



August 25, 2020

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
317 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Nancy Pelosi
Speaker
House of Representatives
1236 Longworth Office Building
Washington, D.C. 20515

The Honorable Chuck Schumer
Democratic Leader
U.S. Senate
322 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Kevin McCarthy
Minority Leader
House of Representatives
2468 Rayburn House Office Building
Washington, D.C. 20515

Dear Leader McConnell, Speaker Pelosi, Leader Schumer and Leader McCarthy:

We write to encourage you to provide funding in the next COVID-19 relief package to test the efficacy of low-cost, existing vaccines against the virus.

Existing, widely-available vaccines have the potential to protect against COVID-19, as well as prevent or mitigate future pandemics caused by other viruses.

For nearly 100 years, it has been known that an existing vaccine— specifically, a “live attenuated vaccine” using a weakened (or attenuated) form of the germ that causes a disease—can have “off-target” effects, providing a broad range of protection, beyond the pathogen it was originally designed to target. Researchers have continuously confirmed this phenomenon, and recently unearthed how it happens. By boosting the overall immune system, including enhancing macrophage and natural killer cell function, certain live attenuated vaccines build a broad umbrella of protection against a wide range of pathogens — a response known as “trained innate immunity.”

While the scientific case for exploring the efficacy of certain existing live attenuated vaccines is strong, the commercial potential is low, as these vaccines are already widely available, cost as little as pennies per dose, and are off-patent. The private sector thus has little incentive to invest. As a result, there is a major market failure, in which the minute level of R&D funding is simply incommensurate with the enormous scale of the public health opportunity.

A small amount of funds - \$10.0 million - would be sufficient to support the work. It would complete Phase 3 clinical trials across multiple vaccine candidates, combinations, and cohorts, create the needed infrastructure, and support related work. If efficacy is found, it would be possible to leverage the large existing manufacturing resources and start to reach the population in as little as six to twelve months. *De minimis* support of \$3 million would fund one Phase 3 clinical trial for one of the potential vaccines, and related work.

Existing, widely-available, off-patent vaccines have a number of potential advantages over proprietary new vaccine candidates:

- *Speed:* Repurposed vaccines are radically faster to develop.
- *Cost:* They are 100-1000 times less costly to develop.
- *Safety:* Repurposed vaccine can have decades of safety history.
- *Manufacturing:* Large scale manufacturing is already in place.
- *Certainty:* Vaccine development is difficult. The proprietary novel vaccine candidates under development are still just candidates; there is no guarantee that a new vaccine will arrive in short order, or that it will be fully effective.
- *Combination:* Repurposed existing vaccines may potentially be used in combination with new vaccines, should they arrive. They can be complementary, with different and valuable scientific effects.
- *Acceptability:* Repurposed vaccines that are already widely utilized and familiar will possibly be better accepted by the public, given their long histories of use.
- *Affordability:* Prices can be as low as pennies per dose.
- *Open IP:* Off-patent repurposed vaccines have open intellectual property (IP), enabling multiple producers to participate in the market.
- *Ethical Use of Public Funds:* Rather than using public funds to subsidize the development proprietary products over which private corporations would hold a monopoly—and for which they may charge a prohibitive price, with taxpayers paying fore and aft—public funds can be directed toward public/open intellectual property and affordable treatments. This presents a better deal for the public.
- *Future Pandemics:* Repurposed vaccines may also prevent or mitigate future pandemics, given the broad umbrella of protection triggered by trained innate immunity. They could be an armamentarium for humanity.

In brief, repurposed existing, widely available, off-patent vaccines could be near the front of the global pandemic vaccine race, as they are at Phase 3, and also have huge advantages in manufacturing, acceptability, and affordability. Further details are attached as an enclosure.

Given the gravity of the situation, the urgency, and the potential for impact, we urge you to include funding for repurposed vaccines in the next COVID-19 legislative action. We would like to request a meeting with you to discuss this at your earliest convenience. Please reach out to vaccine@ospfound.org to coordinate.

Sincerely,

Paul Farmer, MD, PhD
Kolonotron University Professor of Global Health and Social Medicine

Harvard Medical School

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Columbia University

Tachi Yamada, MD
Venture Partner, Frazier Health Care Partners
Former Chair of R&D, GlaxoSmithKline
Former President, Global Health, Bill and Melinda Gates Foundation

CC:

U.S. Senator Richard Shelby, Chairman of the Senate Appropriations Committee

U.S. Senator Patrick Leahy, Ranking Member of the Senate Appropriations Committee

U.S. Senator Roy Blunt, Chairman of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

U.S. Senator Patty Murray, Ranking Member of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies and the Senate Health, Education, Labor & Pensions (HELP) Committee

U.S. Senator Lamar Alexander, Chairman of the Senate Health, Education, Labor & Pensions (HELP) Committee

U.S. Representative Nita M. Lowey, Chairwoman of the House Committee on Appropriations

U.S. Representative Kay Granger, Ranking Member of the House Committee on Appropriations

U.S. Representative Rosa DeLauro, Chairwoman of the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

U.S. Representative Lucille Roybal-Allard, Vice Chair of the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Enclosure: