HHS cancels nearly \$600 million Moderna contract on vaccines for flu pandemics

The decision will be seen as a significant blow to pandemic preparedness

This story will be updated

The Department of Health and Human Services has notified Moderna that it is canceling a nearly \$600 million contract with the company to develop, test, and license vaccines for flu strains that could trigger future pandemics, including the dangerous H5N1 bird flu virus.

Though the possibility of the cancellation had been anticipated — the new leadership at HHS told the company in February that <u>it was</u> <u>reviewing the contract</u>, signed with the Biden administration — the move will be seen as a significant blow to the country's capacity to respond to pandemic influenza.

No other flu vaccine production approach can produce doses with the speed of the messenger RNA platform used by Moderna and other companies that work with mRNA. But the vaccine platform is viewed with deep suspicion by health secretary Robert F. Kennedy Jr. and his political base.

Moderna had conducted a Phase 1/2 clinical trial of its H5N1 vaccine, and was optimistic about the results it was seeing, the company said in a statement.

"While the termination of funding from HHS adds uncertainty, we are pleased by the robust immune response and safety profile observed in this interim analysis of the Phase 1/2 study of our H5 avian flu vaccine and we will explore alternative paths forward for the program," said CEO Stéphane Bancel. "These clinical data in pandemic influenza underscore the critical role mRNA technology has played as a countermeasure to emerging health threats." STAT has reached out to HHS to ask for its rationale for cutting the program.

The funding, granted to the company by the Biomedical Advanced Research and Development Authority, an HHS agency, was aimed at allowing the company to test and license a potential pandemic flu vaccine in advance. The goal of such funding — which BARDA has given to other flu vaccine manufacturers in the past — is to produce safety and immunogenicity data, and to license a prototype vaccine.

Moderna would be able to update the vaccine to target a particular new strain if a pandemic started; the vaccine could then be raced into distribution using the Food and Drug Administration's strain change rule — the approach the agency uses to approve changes to the annual flu shot.

Experts who have worked in the pandemic preparedness field for years were dismayed by the development.

"In a rapidly expanding pandemic, time matters. ... The sooner the population is protected from a lethal virus the more lives that will be saved. Of its many features, what mRNA technology provided most is speed," said Bruce Gellin, a former director of the National Vaccine Program Office in the Bush and Obama administrations.

"If we lose our capability to respond as quickly as we can, we will sadly be able to calculate those who died because we made a decision that speed wasn't important."