The nationalist hijacking of the race for a vaccine against the SARS-CoV-2 virus

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With the pandemic continuing to spiral out of control, and as the race for the vaccine heats up, various US institutions and political entities are jockeying to control who will be first in developing a viable vaccine against the coronavirus and how that vaccine would be distributed among the population. This raises serious concerns about the motives behind these developments which are anything but ingenuous.

There are presently 24 candidate vaccines in clinical evaluation, otherwise known as human trials. More than 140 are in preclinical evaluations across several nations throughout the globe. Of those in clinical trials, only four have reached phase three clinical trials: AstraZeneca (UK-based), Moderna (US-based), and two from China being produced by Sinovac and Sinopharm. Pfizer (US-based) has announced it would start phase 2B and phase 3 trials at the end of July.

According to STAT News, the National Academy of Medicine, tasked by top US health officials, has named a panel to establish a framework for the initial distribution of the vaccine. However, this infringes on the role of the Centers for Disease Control and Prevention and its advisory panel, which makes recommendations on vaccination policy. This is further complicated by the administration's Operation Warp Speed, which has used federal funds to enrich private biotech and pharmaceutical companies.

Michael Osterholm, director of the University of Minnesota's Center for Infectious Diseases Research and Policy, said, "Between ACIP [Advisory Committee on Immunization Practices], and this new committee, the group working within Operation Warp Speed and just in terms of input from the general community, it's not clear to me who will make the final decision and how the process will unfold."

Every US-based COVID-19 vaccine in phase three uses a two-dose regimen separated by 28 days. This adds to the problem that supplies will be quite limited at the start, posing the critical question of what criteria will be used to identify those that should first access this potentially life-saving cure. (The two-dose regimen provides a boost to the immune system that a single dose does not offer.)

During the hearing on "Pathway to a Vaccine" at the House Committee on Energy and Commerce on July 21, with prominent pharma executives present as witnesses, the issue of the dosing and distribution was raised early in the course of the discussion. Republican Congressman Greg Walden of Oregon said, "That's really helpful for us and the public to understand [about two-dose regimens]. When we talk about having 300 million doses or 30 million doses, we probably should cut that in half in terms of the number of people that are actually going to be able to get vaccinated in a worst-case scenario."

The witnesses at the hearing included Dr. Mene Pangalos, executive vice president at AstraZeneca; Dr. Macaya Douoguih, head of clinical development and medical affairs at Johnson & Johnson; Dr. Julie Gerberding, executive vice president and chief patient officer at Merck; Dr. Stephen Hoge, president of Moderna; and Mr. John Young, chief business officer of Pfizer. The title of doctor among these personalities has assumed a figurative sense to provide a modicum of altruism when, in fact, their allegiance is strictly to their shareholders.

Other important issues were raised by the panel including the concern over the rapid pace at which vaccines are being developed that could lead to bypassing the necessary assessment of the efficacy of vaccines in the general population as well as concerns that even severe rare side effects in small cohorts of subjects in phase two and three trials may be compounded by the massive distribution of the vaccine among billions.

The chairman of the Committee, Democratic Congressman Frank Pallone of New Jersey, added, "We all want a COVID-19 vaccine to be developed as soon as possible, but before a vaccine is distributed, public health experts must ensure that it is safe, effective, and available to all who need it. My fear is that the FDA will be forced by the Trump administration to approve a vaccine that lacks effectiveness."

Moderna's Hoge assured the panel, "We do believe it's going to be possible in a safe way to bring forth an effective vaccine in 12 to 18 months. We've been working around the clock to make sure we're doing this in an incredibly responsible way all the way through." Moderna received $483 million in funding through the Department of Health and Human Services in April. Since that partnership was announced, Moderna's stock price has climbed from under $40 per share to over $80, doubling its value. Moderna is moving to start phase three clinical trials this week.

Dr. Albert Bourla, Pfizer's chairman and CEO, said, "We've been committed to making the impossible possible by working tirelessly to develop and produce in record time a safe and effective vaccine to help bring an end to this global health crisis."

Pfizer, which is in collaboration with a small German biotechnology company, BioNTech, was awarded a $2 billion contract for up to 600 million doses of their mRNA coronavirus

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vaccine. According to the agreement, pending the outcome of clinical trials, the US government placed an initial order for 100 million doses with the option of acquiring an additional 500 million doses. Pfizer and BioNTech are moving to start phase 2b and 3 clinical trials at the end of this month and will seek regulatory review as early as October 2020.

Novavax, another US-based biotechnology and vaccine development company, backed by Trump's Operation Warp Speed, announced earlier in July that it was partnering with the federal government to expedite the development of their vaccine.

The contract will provide the Maryland-based company $1.6 billion. The company has also awarded its executives stock options worth tens of millions even if their efforts to produce a viable vaccine fail. In its 33-year history, the company has never delivered a vaccine to market, though its market value has climbed from $250 million to $8 billion during the pandemic.

The executives, speaking before the panel, assured lawmakers that their products would be ready by the end of the year. However, in the bluntest terms, Hoge of Moderna, said, "We will not sell it at cost." Objections and concerns raised by House members are simply formalities. As is evidenced by the hearings on Remdesivir, there is no real mechanism to inhibit the government for pricing for profit. In fact, the government has been at the forefront of providing the funds for access to these therapeutics. "We'll price our potential vaccine consistent with the urgent global health emergency that we're facing," said Young, Pfizer's chief business officer.

Complicating Novavax's relationship with the US government, however, the company has already received grants worth $388 million from the Coalition for Epidemic Preparedness Innovations (CEPI) that stipulated CEPI would have the right of first refusal to ensure delivery of the vaccine to emerging nations. It remains to be determined how binding these agreements will be.

The World Health Organization is in partnership with CEPI and Gavi, the vaccine alliance, to purchase 2 billion doses of COVID-19 vaccines for high-risk populations of the world. The cost of such a massive effort is projected at $18.1 billion, with $11.3 billion needed to be raised by year's end. Additionally, the initiative requires commitments from developed nations to purchase close to a billion doses of a viable vaccine. For their commitments, these countries would be offered shares of nine candidate vaccines that are being supported by CEPI. These arrangements assure governments access to a viable vaccine if others prove ineffective in clinical trials.

These efforts belie the sinister and avarice-ridden decisions being made on the production and distribution of vaccines. Klus Stohr, a German virologist who played a key role in identifying the coronavirus as the cause of SARS, in an interview with Bloomberg, warned that 90 percent of the population remains susceptible to the virus. As with other respiratory pathogens, he added, the winter season will produce another wave, much more severe than the present instance.

He said, "Countries like Germany may have a significant amount of vaccine by the beginning of next year and a rollout that may take four, five, six months for the elderly. The strategy may be different for a country like Brazil, Argentina, or Chile, which may never get a single dose of a vaccine and still has to cope … it's not the vaccine that's going to end the pandemic. The virus will end this pandemic by burning every piece of dry wood it will find. The fire will not go out before the last susceptible person has been affected."

It is in this context that the recent unsubstantiated accusations by the US against Russia and China is part and parcel of the geopolitical struggle to "secure supplies for a scientific breakthrough that could confer enormous economic and political power," according to the *Wall Street Journal*. The recent indictment brought against Chinese citizens for attempting to steal vaccine data stems not from evidence of a crime but to ensure the United States can position itself strategically to be the first to patent a vaccine for the coronavirus. However, such brinksmanship may provide sufficient critical mass for regional aggressions to blossom.

The sudden consternation raised by the mouthpieces of the financial oligarchs such as the *New York Times* and *Washington Post* regarding the attempted theft of intellectual property at this precise moment should be measured against the advances made by Chinese pharmaceuticals in the vaccine race. Sinopharm, using an inactivated virus vaccine, has launched a phase three trial in the United Arab Emirates and is well under way in recruiting thousands of trial subjects, while another Chinese company, Sinovac Biotech, commenced phase three trials in Brazil earlier in the month.

Even the UK is facing an assault on its advanced position in vaccine development through the financial markets. AstraZeneca, in collaboration with the University of Oxford, is currently conducting phase three trials in Brazil and South Africa. However, shares slid seven percent earlier this week despite positive results in their phase one trial that demonstrated both high neutralizing antibody levels and T-cell responses, although the responses may not have been as robust as other vaccines. The pharmaceutical giant announced last month that it is committed to manufacturing two billion doses by the end of the year.

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