

Government Support for COVID Medicines

Global IP Congress October 5, 2020

Zain Rizvi Law & Policy Researcher Public Citizen





Vaccines



Vaccines

- Seven billion people may need a vaccine (potentially up to 14 billion doses)
- 11 have entered late-stage clinical trials
 - mRNA-1273 developed by Moderna (*) is among the leading candidates
- Sharing knowledge could expand supply among qualified manufacturers



JULY 5, 2020 BARDA Funding Tracker

COVID-19 R&D Efforts

COVID-19 BARDA Funding Summary

TYPE OF PRODUCT 🗘	COUNT 🖨	TOTAL AWARDED 🗘	AVERAGE AWARD 🗘	LOWEST AWARD 🖨	HIGHEST AWARD 🗘	PROPORTION OF TOTAL \$ AWARD
Diagnostic	36	84,701,419	2,732,304	111,090	13,692,370	0.6%
Therapeutic	9	945,556,899	105,061,878	7,200,000	617,724,874	7.1%
Vaccine	8	11,064,025,492	1,383,003,187	38,033,570	2,479,894,979	83.1%
Other	5	37,926,044	7,585,209	592,791	34,893,033	0.3%
Vaccine Administration	8	391,486,985	55,926,712	432,990	204,000,000	2.9%
Rapidly Deployable Capabilities	4	7,517,153	1,879,288	720,000	3,833,363	0.1%
Vaccine/Therapeutic Manufacturing	2	788,000,000	394,000,000	160,000,000	628,000,000	5.9%
Total	72	13,319,213,992	201,806,273	111,090	2,479,894,979	





New Results

O Comments (2)

SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness

Kizzmekia S. Corbett, Darin Edwards, Sarah R. Leist, Olubukola M. Abiona, Seyhan Boyoglu-Barnum, Rebecca A. Gillespie, Sunny Himansu, Alexandra Schäfer, Cynthia T. Ziwawo, Anthony T. DiPiazza, Kenneth H. Dinnon, Sayda M. Elbashir, Christine A. Shaw, Angela Woods, Ethan J. Fritch, David R. Martinez, Kevin W. Bock, Mahnaz Minai, Bianca M. Nagata, Geoffrey B. Hutchinson, Kapil Bahl, Dario Garcia-Dominguez, LingZhi Ma, Isabella Renzi, Wing-Pui Kong, Stephen D. Schmidt, Lingshu Wang, Yi Zhang, Laura J. Stevens, Emily Phung, Lauren A. Chang, Rebecca J. Loomis, Nedim Emil Altaras, Elisabeth Narayanan, Mihir Metkar, Vlad Presnyak, Catherine Liu, Mark K. Louder, Wei Shi, Kwanyee Leung, Eun Sung Yang, Ande West, Kendra L. Gully, Nianshuang Wang, Daniel Wrapp, Nicole A. Doria-Rose, Guillaume Stewart-Jones, Hamilton Bennett, Martha C. Nason, Tracy J. Ruckwardt, Jason S. McLellan, Mark R. Denison, James D. Chappell, Ian N. Moore, Kaitlyn M. Morabito, John R. Mascola, Ralph S. Baric, Andrea Carfi, Barney S. Graham doi: https://doi.org/10.1101/2020.06.11.145920

Competing Interest Declaration

K.S.C., N.W., J.S.M., and B.S.G. are inventors on International Patent Application No. WO/2018/081318 entitled "Prefusion Coronavirus Spike Proteins and Their Use." K.S.C., O.M.A., G.B.H., N.W., D.W., J.S.M, and B.S.G. are inventors on US Patent Application No. 62/972,886 entitled "2019-nCoV Vaccine". R.S.B. filed an invention report for the SARS-CoV-2 MA virus (UNC ref. #18752).

The NIH claims joint ownership of Moderna's coronavirus vaccine





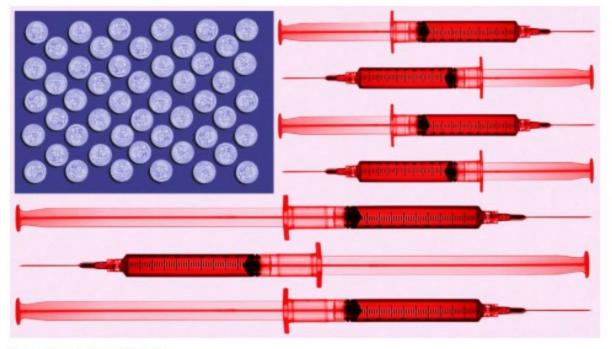




Illustration: Annelise Capossela/Axios

The National Institutes of Health may own intellectual property that undergirds a leading coronavirus vaccine being developed by Moderna, according to <u>documents obtained by Axios</u> and an <u>analysis from Public Citizen</u>.

Why it matters: Because the federal government has an actual stake in this vaccine, it could try to make the vaccine a free or low-cost public good with wide distribution. if the product turns

Moderna reveals it may not hold patent rights for coronavirus vaccine



f 🕑 in 🖴



Photo: Maddle Meyer/Getty Images

Moderna said in new <u>financial filings</u> that it "cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications" — including the company's experimental coronavirus vaccine.

Why it matters: This disclosure comes six weeks after <u>Axios and Public Citizen</u> highlighted how the National Institutes of Health may hold joint ownership claims for this particular vaccine.

What they're saying: Moderna, which had not included this language in previous <u>quarterly</u> investor reports added that "publications of discoveries in the scientific literature often lag





The federal government should use its authority to ensure the vaccine, if proven safe and effective, is available to everyone in the U.S. and around the world. Domestically, this includes:

- In cases where the federal government has ownership rights but Moderna does not, it should nonexclusively license the rights and condition use of its technologies on ensuring reasonable pricing and sufficient supply;[40]
- **2.** In cases where there is joint ownership, the government should license the technologies to competitors; and
- 3. If there are patented technologies the U.S. government does not own needed to produce the vaccine, then the government should exercise its general, preexisting authority to use any patented invention in exchange for appropriate royalty payments to the patent holder. [41]

Globally, the government should share its intellectual property and know-how with the World Health Organization's COVID-19 Technology Access Pool.[42] This would allow manufacturers from around the world to help scale-up production and prevent rationing. If the vaccine proves safe and effective, it should be available to everyone as quickly as possible.

Report last updated June 11, 2020

ongress has appropriated nearly ten billion dollars to support development and manufacturing of COVID-19 diagnostics, treatments and vaccines.[1] Governments around the world are spending billions more.[2] In this report, we use five case studies to trace the role of public funding for COVID-19 vaccines. We focus on the corporations that the Trump Administration has reportedly selected as the most likely to produce a COVID-19 vaccine.

The stories are remarkably similar. To varying degrees, the public has helped fund new ways of designing vaccines ("platform technologies"). These technologies are now being used to develop COVID-19 vaccines, with significant taxpayer support each step along the way.[3] The public is paying for research, development, and manufacturing—with no strings attached. More funding is imminent.[4] Yet unless the government requires these corporations to make these vaccines essentially public goods, a proven vaccine may not reach everyone who needs it.