidance on Marketing - Infant nutrition, U.S. Agency role with the World Health Organization - General information in infant and Child nutrition, World Health Organization	2016/Q1,Q2,Q3,Q4 2016/Q1,Q2,Q3,Q4 2017/Q2 2018/Q3,Q4	Abbott Nutrition, US Dairy Export Council
Intellia Therapeutics	WHO Gene Editing Summit	2019/Q1,Q2	BIO
International Dairy Foods Assn (IDFA)	- World Health Organization (WHO) guidance on rules pertaining to marketing of milk products to children - FY 2018 and FY 2019 State Department and Foreign Operations Appropriations bills, provisions related to funding for the United Nations (WIPO) and the World Health Organization (WHO) - FY 2018 and FY 2019 State Department and Foreign Operations Appropriations bills (S.3108), provisions related to funding for the World Health Organization (WHO) - FY 2019 State Department and Foreign Operations Appropriations bills (H.R.6385 and S.3108), provisions related to funding for the World Intellectual Property Organization (WIPO); World Health	2016/Q1,Q2,Q3,Q4 2017/Q1,Q2 2018/Q1 2018/Q2 2018/Q3	Member

	- Assembly resolution on infant and young child feeding - World Health Assembly resolution on infant and young child feeding	2018/Q4 2019/Q1,Q2,Q3	
Mars Incorporated	Support for WHO and private sector collaborations to achieve positive outcomes for public health and safety	2018/Q3	National Confectioners Assoc., National Foreign Trade Council
Miller Coors LLC	General education on the World Health Organization's global alcohol strategy	2016/Q1,Q2,Q3,Q4 2017/Q1,Q2,Q3,Q4 2018/Q1,Q2,Q3,Q4 2019/Q1,Q2,Q3,Q4	Beer Institute
National Milk Producers Federation	- Advocated for modifications to WHO proposal that discouraged dairy products for children under three years of age - Advocated on WHO issues impacting dairy and trade - Advocated on WHO and Codex issues impacting dairy and trade	2016/Q1,Q2 2016/Q3,Q4 2017/Q1,Q2,Q3,Q4 2018/Q1,Q2,Q3 2018/Q4; 2019/Q1	Member
Nestle	World Health Organization meeting preparation with the U.S. delegation	2016/Q2	IDFA
US Chamber of Commerce	Various issues relating to... World Health Organization (WHO) [within a long list of other organizations and issues]	2016/Q1,Q2,Q3,Q4 2017/Q1,Q2,Q3,Q4 2018/Q1,Q2,Q3,Q4 2019/Q1,Q2,Q3,Q4	Overlapping membership
Electronic Transactions Assn	FDA request for comment on FDA-2019-N-0767-0001 [regarding "World Health Organization (WHO) recommendations to impose international manufacturing and distributing restrictions, under international treaties, on certain drug substances"]	2019/Q1,Q2,Q3,Q4	..

Oregon Farm Bureau Federation	• [Cites WHO as a credible scientific authority while advocating for biotech-derived ingredients.]	2016/Q1	..
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Notes: Data from LobbyView, Secretary of the US Senate Lobbying Disclosure Reports

member of EAGL between 2016 and 2021, or being a firm who is a member of one of these industry associations. Additionally, we consider the Business Round Table and ECAT as linked due to overlapping membership (and USCC, though it is omitted from our lobbying expenditure tallies). EAGL was established by NAM in 2016, launching its public relations activities in 2017.²² According to its website, EAGL is a coalition of industry associations that addresses “problematic and divisive initiatives” by multilateral institutions like the WHO, Organization for Economic Cooperation and Development (OECD), International Labor Organization, and UN Environment Program, which the group claims “reach well beyond” their core missions.²³ In its April 2017 newsletter, NAM names the UN, WHO, and OECD as engaging in activities detrimental to American manufacturing and jobs. It states that

*The [EAGL] coalition will seek robust U.S. leadership in these institutions, including through work with the Trump administration and Congress to hold these institutions accountable, improve U.S. oversight and coordination, and expand the efforts of the U.S. and other governments to speak with one voice.*²⁴

EAGL currently names 28 industry associations as members, listed in Appendix A. The members span a number of sectors, including food processing; chemicals, agrochemicals, and plastics; agricultural producers (dairy, pork, oilseeds); pharmaceuticals; beverage alcohol; electronic gaming software; cookware; cosmetic and personal care products; air conditioning and heating; can manufacturers; and one umbrella group, the National Foreign Trade Council.²⁵ Among EAGL members from the food processing industry, users and producers of sweeteners are prominent in the presence of the National Confectioners Association and Corn Refiners Association, as well as some members of the GMA/Consumer Brands Association. Tables 1 and 2 list clients from individual lobbying disclosures. Documents yielded from our FOIA request showed lobbying by EAGL on behalf of a number of different industries simultaneously within the same documents and meetings, across four different government agencies – USTR in the Executive Office of the President, the Food Safety and Inspection Service and the Foreign Agricultural Service in the US Department of Agriculture (USDA), the Department of State, and the Department of Health and Human Services (HHS).

Given its degree of activity, we describe EAGL’s structure and type of activities in more detail in Appendix B. Public documents named only two authors of EAGL documents, both of whom are officers of NAM. From this point, we refer to them as NAM/EAGL Officers A and B. Appendix B also lists EAGL advocacy letters and position statements that combine positions from multiple industries, especially biotechnology/pharmaceuticals, alcoholic beverages, dairy, and chemicals (FOIA-USTR-FY21-87-023, -102, -230, for instance). We call this simultaneous advocacy on different

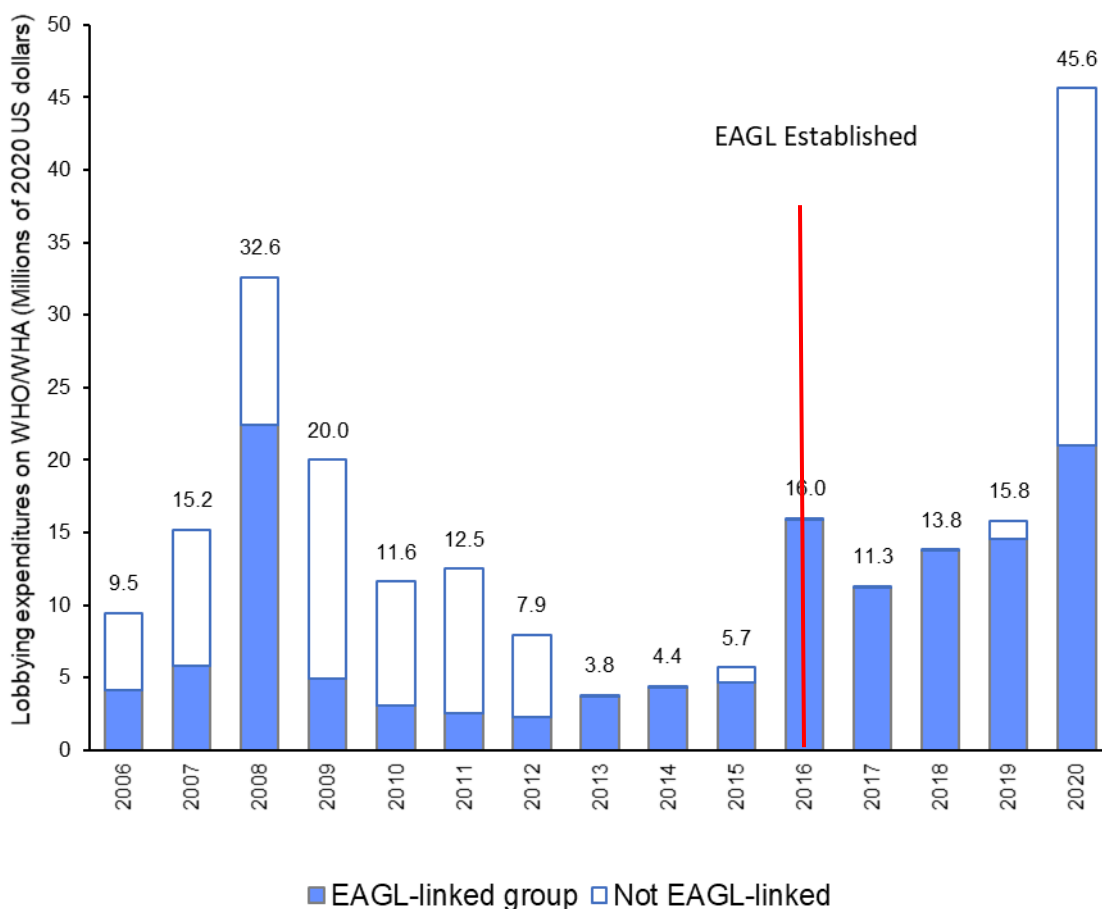
Table 2: WHO-related lobbying activity by business entities in 2020

Firm or Group Name	WHO-related issue disclosed (verbatim except in brackets)	2020 Qtr	EAGL Link
Biotechnology Innovation Organization (BIO)	• United States Withdrawal from the World Health Organization	Q2,Q3,Q4	Member
Business Roundtable	• Issues relating to U.S. participation in the World Health Organization • WHO priorities • Issues relating to U.S. reform efforts and continued participation in the World Health Organization	Q2 Q2 Q3	Overlapping membership
Miller Coors LLC	• General education on the World Health Organization's global alcohol strategy • WHO Priorities	Q1,Q2,Q3,Q4 Q2	Beer Institute
National Assoc. of Manufacturers	• Potential World Health Organization Withdrawal	Q2,Q3,Q4	Founding member
US Chamber of Commerce	• Various issues relating to... World Health Organization (WHO) [within a long list of other organizations and issues] • World Health Organization reform recommendations • Reform of the World Health Organization (WHO); continued U.S. membership in the World Health Organization	Q1,Q2 Q2,Q3 Q3,Q4	Overlapping membership
Electronic Transactions Assn	• FDA request for comment on FDA-2019-N-0767-0001 [regarding "World Health Organization (WHO) recommendations to impose international manufacturing and distributing restrictions,	Q1,Q2,Q3,Q4	..

	under international treaties, on certain drug substances"]		
PMI Global Services Inc. (Philip Morris International)	• H.Res.896, Reaffirming support of fundamental United States principles at the United Nations and encouraging the World Health Organization to embrace technological advancements in tobacco control. • World Health Organization • Issues related to international organizations. • Discussions concerning U.S. engagement with International Organizations	Q1,Q2,Q3,Q4 Q2 Q1,Q2 Q2,Q3,Q4	..
RAI Services Company (formerly RJ Reynolds)	• H.Res.896, Reaffirming support of fundamental United States principles at the United Nations and encouraging the World Health Organization to embrace technological advancements in tobacco control	Q2,Q3,Q4	..

WHO-related concerns from different industries within the same documents and communications *coordination*. EAGL demonstrates or mentions this coordination in public documents, including coordination with industry associations outside the US to influence the engagement of other governments with WHO.²⁶ EAGL and several members also target engagement with specific intent to influence US positions at the WHO through the “interagency process” (FOIA-USTR-FY21-87-023, -063, -098, -100, -105, -177). This refers to the internal (and often confidential) deliberations between government agencies in the Executive Branch managed by the National Security Council.²⁷

Figure 1 shows expenditures on lobbying (in constant 2020 US\$) related to WHO both before and after the establishment of EAGL, noting the proportion of these expenditures attributable to industry associations that eventually would become members of or demonstrate links to EAGL and firms who are members of these associations. Table 2 shows which industry associations and firms were engaged in this activity in 2020 and their link to EAGL. Total expenditures on lobbying by EAGL-linked Figure 1: Lobbying expenditures with WHO-related issue disclosures, 2006-2020 firms and groups averaged US\$13.8 million per year during the period 2016-2019, accounting



Notes: Data from LobbyView for 2006Q1-2020Q2, Secretary of the Senate for 2020Q3 and 2020Q4. Labels at top of bar indicate total. Amounts exclude expenditures by the US Chamber of Commerce. EAGL-linked groups are associations who become a member of EAGL between 2016 and 2021; firms who are a member of one of these industry associations; and the National Business Roundtable and ECAT, due to substantial overlapping membership.

for virtually all expenditure on WHO/WHA-related lobbying in those four years. This is more than double the combined average US\$5.8 million per year that firms who became associated with EAGL spent lobbying on WHO-related issues before EAGL's establishment in 2016; thus, by this measure membership in EAGL on average is associated with increased lobbying on issues related to WHO. In 2020, the lobbying expenditure of EAGL-linked groups about WHO reached an all-time high of US\$21 million, though outpaced by other actors.

Lobbying by other actors

Table 3 shows that there also were many non-EAGL-linked groups who, until 2020, had never disclosed lobbying on WHO matters, suggesting the overall spike in 2020 may have

been linked with the White House announcement of US intent to halt funding and withdraw from WHO. These other actors include associations of medical professionals and academics, religious organizations, and municipal and service organizations.

Table 3. Non-business entities disclosing lobbying on WHO-related issues, 2016-2020

Client Name	WHO-related issue disclosed (verbatim)	Year/Qtr
American Academy of Pediatrics	World Health Organization, UNICEF, UNPFA, UNHCR	2017/Q1
American Assn of Colleges of Nursing	H. Res. 859/S. Res. 500 - A resolution supporting the goals and ideals of the International Year of the Nurse and the Midwife, as designated by the World Health Organization	2020/Q1
American Assn of Nurse Practitioners	S.Res. 500/H.Res. 859: A resolution supporting the goals and ideals of the "International Year of the Nurse and the Midwife", as designated by the World Health Organization	2020/Q1,Q2,Q3,Q4
American Cancer Society Cancer Action Network, Inc.	Issues related to global health funding of the World Health Organization and for cervical cancer screening & treatment and HPV vaccination	2020/Q2,Q3,Q4
American Medical Association	COVID-19/World Health Organization (WHO)/International Classification of Diseases	2020/Q2
American Public Health Association	Support fully funding the World Health Organization in fiscal year 2021 and reject the Trump administrations plans to cut U.S. funding to the WHO. Support increasing U.S. funding to United Nations accounts and lifting the spending cap imposed on contributions to the UN.	2020/Q2
American Society of Hematology	Withdrawal of the United States from the World Health Organization (WHO)	2020/Q3,Q4
American Society of Tropical Medicine and Hygiene	U.S. withdrawal from the World Health Organization; S.Res. 653, expressing the sense of the Senate that withdrawing from the World Health Organization (WHO) undermines our national priorities and endangers Americas public health;	2020/Q3,Q4
American Veterinary Medical Association	Support continued funding for World Health Organization activities.	2020/Q2

Association of American Medical Colleges	Support continued funding support for World Health Organization activities	2020/Q3,Q4
Assn of Women's Health Obstetric and Neonatal Issues	Letter to U.S. Health and Human Services Secretary Alex Azar expressing concern over reports that the United States delegation to the 2018 World Health Assembly sought to weaken a resolution designed to support breastfeeding.	2018/Q3
Catholic Health Assn of the United States	Urged the President to reconsider his decision to withdraw the United States from the World Health Organization.	2020/Q2,Q3,Q4
Center for Individual Freedom [links to tobacco]	Budget Reform Correspondence with President Donald Trump urging 25% reduction in the United States funding for the United Nations World Health Organization; Research relating thereto	2018/Q2
City of Burien	World Health Organization (WHO) aircraft noise guidelines	2019/Q1
Conference of Provincials of North America	Signed petition for the full funding of the World Health Organization.	2020/Q2
FDD Action	World Health Organization	2020/Q4
The Foundation for a Christian Civilization	Support removing funding for the World Health Organization	2020/Q2
International Hearing Society	Support for World Health Organization hearing-related resolution via the Centers for Disease Control	2016/Q2
League of Women Voters of the U.S.	Oppose the withdrawal of the United States from the World Health Organization	2020/Q2,Q3
National Taxpayers Union	WHO COP-8 Meeting; tobacco taxes	2018/Q4
Population Assn of America	Participated in discussions regarding cancellation of WHO funding	2020/Q2
The Rotary Foundation of Rotary International	World Health Organization related issues	2020/Q2,Q3,Q4

One civil society association, the Center for Individual Freedom (CFIF), has links to the tobacco industry. The Founder of CFIF was Founder and President of the National Smokers Alliance (NSA), using funds left from the dissolution of NSA. Although NSA was purported to be independent of the industry, Philip Morris generated the idea for such a group and the NSA President who eventually founded CFIF was a Senior Vice President

handling the Philip Morris account at a public relations firm employed by Philip Morris.²⁸ As of 2021, the Senior Vice President of CFIF was Secretary and Treasurer of the National Smokers Alliance.²⁹ CFIF's Corporate Counsel and Senior Vice President was General Counsel to NSA³⁰ and CFIF's President was a spokesperson for NSA.³¹ Due to these links, we include CFIF in our later examination of positions of the private sector.

Disclosed positions on WHO

We take the issue disclosures in the lobbyist filings from LobbyView as a starting point for understanding the positions of private sector actors when engaging with the federal government. Although lobbyists file these disclosures, we will refer to the issues as being put forward by the clients that the lobbyists represent. Where sufficient detail exists, we see that lobbying involved three different targets: health guidelines and policies deliberated or undertaken by WHO, WHO institutional procedures and operations, and US engagement with or leadership within the WHO.

Disclosed lobbying to shape WHO's health guidelines and policies

In a few cases, one can observe a precise position disclosed on WHO health guidelines and policies. For example, Table 1 shows that NMPF “advocated for modifications to” a WHO proposal to restrict marketing of follow-up milk formula in the first half of 2016. Table 2 shows some detail for positions argued by PMI Global Services (affiliated with Philip Morris International) and RAI Services (formerly RJ Reynolds). Other than these few exceptions, one cannot generally see whether firms and their associations were lobbying for or against particular WHO-related policies or initiatives. For example, in the second column of Table 1 we see that Abbott, IDFA, the Infant Nutrition Council of America, and the GMA lobbied about WHO recommendations related to infant and young child nutrition and marketing of related products. Biotech and pharmaceutical firms and associations (Abbott, AdvaMed, Alere, BD, BIO, and Genentech) lobbied about WHO programs related to diagnostics, access to medicines, prequalification of medicinal products, and pricing for cancer treatments. Alcohol manufacturers (Heineken, Miller Coors) lobbied regarding the WHO global alcohol strategy, while the Entertainment Software Association lobbied regarding “WHO proposed classification of video games.” The last may refer to the WHO classification of ‘gaming disorder’ as a behavioral addiction in 2018,³² in which case the disclosure is both vague and obfuscating. Nonetheless, the disclosures give a sense of the nature and frequency of issue-specific lobbying.

Disclosed lobbying to shape WHO's own procedures and operations

Lobbyists' filings demonstrate advocacy related to how the WHO operates—procedures and processes within WHO and governing WHO engagement with external entities. Table 1 shows disclosures prior to the pandemic. Mars, a producer of confectionary, lobbied in support of “WHO and private sector collaborations.” AdvaMed lobbied on “Issues related to WHO administration of diagnostics access program.” Genentech likewise lobbied on the “Process for Diagnostics.” During the pandemic and after the US announcement of its intent to withdraw from WHO, Table 2 shows that

several private sector actors linked to EAGL lobbied on “WHO priorities” (Business Roundtable, Miller Coors) and WHO “reform” (Business Roundtable, US Chamber of Commerce).

Disclosed lobbying to shape US engagement with WHO

Disclosures also document private sector engagement on the US relationship with WHO in general. This overlaps with lobbying on internal WHO processes; additionally, it involves discussion of *how* the US government itself should make decisions about its policies toward WHO or advocate with respect to WHO initiatives. For example, Table 1 shows that in the second quarter of 2016, Nestle discussed the preparation of the US delegation to WHO when meeting with federal officials. The Infant Nutrition Council lobbied in the second quarter of 2017 on the “U.S. Agency role with the World Health Organization.” Table 1 shows IDFA lobbied in the first three quarters of 2018 on US appropriations bills and specifically mentioned provisions related to funding for WHO. Table 3 shows that CFIF lobbied on US funding for WHO in the second quarter of 2018. We discuss appropriations in more detail below.

Lobbying on US relations with WHO increased in 2020. Table 2 shows that the tobacco industry lobbied on “US engagement with International Organizations” (PMI Global Services) and on House Resolution 896 defining “fundamental United States principles at the United Nations and encouraging the World Health Organization to embrace technological advancements in tobacco control” (PMI Global Services and RAI Services). We discuss this resolution in more detail below. Table 2 also shows that from the second quarter through the end of 2020, BIO, Business Roundtable, NAM, and the USCC all engaged on US participation in the WHO.

Summary of themes in disclosures of lobbying expenditures

In summary, the issue disclosures in the legally required filings of lobbying activity are generally vague. We may see WHO mentioned as a topic of discussion, but little about the client’s position. Sometimes there is detail regarding the WHO-related issue being discussed, but little about whether the party was lobbying in support or opposition. Nonetheless, we can see four overall patterns in private sector positions with these very incomplete data. First, there is a range of industries lobbying on WHO health policies and guidelines related to their products. Second, industries may lobby on specific internal WHO processes and operations. Third, industries and their associations lobbied to influence US engagement with WHO, including preparation for US delegates to an upcoming meeting. Finally, we see two groups lobbied in 2018 on US funding for WHO. While the precise position on appropriations among dairy manufacturers in IDFA is unclear from IDFA filings, with respect to tobacco-linked advocacy, CFIF lobbied to reduce US funding for WHO by 25 percent.

From this point, we integrate findings from the documentary search and FOIA request described in the Methods section above to expand on the nature of these industry positions, identifying three unifying themes: funding, COI, and overlap with the Codex Alimentarius Commission. We then show how these themes tie in with tobacco interests and are being tied to lobbying on pandemic response.

Restricting US funding for the WHO: Appropriations

An online search for IDFA positions on the Senate's State Department and Foreign Operations Appropriations bill listed in their issue disclosure (see again Table 1) produced evidence of EAGL lobbying on appropriations. In September 2017, EAGL posted a press release with the sub-heading "Senate Appropriations State and Foreign Operations Bill Includes Report Language Stressing Greater Accountability and Transparency at International Organizations."³³ The release praised the proposed bill as a "first step toward long overdue accountability and transparency at international organizations" due to new language requiring a cost-benefit analysis of US contributions to various institutions. It lauds the language as a signal that the US will advocate for reform "to address activities that undermine U.S. manufacturers, workers, and interest." EAGL released another statement in March 2018 applauding the inclusion of the review in the Consolidated Appropriations Act, 2018.³⁴ NAM/EAGL Officer A is quoted in the release, saying that the language "helps put U.S. agencies on a path towards smart, strong American investment in international institutions and activities that further American foreign policy and economic objectives."

In July 2017, several months before IDFA disclosed lobbying on the appropriations, NAM/EAGL Officer A wrote an opinion piece, titled "Congress must act to reform rogue international institutions."³⁵ This article begins by discussing the United Nations and OECD broadly as problematic by acting with insufficient "accountability and transparency—repeated process fouls that are not based on sound science or good regulatory practice... activities often stretch far beyond their agencies' core missions, negatively affecting US interests, industries and workers..." The article criticizes the 2016 activities of the UN High-Level Panel on Access to Medicines for advocating a weakening of intellectual property rights in its recommendations to make medicines more affordable, and the International Agency for Research on Cancer for reporting on possible cancer risks in common commodities. It criticizes a WHO plan to reduce NCDs by recommending marketing restrictions and (excise) taxes "that would harm consumers and impede the legitimate business activities and exports of U.S. companies... Such efforts go well beyond the agency's chartered advisory and research roles to target private interests, threatening its own credibility."³⁶ Our FOIA request also produced an email from the NAM/EAGL Officers mentioning that EAGL would be working with Congress and the Trump administration to push back on "troubling initiatives" involving bad policy and regulatory proposals at the UN and WHO (FOIA-USTR-FY21-870-002).

Our documentary search yielded no statement by IDFA specific to its position on the Appropriations Bill. However, IDFA issued a news release³⁷ in February 2016 criticizing WHO draft "Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children," which encouraged countries to tighten restrictions on the marketing of foods for infants and toddlers aged 6-36 months.³⁸ The release says IDFA was engaging with Congress and encouraging members to contact their legislators. It argues that the WHO guidelines "would limit the marketing and promotion efforts of many dairy foods companies throughout the world," and that "the guidelines could have serious trade implications for companies that export dairy products and ingredients, particularly milk powders used in infant nutrition products such as follow-up formula and growing-up milks." IDFA used the term "overreaching" to describe the WHO

recommendations, calling the process in which they were developed “non-transparent” and “flawed.”³⁹

Parties directly connected with commercial milk formulas or listing infant formula-related concerns in their disclosures spent nearly US\$7 million on lobbying activities related to the WHO in 2016, after 10 years with no mention of WHO. These parties consisted of Abbott Laboratories, GMA, the Infant Nutrition Council of America, IDFA, NMPF, and Nestle. This amounted to nearly half of all lobbying expenditure related to WHO in 2016. Lobbying by the USDEC related to WHO does not appear in the lobbyists’ issue disclosures; however, an article published by Dairy Industries International, reports that USDEC lobbied the White House jointly with IDFA and NMPF to protest the same WHO guidance that the IDFA release said prompted its own engagement with Congress.⁴⁰ In 2017, IDFA issued another release expressing strong concerns to US officials about the WHO guidance and efforts to incorporate it into the draft Codex Standard for Follow-up Formula, which contains phytosanitary, compositional, and marketing guidelines used as benchmarks for most trade agreements. The release praises the US delegation to the WHO for preventing a full endorsement of the guidance by the WHA in 2016, urging HHS to make clear in its position at the 2017 WHA that countries are not obligated to implement the recommendations.⁴¹

The EAGL release regarding the appropriations bill led to identification of other EAGL releases welcoming the Multilateral Aid Review Act of 2017 on October 5th, November 15th and December 5th, 2017. The Multilateral Aid Review Act of 2017 (S.1928) was introduced in the Senate by a bipartisan group of eight US Senators, and in the House of Representatives as H.R.4502 by a bipartisan group of three US Congressmen. The proposed legislation would require the US Secretary of State to submit to the Appropriations Committees of the US House and Senate a review of the mission and activities of 38 multilateral entities to which the US allocates funds. The list of entities included the Food and Agriculture Organization (FAO) and WHO, among a number of other bodies inside and outside the UN system.⁴²

The stated purpose of the Review is to assess whether the goals of the entities align with US priorities and benefit US interests. The EAGL press release on October 5th has a quote from Officer A:

*At a time when budgets are tight and discussions about global institutions abound, everyday Americans believe in the need for engagement but want to know that their interests are being protected. This act ensures that taxpayer funds are being responsibly allocated and highlights investments in international institutions that work—and those that are not in line with U.S. foreign and economic policy. It adds a level of accountability, both at home and abroad, that is definitely needed to ensure the nation’s economic interests are furthered.*⁴³

The October 5th release has an additional quote from the President of IDFA: “By helping to assure that international policy is transparently developed, scientifically based and cost-effective, we believe this bill will support our goals and minimize barriers to achieving them.”⁴⁴ IDFA also promoted the bill and EAGL’s release on its website.⁴⁵ In a December 2017 newsletter, NAM referenced EAGL’s October 2017 press release welcoming the introduction of the Multilateral Aid Review Act and included a quote from

NAM/EAGL Officer A saying that the proposed bill is “a heartening signal that our elected officials in Washington are serious about demanding accountability and transparency at international organizations.”⁴⁶

The Multilateral Aid Review Act of 2017 does not appear in WHO-related lobbying disclosures. However, on October 6th, 2017, data obtained from the FOIA request shows NAM/EAGL Officer B emailing the Assistant US Trade Representative for WTO and Multilateral Affairs and four other staff of USTR, with NAM/EAGL Officer A copied on the email. There is evidence of expansive lobbying efforts related to the bill. As Officer B says,

The legislation has direct relevance to our ongoing conversation about the need for strong engagement and improved transparency and accountability at international organizations like the World Health Organization. We’d be happy to discuss further, as we’re engaged with staff from multiple offices on the Hill working on these issues. (FOIA-USTR-FY21-87-079)

Embedded links appear in blue in the pdf file returned with the FOIA documents, but did not function. However, this message said the embedded links led to full text of the bill, a summary of the bill, a press release announcing the bill, the EAGL press release welcoming the bill on October 5th, and a *Foreign Policy* article from Friends of the Global Fight Against AIDS, Tuberculosis, and Malaria. A group of four Republican Senators reintroduced the measure as the Multilateral Aid Review Act of 2020 (S.3626), but it was not voted on by the Senate.⁴⁷

Appendix C contains a timeline of all of these appropriations-related lobbying efforts.

WHO screening and mitigation protocols for private sector COI

Lobbying disclosures in federal filings show Mars, Inc., sponsoring lobbying in support of “WHO and private sector collaborations.” This is the only direct mention of WHO relations with the private sector as a broad topic area in our disclosure data from LobbyView. Our documentary search produced additional data.

In a September 2017 submission by NAM/EAGL Officer B for the Public Consultation on the WHO’s “Approach for the prevention and management of COI in the policy development and implementation of nutrition programs at country level.” The comment on the nutrition program is the first publicly available document observed to formally establish EAGL’s position on WHO engagement with the private sector and its position on WHO COI screening. EAGL introduces itself as

*...a broad coalition of U.S.-based private sector organizations focused on promoting effective U.S. engagement at global institutions such as the World Health Organization (WHO) to promote mission-focused activities that are transparent, accountable to member governments and that are based on science-based approaches that fully include private sector stakeholders.*⁴⁸

This self-description indicates that a key mission for EAGL is advocating for the US government to promote involvement of private sector entities in WHO operations, including its scientific work.

The submission also characterizes WHO's proposed protocols for preventing and mitigating COI in nutrition programs as problematic. It expresses concern that WHO consulted with selected non-state actors like NGOs, academic researchers, and lawyers in drafting the COI protocols, while not consulting with private sector entities. The submission argues for the importance of involving private sector entities and criticizes language in the document indicating as a norm that non-state actors' participation in nutrition programs should conform to domestic governments' agendas. Instead, the submission urges that non-state actors including from the private sector be allowed to shape policy goals and determine how best to accomplish them. The coalition recommends that health ministries be mindful of national policies geared toward economic growth and development to ensure health policies are consistent with these. It concludes that "the approach taken in these documents risks...the WHO's credibility... We strongly encourage the WHO to reconsider immediately key aspects of its approach, including for addressing the legitimate issues of conflict of interest."⁴⁹

Similar statements appear in emails and letters to federal officials retrieved via our FOIA request. The first appears on May 17, 2017, in a letter to the Director of the Office of Global Affairs in the US Department of Health and Human Services, from NAM/EAGL Officer A, presenting EAGL's advice for US positions at the WHA meetings that would take place May 22-31 (FOIA-USTR-FY21-87-023). It states,

EAGL strongly encourages HHS on [access to medicines and non-communicable diseases] and other issues to press the WHO to work with the private sector... In particular, it is critical that the HHS and WHO: (1) Engage the public, including private sector stakeholders, early and often in the identification of problems and the development of solutions... (FOIA-USTR-FY21-87-026)

EAGL Officer B arranged a group call with USTR staff and EAGL members on June 6 to discuss outcomes of the WHA meetings (FOIA-USTR-FY21-87-029). In preparation for the call, USTR staff sent US statements read into the record at the WHA on a Report of the Commission on Ending Childhood Obesity and Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases. Both US government statements included a comment that policy "strategies should also incorporate the use of public private partnerships and other multi-sectoral collaborations" (FOIA-USTR-FY21-87-031, -032).

A position statement from a group of nine EAGL members forwarded to USTR by NAM/EAGL Officer B on May 11, 2018 containing recommendations for US positions within the upcoming WHA meetings (FOIA-USTR-FY21-87-098) reiterated concerns about both the COI screening tools for nutrition programs and about FENSA, the COI screening protocol which applies across a broader swath of WHO activities. The position statement was attached to a letter from these EAGL members addressed to the Secretary of HHS (FOIA-USTR-FY21-87-099). The forwarding email said that the letter was public, but that the position statement, described as a "submission on priorities and issues" was not. The position statement says,

HHS must further remain vigilant to prevent the inclusion of problematic agenda items or report language outside of [WHO's] mandate and ensure full inclusion of all stakeholders, including: ... Exclusionary efforts in various agenda items that use the WHO's May 2016 Framework on Engagement with Non-State Actors (FENSA) to argue that industry should be treated with careful scrutiny prior to any engagement. These are reflected not only in the approach on conflicts of interest in nutrition programmes (A71/23), but also in language on other agenda items, such as preparation for a high-level General Assembly meeting on ending tuberculosis (which mentions WHO support for engagement with other stakeholders but not the private sector in A71/15). (FOIA-USTR-FY21-87-107)

NAM/EAGL Officer B forwarded to USTR a letter from EAGL to the HHS Secretary on January 29, 2020 in advance of the WHO Executive Board meeting repeating the concerns. The letter itself is dated January 29, 2019; however, EAGL forwarded it on January 29, 2020 in regard to a meeting soon to take place, so we presume the correct date is 2020. The letter states,

Continued efforts to limit engagement with the private sector are highly counterproductive, depriving the organization of critical insights and expertise to support global health initiatives that might advance the interests of the United States. These types of activities and policies, which divide rather than unite, will damage the long-term viability of the organizations [sic]. (FOIA-USTR-FY21-87-229)

Appended to the letter is a set of recommendations for the US government on various agenda items for the upcoming Executive Board meeting. Among these is a section on "Stakeholder Engagement and Conflicts of Interest." Within this section, EAGL writes,

EAGL members have been strongly supportive of U.S. government leadership on these issues, and consistent work to highlight ongoing concerns with FENSA implementation, including the clear sense of "risk aversion" among WHO staff at multiple levels... Yet EAGL member experience illustrates that FENSA is still being used to block, and not to enable consistently, public-private engagement as the perception remains that industry engagement is problematic and risky. (FOIA-USTR-FY21-87-236)

The lobbying on greater inclusion of the private sector may have had an effect. In one email chain with a lobbyist from EAGL-member DISCUS in November 2019, an official who is now Assistant US Trade Representative (AUSTR)⁵⁰ discusses information-sharing related to an online consultation on the WHO Global Alcohol Strategy and notifies DISCUS of an upcoming WHO meeting on NCDs, where implementation of the WHO Global Strategy to Reduce the Harmful Use of Alcohol will be discussed (FOIA-USTR-

FY21-87-193). The AUSTR encourages DISCUS to notify HHS if they wish to attend to ensure entry, cautioning that HHS had had to intervene in a previous meeting when WHO rejected requests to attend by other “US stakeholders.” The AUSTR writes that it would be good for HHS to know which stakeholders are planning to attend and be made aware if there are any difficulties registering (FOIA-USTR-FY21-87-192).

An email from the same DISCUS lobbyist on January 31, 2020 to the same AUSTR attaches a position statement mentioning specific concerns from the alcoholic beverages industry about WHO’s COI screening (FOIA-USTR-FY21-87-239). Other employees at USTR are included as recipients, as well as the USDA Foreign Agriculture Service (FAS), Department of Commerce International Trade Administration, and Department of the Treasury Alcohol Tobacco Tax and Trade Bureau. The email includes an attachment (FOIA-USTR-FY21-87-241) with a set of recommendations for the US government in preparation for an upcoming WHO Executive Board meeting. We highlight here not the full range of concerns, but only the repeated emphasis on concerns about COI screening.

In the attached recommendations, DISCUS expresses concern about language in a WHO report posted prior to the meeting saying that health policymaking “should be protected ‘against interference from commercial interests’” (FOIA-USTR-FY21-87-242). DISCUS further lists as problematic the following:

The inconsistent implementation of FENSA and the overly restrictive application of some of its provisions remain a significant concern to alcohol industry, to wit:

- *Industry remain excluded from the WHO's Global Coordination Mechanism on NCDs (GCM), currently the only mechanism enabling multi-stakeholder dialogue on NCDs.*
- *Omission of industry input from public consultations into final reports (e.g. the report to the EB of the findings of the alcohol strategy consultation)*
- *Exclusion of alcohol industry in multi-stakeholder meetings; and negative statements about industry, for example, see paragraphs 4-7 in the EB146/7Add.1. (FOIA-USTR-FY21-87-244)*

The paragraphs (4-7) in document EB146/7 Add.1 listed here as problematic by DISCUS⁵¹ describe perceived challenges in the implementation of a global strategy to reduce the harmful use of alcohol, within a preparatory document⁵² for the upcoming meeting of the WHO Executive Board. These include limited political will to implement effective measures in the face of “powerful commercial interests,” health risks posed by alcohol not being widely known or accepted by policymakers, and both trade agreements and “interference by commercial interests” impeding national implementation of alcohol control efforts. Paragraph 7 points out that alcohol “is the only psychoactive and dependence-producing substance with a significant impact on global health that is not controlled at the international level by legally-binding regulatory instruments,” such as the WHO Framework Convention on Tobacco Control.

Although these last concerns are specific to one industry, Appendix D illustrates cross-industry coordination within EAGL to advance them in support of producers of alcoholic beverages.

WHO, Codex, and the definition of “science”

While describing itself as committed to science- and evidence-based health measures in its submission to the public consultation on the WHO tool for COI screening in nutrition programs described above, our documentary search presents a number of instances where EAGL and its members state that WHO policy is not science- or evidence-based. When announcing the launch of EAGL in spring 2017 to the AUSTR mentioned above, both NAM/EAGL officers express concern that initiatives emerging from the United Nations and WHO are “based on bad science” (FOIA-USTR-FY21-87-001, -002). EAGL Officer A elevates the concern soon afterward in op-eds in the *Global Trade Magazine*, *Washington Examiner*, and *The Hill*.⁵³

In its advice to HHS in preparation for the upcoming meetings of the WHA in May 2017 (FOIA-USTR-FY21-87-023), EAGL suggests that WHO activities do not reflect sound science, but emerge from “narrowly selected experts from academic and non-business organizations and small groups of vocal member states and non-government organizations (NGOs) that fail to conduct rigorous analyses based on scientific evidence and risk assessment” (FOIA-USTR-FY21-87-024). The letter from 9 EAGL members to the HHS Secretary in preparation for the WHA in May 2018 (FOIA-USTR-FY21-87-099) states that a number of initiatives on the agenda “fail to align with good regulatory practices, notably through a lack of transparency and insufficient reliance on sound science and evidence-based approaches.” Their position statement names in particular a list of policy options for prevention and control of NCDs presented in preparatory documents⁵⁴ as “not science or evidence-based” (FOIA-USTR-FY21-87-104). In its letter to the Secretary of State and the HHS Secretary ahead of the UN General Assembly meeting in September 2019, EAGL writes that:

Too often, we see U.N. agencies debating or promoting approaches that are not aligned with good regulatory practices such as transparency, sound science, and open consultation... or do not reflect the core missions of their organizations. (FOIA-USTR-FY21-87-143)

EAGL’s submission on the WHO Global Action Plan for Healthy Lives and Well-Being (FOIA-USTR-FY21-87-134; not found on WHO website, so we cite the version in the FOIA documents) in 2019 asserts the importance of engaging with the private sector to achieve science-based policy. It states that “Deeper engagement through multisectoral partnerships fosters the developing of... outcomes that are built on science- and evidence-based approaches” (FOIA-USTR-FY21-87-136). The coalition’s position statement attached to an advocacy letter to the HHS Secretary in 2020 in preparation for an upcoming WHO Executive Board meeting says that policies listed as measures to reduce the harmful use of alcohol in WHO documents are not consistent with scientific evidence or fail to include science-based measures (FOIA-USTR-FY21-87-233).

The documentary search also reveals EAGL members questioning the scientific basis of WHO programs. In its public comments on the First Report of the Independent High-Level Commission on Non-Communicable Diseases, EAGL expresses concern over language that could “undermine the ability of national governments to develop and implement effective, science-based approaches to address NCDs.” This category includes

excise taxes on specific goods, which it feels may be based on “inadequate scientific substantiation and an inadequate cost analysis.”⁵⁵ The 2018 position statement from 9 members of EAGL states:

The WHO should not lobby national governments to implement the Guidance [on adhering to the WHO International Code of Marketing of Breastmilk Substitutes], nor should the WHO undermine science-based international standards by seeking to incorporate the Guidance into development of the Codex standard on follow-up formula. (FOIA-USTR-FY21-87-105)

Comments filed by NMPF and USDEC for USTR’s annual National Trade Estimate report in 2019 (FOIA-USTR-FY21-87-145) underscore industry concerns that WHO policy recommendations will harm trade and supersede standards set by the Codex Alimentarius Commission. NMPF and USDEC praise USDA’s leadership in protecting science-based standards within the *Codex Alimentarius*, praising especially an unspecified outcome that “ensures continued market access for U.S. food and agriculture exports, and preserves a powerful tool for challenging unjustified trade barriers (FOIA-USTR-FY21-87-177).” They note that advocacy by the U.S. Codex office helped garner the adoption of a strategic plan for 2020-2025 that would “uphold Codex’s mission to develop science-based food standards.” They urge that the U.S. Codex office be equipped with adequate resources to “defend the principles of sound science” (FOIA-USTR-FY21-87-178). In contrast, they express concern that WHO may promote recommendations on dairy products that are not based on sound science and “would constitute *de facto* barriers to trade” and states that:

The WHO process, which is not transparent and tends to be more staff-led than member-driven, is quite different from that followed under Codex. It is critical that each body retain its unique mandate and independence moving forward. (FOIA-USTR-FY21-87-179)

EAGL echoes this elevation of the Codex Alimentarius Commission and other parts of the global trade regime over WHO policies in a position statement appended to a letter to the HHS Secretary in advance of the WHO Executive Board in February 2020 (FOIA-USTR-FY21-87-226, -228). It states that the US government should assure that all WHO activities are “Fully consistent with international norms and standards, including those set by Codex Alimentarius [Commission], the World Trade Organization, and the World Intellectual Property Organization (FOIA-USTR-FY21-87-226).” It further states:

Amidst a range of competing priorities, and increasing WHO ambition, the WHO cannot and must not ignore its important role in food safety in order to focus on nutrition and non-communicable diseases. Communicable, foodborne illness remains a major global public health challenge and needs to remain at the forefront of the WHO food policy agenda. The WHO should direct its efforts at areas not within the remit of Codex Alimentarius, which acts as the lead agency for developing food safety standards. (FOIA-USTR-FY21-87-234)

In several cases, EAGL members also state that WHO policies, staff, or panels are biased or not properly trained and suggest that science or evidence is being overlooked, ignored, or misinterpreted. EAGL argues that the UN High-Level Panel on Access to Medicines report was biased (FOIA-USTR-FY21-87-024, -102) and that the WHO's tool to screen for COI in nutrition programs reflects a bias against the private sector (FOIA-USTR-FY21-87-106). EAGL-member IDFA forwarded (FOIA-USTR-FY21-87-063) a position statement to USTR, HHS, and USDA-FAS from another organization it belongs to, the International Dairy Federation (IDF), stating that the WHO draft tool for managing COI in nutrition programs is biased against the food industry (FOIA-USTR-FY21-87-064). IDF wrote that the COI tool should be broadened to recognize cognitive, financial, publication, statistical, ethical, and philosophical bias, followed by a description of how partnerships with the private sector can help policymakers broaden their views, so that public-private partnerships can drive more innovative public health agendas (FOIA-USTR-FY21-87-065). DISCUS refers to the lack of unbiased analysis and focus on unproven policies within the WHO action plan to strengthen implementation of the Global Strategy to Reduce the Harmful Use of Alcohol (FOIA-USTR-FY21-87-272).

EAGL reinforces this message. It suggests that improved training for WHO staff will be necessary to overcome this negative bias or risk aversion toward the private sector (FOIA-USTR-FY21-87-268). It states that this "undue hesitancy and extra scrutiny applied to potential private-sector engagement continues to impair WHO's access to necessary knowledge, expertise and resources from private-sector actors" (FOIA-USTR-FY21-87-267).

Confluence with tobacco lobbying

ECAT disclosed lobbying on WHO in 2016, the year when the organization dissolved after a half-century of advocacy on trade policy for manufacturers. The University of Bath's TobaccoTactics.org reports that ECAT received membership fees from Philip Morris International (PMI) and was listed in a PMI report along with the US Chamber of Commerce, and now-EAGL-members NAM and NFTC in a list of third-party associations PMI uses to engage with policy makers.⁵⁶ Although its membership was very broad, in its final years, ECAT exerted considerable effort advocating against restrictions on tobacco marketing imposed by US trading partners like Australia, France, Ireland, New Zealand, and the UK.⁵⁷

EAGL emerged very close to the time that ECAT dissolved. Their respective list of members heavily overlap, with the notable exclusion of tobacco interests. American Shipper reports that prior to joining the National Association of Manufacturers, NAM/EAGL Officer A was Vice President of ECAT.⁵⁸ NAM/EAGL Officer A in 2013 was a co-signatory on behalf of NAM for a joint statement with ECAT and NFTC protesting proposed legislation in New Zealand that would impose plain packaging restrictions on tobacco products.⁵⁹ NAM also co-signed a public comment with ECAT opposing plain packaging in Norway in 2015,⁶⁰ the year before ECAT dissolved, though with no officers named. The USCC, which has many overlapping members with EAGL industry associations and lists WHO as a topic on its lengthy list of issue disclosures in every quarter since 2016, is also a co-signatory with ECAT, NAM, and NFTC on both of these statements protesting plain packaging on tobacco products.

Among non-business entities (in addition to efforts by CFIF), Table 3 shows that the National Taxpayers Union (NTU) disclosed lobbying in 2018 in regard to tobacco taxes recommended by the WHO's Conference of the Parties to the Framework Convention for Tobacco Control. Although further detail is not evident in the disclosures, a text search of the NTU's website yielded a letter to the HHS Secretary on October 2017 expressing concern about language in the WHO's plan to recommend excise taxes on tobacco, alcohol, and sugar-sweetened beverages. The NTU questioned the use of US funds in WHO operations that lead to such policies: "It is particularly galling to us that all of these machinations have already been taking place at the expense of U.S. taxpayers, who provide the single largest contribution (nearly 20 percent) to WHO's \$2 billion annual budget."⁶¹

NTU also expressed concern that "ordinary Americans have been denied the simple right to attend WHO meetings where these tax-hike proposals have been devised," a possible reference to WHO's COI screening. It recommended that HHS boycott an upcoming WHO conference on NCDs,

*Publicly repudiate all portions of the Roadmap that overtly or implicitly support tax increases, multinational regulations, or other government-driven policies that undermine... economic rights among citizens; and, ...Affirm that U.S. policy seeks, instead, to empower individuals, encourage private sector innovation, and foster voluntary cooperation among sovereign nations to meet global health challenges.*⁶²

In addition to this letter, NTU was a signatory on letters in 2016 and 2018 to the WHO Director-General, opposing WHO support for plain packaging on tobacco products. The 2016 letter also opposes the idea of plain packaging on infant formula. The 2018 letter opposes plain packaging on any product with specific mention of alcohol, sugary beverages, and foods high in fat.⁶³

Table 3 shows that lobbyists for PMI Global Services, affiliated with PMI, filed a disclosure nearly identical to that of RAI Services, "Reaffirming US principles at the United Nations and encouraging the World Health Organization to embrace technological advances in tobacco control." This is also the opening line of House Resolution 896 introduced in the House on March 11, 2020, *one month* before the US announced its intention to withdraw from the WHO. The Resolution alleged that the "World Health Organization is actively targeting major American industries, including agriculture, food and beverage, and pharmacology, with onerous global regulations." The Resolution criticized the WHO's use of FENSA protocols.⁶⁴

We noted above that EAGL cited IDFA in praising the proposed Multilateral Aid Review Act of 2017, which would make US funding to WHO subject to increased review. Tables 1 and 3 show that IDFA and CFIF both lobbied on issues related to funding for the WHO in the second quarter of 2018, with CFIF requesting a 25-percent cut. EAGL also lists the UN World No Tobacco Day on its "EAGL Calendar of Global Institution Events" that they track, sent to USTR by NAM/EAGL Officer B (FOIA-USTR-FY21-87-131, -140).

Private sector positions during the pandemic

Table 2 presents corporate lobbying disclosures mentioning the WHO during 2020. In addition to these disclosures, two entities lobbied on “proposals regarding infant and young child nutrition marketing” (Abbott) or “multilateral organization issues affecting dairy and trade” (NMPF) without mentioning WHO, after having explicitly disclosed WHO-related lobbying on the same issues between 2016 and 2019. Thus, at least two industry actors stopped explicitly mentioning WHO in their lobbying disclosures in 2020 even though they still appeared to be lobbying US federal officials on WHO-related concerns.

Five EAGL-linked parties lobbied on WHO-related issues in 2020. They did not declare support or opposition to the Trump administration’s threat to withdraw from the WHO. Instead they either mentioned the announcement directly, or inserted new language about WHO “priorities” or “reform” into their usual wording for WHO-related disclosures. For example, Miller-Coors, which had used the exact same wording for their disclosures in the prior 16 quarters, added an additional reference to “WHO Priorities” as an issue for discussion with US federal officials in the second quarter of 2020. Similarly, the US Chamber of Commerce added “World Health Organization reform recommendations” to its disclosure template. Business Roundtable mentioned both “WHO priorities” and reform. No detail is disclosed regarding what priorities or reforms these groups advocated, though the US Chamber of Commerce mentions “continued U.S. membership in the World Health Organization,” suggesting they may have been against withdrawal. NAM’s disclosure in Table 2 mentions only “Potential World Health Organization Withdrawal.”

Our documentary search sheds more light on these positions. In its June 2020 newsletter, NAM writes that “The NAM, both directly and through its leadership in the cross-sector coalition Engaging America’s Global Leadership, has long stressed the importance of U.S. engagement and leadership at the WHO as well as clear *priorities* for WHO *reform*, transparency and accountability [emphasis added].” In its September 2020 newsletter, NAM said that as domestic discussion about the WHO intensified, NAM has “continued to lead the charge” to promote:

...reforms to address initiatives and activities that are harmful to manufacturing. These issues have elevated in recent months... NAM is working both directly and through its cross-sector coalition, Engaging America’s Global Leadership, to advance WHO reforms and express strong concerns about how U.S. withdrawal will impact manufacturers... NAM is engaging directly with senior members of the administration and bipartisan members of Congress to flag these concerns and drive a path toward reform and continued U.S. membership in the WHO.⁶⁵

Thus, NAM describes itself as lobbying to continue membership in WHO while reforming it to mitigate aspects of WHO operations that it views as adverse for manufacturing.

EAGL sent an advocacy letter (FOIA-USTR-FY21-87-256) and detailed recommendations (FOIA-USTR-FY21-87-258) on January 15, 2021 for the upcoming

WHO Executive Board meeting to the HHS Secretary, which NAM/EAGL Officer B forwarded to USTR (FOIA-USTR-FY21-87-255). The letter said that

The WHO's response to COVID-19 has highlighted challenges such as lack of focus, inadequate transparency, inconsistent use of science and evidence-based approaches, and insufficient inclusiveness and transparency. These weaknesses are not unique to the pandemic response and also characterize other WHO workstreams that are problematic for U.S. interests. (FOIA-USTR-FY21-87-256)

In the appended position statement, EAGL explains its view that the WHO must be reformed to solidify its response to future pandemics, linking the pandemic to the coalition's broader existing concerns and suggesting that it presented a special opportunity to address them:

Those reforms must address not only pandemic-specific areas such as the International Health Regulations, but also fundamental concerns about organizational focus, transparency, inclusiveness, accountability, and use of science and evidence-based approaches... This presents the United States government an unprecedented opportunity to lead the global charge for an ambitious WHO reform agenda that provides the organization with critical course corrections and addresses "mission creep. (FOIA-USTR-FY21-87-258)

As examples of suggested reforms, EAGL's statement then describes positions similar to those in prior letters to the HHS Secretary. These include expansion of the private sector's role in WHO operations and a call for science-based policy:

Longstanding trends at the WHO—including the marginalization of private sector voices and the promotion of ideologically driven policies not based on evidence—have undermined public/private cooperation at the time the world has needed it most. (FOIA-USTR-FY21-87-259)

The statement expresses longstanding concerns about violations of intellectual property rights in the WHO approach to expanding access to medicine (see Appendix E for additional detail on these positions) and adds a new one: EAGL criticizes the WHO Secretariat's endorsement of "an extreme and unnecessary proposal" being considered within WTO, aimed at expanding access to vaccines for Covid-19 by exempting them from some protections under the WTO TRIPS agreement. It also repeated long-standing concerns about approaches to prevention of NCDs through excise taxes and marketing restrictions on specific foods and beverages. It pointed to documents discussing measures restricting marketing of food to children and for infants, and policies designed to discourage consumption of fats, salt, sugar (including sugary drinks), alcohol, and tobacco as problematic. The letter repeats concerns about limitations on WHO engagement with the private sector, especially WHO's implementation of FENSA, stating that

“FENSA is *still* being used to block or stunt public-private engagement” (FOIA-USTR-FY21-87-267). It repeats concerns that WHO may encroach upon work by the Codex Alimentarius Commission.

A position statement from USDEC and NMPF sent to the incoming US Trade Representative Katherine Tai (FOIA-USTR-FY21-87-281, -283) echoes this approach, stressing longer-standing concerns. While it expresses support for continuation of US participation in the WHO, they write that the aim of participation would be to push for reform. In particular, they recommend that the US government

...pursue a long overdue reform agenda that could focus WHO staffing and spending on its core mission areas, enhance transparency and participation of all stakeholders, reassert the importance of science-based decision-making, and ensure that the WHO secretariat acts at the direction of WHO member states. (FOIA-USTR-FY21-87-288)

They likewise emphasize that Codex plays an “indispensable” role in establishing science-based standards for food safety, contrasting this with WHO, which has “not always shown the same strong commitment to grounding their recommendations and guidelines in sound science, nor to evaluating the real-world impacts of their policy prescriptions” (FOIA-USTR-FY21-87-287).

IDFA’s position statement says little about US participation in the WHO except that WHO workstreams, along with Codex and the UN, “are increasingly driven by positions that are not based on science... At the same time, the United States is uniquely positioned to lead a global strategy to correct these shortcomings” (FOIA-USTR-FY21-87-296).

After a link to an article criticizing the WHO for not enough transparency on May 13th, 2021, the news posts on EAGL’s website end on May 16th. We do not know whether lobbying activities under the EAGL name continue.

DISCUSSION

While the withholding of funds and threat to withdraw from WHO is consistent with some of the anti-globalist aspects of the Trump administration, as described by the recent *Lancet Commission on Public Policy and Health in the Trump Era*,⁶⁶ our data demonstrate a pre-existing, coordinated effort by the corporate sector not only to influence global health policy, but also to sow doubt in the integrity of the WHO. While proposals to curtail or withdraw US funds from WHO have gone on for decades, our analysis demonstrates an intensified and coordinated effort to influence US appropriations for the WHO starting around 2016. The effort is associated with specific demands for greater private sector involvement in WHO health policymaking.

The demands continue and have now been tied in with pandemic-related reform in industry lobbying. At the head of this effort are producers and trade associations spanning several industries, including food processing and ultra-processed foods, alcoholic beverages, biotechnology products and pharmaceuticals, and the video gaming software industry. They have worked in concert through EAGL and simultaneously with tobacco interests. While the Trump administration’s stance toward WHO may represent

a particularly dramatic swing away from multilateral cooperation to support the global health system, the Biden administration's promise to re-engage with WHO contained equally strong language about reforming it.⁶⁷ It is unclear to what extent this commitment to reform of the WHO by the new administration aligns with industry positions advocated by EAGL members and affiliates.

We see peppered throughout the disclosure data, public statements, and position statements received through a FOIA request that private sector actors are lobbying the federal government to change or override WHO guidelines and recommendations, particularly in relation to national strategies to prevent and control NCDs. Commercial actors are also working to undermine WHO's viability as a UN organization by proposing cuts in funding, urging the US government to narrow the scope of WHO's priorities, lobbying WHO to dismantle its policies designed to avoid conflicts of interest and undue private-sector influence, and calling for US contributions to be contingent on new reviews, overseen by political appointees, about whether WHO is undermining US commercial interests. The EAGL coalition has targeted the internal interagency deliberative process, managed by the National Security Council, to influence US government positions in WHO governance and policy-making. EAGL itself is somewhat ephemeral—no apparent tax filings or federal lobbying disclosures, only a website and letterhead to indicate its activities—and its activities appear to be led by officers of the National Association of Manufacturers. So it is not the existence of EAGL itself, but the realization of common interests across its members, that have resulted in common messages and actions related to US policy at and toward WHO that are of central interest.

The pandemic has illustrated the importance of the WHO being able to operate as an independent technical agency focused on its constitutional mandate to help achieve “the attainment of all peoples of the highest possible level of health.”⁶⁸ The WHO's Framework for Engagement with Non-State Actors (FENSA) which was painstakingly negotiated over a period of many years, was designed to safeguard WHO's integrity as a specialized public health agency from undue influence and conflicts of interest. But it is under a great deal of pressure to be weakened, as is the COI screening protocol for nutrition programs. In a recent WHO online consultation, the US stood alone among member states in aligning with industry groups—including EAGL, IDF, and the International Council of Beverages Associations—to file comments highly critical of FENSA as being too cautious and exclusionary toward industry participation, rejecting any argument that commercial interests present a special category of conflicts of interest that should hinder industry participation in nutrition policy.⁶⁹ Similarly, it is notable that the US government included language about public-private partnerships in its official position on the Ending Childhood Obesity report, and made sure to let EAGL know by sending the statement that the US delegation read into the WHA record.

One might ask why the private sector is attacking WHO guidelines and policies when those guidelines and policies are voluntary. Member states can ignore or opt out of any Resolutions or treaty frameworks that the WHO generates. The most legally binding framework the WHO has established is the Framework Convention on Tobacco Control, to which the US is not a party, as it never ratified the treaty.⁷⁰ To this end, language in the FOIA documents—describing concerns about WHO health and nutrition policies becoming a supplement to the *Codex Alimentarius* and the WTO TRIPS agreement as legal benchmarks in complaints about technical barriers to trade or intellectual property rights infringement—may offer important insight.⁷¹

In particular, our findings demonstrate coalition members sending a pervasive message that UN bodies and the WHO in particular have issued recommendations for global health policy that are not science-based and may endanger the scientific integrity of food safety standards established within the *Codex Alimentarius*. They argue specifically that screening for COI in WHO processes both prevents WHO personnel from being transparent or well-informed and is motivated by a bias against commercial actors. Coalition members draw a contrast to the standard-setting process within the Codex Alimentarius Commission, which they assert is more science-based. A concern that WHO recommendations may become recognized as legal justification in the eyes of trade dispute settlement bodies for national public health measures that are more stringent than the benchmarks of the *Codex Alimentarius* could be one reason for the coordinated effort to weaken confidence in WHO policies as standards for global health observed in the data above.

Research has shown that commercial actors have much more opportunity to shape the *Codex Alimentarius* standards as unfettered participants within CAC processes. There is little or no COI screening protocol for these standards.⁷² As observed in industry complaints above, participation by commercial actors in shaping policies and guidelines at the WHO is much more restricted. Russ et. al (2021) and Boatwright et al (2021) explain this emerging conflict between WHO and industry interests in shaping *Codex Alimentarius* standards for the case of commercial milk formulas, while Thow et al (2017 and 2019) and Garton et. al (2021) do so for front of packaged food labelling and other nutrition policies.⁷³ As long as this tension exists, a strong profit motive to cut funding for and weaken guidance produced by the WHO will exist. This inconsistency in the overlapping global health and trade regimes must be thoughtfully and intentionally addressed to resolve these recurrent struggles between commercial actors and institutions of global health governance.

Although tobacco companies are not members of EAGL, the results above raise questions about activities of the new coalition being aligned with tobacco lobbying. EAGL arose just as ECAT disbanded. ECAT engaged in aggressive lobbying against plain packaging, in support of tobacco company interests. The senior EAGL/NAM officer worked for ECAT prior to joining NAM and co-signed a letter with ECAT in protest of a proposed plain packaging law on behalf of NAM. The one EAGL member disclosing lobbying on a measure that would subject US funding for the WHO to more restrictive review did so in the same quarter as lobbying to cut US funding to the WHO by CFIF, which is tied to tobacco interests. Expansive lobbying by EAGL critical of WHO was followed in 2020 by a House Resolution, named by tobacco companies in their issue disclosures, advocating more favorable treatment of the US tobacco industry by WHO and jointly naming industries participating in EAGL as targets of WHO for onerous regulations. The resolution also criticized FENSA as discouraging WHO engagement with the private sector. These are similar to complaints lodged by EAGL in its own position documents. EAGL reports tracking the UN World No Tobacco day on its calendar of events of interest. A fresh reckoning with the expanse of global tobacco lobbying may be needed to protect the integrity of WHO policymaking processes and safeguard policies intended to reduce harm from tobacco use.

This study shines a light on the domestic relationship between member states and commercial or corporate interests. Keeping WHO free from inappropriate industry influence is of special importance for the US government because of its disproportionate

influence over WHO. National governments should consider whether and how their positions at WHO should be screened for conflicts of interest. In principle, the relative weight of stakeholder ministries—like USDA, Commerce or USTR—versus health ministries—like the HHS or its internal Food and Drug Administration—in interagency processes can make a big difference in whether the US is a constructive contributor to global health governance in organizations like the WHO, or is a conduit for promoting commercial interests inside them. Notwithstanding, our analysis shows that HHS is also subject to lobbying, with little guaranteed transparency. At this time, HHS has been the least responsive agency to our FOIA requests. We can find no record of expenditures related to advocacy letters sent by EAGL to HHS mentioned in federal disclosures within LobbyView. The extent of influence from corporate lobbying at HHS is a black box that needs documentation and daylight to review domestic protocols used to screen agency positions for conflicts of interest, including its representation of national positions at WHO.

Notwithstanding, the lobbying data used in this analysis exist only because the US has stronger disclosure laws for lobbying activity compared to any other jurisdiction we know. The data on corporate lobbying in the European Union is much poorer, for instance; making a similar analysis impossible. Thus, the US is not alone in requiring an examination of the influence of industry on its official positions in multilateral institutions of global health governance. What is happening here should be a cautionary tale on the importance of strict and detailed lobbying disclosure requirements, transparency in national deliberations over official positions taken in multilateral institutions,⁷⁴ and the importance of screening for conflicts of interest at the national level when formulating official positions for global health governance.

An initiative to increase transparency surrounding lobbying and corporate influence; protect, strengthen, or establish new screening for conflict of interest in health policymaking (including protecting FENSA); resolve institutional gaps in trade and global health governance leading to a tug of war over Codex and WHO health guidelines as benchmarks in trade disputes; and scrutinize representation by national health ministries at WHO is a highly contentious proposition. Political consensus may arise more quickly with a full assessment and public awareness of the implications of not doing so for health equity both within the US and worldwide.

Historically, the US has played an important role in establishing the UN system after the Second World War, with some US leaders playing a prominent role in creating a progressive social and moral mandate for the UN. For example, as Chair of the United Nations Human Rights Commission, Eleanor Roosevelt is widely viewed as the driving force behind the establishment of the Universal Declaration of Human Rights. President Biden himself helped restore US funding to WHO with the difficult compromise he reached in the Helms-Biden Act in 1999, ending the US stalemate over funding for the UN.⁷⁵ Re-engagement with WHO under any administration has the potential to commit the US to promoting a global vision of health for all, or allow it to act as a conduit for intensified industry efforts to erode global health policy from within.

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Appendix A: Engaging America's Global Leadership Coalition Members

National Association of Manufacturers (NAM)
Advanced Medical Technology Association (AdvaMed)
American Apparel & Footwear Association
American Chemistry Council
Air-Conditioning, Heating, and Refrigeration Institute (AHRI)
Beer Institute
Biotechnology Innovation Organization (Bio)
Can Manufacturers Institute
Cookware Manufacturers Association (CMA)
Corn Refiners Association (CRA)
CropLife America
Distilled Spirits Council
Entertainment Software Association (ESA)
The Association of Food, Beverage, and Consumer Products Companies (GMA), formerly known as the Grocery Manufacturers Association, now known as the Consumer Brands Association
International Dairy Foods Association (IDFA)
National Confectioners Association (NCA)
National Foreign Trade Council (NFTC)
National Milk Producers Federation (NMPF)
National Oilseed Processors Association (NOPA)
National Pork Producers Council
Personal Care Products Council
PhRMA
Plastics Industry Association
Plastic Pipe and Fittings Association (PPFA)
Society of Chemical Manufacturers & Affiliates (SOCMA)
The Fertilizer Institute
US Dairy Export Council
Vinyl Institute (Vinyl)

Appendix B: Structure and activities of the cross-industry coalition Engaging America's Global Leadership (EAGL)

Budget and staffing.

We could find no filing by EAGL with the IRS using the IRS Tax Exempt Organization Tool and so could not immediately obtain information on EAGL's budget or funding. However, tax exempt filings by its founding member, NAM, are available in 2015, 2016, 2018, and 2019. NAM lists on Form 990 Schedule J Part II "Officers, Directors, Trustees, Key Employees, and Highest Compensated Employees" a person who wrote an article announcing EAGL's launch in *Global Trade Magazine*.⁷⁶ The text is identical to the text used in EAGL's own announcement of its launch posted 5 days earlier and cited in several EAGL press releases.⁷⁷ This is the only person cited in an article reporting on EAGL's launch in *The Hill* during the same period.⁷⁸ The person signed a letter on behalf of EAGL to the Director of the Office of Global Affairs (FOIA-USTR-FY21-87-023), and to the Secretary of State and the Secretary of HHS in 2019 (FOIA-USTR-FY21-87-143). We refer to this person as NAM/EAGL Officer A.

NAM/EAGL Officer A engages in outreach to US government employees on behalf of EAGL in documents obtained via FOIA. When announcing the coalition to USTR leadership and staff via email, they write that they are a point of contact for the coalition: "As the coalition ramps up its advocacy and communications activity, we look forward to working with you and your team. In the meantime, if you have any questions about the coalition or its plans, please do not hesitate to contact me or my colleague" (FOIA-USTR-FY21-87-002). The colleague named by Officer A in this email is also actively engaged in outreach to USTR according to emails obtained via FOIA (FOIA-USTR-FY21-87-001) also is an officer of NAM (FOIA-USTR-FY21-87-022), though not listed on the NAM tax returns since 2015. We refer to this person as NAM/EAGL Officer B. Officer B is listed as the submitter and point of contact for a comments from EAGL filed for a WHO public consultation on a COI screening tool for nutrition programs⁷⁹ and in advocacy letters introducing EAGL to four Cabinet Secretaries and the Acting USTR, as well as the leadership of the Senate Foreign Relations Committee.⁸⁰ The two officers repeatedly appear as sender or recipient in email chains or position statements by EAGL or EAGL members shared with employees from USTR (FOIA-USTR-FY21-87-069, -079, -081, -098, -108, -117, -142, etc.), the US Department of Agriculture (FOIA-USTR-FY21-87-026), the US Department of Health and Human Services (FOIA-USTR-FY21-87-026, FOIA-USTR-FY21-87-226 through 228), and the Department of State (FOIA-USTR-FY21-87-142). These are the only two people identified so far in our documentary search of individuals writing on behalf of EAGL.

Types of outreach.

As far as lobbying activity, the two officers of NAM representing EAGL engaged in emails with agency staff across the four agencies named above and mentioned concurrent lobbying of Congress (FOIA-USTR-FY21-87-001). We saw mainly correspondence with USTR employees, but at times employees from USDA, State and HHS were copied, or an email from EAGL to HHS (for instance, FOIA-USTR-FY21-87-255) or the State Department (FOIA-USTR-FY21-87-142) was forwarded to USTR. One of the NAM/EAGL

officers arranged a meeting with EAGL members from different industry associations and USTR staff (FOIA-USTR-FY21-87-222). Open letters to Cabinet members from EAGL or a subset of EAGL members and detailed position statements on WHO initiatives were sometimes attached to emails from the NAM/EAGL Officers and from individual EAGL members (FOIA-USTR-FY21-87-099, -143, -228, -252, -256). The open letters and position statements from EAGL contained positions that we also observed in position statements from the individual EAGL members, for instance the Distilled Spirits Council (see Appendix D). The advocacy letters and position statements shared by EAGL generally combined positions from multiple industries, especially biotechnology/pharmaceuticals, beverage alcohol, dairy, and chemicals (FOIA-USTR-FY21-87-023, -102, -230, -258). We call this simultaneous advocacy on different WHO-related concerns from different industries within the same documents and communications *coordination*. EAGL demonstrates or mentions this coordination in public documents, including coordination with industry associations outside the US to influence the engagement of other governments with WHO.⁸¹

NAM/EAGL officers and representatives from individual EAGL members raised concerns to USTR and HHS about WHO reports and processes or agenda items for upcoming WHA, Codex Alimentarius Commission committee, or UN General Assembly Meetings. One email attachment was an expansive list of meetings of UN bodies that EAGL finds of interest and were tracking in a calendar (FOIA-USTR-FY21-87-131). An EAGL member suggested that government statements be filed (FOIA-USTR-FY21-87-181), shared their own advocacy documents to aid in the drafting of US government statements or positions (FOIA-USTR-FY21-87-006, -089), and tracked the evolution of US positions through the interagency process leading up to particular meetings (FOIA-USTR-FY21-87-100, -112, -270). In at least one instance, an EAGL member asked to view a US comment in a WHO consultation before public posting (FOIA-USTR-FY21-87-112, -180).

By 2018, EAGL and some members' correspondence explicitly mentioned the interagency process and urged recipients of advocacy email messages and letters to support industry's position during the interagency process (FOIA-USTR-FY21-87-023, -063, -098, -100, -105, -177). The interagency process is an ongoing series of meetings and protocols managed by the White House National Security Council, intended to "advance the President's policy priorities and, more generally, to serve the national interest by ensuring all USG departments and agencies, and perspectives contribute to achieving these priorities, and participate in formulating and implementing policy. (p.II-1)"⁸² USTR staff requested input from lobbyists on draft WHO policy recommendations, explaining how the timing of the input mattered for its influence on US government positions at WHA being formed within the interagency process (FOIA-USTR-FY21-87-004). IDF submitted comments to USTR, the Commerce Department, HHS, and USDA regarding the WHO proposed COI screening protocol for nutrition programs, with the express intent that they be used within the interagency discussion of the US position for an WHO online consultation about the proposal. EAGL officer B shared a position statement from 9 EAGL member associations with USTR, expressing a hope that it help in the interagency process to prepare US positions for the 2018 WHA meetings.

Advocacy letters and emails shared or written by EAGL praised USTR and HHS staff or leadership for advocating for industry interests within WHO, WHA, and

elsewhere. One example is the cover letter for the position statement shared by EAGL for 9 of its members (FOIA-USTR-FY21-87-098):

We greatly appreciate HHS's recent efforts to accomplish these goals and want to recognize particular efforts by HHS and the U.S. interagency team to strengthen coordination and take strong positions at the January 2018 WHO Executive Board (EB) meeting. We also wish to note how helpful your role can be: for example, comments at the May 2017 WHA by your predecessor (former Secretary Tom Price) that highlighted the importance of "transforming" the WHO to deliver on its "most important mission: ensuring a rapid and focused response to potential global health crises" sent a clear, strong message of the United States' commitment to global health and its expectation to see transparency, accountability, and mission focus. (FOIA-USTR-FY21-87-100)

Another example is a position statement from EAGL members NMPF and USDEC praising USDA for "successful execution of the U.S. interagency Codex strategy developed under the leadership of USDA" (FOIA-USTR-FY21-87-177). Codex is the UN body that sets food safety standards, described in the main text. They recommend resources and support be accorded for these efforts from "interagency partners, including amplification of outreach to additional foreign Ministries via those interagency partners" (FOIA-USTR-FY21-87-178). EAGL expressed appreciation for work by USTR and "interagency counterparts" preparing for upcoming meetings of the WHO Executive Board as a preface to requesting a meeting to discuss the concerns of EAGL members related to the meeting (FOIA-USTR-FY21-87-225), and followed up after the conversation by urging USTR consideration of views during interagency discussions (FOIA-USTR-FY21-87-226). In May 2020, after the pandemic had set in, EAGL wrote to the HHS Secretary in advance of the WHA, stating that

EAGL and its members encourage HHS and its interagency counterparts to continue raising the issue of private sector inclusion as part of the broader WHO reform agenda, and to oppose unbalanced initiatives that exclude the private sector. (FOIA-USTR-FY21-87-253)

Appendix C: Timeline of lobbying on US appropriations for WHO

Here, we summarize the timeline of appropriations-related lobbying, to provide context for the timing of lobbying on other topics in results below:

1. The first direct evidence of lobbying related to US funding for the WHO is an EAGL statement in September 2017 praising language requiring the Department of State to provide the Appropriations Committee with reviews analyzing whether its activities aligned with US economic interests.
2. Given that the formulation and insertion of the language takes time, we explored whether lobbying of Congress for this to happen plausibly began earlier than September 2017. Suggestive data include the following:
 - i. A member of EAGL, IDFA, publicly said in February 2016 that they were lobbying Congress to “take action against flawed World Health Organization guidelines” on marketing of follow-up formula and encouraging their members to lobby legislators.
 - ii. NAM/EAGL Officer A wrote in an email to a USTR official in April 2017 mentioning that EAGL and its members would be lobbying Congress and the Executive Branch to push back on problematic policy and regulatory proposals at the UN and WHO.
 - iii. NAM/EAGL Officer A wrote an op-ed urging Congressional action to take a more activist role in WHO governance in July 2017.
3. Disclosures of lobbying on appropriations to the WHO appear in federal filings starting in 2018. IDFA disclosed lobbying on US appropriations to the WHO in the first three quarters of 2018. In 2018Q2, CFIF concurrently lobbied the White House to cut US funding to the WHO by 25 percent.

Appendix D: Cross-industry coordination to protest WHO alcohol policy

Cross-sectoral coordination with producers of alcoholic beverages

During outreach to USTR, DISCUS raised specific concerns regarding WHO policies and guidelines in an update to Appendix 3 of the WHO Global Action Plan for the Prevention of Non-Communicable Diseases 2013-2020.⁸³ In particular, they expressed opposition to WHO recommendations that countries consider as policy tools to reduce harmful use of alcohol levying excise taxes on alcohol sales and restricting both marketing and points of sale for alcoholic beverages (FOIA-USTR-FY21-87-006, -008). USTR coordinated the timing of the US domestic process to formulate a position on the document with DISCUS to enable incorporation of DISCUS concerns into the US position (FOIA-USTR-FY21-87-004). EAGL also sent a letter expressing concerns about recommendations in this Appendix to the Director of the Office of Global Affairs in HHS (FOIA-USTR-FY21-87-023) and forwarded (FOIA-USTR-FY21-87-022) the letter to USTR. In the letter, EAGL says that the failure of WHO to modify the draft Appendix (also presented in EB140/27 Annex 1) or a related resolution for the Executive Board (EB 140.R7) presents “major questions about transparency and accountability to member state interests” (FOIA-USTR-FY21-87-025). The US ultimately refused to endorse Appendix 3 for the Global Action Plan for the Prevention and Control of NCDs 2013-2020 and specifically mentioned recommendations related to taxation as problematic (FOIA-USTR-FY21-87-032).

EAGL and a cross-sectoral group of 9 EAGL members continued to echo the concerns expressed by DISCUS about Annex 3 in spring 2019. EAGL wrote that the WHO’s refusal to modify or delete contested policy measures mentioned as options in Annex 3 meant that WHO ignored feedback from stakeholders, including members states and non-state actors (FOIA-USTR-FY21-87-098, -99, -108, -109). In January 2020, NAM/EAGL Officer B wrote to the Assistant USTR requesting a group conversation with USTR staff to discuss the upcoming WHO Executive Board meeting. Officer B mentioned agenda items related to non-communicable diseases, in particular the global alcohol strategy and the GSPOA on public health, innovation, and intellectual property as priority issues for EAGL members (FOIA-USTR-FY21-87-222). Officer B listed representatives from the Beer Institute, Corn Refiners Association, Croplife America, DISCUS, PhRMA, and NMPF as planning to attend.

Appendix E: Intellectual property

Six of the seven pharmaceutical firms or organizations lobbying on WHO-related issues between 2016 and 2019 (Table 1) mentioned WHO guidance or programs related to prequalification, diagnostics, or access to medicines. The Biotechnology Innovation Association (BIO) was the most active among these and focused on intellectual property protection as it relates to programs promoting access to medicines. In 2016, a year when Intellectual Property Watch described the biotechnology industry as coming “under attack... about the unaffordability of new drugs,”⁸⁴ BIO released a position paper to the United Nations High-Level Panel on Access to Medicines arguing against the view that intellectual property protections impede access to medicines.⁸⁵

BIO is a member of EAGL, and has issued joint letters or lobbied concurrently with AdvaMed (another EAGL member) on various issues affecting medical technology firms. AdvaMed’s lobbying disclosures show discussion with US federal officials about a “diagnostics program” at the WHO. In 2018, the WHO released for the first time an Essential Diagnostics List, which recommends a list of priority *in vitro* diagnostics that should be available in all point-of-care health facilities and laboratories across the world. The list provoked two industry concerns. The first concern was the “prequalification” process by which the WHO identifies priority tests and then lists specific suppliers (brands) of those tests it has evaluated and found to be safe and reliable.⁸⁶ Thus, we see Abbott, and Genentech disclosing lobbying of US officials regarding WHO prequalification and diagnostics. Another firm, BD, also lobbied on prequalification without specifying diagnostics, but it is a supplier of diagnostic tests and equipment and linked with AdvaMed.

The second concern was that the Essential Diagnostics List may be used by countries to bargain down the prices for essential tests. This was mentioned as a risk by 40 percent of surveyed industry representatives attending the 2018 McGill Summer Institute in Infectious Diseases and Global Health.⁸⁷ Neither AdvaMed nor the four pharmaceutical firms lobbying on the prequalification program disclosed pricing as an issue. However, AdvaMed is one of eight members of the Global Diagnostics Alliance which in March 2019 submitted public comments to the WHO jointly with the Global Medical Technology Alliance stating:

*Taking lessons learned from the implementation of the Essential Medicines List (EML) of many decades, we understand that member states have utilized the EML to implement restrictive pricing of medicines to drive down their cost. The implementation of price controls on diagnostic tests... could lead to stifled innovation and reduced access to diagnostic tests... The true value of diagnostic tests goes well beyond price.*⁸⁸

Like EAGL’s statements, the submission also emphasized the need for greater collaboration with stakeholders in industry. AdvaMed disclosed lobbying on this issue only in 2016, but one of its members, Abbott, continued lobbying in 2017 and 2019.

EAGL also advocated for intellectual property rights in a letter to the HHS Secretary by opposing any references to the U.N. High-Level Panel on Access to medicines report in WHA and WHO documents and proceedings, on the grounds that “UNHLP singled out IP as the sole cause of problems with access to medicines in developing

countries” (FOIA-USTR-FY21-87-025). The coalition said that the process used to create the report was not transparent, reflected bias, and did not take into account the views of all stakeholders regarding causes of lack of access to medicines, making “the report and its findings highly flawed.” EAGL writes that two WHO proposals referencing the report (related to cancer treatments and to address shortages of medicines and vaccines) “represent an unacceptable attack on U.S. innovation and IP, a fundamental component of U.S. economic competitiveness and manufacturing innovation. NAM/EAGL Officer A posted two articles criticizing the report.⁸⁹

Nine EAGL members writing to HHS Secretary Alex Azar ahead of the World Health Assembly in May 2018 echoed these concerns, saying that “In spite of these grave flaws, WHO continues to reference this discredited report in it[’s] work on access to medicines” (FOIA-USTR-FY21-87-099). They express related concerns about the WHO Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation, and Intellectual Property,⁹⁰ as did EAGL in a January 2020 letter (FOIA-USTR21-87-228) to the HHS Secretary with EAGL’s comments for the upcoming WHO Executive Board meeting, forwarded to USTR by NAM/EAGL Officer B (FOIA-USTR21-87-226). In this letter, EAGL recommended that the US should “continue to press for effective—not perfunctory—trilateral cooperation with [the World Intellectual Property Organization] and the [World Trade Organization] to foster a better understanding of the linkage between public health and intellectual property policies,” which they write would require specific organizational reforms to ensure that the trilateral coordination takes place.

EAGL lobbied against two initiatives that the Biden Administration has since supported (with some apparent reluctance⁹¹) as mechanisms to broaden access to pharmaceutical products integral to fighting the pandemic:

The WHO also established, without consulting the private sector, the COVID-19 Technologies Access Pool, a mechanism for rights holders to cede their IP. C-TAP was essentially a solution in search of a problem, an unnecessary effort that has distracted attention and resources that could have been better used to tackle the pandemic in other ways. The WHO Director-General has also publicly supported an extreme and unnecessary proposal in the WTO TRIPS Council to waive certain IP obligations. (FOIA-USTR-FY21-87-261)

Appendix F: Video game industry

Lobbying issue disclosures by the Entertainment Software Association pertaining to WHO do not disclose its position. However, the Entertainment Software Association and other industry partners have been vocal in their opposition to the WHO's recent establishment of "Gaming Disorder" as an addictive behavior.⁹² The WHO proposed listing the disorder in its compendium, *International Classification of Diseases 11th Revision (ICD-11)*, in 2018, explaining that "[t]he pattern of gaming behaviour results in marked distress or significant impairment in personal, family, social, educational, occupational, or other important areas of functioning." The ICD-11 will go into effect in 2022.⁹³ EAGL also mentions this categorization in ICD-11 as evidence of a problematic degree of risk aversion on the part of WHO (FOIA-USTR-FY21-87-236).

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FRAMING GLOBAL MENTAL HEALTH: NEW LAYERS OF MEANING WITH THE COVID-19 PANDEMIC?

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Since the 1990s, global mental health has been framed in different ways to draw attention to this neglected issue. Initially framed by the UN and psychiatrists as a human rights concern, global mental health now is also framed as a mainstream health issue, an economics concern, and, with the COVID-19 pandemic, a crisis. This frame layering emerged because the number of interested actors has expanded to include WHO, economists, NGOs, the World Bank, advocates for people with mental illness, donors, and celebrities. Frame layers have not been well integrated, may promote contradictory approaches, and have yet to foster significant funding increases. The COVID-19 crisis framing, while salient and credible with the public and policymakers, has the potential to undermine attention to chronic mental health issues. The article is based on analysis of UN, WHO, donor, NGO and advocacy documents, as well as interviews with key stakeholders.

INTRODUCTION¹

Mental and substance use disorders, suicide, and neurological diseases like dementia affect an estimated one billion people worldwide.² They are responsible for one-third of the global burden of disability and 14 percent of deaths.³ Yet these conditions have suffered from relative neglect on the global health agenda,⁴ leading advocates to use various frames to bring more attention to global mental health.⁵ This article interrogates these frames. It argues that diverse actors have contributed to frame layering, with the “COVID crisis” frame being the latest articulation. Starting in the 1990s, advocates adopted a human rights frame. But as the number of actors grew, new frames layered on top of the human rights message. These included mainstreaming mental health with physical health and emphasizing economic costs and benefits. The COVID-19 pandemic has significantly affected this framing trajectory. Leading to over 3.6 million global deaths by June 2021,⁶ economic downturns,⁷ and declines in life expectancy,⁸ the pandemic has brought greater attention to mental health. This crisis frame portrays mental health as a short-term emergency intricately tied to the pandemic. Paradoxically, this message may undermine investments in programs for chronic mental health conditions and further dilute mental health messages.

This article has six sections. We begin by exploring the role of framing in global health. We then describe our methodology. The fourth section analyzes pre-pandemic mental health framing, as evidenced in the statements, policies, and programs of an expanding number of actors. The fifth focuses on the crisis framing during the pandemic and the widening array of mental health voices. The sixth questions the implications of framing for funding before and during the pandemic. The conclusion raises policy implications.

FRAMES IN GLOBAL HEALTH

Global health governance encompasses formalized institutions, opaque practices such as norms of behaviors, and the world of ideas.⁹ Actors from various sectors and levels operate within an unbounded space,¹⁰ often through “cross-national webs ... linked to a common health concern.”¹¹ To gain support for issues, actors rely on frames, or “linguistic, cognitive and symbolic devices ... that identify, label, describe and interpret problems to suggest particular ways of responding to them.”¹² Framing entails problem definition (building an internal consensus on the nature of the problem and its solutions) and positioning (using language that urges policymakers to act).¹³ Issue positioning requires frames that audiences view to be credible (believable) and salient (important to their lives).¹⁴ Issues may be framed in multiple ways, though when these frames appear to be inconsistent they can confuse audiences or lead to contradictory approaches to solving the problem.¹⁵

We are interested in how an issue may be framed in multiple ways over time, through a process of frame layering. Our investigation differs from the work of Agyei and Johnson, who examine the integration of ideational policy discourses that incorporated frames on human rights, development, partnership, and inclusion to generate action on reproductive health in Ghana.¹⁶ Although some frame integration has occurred in mental health, frame layers may at times contradict. Echoing other studies on framing,¹⁷ we argue that frame layering may occur in response to exogenous forces and the involvement of new actors. Our work contrasts with studies illustrating constancy in human rights framing for AIDS,¹⁸ or the role of new actors in developing a coherent frame for maternal survival.¹⁹ Instead, we examine how frames change over time and how new actors shape frame coherence.

Frame layering may be more likely to occur with issues with nascent, unfolding scientific findings and unclear solutions.²⁰ This is true of mental health. Researchers constantly update knowledge about how genetics, environment, and epigenetics shape mental health; mental illness diagnostic classifications are constantly changing; pharmaceutical companies continuously develop new psychotropics;²¹ and experts provide new treatment guidelines. For example, in 2021 the director of the US National Institute of Mental Health recommended that global mental health prioritize depression and schizophrenia; depression, because it is common, treatable, and debilitating, and schizophrenia, because there are several effective medications for this rare but devastating condition.²² Yet, medical science’s grasp of the etiology of mental disorders is weaker than it is for physical diseases, and low levels of research spending mean the field has many unanswered questions. In addition, stigma against mental health disorders, as well as perceptions that affected people are dangerous or irrational, problematize frame salience and credibility.²³ The fact that most people with mental illness live in low and middle-income countries (LMICs) and face additional challenges of poverty and poor-health care services may make the issue seem impossible to address.

METHODS

We use several sources to analyze frame layering on global mental health. First, we read statements and mental health policies/plans/guidelines from the World Health Organization (WHO), World Bank, EU Commission, the Global Fund to Fight AIDS,

Tuberculosis and Malaria (Global Fund), the US Emergency Plan for AIDS Relief (PEPFAR), the UK Department for International Development (DfID), and the Bill and Melinda Gates Foundation. We then looked at advocacy initiatives from United for Global Mental Health, programs on mental health from 16 health-related international NGOs,²⁴ and the efforts of epistemic communities such as the *Lancet* Commissions on Mental Health. Our cut-off date was mid-2021. Because we were interested in how the increasing number of layers of mental health frames might align with funding, we looked at data on development assistance for health (DAH) from the Institute for Health Metrics and Evaluation (IHME) between 1990 and 2020.²⁵ IHME data on DAH comes from financial statements, annual reports, budget documents, and project disbursement records reported by international development agencies such as the OECD Creditor Reporting System, the World Bank, the Global Fund, the Gates Foundation, Rotary International, UN agencies (e.g., UNICEF, WHO), and over 100 NGOs; most data was only available through 2019 or 2020. IHME includes funding on mental health, which it determines using over 70 search terms including “psychosocial.”²⁶ At the time of writing, IHME data, as well as WHO budgetary data, was unavailable after 2020. When we searched in mid-2021, publicly available information from the Global Fund, the EU and PEPFAR for mental health projects was not available. Fortunately, the World Bank provides detailed information about its financial commitment to the COVID-19 response. We analyzed documents from the World Bank’s COVID-19 Fast Track program as well as social service projects approved during the pandemic. (As of June 2021, this was a total of 319 projects).

Finally, 40 key informant interviews conducted between 2017 and 2021 deepen the analysis. Respondents include WHO and PAHO mental health officials; advocates, donors, and health officials in Ghana and Tanzania; and global mental health advocates and NGO mental health program officials. Respondents were identified through their organizations and snowball sampling. Interview questions were semi-structured, revolving around topics like framing, key actors, and resource challenges. They lasted between 30 and 90 minutes, and were audio-taped (with permission). Interviews were transcribed, read for accuracy and thematic content, and hand-coded. All respondents were assured of anonymity in publications, and the authors’ home institutions provided ethics approval.

FRAMING MENTAL HEALTH BEFORE THE PANDEMIC

As Figure 1 illustrates, mental health framing has expanded from a narrow focus on human rights to a broad focus on the entanglement of mental and physical health, the economic costs of mental illness, and the ties between mental health and sustainable development. The addition of frame layers over time has been the result of a growing number of involved actors beyond the WHO and health ministries.

The Human Rights Frame

This frame is particularly concerned with institutionalized populations and rules about involuntary commitment and the maltreatment of custodial psychiatric patients. More broadly, human rights advocates seek to end discrimination against people suffering from mental illness in multiple areas (housing, education, health, criminal justice). The most important actor in elevating this frame may be the United Nations, which declared 1983-

Figure 1: Frame Layers, Actors, and Approximate Date of Initial Frame Appearance in Global Forums

Human Rights	+	UN, WHO-Geneva, PAHO, Inter-American Commission on Human Rights, European Court of Human Rights, US government, legal scholars, regional human rights activists, World Psychiatric Association	1989
Mainstreaming	+	Lancet Global Mental Health Commission and PLOS authors (psychiatrists, epidemiologists), WHO regional officials, Movement for Global Mental Health, United for Global Mental Health	2007
Economics/ Development	+	World Bank, health economists, IHME, UNIATF, development NGOs (World Vision)	2016
Crisis Linked to the COVID-19 Pandemic		Gates Foundation, Global Fund, World Economic Forum, national governments, global businesses, media, celebrities, clinicians (e.g., pediatricians), social workers	2020

1992 to be the Decade of Disabled Persons, including those with mental disabilities. At the recommendation of the UN Economic and Social Council's Commission on Human Rights, the General Assembly adopted the Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care in 1991.²⁷ The UN eventually passed the Convention on the Rights of Persons with Disabilities in 2006.

Meanwhile, regional bodies in the Americas and Europe began to defend the human rights of people with mental illnesses. The Inter-American Commission on Human Rights and the Pan-American Health Organization (PAHO, WHO's regional office for the Americas) have worked together since 1990 to improve the observation of human rights in mental health. PAHO has lent technical assistance to the Commission for inspecting psychiatric institutions for compliance with human rights conventions, and the Commission has assisted PAHO in developing legal arguments for restructuring mental health services.²⁸ For member states of the Council of Europe, the European Commission on Human Rights and the European Court of Human Rights have interpreted the European Convention of Human Rights to limit involuntary confinement and treatment and guard against degrading or inhumane conditions.²⁹

Publications based on site visits by professional associations and the US government also contributed to shedding light on the human rights violations and lobbying for better protections. Psychiatric abuse in the Soviet Union was of particular concern. Political dissidents had reported psychiatric abuse against political enemies for many years, but only with the advent of *glasnost* and *perestroika* in the mid-1980s were outside delegations able to visit Soviet psychiatric hospitals. The U.S. government sent a delegation including experts from the National Institute of Mental Health in 1989 and the World Psychiatric Association sent another in 1991. Both circulated reports based on their site visits.³⁰ The British Medical Association also published a book on human rights violations perpetrated by physicians that included psychiatric abuses in the Soviet Union, Romania, Cuba, Germany, Japan, Greece, and the UK.³¹

The WHO mental health department in Geneva contributed to the human rights framing by producing guidance on how countries should respond.³² Mental health was the theme of the 2001 *World Health Report*, a publication featuring repeated calls for reducing stigma and discrimination toward people with mental disorders.³³ The WHO sees the adoption of national mental health laws spelling out the rights of people with mental illness as the key tool for improvement.³⁴ Though global mental health advocates have come to use other frames for making their cases, WHO continues to assist countries to adopt legislation and policies meant to protect the rights of mental health service users through its training materials.³⁵

Mental Health as a Mainstream Health Issue

The notion that almost all psychiatric patients could be better managed in ambulatory settings instead of custodial institutions was part of the human rights campaign described above. Part of the argument for community mental health care was first, that services should be provided to a broader swath of society than only those with severely disabling conditions and second, that nonspecialists could be trained to render such care.³⁶ But providing such care meant combatting the perception that mental disorders were not "amenable to defined, easily costed, readily understood and easily implemented solutions."³⁷ In addition, in the new millennium, global mental health advocates entered

into something of a competition for attention with other chronic or noncommunicable diseases (NCDs). Health experts increasingly realized that NCDs were overtaking infectious diseases as top killers in many places. Longitudinal studies indicated that controlling four common risk factors (diet, sedentary lifestyle, tobacco use, and harmful use of alcohol) could help prevent four leading causes of premature mortality: cardiovascular disease, cancers, chronic lung problems, and diabetes.³⁸ In 2008, the World Health Assembly approved the WHO's *2008-2013 Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases* that outlines this "4x4 strategy."³⁹ The UN Special Session on NCDs in 2011 prioritized these four chronic diseases and left out mental health disorders even though they ranked among the top four NCD causes of premature death and disability.⁴⁰

In response, the WHO mental health department and interested country representatives developed the *Mental Health Action Plan 2013-2020* to enumerate actionable goals.⁴¹ They framed mental health as a mainstream medical issue related to other NCDs and essential to universal health coverage. Utilizing epistemic power (the power of expertise), the Global Mental Health Group of *The Lancet* published a series of articles in 2007 and 2011, and an overlapping group of scholars published in *PLOS Medicine* in 2012 and 2013. These papers demonstrated the efficacy and feasibility of therapies in low-resource environments and brought visibility to the issue. Many countries accepted these arguments, and the WHO reported that by 2020, 75 percent had mental health policies and 80 percent provided coverage for mental disorders via national health insurance schemes.⁴² Mainstreaming mental health led low-income countries like Liberia and Tanzania to train nurses to recognize major mental health disorders, refer patients, and administer medications.⁴³

Growing knowledge of the comorbidities between mental health and other NCDs strengthened the mainstream frame, best captured by the oft-used slogan "no health without mental health." In 2018, WHO leaders acknowledged the place of mental and neurological disorders on the NCD priority list. Supporting an integrated health response, they stated that several conditions (depression, anxiety disorders, bipolar disorder, schizophrenia and dementia) shared risk factors and impacts with the top four NCDs and were also important sources of comorbidity.⁴⁴ In May 2018, UN Secretary General António Guterres acknowledged that mental health had been neglected,⁴⁵ and at the UN's third High-level Meeting on NCDs in September 2018, mental health effectively became the fifth NCD. A year later, at the UN High-level Meeting on Universal Health Coverage, mental health figured prominently in the political declaration that called for scaling up services for both serious mental health disorders and psychosocial events resulting from trauma.⁴⁶ The WHO also announced its initiative to extend quality, affordable mental health services to 100 million more people in 12 countries by 2023.⁴⁷ Emphasizing universal health care access, the program helps participant countries fund or find donors to support the expansion of mental health services.⁴⁸

The Economics Frame

As mental health experts pushed mainstreaming, health economists increasingly examined the costs of mental illness; studies pointed out that the direct and indirect costs of mental health disorders lay between \$2.5 trillion and \$8.5 trillion in 2010.⁴⁹ This included medication, hospitalization, physician visits, income losses, and lost

productivity.⁵⁰ Economists have highlighted the cost-effectiveness of interventions such as screening and cognitive-based therapy at the community level, with a particular focus on programs targeting pregnant women and adolescents. Their work relies on prevalence data on mental illness, which was made possible when the WHO began in 2001 to conduct epidemiological surveys for the *Mental Health Atlas*.⁵¹

The economics frame undergirds efforts by the UN Interagency Task Force on NCDs (UNIATF) to prepare investment cases so countries can design policies to control NCDs (including mental health) and request donor funding. The investment cases include quantitative estimates of the economic and social burdens of NCDs and suggest “best buy” policies that center on regulating and taxing industries as well as promoting lifestyle changes. The Task Force meets with ministers of health, finance, economy, industry, and, sometimes, sports, to discuss the recommendations.⁵² In 2019, the Task Force developed a methodology for calculating the costs of the mental health disease burden and modeling the benefits of various interventions. It then issued investment reports for Jamaica and the Philippines in 2019-2020.⁵³ In addition, the advocacy group United for Global Mental Health (partially supported by the Gates Foundation) started working with countries to audit national health budgets and promote service efficiencies and savings in order to find additional public resources for mental health.⁵⁴ The economics frame underpinned messages for World Mental Health Day in 2020: “Move for mental health: Let’s invest!” A *Lancet* editorial said, “The economic case for investment in mental health is strong: for every \$1 invested in scaled-up treatment for depression and anxiety, there is a \$4 return in better health and productivity.”⁵⁵

Part of the economics frame revolves around the negative effects of mental illness for economic growth and development. In 2016, the World Bank and WHO co-hosted a major side event “Out of the Shadows: Making Mental Health a Global Development Priority” at the 2016 IMF-World Bank joint meeting in Washington, D.C. In the accompanying report, the Bank stressed the 2.3–4.4% annual drain on GDP because of mental illness, a cost that LMICs cannot afford.⁵⁶ UN Sustainable Development Goal target 3.4 amplifies the connection between development and mental health, since it seeks to “reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being” by 2030.⁵⁷ The 2018 *Lancet* Commission on Mental Health and Sustainable Development called for a reframing of global mental health that focused on the global scope of mental illness and the vast inequities in mental health care. It recognized how socioeconomic determinants such as poverty, childhood adversity, and violence—all factors more prevalent in LMICs—contribute to mental illness, and it called on donors to contribute more resources to providing this public good.⁵⁸ In response, the United Kingdom announced it would incorporate mental health into its development initiatives.⁵⁹

In summary, prior to the COVID-19 pandemic, mental health was framed as a human rights issue, a mainstream health concern, and an economic/development concern. As new voices joined the discussion, they emphasized new frame layers for global mental health. The UN, organizations of psychiatrists, and human rights advocates stressed human rights, while the WHO mental health office and mental health experts pushed mainstreaming. Health economists, development NGOs, and the World Bank added to the economics frame. Throughout the process, actors seemed to grapple for a message that would be both credible and salient, in order to resonate with decision makers and the public. The pandemic appeared to provide such an opportunity.

FRAMING MENTAL HEALTH DURING THE PANDEMIC

The crisis frame linked mental health to the pandemic, highlighted inadequate services, stressed urgency, and prioritized particular populations and mental illnesses. It provided an additional framing layer, as health officials continued to use human rights, mainstreaming, and economic/development frames. For example, in 2020 UN Secretary General Guterres illustrated a human rights frame when he highlighted the misery, suffering, stigma, and discrimination people with mental health disorders face,⁶⁰ and the WHO Executive Board echoed the mainstream perspective when in early 2021, it recommended that the *Mental Health Action Plan* be extended to 2030 so that WHO could more fully integrate mental health into universal health coverage.⁶¹ But the crisis frame tended to dominate during the pandemic. It stressed that social isolation, remote work, grief and worry over lost or ill loved ones led to depression and anxiety for many.⁶² It argued that lockdowns and economic stress contributed to increases in intimate partner and sexual violence,⁶³ depression, suicide, and drug overdoses.⁶⁴ In ways that prior frames had not, the crisis frame was both credible and salient: reports indicated higher prevalence of mental health disorders during the pandemic as individuals were more likely to report psychological distress, sleep problems, and anxiety.⁶⁵ In short, mental health became a proximate and “real” issue for many.

The framing situated mental health within the exceptional situation of a health emergency. This was evident when the WHO Executive Board formally recommended in January 2021 that the WHO “study the impact of COVID-19 on mental, neurological and substance use conditions” and help countries to “monitor changes and disruptions in [mental health] services.” The WHO was charged “to promote and expand access to inclusive, integrated, evidence-based primary and community mental health services and psychosocial supports, which boost community resilience and engagement, *especially in the context of public health emergencies*, while sustaining and scaling up, as appropriate, the provision of existing mental health services.”⁶⁶ At the regional level, 22 of 24 WHO Eastern Mediterranean member states incorporated mental health programs into their COVID-19 response.⁶⁷ Although these efforts called attention to mental illnesses, they also linked those illnesses to the pandemic.

The crisis frame translated into the need for immediate action. As WHO Director General Dr. Tedros Adhanom Ghebreyesus said, “If there was a time to invest in mental health, it’s now.”⁶⁸ Urgency attracted attention from the Global Fund, Gates Foundation, and World Economic Forum, organizations that had previously done little on mental health. Global Fund Executive Director Peter Sands said mental health is inextricably linked to the fight against AIDS, tuberculosis, and malaria, and urged applicants to include mental health and psychosocial support in projects.⁶⁹ Initiating a new program on mental health and youth in the United States, Bill and Melinda Gates wrote, “Stress and isolation have triggered far-reaching impacts on mental health.”⁷⁰ The World Economic Forum cooperated with the WHO’s #MoveforMentalHealth campaign and the United for Global Mental Health campaign #TimetoInvest.⁷¹ Advocates in over 40 countries signed a statement supporting greater attention to mental health.⁷² Celebrity voices joined the conversation: Prince Harry revealed his mental health struggles,⁷³ tennis star Naomi Osaka withdrew from tournaments, citing struggles with depression,⁷⁴ and Simone Biles, world champion gymnast, withdrew from most events in the 2021 Tokyo

Olympics just days before competition due to mental health challenges.⁷⁵ Mainstream media reported almost daily on studies on mental health and the pandemic.

The crisis frame tended to focus on select populations such as health-care workers and adolescents. Studies showed that overworked and frightened health-care workers experienced rising rates of depression and anxiety.⁷⁶ These reports fed the crisis frame, because health-care workers are essential not just during a pandemic. Reports that at least 20 percent of health-care workers in the United States had seriously contemplated leaving the profession⁷⁷ and stories that COVID killed over 500 doctors in India contributed to the frame's frenzied nature.⁷⁸ Studies illustrated increased rates of suicide ideation,⁷⁹ higher use of illicit substances, and greater rates of anxiety and depression among youth.⁸⁰ These studies deepened the credibility and salience of the crisis frame, as parents reported to school counselors and pediatricians about troubled children and patients experienced health-care lags for non-COVID problems. As Kapstein and Busby find, frames that center on population groups with whom society tends to sympathize such as children often gain traction.⁸¹

The frame highlighted the common mental health disorders of episodic depression and anxiety instead of chronic conditions such as major depression, bipolar disorders, or schizophrenia. As one example, in October 2021, the *Lancet* issued a study reporting that in 2020, depression increased 28 percent and anxiety, 26 percent, with women and young people being most affected.⁸² Long-term mental health and/or addiction challenges that require consistent medication, therapy, and possibly, hospitalization received less attention. This sidelining was evident in reports from the WHO Regional Offices for the Americas, the Eastern Mediterranean, South-East Asia, and Europe, which all documented how the pandemic undermined access to mental health services for people with chronic conditions.⁸³ PAHO discovered that 27 of 29 countries had underfunded mental health services,⁸⁴ and WHO Europe reported that 82 percent of long-stay mental health care residential institutions in 23 countries experienced cuts in services.⁸⁵ As one World Bank official asserted, "The pandemic has further worsened the status of mental health."⁸⁶ Beyond the implications for services, which all countries surveyed for the 2020 World Health Organization *Mental Health Atlas* said had suffered disruptions, there was also the challenge of just collecting data during the pandemic on the extent of mental health disorders and the overall ability of countries to cope with that increased need.⁸⁷

There was the potential for positive and negative effects with the crisis frame. On one hand, it helped to destigmatize mental health challenges and validate calls for psychosocial assistance during extreme events. It raised awareness through media reports and offered the general population advice on coping with the mental health effects of COVID-related restrictions via outlets such as the WHO's social media campaign #HealthyAtHome. This new openness may mean short-term therapies become a standard part of the response to other epidemics; it also may promote greater understanding of how trauma contributes to chronic mental health problems. On the other hand, the crisis frame contributed to the politicization of mental health, as some leaders pointed to extreme mental health outcomes like suicide and opioid use disorder to justify policy preferences, particularly on opening economies.⁸⁸ In addition, if mental health is intricately tied to the pandemic, what happens to mental health once the pandemic recedes?

FRAMING AND FUNDING

The compounding of frames has yet to generate substantial increases in mental health spending, as Table 1 indicates. In 2018, national governments spent a global average of 2 percent of their health budgets on mental health.⁸⁹ DAH on mental health slowly increased from \$66 million in 2000—with a dip to \$37 million in 2009—to \$160 million in 2020.⁹⁰ Despite increases, amounts are still trivial compared to other diseases and conditions – estimated to account for 0.3 to 0.4 percent of DAH (It was 0.28 percent in 2020).⁹¹ Funding for research that might inform policies was miniscule, with research on cancer and infectious diseases both getting twice the amount that mental health does.⁹²

There are several notable points about pre-pandemic funding and its relation to issue framing. First, although amounts increased, there is inconsistency, illustrating mental health's impermanence in budgets. Multiple frames may have contributed to the perception that the field is not a “credible option for donors, investors and countries for the strategic allocation of funds.”⁹³ Layered messages may confuse donors, making it unclear exactly what they should fund. Second, funding illustrates the expanding number of actors in mental health; NGOs and foundations supplied 24 percent of resources in 2000 but 60 percent in 2020. Although the UN agencies provided 68 percent of monies in 2000, they gave only 21 percent in 2020. Due to shrinking resources, in 2018-2019 (the last year with available data), the WHO invested only 0.54 percent of its total budget on mental health and substance abuse.⁹⁴ Third, just as there is no central actor framing the issue, there is no major donor. As the leader in global health spending, the United States provided only 0.1 percent; the Gates Foundation, even less. Dispersed actor power leads to diluted, multi-layered messaging.⁹⁵

It was difficult to see that the crisis frame led to increased funding for mental health during the pandemic. The Global Fund made an additional \$1 billion available in 2020 to mitigate the effects of COVID-19 for people with TB, HIV and malaria, but it was unclear if this included mental health or psychosocial support.⁹⁶ The proposed 2021 US global health budget (separate from PEPFAR) did not mention global mental health, though global health security received a 90 percent increase from 2020.⁹⁷ In early 2021, DfID faced significant cuts that would undermine all health programs,⁹⁸ and none of the NGOs we examined started new mental health projects during 2020. Only one-third of the 22 states in the WHO Eastern Mediterranean Region increased funding.⁹⁹ And even though the US, UK, Sweden, Germany, and Australia proposed new mental health allocations, this was not global mental health.¹⁰⁰ WHO reported that 89 percent of 130 countries surveyed had included psychosocial support in their COVID-19 plans, but only 17 percent had allocated additional money.¹⁰¹

To further illustrate, we examined the World Bank's \$160 billion response to COVID-19, particularly the 259 projects aimed at emergency efforts that did not fund vaccine purchases and the 60 social service programs approved during the COVID era (beginning in March 2020).¹⁰² Of the 319 projects, 53 included funding for what the World Bank called psychosocial, socioemotional, or mental health activities; all were embedded in larger pandemic or social service delivery projects.¹⁰³ The first two terms (psychosocial and socioemotional) were more common among the project documents and referred to short-term, crisis-related, non-medical support often provided by professionals outside of the health sector (i.e., teachers), public awareness campaigns, or written guidelines for self-care aimed at particular populations. The most common target populations were

people subject to lockdowns and school closings followed by healthcare workers and patients directly affected by COVID-19. Some projects funded school-based training for life skills and psychosocial needs identification while others focused on the needs of people victimized or exposed to violence, such as survivors of sexual/gender-based violence or children living in gang-ridden neighborhoods. None funded inpatient or free-standing mental health facilities, indicating a lack of emphasis on serious mental illnesses such as schizophrenia. The pattern of funding short-term, psychosocial support projects especially for individuals who have experienced disruption, trauma, or violence echoes the pre-pandemic finding that most DAH in mental health goes to emergency or conflict-affected locations.¹⁰⁴

IMPLICATIONS OF FRAME LAYERING FOR GLOBAL MENTAL HEALTH

Global mental health has been framed as a human rights issue, a mainstream health concern, an economics/development issue, and, during the pandemic, a crisis. Each frame has added a layer to the discourse on global mental health, but like the layers of an onion, these frames have not been sufficiently integrated. Their emergence reflects the entry of new actors into the global mental health arena, including health advocates, economists, the media, donors, celebrities, and development NGOs. The informal network's breadth brings attention, creativity, and new ideas. For example, in late 2020 a former Global Fund executive established the Healthy Brain Global Initiative, a public-private partnership with support from Wellcome Trust, Bank of America, Johnson and Johnson, World Economic Forum, One Mind, the WHO, and UNICEF that aimed to start a \$10 billion fund for mental health.¹⁰⁵ But the growing network also may exacerbate power imbalances, with voices in high-income countries dominating. Because 80 percent of people living with mental health disorders globally reside in LMICs, part of a human rights frame requires their inclusion in advocacy and policy-making arenas.¹⁰⁶

The multiplicity of mental health frames may undermine coherence and create spaces in which messages that challenge biomedical approaches can proliferate. While many global health proponents support biomedical treatments, some assert that global mental health has been inappropriately medicalized.¹⁰⁷ Some anthropologists also illustrate how biomedical approaches may downplay the traditional, spiritual understandings of mental illness that are predominant in some contexts.¹⁰⁸ Frame incoherence makes it difficult to define mental health activities for the purposes of funding projects and measuring outcomes. What activities should be counted as "mental health?" And how can mental health programming be disaggregated from other health areas, such as treatment adherence, primary care, or health system strengthening? For example, PEPFAR and the Global Fund give funds to support groups for people living with HIV that provide members with psychosocial help. Should such activities count as mental health interventions? We need better data on not just overall spending, but also spending on various mental-health components, such as medications, workforce training, hospital care, and school counseling.

Because frames promote particular policies, frame layering leads to a haphazard collection of projects and approaches.¹⁰⁹ Some of these may even work at cross-purposes. By stressing economic efficiency, an economics frame may focus on community-based projects and ignore people living with chronic mental health disorders, though a human rights frame asserts that all people have the right to mental health, regardless of cost.

Table 1: Development Assistance for Mental Health, Largest Donors, Select Years**

Year	Total	NGOs & Foundations	UN Agencies	EU Commission	UK	Other Bilateral Donors	Gates	US
2020	160	95 (60%)	34 (22%)	*	16 (10.4%)	7 (4.4%)	*	1.4 (0.89%)
2019	190	110 (58%)	35 (19%)	18 (10%)	14 (7.4%)	7.8 (4.2%)	*	1.4 (0.7%)
2018	150	86 (58%)	32 (21%)	16 (11%)	5.8 (3.9%)	4.1 (2.7%)	2.6 (1.8%)	0.24 (0.16%)
2017	130	69 (52%)	32 (24%)	17 (13%)	6.1 (4.6%)	3.4 (2.5%)	1.3 (0.9%)	0.38 (0.3%)
2014	83	49 (59%)	17 (21%)	5.2 (6.2%)	2.2 (2.7%)	7.4 (8.9%)	0.082 (0.1%)	0.49 (0.6%)
2013	86	52 (61%)	16 (18%)	8.7 (5.6%)	1.9 (2%)	4.8 (5.6%)	0.46 (0.54%)	0.55 (0.6%)
2012	57	30 (51%)	14 (25%)	5.4 (9.5%)	1.6 (2.9%)	3.7 (6.5%)	0.16 (0.28%)	0.43 (0.74%)
2011	43	30 (69%)	*	2.7 (6.3%)	0.7 (1.6%)	5.6 (13%)	0.042 (0.1%)	0.32 (0.74%)
2009	37	23 (62%)	*	1.8 (5%)	0.9 (2.5%)	8 (21.6%)	*	0.27 (0.74%)
2006	50	23 (45%)	12 (23%)	*	0.6 (1.17%)	10 (20%)	*	*
2001	86	38 (44%)	44 (51%)	*	0.2 (.24%)	3.3 (2.5%)	*	*
2000	66	16 (24%)	45 (68%)	*	0.5 (.75%)	4.2 (6%)	*	*

(USD in millions. Percentages given are percentage of total DAH for mental health)

Source: IHME, “Financing Global Health,” Dataset and visual graphics, 2021, <https://vizhub.healthdata.org/fgh/>.

*= no information reported

**We chose the year after a major event on NCDs and/or mental health, such as the 2011 UN session on NCDs or the 2016 World Bank-WHO conference on mental health, as well as providing data on the last four years. 2000 and 2020 serve as start and end dates.

With its neoliberal undercurrent, the economics frame could minimize state efforts to reduce poverty or combat socioeconomic inequalities through long-term development projects. Yet mental wellbeing necessitates reducing these social determinants of mental illness.¹¹⁰ When mental health is framed as a crisis, the priority becomes emergency psychosocial support for common mental health disorders and key populations, not investment in serious, chronic conditions for marginalized peoples. Resources then flow to psychosocial projects that respond to transitory if traumatic events. The crisis frame could deemphasize the human rights concerns that global mental health advocates have long stressed. Most crucially, if the pandemic has, as WHO Director General said, the “potential for a long term impact” on mental health,¹¹¹ how does the crisis frame provide the impetus for needed long-term solutions?

This study has implications for advocacy and policy. First, advocates must be cautious about how they use the crisis frame to mobilize long-term support for mental health. Although the frame may generate short-term attention, it may not generate long-term commitments. This is because one policy crisis is often rapidly replaced by the next one. In addition, advocates for many health issues—from adolescent pregnancy to diabetes—can make connections to the pandemic to lobby for more attention, setting up a fierce competition for recognition. Second, advocates and policymakers who care about mental health should heed visions of global health governance that stress the promotion of health capabilities for all people and call for a renewed global health system grounded in global justice; such a normative framework would facilitate a global health architecture based on the right to health.¹¹² For mental health this would mean adequate capacity to meet demands during both emergencies and non-emergencies. Framing messages coherently around an ethical call for human dignity and health could facilitate this outcome.

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INFORMING FOOD-SECURITY POLICY ANALYSIS WITH ENGINEERING THEORY: SECURING DIETARY HEALTH DURING AND AFTER COVID-19

Romana Salmah Hussain

Public health policy analysis lacks theoretical foundations and tends not to be evidence-based. This is apparent in the areas of dietary health needs assessment, the problematization of issues, and subsequently, conceptual policy generation. However, this paper will demonstrate that theory utilised in process engineering can lend itself to dietary health policy analysis; it will show that a scheme which addressed a UK food issue during the COVID-19 pandemic was based upon apparent public needs, rather than being based on public actual needs, and so rather than safeguarding health, the scheme may have resulted in the unintended, reverse consequence of being injurious to health. Using such theory, this paper then presents a proposal which could help to meet global governance drivers which address food and nutrition insecurity.

INTRODUCTION: FOOD PACKS FOR THE VULNERABLE

To date, very little progress has been made towards implementing policies which improve public health and address obesity¹, which in England increased from 15% in 1993 to 29% in 2017². This could be, in part, because public health policy research is limited, lacks theoretical foundations^{3 45}, and tends not to be evidence-based^{6 78} - this is apparent regarding the capturing of public nutritional needs and issues, the problematization of issues, and subsequently, conceptual policy generation. An example of this is the *Emergency Food Pack* scheme (the case study in this paper), which experts in nutrition disparaged because they claimed that the packs disregarded the basic nutrition of the most vulnerable members in society⁹.

In March and April 2020, communiqués were issued instructing people in the UK (1.5 million¹⁰) who had significant underlying conditions¹¹ to ‘shield’ (that is, self-isolate at home) starting from that day [see Supplemental 1.1], to protect themselves from COVID-19. As these vulnerable people had been directed not to go out shopping, and as there had been a run on supermarket home deliveries, the UK government issued free *Emergency Food Packs* each week for the first few months of the pandemic [see Supplemental 1.2 and 1.3]. These packs aimed to provide enough food and household items for one week, per person [see Supplemental 1.4 a)] and were delivered until the end of July 2020 [see Supplemental 1.5]. The foods were typically British foods that the public tend to consume regularly.

It was important to protect vulnerable people as *The Lancet* reported in May 2020 that patients with COVID-19 who have underlying conditions (such as type 2 diabetes, hypertension, obesity, cancer, or cardiovascular disease) place the UK *National Health Service* (NHS) under an unprecedented amount of strain as they have a greater risk of being admitted to intensive care units, and result in higher fatalities¹². Such medical conditions tend to be diet-related and, similarly, nutritional deficiency affects the immune response which is a serious issue during the COVID-19 pandemic¹³.

This paper now provides an overview of food-related ill health and obesity, the need for pre-prepared food, the socio-political obstacles facing current global governance in tackling food-related ill health, and how engineering theory could help to overcome those obstacles. It examines how deleterious to health the *Food Packs* were, and the underlying theory as to how the food items within the packs could have been selected. It then considers how theory utilised in engineering can be applied to nutrition policy analysis to culminate in a new proposal to improve dietary health which, hitherto, had not been previously considered.

LITERATURE REVIEW

Food-Related Ill Health and Obesity

Ultra-processed food (UPF) tends to contain high amounts of sugar, salt, unhealthy fats, and additives which can be quite deleterious to health^{14 15}. In 2016 *Mars* (a company known primarily for its chocolate bars) made an announcement that some of its *Dolmio* pasta sauces would carry a manufacturer's health warning stating that they should be consumed not more than once a week because of their high sugar, fat, and salt content^{16 17} as these are correlated with various forms of ill-health^{18 19}. Included in the *Food Packs* were *Dolmio Bolognese Original Pasta Sauces* which contains a sizeable amount of added sugar.

Added sugar (also referred to as free sugar) is sugar that is added either as an extra ingredient to food during preparation and processing, or at the table; it does not include (and is not to be confused with) *naturally* occurring sugars that are already present in foodstuffs such as fruit and milk²⁰. The excessive consumption of added sugar has been linked to chronic conditions such as obesity, heart disease, and prediabetes (also known as metabolic syndrome²¹) which is a condition that often leads to type 2 diabetes^{22 23} within several years if left untreated²⁴. It has also been linked to cancer²⁵. A report commissioned by the consultancy firm *McKinsey and Company* states that the cost of obesity and diabetes to the healthcare system equals the UK's combined budget for the police and fire services, law courts, and prisons. Furthermore, it states that the cost to the *NHS* could increase to up to £12 billion in 2030²⁶.

In April 2020, the World Health Organisation (WHO) recommended a salt consumption of less than 5g per day to help adults reduce their blood pressure, and consequently reduce the risk of cardiovascular disease, stroke, and heart attack²⁷. High blood pressure is the third biggest risk factor for disease after smoking and poor diet²⁸; note that there has been a spike in stroke deaths in patients who have had only minor COVID-19 symptoms²⁹.

The Need for Pre-Prepared Food

Besides those who needed to self-isolate, there have always been people who have little time, are too exhausted, or do not have the extensive skills, abilities, or accoutrements on hand to meal plan, shop and make from scratch everything they consume; even dedicated housewives, generations ago (whose main task was often food preparation), routinely relied upon manufactured food such as *Hovis* brown bread, *Bisto Gravy* and *Bird's Custard Powder*. Furthermore, the need for readymade food is expected to increase for the following reasons:

- **Key workers have lack of time** - There are those in society who have zero time to commit to food preparation. For example, the health care workers who battled the COVID-19 pandemic at great personal cost; to show appreciation, several fast-food providers offered discounted or free food to these workers. *Pizza Hut* donated 300,000 meals to *NHS* workers in recognition of the non-stop hours and gruelling work they performed³⁰. However, in 2018, it was reported that *Pizza Hut's Large Stuffed Crust Pizza* had 2,740 calories, 64g saturated fat and a huge 8.5g of salt per pizza³¹. If such food was routinely relied upon by *NHS* staff, then their health may have been adversely impacted upon. Even before the pandemic, health care workers were often under a great deal of strain and lacked time due to shift patterns and the demands of patient care, which meant that many would often opt for convenience foods³² and, in doing so, side-line their own health with many becoming obese³³.
- **Future pandemics** - In July 2020, *McKinsey and Company* along with various experts in the field reported that addressing obesity and high blood pressure could protect millions against future pandemics^{34 35}, and these are likely, given that infectious diseases are emerging increasingly quickly³⁶. During such times, governments may again (as with the COVID-19 pandemic in the UK) have to stage an intervention and ensure that groceries (some of which would be readymade) are delivered to the vulnerable, who may have difficulty in preparing much food because of their medical conditions.
- **Food banks** - In November 2019, *The Guardian* reported that (even before the pandemic) there had been a record increase in food bank use – mostly, but not exclusively, to do with insufficient or deferred benefit payments³⁷. However, the pandemic is expected to accelerate job losses through automation as many companies have used this time to further replace human workers³⁸. There have also been nurses who have had to resort to using food banks as, in 2017, it was reported that in just six years, UK nurses' salaries had plummeted in real terms by 14 per cent³⁹. The use of food banks (largely offering readymade food) is forecast to further spike as (because of the pandemic), the global economy is expected to enter the worst recession since the Great Depression⁴⁰.
- **Climate change emergencies** – *Oxfam* states that climate-related disasters have tripled in the last 30 years and so there will be times when people require emergency relief⁴¹.
- **An increasingly ageing population** - The *Office for National Statistics (ONS)* predicts that more than 24% of the UK will be aged 65 or older by 2042 – a rise of 18% from 2016⁴². The delivery of readymade food would support independent living for many of that group.

Global Governance in Tackling Food-Related Ill Health

In the *BMJ*, Mozaffarian et al.⁴³ recently reviewed key schemes and policies that governments internationally can adopt to improve diet quality. A brief synopsis of these follows, along with their merits and demerits:

1. **Existing manufacturers** - the ideal scene would be for existing food manufacturers to (at least for some of their food) reduce excessive salt and sugar, remove deleterious additives, replace unhealthy ingredients with healthier ones, and prepare food in healthy ways (for example, cook at normal temperatures, rather than at ultra-high temperatures). The WHO's discussion paper in 2021 which is titled *Draft Recommendations for the Prevention and Management of Obesity over the Life Course, Including Potential Targets*⁴⁴, promotes policies across member states to address this; emphasis is placed upon increasing the consumption of unprocessed (or minimally processed) foods such as whole grains, legumes, nuts, vegetables, and fruits, and encouraging manufacturers to reformulate their products. However, this increases costs and manufacturers often regard any possible diminution of their profits as a direct attack from which they must protect themselves. This conflict of interests⁴⁵ is a zero-sum game - that is, the gain of one party (the public health) hurts the other party (food manufacturers' profits), and vice-versa. This has led to an issue of trust regarding engaging the food industry to meet nutritional objectives as it has been breached many times. For example, to reduce the consumption of free sugars in food and drink, the WHO recommends price policies such as the sugar tax which has been introduced in many countries. However, when manufacturers replace sugar with artificial sweeteners⁴⁶, little may be gained health-wise as artificially sweetened drinks can also linked to obesity, type 2 diabetes, cardiovascular disease, and early death⁴⁷.
2. **Eateries** - canteens and other eateries could prepare (some or all) the food they make more healthily, or they could procure (at least some) food from a supplier of readymade food which is guaranteed to be healthful, and this is a recommendation of the WHO. However, there can be the same issues of trust regarding eateries claiming to make healthy food or procuring food that is claimed to be healthful.
3. **Governments** - the WHO prompts governments to regulate the marketing of unhealthy foods by restricting or banning the advertising, or even the outlets of unhealthy food. However, the societal need for readymade food (which is healthful) would still need to be satisfied.
4. **Consumers** - the WHO prompts for improved labelling of foodstuffs and on menus, and the public have been directed to scrutinise labels to ensure that they do not overconsume calories, sugar, salt, unhealthy fats, or additives. However, it can be near impossible for the public to gain the information they require from food labels as much can be incomprehensible, erroneous or even missing. A prime example is the horsemeat scandal in Europe in 2013 - foods that were labelled as beef contained up to 100% horsemeat^{48 49} - apparently unbeknownst to the food manufacturers who had used that meat supply. There were further concerns about the possibility of that horsemeat containing traces of the veterinary drug phenylbutazone (a horse analgesic) which is harmful to humans⁵⁰ even though there are regulations that horses treated with that drug cannot legally be used for human consumption^{51 52}. This prompted the British political economist, Will Hutton, to write an article in *The*

Guardian called ‘*The meat scandal shows all that is rotten about our free marketeers*⁵³, which questions the leaving of public health to the free market, and raises questions about regulation as well as long-supply chains which can make it near impossible to trace food elements. The public could also be prompted or enabled to make more food at home, and these are WHO drivers; however, there are many times when preparing food at home is simply not feasible.

Socio-Political Obstacles to Extant Dietary Health Policies

The tremendous leverage of food manufacturers can frustrate attempts to improve dietary health. For example, because of the corporate power of infant milk formula manufacturers, attempts to urge mothers to breastfeed their babies have been unsuccessful. This is a grave issue because for children to achieve their full intellectual potential and thus perform better throughout life, the WHO strongly recommends that babies are exclusively breastfed from birth to 6 months old, and then breastfed whilst being weaned until 2 years old or more. This is because breastmilk is safe, nutritionally appropriate, improves child survival and, for both mother and baby, breastfeeding protects against infection and disease, reduces stress, and fosters bonding^{54 55}. However, 56% of those with children do not follow this advice. Baker et al.⁵⁶ assert that a major reason for this appears to be that the corporate power of infant milk formula manufacturers lends itself to political manoeuvring and aggressive global marketing which has been undermining the promotion of breastfeeding since the 1970s⁵⁷.

Additionally, there have been structural changes in society which have led women to work much more outside of the home (where the main task was often food preparation), as compared to previous generations⁵⁸. Therefore, expecting the public to adopt this domestic role whilst also performing other roles would appear to be untenable.

To overcome these obstacles, the adoption of a political solution would appear to be more apposite than continuing to prompt the public to make personal changes.

The Applicability of Engineering Theory to Dietary Health

As creating food is a process, process engineering could lend itself to improving the healthfulness of manufactured food. For example, attempts to prompt the public to examine labels or to prepare more food at home have had little impact in reducing obesity and diet-related ill health. However, applying TRIZ here could be useful; derived from the study of patterns of invention in the global patent literature⁵⁹, TRIZ has a methodology which is used in engineering for analysis and problem-solving. Inventive principle 13 of TRIZ reverses the extant action that was being used to solve a problem⁶⁰; in dietary health this would mean that, rather than trying to continue to change the eating behaviours of the populace to become more healthful, instead deliberation should be given to changing the food they consume to become much more healthful.

In recent decades, marketing has been shifting from a transactional (product-centric) view to a relational view^{61 62}, which is concerned with enhancing relationships with customers by building trust and improving the firm’s reputation⁶³, and this can be achieved by catering for the consumer’s deeper needs. Moreover, in recent years, the distinction between transactional (apparent and surface) needs and functional (actual and deeper) needs has been greatly laboured and theoretically

adopted in state-of-the-art, capital-intensive, hi-tech engineering design – in particular, within the product-service systems domain. This profound concern with the consumer's '*need behind the need*' (the underlying reason - the functional need) as to why a given demand may exist⁶⁴ has resulted in the production of improved technological conceptions^{65,66} which much more closely meet the customers actual needs.

Such understanding could lend itself to dietary health policy analysis. For example, rather than being interested in the acquisition of specific food products, the public is actually interested in *value in use*⁶⁷ – that is, they are in need of food that they not only find tasty, but that is *nutritious* and *not deleterious to health*. Although this is generally not stipulated by consumers, it is assumed – it is 'the '*need behind the need*' and this should be catered for. However, when satisfying transactional needs, the provider tends to be interested in simple demand fulfilment or issue removal, rather than tending to the consumer's deeper needs and well-being. For example, the sugar tax policy has simply missed the point that the public are not in need of 'sugar-reduced food and drinks' (transactional needs) but require food and drinks that are not deleterious to health and, ideally, nutritious (functional needs). Similarly, the *Food Pack* scheme also appears to be based on the public's transactional needs rather than their functional needs for food and drink.

METHODOLOGY

Detailed demographic information of three geographically dispersed recipients (Recipients A) of *Emergency Food Packs* was recorded as were their medical conditions.

To determine the contents of the *Emergency Food Packs* and their similarity across geographies, and their similarity from week to week:

- **Recipients A** - Each week, the *Food Pack* delivered to each recipient in this group (n=3) was photographed, itemised, and compared with the other *Food Packs* received by that group, that week, and in previous weeks. This occurred for 2 months.
- **Recipients B** – 10 weeks into the study, each member of this group (n=5) of pack receivers were asked separately to basically describe the sorts of pack contents they had received, and these descriptions were compared with the photographs and item lists of the *Food Packs* received by Recipients A. They were then shown photographs of *Food Packs* that Recipients A had received and asked if they believed their packs differed in any way from those photographs; no differences were reported.

To determine how the *Food Packs* were typically used:

- **Recipients A** - For three weeks, everything consumed by Participant 1 (from the *Food Pack* and elsewhere) was observed, recorded and the basic nutrition calculated. Two typical days of consumption were calculated for each of the three weeks. The other two participants were asked (for each week of those three weeks) if they would receive or buy any other food and drink (besides the *Food Packs*), and, given that week's pack, what two typical day's food and drink would be for them. They were then asked to

Table 1: A Typical Day's Food and Drink

BREAKFAST: Ready Brek (30g), Skimmed Milk (150ml), Cherries in Syrup (100g)
LUNCH: A Baked Potato (180g), 415g Beans and Sausage, 1 Easy Peeler, 1 Apple
DINNER: Dolmio Sauce (187g), Half a Tin of Ham (120g), Penne Pasta (75g), 3 Digestive Biscuits (43.5g)
SUPPER: A Tin of Tomato Soup (400g), 1 Slice of Bread,
DRINKS: Skimmed Milk (25ml per cup) in 6 cups of tea (6 x 25ml = 150ml)

The total calorific content of all the meals above (if the labels on the processed items are factual) add up to just shy of 2,000 calories; this is moderate as the *NHS* (*National Health Service*) states that that, per day, women require around 2,000 calories, and men require 2,500⁶⁸. However, the amount of refined carbs (especially sugar) is high; obesity is not just linked to the number of calories – it is also linked to the quality of those calories, and excessive sugar is correlated with obesity⁶⁹.

The food and drink above would provide (if the items' labels are accurate) over 33g of fibre which is acceptable as the *British Heart Foundation* recommends that adults consume at least 30g of fibre per day⁷⁰. Judging by the labels, the meals would also exceed the recommended minimum of 5-a-day by providing seven portions of fruit and vegetables. However, there is a question mark as to the veracity of such labels: for example, *Heinz* has previously been censured by the *Advertising Standards Authority* (ASA) over advertising its tomato soup as having two portions of fruit or vegetables – when, actually, there was just *one* – only half the amount stated^{71,72}.

Variety

Although a wide and varied diet is recommended by health professionals, each *Emergency Food Pack* was almost identical to the ones before it, and the ones after it [see Supplemental 1.8]. However, note that even if making food and drink from scratch at home, achieving a wide and varied diet is also very difficult; the incorporation of a huge variety of vegetables, fruits, proteins, herbs, spices and so forth would mean that a huge number of ingredients would have to be purchased and stored at home and much of it may go off before it was used.

Additionally, there is concern regarding the high amount of salt, sugar, and some of the additives in the *Food Packs*. This follows next.

Salt

A typical day's food and drink from the *Emergency Food Pack* can easily contain almost 10g of salt [see Supplemental 1.6] – about double the recommended amount. Nearly all the salt comes from the processed food items as they tend to contain far more salt than one would normally add when preparing food at home.

More than a quarter of adults are affected by high blood pressure⁷³, and it is likely that far more than that will be on the UK government's vulnerable list; a participant in this study is a sufferer of high blood pressure and has severe headaches because of it, even though he has been prescribed atenolol and ramipril.

Sugar

The *World Health Organisation* recommends that adults should have no more than 25g (six teaspoons) of free sugar (that is, added sugar) per day⁷⁴. However, calculating the sugars in processed food can be extremely difficult as labels often contain information on total sugars per serving, but do not distinguish between naturally occurring sugars and added sugars⁷⁵. Nevertheless, some estimates can be made. For example, the sugar in 220g of *Branston's Baked Beans* (supplied in the first *Emergency Food Pack*, received on 13th April 2020) is 10.3g, whereas the sugar in 220g of *Tesco's No Sugar Baked Beans* (not supplied in the *Food Packs*) is 2.4g - a difference of 7.9g [see Supplemental 2.1]. This could indicate that 220g of *Branston's Baked Beans* contains up to 7.9g of added sugar - around 2 teaspoons in just a single serving. A 400g tin of *Heinz Cream of Tomato Soup* has (as stipulated on its label) 19.4g sugar and some of this sugar naturally occurs in the tomatoes. However, a 400g tin of tomatoes has 13.6g sugar - a deficit of 5.8g (about 1.5 teaspoons) [see Supplemental 2.2], and so it is reckoned that most of that difference is table sugar which has been added to the soup. Therefore, a basic reckoning of the added sugar in the typical day's food and drink [see Supplemental 1.7] would be that, by far, it exceeds the recommended maximum of 25g of added sugar per day. Note that potatoes, and refined carbohydrates such as white bread and pasta also spike blood sugar levels⁷⁶.

Additives

The surge in food allergies, obesity, diabetes, and inflammatory bowel disorders appear to be linked to food additives such as emulsifiers which are found in many processed foods⁷⁷. The *Pek Ham* in the *Emergency Food Pack* contains an array of additives. For example, it contains the preservative sodium nitrite, which is a preservative used in processed meats that has been linked to cancer⁷⁸.

Note that even if an effort is made to eat very healthily [see Supplemental 3] (with only small inclusions of processed food from the *Food Packs*), even that day's food would exceed salt and sugar limits.

All the participants stated that the "typical day" lists generated would be mostly fairly typical of what the average British person would often consume in a day, although the participants had been trying to eat much more healthily before the pandemic.

CONCLUSION

The Food Pack Selection of Contents

The *Emergency Food Pack* contents may have been selected by gathering data on high-selling food items in the UK and supplying that same food during lockdown. For example, Heinz beans and soups (particularly tomato) were included in nearly all the *Food Packs*, most likely because Heinz is the most popular brand amongst British women, and tomato soup (classic cream of tomato soup being Heinz's bestselling soup⁷⁹) and baked beans⁸⁰ are liked by over two thirds of the UK population⁸¹; decades ago, it was recognised that the UK consumes more baked beans than any other country⁸², and that consumption has been reported to be more than two million cans of baked beans every day⁸³.

The Effect of the Food Pack Scheme

Along with vulnerable people, university students (in October 2020) who had been exposed to COVID-19 also had to self-isolate, and the food packages they were given were also lacking, nutritionally^{84 85 86}. During the beginning of the pandemic, the *Emergency Food Packs* may have been basically all that some vulnerable people consumed for months on end. Although the packs would have removed the possibility of starvation, after several months, it is likely that some conditions could have been exacerbated – or new ones may have developed. Diabetes is becoming a major epidemic of our time⁸⁷ and the *Emergency Food Packs* could have accelerated this major killer, along with high blood pressure and metabolic syndrome. UPF is a significant contributing factor in many underlying conditions, and so even with the best of intentions by the UK government, supplying more of the very same food which contributed to such conditions in the first place could result in the reverse of the desired effect – it may have simply augmented ill health, resulting in greater *NHS* strain.

Implications for Global Governance

The WHO's drivers and the Mozaffarian et al. summary of policies and possible options⁸⁸, have had little impact, possibly because the deeper needs of the primary stakeholders had not been considered, and there also appeared to be an inattention to structural changes in society as well as to corporate power. To address this, Baker et al. have called for new modalities of public health action⁸⁹. To combat food and, indeed, nutrition insecurity, a reliable, affordable, nutritious source of food which does not contain deleterious additives is required. As it appears that there are long-term issues of trust regarding commercial food manufacturers fulfilling this brief, new options of government-led initiatives involved in the manufacture of healthful food should be seriously considered which, like the *NHS*, would not leave health entirely to the mercy of the free market; food is meant to maintain health, not destroy it. How this could be achieved is next.

DISCUSSION

A New Public Health Action Proposal: Healthy Food Joint Ventures

Although the WHO have provided valuable drivers for dietary health, how to actually accomplish these missions are absent as they are left for member states to design and implement apposite policies and schemes. A politic strategy could be for joint ventures between governments and food manufacturers which would create government approved dishes, and the whole manufacturing process and the engagement of suppliers would be primarily sanctioned and overseen by governmental food specialists who would be at the food manufacturers' premises to ensure that wholesome ingredients and cooking methods are used such as those typically used at home. Food manufacturers have honed capabilities in food production, marketing, and political manoeuvring which could be harnessed for dietary health, and there could be many manufacturers who would want the kudos of winning large governmental contracts. Note that the dishes created should be culturally appropriate food.

Although healthful food from such joint ventures could be more costly, the cost could be mitigated by less burden on health services. Furthermore, governments

do not need to make huge profits, and could buy ingredients in bulk - these facts should lower the price of that food. Governments could also direct some eateries and shops to stock a little of its readymade food so that consumers would always have access to some healthy food and drinks on demand.

It is important to note that, even before the COVID-19 pandemic, the *NHS* was set to buckle given the continuing increase in type 2 diabetes⁹⁰. However, a low refined-carbohydrate diet (particularly one that is low in added sugars), without excessive salt, can significantly and quickly improve blood pressure and blood sugar levels^{91 92}. A joint venture need not displace existing manufacturers as just a few staple, affordable, guaranteed-to-be nutritious items which do not contain deleterious additives could be provided. Furthermore, unlike the COVID-19 pandemic, supplies of staples such as rice, pasta and meat could be apportioned by such joint ventures so as to mitigate hoarding, and shortages due to meat processing plants closing due to their workforce becoming ill⁹³.

Besides high levels of nutrition, there could also be a focus on low waste, sustainable production and processing systems, and reduced packaging - this scheme would meet the United Nations' definition of a healthy diet which also safeguards planetary health⁹⁴, and many of the following WHO drivers:

- **Portion control and consuming the recommended level of healthy ingredients**⁹⁵ - it can be difficult for the public to gauge appropriate portion sizes, as well as the number of portions of vegetables and fruit that should be consumed, without continually weighing and measuring all foodstuffs and drinks they consume; this can be extremely tedious and, at times, even impossible. Furthermore, many are unaware that mushrooms can be included as a portion of vegetables, or that pulses consumed in a day can only be counted as one portion of vegetables - no matter how much are consumed. However, readymade healthy food could be designed to ensure that the appropriate portion sizes and recommended amount of nutrients are present.
- **The availability of readymade healthy food** – there could be policies and schemes for at least a couple of healthful, readymade dishes and drinks to be available in, not just all public canteens as suggested by the WHO, but also some cafés and shops.
- **Appropriate reformulation of manufactured food** – government involvement could ensure that unhealthy ingredients are not replaced by other unhealthy ingredients, but with healthy ones.
- **Labelling and daily consumption suggestions** – government involvement could allow healthy, readymade food to be bought online. Currently product labels can be too small to be fully inclusive and they can be very difficult to read, but the item's nutritional information could also be put online and so be fully comprehensive, clear, and easy to read. On such a website, suggestions could be made for a day's food and drink consumption referencing a large amount of the healthy readymade food; this would have the appropriate level of calories, sugars, salt, fibre, fruit and vegetable portions, and macro- and micronutrients so that the consumer (if they wished to follow the suggested plan for that day) would be sure that their diet that day was healthful. There could also be plans for

diabetics, children, those with 'flu and so on. The consumer could also select various items online that they were considering consuming in a day or week, and have the nutrients automatically totalled with suggestions to make improvements if they were not at the appropriate levels.

Furthermore, a joint venture with government would likely channel the corporate power of the engaged manufacturer into promoting and advertising the healthy food product produced, along with its benefits. That influence could also be channelled into lobbying for canteens, cafés, and shops to stock that item over and above similar products from other manufacturers which are unhealthy; it may also prompt other manufacturers to raise their game and become more socially responsible⁹⁶. This capturing and diverting of corporate power to promote a healthy diet could be extremely beneficial.

Recommendations for Further Work

- In policy analysis, solution-evaluating (so called 'traditional') approaches tend to rely on theoretical frameworks and methods which are economic, scientific, or behavioural. However, state-of-the-art engineering should now also be considered for a theoretically-sound, solution-generating, evidence-based, closed-loop method, which starts with the primary stakeholder (the public - while recognising that their needs are functional), that can generate an extensive range of first-cut options – this will help to avoid future health policy failures, and help to address the fact that public health evidence (as with the *Emergency Food Packs* scheme) is not often translated into policy^{97,98,99}. Such a method could then be used to further evaluate the merits and demerits of the afore-mentioned joint ventures, as well as develop other possible options.
- Some western-style diets (such as those in the UK, USA, Australia, Republic of Ireland and New Zealand), even when made from scratch, tend not to be quite as healthful as other diets, such as the Mediterranean diet. However, creating a dish is a process, and there are experts in the domains of cuisine and in state-of-the art process engineering whose expertise could lend itself to the reengineering of dishes so that they look and taste the same, whilst also becoming much more healthful by, for example, substituting some less healthful fats with olive oil. Such an approach is also absent from the Mozaffarian et al.¹⁰⁰, summary of policies and options, although an acceptable method to accomplish such reengineering that could be adopted is required.

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Supplemental materials can be accessed via this link:
<https://blogs.shu.edu/ghg/files/2022/05/Hussain-Annex.pdf>

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POLITICAL ASPECTS OF THE ETHICAL ISSUES IN GLOBAL HEALTH

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On an international scale, factors of political significance, such as wars, domestic political crises, are of decisive importance for the health of citizens of individual countries or even entire regions. The dependence of political and medical factors is most clearly seen against the background of the coronavirus (COVID-19) pandemic. Often, ethical issues related to health at the global level are also not devoid of political overtones. The humanitarian assistance of countries, rendered as an act of good will - an ethical gesture - at the global level can be determined not by noble ideas, but by aim to achieve political interests. This article substantiates the presence of a political aspect in the context of healthcare ethics, both at the global and national levels.

INTRODUCTION

The policy to protect the health of the population of the country is an integral part of ensuring national interests, since it is the population that is one of the attributes of the state. Health care has traditionally been considered a medical issue, and related ethical issues in the scientific literature are usually addressed by medical scientists. However, the field of healthcare, especially on an international or global scale, requires the collective work of representatives of various fields, including politics, law, economics, etc. Physicians - unless they are politicians - do not have the power to develop a health policy in the country. All that medical science can offer is advice on the development of necessary measures, but their ultimate implementation is up to politicians. Public health as an independent field of study¹ has confirmed its primary dependence on politics amid the coronavirus pandemic (COVID-19). Unfortunately, political research rarely focuses on ethical issues in healthcare. Those issues more often represent interest for health/medical scientists. Although it is political science that can help in the analysis of health policy both at the national and international levels.

HEALTH AS A POLITICAL DETERMINANT

The Overton Window model (or “window of political opportunities”) reflects the influence of public ideas on politics². This model, developed by Joseph P. Overton, is based on ideas explaining the limitations of politics/politicians depending on public opinion or ideas supported in society, i.e., from the electorate. Thus, socially acceptable ideas (public opinion) proposed by politicians can strengthen their position and vice versa. Moreover, political goals and objectives, depending on the political course, can change public opinion. It is the variety of social, economic, environmental, legal, and other factors that have a dominant influence on political courses, slogans, and the political atmosphere as a whole. Internal political need tends to support ethically sound decisions. It is the support by the population of measures taken or announced for implementation by politicians that is of key importance in the struggle for votes and ratings. This, for example, can explain the high support for the program of reforming the insurance system in the US, called “Obamacare”.

In domestic politics, political parties can use the factors of social protection of the population, the most important of which is health care, as their election slogans, political campaigns, etc.³⁴ Obviously, depending on the declared slogans, political

parties differ; there are parties of various ideologies, such as socialist, liberal democratic, etc. For example, in Australia there is a political party called Health Australia Party, which official goal is “to improve the health of the Nation starting with the health of individual citizens, through to local councils, to state and territory governments, and finally to the national government and to international alliances.”⁵

Studies confirm direct relationship between the health indicators of the population and the political ideology of the ruling parties. Thus, V. Navarro and others⁶, examining the relationship between politics and the consequences for public health, concluded that parties with an egalitarian (French *égalité* - equality) ideology, as a rule, pursue a distributive policy. The researchers concluded that a policy aimed at reducing social inequality has a beneficial effect on population health outcomes. Distributive policy as the most important direction of the internal social policy of the state is aimed at allocating funds depending on social needs, i.e., assistance to the most vulnerable segments of the population. Naturally, the problems of such a part of the population are especially acute with issues of medical care, i.e., health. In this context, a socially oriented state develops state programs to help the population in order to protect health. One of the key goals and criteria of democratic governance is precisely to ensure a close connection and harmony between the preferences of citizens and state policy⁷. J. Grad and M. Frischhut in their study of the legislation of the European Union (EU) and the European Commission indicate the increasing role of ethical/moral concepts⁸. It ensures that citizens and representatives of associations are able to publicly exchange views in all areas of the EU activities. We believe that, accordingly, increasing the role of not legal, but specifically ethical factors in making political decisions is an integral part of the internal policy of a democratic state.

At the global level, humanitarian activities of countries, a significant part of which are related to health issues, have received a corresponding definition in the literature - humanitarian diplomacy⁹¹⁰. Although this type of diplomacy is aimed at providing preferential or gratuitous assistance (which in itself has an ethical component), it is usually based on the political interest of the donor state. Political processes, especially those taking place at the global level, are subject to rationalization. That is why humanitarian aid is considered by some authors¹¹¹² as one of the manifestations of “soft power” from a political point of view. In this context, there is a close relationship between the concepts of “humanitarian diplomacy” and “health diplomacy”, which is also referred to by some authors¹³¹⁴ as soft power. Representatives of the neorealism theory explain the participation of states in international organizations, such as the WHO, by narrow national interests¹⁵. The ethical framework is a good platform for policymaking, for the negotiation process.

The development of the field of “global health diplomacy”¹⁶¹⁷ is a vivid example of the fact that the study of political aspects in health - seemingly purely medical - issues are of particular significance. Issues related to ensuring the security of the state and its population are in the sphere of study of representatives of both scientists in the field of political science and public health. In this context, ethics can become one of the connecting links for dialogue. In the conditions of unprecedented scientific and technological development, when the proliferation of biological weapons and bioterrorism become real, i.e., possible from a scientific point of view, threat, the need to comply with ethical principles increases. Ethics can facilitate dialogue between representatives of the two disciplines in the context of sustainable development and security in the framework of the “political science of public health”¹⁸.

HEALTH AS A HUMAN RIGHT AND ETHICAL ISSUE

Democratic states in their internal health policy are primarily guided by the norms and principles enshrined in international documents. As stated in the Charter of the World Health Organization (WHO), "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."¹⁹ The policy developed by the state creates conditions for the provision of medical care and, therefore, the protection of the health of every citizen, the entire population. In this regard, cooperation between medical, educational, economic, and other authorities comes to the fore. Communication is essential because only well-coordinated fieldwork and the implementation of democratic public policies can ensure the protection of the population.

The promotion and protection of health are important conditions for human well-being and dignified life. All states are responsible for the health of their citizens and, although they cannot guarantee the health of every citizen, they must create favorable conditions for ensuring its protection. The protection of human health is set out in the preamble of the WHO Constitution and is recognized by the United Nations (UN): "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."²⁰ It should be noted that it is precisely the appeal to the "highest" attainable level, which should not depend, among other things, on socio-economic factors, that generates many ethical controversies. The reference to the need for freedom of political opinion on the issue of health in the UN definition reaffirms the relationship between politics and health.

Great changes have taken place in our life since the adoption of the WHO Charter and the UN Universal Declaration of Human Rights. Global trends in health care are closely related to the development of medical science, which is increasingly shifting towards the introduction of innovative achievements, i.e., the development of electronic services, the development of a new generation of drugs such as monoclonal antibodies, the research of stem cells and human DNA, the genetic modification of living organisms, and the introduction of biotechnology. Rapid scientific development plays a dual role in public health. On the one hand, it significantly increases the ability to provide timely, high-quality care, thereby improving the quality and length of life. On the other hand, it exposes and further strengthens the inequality between different social groups, countries, and even regions. The example of the distribution of vaccines against the background of the coronavirus has become another reminder - already widely publicized - of this in practice.

Science without an ethical basis is not only a threat of bioterrorism, but also a question of the existence of humanity itself. The activity of politicians rarely proceeds from ethical principles; however, public health issues cannot be considered without them. Ultimately, the preservation of the human race, in our opinion, is a universal value. Moreover, political processes, negotiations at the level of artificial intelligence seem to us to be a rather controversial prospect. Therefore, the protection of the population at this stage of history is a vital necessity. In this regard, the UNESCO Universal Declaration on Bioethics and Human Rights adopted in 2005²¹ that reflects fifteen universal bioethical principles is of extremely high value. Since it considers both legal and ethical components in relation to various states, societies in the context of modern scientific development.

Several universal bioethical principles, enshrined in the 2005 UNESCO declaration, are of particular interest to us from the point of view of the foreign policy of the state in the field of healthcare. Those principles are 1) Equality, justice and

equity (Article 10), 2) Solidarity and cooperation (Article 13), 4) Sharing of benefits (Article 15). The principle of “equality, justice and equity” is the basis for building any democratic state. It is the concept of justice that justifies the policy of state financing of global projects in the field of health. Equality and equal rights are a direct consequence of ensuring justice. When the government acts in the interests of the common good - it carries out humanitarian projects, this is positively assessed by the population.

One of the recent examples of politicization of ethical issues such as providing assistance to other states was clearly traced against the background of the COVID-19. Such humanitarian aid at some stage even introduced a certain split between the member countries of the political union - the EU. At a certain stage, the issue turned out to be especially acute for Italy, which did not receive proper assistance from the EU countries in time, as a result of which it was provided by China, Russia, and Cuba. Such assistance, against the background of the political contradictions of the allies, according to some sources, should be perceived as a “geopolitical move”²² rather than as generosity. That ethical component of political moves is often only the visible side. However, “Solidarity and cooperation” in extraordinary conditions can fade into the background.

The implementation and adherence of bioethics principles is recommended to all states that have signed the Declaration. In practice, however, it is characterized by the need to address ethical dilemmas. Thus, the bioethical principle “social responsibility and health” (Article 14) declares that progress in science and technology should contribute to the availability of high-quality medical services and medicines, improve living conditions, and the environment²³, etc. The same article 14 characterizes health as a “social and human good”. In practice, many people are deprived of all or most of the benefits noted in Article 14 due to socio-economic and political factors, such as armed conflicts or a state of war, as well as factors beyond the control of the political will - natural disasters, during which the provision of benefits is almost impossible.

Domestic political stability is critical to the success of the health care system. Thus, according to scientists from the Democratic Republic of the Congo, the main reason for the subsequent outbreak of the Ebola virus in August 2018 and the impossibility of its timely control was the unrest and violence in the region caused by political factors, ultimately resulting in rebel groups limiting access to various areas, thereby preventing necessary medical measures²⁴.

Similar situations are observed in countries facing a crisis of state political power. Thus, because of domestic political protests in Venezuela, by the end of 2018, the country was on the brink of a humanitarian crisis²⁵. In the course of military conflicts, such as the recent war in Syria, where the health infrastructure was practically destroyed, the most pressing issue was precisely the provision of the benefits of the affected citizens, and the protection of their health. Moreover, as a result of the internal political crisis and the war in Syria, as of 2021, more than 6 million people were forced to leave the country²⁶. As a result, assistance to refugees from Syria has created a number of ethical dilemmas, primarily related to health issues, for host countries such as Turkey, Lebanon, and others. Against the background of the coronavirus pandemic, refugee host countries also faced acute ethical dilemmas regarding refugee treatment and vaccination.

A complicated situation, which the WHO described as a “crisis” was also observed in Afghanistan where, as a result of political instability in 2021, more than 18 million people required humanitarian aid, and the number of fully functioning hospitals reached only 17%²⁷. Thus, not only international or interstate conflicts can

cause disruption to the health care system, but also internal political ones. Against the background of the coronavirus pandemic, the situation, accompanied by a global decline in economic activity, has itself become the cause of large-scale tensions. In unstable and conflict-affected countries, according to forecasts, this will lead to an additional 18-27 million people that will end up in extreme poverty²⁸. Ensuring the protection of public health in conditions when the very political regime of the state is experiencing an internal political crisis becomes almost impossible. The protection of refugees and migrants who find themselves in conditions of threat to their lives, especially such as war, is becoming an extremely difficult political and socio-economic ethical problem.

Political instability creates conditions for the threat to public health in the first place, and inequality between certain groups is growing. It is clear that more affluent groups are more likely to move to safer areas, get needed medicines, and so on.

GLOBAL HEALTH AND COVID-19

The heterogeneity of socio-economic development both between states and between representatives of different groups of the population on a global scale is the most important reason for the emergence of most ethical problems in the social sphere. Consequently, conditionally ethical issues related to healthcare can be divided into national and global ones.

When looking at the health field from a global perspective, one of the significant ethical issues is the distribution of benefits and its relationship to intellectual property rights. This issue closely intersects with many bioethical principles affecting equality, equity, and justice, however, in the context of international relations in the field of health and economics, it becomes especially acute. The presence of ethical issues in global health in the context of the implementation of bioethical principles and the need for international solidarity in their observance was most clearly manifested during the coronavirus pandemic. This issue has become especially acute for developing countries. The economic development of states predetermines their insolvency in the acquisition of effective modern tools vital for the protection of the health of the population, such as vaccines. The aforementioned problems, directly related to the level of economic development of states, put on the agenda a humanitarian component, such as investments in the development of health care in low-income countries. However, the conditions when the whole world is experiencing a health crisis, unfortunately, the humanitarian, i.e., the ethical side of the issue can be relegated to the background.

The coronavirus pandemic has reminded the world community of the importance of paying attention to various aspects of the economic factors of global health. In poorly educated low-income states, the observance of social distance, the need to wear masks, and personal hygiene have become not only elusive tasks but often “difficult to explain”. So, in most cases, the economically vulnerable population in those countries, working in “unfavorable conditions” such as work in slums, etc., could not adhere to the recommended physical distance²⁹. Moreover, in such socially vulnerable groups, one could observe the existence of inequalities not only in relation to receiving quality treatment but also in the provision of medical masks. For example, one study found that in Bangladesh, the Democratic Republic of the Congo, Nepal, and Tanzania, only less than a third of clinics and health centers had masks of any kind; moreover, “if in the United States there were about 33 beds in intensive care units per 100,000 population, then in Uganda this figure was 0.1 beds”³⁰. Obviously, in conditions where even medical institutions have limited resources, hygiene

requirements, for example, for frequent changes of masks, etc., could not be met by the population. Low-income states could not afford to fully implement measures to contain the spread of the virus, such as mass testing, contact tracing, etc.

Against the background of the pandemic, governments at both the local and global levels focused their attention and most of their resources on solving the tasks of combating the pandemic. During the pandemic, in many cases, the treatment of other diseases was put on the back burner. Undoubtedly, the fight against coronavirus was an important goal, however, other infectious and non-infectious diseases, unfortunately, also continued to affect human health. Many were unable, for example, to receive proper treatment on time due to overcrowding in hospitals, non-urgent procedures were canceled, medical tourism became impossible due to the ban on flights, etc. For example, in Uganda, from January to March 2020, “maternal mortality increased by 82%”³¹. Negative statistics were also typical for the diagnosis of HIV and the number of people starting antiretroviral treatment for tuberculosis, malaria, etc. Thus, compared to 2019, the testing of people for tuberculosis decreased by 29% and according to the Stop TB Partnership, the first year of COVID-19 “canceled out 12 years of progress” in the fight against tuberculosis³². That is, as statistics show, the coronavirus did not stop the spread of other diseases but only made the fight against them more difficult. The complexity of the coronavirus pandemic was that not only did the virus itself harm global health, but the concentration of efforts to combat it also negatively affected the treatment of other diseases. But that again echoes the economic opportunities of countries.

Difficulties also affected non-communicable diseases, such as diabetes, cardiovascular diseases, etc. Thus, according to WHO, as a result of the pandemic, the provision of services for the treatment of many diseases, such as cancer, diabetes, etc., has significantly decreased; for example, 49% of countries had to partially suspend or even stop treatment for diabetes and related complications, and the corresponding rate of cancer treatment was 42%³³. Moreover, numerous studies have confirmed a direct link between the severe course of coronavirus disease and the presence of concomitant chronic diseases³⁴³⁵ such as diabetes; therefore, deterioration in the quality of treatment of the underlying disease increased the risks of poor outcome for patients. This, in turn, had a negative impact on their psychological condition³⁶.

From the outset of the pandemic, it became clear that certain populations would be more affected by the pandemic. The negative impact of the pandemic altered not only physical, but also psychological health. The psychological aspects associated with global restrictive and other measures have increased the level of suicides, facts of xenophobia, and even racism³⁷. Thus, a study published in the journal “The Lancet Psychiatry” showed that “every third patient with COVID-19 within six months” was diagnosed with mental or neurological diseases³⁸. It is obvious that the anxiety and stress associated with the threat of COVID-19, restrictive measures, the lack of habitual social contacts had a negative impact on people's mental health, and thereby increased the burden on health care workers. Thus, in Japan, against the background of the pandemic, an increase in suicide and other psychological problems led to the appointment of a “loneliness minister” - Tetsushi Sakamoto, who became the first minister whose duty was solely to combat the crisis of loneliness and isolation³⁹.

Taking the coronavirus pandemic as an example, it becomes clear that the level of economic development (poverty) is one of the most important socio-economic determinants of health, causing the majority of ethical issues in the field of health. Poverty is the indirect cause of most preventable deaths. According to the WHO, “the poor are at greater personal and environmental health risks, have poorer nutrition, less information and fewer opportunities to access health care”; as a consequence,

“they have a higher risk of disease and disability”⁴⁰. Thus, about 5.2 million children under the age of five died in 2019⁴¹. Most of these early deaths occurred in low-income countries. They could potentially be prevented, the sick could be cured, but mortality rates are still high due to the lack of simple, affordable treatments. Moreover, about 45% of all deaths among children are associated with malnutrition⁴². The fact that there is a direct link between lack of adequate nutrition (malnutrition) and socio-economic indicators is obvious.

In the context of health protection, the ethical issues are not solely medical or legal. When it comes to the threat to a significant part of the population, these issues acquire the status of strategic from a political point of view. Since the citizens of the country, its population, determine the fate of the state. For example, in the United States in 2020, more than \$1.5 million was allocated to the “State Program of Physical Activity and Nutrition” in the state of Alaska alone; the maximum funding for this program was received in the state of Texas - more than \$4 million⁴³⁴⁴. In the UK, as part of the government's fight against obesity and the promotion of a healthy lifestyle, a campaign was launched in which special telephone applications were developed. The Chinese government has come to the fore in this regard with the announcement of the Healthy China program; President Xi Jinping identified the centrality of health care in public policy, which also signified investment in this area⁴⁵. The promotion of a healthy lifestyle is also reflected in the programs of the European Union (EU). Thus, the EU4Health program, adopted in response to the coronavirus pandemic, is predicted to become the largest health care program with investments of 5.1 billion euros, including funding not only from EU member states but also health organizations and non-governmental organizations (NGOs)⁴⁶. Also, states widely subsidize programs of incentives or even material rewards aimed at stimulating and promoting healthy lifestyles. The participation of states in the development of such programs is explained, first, by the fact that the population and the health sector are strategically important components of the state's security.

PANDEMIC TREATY - ETHICAL BASIS FOR POLITICAL COOPERATION

The adoption of a pandemic treaty has become one of the important issues discussed on the global political agenda accompanying the coronavirus pandemic. This issue was raised at the level of political leaders, the head of WHO, and was studied by many scientists⁴⁷⁴⁸⁴⁹. The principles of cooperation underlying such a potential treaty have a distinct ethical component. However, during the coronavirus pandemic, we have seen that non-legally binding ethical principles, including those reflected in the Universal Declaration on Bioethics and Human Rights, cannot ensure their implementation. The distribution of vaccines in this context has become a clear example. It's not just the copyrights of vaccine manufacturers, but also ethical principles, such as equality and social justice, which have been violated in many ways due to uneven distribution of vaccines between countries.

Rapid development of ties in the modern world significantly increases the risks of local problems moving to the international level, as is the case with infectious diseases. That is why, in order to develop unified approaches to solving various issues, it is necessary to have “universal policy”. International concerns require universal solutions, or at least approaches to their solution. Global health policy trends cannot take into account the diversity of local conditions that affect health care. However, guidelines developed on the basis of universal principles can be used to plan and develop health care in the key of internationally recognized norms. The critical aspect here is that state policy or politics brings to the fore the role of politicians, because it

is politics that determines the goals, objectives and methods for achieving them in the field of public health. For example, in the absence of an environmental policy and relevant legislation, it is impossible to promote smoking cessation; in the absence of a vaccination policy against influenza, it is impossible to avoid its massive spread - an epidemic etc.

The UN in its resolution “Global Health and Foreign Policy”, adopted on December 12, 2012, emphasized the importance of the political aspect in health care⁵⁰. It is possible to exchange knowledge and scientific and technical innovations through the international cooperation only if there is an appropriate interest and political line of the state. Ensuring the protection of public health, being one of the priorities of state policy, depends not only on factors, such as the economy, but also, foremost, on the will of politicians. In the rapidly changing world of high technologies, we believe that it is bioethics that can provide protection for the ethical justification of political positions. Analyzing “the politics of bioethics” M. Brown comes to the conclusion that “any system for making ethical decisions is inevitably structured by political prerequisites” and even scientific dialogue within the framework of legal and institutional relations acquires political value⁵¹.

CONCLUSION

On the domestic level ethical principles can help policymakers, legislators, and healthcare professionals to unite in development of national and global programs. In this article, we refer specifically to the bioethical principles, since they represent an already existing global instrument of an ethical nature in the field of science and health on which countries have managed to achieve consensus. State cannot prevent all potential threats to the population that may arise. In this context, it is important to have a state mechanism for researching models for the implementation of preventive policies aimed at developing appropriate response strategies in various situations.

Ethical issues in health care have a political dimension for several reasons. First, at the state level, poor health of the nation, mass morbidity is an extremely undesirable phenomenon. Ultimately, the borders and internal security of the country is guarded mainly by people. Secondly, inequality and injustice in the social sphere is tantamount not only to a drop in the political rating within the country, but can also lead to international consequences, such as sanctions, isolation, undermining political trust and a general decline in the country's image. Political scientists rarely turn to the research of health ethics or bioethics. However, political scientists can direct their efforts to consider the political possibilities in detailing universal bioethical principles. For example, the principle of “protecting future generations” can become a platform for international political initiative in the field of the already existing UN Global Development Goals.

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