



Exclusion of vulnerable populations from vaccination due to public-private indemnity agreements

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Uncertain liability: vaccine manufacture during a pandemic



- Vaccines always carry a risk of injury.
- Injured vaccine recipients may have legal claims for compensation against manufacturers.
- During a pandemic, vaccines are developed quickly and may not be subject to full regulatory authorization when marketed.

This impacts manufacturers by making it more difficult to (1) anticipate the likely frequency and severity of any injuries and (2) obtain insurance coverage for any claims for vaccine injury.

Problem...

Manufacturers have sought reassurance from purchasers regarding their exposure to compensation claims before they will deliver vaccine doses.

Potential Solutions:

1. **Immunity** – a total bar on claims.
2. **Indemnity** – the purchaser agrees to compensate the manufacturer for any liability or loss.
3. **No-fault compensation schemes** – an alternative means of compensating injured people. Civil claims may still be permitted in parallel.

Purchase Agreement between Pfizer BioNTech and Brazil

8.1 Indemnification by Purchaser

Purchaser hereby agrees to indemnify, defend and hold harmless Pfizer, BioNTech, each of their Affiliates..., from and against any and all suits, claims, actions, demands, losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' and other counsels' fees and other expenses of an investigation or litigation), whether sounding in contract, tort (delict), intellectual property, or any other theory, and whether legal, statutory, equitable or otherwise by any natural or legal person (collectively, 'Losses') caused by, arising out of relating to, or resulting from the Vaccine, including but not limited to any stage of design, development, investigation, formulation, testing, clinical testing, manufacture, labeling, packaging, transport, storage, distribution, marketing, promotion, sale, purchase, licensing, donation, dispensing, prescribing, administration, provision, or use of the Vaccine, any information, instructions, advice or guidance provided by Pfizer and relating to the use of the Vaccine...

Further Impacts – Restrictions on Donation

- Manufacturers have included clauses in purchase agreements restricting States from donating vaccine doses to other countries, due to concerns that they will incur liability in those States.
- States have been required to conclude separate bilateral indemnity agreements with manufacturers before they can receive donated doses.

Vaccine Cooperation: in theory and practice

The COVAX Advance Market Commitment. A partnership between wealthy and low-and middle-income countries to ensure global vaccine coverage. COVAX would invest in a portfolio of vaccine candidates using contributions from 79 wealthy “self-financing” governments. 92 lower-income “donor supported” governments would provide reduced financial commitments and receive subsidized prices for doses.

If all participating States had utilized the COVAX AMC to procure doses, the Facility could have presented a united front to manufacturers on issues like indemnification and enjoyed greater leverage as a result of the involvement of the wealthy States.

Instead of purchasing doses through COVAX, States in the Global North concluded bilateral agreements with vaccine manufacturers. This **failure to cooperate** reduced the doses available through COVAX and set the tone in relation to indemnities by:

1. Leading manufacturers to believe that demands for indemnities would be met; and
2. Setting a precedent that indemnities would be concluded on a country-by-country basis. As a result, donor-supported governments receiving doses through COVAX are required to conclude indemnity and liability agreements with manufacturers.

Vaccinating the Vulnerable: The COVAX Humanitarian Buffer

- A measure of last resort for high-risk and vulnerable populations.
- Up to 5% of COVAX’s doses can be delivered through this arrangement.
- Applications can be made by States that are COVAX participants and humanitarian agencies.
- Buffer doses are likely to be needed where States are unwilling or unable to include populations in their national plans. Therefore, applications are most likely to come from humanitarian agencies.

...the impact of failure to cooperate around indemnities - paralysis of the Humanitarian Buffer

- Like States, humanitarian agencies are required to indemnify manufacturers before doses will be delivered.
- In June 2021, it was reported that the WHO, UNICEF, the Red Cross, and Médecins Sans Frontières could not administer vaccines under the Humanitarian Buffer if they had to assume liability.
- No doses were delivered before November 2021. As of 6 May 2022, doses have only been delivered to the Ministries of Health in Iran and Uganda.
- Gavi has now secured indemnity waivers for seven vaccines, but many manufacturers (including Pfizer, AstraZeneca and Moderna) have not provided such indemnities.

Potential Solutions:

Cooperation to ensure vulnerable actors are not left behind. A framework agreement to structure future legal negotiations. Immunities for manufacturers and a globalized no-fault compensation fund to compensate injured people.