



# Creating Advanced Market Commitments and Prizes for Pandemic Preparedness

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## Summary

As part of its [American Pandemic Preparedness plan](#), the Biden Administration should establish an interagency working group (IWG) focused exclusively on the design, funding, and implementation of advance market commitments (AMCs) and prizes for vaccine development. Under an AMC, pharmaceutical companies commit to providing many vaccine doses at a fixed price in return for a per-dose federal subsidy. Prizes can support AMCs by rewarding companies for meeting intermediate technical goals.

The IWG would immediately convene experts to identify suitable targets for ambitious vaccine-development and deployment efforts. The group would then work with stakeholders to implement AMCs and prizes crafted around these targets, offering a concrete and durable demonstration of the Administration's commitment to proactive pandemic preparedness. As the American Pandemic Preparedness plan argues, an important part of rapid vaccine deployment is maintaining [“hot manufacturing capacity”](#). Clear federal AMCs would create the market incentive needed to sustain such capacity, while simultaneously advancing procurement expertise within the federal government, in line with recent recommendations from a government [review on the US supply chain](#).

## Challenge and Opportunity

Vaccines are very cost-effective medical interventions that have played a large role in reducing pathogen-induced deaths over the last 200 years. But vaccines do not yet exist for many diseases, including diseases concentrated in the developing world. Vaccines are [undersupplied](#) relative to their social benefit because their target populations are often poor and because strong political pressure for lower prices leads to low expected profits. When new vaccines *are* approved, scaling up production to fully supply low and middle-income countries (LMICs) can take up to 15 years. AMCs solve these issues by incentivizing vaccine development and hastening production scale-up. Prizes play an intermediate role by offering rewards for meeting technical goals along the way.

Vaccine AMCs have a track record of success. In 2007, GAVI, a public-private global health partnership based out of Geneva, launched an AMC for a pneumococcal conjugate vaccine (PCV) that covered pneumococcal strains more common in the developing world. The partnership received its first supply offers in 2009 (a fairly rapid response enabled by the fact that some PCV candidates were already in late-stage clinical trials). Compared to the rotavirus vaccine — which was developed around the same time but did not receive an AMC — PCVs achieved 3–4x greater coverage (defined as the fully vaccinated fraction of the target population). Moreover, new vaccines typically take about 10–15 years to become widely available in LMICs. PCV became available in those countries within a year. This example demonstrates the

capacity of [AMCs to incentivize rapid scaling](#). More recently, the United States (through Operation Warp Speed) and several other countries and organizations purchased substantial COVID-19 vaccine doses [far in advance of approval](#), albeit using a more flexible AMC model that prioritized scaling production before data from clinical trials were available.

## Plan of Action

To build on the progress and demonstrated success outlined above, the Biden Administration should invest in AMCs and prizes for vaccine development and deployment as part of its [American Pandemic Preparedness plan](#). Below, we detail three specific recommendations for moving forward.

### Recommendation 1. Form an Interagency Working Group (IWG) on Rapid Vaccine Innovation

Vaccine development and manufacturing is a multi-stage process that is too complicated for any single federal agency to manage. The Biden Administration should issue an Executive Order establishing an IWG on Rapid Vaccine Innovation.

#### *Roles and responsibilities*

Under emergency circumstances, the IWG would be the government hub for time-sensitive vaccine-procurement efforts. Under normal (non-pandemic) circumstances the IWG would focus on extant communicable diseases with a high disease burden and on potential future threats. This latter function would be carried out as follows.

- **Step 1: Vaccine targeting.** A “horizon scanning” IWG subgroup would identify priority targets for rapid vaccine development and broad deployment. The subgroup would consider factors such as pandemic potential, current disease burden, and vaccine tractability. The IWG would also consult with scientists at the VRC (whose [work was essential](#) to the rapid development of COVID-19 vaccines, and who already focus on viruses with pandemic potential) and at the CDC (which already performs pathogen surveillance) in making its determinations. Options for initial vaccine targets could include:
  - A [universal coronavirus vaccine](#) in response to the emergence of [potentially immune-evading variants](#) of COVID-19.
  - A [universal influenza vaccine](#), like the one already under early-stage development at the National Institutes of Health (NIH).
  - A vaccine against **Group A streptococcus (GAS)**. GAS kills about 500,000 people globally annually, mostly through heart and kidney complications or [severe infections](#). Much of this burden falls on LIMCs.

GAS also drives [high use of antibiotics](#), which may contribute to antibiotic resistance. A successful AMC for a GAS vaccine would save hundreds of thousands of lives. Fortunately, there are [multiple](#) promising GAS [vaccine](#) candidates in early trials. A [human-challenge](#) model with potential to accelerate development already exists, and [relevant experts and the World Health Assembly](#) acknowledge that GAS prevention should be prioritized. Since two of the leading vaccine candidates are being developed by close U.S. allies (Australia and Canada), prioritizing GAS vaccine development would have the added benefit of strengthening us and our allies as global tensions rise.

- **A better tuberculosis vaccine.** The technological distance to a better tuberculosis vaccine is greater than the technological distance to a GAS vaccine. But since tuberculosis likely kills twice [as many](#) people each year, development of a tuberculosis vaccine would also have a greater payoff.
- An AMC could be deployed to incentivize rapid scale-up of the [recently tested malaria vaccine](#). This could be a flagship program of the United States' response to China: the [Build Back Better World \(B3W\)](#) initiative, which includes “health and health security” as one of its four priorities. Scaling up deployment of the malaria vaccine in Africa and Southeast Asia would be an excellent way for the United States to regain influence lost in those regions to China’s Belt and Road initiative.
- Recent studies indicate a strong connection between [multiple sclerosis and the Epstein-Barr virus](#) (EBV) and Moderna has recently performed early-stage trials targeting EBV with an [mRNA vaccine](#) candidate. Acutely, EBV causes mononucleosis and has been linked with multiple cancers and autoimmune diseases.
- The Strategic National Stockpile (SNS) purchases and stores substantial quantities of vaccines and therapeutics for availability during an emergency. As more countermeasures are developed and then stocked, the [financial burden of maintaining the stockpile increases](#), since expired medications must be replenished over time. There is already an [FDA initiative](#) to extend the shelfspan of therapeutics but a targeted strategy to develop vaccines that are shelf-stable for longer and in more varied conditions could reduce the budgetary burden of stockpile maintenance.
- **Step 2: Incentive design.** Once one or more vaccine targets are identified, an IWG subgroup comprising health economists and budget officers would design the AMC(s) and intermediate prizes intended to spur development and deployment of the target(s). Incentive design would (i) be carried out with

substantial input from BARDA, which is familiar with the vaccine-manufacturing landscape, and (ii) consider both the technological distance of the target and market competitiveness. An output from this step would be a Vaccine Incentive Roadmap describing the different prizes and incentives that federal agencies will offer to ensure fast, consistent progress towards development and deployment of the target(s) in question. In other words, the linked prizes included in the roadmap will produce sustained incentives for continued forward progress on vaccine development. More information on this roadmap is provided below.

### *Structure and participation*

The IWG should be structured as an [integration](#), with each participating agency providing specific expertise on each aspect of the IWG's charge. Participants should include senior leaders from the Biomedical Advanced Research and Development Authority (BARDA), the Centers for Disease Control and Prevention (CDC), the Department of Defense (DOD), the Food and Drug Administration (FDA), the U.S. Agency for International Development (USAID), US International Development Finance Corporation (DFC), and the Vaccine Research Center (VRC). BARDA has a track record of successful procurement of vaccines and expertise in negotiating with manufacturers. VRC's founding mission is vaccine development and it has collaborated with manufacturers on large-scale production for multiple vaccines. They would provide expertise on vaccine tractability. Through upfront guidance on minimum efficacy requirements, the FDA will ensure vaccine standards. FDA will also work with global regulators on the possibility of regulatory reciprocity, akin to their [PEPFAR program, which assists low-resource regulators](#) in low and middle-income countries with decision-making.

The IWG should be chaired by a biosecurity expert housed at the White House Office of Science and Technology Policy (OSTP).

### *Congressional notification*

The IWGs recommendations (regarding both targets and AMC/prize design), once finalized, would be submitted to the Senate Health and House Ways and Means Subcommittee to request funding. Because federal agencies must notify Congress if they plan to disburse large prize sums (with agency-specific thresholds), this submittal would also serve as the required formal notification to Congress of prize amounts.

## **Recommendation 2. Carry out the IWG’s Vaccine Incentive Roadmap**

After the IWG has issued its recommendations on vaccine target(s) and incentive (AMC and prizes) design, implementation must follow. Where implementation support comes from will depend on the “technological distance” of the target(s) in question.

**Early-stage development** focused on in-vitro or animal research should be supported with prizes from BARDA, the Department of Health and Human Services (HHS), and NIH. All federal agencies already have the authority to award prizes under the [America Competes Act](#). Initial prizes could be awarded to vaccine candidates that successfully protect an animal model against disease. Later prizes could be awarded to candidates that hit clinical milestones such as completion of a successful Phase 1 trial in humans. We note that while agencies can theoretically pool funds for a multi-stage prize, cumbersome interagency processes mean that it will likely be easier to have separate agencies fund and oversee the separate prizes included in the roadmap.

**Later-stage development** should be supported with larger prizes or purchases from USAID and DOD. Once a vaccine candidate has reached early-stage human clinical testing, larger prizes and/or different funding mechanisms will likely be required to advance that candidate to later-stage human testing. This is because costs of moving a vaccine candidate from the preclinical stage to the end of phase 2A (early-stage human clinical testing) range from \$14 to \$159 million dollars.

It is unlikely that a single federal agency would have the discretionary funds or willingness to sponsor a prize sufficient to incentivize participation in this process. Federal partnerships with private-sector entities and/or philanthropies could supplement federal prize funding. The promise of being a government-approved vendor of a vaccine or a DOD-supported prototype would serve as incentive for external entities to enter into such partnerships. USAID could also leverage its relationships with global health stakeholders and funders to provide incentive funding. Of course, external funding partnerships would be unnecessary if Congress appropriated sufficient designated funding for large vaccine-incentive prizes to relevant agencies.

An alternative to prize funding that would be appropriate for incentivizing later-stage R&D is use of the DOD’s [Defense Commercial Solutions Opening \(CSO\)](#) purchasing authority. DOD could use its CSO authority to pre-purchase vaccine doses in large quantities, effectively creating an AMC. Purchases of up to \$100 million can be made [through CSO authority](#). Early prize negotiations would use the leverage provided by becoming a government-approved vendor of vaccines (part of the CSO process) to negotiate for fair prices.

A second DOD purchase authority that could be used as an AMC-like incentive is the [Other Transaction Authority \(OTA\)](#), which exempts the DOD from some federal

procurement regulations. OTA authority could likely be used to support vaccine research, purchase vaccine prototypes, and pay for some manufacturing of a successful prototype. OTA has also been used to fund research consortia, a possible alternative to a multi-stage prize roadmap. Purchases of up to \$20 million can be made through OTA authority. In the context of diseases that affect low and middle income countries, a loan from the [US International Development Finance Corporation](#) (DFC) may be an option for supplementing an AMC.

**Recommendation 3. Permanently expand BARDA’s mandate to include all communicable diseases, expand BARDA’s funding, and make BARDA the IWG’s permanent home**

An IWG is a powerful tool for bringing federal agencies together. With existing prize authority and an administration that prioritizes vaccine development and deployment, much could be accomplished through only the steps outlined above. However, achieving truly transformative results requires a permanent and sustainably funded federal agency to be working consistently on advancing vaccines. Otherwise, future administrations may cancel ongoing IWG projects and/or fail to follow through. As the part of the federal government with the most expertise in therapeutics procurement, BARDA is an ideal permanent home for the IWG’s functions.

BARDA’s mandate is currently limited to biological, chemical, or radiological threats to the health of Americans. This mandate should be expanded to include all important communicable diseases. The newly empowered BARDA would manage public-private partnerships for vaccine procurement, while the NIH would remain the fundamental health-research arm of the U.S. government. Expanding BARDA’s mandate would require Congressional action. Congress would need to amend the [Pandemic and All-Hazards Preparedness and Advancing Innovation Act](#) appropriately, and would also need to appropriate specific funding for BARDA to carry out the roles and responsibilities of the IWG over the long term.

## Frequently Asked Questions

### **1. What if we give pharmaceutical companies a bunch of taxpayer money to develop vaccine targets and they fail?**

Prizes and AMCs only pay out when a product that meets pre-specified requirements is approved, so taxpayers won't pay for any failures.

### **2. Tell me more about AMC design. What changes if a vaccine candidate is in the early-stage as opposed to the later-stage?**

For technologically “close” vaccine targets with a high chance of imminent Phase 3 trial success, an AMC incentivizes rapid scale-up of manufacturing and ensures that more doses reach more people sooner. The AMC does this by circumventing a type of “hold-up” problem wherein purchasers negotiate vaccine prices down to per-unit costs. The 2007 GAVI Pneumococcus AMC was of this type. A GAS or malaria vaccine would similarly be “close” targets.

For more technologically distant targets, AMCs should incorporate “kill switches” that give future customers of the vaccine an effective veto over the AMC by way of not paying co-payments. This feature is designed to be a final check on the utility of a vaccine and avoids the difficulty of specifying standards for a vaccine many years ahead of time. An AMC structured in this way works well if a company manufactures a vaccine that meets pre-specified technical details but for hard-to-predict reasons is not useful.

For an especially distant target, a series of prize competitions could substitute for a traditional AMC. In this scenario, an initial prize could be awarded for any vaccine candidates that successfully protect an animal model against disease. A later prize could be awarded to candidates that hit clinical milestones such as completion of a Phase 1 trial in humans.

Other details of AMC and/or prize implementation depend on the market structure and cannot be determined ahead of time. For instance, the optimal AMC design is very different in monopoly versus competitive markets.

### **3. Why does this memo you propose a complicated multi-stage prize process instead of something simple like Operation Warp Speed?**

Operation Warp Speed spent about \$12 billion dollars on COVID-19 vaccine development and purchased hundreds of millions of vaccine doses far in advance of approval or clinical trials. While this was very effective, it is unlikely that Congress would be willing to appropriate such a large sum of money — or see that money disbursed so freely — in non-pandemic situations. A multi-stage prize process still incentivizes vaccine development and deployment but does so for a lower cost.



#### **4. How can the federal government carry out these recommendations without provoking anti-vax sentiment?**

The government could fund research into market segmentation for vaccines, since many who are vaccine-hesitant are avid consumers of alternative health products/supplements. There may be marketing and promotional strategies inspired by “natural” supplements that can increase vaccine uptake.

#### **5. Doesn't the federal government already fund influenza vaccine preparation? Why do we need a universal flu vaccine?**

The federal government does fund influenza vaccine preparation, but that funding is only for a seasonal flu vaccine that works with [40–60% efficacy](#): a rate that is well below what other vaccines, such as the [measles](#) (97%) and [mumps](#) vaccines (88%) achieve. A pandemic influenza with an unexpected genetic background could still catch us by surprise. Investing in a universal influenza vaccine is essential in preparing for that eventuality.

#### **6. What are the most likely points of failure for the steps outlined in this memo?**

One issue is staffing. Drafting a high-quality AMC contract may require legal and economic expertise that isn't available in-house at federal agencies, so the administration may need to engage external AMC experts. Another issue may be ensuring that activities outlined herein do not fall between interagency “cracks”. Assigning dedicated staff to oversee each activity will be important. A third issue is the potential for interagency friction. The more agencies that are involved with prize design, the longer it may take to design and authorize a given prize. One possible solution is to have only one agency administer each prize, with informal input from staff in other agencies when required.

## About the Author



**Willy Chertman** is a recently graduated physician working with 1Day Sooner as advocacy lead. He is fascinated by health policy and research regulation and hopes to popularize innovative mechanisms to solve market failures in global health. In his spare time, he reads and blogs about the history of medicine and its regulation. He graduated from the University of Miami Miller School of Medicine with a MD/M.S. in Genomic Medicine and from the University of Miami with a B.S. in Biology and Political Science.

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