

COVID vaccine makers vow science—not Trump—will dictate release timing



Enlarge / Woman receives an experimental COVID-19 vaccine at the University of Massachusetts Medical School in Worcester, MA, on September 04, 2020, as part of a clinical trial.

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In an extraordinary move Tuesday, nine top pharmaceutical executives made a public pledge that they will not prematurely release a COVID-19 vaccine and that they will only seek federal approval to distribute a vaccine after rigorous ethical and scientific standards are met.

The pledge was signed by the CEOs of AstraZeneca, BioNTech, GlaxoSmithKline, Johnson & Johnson, Merck, Moderna, Novavax, Pfizer, and Sanofi. All of the represented companies are working on a vaccine against COVID-19 and four—AstraZeneca, Moderna, and a joint venture between BioNTech and Pfizer—have vaccines in phase 3 clinical trials.

The vow appears to be a coordinated resistance to pressure from the Trump administration, which is pushing for a rollout of a vaccine by November 1, just before the presidential election. Last week, the Centers for Disease Control and Prevention told states to be ready to start distributing vaccines by November 1.

Critics have called the timeline unrealistic, noting it's unlikely that vaccine developers would have sufficient data from the phase 3 trials by that time, let alone the necessary vaccine manufacturing and distribution infrastructure ready. They also pointed out that the pre-election target for a vaccine release appears solely based on politics, not public health.

Covid-19 Coverage

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In a press conference Monday, President Trump denied that he was racing to distribute a vaccine for political reasons or pushing for a pre-election release. However, his denial was weakened by repeated references to a pre-election release. In his opening remarks, Trump said we “could even have [a vaccine] during the month of October... the vaccine will be very safe and very effective, and it will be delivered very soon. You could—you could have a very big surprise coming up.”

At one point in the question-and-answer session with reporters, Trump obviously alluded to Election Day, saying:

“So we’re going to have a vaccine very soon, maybe even before a very special date. You know what date I’m talking about.”

Such politicization of public health efforts amid the pandemic has already taken its toll. Public trust in the CDC and the Food and Drug Administration has eroded following questionable decisions and reversals. And although vaccines for COVID-19 are still in various stages of testing, several polls have already indicated that the public is wary of whatever vaccine eventually does earn federal approval.

Trust testing

The nine pharmaceutical companies appear to be both bucking the politicization of their potential vaccines as well as attempting to quell public concern that an eventual vaccine will be tested thoroughly for safety and efficacy.

For instance, the companies noted that the FDA “requires that scientific evidence for regulatory approval must come from large, high-quality clinical trials that are randomized and observer-blinded, with an expectation of appropriately designed studies with significant numbers of participants across diverse populations.”

They pledged to “only submit [a potential vaccine] for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA.”

The companies went on: “We believe this pledge will help ensure public confidence in the rigorous scientific and regulatory process by which COVID-19 vaccines are evaluated and may ultimately be approved.”

Such a message was recommended in another open letter, released last week by the trade organization

Biotechnology Innovation Organization (BIO). The letter called for biotechnology companies to lay out “key principles” that ensure “integrity, transparency, and objective assessment” of COVID-19 treatments and vaccines. With that, the organization also pressed that the FDA “should maintain its historic independence as the gold-standard international regulatory body, free from external influence.”

Last, “political considerations should be put aside by Republicans and Democrats alike,” the letter said. “Our nation’s leaders should reassure the public that politics will not influence the development and approval of new medicines.”

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