The Daily Dish

Vaccine Politics

DOUGLAS HOLTZ-EAKIN | AUGUST 31, 2020

Eakinomics: Vaccine Politics

It is not my area of expertise, but the development of COVID-19 vaccines under the administration's Operation Warp Speed (OWS) is nothing short of astonishing. Despite starting only in early 2020, there are now six candidate vaccines, three of which are in, or entering, Phase 3 trials. Moreover, millions of doses of the three Phase 3 vaccines are being manufactured. If any are approved for use by the Food and Drug Administration (FDA), high priority individuals will be able to be vaccinated immediately. The key to this success is taxpayer money – to pay for development and production costs – and an aggressive approach to overlapping trials. For example, Phase 2 is started as soon as Phase 1 appears successful. Phase 1 continues to collect data, but the two trials coincide and similarly for Phase 2 and 3. But no steps are skipped and the usual Data Safety Monitoring Boards are used to check the efficacy and safety of the vaccines. Overall, it is an astonishing accomplishment.

Further, the FDA has indicated it would be willing to allow use of the vaccines under an emergency use authorization before the end of the Phase 3 trials. Speaking to the *Financial Times*, FDA head Stephen Hahn said, "It is up to the sponsor [vaccine developer] to apply for authorisation or approval, and we make an adjudication of their application. If they do that before the end of Phase Three, we may find that appropriate. We may find that inappropriate, we will make a determination." Given all this, the notion of having a vaccine toward the end of 2020 does not appear fanciful at all.

But what if we had a working vaccine and nobody took it?

My concern is not that there will be a spontaneous, sweeping anti-vaxxer sentiment. The concern is that the FDA approval will appear politicized, undercutting the confidence of the public in the safety and efficacy of the vaccine. This concern comes at the end of a bad week for the FDA which began with the president tweeting "The deep state, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd. Must focus on speed, and saving lives! @SteveFDA"

That's right. The president – who needs the FDA's unblemished approval of a drug more than anyone – drags the agency into the political mud. It then gets worse when the FDA issues an emergency use authorization of convalescent plasma as a treatment for the coronavirus and completely mischaracterizes its efficacy. The president said that the plasma "has proven to reduce mortality by 35%. Hahn echoed these remarks, saying: "What that means is – and if the data continue to pan out –100 people who are sick with Covid-19, 35 would have been saved because of the administration of plasma." Those facts are all wrong, as the FDA has admitted.

At this juncture in the vaccine development process, the FDA needs to be left alone to pursue its mission unpressured. Too much is riding on the vaccine development effort to have it any other way.