

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

BOARD ON GLOBAL HEALTH
FORUM ON PUBLIC-PRIVATE PARTNERSHIPS FOR GLOBAL HEALTH AND SAFETY

The following document was provided to workshop participants as read-ahead material for the workshop session on “Legal Considerations for PPP Governance in Global Health.” The document was developed by the session moderator, with input from the workshop planning committee and forum staff, to create a scenario that would act as a problem-solving exercise for session panelists to respond to in order to surface legal considerations within different sectors when developing global health PPPs. The exercise allowed for a richer panel discussion.

II. Legal Considerations for PPP Governance in Global Health

Through a problem-solving exercise, this session will surface legal considerations within different sectors when developing global health PPPs. The discussion will aim to address questions including—What governance structures, processes, and practices are advisable from a legal perspective given a myriad of considerations such as leadership, conflicts of interest, data ownership, publicity, and flexibility in decision making? How does or should PPP governance emulate private sector governance? How does it differ? What are the legal considerations when operating across countries and international systems? In terms of acknowledging and valuing resources from all partners questions include—How are resources contributed from each partner acknowledged within the governance document? How is the value of in-kind resources defined? Panelists will discuss these questions and elaborate on the legal and regulatory constraints they have encountered and problem-solved for when structuring PPPs.

Fact Pattern

PARTIES:

- A. **Pharm Co** has a relatively new drug for vaccinating children.
- B. **Philanthropic Foundation** makes strategic investments in children's health.
- C. **Multilateral Alliance** represents country governments and their Ministries of Health, and is the lead coordinating body for global vaccination programs.
- D. **NGO** implements programs on the ground
- E. **The U.S. Department of State** has an office dedicated to setting policy and providing foreign assistance for children's health. This office provides funding to NGO to implement programs on the ground, and has a seat on the Board of Multilateral Alliance.

SITUATION:

- I. Pharm Co wishes to donate vaccinations to 1,000,000 children in Sub-Saharan Africa.

They wish to do so in partnership with a consortium of organizations that have a vested interest in children's health. All of the organizations share the same end goal: vaccinate 1,000,000 children.

The parties agree to create a new public-private partnership.

- II. The parties decide to put together a Memorandum of Understanding (MOU) outlining their respective roles and responsibilities in the partnership. That's when the lawyers get involved.

As with any corporate deal, the parties start doing due diligence on each other. In a routine due diligence search, a few interesting details emerge:
 - a) Pharma Co. was recently involved in litigation related to their business operations.
 - b) The Undersecretary of the Child Health Office at State owns stock in Pharma Co.
 - c) The President and benefactor of the Philanthropic Foundation is on the Board of the NGO.

SESSION II. LEGAL CONSIDERATIONS FOR PPP GOVERNANCE IN GLOBAL HEALTH

- III.** As part of their contribution to this partnership, the Philanthropic Foundation is providing funding to Pharm Co to adapt the drug compounds to make them more fit for purpose in developing countries.
- IV.** The US Government is providing funding through an existing, openly-competed grant to the NGO to handle the supply chain distribution, as well as the programmatic implementation on the ground.
- V.** The NGO is tasked with the monitoring and evaluation of the program, including data collection and analysis.
- VI.** In addition to this planned donation, both State and the Multilateral Alliance also procure \$1 million worth of other medications for treatment of other childhood illnesses.
- VII.** The donated drugs will be distributed and delivered through a supply chain managed by the Country Government.
- VIII.** There are three pharmaceutical manufacturers of this vaccine.
- IX.** The MOU lays out the planned contributions of each party. Each of the parties plans to assign a monetary value to their contribution to this partnership. Pharma Co.'s initial valuation includes all of the funding they invested in research and development of the drug.
- X.** The partners agree to set up a Secretariat, but haven't decided whether it should be staffed by an independent organization or be nested within one of the Partner organizations. Each organization will have one vote on the Secretariat. The parties are united on their programmatic priorities, but there are some differences in where they want to work geographically.
- XI.** The partners are also divided on their approach. The NGO and Multilateral Organization want to ensure broad coverage and are willing to take great efforts to find hard to reach children. State has prioritized impact. The Philanthropic Foundation is focused on sustainability and wants to ensure that there is a plan for absorbing costs in the future. Pharm Co wants to operate at scale.
- XII.** The MOU also includes provisions on reporting, branding, and publicity.