



October 2020

Fighting to Ensure a Safe and Effective COVID-19 Vaccine

COMMITTEE ON ENERGY & COMMERCE

While President Trump exerts political pressure on the COVID-19 vaccine development process, the Food and Drug Administration (FDA) nonetheless took action to ensure that patient safety and scientific evidence of efficacy will guide its review of potential COVID-19 vaccines. Trump and his Administration must not interfere with the FDA's regulatory oversight.

The Trump Administration has failed to develop a comprehensive national COVID-19 vaccine plan, threatening the future distribution and equitable allocation of a COVID-19 vaccine. To address this, House Democrats have passed comprehensive legislation that requires the creation of a national vaccine plan and \$28 billion in funding to develop, manufacture, and promote access to vaccines.

NEW FDA GUIDANCE:

After initially being blocked for weeks by the White House, on October 6, FDA released guidance outlining the data and information it will need from manufacturers to support Emergency Use Authorization (EUA) for a COVID-19 vaccine.

- This EUA guidance requires that developers follow Phase 3 clinical trial participants for at least two months after they receive the full vaccine regimen to help assess the risks and benefits of the vaccine, including any adverse events and immune response, before submitting a request for an EUA.
- The safety monitoring standards included in the EUA guidance make clear that data supporting an EUA request for a vaccine must be more closely evaluated to ensure risks have been uncovered and/or mitigated. The standards for an EUA are less stringent than the standards for approval, making this safety data even more important.
- Developers benefit from the FDA guidance by having clear standards and a path forward for conducting clinical trials and evaluating their vaccine.
 - Public health experts and researchers also benefit as it provides greater transparency on how vaccines will be evaluated by FDA, allowing external experts to verify that developers are truly meeting these standards—contributing to the confidence of the American people.

FDA must be allowed to fulfill its mission to protect public health by ensuring the safety, efficacy and trust of any future COVID-19 vaccine.

- **Any attempt by President Trump and his Administration to override FDA or to force manufacturers to prematurely bring a vaccine to market will do catastrophic harm to public health and undermine the American people's trust in a future vaccine.**

HOUSE DEMOCRATS' LEGISLATIVE ACTION:

House Democrats have taken bold action to pass legislation to create a national vaccine plan, to ensure vaccines are free of cost-sharing, and to provide more than \$28 billion in funding.

- The Heroes Act, passed by the House in May, requires the creation of a national vaccine plan to distribute and administer COVID-19 vaccines and enhances vaccine manufacturing capacity.
- The Heroes Act passed in May also ensures that all vaccines are free of cost-sharing for all Americans when they are finally available.
- **The updated Heroes Act, passed by the House on October 1, includes both of these provisions but also adds new language and \$28 billion in funding for COVID-19 vaccine development, manufacturing, procurement, and awareness campaigns. It also continues to require a national vaccine plan.**
 - **\$20 billion would be authorized** for the Secretary of Health and Human Services (HHS) to provide grants or contracts for development, research, manufacturing capacity, and procurement of COVID-19 vaccines, therapeutics, and ancillary supplies.
 - **\$7 billion would be authorized** for the Secretary to conduct activities to enhance, expand, and improve nationwide COVID-19 vaccine distribution and administration. The legislation also requires the Secretary to provide grants to State, local, Tribal, and territorial public health departments for procurement of vaccines, ancillary medical products, workforce enhancements, IT and data enhancements and facilities enhancements (such as if there are cold storage needs or outdoor tents for administration). These funds are important to States, which are required by the Centers for Disease Control and Prevention (CDC) to develop a vaccine plan by October 16.
 - **\$1 billion would be authorized** for a national evidence-based vaccine awareness campaign, including State and local grants to support vaccine data collection and awareness, and activities related to better surveillance of underutilization of vaccines or vaccine hesitancy.

THE COMMITTEE'S OVERSIGHT ACTION:

The Energy and Commerce Committee continues to demand answers from this administration and to hold them accountable for their continued attempts to politicize the vaccine development process.

- In a May 21 bipartisan [letter](#) to White House Coronavirus Task Force Coordinator Deborah Birx, the Committee urged the Administration to develop a comprehensive COVID-19 vaccine plan.
- The Committee reiterated the importance of ensuring any vaccine made available is both safe and effective in an [oversight hearing](#) on July 21 to a panel of vaccine manufacturers engaged with Operation Warp Speed (OWS).
- Committee leaders again demanded answers and stressed vaccine distribution logistics and equitable allocation concerns in a [letter](#) to Dr. Birx and HHS Secretary Alex Azar on August 5, followed by a [letter](#) to FDA Commissioner Stephen Hahn on August 24 urging that science and not politics guide the COVID-19 vaccine authorization and approval process.
- In September, Committee leaders [demanded](#) a briefing from CDC Director Robert Redfield on its notification to states that they be prepared to distribute a potential vaccine by November 1.
- On September 30, the Committee held an oversight [hearing](#) on considerations for the development and distribution of a safe and effective vaccine that the American people can trust.