May 22, 2025

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 for Public Comment on the Vaccines and Related Biological Products Advisory Committee (VRBAC) [Docket No. 2025-N-1146]

The undersigned organizations respectfully submit these comments to urge the Vaccines and Related Biological Products Advisory Committee (VRBAC) and the FDA to:

1. Provide manufacturers with a timely recommendation regarding the 2025-2026 updated strain for COVID-19 vaccines for use in the United States,
2. Work to facilitate continued availability of both mRNA-based and protein-based vaccines for the 2025-2026 season so that healthcare professionals, patients, and family caregivers have a choice among options that have met regulatory standards for safety and effectiveness, and
3. Continue to ensure that the labeling of COVID-19 vaccines covers both the adult and pediatric populations so that healthcare professionals, patients, and family caregivers have options and appropriate information for individual decision-making.

As individuals and organizations representing public health, patients, family caregivers, and healthcare providers, we have a clear stake in the availability of 2025-2026 COVID-19 vaccines. In the years since FDA first authorized vaccines to stem the tide of COVID-19, vaccines have become an essential public—and personal—health tool. In preparation for the upcoming 2025-2026 respiratory virus season, FDA should follow its preexisting processes for review and, as appropriate, updates to the approved and authorized COVID-19 vaccines.

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

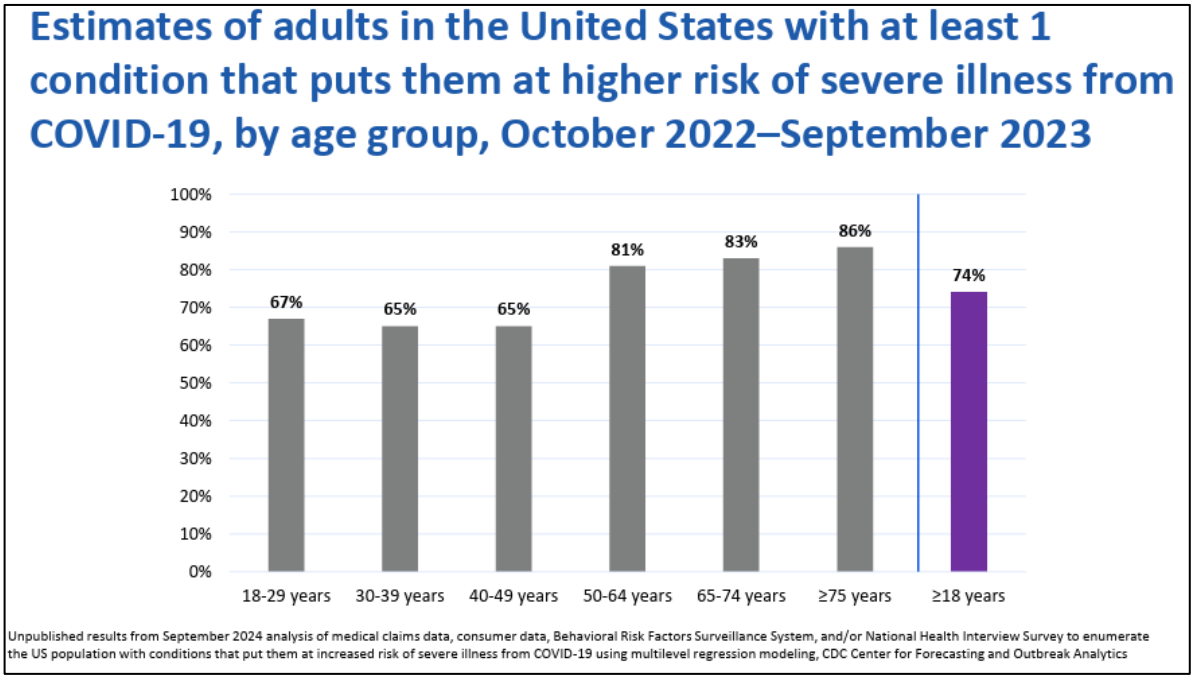
Like influenza, COVID-19 has become endemic. However, unlike influenza, spikes in SARS-CoV-2 activity that cause COVID-19 are not yet confined to seasonal patterns. Severity indicators for COVID-19, such as rates of hospitalization and death, have declined considerably since their peak during the 2021-2022 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 3, 2025, preliminary data from the 2024-2025 COVID-19 season in the United States indicate that COVID-19 infections were responsible for an estimated 2.2-3.6 million outpatient visits; 250,000-410,000 hospitalizations; and 29,000-48,000 deaths, and to date in calendar year 2025, 10,373 COVID-19 deaths have been reported.[2]

This burden of COVID-19 deaths is shouldered disproportionately by Americans aged 65 and older and other high-risk groups. At the CDC's April 2025 meeting of the Advisory Committee on Immunization Practices (ACIP), the COVID-19 Vaccines Work Group led a discussion on policy

[1] *See* CDC, "Covid Data Tracker," https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00.
[2] CDC, "Preliminary Estimates of COVID-19 Burden for 2024-2025," https://www.cdc.gov/covid/php/surveillance/burden-estimates.html.

considerations for annual use of the 2025–2026 vaccines, and whether to maintain a universal vaccine policy for everyone ages ≥6 months; advance a risk-based recommendation only for groups at increased risk of severe COVID-19; or, to put forward a combination of risk-based and universal vaccine recommendations (e.g., risked-based recommendation for ages 6 months-64 years and universal recommendations for ages ≥65 years).[3]

In addition to older age, there are more than 20 underlying-condition categories linked to higher risk of severe COVID-19 illness. 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]**



[3] Lakshmi Panagiotakopoulos, MD, MPH, Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations, April 2025 ACIP Meeting at https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf.
[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-COVID-508.pdf.

Additionally, the COVID-19 pandemic has highlighted racial, ethnic, and socioeconomic disparities in COVID-19 illnesses, hospitalizations, and deaths.[6] Data has shown that compared to non-Hispanic White people, people from racial and ethnic minority groups are more likely to be infected with the virus that causes COVID-19—and, once infected—are more likely to be hospitalized, be admitted to the ICU, and die from COVID-19 at younger ages.[7] Some racial and ethnic minority groups are also more likely to face multiple barriers to accessing health care including lack of insurance, transportation, childcare, or ability to take time off from work.

When it comes to vaccinations for COVID-19, it has been noted that the U.S. stands apart in recommending "updated" (i.e., booster) shots for children ages ≥6 months. However, comparing CDC's recommendations to those in other countries may not be appropriate, given the differing epidemiology of SARS-CoV-2 in different locations along with the associated morbidity and mortality. The CDC's COVID-19 Vaccines Work Group presented data at the April 2025 meeting showing that, during the 2023-2024 season, an estimated 152 children under age 18 in the United States died because of COVID-19.[8] Additionally, 300,000 children in the U.S. have long COVID.[9]

The FDA should continue to ensure availability and appropriate labeling of vaccines for the pediatric population so that parents have access to as many safe and effective options as possible. **It is worth noting that, while the FDA's authorization or approval of COVID-19 vaccines with accompanying ACIP recommendations influence clinical guidelines and payer coverage, they do not determine mandates.** According to the National Academy for State Health Policy (NASHP), "While most health care providers follow ACIP guidance when making vaccine recommendations for their patients, adding vaccines to the CDC's pediatric immunization schedule does not constitute a vaccine mandate. State governments determine school immunization requirements for their jurisdictions."[10] Additionally, no state requires/mandates COVID-19 vaccines for children or adults at this point and many states have laws that prohibit such mandates.[11] **However, ACIP recommendation of FDA-approved or authorized vaccines are fundamental to ensuring that vaccines are not only available but also covered under both public and private insurance programs**, including the Vaccines for Children Program (VFC) which covers more than half of the children in the United States.[12]

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[6] Okasako-Schmucker DL, Cornwell C, Mirabelli M, et al. Brief Summary of Findings on the Association Between Asthma and Severe COVID-19 Outcomes. CDC COVID-19 Scientific Brief. June 2022 at https://www.cdc.gov/covid/media/pdfs/2025/02/K-Brief-Summary-of-Findings-on-the-Association-Between-Asthma-and-SevereCOVID-19-Outcomes-508_1.pdf. Kumasaka JK, Weissman D, Mazurek J, et al. Brief Summary of Findings on the Association Between COPD and Severe COVID-19 Outcomes. June 2022 at https://www.cdc.gov/covid/media/pdfs/2025/02/L-Brief-Summary-of-Findings-on-the-Association-Between-Underlying-COPD-and-Severe-COVID-19-Outcomes-508.pdf. So CN, Green RF, Drzymalia E, et al. Brief Summary of Findings on the Association Between Cystic Fibrosis and Severe COVID-19 Outcomes. June 2022 at https://www.cdc.gov/covid/media/pdfs/2025/02/M-CysticFibrosis-print.pdf.

[7] Magesh S, John D, Li WT, et al. Disparities in COVID-19 Outcomes by Race, Ethnicity, and Socioeconomic Status: A Systematic Review and Meta-analysis. JAMA Netw Open. 2021;4(11):e2134147 at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2785980#google_vignette.

[8] *Id.* (describing total number of COVID-19 and influenza deaths among ages 0-17 years, September 2023-August 2024).

[9] Ford ND, Vahratian A, Pratt CQ, Yousaf AR, Gregory CO, Saydah S. Long COVID Prevalence and Associated Activity Limitation in US Children. JAMA Pediatr. Published online February 03, 2025.

[10] https://nashp.org/state-tracker/states-address-school-vaccine-mandates-and-mask-mandates/

[11] https://nashp.org/state-tracker/state-efforts-to-ban-or-enforce-covid-19-vaccine-mandates-and-passports/

[12] Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program — United States, 1994–2023, Weekly / August 8, 2024 / 73(31);682–685,

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

Use of a safe and effective vaccine remains the most effective way for an individual to reduce the risk of serious illness, hospitalization, and death from COVID-19.

FDA has reviewed and affirmed the safety and efficacy of COVID-19 vaccines available in the United States, either under FDA's authority to approve biologics license applications (BLAs)[13] or its authority to grant emergency use authorizations (EUAs).[14] Although the statutory standards for these review pathways differ, both standards involve a rigorous evaluation by FDA experts of the safety and efficacy data for a product to determine whether the products should be made available to patients.[15] The COVID-19 vaccines authorized and approved by FDA have undergone a rigorous research and development process, including well-designed, placebo-controlled phase 3 trials, and have been thoroughly evaluated by FDA prior to approval or authorization. Throughout the development process, FDA has provided scientific and regulatory advice to industry, researchers, and others across the vaccine development spectrum. FDA scientific and medical experts have reviewed thousands of pages of data and information; conducted their own analyses of the vaccines' safety and effectiveness; and performed detailed reviews of the manufacturing processes, including facility inspections as warranted.[16]

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, both of which are approved for individuals 12 years of age and older; and the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, both of which are authorized for emergency use for individuals 6 months through 11 years of age.

- The Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula), which is authorized for use in individuals 12 years of age and older.

FDA approved Comirnaty and SpikeVax vaccines, under BLAs, for use in individuals 12 years and older, based on clinical data showing that vaccines are "safe, potent, and pure."[17] 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 used under the conditions described in the

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https://www.cdc.gov/mmwr/volumes/73/wr/mm7331a2.htm#:~:text=In%202023%2C%20approximately%2054%25%20of,)%20born%20during%201994%E2%80%932023.

[13] *See* 42 U.S.C. § 262(a)(2)(C); 21 C.F.R. § 601.2.

[14] *See* 21 U.S.C. § 360bbb-3(c), (d), and (e).

[15] *See* 42 U.S.C. 262 (outlining the standard for approval of a biologics license agreement (BLA)); 21 U.S.C. 360bbb–3(c) (outlining the standard for emergency use authorization (EUA)).

[16] *See, e.g.*, Comirnaty regulatory history, https://www.fda.gov/vaccines-blood-biologics/comirnaty; Spikevax regulatory history, https://www.fda.gov/vaccines-blood-biologics/spikevax; Novavax regulatory history, https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/novavax-covid-19-vaccine-adjuvanted; FDA, "FDA Approves First COVID-19 Vaccine: Approval Signifies Key Achievement for Public Health," FDA News Release (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

[17] 42 U.S.C. § 262(a)(2)(C)(i)(I).

labeling.[18] FDA authorized the same vaccines for use in patients ages 6 months to 11 years based on data showing that the vaccines met the standard for EUAs—namely that the known and potential benefits of the vaccines outweigh the potential risks and that there are no adequate alternatives.[19] In addition, FDA authorized the Novavax for use in individuals 12 years old and older via EUA.[20] Novavax is the only non-mRNA vaccine available in the U.S.[21]

These vaccines provide a mechanism for individuals and families to mitigate the risk of COVID-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 2024-2025 formulations of the COVID-19 vaccines show that, for individuals that had received the dose between 7-119 days earlier:[22]

- In adults 18-64 years old, vaccination was approximately 30% effective against COVID-19 associated emergency department/urgent care encounters.

- In adults 65 years old and older, vaccination was approximately 35% effective against COVID-19 associated emergency department/urgent care encounters; and

- In adults 65 years old and older, vaccination was approximately 40-45% effective against COVID-19 associated hospitalization.

These findings indicate that the updated 2024-2025 COVID-19 vaccines provided protection (compared to not receiving the 2024-2025 vaccination) against COVID-19–associated office visits and hospitalization. Note that the levels of protection provided were like the levels of protection seen by seasonal influenza vaccines, which have been accepted to have a favorable benefit to risk profile for use across all age groups.[23]

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.[24] Most reported side effects of the vaccines are mild and transient,

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[18] 21 U.S.C. § 355(d).
[19] 21 U.S.C. § 360bbb-3.
[20] Novavax COVID-19 Vaccine, Adjuvanted: Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) Authorized For Individuals 12 Years of Age and Older, FDA, Nov. 4, 2024.
[21] Comparing the COVID-19 Vaccines: How Are They Different?, Yale Medicine, Nov. 22, 2024, https://www.yalemedicine.org/news/covid-19-vaccine-comparison.
[22] Link-Gelles R, Chickery S, Webber A, et al., "Interim Estimates of 2024–2025 COVID-19 Vaccine Effectiveness Among Adults Aged ≥18 Years — VISION and IVY Networks, September 2024–January 2025." MMWR Morb Mortal Wkly Rep 2025;74:73–82. DOI: http://dx.doi.org/10.15585/mmwr.mm7406a1.
[23] https://www.cdc.gov/flu/vaccines/index.html; https://www.cdc.gov/flu-vaccines-work/php/effectiveness-studies/index.html
[24] *See, e.g.*, Jayesh Beladiya, et al. (2024) "Safety and efficacy of COVID-19 vaccines: A systematic review and meta-analysis of controlled and randomized clinical trials," Rev Med Virol. 34(1):e2507. doi: 10.1002/rmv.2507; Graña C, et

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. Specifically, an increased risk of myocarditis following COVID-19 vaccines was observed during 2020-2022 following the primary series and first booster doses; however, virtually no increased risk was observed with the 2022-2023 and 2023-2024 vaccines or the 2024-25 vaccine to-date.[25] Moreover, data indicate that symptoms of myocarditis after COVID-19 vaccine tend to resolve quickly and that post-COVID-19 vaccination myocarditis is associated with less severe cardiovascular events than post-COVID-19 myocarditis and conventional myocarditis.[26]

Recently, the U.S. Department of Health and Human Services announced its intention to require all new vaccines be compared with inert placebos, like saline shots, in clinical trials.[27] The World Health Organization (WHO) guides the ethical use of placebos in vaccine trials[28] in certain situations. The WHO states that a placebo-controlled vaccine trial is acceptable when no effective vaccine is available, and the new vaccine is intended to benefit the population being studied. However, the WHO guidelines state that using placebos is considered unacceptable when there is already an effective and safe vaccine accessible in the public health system of the country where the trial is planned. In such cases, it would be unethical to withhold the existing vaccine from participants if not receiving it would pose a significant risk to their health.

Based on previously issued guidance for the COVID-19 vaccines, strain updates like those undertaken by manufacturers of influenza vaccines based on careful epidemiologic surveillance and immunogenicity data obtained in non-clinical studies are both scientifically appropriate and justified based on the rapidly emerging nature of SARS-CoV-2 variants.[29] In fact, any attempt to conduct traditional large, randomized trials using a given variant vaccine would likely result is such a delay of vaccine availability so as to render the updated vaccine irrelevant. Instead, over the past years since their introduction, large real world evidence data, cited above, has been obtained across different locations globally. As noted, these data confirm the soundness of an approach for COVID-19 vaccines that mirrors that used for influenza vaccines.

The data show that the FDA approved and authorized vaccines are among the safest and most effective public health measures available to continue to prevent or lessen the substantial, ongoing disease burden of COVID-19. Vaccines are directly responsible for reducing suffering and saving lives in the United States. Although the benefits are most clear in older individuals, the vaccines continue to benefit all ages for which they are approved or authorized.

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al. (2022) "Efficacy and safety of COVID-19 vaccines." Cochrane Database of Systematic Reviews, Issue 12. Art. No.: CD015477.DOI: 10.1002/14651858.CD015477.

[25] 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).

[26] *Id.*

[27] RFK Jr. to require placebo-controlled studies for new vaccines, May 1, 2025, https://www.npr.org/sections/shots-health-news/2025/05/01/nx-s1-5383172/rfk-jr-placebo-vaccine-testing-studies

[28] "Expert Consultation on the Use of Placebos in Vaccine Trials," World Health Organization (WHO) 2013.

[29] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19.

III. FDA Should Continue to Timely Fulfill Its Responsibility to Appropriately Review and Approve or Authorize Updated Vaccines for the 2025-2026 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.[30,31]

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:

1) Provide Manufacturers with a Timely Recommendation for the Updated Strain to Be Included in the 2025-2026 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 mid-Fall.

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 2025-2026 respiratory virus season.

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[30] 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 long-lasting. *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.

[31] 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.

2) Ensure the Availability of Both Updated mRNA-Based and Protein-Based Vaccines for the 2025-2026 Season Based Upon Timely Review of Applications or Supplements Submitted by the Manufacturers

Once strains are selected for the upcoming season (e.g., existing strains or new strains), 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.[32] We urge 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 FDA to continue facilitating a resilient supply chain for COVID-19 vaccines.

3) Ensure That the Labeling of the COVID-19 Vaccines Covers Both the Pediatric and Adult Populations as Supported by Data Submitted by the Manufacturers

We urge the FDA to continue ensuring COVID-19 vaccine availability for everyone aged 6 months and above. During the 2023-2024 and 2024-2025 seasons, approximately 13-14% of children in the United States received a COVID-19 vaccine.[33] These data reflect a substantial number of parents in the United States who immunize their children for COVID-19 and for whom appropriate labeling about pediatric use can help inform their future decision-making. Conversely, this statistic confirms that parents are maintaining choice and that a recommendation from VRBAC and ACIP are not mandates.

IV. 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.

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[32] 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.

[33] 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 changes in vaccine coverage between the 2023-2024 and 2024-2025 seasons).

Although FDA is not responsible for providing recommendations to the public about when and how to use COVID-19, the Agency serves a critical role in ensuring the availability of safe, effective, and high-quality vaccines as well as accurate labeling. We urge FDA to continue fulfilling this mandate. Specifically, we urge FDA to work expeditiously with the VRBPAC, government partners, and vaccine manufacturers to make strain selection recommendations for the 2025-2026 season, facilitate continued availability of both mRNA-based and protein-based vaccines, and continue to ensure that the labeling of COVID-19 vaccines covers both the adult and pediatric populations so that providers, patients, and family caregivers have appropriate information for their individual decision-making.

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

Sincerely,

Alliance for Aging Research
Alliance for Patient Access
Alliance for Women's Health and Prevention
American Pharmacists Association (APhA)
American Society of Consultant Pharmacists (ASCP)
Arthritis Foundation
Asian & Pacific Islander American Health Forum (APIAHF)
Asthma and Allergy Foundation of America
Autoimmune Association
Bone Health and Osteoporosis Foundation
California Chronic Care Coalition
Caregiver Action Network
CaringKind
Chronic Care Policy Alliance
Crohn's & Colitis Foundation
Families Fighting Flu
Generations United
Gerontological Society of America
Global Alzheimer's Platform Foundation
Global Coalition on Aging
HealthyWomen
Immune Deficiency Foundation
Immunize.org
Infectious Diseases Society of America
Lupus and Allied Diseases Association, Inc.
Men's Health Network
National Alliance for Caregiving
National Association of Nutrition and Aging Services Programs (NANASP)
National Coalition for Cancer Survivorship
National Community Pharmacists Association
National Consumers League
National Council on Aging
National Health Council
National Hispanic Council on Aging
National Hispanic Health Foundation
National Minority Quality Forum
NCBA Inc
Nurses Who Vaccinate
Partnership to Fight Chronic Disease
Partnership to Fight Infectious Disease
Prevent Blindness
RetireSafe
Society for Women's Health Research
The Headache and Migraine Policy Forum
The Mended Hearts, Inc.
Vasculitis Foundation
Voices of Alzheimers