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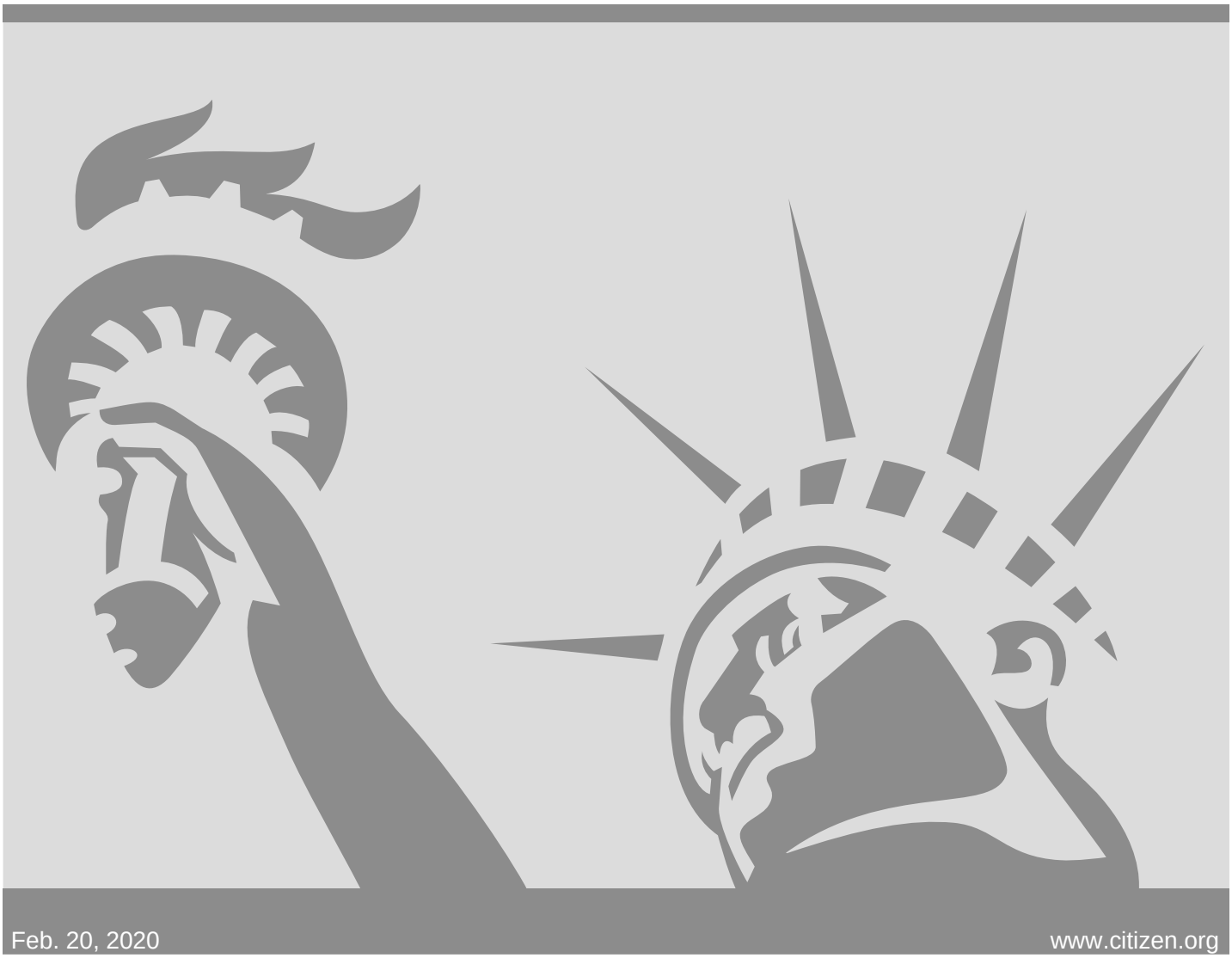

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Blind Spot

How the COVID-19 Outbreak Shows the Limits of Pharma's Monopoly Model

Acknowledgments

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A New Decade, A New Epidemic

As yet another coronavirus spreads around the globe, scientists are once again trying to develop new treatments and vaccines. Much remains unknown about this family of viruses. But we know that this is the third time in the last twenty years that a coronavirus has made the leap from animals to humans—severe acute respiratory syndrome (SARS) coronavirus in 2002, Middle East respiratory syndrome (MERS) coronavirus in 2012, and the novel coronavirus in 2019.[1] There are no proven treatments and vaccines effective against coronaviruses.

The latest "race" to develop new treatments and vaccines against coronavirus disease 2019 (COVID-19) highlights the critical importance of government-funded research. Since the SARS outbreak, the National Institutes of Health (NIH) alone has spent nearly $700 million on coronavirus R&D.[2]

Table 1: NIH Coronavirus Funding by Type of Organization, FY 2003 - 2020[3]

Organization Type	Funding
Domestic For-Profits	101,661,168
Domestic Higher Education (Cumulative)	336,240,501
Foreign Institutions	7,452,082
Independent Hospitals	11,486,217
Organized Research Units	1,814,386
Other Domestic Non-Profits	6,271,075
Research Institutes	35,207,116
U.S. Government	184,444,883
Grand Total	**684,577,428**

The NIH has played a singular role. The pharmaceutical industry, meanwhile, has broadly claimed that that the monopoly-based patent system "is the most effective tool to reward and incentivize innovation"[4] and that it "fulfills the promise of breakthroughs in treatments and cures for . . . scores of debilitating or life-threatening illnesses around the world."[5] Yet the monopoly model

[1] Stanley Perlman, Another Decade, Another Coronavirus, NEW ENGLAND JOURNAL OF MEDICINE (Jan. 24 2020), https://www.nejm.org/doi/full/10.1056/NEJMe2001126. NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, Coronaviruses (Jan. 31 2020), https://tinyurl.com/u37y25u ("Coronaviruses are a large family of viruses that usually cause mild to moderate upper-respiratory tract illnesses, like the common cold, in people. However, three times in the 21st century coronavirus outbreaks have emerged from animal reservoirs to cause severe disease and global transmission concerns.)"

[2] Data is from NATIONAL INSTITUTES OF HEALTH REPORTER. *See* APPENDIX, TABLE 1 for methodology and additional data. This figure excludes funding by the U.S. Department of Defense, the Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Department of Health and Human Services, and other global funders.

[3] *Id.*

[4] Tom Wilbur, IP Explained: Myth vs. fact about strong patent protections in the biopharmaceutical industry, PHRMA (May 2 2019), https://tinyurl.com/rv5yntq.

[5] Mark Grayson, 5 Reasons why biopharmaceutical patents are different, PHRMA (Sept 10. 2015), https://catalyst.phrma.org/5-reasons-why-biopharmaceutical-patents-are-different

has not driven significant industry investment in infectious diseases, including coronaviruses. [6] Consider the industry pipeline for coronaviruses like SARS and MERS before the latest outbreak.

Table 2: Active Coronavirus Industry Pipeline Before COVID-19 Outbreak[7]

Stage	Coronavirus (including SARS and MERS)
Research and preclinical	10
Clinical trials	6
Marketing and registration	0
Total	16

Last year, there were only six active coronavirus clinical trials involving pharmaceutical companies. All of them depended crucially on public funding. Emerging viruses, like the latest coronavirus, pose complex new scientific challenges. But more sustained interest in coronaviruses could have provided greater scientific understanding, and a stronger toolkit to inform the latest response. For example, new antiviral treatments could have offered a promising pool of candidates for COVID-19 clinical trials.[8] In addition, more platform technologies used to develop new vaccines could have been developed and tested.[9]

Table 3: Active Coronavirus Clinical Trials Involving Pharmaceutical Companies before COVID-19 Outbreak[10]

Name	Originator	Developer	Public Support	Status
NTM 1634	Dana Farber Cancer Institute, Harvard Medical School and University of California at San Francisco	Ology Bioservices	NIH[11]	Phase I
REGN 3048	Regeneron Pharmaceuticals	NIH, Regeneron Pharmaceuticals	NIH, BARDA[12]	Phase I

[6] *See* A QUESTION OF PRIORITIES.
[7] Data is from WORLD HEALTH ORGANIZATION, GLOBAL OBSERVATORY ON HEALTH R&D, VIA SPRINGER, ADISINSIGHT (2020). *See* APPENDIX, TABLE 2 FOR METHODOLOGY AND FULL DATASET.
[8] There are many clinical trials attempting to repurpose existing antivirals. *See* TABLE 4 – NEW DEVELOPMENT PROGRAMS FOR COVID-19. *See also* William Haseltine, Want to Prevent Another Coronavirus Epidemic? SCIENTIFIC AMERICAN (Jan. 29 2020), https://tinyurl.com/touk5r7 ("These enzymes are very similar to one another in all coronaviruses. This is a critical point. This common molecular pattern of all coronaviruses makes the challenge of identifying drugs to control coronaviruses less daunting.")
[9] Some technologies funded by the public for MERS-CoV and other pathogens are being now used against the new coronavirus. *See* CEPI to fund three programmes to develop vaccines against the novel coronavirus (Jan 23. 2020), https://tinyurl.com/wqkzcq8.
[10] Unless otherwise specified, the source is WORLD HEALTH ORGANIZATION, GLOBAL OBSERVATORY ON HEALTH R&D, VIA SPRINGER, ADISINSIGHT (2020). *See* APPENDIX, TABLE 2 for methodology and full dataset.
[11] NIH, Study to Evaluate Safety and PK of NTM-1634 vs Placebo Administered Intravenously in Healthy Adults, https://clinicaltrials.gov/ct2/show/NCT03046550.
[12] Regeneron Announces Agreement with BARDA (Aug. 22 2016), https://tinyurl.com/yx6zhnsh.

REGN 3051	Regeneron Pharmaceuticals	NIH, Regeneron Pharmaceuticals	NIH, BARDA[13]	Phase I
MERS coronavirus vaccine	Korea Investment Partners, Vaccitech	University of Oxford, Vaccitech	U.K Dept. of Health, CEPI [14]	Phase I
MERS coronavirus vaccine	Inovio Pharmaceuticals	Inovio Pharmaceuticals	DoD, CEPI[15]	Phase I
MVA MERS S	German Center of Infection Research	IDT Biologika, German Center of Infection Research	CEPI, German Center of Infection Research [16]	Phase I

After the latest coronavirus outbreak, many companies announced new vaccine and therapeutic programs. One biotech investor issued a cautionary note: "There's two things that biotech companies, especially small ones, are always looking for: Attention and cash. And, sadly, a lot of them take advantage of situations...putting out a press release saying they are working on something and you see their stocks zoom."[17] As of February 5, there were at least 25 different vaccine and treatment efforts for COVID-19—two-thirds with support from nonprofit and public institutions. Despite its significant support, the U.S. government has so far imposed no conditions for safeguarding affordable access.

The public sector has helped drive the COVID-19 response. We cannot rely on industry's monopoly model to deliver the medicines we need.

[13] *Id.*
[14] Coalition for Epidemic Preparedness Innovations, which includes funding from several national governments and foundations. Vaccitech licenses MERS rights to Oxford University (Sept. 29 2018), https://tinyurl.com/sbvsuth.
[15] Department of Defense and Coalition for Epidemic Preparedness Innovations. Inovio's MERS Vaccine Generates High Levels of Antibodies and Induces Broad-based T Cell Responses in Phase 1 Study (June 27 2018), https://tinyurl.com/ucz2mvr.
[16] The development of a vaccine against MERS virus gets international support (Aug. 24 2018), https://www.dzif.de/en/development-vaccine-against-mers-virus-gets-international-support
[17] Anjalee Khemlani, Biotech stocks get a boost from coronavirus fears -- but here's why investors should be wary, YAHOO FINANCE (Feb. 1 2020), https://tinyurl.com/sx8g2f9.

Table 4: New Development Programs for COVID-19[18]

Originator	Technology	Public and Private Nonprofit Support
Big Pharma		
AbbVie Inc.	Repurposing lopinavir/ritonavir	NIH,[19] Tongji Medical College, Huazhong University of Science and Technology[20]
Gilead Sciences Inc.	Repurposing remdesivir	NIH,[21]China Academy of Sciences[22]
Johnson & Johnson	Vaccine	BARDA[23]
Johnson & Johnson	Repurposing darunavir/cobicistat	Wuhan University[24]
Small Biotechs		
AbCellera Biologics	Treatment	DoD, NIH[25]
Ascletis Pharma Inc	Repurposing ASC09/ritonavir	NIH[26]
Codagenix	Vaccine	
CureVac	Vaccine	CEPI[27]
GeoVax Labs and BravoVax	Vaccine	
Inovio Pharmaceuticals	Vaccine	CEPI, DoD[28]

[18] On February 5th, we compiled the list of technologies using several industry websites, including drawing from a table compiled by *BioCentury*. *See* Winnie Pong, Steve Usdin, A dozen vaccine programs under way as WHO declares coronavirus public health emergency, BIOCENTURY (JAN. 30 2020), https://tinyurl.com/rloe6wz. We then reviewed the news media for new coronavirus development programs on or before February 5th. We considered support in research and development of medicines, including clinical trials, when determining public and private nonprofit support. For biotechnology companies and academic labs, we also considered whether they received any general operational funding from public and private nonprofit sources.

[19] Knowledge Ecology International, Request for March-In on Abbott Patents (Oct 25. 2012), https://tinyurl.com/srrw9ro.

[20] A randomized, open-label study to evaluate the efficacy and safety of Lopinavir-Ritonavir in patients with mild 2019-nCoV pneumonia, Chinese Clinical Trial Registry, http://www.chictr.org.cn/showprojen.aspx?proj=48991.

[21] Remdesivir - Gilead Sciences, ADISINSIGHT (Feb 5. 2020), https://adisinsight.springer.com/drugs/800043325.

[22] China's Wuhan Institute Files to Patent the Use of Gilead's Remdesivir for Coronavirus (Feb 5. 2020), https://tinyurl.com/vql4wdf.

[23] Johnson & Johnson Announces Collaboration with U.S. Department of Health & Human Services to Accelerate Development of a Potential Novel Coronavirus Vaccine (Feb 11. 2020), https://tinyurl.com/thx5p6s.

[24] A randomised, open, controlled trial for darunavir/cobicistat or Lopinavir/ritonavir combined with thymosin a1 in the treatment of 2019-nCoV pneumonia, http://www.chictr.org.cn/showprojen.aspx?proj=48992.

[25] Steve Usdin, DARPA-funded AbCellera to pursue mAbs to treat coronavirus outbreak (Jan 28. 2020), https://tinyurl.com/v36um3f.

[26] Knowledge Ecology International, Request for March-In on Abbott Patents (Oct 25. 2012), https://tinyurl.com/srrw9ro.

[27] CureVac and CEPI extend their Cooperation to Develop a Vaccine against Coronavirus nCoV-2019 (Jan 31. 2020), https://tinyurl.com/sn2ybev.

[28] *See* Inovio Selected by CEPI to Develop Vaccine Against New Coronavirus, (Jan. 23 2020), https://tinyurl.com/vteusjn. The DNA medicine platform was initially tested in a MERS vaccine supported by the DoD. Middle East respiratory syndrome coronavirus vaccine - GeneOne Life Sciences/Inovio Pharmaceuticals, ADISINSIGHT (Feb 5. 2020), https://adisinsight.springer.com/drugs/800043325.

Moderna	Vaccine	CEPI, NIH[29]
Novavax	Vaccine	Gates Foundation, PATH[30]
Regeneron Pharmaceuticals	Treatment	BARDA[31]
Sichuan Clover Biopharmaceuticals	Vaccine	
Sirnaomics	Treatment	NIH[32]
Sorrento Therapeutics and Celularity	Treatment	
Vaxart	Vaccine	
Vir Biotechnology	Treatment	Gates Foundation[33]
WuXi Biologics	Treatment	
Academic Institutions and Foundations		
Baylor College of Medicine, University of Texas, New York Blood Center, Fudan University	Vaccine	NIH, DoD[34]
National Institutes of Health	Treatment	NIH
Pasteur Institute Foundation	Vaccine	
Stermirna Therapeutics and Tongji University	Vaccine	
University of Queensland	Vaccine	Government of Australia, CEPI[35]
University of Saskatchewan	Vaccine	Government of Canada[36]

[29] Moderna Announces Funding Award from CEPI to Accelerate Development of Messenger RNA (mRNA) Vaccine Against Novel Coronavirus (Jan. 23 2020), https://tinyurl.com/v6g65mo.
[30] Novavax JPM Presentation (Jan 16. 2020), https://www.novavax.com/20200116-JPM-Presentation.pdf
[31] Regeneron Announces Expanded Collaboration with HHS to Develop Antibody Treatments for New Coronavirus (Feb 4. 2020), https://tinyurl.com/vs9fkat.
[32] Research programme: siRNA therapeutics – Sirnaomics (Feb. 5 2020), https://adisinsight.springer.com/drugs/800027640
[33] Vir Biotechnology launches to cure, treat, and prevent challenging infectious diseases using latest advances in immunology (Jan. 6 2017), https://tinyurl.com/rktyj77.
[34] The initial SARS and MERS vaccine work—which forms the basis for the COVID-19 work—was funded by NIH and the DoD. See Baylor College of Medicine, MERS-CoV Vaccine and SARS Vaccine, https://tinyurl.com/t4ya7p2 and https://tinyurl.com/qqteskv.
[35]University of Queensland, Partnership to supercharge vaccine production (Jan. 16 2019), https://tinyurl.com/s587awk.
[36] VIDO-InterVac 2017-2018, https://tinyurl.com/wd8p5k7.

A Question of Priority

Under the existing monopoly model, the government attempts to incentivize private sector investment by providing patent monopolies. These monopolies allow drug corporations, in theory, to make a reasonable return on their R&D investment. In practice, the system works very differently. In addition to minimizing the role of taxpayer investments, monopolies provide incentives for corporations to set exorbitant launch prices, to use dubious tactics to delay competition, and to spend tens of billions of dollars to aggressively and inappropriately market products.[37]

Another pernicious effect is that pharmaceutical companies overwhelmingly invest in research and development (R&D) for treatments that hold the promise of extravagant returns, not necessarily those that meet critical health needs. As one analyst notes, "The possibility for blockbuster sales motivates large drugmakers; little else moves the needle."[38]

Private sector R&D is consequently heavily directed towards medicines for chronic conditions and rare diseases. Cancer medicines, in particular, are an attractive target because they command extraordinarily high prices, even if they sometimes offer marginal or no therapeutic improvements compared to existing treatments.[39] The average price of a new cancer medicine is $149,000 per year.[40] According to Bloomberg Intelligence, last summer there were 195 new chemical entities for cancer in Big Pharma pipelines, more than any other disease area.[41]

Private sector R&D largely neglects less lucrative health needs such as vaccines and treatments for infectious diseases. The same analysis found just 65 new chemical entities for infectious diseases and vaccines in the pipeline. Out of the 20 largest pharmaceutical companies, only four have major vaccine programs.[42] One of the remaining vaccine producers, GSK, has decided to curtail its epidemic response work. A senior executive noted, "We do not want to have these activities compete with in-house programs. And our learnings from Ebola, from pandemic flu, from SARS previously, is that it's very disruptive and that's not the way that we want to do business going forward."[43]

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[37] *See* Zain Rizvi, By Any Means Necessary: How Allergan Gamed the System to Raise Drug Prices and Flood the Country with Pills, PUBLIC CITIZEN (2020). *See also* Lisa Schwartz et al., Medical Marketing in the United States, 1997-2016, JAMA (2019), https://tinyurl.com/y5hqbk82.
[38] Max Niesen, Deadly Viruses Aren't Pharma's Top Priority. Why Not? BLOOMBERG (Jan. 23 2020), https://tinyurl.com/vs2287x.
[39] Vinay Prasad, Do cancer drugs improve survival or quality of life?, BRITISH MEDICAL JOURNAL (2017), https://tinyurl.com/rmqcffp.
[40] IQVIA, Global Oncology Trends 2019 (May 30 2019), https://tinyurl.com/yx29ewc8.
[41] Max Niesen, Deadly Viruses Aren't Pharma's Top Priority. Why Not? BLOOMBERG (Jan. 23 2020), https://tinyurl.com/vs2287x.
[42] *Id.*
[43] Helen Branswell, Who will answer the call in the next outbreak? Drug makers feel burned by string of vaccine pleas, STAT (Jan. 11 2018), https://tinyurl.com/wytelhu ("GSK has made a corporate decision that while it wants to help in public health emergencies, it cannot continue to do so in the way it has in the past.").

After the COVID-19 outbreak, a Johnson & Johnson (J&J) executive explained his company's decision to invest in research and development by saying "You have to be brave and you have to be a solid company to do this, because there is no real incentive to do this, no financial incentive."[44]

Yet what is remarkable about this statement—and this story—is what it leaves out. J&J brought in $82 billion in revenue last year, making it larger than the economy of countries like Guatemala and Croatia.[45] The Government Accountability Office found that the top 25 largest pharmaceutical companies, including J&J, were on average more than twice as profitable as the largest 500 companies.[46] In other words, there is an immense amount of money sloshing around the system. But is it paying for what we need?

Beyond Market Failures

In 2014, as the Ebola epidemic raged on, a promising vaccine sat on the shelf.[47] The small company that licensed the vaccine from the Canadian government for approximately $200,000 had failed to complete basic safety trials.[48] It was only after the company further sub-licensed the vaccine to Merck for $50 million that it was finally made available through clinical trials.[49] The process took over a year, producing a substantial profit for the small company.[50]

Experts responded by calling for a global mechanism to expedite vaccine development.[51] Several governments and foundations eventually banded together to form the Coalition for Epidemic Preparedness Innovations (CEPI).[52]

CEPI describes itself as filling "a number of critical gaps" in vaccine funding.[53] It has pumped millions of dollars into R&D for emerging infectious diseases, including recently for the COVID-19 response. By funding at least four new vaccine projects, CEPI has jumpstarted efforts to contain the epidemic. But the coalition has also been the subject of criticism. Médecins Sans Frontières recently chastised the coalition's new access policy, including its failure to "ensure [that] CEPI-funded vaccines will be affordable for people who need them most."[54]

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[44] Knvul Sheikh and Katie Thomas, Researchers are racing to make a coronavirus vaccine. Will It Help? NY TIMES (Jan. 28 2020), https://tinyurl.com/t96mbje
[45] Johnson and Johson, SEC Filing: Form 10-K (Dec 30. 2018), https://tinyurl.com/r7f5vru. See World Bank, GDP, https://tinyurl.com/tvm7sqv
[46] In 2015. Government Accountability Office, Drug Industry: Profits, R&D Spending, and Merger and Acquisition Deals (Nov. 2017), https://www.gao.gov/assets/690/688472.pdf
[47] Karen Pinchin, Behind the Life-saving Ebola Vaccine is a Story of Missed Opportunity, PBS (Aug 13. 2019), https://tinyurl.com/r8wbr8t.
[48]Médecins Sans Frontières, Lives on the Edge (May 2016), pg. 8 https://tinyurl.com/vfckmcu.
[49] *Id.*
[50] *Id.*
[51] Stanley Plotkin et al., Establishing a Global Vaccine-Development Fund, 373 NEW ENGLAND JOURNAL OF MEDICINE (July 23 2015), https://www.nejm.org/doi/full/10.1056/NEJMp1506820
[52] CEPI, Why We Exist, https://cepi.net/about/whyweexist/
[53] *Id.*
[54] Médecins Sans Frontières, Open letter to CEPI Board Members: Revise CEPI's access policy (Mar. 5 2019), https://tinyurl.com/scx7kay. CEPI has defended its new policy by saying it provides more flexibility.

At its core, CEPI has a limited mandate. This narrow focus on patching up a single market failure overlooks the government's role in structuring the market itself.[55] The failure to develop vaccines, after all, is only the latest illustration of the limits of the monopoly-based model. Consider industry's failure to deliver new antibiotics—a critically important public health need. A report commissioned by the U.K. Prime Minister found that drug-resistant bacteria could kill 10 million people a year by 2050.[56] Many major pharmaceutical companies have "waved the white flag" and ended research into new antibiotics, including Novartis, Allergan, AstraZeneca and Sanofi.[57] Or consider the outcry when a Goldman Sachs analyst publicly asked "Is curing patients a sustainable business model?"[58]

Developing A Better Way

We need a system that prioritizes public health. For more than a decade, academics, economists and activists have proposed developing alternative models to incentivize R&D that do not rely on monopolies.[59] In 2016, the United Nations High-Level Panel on Access to Medicines recommended a mechanism to "delink the costs of research and development from end prices to promote access to good health for all."[60] The idea now enjoys a wide range of support—from the libertarian CATO institute, to the center-left U.K. Labour Party.[61]

The COVID-19 crisis highlights the urgent need for a new model. We should have dedicated funding and an established research infrastructure to quickly develop drugs and vaccines.[62] For example, the government could take a greater role in full-cycle drug development by creating a new

[55] UCL Institute for Innovation and Public Purpose et al., People's Prescription (Oct. 2018), https://tinyurl.com/yxhcgatt. ("Governments should not be limited to 'fixing market failures' – financing high-risk basic research where private investments are scarce and regulating high prices after they have been set. Instead they should be actively setting the directions for health innovation in the first place, in order to serve real public health needs.")
[56] Review on Antimicrobial Resistance, Tackling Drug-Resistant Infections Globally (May 2016), https://tinyurl.com/la9b5cb
[57] James Paton, Naomi Kresge, Superbugs Win Another Round as Big Pharma Leaves Antibiotics, BLOOMBERG (July 13 2018), https://tinyurl.com/sj5hftt.
[58] Tae Kim, Goldman Sachs asks in biotech research report: 'Is curing patients a sustainable business model?' CNBC (Apr. 11 2018), https://tinyurl.com/y58utata.
[59] Tim Hubbard and James Love, A New Trade Framework for Global Healthcare R&D, 18 PLOS BIOLOGY (2004). *See also*, Aidan Hollis, The Health Impact Fund: A useful supplement to the patent system? PUBLIC HEALTH ETHICS, (2008), Dean Baker, Rigged: How Globalization and the Rules of the Modern Economy Were Structured to Make the Rich Richer (2016), UCL Institute for Innovation and Public Purpose et al., People's Prescription (Oct. 2018), https://tinyurl.com/yxhcgatt, Dana Brown and Ameet Sarpatwari, A National Pharmaceutical Research and Development Institute (Nov. 4 2019), https://tinyurl.com/sungkn2
[60] United Nations Secretary-General's High-Level Panel on Access to Medicines (Sept. 14 2016), http://www.unsgaccessmeds.org/final-report.
[61] Charles Silver and David Hyman, Here's a Plan to Fight High Drug Prices That Could Unite Libertarians and Socialists (June 21 2018), https://tinyurl.com/y9vlq5la. U.K Labour Party, Medicines for the Many: Public Health Before Private Profit (2019), https://tinyurl.com/u4ux5w9.
[62] This should also be supplemented by additional funding for national and global public health preparedness.

pharmaceutical research and development institute.[63] One approach could involve the government directly conducting the research and development of treatments and vaccines, and either manufacturing the products or issuing open licenses for generic production. Another approach could involve using grants and cash prizes—instead of the promise of monopolies—to incentivize drug development for important public health needs.[64] By delinking the price of the drug from its cost of development, the government could help deliver the products we need at a price we can afford.[65]

We already have a blueprint in place for an approach that prioritizes public health. The U.S government engages in transformative work, increasingly through the later stages of development. Indeed, the coronavirus example shows how deeply the pharmaceutical industry depends on public investment. Since the SARS outbreak, the National Institutes of Health alone has spent nearly $700 million on coronavirus R&D.

The coronavirus funding is a sliver of the $41 billion the NIH now invests annually. In the past twenty years, the NIH has spent more than a half trillion dollars.[66] This helps drive innovation. Research funded by the National Institutes of Health contributed in part to every one of the 210 new drugs approved by the Food and Drug Administration (FDA) from 2010–2016.[67] In addition, a quarter of small-molecule drugs approved over the last decade had key late stage research contributions from public sector research institutions and related private spin-offs.[68]

Implementing an approach that looks beyond monopolies could help ensure that taxpayers do not pay twice. U.S. taxpayers are compensated for their significant investment in biomedical research and development by being charged the highest medicine prices in the world.[69]

Consider the case of Regeneron. On February 4th 2020, the Biomedical Advanced Research and Development Authority (BARDA) of the Department of Health and Human Services announced it would partner with the biotech company to develop antibody treatments for COVID-19.[70] Under a general agreement signed in 2017, BARDA agreed to pay 80% of R&D and manufacturing costs for the antibodies it selected to target pathogens.[71] A year earlier, another arrangement specific to a MERS treatment went as far as to pay up to $8.9 million to:

> support packaging and labeling of the antibodies for human use, the preparation and submission of an Investigational New Drug application with

[63] Dana Brown and Ameet Sarpatwari, A National Pharmaceutical Research and Development Institute (Nov. 4 2019), https://tinyurl.com/sungkn2
[64] James Love, Judit Rius submission to the UN SG High-Level Panel on Access to Medicines (2016), https://tinyurl.com/quzwvgl.
[65] Knowledge Ecology International, Delinkage, https://delinkage.org/
[66] National Institutes of Health (NIH) Funding: FY1994-FY2020, https://fas.org/sgp/crs/misc/R43341.pdf
[67] Ekaterina Cleary et al., Contribution of NIH funding to new drug approvals 2010–2016, 115 PNAS.
[68] Rahul Nayak et al., Public sector financial support for late stage discovery of new drugs in the United States. 367 BRITISH MEDICAL JOURNAL (2019).
[69] Aaron Kesselheim et al, The High Cost of Prescription Drugs in the United States, 316 JAMA 858 (2016).
[70] https://www.biopharmadive.com/news/regeneron-hhs-coronavirus-antibody-development/571651/
[71] Regeneron Announces New Collaborations with HHS (Oct. 2 2017), https://tinyurl.com/vs9fkat.

the U.S. Food and Drug Administration (FDA), and a National Institutes of Health-conducted clinical trial in healthy volunteers.[72]

The government has provided the corporation enormous support in drug development. Regeneron, unlike so many other companies, has not turned away from infectious diseases. Yet despite providing crucial support, the government has attached no conditions on affordability, which means the company will be able to gain a monopoly to charge whatever the market will bear for a drug that taxpayers helped develop. The government subsidies are particularly remarkable given the fact that the two executives at Regeneron are the two highest paid executives in the entire pharmaceutical industry, having brought in more than $200 million together just in 2018.[73] Since 2012, Regeneron's executive compensation has doubled.[74]

As we move towards a better alternative, a minimum first step should be to require conditions to safeguard affordable global access in all COVID-19 government grants, contracts, and licensing arrangements. This should include prohibiting exclusive licenses on government-funded inventions. If the government nonetheless grants an exclusive license, it should ensure that the scope of rights is not broader than reasonably necessary to induce the investment needed to commercialize the technology, and ensure reasonable pricing.[75]

The Choices We Make

David Quammen, an author, wrote last month that "We must remember, when the dust settles, that [the new coronavirus] was not a novel event or a misfortune that befell us. It was—it is—part of a pattern of choices that we humans are making."[76] One choice that determines how this virus, and others like it in the future, will spread is how we structure our institutions for innovation. The current monopoly-based model prioritizes short-term corporate profits over public health. A new approach could help make the medicines we need for a price that we can afford.

[72] Regeneron Announces Agreement with BARDA (Aug. 22 2016), https://tinyurl.com/yx6zhnsh.
[73] This includes "the actual realized gains from exercising stock options and the vesting of stock awards." William Lazonick et al., Financialization of the U.S. Pharmaceutical Industry, Institute for New Economic Thinking (2019), https://www.ineteconomics.org/uploads/papers/Lazonick_financialization.pdf
[74] *Id.*
[75] 35 U.S.C. § 209, Licensing Federally Owned Inventions. Knowledge Ecology International, Joint Comments by KEI, UACT, Social Security Watch and Health Gap on the proposed NIH Exclusive License in CAR Therapy to Lyell Immunopharma (Sept. 19 2019), https://www.keionline.org/31713.
[76] David Quammen, We Made the Coronavirus Epidemic, NY TIMES (Jan. 28 2020), https://www.nytimes.com/2020/01/28/opinion/coronavirus-china.html.

Appendix

Table 1: NIH Funding Related to Coronaviruses Since SARS Outbreak (source: NIH Reporter)[77]

Methodology: We searched for "coronavirus" in the NIH RePORTER database on Feb. 6. The search produced 1730 results. We reviewed all hits to make sure that the projects were related to R&D for coronaviruses, and excluded all hits before FY 2003 (i.e., the emergence of SARS). We included all projects that had at least some funding for coronavirus R&D. We excluded indirectly related projects, such as those purely tracing the epidemiology of coronaviruses. We also counted subprojects that were not included in other main projects. The full dataset is available on request.

Organization Name	Total Funding	Distinct Projects[78]
AARON DIAMOND AIDS RESEARCH CENTER	1247415	1
AKONNI BIOSYSTEMS, INC.	890768	2
ARIZONA STATE UNIVERSITY-TEMPE CAMPUS	1992975	4
AUTOIMMUNE TECHNOLOGIES, LLC	225000	1
BAYLOR COLLEGE OF MEDICINE	6109110	2
BIOFIRE DEFENSE, LLC.	715172	1
BIOFIRE DIAGNOSTICS, INC.	1346410	1
BOISE TECHNOLOGY, INC.	237248	1
BOSTON CHILDREN'S HOSPITAL	1921321	1
BRIGHAM AND WOMEN'S HOSPITAL	136008	1
CANTONAL HOSPITAL ST GALLEN	247063	1
CARNEGIE-MELLON UNIVERSITY	1244	1
CASE WESTERN RESERVE UNIVERSITY	647510	1
CLEVELAND CLINIC LERNER COM-CWRU	3225451	2
COLORADO STATE UNIVERSITY	85585	1
COLUMBIA UNIVERSITY HEALTH SCIENCES	7715325	2
CORNELL UNIVERSITY	3456656	7
CROSSLIFE TECHNOLOGIES, INC.	299766	1
DANA-FARBER CANCER INST	6828176	2
DARTMOUTH COLLEGE	636670	1
DREXEL UNIVERSITY	1002023	3
DYNPORT VACCINE COMPANY, LLC	1774468	1
ECOHEALTH ALLIANCE, INC.	1201431	2
EMORY UNIVERSITY	1343967	2
FRED HUTCHINSON CAN RES CTR	615972	1
FRED HUTCHINSON CANCER RESEARCH CENTER	1826838	3

[77] To preserve data integrity, we did not eliminate potential redundancies in this table. NIH, Research Portfolio Online Reporting Tools, https://projectreporter.nih.gov/reporter.cfm

[78] Based on unique project application serial number.

HARVARD MEDICAL SCHOOL	7499601	4
HARVARD UNIVERSITY	2226606	3
HARVARD UNIVERSITY (MEDICAL SCHOOL)	1085757	2
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	1592528	3
INDIANA UNIVERSITY BLOOMINGTON	1808242	1
INIMMUNE CORPORATION	613880	1
INSTITUTE FOR GENOMIC RESEARCH	93020	1
INSTITUTE OF MATERIA MEDICA	1060038	1
INTERNATIONAL AIDS VACCINE INITIATIVE	1297428	1
IOWA STATE UNIVERSITY	1090241	1
J. CRAIG VENTER INSTITUTE, INC.	4506896	1
JOHNS HOPKINS UNIVERSITY	5009136	7
KANSAS STATE UNIVERSITY	1826890	2
KEYSTONE SYMPOSIA	28000	3
KINETA, INC.	1504162	1
LAVAL UNIVERSITY	4059440	1
LEIDOS BIOMEDICAL RESEARCH, INC.	72410171	1
LOUISIANA STATE UNIV A&M COL BATON ROUGE	40397	1
LOVELACE BIOMEDICAL & ENVIRONMENTAL RES	6299244	2
LOYOLA UNIVERSITY CHICAGO	9926573	5
MASSACHUSETTS GENERAL HOSP	638451	1
MEDICAL COLLEGE OF WISCONSIN	8417066	2
MFLUIDX, INC.	702922	1
MICROBIAL NOVOTEQS, INC.	1200548	1
MICRONICS, INC.	444080	1
MONTANA STATE UNIVERSITY - BOZEMAN	1069167	1
NATIONAL INSTITUTES OF HEALTH	184444883	19
NAVIGEN, INC.	147660	1
NEW YORK BLOOD CENTER	9146571	6
NOVARTIS VACCINES AND DIAGNOSTICS, INC.	10427728	1
NOVAVAX, INC.	509590	1
OHIO STATE UNIVERSITY	2751713	2
OREGON HEALTH & SCIENCE UNIVERSITY	10299899	1
OREGON STATE UNIVERSITY	178510	1
PASTEUR INSTITUTE FROM MADAGASCAR	134900	1
PHELIX THERAPEUTICS, LLC	4382085	1
PLANET BIOTECHNOLOGY, INC.	2036730	2
PRINCETON UNIVERSITY	560993	1
PROTEIN SCIENCES CORPORATION	37549	1

PUBLIC HEALTH ENGLAND	375261	1
PURDUE UNIVERSITY	537415	2
PURDUE UNIVERSITY WEST LAFAYETTE	501158	2
RBHS-NEW JERSEY MEDICAL SCHOOL	5784707	1
RESEARCH INST OF FOX CHASE CAN CTR	223125	1
RIDGEWAY BIOSYSTEMS, INC.	189967	1
SCRIPPS RESEARCH INSTITUTE	2096393	5
SEATTLE BIOMEDICAL RESEARCH INSTITUTE	455046	1
SOUTHERN RESEARCH INSTITUTE	145380	1
SRI INTERNATIONAL	521428	1
ST. LOUIS VA MEDICAL CENTER	UNAVAILABLE	1
STANFORD UNIVERSITY	487912	2
STATE UNIVERSITY NEW YORK STONY BROOK	409500	1
STATE UNIVERSITY OF NEW YORK AT BUFFALO	426957	1
TEXAS A&M UNIVERSITY	928034	2
TEXAS A&M UNIVERSITY HEALTH SCIENCE CTR	992168	3
THOMAS JEFFERSON UNIVERSITY	468000	1
TRUDEAU INSTITUTE, INC.	1724320	1
TULANE UNIVERSITY OF LOUISIANA	91681	1
UNITED BIOMEDICAL, INC.	1565264	1
UNIV OF ARKANSAS FOR MED SCIS	1646917	1
UNIV OF MARYLAND, COLLEGE PARK	1543072	2
UNIV OF MASSACHUSETTS MED SCH WORCESTER	3397728	2
UNIV OF NORTH CAROLINA CHAPEL HILL	64129175	16
UNIVERSITY OF ALABAMA AT BIRMINGHAM	43357565	3
UNIVERSITY OF ALBERTA	536632	1
UNIVERSITY OF ARKANSAS MED SCIS LTL ROCK	2501212	2
UNIVERSITY OF CALIF-LAWRNC LVRMR NAT LAB	1166241	1
UNIVERSITY OF CALIFORNIA	701575	1
UNIVERSITY OF CALIFORNIA RIVERSIDE	488988	1
UNIVERSITY OF CALIFORNIA SAN FRANCISCO	28985	1
UNIVERSITY OF CALIFORNIA, SAN DIEGO	2167754	1
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	902982	2
UNIVERSITY OF CALIFORNIA-IRVINE	535318	1
UNIVERSITY OF CINCINNATI	1016093	1
UNIVERSITY OF COLORADO	427504	1
UNIVERSITY OF COLORADO DENVER	10881621	6

UNIVERSITY OF FLORIDA	1458409	1
UNIVERSITY OF GEORGIA	416969	1
UNIVERSITY OF IDAHO	307575	1
UNIVERSITY OF ILLINOIS	1831732	2
UNIVERSITY OF ILLINOIS AT CHICAGO	5648691	4
UNIVERSITY OF IOWA	15472766	8
UNIVERSITY OF KANSAS LAWRENCE	309202	2
UNIVERSITY OF MARYLAND BALT CO CAMPUS	216567	1
UNIVERSITY OF MARYLAND BALTIMORE	9808891	9
UNIVERSITY OF MARYLAND COLLEGE PK CAMPUS	386308	1
UNIVERSITY OF MICHIGAN AT ANN ARBOR	1140979	1
UNIVERSITY OF MINNESOTA	3679265	1
UNIVERSITY OF MISSOURI-COLUMBIA	392973	1
UNIVERSITY OF NEW MEXICO	437155	2
UNIVERSITY OF NORTH CAROLINA CHAPEL HILL	4390880	3
UNIVERSITY OF PENNSYLVANIA	14574842	13
UNIVERSITY OF PITTSBURGH AT PITTSBURGH	381629	1
UNIVERSITY OF ROCHESTER	1364134	1
UNIVERSITY OF SOUTH DAKOTA	76421	1
UNIVERSITY OF SOUTHAMPTON	1038748	1
UNIVERSITY OF SOUTHERN CALIFORNIA	650000	1
UNIVERSITY OF TENNESSEE HEALTH SCI CTR	190000	1
UNIVERSITY OF TENNESSEE KNOXVILLE	3179414	1
UNIVERSITY OF TEXAS EL PASO	994098	2
UNIVERSITY OF TEXAS MED BR GALVESTON	12331514	8
UNIVERSITY OF TEXAS MEDICAL BR GALVESTON	1823872	3
UNIVERSITY OF TEXAS, AUSTIN	1240189	1
UNIVERSITY OF TOLEDO HEALTH SCI CAMPUS	1082056	1
UNIVERSITY OF UTAH	1260978	1
UNIVERSITY OF VIRGINIA	5735502	3
UNIVERSITY OF WASHINGTON	3501555	4
UNIVERSITY OF WISCONSIN-MADISON	838413	2
UNKNOWN	51912	1
UT SOUTHWESTERN MEDICAL CENTER	266250	1
UTAH STATE UNIVERSITY	811338	1
VANDERBILT UNIVERSITY	7305140	7
VANDERBILT UNIVERSITY MED CTR	653691	3
VANDERBILT UNIVERSITY MEDICAL CENTER	2555159	3
VITALANT	2526063	2

WADSWORTH CENTER	6305468	3
WASHINGTON UNIVERSITY	6345739	1
YALE UNIVERSITY	2069918	3
Grand Total	**684,577,428**	**271**

Table 2: Coronavirus Projects by Pharmaceutical Companies before COVID-19 Outbreak (source: World Health Organization via AdisInsight).
Methodology: We primarily relied on the World Health Organization's Global Observatory on Health R&D, which draws from the commercial AdisInsight database.[79] We compiled data for treatments and vaccines under the "SARS," "MERS," and "coronavirus (unspecified)" categories. The database includes projects that have at least one commercial developer.

Active Projects before COVID-19 Outbreak			
Name	**Originator**	**Developer**	**Status**[80]
Medicines			
GS-5734	Gilead Sciences	Gilead Sciences, National Institute of Allergy and Infectious Diseases	Preclinical
NTM 1634	Dana Farber Cancer Institute, Harvard Medical School and University of California at San Francisco	Ology Bioservices	Phase I
REGN 3048	Regeneron Pharmaceuticals	National Institute of Allergy and Infectious Diseases, Regeneron Pharmaceuticals	Phase I
REGN 3051	Regeneron Pharmaceuticals	National Institute of Allergy and Infectious Diseases, Regeneron Pharmaceuticals	Phase I
Research program: viral therapeutics	Genekam Biotechnology		Research
Research program: severe acute respiratory syndrome-coronavirus 3CL protease inhibitors	Microbial Novoteqs	Microbial Novoteqs	Research
Research program: severe acute respiratory syndrome-coronavirus PL protease inhibitors	Microbial Novoteqs	Microbial Novoteqs	Research

[79] World Health Organization, Global Observatory on Health R&D, https://www.who.int/research-observatory/monitoring/processes/health_products/en.

[80] The status column in the tables above reflect the development stage of each drug. The WHO database, based off the AdisInsight database, categorized each vaccine and medicine as active or inactive. Active products include those in research, preclinical studies and clinical trial phases I-IV. They also include registered and marketed medicines. "Research" refers to the earliest stage of development that includes bench lab analysis. "Preclinical" refers to a more advanced stage that involves animal testing. Inactive products include drugs whose research was discontinued or had no development, as well as drugs withdrawn from the market. "Discontinued" refers to drugs with studies that were explicitly suspended. "No development" refers to drugs with studies that did not report new findings for at least 2 to 4 years. The bracketed text refers to the last known active phase.

Research program: adenosine A3 antagonists	Future Medicine	Future Medicine	Preclinical
Rintatolimod	Hemispherx Biopharma	AIM ImmunoTech	Research
Vaccines			
FBR 001	Fabentech	Fabentech	Research
Middle East respiratory syndrome coronavirus vaccine	Korea Investment Partners, Vaccitech	University of Oxford, Vaccitech	Phase I
Middle East respiratory syndrome coronavirus vaccine (intradermal)	Inovio Pharmaceuticals	Inovio Pharmaceuticals, Walter Reed Army Institute of Research	Phase I
MVA MERS S	German Center of Infection Research	IDT Biologika, German Center of Infection Research	Phase I
Research program: DNA vaccines	Greffex Inc	Greffex Inc	Preclinical
Research program: infectious disease vaccines	Themis Bioscience	Themis Bioscience	Preclinical
Research program: viral infection vaccines	Protein Potential	Protein Potential	Preclinical
Inactive Projects before COVID-19 Outbreak			
Medicines			
AMZ 0026	Advanced Plant Pharmaceuticals	Amazon Biotech	Discontinued
BG 777	Virocell		No Development (Phase 1)
CEL 1000	CEL-SCI Corporation	United States Medical Institute of Infectious Diseases	No Development (Preclinical)
CRV 431	Isotechnika	Hepion Pharmaceuticals	Discontinued
Galidesivir	BioCryst Pharmaceuticals	BioCryst Pharmaceuticals	No Development (Preclinical)
Interferon alfacon-1	Amgen	Astellas Pharma, Three Rivers Pharmaceuticals	Discontinued
Interferon-alpha-n3	Stem Cell Innovations	AIM-Immunotech	No Development (Preclinical)
Nelfinavir	aRigen	aRigen	No Development (Preclinical)
Research program: anti-coronavirus monoclonal antibodies	Medarex, University of Massachusetts Medical School		Discontinued
Research program: antiviral and anticancer ribonucleases	Alfacell Corporation	National Institute of Allergy and Infectious	No Development

		Diseases, Tamir Biotechnology	(Preclinical)
Research program: antivirals	Biota Holdings	Biota Holdings, National Institute of Allergy and Infectious Diseases, United States Army Medical Research Institute of Infectious Diseases	Discontinued
Research program: biodefence antibodies	Dana Farber Cancer Institute, Harvard Medical School, University of California at San Francisco	XOMA	No Development (Preclinical)
Research program: biodefence vaccines	GenPhar		No Development (Preclinical)
Research program: coronavirus antisense therapy	Isis Pharmaceutical		No Development (Preclinical)
Research program: coronavirus inhibitors	EpiCept Cororation	Immune Pharmaceuticals Inc, National Institute of Allergy and Infectious Diseases	Discontinued
Research program: coronavirus inhibitors	Fulcrum Pharmaceuticals, John Hopkins University		Discontinued
Research program: coronavirus inhibitors	Kucera		No Development (Preclinical)
Research program: coronavirus inhibitors	TaiGen		No Development (Preclinical)
Research program: coronavirus inhibitors	United States Army Medical Research Institute of Infectious Diseases, ViroPharma	United States Army Medical Research Institute of Infectious Diseases, ViroPharma	Discontinued
Research program: dipiperidine anti-infectives/anti-inflammatories	Sequella	Sequella	No Development (Preclinical)
Research program: Middle East respiratory syndrome coronavirus nanoparticle therapies	Nanoviricides	Lovelace Respiratory Research-Institute, Nanoviricides	Discontinued
Research program: monoclonal antibodies	Humabs Biomed	Humabs Biomed	No Development (Preclinical)

Research program: peptide-based viral entry inhibitors	Autoimmune Technologies, Tulane University School of Medicine	Autoimmune Technologies, Tulane University School of Medicine	No Development (Preclinical)
Research program: polyclonal immunoglobulins	Fabentech	Fabentech	No Development (Preclinical)
Research program: SARS therapies	Pfizer	Pfizer	No Development (Preclinical)
Research program: SARS-coronavirus antibodies	Diversa	Diversa	No Development (Preclinical)
Research program: SeV-based gene therapies	DNAVEC Corporation	ID-Pharma	No Development (Preclinical)
Research program: short interfering RNA-based therapeutics	Intradigm Corporation	Intradigm Corporation	Discontinued
Research program: small-molecule antivirals	Kemin Phama	United States Medical Army Institute of Infectious Disease	Discontinued
Research program: therapeutic agents	Pharmagenesis	Pharmagenesis	No Development (Preclinical)
Research program: viral budding inhibitors	Biotron	Biotron	No Development (Preclinical)
Research program: viral immunotherapy	Lipid Sciences		No Development (Preclinical)
Research program: viral infection therapies	Quigley Pharma	Quigley Pharma	No Development (Preclinical)
SAB 301	SAB Biotherapeutics	SAB Biotherapeutics, National Institutes of Health	No Development (Phase I)
SARS virus hyperimmune globulin	Cangene Corporation		Discontinued
Ulinastitin	Techpool Bio-Pharma	Techpool Bio-Pharma	No Development (Phase I)
Vaccines			
Coronavirus vaccine	Beijing Kexing Bioproduct Co		No Development (Phase I)
Coronavirus vaccine	Berna Biotech	Berna Biotech	Discontinued

Coronavirus vaccine	GlaxoSmithKline, Institut Paseur		No Development (Preclinical)
Coronavirus vaccine	ID Biomedical Corporation	ID Biomedical Corporation	No Development (Preclinical)
Coronavirus vaccine	Sanofi Pasteur	Sanofi Pasteur, NIAID	Discontinued
Coronavirus vaccines	Baylor College of Medicine, Sabin Vaccine Institute	Brighton Biotech, Baylor College of Medicine, Sabin Vaccine Institute, Texas Children's Hospital for Vaccine Development	No Development (Preclinical)
Middle East respiratory syndrome coronavirus vaccine (intramuscular)	GeneOne Life Sciences, Inovio Pharmaceuticals	GeneOne Life Sciences, Inovio Pharmaceuticals	No Development (Unknown)
Middle-East respiratory syndrome coronavirus vaccine	National Institute of Health, Organic Vaccines	Organic Vaccines	No Development (Preclinical)
Research program: coronavirus vaccine	Baxter Healthcare Corporation	Baxter Healthcare Corporation	No Development (Preclinical)
Research program: coronavirus vaccines	Novavax	Novavax	Discontinued
Research program: coronavirus vaccines	Antigen Express, Generex Biotechnology Corporation		No Development (Preclinical)
Research program: MERS vaccines	Replikins	Replikins	No Development (Preclinical)
Research program: SARS-coronavirus vaccine	Alphavax	Alphavax	No Development (Preclinical)
Severe acute respiratory syndrome vaccine	Protein Sciences Corporation	Protein Sciences Corporation	No Development (Preclinical)
VRC-SRSDNA015-00-VP	NIH Vaccine Research Center		No Development (Phase I)