

Immunocompromised Collaborative

June 11, 2025

FDA's new COVID-19 vaccine framework places immunocompromised people at risk

The [Food and Drug Administration's \(FDA\) newest framework](#) would limit approved use of updated versions of COVID-19 vaccines to those 65 years of age and older and those under 65 who have specific chronic conditions unless manufacturers run costly, unethical, and time-intensive randomized, placebo-controlled trials. Instead of encouraging the general public to continue to vaccinate against COVID-19, FDA has chosen to enact a framework that will likely limit insurance coverage and access to this vital protection. **This framework will put people who are immunocompromised at risk.**

While the list of vaccine-eligible chronic conditions includes many immunocompromising conditions, such as primary immunodeficiency (PI), leukemia, and use of immunosuppressive medication, that have been shown to increase the risk of serious COVID-19 infection and death, **many immunocompromised people cannot themselves mount protective immune responses to vaccines.** Just providing access to these individuals does not mean they are protected from infection.

The best protection for individuals who are immunocompromised is to ensure that there are enough people in the community who are vaccinated, creating community or 'herd' immunity to minimize everyday exposure to COVID-19. Many immunocompromised people still wear masks in public precisely because COVID-19 vaccination rates are so low. In justifying its change in policy, the FDA cites *recommendations* (note, not marketing authorizations or approvals from FDA-equivalent agencies) in several other countries as comparators, including Germany, Belgium, and Canada; however, many of these countries explicitly recommend the COVID-19 vaccine for healthcare workers or household contacts of the immunocompromised, at least acknowledging the role of community immunity.

The agency has likened the new framework to that for vaccines against respiratory syncytial virus (RSV), however, RSV vaccines have not been tested in younger, healthy

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individuals. In contrast, all three COVID-19 vaccines have been tested in healthy individuals spanning many age ranges. The new FDA framework treats COVID-19 vaccines updated to target different antigens as entirely new vaccines, which they are not. **There is no justification for approving updated COVID-19 vaccines in only certain populations.**

FDA has abdicated its responsibility to protect people who are immunocompromised. **A decrease in vaccination rates weakens community immunity**, putting those with compromised immune systems at a higher risk of severe, preventable infections.

This framework is a step backward in efforts to prevent the spread of infectious disease.

Sincerely submitted for your consideration,

AIDS Foundation Chicago
Alliance for Aging Research
American Kidney Fund*
Autoimmune Association*
Avery's Hope
COPD Foundation
Family Voices NJ
Foundations for Sarcoidosis Research
GBS/CIDP Foundation International
HealthHIV*
HealthyWomen
Immune Deficiency Foundation*
Immunize Colorado
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America*
Lymphoma Research Foundation*
National Association of Social Workers - TX Chapter
National Coalition for LGBTQ Health
National Consumers League
National Fabry Disease Foundation
Pulmonary Hypertension Association
SCID Foundation
SPAN Parent Advocacy Network
Transplant Recipients and Immunocompromised Patient Advocacy Group
Vasculitis Foundation
Wiskott-Aldrich Foundation

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