

Will COVID 19 Vaccines & Medicines Serve Profits or People?

No matter where you live, what you look like or what's in your wallet, we're all human and we can all get sick. Congress is investing billions in a vaccine and treatments for COVID 19, but new medicines won't help if they aren't safe and affordable. That's why Congress must take action now to ensure drug corporations don't get monopoly control to charge us high prices so that medicines and vaccines developed with our tax dollars are affordable for everyone.

DRUG CORPORATION	TAXPAYER FUNDING OPERATION WARP SPEED/BARDA	PRICE GOUGING, PROFITEERING
AstraZeneca	\$1.2 billion	-In 2018, AstraZeneca increased the price of Crestor, a medicine to treat high cholesterol several times before the generic version was released in order to drive up the price of the generic version a common industry practice. -AstraZeneca is currently facing a lawsuit for fraudulent marketing of Crestor and offering kickbacks to physicians who prescribed the drug.
Johnson & Johnson	Over \$600 million	-Johnson & Johnson controls 7 of the top 50 selling drugs in the world, and already raised prices on 6 of them in 2020Johnson & Johnson hiked the price of their blood thinner Xarelto 87% and arthritis and ulcerative colitis medication Remicade by 63% over 5 years.
Merck	More than \$38 million	-Merck has a history of price gouging, raising prices on 15 medicines in 2020 aloneMerck tripled the price of its diabetes medicine Januvia to \$1,578 and doubled the price of its HIV medicine Isentress to \$1,653 since 2007Merck launched its blockbuster cancer drug Keytruda at more than \$4,000 per vial.
Moderna	More than \$483 million	-Moderna stock prices grew more than 300% in just five months to almost \$30 billion at the end of May, making Moderna one of the most valuable biotech businesses. -Since January, Moderna executives have sold more than \$200 million in stocks, benefiting from just the rumors of a vaccine prompting former SEC officials to call Moderna's stock sales "highly problematic" and caution from one official about dumping stock after speculation surges. -Since March, the company has amassed a \$29 billion market value despite having no approved drugs on the market.
Novavax	\$1.6 billion	-In it's 30 year history Novavax has never successfully developed a vaccine but in July, Novavax shares jumped over <u>40 percent</u> from around \$4 per share to over \$100 after announcing its \$1.6 billion deal with the federal governmentSo far, shares of Novavax have <u>surged up to 2,300%</u> .

Pfizer	Pfizer has not sought funding from Operation Warp Speed, but has significantly benefited from tax breaks and other subsidies.	-In January 2020, Pfizer increased the list prices on about 50 drugs, including cancer treatment Ibrance and rheumatoid arthritis drug Xeljanz. Ibrance is on track to bring in nearly \$5 billion in revenue in 2020. -The company raised prices on around 27% of its portfolio in the U.S. by an average 5.6%. -Pfizer increased the price of Nitrosat, a heart medication, by 56% in 2015, the year before a generic version came on the market.
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Taxpayer Funding is Fueling Innovation To Develop Vaccines and Treatments

Congress has allocated at least \$10 billion for development of COVID medicines so far,¹ including \$3.5 billion to BARDA in the recent CARES package for COVID vaccine development. As of June 2nd it was reported the agency had over a dozen contracts to pharmaceutical companies for vaccines, treatments and therapeutics. These are catalogued on BARDA's COVID Medical Countermeasures site.²

Handing taxpayer money over to drug corporations for research and development with no strings attached is nothing new. Most new medicines are developed with public funding: in fact, National Institutes of Health (NIH) contributed research funding to every single one of the over 200 new drugs approved for use between 2010 and 2016.³

There are dozens⁴ of vaccines in development all over the world by companies including: Altimmune, BioNTech/Pfizer; GSK, Heat Biologics, Inovio Pharmaceuticals, Johnson & Johnson, Moderna; Novavax; Sanofi; and Vaxart. This is concerning because, historically, only five companies have extensive experience in this area: Sanofi, GlaxoSmithKline (GSK), Johnson & Johnson, Merck and Pfizer. Some of the corporations receiving significant funding from the United States to develop vaccines, like Moderna and Novavax, have no history of developing vaccines and have no other vaccines on the market. Other companies including, CytoDyne, Amgen, Gilead. Regneron, Sanofi, Roche and Vir Biotechnology are working on various types of non-vaccine treatments. Sanofi is working on both. Phlow is set to manufacture, but not develop.

Most public health experts expect that more than one vaccine will be developed for COVID. There's widespread speculation about how long it will take to develop a vaccine and get it on the market, but the average timing for vaccine development historically has been at least 5 years.⁹

President Trump has promised a vaccine by the end of the year, ¹⁰ though others in the Administration are suggesting longer timelines. ¹¹

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https://www.hhs.gov/about/leadership/secretary/speeches/2020-speeches/secretary-azar-white-house-remarks-on-operation-warp-speed.html

² https://medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx

³ https://www.statnews.com/2018/02/12/nih-funding-drug-development

⁴ https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus-landscape-ncov.pdf

⁵ Lee, Jaime; <u>These 23 companies are working on coronavirus treatments or vaccines — here's where things stand</u> Market Watch 5/6/20.

https://www.wsj.com/articles/inside-moderna-the-covid-vaccine-front-runner-with-no-track-record-and-an-unsparing-ceo-11 593615205

⁷ https://www.nytimes.com/2020/07/16/health/coronavirus-vaccine-novavax.html

⁸ Gay Stolberg, Cheryl and Thomas, Katie.<u>Trump to Tap New Company to Make Covid-19 Drugs in the U.S.</u> New York Times 5/18/20.

⁹ https://www.nytimes.com/interactive/2020/06/09/magazine/covid-vaccine.html

¹⁰ https://abcnews.go.com/Politics/trump-promises-coronavirus-vaccine-end-year-experts-temper/story?id=70712823

¹¹ https://www.businessinsider.com/fauci-offers-coronavirus-vaccine-timeline-phase-3-trial-2020-6

The companies listed in the table above are receiving taxpayer funding from BARDA (Biomedical Advanced Research Development Authority), a subsidiary of NIH (National Institutes of Health) to develop vaccines, medicines and therapeutics in response to COVID 19. BARDA's dashboard provides basic, but limited, information about the agreements. Nor has the Trump Administration increased transparency about the content of government contracts with these taxpayer-funded corporations.

Operation Warp Speed and President Trump's Vaccine Rush

The Trump Administration's Operation Warp Speed (OWS) program initially identified AstraZeneca (AZN), Johnson & Johnson (JNJ), Moderna Inc. (MRNA), Merck & Co. Inc. (MCK) and the combo of Pfizer/BioNTech as the most likely to succeed in expedited development of a vaccine. Most recently, the list of corporations receiving money for expedited development of a vaccine expanded to include Maryland-based Novavax. So far, Operation Warp Speed has provided around \$4 billion to these targeted corporations.

The Administration is moving full speed ahead with OWS to develop and deliver 300 million doses of a COVID vaccine by January 2021. OWS is run by the Department of Health and Human Services (HHS) and the Department of Defense (DoD). But President Trump's aggressive timeline for a vaccine before the end of the year is raising tremendous questions and concerns¹⁴ about scientific rigor, evidence-based conclusions and safety when it comes to finalizing a vaccine.

OWS may be poised for scientific and ethical failure, as it ignores established methods of vaccine development, relies on unproven technology and is being overseen by ethically compromised staff including Moncef Slaoui, the OWS co-director, who has deep ties to the drug industry.¹⁵

Infectious disease experts have questioned why the Administration is failing to simultaneously use new technology and established methods that have worked in the past on diseases including flu, hepatitis and rabies. Instead of two approaches, one already proven, Trump has chosen to use one. Saad Omer, a Yale University infectious disease expert, said Operation Warp Speed needs to widen its portfolio to include the older technologies. "New technologies are good, and they could perform well, but we should really be hedging our bets," said Omer, who has helped develop several vaccines.¹⁶

While these newer approaches may be promising, they have not delivered a vaccine, let alone one with a long track record against a specific disease. Nor do they have the necessary research to assess their safety. Taxpayer money is being spent on new technology that has been studied experimentally, but has never been in wide use. Added University of Pennsylvania Professor Paul Offit, "We just don't know if they're really safer." 17

¹² Lee, Jaimy MarketWatch NYT: Trump identifies five drugmakers most likely to produce a viable COVID-19 vaccine 6/3/20.

¹³ https://www.nvtimes.com/2020/07/07/health/novavax-coronavirus-vaccine-warp-speed.html

¹⁴ https://www.washingtonpost.com/health/2020/06/17/trump-coronavirus-vaccine/

¹⁵ Slaoui owned approximately \$10 million in Moderna stock when he was appointed to the position. In his first week at OWS director, his stock generated another \$2.5 million. is also a partner in biotech investment firm Medicxi--which invests in pharmaceutical companies.

¹⁶ Florko, Nicholas. <u>Amid conflict-of-interest criticisms, top FDA officials recuse themselves from Covid-19 vaccine approvals</u>
Stat News, 5/19/20

¹⁷ Ibid

Conflicts of interest abound in the Trump Administration, which includes many former Pharma executives¹⁸ as well as in OWS. The larger Coronavirus Task Force is raising questions about why they are being trusted with \$10 billion in the midst of a pandemic.

- Moncef Slaoui, who leads Operation Warp Speed, has deep ties to the pharmaceutical industry. He's a former Director of Moderna who was appointed to chair OWS with over \$10 million in Moderna stock options.¹⁹ Slaoui later had to divest nearly \$12.4 million worth of shares in Moderna (which received \$483 million from taxpayers to develop a vaccine) because of conflict of interest concerns. Slaoui continues to be a large shareholder in GlaxoSmithKline (GSK)²⁰ and serves on the board of a biotech company that invests in new medicines. Slaoui has been hired as a private contractor and is not subject to normal government oversight rules or disclosures.
- Marc Short, the Chief of Staff to Vice President Mike Pence and member of the White House COVID taskforce, holds stock in pharmaceutical companies working on COVID vaccines and treatments. Short is currently facing a complaint lodged with the FBI over his failure to recuse himself
- Prior to becoming the Assistant Secretary for Preparedness and Response at Health and Human Services (HHS) Robert Kadlec consulted for Emergent Biosolutions. Since he joined HHS Emergent has received more than \$1.2 billion in tax dollars from the division Kadlec oversees. In the whistleblower complaint filed by Dr. Rick Bright before being removed as head of BARDA, Dr. Bright says Kadlec and others awarded lucrative contracts to former business acquaintances and friends.²¹
- Two senior FDA officials, Janet Woodcock and Peter Marks, were forced to recuse themselves from roles in approval of a vaccine. Given the role of the FDA in evaluating and approving a vaccine, their involvement was criticized as "beyond frightening." In May of this year, the Administration doubled down and named Marks to the Coronavirus Task Force.
- Secretary of Health and Human Services (HHS) Alex Azar was a top lobbyist for Eli Lilly and Joseph Grogan, a Task Force member, was a lobbyist for pharmaceutical giant Gilead Sciences.²³

No Shareholder Left Behind

Companies developing vaccines for Covid-19 have seen their stock prices increase, often dramatically. These outsized increases have been driven by news that can be considered speculative (the decision to develop a vaccine) or involves data from very early trials, which may never come to fruition. It's incredibly difficult to develop vaccines and takes a long time. Just listen to industry insiders talk about how hard it is to make a new vaccine:

Roger Connor, GSK's president in charge of vaccines: "A vaccine is probably one of the most complex pharmaceutical products to develop," he told Investor's Business Daily. "Normally, it takes us years — can take up to 10 years — to go through discovery and development. To compress that into an accelerated timeline is ambitious."

¹⁸ https://www.bigpharmasbestfriends.org/

https://www.cnbc.com/2020/05/18/coronavirus-vaccine-adviser-moncef-slaoui-to-divest-12point4-million-of-moderna-holdings.html

²⁰ https://www.nytimes.com/2020/05/20/health/coronavirus-vaccine-czar.html

²¹ https://www.rollcall.com/2020/06/10/trump-health-officials-approach-to-contracts-faces-scrutiny/

²² White House Press Release 5/15/20.

²³ Lerner, Sharon: <u>CRONYISM AND CONFLICTS OF INTEREST IN TRUMP'S CORONAVIRUS TASK FORCE</u> The Intercept 2/29/20.

²⁴ Gatlin, Allison. <u>Investors.com Covid Report: Vaccine Giants Announce Match-Up Against Coronavirus</u> 4/14/20.

Merck CEO Ken Frazier recently told the Financial Times a 12-18-month timeline is "very aggressive." Despite this, companies working on vaccines are making their shareholders happy. Five biotech companies that are developing Covid-19 vaccines or therapeutics have gained a combined \$57 billion in market capitalization this year. The companies that have benefited the most include:

- Altimmune stock is up 181% over the last 3 months. Interestingly 18% of this came after it announced a 1st quarter <u>loss</u> that included positive initial results on preliminary vaccine data.
- **BioNTech** (4.8%) and **Pfizer** (1.3%) both saw jumps in share price after announcing their initial set of clinical trials.²⁸
- **GSK** saw gains of over 3.5% in one day, merely after announcing a partnership to develop a vaccine with Sanofi. ²⁹ The 3.5% gain means that GSK added approximately \$2.15 billion in value, for little more than issuing a press release.
- Innovio announced it hoped to begin clinical trials in May. That day the stock rose 70%.
- **Novavax** stock jumped 15.2% in one day after it received a contract for its vaccine. This was followed by a 15.3% jump when it announced the enrollment of the first participants in clinical trials. Overall the company's stock has risen 1227.9% this year. ³¹
- **Vaxart** stock has surged 750% year to date. The majority of these gains have been since the company announced its intention to develop a vaccine and the release of favorable pre-clinical data.
- Moderna stock is up 76% year to date. Almost one third (20%) of that gain came in one day after it announced positive pre-clinical trial results.
 - Per MarketWatch, since 5/29, CEO Stephane has sold more than \$1.5mn in stock. CFO Lawrence Kim has sold over \$12.5mn.
 - Moderna is seeking to raise \$1.374 billion from a stock sale. The company is pricing shares at \$76 per share; not bad considering it started the year trading around \$18.89.
 - Moderna's market value rose to \$29 billion despite it having no products.
 - Flagship Pioneering, Moderna's largest shareholder, is owned by Moderna co-founder Noubar Afeyan. During this sequence of events, it sold \$69.5 million worth of stock.
 - Moderna may be in trouble here. After the announcement, the subsequent jump in share prices, the corporate stock sale and the insider transactions, former SEC officials weighed in with one calling the sequence of events "highly problematic" and another suggesting the SEC investigate the company: "This isn't really insider trading as much as

²⁵ Lee, Jaimy MarketWatch NYT: Trump identifies five drug makers most likely to produce a viable COVID-19 vaccine 6/3/20.

²⁶ Whitfill. Travis. Biopharma companies are spreading misinformation — and taking advantage of it Stat News 5/26/20.

²⁷ Weil, Dan Altimmune Rises as Preclinical Tests for Coronavirus Vaccine Begin TheStree.com 5/14/20.

²⁸Kilgore, Tomi. <u>BioNTech. Pfizer stocks rally after first participants in U.S. trial of COVID-19 vaccine were dosed</u> MarketWatch 5/5/20.

²⁹ Gatlin, Allison. Investors.com Covid Report: Vaccine Giants Announce Match-Up Against Coronavirus 4/14/20.

³⁰ Yahoo Finance. Data accessed on 6/4.

³¹ Nathan-Kazis, Josh, Barron's. <u>Novavax Stock Is Soaring. The Company Is Starting Covid-19 Vaccine Trials</u> 5/26/20.

³² Yahoo News <u>Vaxart Shows Strong Progress in Its COVID-19 Program: 5-Star Analyst Boosts Price Target 4/30/20.</u>

³³ Shtrubel, Marty. Vaxart (VXRT) Stock Is a Winner, But How Much Higher Can It Go? Nasdaq.com 4/24/20.

³⁴ Kim, Jasmine <u>CNBC After positive data on a coronavirus vaccine</u>, <u>Moderna will try to raise \$1.34 billion with a stock sale</u> 5/18/20.

³⁵ Yahoo Finance Stock Chart, accessed on 6/4/20.

³⁶ Egan, Robert and Kuznia, Matt. <u>Moderna's coronavirus vaccine announcement set off a frenzy on Wall Street. Now some are calling for an investigation</u> CNN Business 6/1/20.

³⁷Egan, Robert and Kuznia, Matt. <u>Moderna's coronavirus vaccine announcement set off a frenzy on Wall Street. Now some are calling for an investigation</u> CNN Business 6/1/20.

it's market manipulation and "It looks like you're hyping the stock so you can then go and sell it." While all of this may end up being legal, it certainly looks bad.

- **J&J** rose 9% after stating it would begin human testing by September 2020.³
- Sanofi (3.5%); Merck (1.5%) and Heat Biologics (9%) all jumped after news they intended to develop a vaccine.
- **AstraZeneca** rose 3.7% on news of a \$1.2 billion contract with the government.

Will Drug Corporations Get Monopoly Control to Price Gouge on Vaccines and Medicines?

There is tremendous speculation about what prescription drug corporations will charge for COVID treatments and vaccines. Drug corporations, seeking to redeem their tarnished reputations are promising low prices and free contributions of doses but the reality is that without regulation, there is no accountability for follow through.

Moreover, any drug company that receives an exclusive patent on a drug then gets twenty years of exclusivity--that means the corporation has monopoly control to set the launch price and charge whatever price they want. The monopoly control provided by an exclusive patent leads to consumers paying more, even after generics become available. It is the monopoly control to set prices and keep them high that has made prescription drug corporations the most profitable in the nation.⁴⁰ Since the industry is not required to negotiate lower prices with government programs like Medicare, the corporations' regular practice is to price-gouge patients on everything from new lifesaving medicines to common medicines that have been around for decades--like insulin, for example.⁴¹

Lower Drug Prices Now (LDPN) is working with grassroots groups and elected officials at all levels to ensure that drug corporations will not get monopoly control over COVID medicines and vaccines developed with taxpayer funding and toward long-overdue reforms. There's no better time than a pandemic to re-write the rules of the pharmaceutical industry to end abusive price-gouging of patients through legislative reforms that would finally guarantee affordable medicines for all.

³⁸ Egan, Robert and Kuznia, Matt. <u>Moderna's coronavirus vaccine announcement set off a frenzy on Wall Street. Now some are calling for an investigation</u> CNN Business 6/1/20.

³⁹ Reinicke, Carmen. Markets Insider 3/30/20.

⁴⁰ https://jamanetwork.com/journals/jama/article-abstract/2762308

⁴¹ https://www.vox.com/2019/4/3/18293950/whv-is-insulin-so-expensive