

# U.S. Sen. Baldwin: Tells FDA to maintain public trust in COVID-19 vaccine decisions by making reviews transparent

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WASHINGTON, D.C. – U.S. Senator Tammy Baldwin (D-WI), a member of the Senate Health, Education, Labor and Pensions (HELP) Committee, and her colleagues are [calling](#) on the U.S. Food and Drug Administration (FDA) to commit to full transparency in the COVID-19 vaccine review process amidst mounting political pressure from the President to approve a vaccine before Election Day. The lawmakers, led by Senators Elizabeth Warren (D-MA) and Maggie Hassan (D-NH), expressed concern that the Trump administration has overruled scientists and pressured federal agencies to approve products based on weak evidence, and they urged the FDA to ensure transparency in vaccine review efforts in order to maintain public trust.

*“We write to seek your commitment that the Food and Drug Administration’s (FDA) review process for potential vaccinations against the coronavirus disease 2019 (COVID-19) will be fully transparent and accountable,” wrote the Senators. “We are encouraged by the [development](#) of a number of vaccine candidates, and we share the FDA’s goal of facilitating ‘the timely development of safe and effective vaccines to prevent COVID-19.’ However, we are concerned that the accelerated timeline and intense political pressure around the vaccine development process could have the unintended consequence of undermining public confidence in the safety and quality of an eventual vaccine.”*

More than [100 vaccines](#) against COVID-19 are currently in development worldwide, with [37](#) in human clinical trials proceeding at an unprecedented pace. To address public concerns that the rapid speed of vaccine development could compromise the integrity of the review process, the FDA [issued guidelines](#) in June 2020 to assist in the clinical development and licensure of vaccines for COVID-19. However, President Trump and his administration have continuously applied political pressure to the agency — including [promising](#) that a vaccine will be approved by the end of 2020, or even by Election Day. The Centers for Disease Control and Prevention (CDC) also recently notified states that they should be [prepared](#) to distribute a vaccine by November 1, further raising concerns that the approval process will be rushed. Such recent statements made by the Trump administration may risk undermining public confidence in the FDA unless the agency commits to greater transparency in the vaccine development and review process.

Recent polling shows significant public skepticism about a future vaccine, including a [recent poll](#) that found that only 49% of American adults plan to accept a coronavirus vaccine, with 20% not planning to be vaccinated and 31% remaining unsure. The [same poll](#) found that only 25% of Black Americans and 37% of Hispanic Americans plan to be vaccinated.

*“In order to achieve broad acceptance with the public, a future vaccine for COVID-19 will need to overcome public skepticism about the speed of the process, underlying doubts about vaccine safety, long-standing mistrust of the medical system among communities of color – and the effects of the President’s ongoing political interference,”* **wrote the Senators.** The Senators asked a series of questions, including whether meetings of the Vaccine and Related Biological Products Advisory Committee would be open to the public, if data and design details from clinical trials will be made available to the public, and how the FDA is involving representatives of communities of color, people with disabilities, older Americans, and other groups at elevated risk from COVID-19.

The letter was also signed by Senators Dianne Feinstein (D-CA), Kirsten Gillibrand (D-NY), Richard Blumenthal (D-CT), Tina Smith (D-MN), Jeffrey A. Merkley (D-OR), Angus S. King, Jr. (I-ME), Jack Reed (D-RI), Christopher S. Murphy (D-CT), Mazie Hirono (D-HI), Bernard Sanders (I-VT), Michael F. Bennet (D-CO), and Sherrod Brown (D-OH).

The Senators requested a response to their letter no later than September 28, 2020. The full letter is available [here](#).