How the Next President Can Ensure Everyone Gets the Medicine They Need, Through the Pandemic and Beyond

The coronavirus pandemic threatens everyone. Yet millions of people and many communities are especially vulnerable to viral transmission, economic disruption and systemic discrimination, and the pandemic places their future in exceptional danger. For people who cannot afford to wait for a vaccine and people who cannot afford treatment, for people who live with underlying medical conditions or without insurance, the monopoly control of medicine is a grave risk.

Forthcoming coronavirus treatments and vaccines will be patented by single corporations selling limited supply at high prices unless governments, especially the U.S. government, make new choices. Even if public programs spend to make treatments and vaccines free to people, high prices may force those programs to ration or limit other essential services. The monopoly control of data, knowledge and patented inventions will slow the development of better medicine. Perhaps most dangerous of all, no corporation manufactures at scale to supply the entire world. In the United States, the rich may buy their way to the front of the line while the poor wait. In developing countries, the wait could be years. Scarcity may contribute to conflict. Many more people could die needlessly, and vulnerable communities suffer enduring economic hardship, through rationing and delay that could become a form of global vaccine apartheid.

As we course deeper into the pandemic, challenges to people's existing health conditions will deepen as well. Cost-related rationing of insulin may become more frequent. Social isolation and unemployment are likely to contribute to addiction and overdose. Cities will need plentiful supplies of naloxone to prevent a spike in deaths of despair.

The U.S government has the capacity and authority to research, develop and manufacture medicine at immense scale, or have this done on its behalf under existing law. Upon taking office, **the next President must urgently**:

- **Share medical technology** with the public and the world, by licensing patents, sharing data and providing technical assistance, so that tests, treatments, protective equipment and vaccines can be widely manufactured and made available at robust affordable supply.
- **Support public manufacturing of medical tools**, by and for the people, including protective equipment, medicines in shortage, COVID-19 treatments and vaccines.
- **Require affordability** as a condition of government contracts with medical manufacturers.
- **Publish research data** to accelerate science and help experts assess safety and efficacy.
- **Publish the contracts** with medical manufacturers, so people can know what access terms have been negotiated in exchange for billions of taxpayer dollars.

In a sense, the world's vaccine response is heartening. There are more than one hundred vaccine candidates under investigation. Governments and major foundations are spending billions to accelerate future manufacturing. But there is a critical element missing in their plans: Few seem prepared to require basic conditions of the corporations benefiting from massive taxpayer giveaways. Instead, funders, especially the Trump administration, offer deference (or worse, apparent corruption). That deference could mean delays in public vaccine access, through limited supply, high costs or inadequate science.

An effective vaccine may not be available until 2021 or later. It may take longer still to manufacture at scale. The pandemic itself could course for several years. As terrible as this is, it also means the next administration has time to make a major difference if it acts quickly and with resolve. President Trump will be useful only for his illustration of what not to do. But early action by a new administration in 2021 still would be timely to accelerate vaccine and treatment production, ensure fair prices and share technology with the world.

Leveraging Taxpayer Support for Research and Development

The National Institutes of Health (NIH) spend approximately $40 billion annually on biomedical research, ultimately contributing to underlying basic research of virtually all new medicines that reach the market, and increasingly supporting late stage development. Recently Congress has allocated billions of dollars to the Biomedical Advanced Research and Development Authority (BARDA) to support pandemic response. BARDA is giving grants in the hundreds of millions of dollars to pharmaceutical corporations. Both NIH and BARDA typically rely on private sector partnerships to commercialize medicines. Unfortunately, neither attaches conditions sufficient to ensure medicine affordability or accelerate science through open research. Neither requires the technology transfer needed to help the world manufacture at scale.

The U.S. government can change this with tools under existing law -- no congressional action needed. BARDA and NIH can attach technology transfer and reasonable pricing conditions to future contracts. Government agencies can clear patent barriers and authorize competition with 28 USC 1498 (government use of patents, in exchange for reasonable royalties to patent holders). The government can license medical inventions it owns, as well as those it has funded to qualified manufacturers through paid-up, worldwide licenses (retained pursuant to 35 USC 202, 35 USC 209, 15 USC 3710a or otherwise), to partner governments, to the World Health Organization and other entities, so that research institutions can draw on the latest science and manufacturers worldwide can help ensure adequate and affordable supply, for people everywhere.

Importantly, if the President were to announce a commitment to this approach, it very likely could be negotiated with vaccine intellectual property holders and manufacturers, without resort to compulsory tools. The vaccine companies would be well and fairly compensated; and it would be very hard for them to resist the humanitarian imperative if the President were calling on them to meet a once-in-a-hundred-year crisis.

Public Production

The government can ramp up manufacturing under authorities included in the Defense Production Act and Pandemic and All-Hazards Preparedness Act among others. These include authorities to prioritize government contracts with manufacturers, to install public manufacturing capacity in private facilities and to advance new public manufacturing of tests, treatments, protective equipment and medicines. The U.S. should scale up its several existing manufacturing facilities for this purpose and build more.

If the U.S. government takes these steps for COVID-19 related treatments and vaccines, for medicines in shortage and medicines to care for the most vulnerable (for example, producing reliable and affordable supplies of insulin and naloxone delivery devices domestically), the pandemic will do far less damage. Many people's lives will be saved, and many more will get the help they need.

An Alternative to Scarcity

Shortages of protective equipment have contributed to the deaths of many. Limited supplies of treatments and vaccines could kill many more. Scarcity early in the pandemic aggravated political tension as states competed for early access to PPE from manufacturers. We can imagine this problem getting much worse. The world will resent the United States if it hoards available doses of a vaccine. People living in the United States will suffer if China develops an effective vaccine and has not shared the technology.

There is an alternative to scarcity. While only one person can take any given dose of a vaccine, all of humanity can benefit from the underlying science. Many countries and manufacturers worldwide can help make vaccines and medical tools, if they know how and have access to the technology. This will not happen automatically. Many key technologies are owned or otherwise held secret by corporations (even though public investment and federal scientists were essential in their development). Corporations license these technologies and share knowledge when the price is right and alliances suit their interest. The same is holding true for vaccines and will continue to do so, unless governments make a different choice. Through technology transfer – licensing patents, publishing data and sharing know-how and where necessary ensuring effective training and technical assistance – countries can provide for their own people and share with humanity at the same time. The United States can help other countries help themselves. This is one way to help humanity, save lives and restore American leadership.