May 27, 2026

Division of Dockets Management
U.S. Food & Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments to the Docket No. FDA-2026-N-3962 for Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—United States (U.S.) 2026-2027 Formula for COVID-19 Vaccine Composition

The undersigned organizations thank the FDA for scheduling the May 28 Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting and recognizing the importance of this annual convening to discuss and make swift recommendations on the strain composition of COVID-19 virus vaccines for use in the United States during the 2026-2027 respiratory virus season. Advisory committees, including VRBPAC, play an important role in the regulatory ecosystem by providing an opportunity for independent scientific expertise and transparent public discussions of complex evidence. This open forum helps strengthen confidence that regulatory decisions are informed by rigorous analysis and diverse expert perspectives, and we encourage the Agency to continue leveraging these venues to support transparent scientific dialogue going forward.

As individuals and organizations representing public health, patients, family caregivers, and healthcare providers, we have a clear stake in the availability of 2026-2027 COVID-19 vaccines. In preparation for the upcoming 2026-2027 respiratory virus season, we respectfully submit these comments to urge the Vaccines and Related Biological Products Advisory Committee (VRBAC) and the FDA to:

1. Provide manufacturers with an immediate recommendation regarding the 2026-2027 updated strain for COVID-19 vaccines for use in the United States so that production can begin without delay and vaccines are available ahead of the upcoming respiratory season; and
2. Work to facilitate continued availability of both mRNA-based and protein-based vaccines for the 2026-2027 season so that healthcare professionals, patients, and family caregivers have a choice among options that have met regulatory standards for safety and effectiveness.

COVID-19 Continues to Cause a High Disease Burden in the United States

Like influenza, COVID-19 has become endemic. However, unlike influenza, spikes in SARS-CoV-2 activity that cause COVID-19 are not yet confined to seasonal patterns. Severity indicators for COVID-19, such as rates of hospitalization and death, have declined considerably since their peak during the 2021-2022 season,[1] but COVID-19 remains a leading cause of doctor visits, hospitalizations, and deaths caused by respiratory viruses in the United States. As of May 9, 2026, preliminary data from the 2025-2026 COVID-19 season in the United States indicate that COVID-19 infections were responsible for an

[1] See CDC, "Covid Data Tracker," https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00.

estimated 780,000 thousand to 2.3 million outpatient visits; 120,000 to 250,000 hospitalizations; and 13,000 to 41,000 deaths.[2]

This burden of COVID-19 deaths is shouldered disproportionately by Americans ages 65 and older and other high-risk groups. A recent study published in the Public Library of Science found that the life expectancies of those who died with COVID-19 were substantial and most of those who died at ages 65 and over were unlikely to have been close to death prior to infection, with 28% of those dying with COVID-19 ages 65 and over, estimated to survive five years or more without the infection.[3]

Higher risk is defined by the CDC as "an underlying medical condition or risk factor that has a published meta-analysis or systematic review or underwent the CDC systematic review process. The meta-analysis or systematic review demonstrates a conclusive increase in risk for at least one severe COVID-19 outcome."[4] Such conditions include asthma, cerebrovascular disease, chronic kidney disease, cystic fibrosis, diabetes mellitus (type 1 and type 2), and certain types of cancer, chronic lung diseases, and chronic liver diseases, among many others. Notably, the CDC identifies being overweight or obese as a strong, independent risk factor for severe infection and death due to COVID-19. This is especially significant for the U.S., where nearly 3 in 4 adults are now considered overweight or have obesity. In total, an estimated 74% of adults in the United States have at least one condition that puts them at higher risk of severe illness from COVID-19.[5]

COVID-19 Vaccines Meaningfully Reduce Risk of Serious Illness and Death

To-date, the FDA has approved or authorized three COVID-19 vaccines that provide different options for patients and providers, depending on an individual's age and preferences:

- The available mRNA COVID-19 vaccines are Comirnaty and Spikevax. The Pfizer COVID-19 vaccine, Comirnaty, which is approved for individuals 5 years of age and older; and the Moderna COVID-19 vaccine, SpikeVax, which is approved for individuals 6 months and older; and
- The Novavax COVID-19 Vaccine, Adjuvanted (2025-2026 Formula), which is authorized for use in individuals 12 years of age and older.

FDA approved the Comirnaty and SpikeVax vaccines, under BLAs based on clinical data showing that vaccines are "safe, potent, and pure."[6] In order to meet that standard, the manufacturers had to provide FDA with "substantial evidence" of effectiveness as well as "adequate tests" showing that the vaccine is safe for use under the conditions described in the labeling.[7] Novavax is the only non-mRNA vaccine available in the U.S.[8] These vaccines provide a mechanism for individuals and families to mitigate the risk of COVID-

[2] CDC, "Preliminary Estimates of COVID-19 Burden for 2025-2026," https://www.cdc.gov/covid/php/surveillance/burden-estimates.html.
[3] Hughes, Andrew, et al. "Life Lost due to the COVID-19 Pandemic: A Model-Based Cohort Analysis of Mortality Displacement in the Registered Population of England." *PLOS One*, vol. 21, no. 5, 8 May 2026, p. e0348575, https://doi.org/10.1371/journal.pone.0348575. Accessed 15 May 2026.
[4] Underlying Conditions and the Higher Risk for Severe COVID-19, CDC website at https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html
[5] Lakshmi, slide 14 at https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID508.pdf
[6] 42 U.S.C. § 262(a)(2)(C)(i)(I).
[7] 21 U.S.C. § 355(d).
[8] Comparing the COVID-19 Vaccines: How Are They Different?, Yale Medicine, Nov. 22, 2024, https://www.yalemedicine.org/news/covid-19-vaccine-comparison.

19, including potentially severe illness, hospitalization, and death. Although COVID-19 vaccines may not prevent infection or mild disease in every case, there is no doubt that – as with flu vaccines – vaccination meaningfully decreases the overall disease burden, particularly for high-risk groups. For instance, recently published statistics regarding the effectiveness of the 2025-2026 formulations of the COVID-19 vaccines show that XBB.1.5-adapted Covid-19 vaccines showed moderate-to-high effectiveness against hospitalization across age groups, including clinically meaningful effectiveness among older and immunocompromised adults, and remained substantial within 6 months after vaccination.[9]

These findings indicate that the updated 2025-2026 COVID-19 vaccines provided protection (compared to not receiving the 2025-2026 vaccination) against COVID-19–associated office visits and hospitalization. Meanwhile, extensive clinical trial data, as well as ongoing monitoring of real-world experience, continue to confirm the COVID-19 vaccines' safety. Not only has FDA used real-world data to monitor the safety of vaccines through both passive and active post-market surveillance, independent researchers from around the globe have performed extensive high-quality systematic and meta-analyses of the vaccines' safety.[10] Most reported side effects of the vaccines are mild and transient, including injection site pain, fatigue, headaches and body aches. In addition, the incidence of the most serious adverse events, myocarditis and pericarditis, has been rare and appears to be further falling.[11]

FDA Should Continue to Timely Fulfill Its Responsibility to Appropriately Review and Approve or Authorize Updated Vaccines for the 2026-2027 Season

The number of individuals who have been previously exposed to SARS-CoV-2 antigens has been increasing in the United States and worldwide, due to vaccinations and infections. However, the virus continues to evolve rapidly and has been doing so to become increasingly immune evasive and even with the development of immunity, it wanes over time.[12][13] Accordingly, there remains an urgent public health need for continued availability of safe and effective COVID-19 vaccines that can help boost individual and group immunity. Further, should there be a significant seasonal outbreak, ready patient access to vaccines that closely track the dominant viral strains will be critical to help patients protect themselves and their families, as well as reduce the overall strain on community healthcare resources.

To enable patient access to COVID-19 vaccines in the United States, we urge FDA to:

---

[9] Scott, Jake, et al. "Updated Evidence for Covid-19, RSV, and Influenza Vaccines for 2025–2026." *New England Journal of Medicine*, vol. 353, no. 22, 29 Oct. 2025, https://doi.org/10.1056/nejmsa2514268.

[10] See, e.g., Jayesh Beladiya, et al. (2024) "Safety and efficacy of COVID-19 vaccines: A systematic review and metaanalysis of controlled and randomized clinical trials," Rev Med Virol. 34(1):e2507. doi: 10.1002/rmv.2507; Graña C, et al. (2022) "Efficacy and safety of COVID-19 vaccines." Cochrane Database of Systematic Reviews, Issue 12. Art. No.: CD015477.DOI: 10.1002/14651858.CD015477.

[11] Lakshmi Panagiotakopoulos, MD, MPH, Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations, April 2025 ACIP Meeting, https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf (describing data from the CDC's Vaccine Safety Data Link and FDA's Vaccine Adverse Event Reporting System).

[12] The extent of the longevity and durability of immunity is unclear. Some research has shown that the effectiveness of COVID-19 vaccines wanes within months of the last administered dose. See, e.g., Menegale F, et al. (2023). "Evaluation of Waning of SARS-CoV-2 Vaccine–Induced Immunity: A Systematic Review and Meta-analysis." JAMA Netw Open. 6(5):e2310650. doi:10.1001/jamanetworkopen.2023.10650. Some research concludes that antibody responses are longlasting. See, e.g., Komal Srivastava, et al. (2024) "SARS-CoV-2-infection- and vaccine-induced antibody responses are long lasting with an initial waning phase followed by a stabilization phase," Immunity, 57(3); 587-599. doi 10.1016/j.immuni.2024.01.017.

[13] Yan VKC, Wan EYF, Ye X, Mok AHY, Lai FTT, Chui CSL, Li X, Wong CKH, Li PH, Ma T, Qin S, Lau CS, Wong ICK, Chan EWY. "Waning effectiveness against COVID-19-related hospitalization, severe complications, and mortality with two to three doses of CoronaVac and BNT162b2: a case-control study." Emerg Microbes Infect. 2023 Dec;12(1):2209201.

1.) **Provide Manufacturers with a Timely Recommendation for the Updated Strain to Be Included in the 2026-2027 COVID-19 Vaccines**

Since the initial emergence of SARS-CoV-2, a hallmark of the virus has been its ability to evolve and generate variants, underscoring the importance of ensuring a close match between the COVID-19 vaccine and the dominant strain of circulating virus. In recent years, similar to the process used to develop annual updates to the influenza vaccines, FDA has played a critical leadership role in identifying and recommending virus strains for annual updates to the COVID vaccines. In consultation with the CDC, the WHO, the VRBPAC, and others, FDA has established a highly functional timeline and process. Strain selection in June enables FDA to conduct premarket review of the vaccines by August. The predictability of this timeline for strain selection is crucial to ensuring vaccine availability in advance of the upcoming season. We urge FDA to faithfully follow this well-established, highly functional process in preparation for the 2026-2027 respiratory virus season.

2.) **Ensure the Availability of Both Updated mRNA-Based and Protein-Based Vaccines for the 2026-2027 Season Based Upon Timely Review of Applications or Supplements Submitted by the Manufacturers**

Once strains are selected for the upcoming season, it is incumbent upon the FDA to facilitate availability of COVID-19 vaccines from multiple sponsors, including both mRNA and protein-based vaccines – if the data submitted to the Agency meets the legal standards for approval or authorization. The FDA approved and authorized vaccines are roughly comparable in terms of safety and effectiveness. However, patients may either prefer one vaccine over another, especially considering the difference in technologies, i.e., with the advent of the mRNA vaccines arose the inevitable concerns for its dangers. Without any eminent historic substantiation, the fear of potential side-effects accounted for vaccine hesitancy in almost 50% of the population.[14] We urge the FDA to continue to honor patient choice and promote uptake by facilitating continued availability to all three existing vaccine options. Beyond issues of choice, supply chain stability is a practical and public health imperative. Relying on multiple vaccine manufacturers decreases the risk of a potential vaccine shortage, should there be a future supply chain disruption. In addition, maintaining multiple production lines helps ensure that updated vaccines can be produced as necessary to address new virus variants. We urge the FDA to continue facilitating a resilient supply chain for COVID-19 vaccines.

Conclusion

Vaccines offer the single best method for preventing infection, severe illness, and death from COVID-19 for all age groups. And while the benefits of vaccination in terms of protection against death are disproportionately realized by older Americans and other immunocompromised individuals, vaccines remain an important protective option for both adults and children to reduce acute morbidity from COVID-19 as well as long COVID. Preventing severe respiratory viral illness also helps reduce downstream complications, including sepsis and other life-threatening conditions that disproportionately impact medically vulnerable populations.

[14] Coustasse A, Kimble C, Maxik K. COVID-19 and vaccine hesitancy: A challenge the United States must overcome. J Ambul Care Manage. 2021;44:71–5.

We urge the FDA to work expeditiously with the VRBPAC, government partners, and vaccine manufacturers to make strain selection recommendations for the 2026-2027 season and facilitate continued availability of both mRNA-based and protein-based vaccines.

We appreciate the opportunity to provide this input and thank you for your attention to these comments.

Sincerely,

AiArthritis
Alliance for Aging Research
Alliance for Patient Access
ALS Association
America's Physician Groups
American Association of Psychiatric Pharmacists (AAPP)
American Public Health Association
ASCP - Age Friendly Pharmacists and Pharmacies
Association of Black Cardiologists
Asthma and Allergy Foundation of America
Caregiver Action Network
CaringKind, The Heart of Alzheimer's Caregiving
Gerontological Society of America
Global Coalition on Aging
HealthHIV
HealthyWomen
Immune Deficiency Foundation
Lupus and Allied Diseases Association, Inc.
National Association of Nutrition and Aging Services Programs (NANASP)
National Coalition for LGBTQ Health
National Consumers League
National Foundation for Infectious Diseases
Neuropathy Action Foundation
Nevada Chronic Care Collaborative
Partnership to Fight Infectious Disease
Pediatric Nurse Practitioner House Calls
Sepsis Alliance
Vaccinate Your Family
Vasculitis Foundation
Voices of Alzheimer's