Trump Crash Program Brings COVID Vaccines; Some Dems Prefer Dying for Biden

by David Shavin

Nov. 14—John Kennedy posed to the nation that we should have a crash program to get to the Moon—and the bottom line in his case to the country was: We should go because, as with the highest mountain, it is there. It "will serve to organize and measure the best of our energies and skills …" And the population enjoyed having the better angel of their nature addressed. It has been a long time, and a twisted path, since the United States has had a successful crash program and enjoyed a good outcome.

U.S. Army/Jason W. Edwards

A biomedical laboratory technician.

By the time this article goes to print, a remarkably successful vaccine against the COVID-19 virus should be at the Food and Drug Administration (FDA) awaiting approval, one showing an excellent efficacy of over 90%, and also having compelling indications of safety. (A really good flu vaccine rarely exceeds 60% efficacy.) With any luck, a second vaccine will show up there five to ten days later. Both are messenger-RNA (mRNA) vaccines, one by Pfizer/BioNTech, the other by Moderna. Twenty million elderly and at-risk Americans will get first access to the vaccines during the month of December. Families throughout the country won't find a better Christmas gift. They are the result of a crash program launched last Spring, entitled Operation Warp Speed (OWS).

OWS involved the government stepping in and identifying three avenues of attack, with three different types of COVID vaccines (mRNA, Replication-defective live-vector, and recombinant-subunit-adjuvanted protein). Then two top vaccine candidates were picked in each of those three categories. They were picked from amongst dozens and dozens of rival vaccine proposals, based upon a pre-set, top-down government-dictated list of standards and measurements—so that the various candidates could be efficiently compared, apples-to-apples. (Typically, the pharmaceutical companies run their clinical trials on their own designs, and then the FDA can approve the result or not.)

The six winners were awarded with massive contracts for tens and hundreds of millions of vaccines to be purchased. Manufacturing capacity was expanded massively, long before any of the vaccines were accredited. Further, physical production of millions of vaccine doses was pushed, even if the possibility of a failed candidate meant wastage—because it was more important not to waste time or lives.

In the Spring of 2020, the best estimations for a successful vaccine put it at least a year into the future. The goal on May 15 was set for the end of 2020.

Trump Derangement Syndrome Breaks Out

Along the way, some calculating souls figured out that there was a danger that good news from a successful vaccine might work in President Trump's favor—and the priority must be to delay such a development until after the November 3 election. Congressional Democrats argued that the very fact that this was a crash program meant that the speed of the endeavor made it unsafe, so that we must have a slow crash program! Candidate Biden issued a campaign statement warning against any pressure from Trump to change FDA procedures—and made his own political demand, in the same statement, that the FDA *must* change its procedures, so as to slow things down. Kamala Harris stated that a vaccine "from Trump" should not be trusted, and she would not take it. In effect, Democratic leaders began to encourage the "anti-vaxxer movement" on the issue of a COVID vaccine.

FDA/Michael J. Ermarth

Dr. Peter Marks, Director of the FDA's Center for Biologics Evaluation and Research.

On September 3, when Pfizer announced that 23,000 volunteers were already in its Phase 3 trial, and that no safety issues had arisen so far, the possibility (threat, as leading Democrats saw it) that Pfizer could deliver a vaccine for the last half of October became real. Around the third week of September, Dr. Peter Marks, the lead official at the FDA in charge of making a decision on the approval or denial of a new vaccine, created a new FDA guidance—whereby a two-month further study was to be required on the trial volunteers, after their second and final dose—ostensibly to monitor longer-term effects.

WEF/Sikarin Thanachaiary

Dr. Albert Bourla, Chairman and Chief Executive Officer of Pfizer, the biopharmaceutical company.

Dr. Marks knew, or should have known, that the delay would result in over 20,000 extra deaths—simply amongst those in the long-term care facilities, where the first vaccines were scheduled to go. Marks was supposed to be, under the terms of an Emergency Use Authorization, balancing scientific concerns with the risks of not addressing the actual emergency, with lives directly on the line. He turned his back on the latter.

The White House intervened to stop the promulgation of the FDA guidance. Then, on Monday, October 5, Marks asserted that it made no difference, as he had already communicated to the vaccine developers that he simply wouldn't approve any vaccine that didn't take the extra two months—whether it was official or not. The White House submitted to the ultimatum and extracted a compromise that the safety study would only apply to half of the vaccinated—"only" pushing back the vaccine's arrival by 4-6 weeks. In so doing, they saved over 10,000 lives from Marks' highjacking while giving up any chance of the vaccine's deployment in October.

Marks' ally, Dr. Eric Topol, messaged his collaborators on October 10: "We were on a path for a vaccine emergency authorization before Nov. 3rd. Thanks to the FDA, Trump's plan was disrupted. That won't happen." This was a classic case showing that Trump Derangement Syndrome kills.

On Monday, November 9, Pfizer was able to announce the results of its first analytical review, described by Pfizer CEO Albert Bourla as a "great day for science and humanity!" That same day, the *New York Times*, even though it was safely beyond election day, still went out of its way to claim that the vaccine success had nothing to do with OWS—apparently because nothing good could come out of a Trump White House. Pfizer issued a disclaimer that day, stating that, of course, it was part of OWS, including a $1.95 billion contract signed in July for 100 million doses of

governor.ny.gov

Andrew Cuomo, Governor of New York, supported delays in the approval and distribution of a COVID vaccine, so that it could not be deployed until after the November 3 election, hoping to deny Trump any credit for its deployment.

the vaccine. The *Times* had, with reckless disregard, taken a Pfizer Vice-President's words—about Pfizer bearing all of the *research and development costs* on itself—out of context. Pfizer's correction got scarce notice in the media.

Meanwhile, New York Governor Andrew Cuomo had his own meltdown over the good news. Appearing on George Stephanopoulos' "Good Morning America," Cuomo was asked about the just-announced success of the Pfizer vaccine. He went off. "It's good news, bad news, George. The good news is that the Pfizer tests look good and we'll have a vaccine shortly. The bad news is that it's about two months before Joe Biden takes over and that means this [present] administration is going to be implementing a vaccine plan …" Cuomo goes on to claim that the OWS's distribution is "going to be slow ... [Y]ou have two months and we can't let this vaccination plan go forward the way the Trump Administration is designing it. Biden can't undo it two months later ... I've been talking to governors across the nation about that—how can we shape the Trump Administration vaccine plan to fix it or stop it before it does damage."

Cuomo, it seems, had not caused enough deaths by ordering that elderly patients with COVID infections be sent back into elderly care facilities in New York.

This, from a governor who supported delays in the approval process, and even now will not accept the FDA's approval of the vaccine until after his state carries out its own health studies. His newfound concern for speeding things up is heartwarming. But he's organizing governors to go into a revolt—even to stop the distribution plan for two months. One is hard-pressed to find a more overt case of Trump Derangement Syndrome.

In reality, OWS' logistical plan for the deployment of vaccines was developed by General Gustave Perna, a veteran of logistical planning for the U.S. military, which is unmatched in this regard. He constantly emphasizes that "This is about saving lives" and stresses that he's been able to get the private sector—including CVS, Walgreens, FedEx, UPS, and McKesson (a medical delivery company) to be "thinking differently," beyond usual business concerns. He has worked out with both CVS and Walgreens to have trained staff travel to elderly care facilities and provide the vaccines free of charge to both residents and staff. OWS has been working with each state to co-ordinate and fine-tune local arrangements. The Centers for Disease Control develops the priority list for the vaccine with the elderly, the at-risk, medical personnel, and first responders up at the top.

DIA

General Gustave Perna, Chief Operating Officer of Operation Warp Speed.

There are about 80 million Americans likely to be prioritized. The leaders of Operation Warp Speed have said, right up to this point, that the vulnerable elderly can be vaccinated before the end of December, and frontline personnel in January and possibly February.

The Vaccines

The Pfizer vaccine doses present logistical challenges, as they require cryogenic

storage at –94 degrees Fahrenheit. Both CVS and Walgreens have been equipped with special freezers to handle this, and many hospitals already are so equipped. Corning Glass has produced massive amounts of specialized, pharmaceutical-quality glass containers for this vaccine. Pfizer has developed a packaging system, which it calls "pizza boxes," which itself will preserve the low temperature for 10-14 days—at which point dry ice can be added to extend the time. At any point, the vaccine doses can be put into a regular refrigerator's freezer section and used for another five days.

Moderna's vaccine—next in line—and the other four vaccine candidates can all be stored in a regular freezer. As one or more of them get approved, their already-produced doses can be immediately added into the supply line, but there will be a ramping up of production to cover hundreds of millions. Most Americans' opportunity will come no earlier than March or April, when there will be massive amounts of data already on the various safety records.

In addition, those vaccines needing less cold-storage logistics and requiring only one injection, can be shipped abroad for COVID vaccination campaigns in other nations.

The Pfizer and Moderna mRNA vaccines employ a new technology that uses the genetic code (mRNA) for the coronavirus' spike protein—the part required to make it so infectious. The mRNA, which is a manufactured facsimile of the genetic-code template for manufacturing the spike protein, is encapsulated in very small lipid particles and is injected into the subject. This mRNA enters the subject's cells, which respond by using it to produce, not the virus, but only its spike protein, which then stimulates an immune reaction. The body acquires the immunity without the virus ever being present. Both companies are presenting data analysis, last week and this week, showing how well the vaccine actually protects against infection.

Vaccine Efficacy

The trick in the Phase 3 trials is, with a small sample of actual COVID-19 infections, to discover that significantly more of those infections occurred amongst the placebo, not the actually vaccinated, population. That at least 85 of Pfizer's 94 new infections were in the placebo group—out of around 39,000 volunteers already analyzed—showed a remarkably good disparity. Moderna evidently has at least 53 infections to analyze in the data they will shortly submit.

In Pfizer's case, such a dramatic case by October 8 that the vaccine is effective, suggests the company could have shown a clear and statistically significant separation between vaccinated and non-vaccinated volunteers weeks earlier. If 94 cases were in the October 8 study, how many of those cases were known a month earlier? Remember that thousands of volunteers were enrolling in the Pfizer trial in late July and all during August, receiving their first injections then and their seconds all during September. Even half, or 47 cases, with anything like the 9:1 ratio eventually displayed, would have made a clear case for issuing an Emergency Use Authorization, accompanied by a temporary advisory, that the vaccine was for the long-term care facilities—where one-third of the COVID deaths were occurring.

On November 13, in the Rose Garden and under a beautiful "Indian summer" sky, President Trump convened a presentation by the OWS crash program team on America's mobilization in the war against COVID-19. He pointedly referenced that he'd been receiving calls from many leaders of other countries, congratulating him upon the announcement of the Pfizer vaccine's high efficacy. He rather politely called the *New York Times'* embarrassing effort to present Pfizer's vaccine as not connected with OWS, an "unfortunate misrepresentation." Then he took the gloves off and put New York Governor Andrew Cuomo in his place.

Trump said that, while politics had been kept out of the OWS achievement, the New York state governor was an exception. The governor objected to the vaccine deployment because it was associated with Trump. Therefore, Trump announced that vaccines will shortly go to 49 states, but, unfortunately, nothing to New York. He explained they won't send precious vaccine doses where politicians have decided to leave them undeployed. "The Governor will let us know when he's ready. I hope he doesn't run this as badly as he did the nursing homes."

Dr. Moncef Slaoui, the medical head of OWS, sounded like a proud and happy father when he characterized the Pfizer success as the first real proof that they had bet on the right horses back in the Spring. And the beautiful sky overhead suggested that God would be happy if the nation might regain its moorings and sense of mission for the world, should they get re-addicted to that characteristically American talent for crash programs.