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Backgrounder: Scaling-up COVID-19 Treatment and Vaccine Access

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Public health experts agree we will not escape from the pandemic until we have an effective vaccine. However, too little attention is being paid to the problem of scaling up vaccine production, something that will be impossible if one or a couple firms maintain exclusive control over a vaccine's (or multiple vaccines') intellectual property and associated know-how. There is a very real risk that, on our current course, it will take years to produce enough vaccine to meet the global need. That in turn raises disturbing prospects of rationing and misallocation, with poor countries left to suffer the ravages of COVID-19 while rich countries – or at least the wealthy in rich countries – obtain access. We are facing very foreseeable nightmare scenarios of our own making, but they are entirely avoidable, if the world acts proactively and cooperatively, now.

The COVID-19 pandemic raises pressing concerns about treatment and vaccine access, including:

- How can governments prevent rationing of forthcoming COVID-19 treatments and vaccines, given limited manufacturing capacity?
- Will people, payers and health programs be able to afford vaccines and treatments?
- Will patents and commercial secrecy inhibit the COVID-19 response?
- How can governments work together to accelerate technology transfer and scale up manufacturing?

This backgrounder briefly addresses each in turn.

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How can governments prevent rationing of forthcoming COVID-19 treatments and vaccines, given limited manufacturing capacity?

- Once a treatment or vaccine is proven safe and effective, it must be available to everyone who needs it as soon as possible, with priority to healthcare workers and vulnerable populations.
- **Manufacturers are not prepared to operate at the massive necessary scale.** There could be a significant lag time between readiness of the first vaccine and its availability to all.
 - No major company has agreed to mass produce the vaccine being co-developed by the National Institutes of Health. Dr. Anthony Fauci, director of the NIH's National Institute of Allergy and Infectious Diseases, said the amount of time needed to start scaling up vaccine production could be "as problematic" as the time to develop the vaccine itself.¹
- Governments and major donors should urgently invest in developing public manufacturing capacity and license the needed patents and proprietary information for public use.

¹ <https://www.fiercepharma.com/pharma/amid-deadly-outbreak-nih-hasn-t-found-its-pharma-partner-to-manufacture-coronavirus-vaccines>

- The **Pandemic and All Hazards Preparedness Act** allows the U.S. government to produce qualified pandemic or epidemic products, which can include medicines in shortage.² The **Defense Production Act** allows the U.S. government to enlist the private sector and coordinate the response. **28 U.S.C Section 1498** allows the government to overcome any patent barriers and authorize additional generic producers.³

Will people, payers and health programs be able to afford vaccines and treatments?

- In the U.S., Medicare and private insurers are covering diagnostic tests with no cost sharing, and the stimulus bills recently passed by Congress require insurers and Medicare Part B to provide a future vaccine with no cost sharing as well. Congress has yet to provide protection to people without insurance, or to address cost sharing for treatments.
- Tests, treatments and vaccines available to people at the point of care may still be extremely expensive to health programs that purchase them, contributing to increased premiums in the United States and **treatment rationing in resource-poor countries**.
- The major manufacturers developing candidate treatments and vaccines are slated to benefit from patent monopolies and regulatory exclusivities, and have yet to make firm commitments regarding price and availability.
- **Public funding has driven most of the research and development for treatments and vaccines.**
 - o In February, Public Citizen found that the National Institutes of Health alone had spent nearly \$700 million on coronavirus R&D since 2002, laying the groundwork for the COVID-19 response.⁴ Since then, Congress has appropriated billions more.⁵
 - o For example, the federal government's Biomedical Advanced Research and Development Authority has so far awarded Johnson & Johnson \$605 million and Regeneron \$93 million to develop medicines and scale-up manufacturing capacity.⁶
- Lawmakers have demanded that federally-funded products be affordable.
 - o Rep. Jan Schakowsky (D-III.) joined 45 colleagues asking the government not to provide monopoly rights to any private manufacturer for a coronavirus vaccine or treatment through federal contracts and, at a minimum, **require reasonable pricing**.
- The U.S. government has power under existing law to authorize generic competition and, separately, ensure reasonable pricing of federally-funded inventions.
- Public Citizen and 70 other groups have issued a call to prevent pharma profiteering.⁷

² Among other things, this includes a drug, biological product, or device "manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic, or *limit the harm such a pandemic or epidemic might otherwise cause.*" [emphasis added] 42 USC § 247d-6d(i)(7).

³ <https://digitalcommons.law.yale.edu/vjolt/vol18/iss1/7/>

⁴ <https://www.citizen.org/article/blind-spot/>

⁵ Congress has appropriated \$415 million to DOD, \$1.8 billion to the NIH, and at least \$6 billion to BARDA for research, manufacturing and procurement combined. See Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 and Coronavirus Aid, Relief, and Economic Security Act, 2020.

⁶ https://www.usaspending.gov/#/award/CONT_IDV_HHSO100201700018C_7505 and

https://www.usaspending.gov/#/award/CONT_AWD_HHSO100201700020C_7505_-NONE_-NONE-

⁷ <https://www.citizen.org/news/public-citizen-and-70-organizations-call-on-trump-to-prevent-pharma-profiteering-on-coronavirus/>

Will patents and commercial secrecy inhibit the COVID-19 response?

- Patents and other government-granted exclusivities allow manufacturers to prevent competitors from using the same technology. This already appears to be inhibiting the production of **N95 masks**.⁸ Exclusivities and commercial confidentiality could **slow the rollout of new medical tools, limit manufacturing capacities, impose monopoly pricing and fragment the available science**.
- Governments around the world are considering compulsory licensing. A **compulsory license** allows the government or other manufacturers to use and produce patented inventions, including medical tools, treatments and vaccines, in exchange for royalty payments to the patent holder.
 - o **Canada and Germany** streamlined their compulsory licensing processes to support the fight against COVID-19; the congresses of **Brazil, Chile and Ecuador** have advanced measures to expand compulsory licensing; and **Israel** issued a compulsory license on a possible treatment due to supply concerns.
- After facing public pressure, some companies have responded by limiting their monopolies.
 - o Following Israel's decision to issue a compulsory license for its candidate treatment, **AbbVie** announced it would no longer enforce patents on the treatment globally, paving the way for generic suppliers.
 - o **Gilead Sciences** relinquished its seven-year **orphan drug exclusivity**, an additional monopoly protection intended for treatments for rare diseases, on an experimental COVID-19 treatment after Public Citizen and 50 groups sent a letter to the CEO of the pharmaceutical giant demanding the company renounce its claim.⁹

How can governments work together to accelerate technology transfer and scale up manufacturing?

- Governments are spending billions of dollars to support the development and manufacture of new treatments and vaccines. A potential breakthrough could come from anywhere.
- President Trump so far has preferred nationalism to cooperation. Last month, he tried unsuccessfully to buy an experimental vaccine from a German company exclusively for the U.S. The move sparked outrage. But there is a better way.
- Governments should support open science and research practices for COVID-19 related health needs that align innovation and timely access.
- The Director-General of the **World Health Organization** recently called for a global collaboration against COVID-19, asking "countries, companies and research institutions to support open data, open science and open collaboration so that all people can enjoy the benefits of science and research."¹⁰
 - o The proposed **technology pool** could allow countries and companies to voluntarily share scientific knowledge, licensing rights and manufacturing know-how.
 - o The effort could help everyone access treatments, vaccines and other medical technologies.

⁸ "Kentucky Gov. Andy Beshear calls on 3M to release patent for N95 respirator amid pandemic," Morgan Watkins, Louisville Courier Journal, April 3, 2020, available at: <https://www.courier-journal.com/story/news/2020/04/03/beshear-calls-3m-release-patent-n-95-respirator-amid-pandemic/5112729002/>.

⁹ <https://www.citizen.org/news/after-caving-on-orphan-drug-designation-gilead-must-commit-to-licensing-and-mass-production/>

¹⁰ <https://www.statnews.com/pharmalot/2020/04/06/covid19-coronavirus-patents-voluntary-pool-world-health/>