D4 | GAVI AND GLOBAL FUND: PRIVATE GOVERNANCE STRUCTURES TRUMP PUBLIC OVERSIGHT IN PUBLIC PRIVATE PARTNERSHIPS

Global Public Private Partnerships (PPPs) have emerged as the new medium of global governance, replacing over time the nation state driven governance system which was embodied in the UN system. In other chapters (DI and D2) we have commented on the process and motivation underlying this shift in global governance for health. In this chapter we examine, arguably, the two largest PPPs in the health sector, the Global Alliance for Vaccines and Immunization (GAVI) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Both these organizations were deliberately positioned outside the UN system and provide a space for private entities in their governance structures. It is interesting to note that the Bill and Melinda Gates Foundation (BMGF) is closely linked with both these partnerships. Specifically the chapter looks at distortions in global governance that arise as a result of such partnerships. The chapter also focuses on how private actors appear to have hijacked both these partnerships and utilize them to expand the space for a range of private entities to intervene in areas of activities which are essentially public in nature. This is particularly problematic given that both these partnerships are largely funded from public sources - mainly through contributions from countries.

GAVI: Publicly funded with a private vision

Formation, objectives and governance The Global Alliance for Vaccines and Immunization (GAVI) was launched in 2000 with an initial grant of US\$ 750 million over five years from the Bill and Melinda Gates Foundation. Countries are eligible to apply for support from GAVI when their Gross National Income (GNI) per capita is below a certain level (currently US\$ 1,580) on average over the past three years (according to World Bank data published every year on 1 July)¹.

GAVI owes its existence to a meeting hosted by the World Bank President James Wolfensohn in March 1998 that brought the prospective GAVI board members together. GAVI's objectives, outlined in the first board meeting were: affordable prices for governments; adequate investment in capacity to supply global needs; and private investment in research and development of high priority vaccines for developing countries².

GAVI has a hybrid governance structure that involves non-state actors, such as pharmaceutical corporations, in its decision-making processes. The

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Bill & Melinda Gates Foundation (BMGF), as a founding member, have played a key role in shaping GAVI's policies. The BMGF holds one of the four permanent seats on GAVI's Board (the others are UNICEF, WHO, and the World Bank). Beside thirteen members from governments and international organizations, two representatives from the vaccine industry (currently Sanofi Pasteur and Serum Institute of India, Ltd.) sit on GAVI's board³. In addition, several representatives from auditing companies, banks, investment companies, and foundations are among the nine 'independent board members' who have no connection with GAVI's technical work⁴. 79% of GAVI's funding comes from governments and the rest from foundations, corporations and individuals⁵.

GAVI places emphasis on technological solutions to achieve quantifiable, quick, short-term results (see Chapter D2 about how this is the hallmark of BMGF supported initiatives) (Wirgau et al., 2010). Through its way of working which we discuss later, GAVI's strategies are geared towards promoting the interests of private vaccine manufactures. This is reflected in GAVI's adoption of Advanced Market Commitments and Tiered Pricing as the organization's fundamental approach towards promoting access to vaccines. GAVI does not promote local production and technology transfer.

GAVI follows the key strategies of market shaping and co-financing⁶. 'Market shaping' is understood as a strategy where both the demand and the supply of a vaccine are intentionally altered (Castro et al 2017) GAVI promotes this strategy on the ground that it will lead to lower prices: while countries gain bargaining power by pooling and guaranteeing demand, vaccine manufacturers realize economies of scale. However, GAVI's 'market shaping' strategy is entirely non-transparent. Through this strategy GAVI has been able to create a captive market for new vaccines for a small set of vaccine manufacturers by pushing these on national immunization schedules of the countries it supports. GAVI's Co-financing strategy involves cost sharing of vaccines by participating countries.

Contrary to what GAVI would like to project, there are serious doubts regarding GAVI's real impact on the promotion of public health goals. The Strategic Advisory Group of Experts on Immunization (SAGE), in the Midterm Review of the Global Vaccine Action Plan (2012-2020), observed that while the global rate of new vaccine introduction has remained strong, the progress towards the goals to eradicate polio, eliminate measles, rubella, maternal and neonatal tetanus, and increase equitable access to lifesaving vaccines remained slow. Since 2010, global average immunization coverage has increased by only I per cent. However, new or under-utilized vaccine introductions have overshot their target. Between 2010 and 2015, 99 low- or middle-income countries (LMIC) introduced one or more new or under-utilized vaccines. GAVI had provided support to 64 of these countries (SAGE, 2016).

Advanced Market Commitments An 'Advance Purchase Commitment', rebranded by GAVI as 'Advanced Market Commitment' (AMC) is GAVI's key strategy. Essentially AMC involves purchasers (in this case countries) committing to buy a certain quantity of a product (in this case vaccines) in advance, that is well before the product is supplied. It is a concept developed by Michael Kremer, the Bill and Melinda Gates Professor of Developing Societies and Economics at Harvard University (Light, 2009). From conception to execution the motivation to promote AMC has changed to accommodate pharmaceutical industry needs. Initially, the purpose of an AMC was to motivate private vaccine industry to conduct research and development for 'neglected diseases' that primarily afflict low-income countries. The logic being that vaccine manufacturers would be incentivized to develop new vaccines if they were guaranteed a market for their product. However, in GAVI's first major foray, an AMC was used to guarantee the purchase of new 'blockbuster' vaccines for pneumococcal diseases. It was clearly designed to benefit four multinational giants in vaccine development and manufacturing. It has been argued that AMCs promoted by GAVI "deliberately favour large pharmaceutical firms over small and new biotechs and not-for-profit, university-based, and developing-country-based research. Yet, they present no empirical evidence that such firms are the most efficient at vaccine research" (Farlow, 2004). The goal of developing regional vaccine production capacity through technology sharing was on GAVI's early agenda, but was quietly dropped. Instead, the economics, structure, legal terms, and handling of GAVI's AMCs favour a few multinational corporations. This is in spite of the widely accepted fact that more than four-fifths of all money for basic research to discover new vaccines or medicines comes from public sources (Light, 2006).

In AMCs the price and volume of purchase are pre-set by a committee, and companies promise, to make their product available at a low initial price, while keeping their intellectual property (IP) rights intact (Light, 2009). AMCs include no arrangement for acquiring IP rights, technology transfer or promoting local production – all key components of improving and sustaining access to medical products (Sell, 1998). The legal advisers for drafting the legal terms of the purchase commitment were Covington & Burling, one of the most powerful international firms offering IP related services to the pharmaceutical industry. Kremer's design of AMCs draws on industry-supported studies that exaggerate R&D costs for developing a new drug – industry driven estimates of product R&D are many times higher than what independent evidence suggests. This results in donors paying much more for development costs than the actual cost of research (Light, 2007).

An AMC was first applied by GAVI for the procurement of the pneumo-coccal conjugate vaccine (PCV). Contrary to the stated principle that AMCs would incentivize new vaccine development, the AMC had nothing to do with R&D as pneumococcal vaccines had already been developed, and were

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looking for lucrative markets (which the AMC provided) (Johns Hopkins, 2006). Prevnar by Pfizer-Wyeth was already in the market and two other versions of the vaccines by Pfizer-Wyeth and Merck, were close to gaining market approval (Balasubramaniam et al., 2014).

The entire market of pneumococcal conjugate vaccine, worth US\$ 30 billion until 2016, is served by just two companies: Pfizer and GlaxoSmithKline (Cooper, 2016). An independent economic analysis of the 2006 PCV AMC pricing, commissioned by Médecins Sans Frontières (MSF), concluded that US\$ 600 million would go as extra profits above the "regular" profits built into the pricing structure (Schoen-Angerer, 2008). Tore Godal, the former executive director of GAVI, conceded that the AMC price of US\$ 5 a dose was too high (Gjerde, 2008). Despite this the price was raised to US\$ 7 under pressure from private vaccine manufacturers (GAVI, 2008). By March 2015 Pfizer and Glaxo Smith Kline (GSK) had received US\$ 1.095 billion from the AMC funds. Despite the discount it has negotiated, GAVI also recognizes that pneumococcal vaccine costs more than GAVI-eligible countries can afford (Johns Hopkins, 2006).

While the number of diseases against which a child is immunized has doubled between 2001 and 2014, the cost of the vaccines to fully immunize a child (after introduction of the new vaccines) has disproportionately multiplied 68-fold. This estimate represents a theoretical, best-case scenario, based on the lowest available prices for the UNICEF Supply Division and restricted to a select group of developing countries, usually only GAVI-eligible countries. The cost will be higher for countries not eligible for GAVI support (MSF, 2015).

If AMCs had really been designed to incentivize R&D by the private sector for requirements of low- and middle-income countries (LMICs), then R&D activities would have focused on real needs in these countries. Vaccine delivery can be extremely difficult and expensive, especially in countries where health systems are poorly developed. Most vaccines have stringent cold chain requirements, posing a challenge in places without uninterrupted power supply. Investments are required on R&D designed to develop products that are free of strict cold-chain requirements (ibid.).

GAVI and tiered pricing In the first board meeting in 1999, GAVI's Board endorsed use of differential or 'tiered pricing' as a pricing strategy. Tiered pricing⁸ is a business strategy of charging different prices for the same product in different markets or consumer groups. It could be applied in different geographical segments: high and low income countries; and within a country across different consumer groups: private and public sector. This strategy allows pharmaceutical companies to maintain market monopoly by blocking generic competition, preventing use of TRIPS flexibilities and maximizing profits by selling at different prices to different market segments. It also helps skirt criticism of overpricing in low income country markets (Modi Pandav, 2014). Tiered

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pricing is a strategy that allows pharmaceutical MNCs to continue to charge monopoly prices, tailored to what different markets can absorb. The prices set are based on what markets can absorb and not on the actual cost of manufacture (even after factoring in research costs). Companies retain their monopoly Patent rights and continue to bar generic manufacturers from manufacturing and selling the products. While companies reduce prices in low income settings when they apply tiered pricing, the price set is still much higher than what would have obtained if competition from generic manufacturers was allowed.

Tiered-pricing policies of GAVI are voluntary, arbitrary, ad hoc and conditional (GAVI and non-GAVI countries) and pricing decisions lack transparency. Companies may offer discounts on some drugs but not others, to some high-burden countries but not others, for a limited time or subject to conditions attached (ibid). For example, in case of the 10-valent pneumococcal conjugate vaccine, GAVI negotiated an initial price of US\$ 7/dose with GSK. The Pan American Health Organization (PAHO) could not obtain the same price and initially opted not to purchase the vaccine. Brazil independently negotiated an initial price of US\$ 16/dose. PAHO subsequently settled for a price of US\$ 14.85/dose (ibid.). In 2010, India's Serum Institute was offering the pentavalent vaccine at US\$ 1.75 per dose as compared to US\$ 3.2 paid with GAVI funds for a single dose vaccine from Crucell and US\$ 2.95 for a two dose vaccine from GSK. GAVI justified this on grounds it could only rely on Western companies to provide uninterrupted supplies on a large scale. Till 2011 only GSK and Pfizer had qualified for this money with their pneumococcal vaccines (Arie, 2011).

Often the prices offered by GAVI, even after application of tiered pricing, are not affordable in LMICs. When Gardasil, the first vaccine against the Human Papilloma Virus (HPV) that is implicated in cancer of the cervix, was launched in 2006, it cost between US\$ 100 and US\$ 233 per dose in developed countries and between US\$ 30 and US\$ 100 per dose in developing countries. In 2011 PAHO negotiated a price of US\$ 14 per dose for its member countries. Despite this decrease in price, it is still too expensive for many LMICs (Castro, 2017).

Robust generic competition, and not tiered pricing, offers a sustainable solution to the problem of higher prices of new medicines and vaccines. Tiered pricing only offers a short-term option to increase access to a product only when market volumes are very small or highly uncertain and/or multisource production capacity is lacking. Experience demonstrates that entry of additional manufacturers with WHO-prequalified vaccines, in particular developing-country manufacturers, stimulates competition and drives down prices (MSF, 2015). Policies which encourage technology transfer and promote competition should be adopted, which are not yet part of GAVI's strategy.

As has been argued (Balasubramaniam, 2001): "[T]he problem of lack of access to the two billion people who have no access to essential drugs

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cannot be solved by negotiating discounts country by country, company by company and drug by drug. Negotiations take place in total darkness since the real costs of production of drugs are not known to the negotiators. All pricing information is kept in confidence by the manufacturers. These are not therefore fair negotiations".

GAVI's bargaining power helps vaccine manufacturers A rationale for the setting up of GAVI was that it would, as a large pooled purchaser of vaccines, curb the monopoly power of large vaccine manufacturers to set high monopoly prices for new vaccines. However, evidence suggests that the reverse seems to have happened and vaccine manufacturers utilize the leverage they have in GAVI's governance to milk the system and accumulate super profits (see Box D4.1).

It is estimated that by 2025, 29 of the original 73 eligible countries will have lost Gavi support entirely. These countries will then face the dual challenge of meeting the higher cost of new vaccines and fully self-financing their national immunization programmes. They may have to pay up to six times more for pneumococcal conjugate vaccine, for example (GAVI Alliance, 2015). It is estimated that currently 'graduating' Honduras (meaning that it would no longer receive support from GAVI) will need to cover US\$ 5 million paid annually by GAVI for new vaccines, a 38 per cent increase in the government's present expenditures for immunization (Government of Honduras, 2013). Other estimates of increase in immunization budgets to cover cost of new vaccines are: 197 per cent for Sri Lanka between 2012 and 2018, 801 per cent for Congo, 1,523 per cent for Angola and 1,547 per cent for Indonesia (Ryckman et al., 2014). The ultimate beneficiaries are vaccine manufacturers, largely situated in the North, who secure access to a large market through GAVI's AMCs and tiered pricing mechanisms.

Five companies control 80 per cent of the vaccine market - GSK, Merck, Sanofi-Pasteur, Pfizer and Novartis (Balasubramaniam, 2014). The business of vaccines is slated to become a major source of profits for the world's largest pharmaceutical corporations and the profits from vaccines are projected to reach US\$ 61 billion by 2020 (Guzman, 2016).

GAVI's role in attempting to undermine the principles of the Pan American Health Organization's (PAHO) revolving fund for vaccines is particularly illuminating as regards the role GAVI plays vis-à-vis vaccine manufacturers. The PAHO Revolving Fund for Vaccine Procurement is a mechanism introduced in 1977 that facilitates timely access to high-quality vaccines at the lowest prices for national immunization programs of Member States. It offers vaccines to all participating Member States at the same single price. "Furthermore, the Fund establishes contractual terms and conditions in its international tenders in order to guarantee that the prices of the procured products are the lowest globally"9.

Box D4.1: MSF Rejects vaccine donation from Pfizer

In October 2016 MSF refused a donation of one million PCV13 vaccine doses from Pfizer. MSF called this a principled stand against the extremely high cost of many vaccines. MSF while refusing the donation pointed out that while they value donations, this was not straightforward philanthropy. Donations from pharmaceutical companies are ineffective against a problem of massive dimensions. MSF said that while the donation would benefit people receiving care from MSF, accepting it could mean problems for others, and longer-term problems. "By giving the pneumonia vaccine away for free, pharmaceutical corporations can use this as justification for why prices remain high for others, including other humanitarian organizations and developing countries that also can't afford the vaccine" (Hamblin, 2016).

PCV13, sold under the name Prevnar 13 is among the best-selling vaccines on the market. In 2015 alone, Pfizer's revenue from its sale was US\$ 6.245 billion. Its technology is protected by multiple product and process patents preventing generic competition. A South Korean company SK Chemicals came close to producing an analogue, but Pfizer sued the company and won (ibid.).

Even after five years of negotiations MSF has failed to secure lower prices from GSK and Pfizer for pneumococcal vaccines. MSF notes that "The GAVI price is still expensive when you compare it to other traditional vaccines where there is actual competition in the market (Cooper, 2016)." What these companies charge governments is shrouded in secrecy and the only price known is the price negotiated by GAVI – US\$ 10 per child. MSF has been calling on both companies to reduce the price to US\$ 5 per child for all developing countries, regardless of GAVI status, and to all humanitarian organizations. While Pfizer and GSK are happy to talk about the discounts they provide to GAVI neither company was willing to give a breakdown of their international sales, disaggregated by 'GAVI-price' and 'non-GAVI price (ibid.).

Since 2007, the fund had come under pressure from GAVI and BMGF to pay higher prices, while they themselves procured the new vaccines at lower prices. The Fund conceded three exceptions (to the principle that the revolving fund would negotiate the lowest price obtainable globally) for the prices of pneumococcal, rotavirus and HPV vaccines in expectation of obtaining reduced prices for its Member States. Despite negotiations the price reduction offered to the revolving fund was minimal compared to the prices obtained by GAVI. GAVI, BMGF and some vaccine manufacturers continued to exert pressure

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Image D4.1 Bill Gates addresses meeting of the GAVI alliance (Ben Fisher/GAVI Alliance; License: CC BY 2.0, https://creativecommons.org/licenses/by/2.0/)

for additional exceptions for other vaccines like the inactivated polio vaccine (IPV) (PAHO, 2013).

In 2013, PAHO adopted a resolution to ensure that the PAHO Revolving Fund is administered without exceptions. Member States also requested review of the previously conceded exceptions¹⁰. PAHO Member States were concerned about the continued erosion of the Revolving Fund's principles and the significantly higher prices it paid11. They overwhelmingly voted in favour of a Resolution that ratified the principles of the Revolving Fund and requested the PAHO Secretariat to ensure that the Revolving Fund is administered, without exception (PAHO, 2013).

GAVI's close association with BMGF raises further concerns regarding conflict of interest. Since 2008, the BMGF has been supporting establishment of National Vaccine Advisory Committees in Africa and Asia. In 2008, the French agency, Agence de Médecine Préventive (AMP), received a grant of 10 million dollars from the Gates Foundation to support the development of National Vaccine Advisory Committees in Africa and Asia. These committees help the national health authorities of GAVI-eligible countries to implement vaccination policy and programmes.

Conflict of interest is obvious. The Gates Foundation plays a key role in GAVI and simultaneously finance the National Vaccine Advisory Committees

that guide Governments on immunization policies. The National immunization technical advisory groups are expert groups who provide guidance to national governments and policy-makers to develop and implement evidence-based, locally relevant immunization policies and strategies that reflect national priorities. These should be independent and should be funded by national governments to maintain autonomy.

GAVI and Health System Strengthening Despite the undisputed increase in the number of immunized children, GAVI has been criticized for following a "Gates-approach", focusing on disease-specific vertical health interventions (through vaccines) over a holistic approach of health system strengthening (Martens et al., 2015). Responding to the criticism, in 2005, GAVI included a health system strengthening (HSS) component in its programme portfolio¹². However, only 10.6 per cent (US\$ 862.5 million) of GAVI's total commitments between 2000 and 2013 have been dedicated to health system strengthening, whereas more than 78.6 per cent (US\$ 6,405.4 million) have been used for vaccine support (Storeng, 2014).

The WHO defines Health System Strengthening (HSS) as "improving these six health system building blocks (Service Deliver; Health Workforce; Information; Medical Products, vaccines and Technologies; Financing; and Leadership/Governance) and managing their interactions in ways that achieve more equitable and sustained improvements across health services and health outcomes" (WHO, 2007). In practice, however, GAVI's interpretation of HSS is very different. GAVI's main emphasis as regards HSS is on resources such as cars, boats, bikes, kits for community health workers and cold chain equipment. The interconnectedness between the 'building blocks' is not part of GAVI's approach to HSS.

For example, GAVI funds a HSS programme in Kenya, with the aim to convince the population to vaccinate children. However, given weaknesses in the local health system, the demand for vaccination is not adequately met. Thus while GAVI creates a demand, in practice it remains challenging to vaccinate all children, thus eroding public trust in the health system. Further, even when immunization services are available, the absence of other care services in primary care settings erodes public trust in the system. This in turn decreases uptake of public immunization programmes. However GAVI appears satisfied with its HSS work as progress is measured (and reported) by vaccination follow up rates and other 'measurable' indicators directly related to vaccination¹³. (See Chapter D7 on the politics of measurement.)

GAVI's claimed focus on health systems has, however, *enhanced* GAVI's political appeal, to its more 'systems-oriented' donors. This has provided donors further justification for diverting ever-greater proportions of their development budgets to GAVI at the cost of crowding out other, and more flexible, funding for health systems (Storeng, 2014).

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The Strategic Advisory Group of Experts on Immunization (SAGE), in the Midterm Review of the Global Vaccine Action Plan (2012–2020), pointed to the persistent disconnect between immunization and the broader health system agenda (SAGE, 2016). The weakness of a vertical disease based approach is highlighted by the measles outbreaks that have occurred in numerous countries – a result of sub-optimal immunization coverage through both routine services and campaigns, along with increased susceptibility in older age groups. Surveillance for measles remains weak in many countries. Rubella control lags even further behind.

Global Fund's demand for Immunities and Privileges

Global Fund: governance structure The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), a global public–private partnership, was launched in 2002 with a US\$ 100 million grant from the Bill and Melinda Gates Foundation (BMGF) (Birn, 2014). It is an international public–private development finance organization that relies on voluntary financial contributions from all sectors: governments, private sector, foundations and individuals. In September 2016, the Global Fund Fifth Replenishment Conference secured pledges of financing for the 2017–2019 period¹⁴. Of the total US\$ 12.9 billion raised at the conference, US\$ 12 billion was pledged by donor governments. Thus, 93 per cent of all Global Fund support comes from donor governments¹⁵. These are held in a trust account at the International Bank for Reconstruction and Development (ILO, 2008).

It incorporates non-state actors as equal players in its core governance structures (Aziz, 2009; Schoofs and Philips, 2002; Yamey, 2002; The Economist, 2001). The private sector influence on the Global Fund is disproportionately large compared to its 7 per cent contribution. The Global Fund Board consists of eight "constituencies" comprising of 20 voting and eight non-voting members. All voting constituencies participate equally¹⁶. Private sector is one of the voting constituencies¹⁷. While, WHO and UNAIDS have no vote on the board of the Global Fund, the private sector does, represented by pharmaceutical Merck/MSD, and private foundations such as the BMGF (Birn, 2014).

The Global Fund's definition of private sector is broad. It includes interested corporations including pharmaceuticals, oil and gas, banking, management consulting, food and beverage, etc¹⁸. Many of these industries, such as pharmaceuticals, food and beverage, interests often conflict with public health policies. The remit of private sector influence also extends through funding to other Global Fund constituencies: Foundations and Civil Society. The Global Fund lacks an independent and accountable decision-making process as decision making is entrusted to a small group of representatives. Global Fund's policy is that public sector monies are not 'earmarked' for specific countries or programs, and that the allocation of funding is the responsibility of the Board of the Global¹⁹. Therefore, private sector with

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only 7 per cent contribution plays an equally important role in deciding the allocation of funding.

Immunities and privileges sought by Global Fund Since 2009 it has been asking for blanket immunities and privileges from the grant recipient countries. Until 31 December 2008, under an Administrative Services Agreement with the World Health Organization (WHO), all those working in the Global Fund's Secretariat were WHO officials. This meant that Global Fund staff was employed on WHO contracts with all the immunities and privileges of United Nations employees. On 1 January 2009, the Global Fund became an administratively autonomous international financing institution, employing staff directly under its own policies, regulations, and procedures (ILO, 2008). The Global Fund justified this move as a means of attaining greater flexibility as an institution and at the same time retaining status as an international institution with privileges and immunities similar to UN organizations in Switzerland and the United States²⁰. Staff obtained new contracts governed by Global Fund rules and regulations, and their UN privileges and immunities were terminated²¹.

In 2009 itself, the Global Fund started asking States to consider granting it blanket privileges and immunities either by: a) Applying legislation to confer upon the Global Fund the privileges and immunities ordinarily provided to international organizations; or by b) Signing an Agreement on Privileges and Immunities (the "P&I Agreement")²². It argued that the blanket privileges and immunities would assist it in fulfilling its mandate and in securing its investments in countries supported by it.

Under the P&I Agreement, described by the Global Fund as an *international instrument*, blanket privileges and immunities extend to the Global Fund, its assets, archives and officials acting in their official capacity. All goods, supplies, materials, equipment, services or funds introduced into, acquired, or used in a country as part of, or in conjunction with, funding provided under a Global Fund grant are exempt from taxation²³. This raises a fundamental question: how can an agreement involving a public private partnership (PPP) be an international instrument, when the PPP itself was not established by an international treaty?

Switzerland and the USA had already granted privileges and immunities to the Global Fund, but under different legal arrangements. The Global Fund signed a Headquarters Agreement with the Swiss Federal Council on 13 December 2004 under the terms of which it enjoys privileges and immunities in Switzerland. In addition, the Government of the United States has conferred privileges and immunities on the Global Fund by Executive Order of the President of the United States²⁴. These privileges and immunities have been extensively used as examples by the Global Fund to secure privileges from other countries without clarifying the differences.

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Gülen Atay Newton, Head Legal and Compliance Department, in a 2014 press release on accelerating efforts to secure privileges and immunities writes, that "...The Global Fund's dual legal status has been recognized as representing an innovation in public international law. This unique legal status reflects the nature of the organization as a public-private partnership, distinct from traditional international organizations. Through establishment as a foundation under Swiss law, the Global Fund was able to ensure the equal standing of public and private sectors in the organization's governance, and avoid the transaction costs and delays associated with treaty formation. At the same time, the status of the Global Fund as an international organization has been elaborated through a gradual process of legal recognition by national governments. For example, both Switzerland and the United States have formally recognized the Global Fund as an international organization (sic)...." (Newton, 2014).

Granting privileges and immunity to the Global Fund: The story so far... The Global Fund received a lukewarm response to its demand for privileges and immunity on par with UN agencies. In September 2010, the Republic of Moldova was the first to sign the P&I Agreement on the condition that the agreement would come into effect only when a total of ten countries adhere to it²⁵. Until 2014, eight countries had signed the P&I Agreement: Ethiopia, Georgia, Ghana, Moldova, Montenegro, Rwanda, Swaziland and Uganda²⁶. In 2014, a series of measures were taken to escalate the ongoing efforts. The States represented on the Board were encouraged to support and facilitate the Secretariat's efforts to secure privileges and immunities²⁷.

The Global Fund Board endorsed continued engagement with relevant counterparts such as the Ministry of Foreign Affairs. Coercive measure of making the recipient countries sign the P&I Agreement as a precondition to secure funding were applied. Within three years of signing the P&I Agreement, the host-country grantees are required to ensure all measures are taken to accord privileges and immunities to the Global Fund²⁸.

Between 2014 and 2017, the Global Fund claims seven more countries have signed the P&I Agreement, bringing the total number to 15. However, only 13 names are available in public domain. In March 2017, the Republic of Senegal was the latest to sign the P&I Agreement²⁹.

Privileges and immunity to PPPs: the case against the Global Fund THE GLOBAL FUND IS NOT AN INTER-GOVERNMENTAL ORGANIZATION Granting of privileges and immunities to public private partnerships in general and to the Global Fund in particular will further jeopardize democratic global health governance. If this is not addressed in time, other global public-private partnerships – such as the GAVI Alliance will demand the same concessions (Aziz, 2009). The Global Fund does not qualify for privileges and immunities

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in because it is not an inter-governmental organization as it is not established by an international treaty (ILO, 2008).

Non-state participation in the global public-private partnership structure creates legitimacy and accountability issues that are only compounded by the blanket application of P&I regimes. Global public-private partnerships lack such legitimacy because they differ from formal intergovernmental organizations in at least two ways: they are not constituted by a multilateral treaty based on State consent, and they permit the equal participation of non-state actors in decision-making processes. Both features apply in the case of the Global Fund (Aziz, 2009).

Although, the Global Fund argues that the absence of blanket privileges and immunities exposes its resources, staff and mission to serious risks and challenges (The Global Fund Observer, 2014), yet it provides no valid examples. The Global Fund does not implement programmes directly. With 700 staff based in Geneva, the Global Fund describes itself as a lean and efficient organization that does not have country offices³⁰.

CONFLICTS OF INTEREST: GLOBAL FUND'S ENGAGEMENT WITH PRIVATE ACTORS The Bill & Melinda Gates Foundation (BMGF), Global Fund's key partner, funds 'Friends of the Global Fund' and other organizations in both developing and developed countries to carry out advocacy for Global Fund worldwide³¹. The five regional 'Friends of the Global Fund', erroneously described as 'independent', are entrusted with developing contacts and garnering political and financial support for the Global Fund³².

The Global Fund, offers business opportunities and lucrative contracts to the private sector. International management and auditing firms such as PriceWaterhouseCoopers (PwC), KPMG, Cardno EM, etc. are given lucrative contracts to operate as the Local Fund Agents (LFAs), Fiscal Agents and external auditors.

Evidence shows international management and auditing firms promote policies that favour private sector to the detriment of public health (see Chapter D3). The Local Fund Agents (LFAs) oversee, verify and report on grant performance³³. The Global Fund describes LFAs as its 'eyes and ears' within recipient countries during pre-grant phase, grant implementation period and grant renewal process. Currently, there is a total of 141 LFA's in 150 countries³⁴. LFAs are entrusted with important oversight roles for technical health issues in which they hold negligible or limited expertise. LFAs are expensive and of questionable quality (McCoy, 2013). A revolving door between LFAs, the Global Fund and the grant recipients gives rise to conflicts of interest. LFAs are expected to interact closely with grant recipients and can attend Country Coordinating Mechanism (CCM) meetings³⁵. The CCM meetings provide LFA's opportunity to interact with other development partners and legitimize their role in public health interventions in which these hold no expertise.

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In addition to the LFA's the Global Fund has also appointed fiscal agents in 23 countries for tighter financial control and building the financial management capacity of grant-recipients³⁶. Fiscal agents are also private contractors (for profit agencies, e.g. GFA Group, Cardno consulting, etc.). The Fiscal Agent reviews, pre-approves and verifies all transactions related to grant activities and utilization³⁷. LFAs and Fiscal Agent come at a high financial cost and administrative burden to the programmes as these are 'for profit' private consulting or audit agencies. Exact costs are not available. However, in the 2017 Audit Report on Global Fund Grant Management in High Risk Environments mentioned costs for 23 countries: Fiscal agents cost an estimated US\$ 10 million a year; Local Fund Agents come at an annual cost of US\$ 14 million; and External Auditors at an estimated cost of US\$ 3 million. The report also points out that despite spending significant resources for mitigating fiduciary risks in high risk countries, the gaps in financial management remained³⁸.

DEBT2HEALTH INITIATIVE: GLOBAL FUND'S INVOLVEMENT IN SOVEREIGN DEBT In 2007, with assistance from BMGF, the Global Fund launched the 'Debt2Health' initiative³⁹ while it was still under the Administrative Services Agreement with the WHO – thus, providing it the legitimacy of a multilateral organization. Curiously, this was done just before the Global Fund was set to terminate its agreement with the WHO and launch itself as an independent financing organization. Very little about the initiative is in public domain. What is known is that under these Global Fund facilitated agreements creditors (States) forgo repayment of a portion of their sovereign debts (development aid credits) on the condition that the beneficiary countries (States) invest an agreed upon counterpart amount in health through the Global Fund (part of it going the Fund's overhead costs and part to be paid to private contractors). The Global fund calls this an 'innovative financing initiative' when in fact it is a sovereign debt swap involving a public private partnership.

The pilot phase 2007-2009 involved: Indonesia, Peru, Pakistan and Kenya. With this initiative the Global Fund clearly steps out of its remit as a public private partnership and raises the larger issue of the ethics of private sector involvement in sovereign debts.

Conclusion

GAVI is extolled for massive increase in resources for immunization. What is however not often discussed is that fact that this has come at the cost of promoting the 'Gates approach' to health governance that places emphasis on technological solutions to achieve quantifiable, quick, short-term results (Birn, 2005). It places great emphasis on new and novel vaccines rather than ensuring universal access to known and effective traditional vaccines (Heaton et al., 2002). GAVI promotes a market driven vision that includes protection of IPRs and market based pricing mechanisms. In spite of claims

to the contrary GAVI does not promote Health System Strengthening, nor does it promote national manufacture of vaccines. Key to these deficiencies is GAVI's governance structure, which includes private entities, though the bulk of GAVI's funding is public.

Another mega PPP, the Global Fund, seeks formalization of its status as a global organization that rivals inter-governmental organizations in power and privileges. Since 2009 it has been demanding blanket immunities and privileges from the grant recipient countries. Immunities and privileges to global public private partnerships in general and to the Global Fund in particular would further undermine democratic governance in health.

The unfettered power of both PPPs represent a threat to the hitherto nation state driven system of global governance for health. They clearly represent instances of private sector influence on activities which are public funded and which essentially take place in the public sphere.

Notes

- 1 See GAVI website: http://www.gavi.org/ support/sustainability/countries-eligible-forsupport/
- 2 Global Alliance for Vaccines and Immunization 1999, First Board Meeting, UNICEF House, New York, October 28.
- 3 GAVI, Governance, www.gavi.org/ about/governance/gavi-board/composition/ independent-individuals/
- 4 GAVI, Partners, www.gavi.org/about/partners/bmgf/
- 5 GAVI, Governance, http://www. gavialliance.org/about/governance/gavi-board/ composition/
- 6 GAVI, the Vaccine Alliance, Supply and Procurement Strategy 2016-20.
- 7 Hurvitz, J A 2008, Covington & Burling Biography, http://www.cov.com/jhurvitz/
- 8 Other terms used for tiered pricing are: "differential", "preferential", "discounted pricing", and "market segmentation".
- 9 Pan American Health Organization 1977, Resolution CD25.R27, 25th Directing Council, Washington, D.C.
- 10 PAHO, 52nd Directing Council, Principles of the Pan American Health Organization Revolving Fund for Vaccine Procurement, CD52/17, http://www.paho.org/ hq/index.php?option=com_content&view=ar ticle&id=8833&Itemid=40033&lang=en#resol utions
 - 11 ibid.

- 12 GAVI, HSS Support, www.gavi.org/support/hss/
- 13 GAVI, Health systems goal indicators. http://www.gavi.org/results/goal-level-indicators/health-systems-goal-indicators/. Published 2017. Accessed 22 March, 2017.
- 14 The Global Fund, *Government Donors:*Overview, https://www.theglobalfund.org/en/government/
 - 15 ibid.
- 16 The Global Fund, *Governance*, http://www.theglobalfund.org/en/documents/governance/
- 17 1) Implementing Country governments (7 Seats); 2)donor Country governments (8 Seats); 3) Foundations interested in providing financial and intellectual support to the Global Fund; 4 Private sector); 5) Civil Society, developed Countries; 6) Civil Society, developing Countries; 7) Communities; 8) Non-voting Seats (8 seats) Includes the United Nations Joint Programme on HIV/AIDS (UNAIDS); WHO, Partners (Roll Back Malaria, Stop TB, UNITAID), World Bank, host Country, Chair, Vice-Chair, Executive Director, http://www.theglobalfund.org/en/documents/governance/
- 18 The Global Fund, *Governance*, http://www.theglobalfund.org/en/documents/governance/
- 19 The Global Fund, *Government Donors*: *Overview*, https://www.theglobalfund.org/en/government/

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- 20 The Global Fund 2008, The Global Fund becomes an administratively autonomous institution as of 2009, 19 Decemberhttp:// www.theglobalfund.org/en/mediacenter/ newsreleases/2008-12-The Global Fund becomes an administratively autonomous institution as of 2009/
- 21 The Global Fund 2010, Moldova signs agreement to grant privileges and immunities to the Global Fund, 28 September, https://www.theglobalfund.org/en/news/ 2010-09-28-moldova-signs-agreement-togrant-privileges-and-immunities-to-the-globalfund/
- 22 Global Fund 2014, Thirty-Second Board Meeting, GF/B32/19 Montreux, Switzerland, 20-21 November.
 - 23 ibid.
- 24 The Global Fund 2010, Moldova signs agreement to grant privileges and immunities to the Global Fund, 28 September, https:// www.theglobalfund.org/en/news/2010-09-28moldova-signs-agreement-to-grant-privilegesand-immunities-to-the-global-fund
- 25 The Global Fund 2010, Moldova signs agreement to grant privileges and immunities to the Global Fund, 28 September, https:// www.theglobalfund.org/en/news/2010-09-28moldova-signs-agreement-to-grant-privilegesand-immunities-to-the-global-fund/
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 - 27 ibid.
 - 28 ibid.
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- 30 The Global Fund, Staff, https://www. theglobalfund.org/en/staff/>.
- 31 The Global Fund, Bill and Melinda Gates Foundation, https://www.theglobalfund.org/ en/private-ngo-partners/bill-melinda-gatesfoundation/
- 32 The Global Fund, Friends, https://www. theglobalfund.org/en/friends/
- 33 The Global Fund, LFA, http://www. theglobalfund.org/en/lfa/
 - 34 ibid.
- 35 The Global Fund, CCM, http://www. theglobalfund.org/en/ccm/

- 36 The Global Fund 2017, Audit Report: Global Fund Grant Management in High Risk Environments, Geneva, Switzerland, GF-OIG-17-002,23 January.
 - 37 ibid.
 - 38 ibid.
- 39 The Global Fund 2007, OQA Debt2Health, August.

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