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Trump Administration Is Paying Big Pharma Billions in Rush for Vaccine

By Prof. Marjorie Cohn
Global Research, October 21, 2020
Region: USA
Theme: Science and Medicine

Desperate to distract the national discourse from his criminal mishandling of the coronavirus pandemic, ***Donald Trump*** *is promising that a vaccine will be available before Election Day. His vaccine campaign is named "Operation Warp Speed" and there is a real danger that its speed will warp the results. Ironically, the Trump administration is comparing this effort to the Manhattan Project, the highly secret government program to develop the first atomic bomb. "This isn't a secret government weapon we're trying to keep from an enemy," said David Mitchell, founder of Patients for Affordable Drugs. "The enemy is the virus. This is actually a rescue mission to save Americans and humanity from the virus."*

Vaccines generally take 10 years to develop, test and distribute. The shortest time it has taken to develop a vaccine is four years. Yet four pharmaceutical companies are in late stages of clinical trials. Pfizer, apparently the front-runner in the vaccine race, says it won't have results before mid-November. Moderna, AstraZeneca, and Johnson & Johnson say they hope to have results by the end of the year.

> "Trying to produce a vaccine at 'Warp Speed' is a terrible gamble with public health," Clifford Conner, a science historian and author of the new book, The Tragedy of American Science: From Truman to Trump, said in an interview with Jeff Mackler of Socialist Action USA. "If none of the inadequately tested trial vaccines kill anybody — and if one of them should actually prove therapeutically worthwhile — it will be a matter of dumb luck, and dumb luck is never a good plan in a deadly crisis."

In July, AstraZeneca halted its clinical trials because a participant became seriously ill. Although AstraZeneca refused to identify the malady, citing privacy concerns, the patient's symptoms were consistent with transverse myelitis, or inflammation of the spinal cord. Several researchers decried AstraZeneca's lack of transparency.

Last week, Johnson & Johnson announced it had paused its clinical trial due to an unexplained illness in one of its volunteers. The company refused to provide details, claiming the need to protect the patient's privacy.

Robert R. Redfield, director of the Centers for Disease Control and Prevention, told a Senate panel on September 16 that a vaccine wouldn't be readily available until mid-2021. A few hours later, Trump declared, without evidence, that Redfield "made a mistake" and a vaccine would be widely available in weeks.

Shortly before Trump contradicted Redfield, four senior physicians directing the national coronavirus response team endorsed the Food and Drug Administration's (FDA) new stricter

safety rules. Those requirements mandate the approval of outside experts before the FDA will pronounce a vaccine safe and effective.

The new FDA emergency rules also require that participants in clinical trials be followed for two months after administration of the immunizations before final authorization, in order to identify possible side effects.

But desperate to win an electoral advantage in the face of Trump's falling poll numbers, the administration stalled its approval of the FDA's new policies for two weeks. Trump accused the FDA of preventing authorization of a vaccine before Election Day, calling it a "political hit job." The day after *The New York Times* reported that White House officials were blocking the FDA's new guidelines, the administration did an about-face and approved them.

> "I have tremendous trust in these massive companies that are so brilliantly organized in terms of what they've been doing with the tests," Trump said at a press briefing. "I don't know that a government as big as we are could do tests like this."

In the race to develop a vaccine as quickly as possible, Operation Warp Speed is "paying out billions of dollars to Big Pharma corporations in advance of any results whatsoever," Conner told *Truthout*. They are not complying with regulatory oversight and traditional federal contracting mechanisms that create transparency, he noted. "Before any of the companies had done any research or developed any products, they were already reaping windfall profits from their association with Operation Warp Speed." What that demonstrates, Conner adds, is that, "Warp Speed is not so much a scientific 'race for a vaccine' among competing research laboratories as it is a speculative frenzy among competing hedge funds."

Three of the pharmaceutical companies that have contracted with Warp Speed to develop a vaccine have never successfully brought any vaccine to market, Conner said. Novavax has a Warp Speed contract for $1.6 billion, Moderna has a $1.5 billion Warp Speed contract, and Vaxart's stock prices have soared, its owners realizing huge profits. Pfizer also has a Warp Speed contract worth $1.95 billion.

The Trump administration is pressuring the FDA to rebrand its emergency authorization of a vaccine as a "pre-licensure." But, concerned it would appear to be politicizing scientific determinations, the FDA is pushing back. An FDA spokesperson cited "important substantive differences" between the emergency use authorization and the more rigorous process to license a vaccine. "There is no such thing as 'pre-licensure' or 'pre-approval' under the laws FDA administers," the spokesperson said.

A data and safety monitoring board has been established to review information about the safety and effectiveness of COVID-19 vaccines. The board has the authority to fast-track or halt a clinical trial. This small panel of 10 to 15 outside scientists and statistical experts works in secret, ostensibly to shield them from company pressure. The secrecy, however, may also lead to undue influence by drug companies. "We want to know they're truly independent," Eric Topol, a clinical trial expert at San Diego's Scripps Research, said. "The lack of transparency is exasperating." The safety board is overseeing trials by Moderna, Johnson & Johnson and AstraZeneca. But Pfizer, which is funding its clinical trials, has its own five-member safety panel.

Topol criticized Moderna and Pfizer for including in their data people who had fairly mild

cases of COVID-19. Topol said evidence of the effectiveness of a vaccine would be more solid if only moderate and severe cases were included. In addition, Topol faulted Pfizer and Moderna for their willingness to halt their clinical trials early, which could prove detrimental later when the vaccine is administered to millions of people.

> "Take the time, the extra weeks. No shortcuts. Nobody will regret it," Topol cautioned. "I've been doing clinical trials for decades. I don't know if there's ever been a more important one than this one. I'd like to see it done right, and not stopped early."

Congress members, advocacy organizations and a former administration official are calling for Operation Warp Speed to release its vaccine contracts with the pharmaceutical companies. "The administration really just seems to be playing a game of hide-and-seek," **Rep. Lloyd Doggett** (D-Texas) told *NPR*.

The Trump administration has ignored requests by the House of Representatives for information on COVID-19 spending.

> "[R]ight now, the entire process is riddled with political interference and a lack of transparency," **Sen. Patty Murray**, (D-Washington), ranking member of the Senate Health, Education, Labor and Pensions Committee, wrote in a statement to NPR. "These contracts need to be made public so Congress and the American people are not left in the dark — there is too much at stake."

Rick Bright, who was fired as director of the Biomedical Advanced Research and Development Authority, filed a whistleblower complaint, charging that some federal COVID-19 contracts were awarded based on "political connections and cronyism" instead of scientific evidence. Bright said there's no reason to hide the contracts, which causes him to suspect "that there's something interesting in there they don't want discovered."

Trump's stubborn insistence on having a vaccine by Election Day does not comport with reality. Neither do Big Pharma's predictions. The shortcuts they threaten to take for political gain and mega-profits endanger the public safety. That should frighten us all.

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