

## FDA commissioner Stephen Hahn: 'Decisions about approving vaccines will be based solely on good science'

The framework in the United States to support a covid-19 vaccine is now in place. Testing is underway and manufacturing capacity is rapidly expanding. But let's be clear: The development effort must adhere to standards that will ensure any covid-19 vaccine's safety and effectiveness.

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To prepare for the completion of tests and data submission, our agency has announced that any authorized or approved covid-19 vaccine would need to show that it prevents the disease or decreases its severity in [at least 50 percent](#) of people who are vaccinated. This is a reasonable standard given the nature and impact of the pandemic.

One key element in the FDA's testing requirements is assuring diversity among the test subjects. All phases of vaccine clinical development should include the people most affected thus far by covid-19, specifically [racial and ethnic minorities](#), elderly individuals, and people with other medical conditions. Only by gathering data on these populations can we gain a full understanding of a vaccine candidate's safety and effectiveness.

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I have been asked repeatedly whether there has been any inappropriate pressure on the FDA to make decisions that are not based on good data and good science. I have repeatedly said that all FDA decisions have been, and will continue to be, based solely on good science and data. The public can count on that commitment.

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