Mark Del Monte, JD, CEO/Executive

Members of the Executive Committee & Board of Directors

American Academy of Pediatrics

345 Park Boulevard

Itasca, IL 60143

October 20, 2026

Dear Mr. Del Monte and Members of the Board of Directors:

On behalf of HealthyWomen's HPV Coalition, a coalition of more than 60 public health, patient advocacy, and medical organizations working to increase HPV vaccination and prevent HPV-related cancers, we write regarding the American Academy of Pediatrics' (AAP) ongoing consideration of HPV vaccination guidance, including initiation at age 9 and the recommended dosing schedule.

HPV vaccination has had a significant public health impact and has moved the United States closer to preventing cancers caused by HPV. Since its introduction, vaccine-type HPV infections have declined sharply among adolescents and young adults, and cervical precancers have fallen substantially among young women most likely to have been vaccinated. This progress demonstrates the value of clear, evidence-based vaccination guidance, consistent with the FDA-approved label, and the importance of building on the gains achieved to date.

We are united by our commitment to preventing HPV-related cancers through vaccination, not only cervical, but vaginal, vulvar, penile, anal, and oropharyngeal cancers as well. We also work to advance systems-level, legislative, and regulatory policy change that protects every population at risk for an HPV cancer.

Importance of Initiating HPV Vaccination at Age 9

The HPV Coalition strongly supports AAP's recommendation to initiate routine HPV vaccination at age 9. Earlier initiation provides a clear and consistent benchmark for providers and families, increases the likelihood that children will be vaccinated before exposure to HPV, and gives them more time to complete the series by age 13. Maintaining clear guidance to begin at age 9, consistent with the FDA-approved label, will help streamline education and implementation across providers, health systems, payers, and families while advancing our shared goal of preventing HPV-related cancers.

Need for Complete Data to Inform HPV Vaccination Dosing Schedule

We appreciate AAP's consideration of how best to strengthen HPV vaccination and improve uptake. At the same time, we urge AAP to maintain the recommended 2- to 3-dose schedule. This regimen is supported by a

substantial body of scientific evidence and is consistent with the FDA-approved label. While a reduced-dose schedule may offer potential benefits in the future, changing the recommendation before the relevant evidence is sufficiently complete could undermine our shared goal of preventing as many HPV-related cancers as possible.

First, the evidentiary foundation supporting a reduced-dose schedule does not support HPV cancer prevention goals. The clinical trials most frequently cited, including KEN SHE, PRISMA, and ESCUDDO, were designed to evaluate cervical HPV infection endpoints in female populations and do not include data on males or on non-cervical HPV-related cancers.[4] While the cited trials offer promising findings with respect to cervical cancer prevention, evidence remains limited for the other five HPV-related cancers the vaccine helps prevent. A recent study of adolescents who received a single dose of the 9-valent HPV vaccine found that males and females had similar rates of detectable antibodies one to four years after vaccination, but antibody concentrations in males were 31% to 50% lower across all nine vaccine types. The authors noted that the clinical significance of these differences is unknown, underscoring the need for additional evidence regarding the durability and clinical protection of a single-dose schedule in males.[9]

The Vaccine Integrity Project's May 2026 report, *Safety and Effectiveness of Human Papillomavirus (HPV) Vaccine: A Systematic Review and Meta-analysis*, reached the same conclusion. After synthesizing 274 studies, the report stated that "increasing evidence suggests single-dose regimens may offer comparable protection to multidose schedules for key outcomes in females; further evidence is needed to assess effectiveness against non-cervical cancers and pre-cancers in males."[11] No subsequent evidence has resolved these critical gaps; if anything, emerging findings have reinforced the need for additional study of protection in males and against non-cervical HPV-related cancers before dosing guidance is changed.

Importantly, additional clinical data directly relevant to HPV dosing recommendations are forthcoming and should inform any change in guidance. The PRISMA study is expected to report in late 2026, followed in 2027 by data on prevention of persistent oral HPV infection, extended-interval two-dose regimens, immunogenicity in girls and adult women, and a reanalysis of the ESCUDDO trial that will include all nine vaccine HPV types, baseline serology, and standard clinical-trial methods. A longer-term ESCUDDO extension is also expected to provide 10-year durability and clinical disease outcomes comparing one- and two-dose regimens. Given the significance of the remaining questions—and the availability of these planned readouts—maintaining the current schedule until this evidence can be fully evaluated would best ensure protection from preventable HPV associated cancers.

This is not a peripheral evidence gap. Of the nearly 50,000 HPV-associated cancer cases diagnosed annually in the United States, approximately two-thirds are non-cervical cancers, and nearly half occur in males. Oropharyngeal cancer is now the most common HPV-associated cancer among men.[5] Yet populations most affected by these cancers are largely unrepresented in the evidence underpinning reduced-dose discussions.

The implications of this evidence gap are particularly significant because there are currently no approved screening tests to detect non-cervical HPV-related cancers in asymptomatic individuals.[6] Unlike cervical cancer, where screening can identify disease at earlier stages, individuals at risk for non-cervical HPV-related cancers

have no comparable screening or early detection safety net. As a result, questions regarding the durability and breadth of protection afforded by a reduced-dose schedule extend beyond academic debate and carry potentially profound public health consequences.

Second, a recommendation that diverges from FDA-approved labeling and existing HPV vaccination recommendations and guidance would fragment an already complex public health landscape at exactly the wrong moment. The FDA-approved label specifies two doses for routine use starting at age 9 and three doses for individuals over age 15 and those who are immunocompromised.[2] The FDA has signaled that current evidence does not meet the threshold required to support a one-dose label change.[3]

An AAP recommendation that departs from both the FDA-approved label and existing vaccination recommendations would create inconsistency across the very institutions providers, payers, and families rely on for clear direction. Such misalignment could add unnecessary complexity to clinical practice, coverage determinations, quality measurement, provider education, and public health communications. We are concerned that it will lead to further opportunities for misinformation to spread.

With only 62.9% of U.S. adolescents aged 13–17 up to date on the HPV vaccine series—a figure that has remained essentially flat for three consecutive years and falls well short of the Healthy People 2030 goal of 80%—the priority should be improving vaccine confidence, uptake, and series completion. At a time when vaccine confidence and uptake remain ongoing public health challenges, conflicting recommendations from leading authorities could create uncertainty among providers, payers, parents, and adolescents, potentially undermining efforts to increase vaccination rates and prevent HPV-related cancers.

Further, changing the dosing recommendation is not proven to change the paradigm. A recent analysis of six high-income countries with at least two years of data after switching to a single-dose schedule found that first-dose vaccination coverage did not increase; rates were stagnant or slightly lower following the change and had not recovered to pre-COVID-19 levels.[10] These findings suggest that reducing the number of doses alone does not address the underlying barriers to vaccination.

Third, any consideration of a change in dosing guidance should include a transparent and stakeholder-informed review process, with participation from the cancer prevention community and peer guideline-issuing bodies. Recommendations of this consequence can affect clinical practice, coverage, public health communications, and vaccine hesitancy. Meaningful engagement with providers and clinicians, public health experts, cancer prevention advocates, patients, survivors, and other affected stakeholders would help ensure that the full implications of any potential change are understood before new guidance is finalized.

We respectfully urge AAP to reaffirm its recommendation to initiate routine HPV vaccination at age 9 and to maintain the current dosing schedule while data collection continues and until one-dose efficacy in males and for non-cervical cancers is established. We remain concerned that a dosing change at this time could outpace the available data, particularly for males and non-cervical HPV-related cancers, and create unintended consequences for cancer prevention, clinical practice, coverage, and public confidence. We request further engagement with HealthyWomen's HPV Coalition and the broader HPV cancer prevention community before any revised dosing

guidance is finalized, and we welcome the opportunity to share the perspectives of our member organizations and work collaboratively toward clear, consistent, and evidence-based recommendations.

We would be delighted to meet with the AAP Board of Directors to discuss these issues and concerns.

Sincerely,

HealthyWomen

Academy of Managed Care Pharmacy (AMCP)
Alabama Department of Public Health
Alliance for a Healthier Generation
Alliance for Immunization in Michigan
Alliance for Women's Health and Prevention
American Association of Nurse Practitioners (AANP)
American College of Obstetricians and Gynecologists
American Families for Vaccines
American Medical Women's Association (AMWA)
American Sexual Health Association
Black Women's Health Imperative
Byrd Cancer Education and Advocacy Foundation
CancerCare
Cervivor
Friends of Cancer Research
FTI Consulting
Head & Neck Cancer Alliance
Healthy Men, Inc.
HPV Cancers Alliance
HPV AND ME
Immunize Arkansas
Immunize Colorado
Immunize Kansas
Immunize Kentucky
Kentucky Department of Health
Kentucky Rural Health Association
Louisiana Vaccines for Families
Men's Health Network
Miami Cancer Institute
Moffitt Cancer Center
National Association of Pediatric Nurse Practitioners
National League for Nursing
National Center and Caucus on Black Aging
National Comprehensive Cancer Network
National Consumers League
National Grange
Norton Cancer Institute
Nurse Practitioners in Women's Health (NPWH)
Nurses Who Vaccinate
Oncology Nursing Society
Prevent Cancer Foundation
Society for Women's Health Research
St Jude Children's Research Hospital
STC Health
Team Maureen
Tennessee Families for Vaccines
The Anal Cancer Foundation
The Balm in Gilead, Inc

healthy women

Immunize Oregon

Indiana Immunization Coalition

ITVA Foundation

Journi For Two

Kelsey Seybold

Touch the Black Breast Cancer Alliance

Unity Consortium

VAX 2 STOP CANCERS

Voices for Vaccines

Kathine Nicol

References

[1] Centers for Disease Control and Prevention. HPV-Associated Cancer Statistics. Based on 2018-2022 data, an estimated 49,908 new HPV-associated cancer cases are reported annually in the United States, of which approximately 36,400 could be prevented by the 9-valent vaccine. Available at: https://www.cdc.gov/united-states-cancer-statistics/publications/hpv-associated-cancers.html

[2] U.S. Food and Drug Administration. GARDASIL 9 Prescribing Information (Label). FDA-approved labeling specifies a 2-dose schedule for individuals who initiate the series at ages 9-14 and a 3-dose schedule for those initiating at ages 15 and older or who are immunocompromised. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125514s096lbl.pdf

[3] National Cancer Institute, Division of Cancer Epidemiology and Genetics. Single-Dose HPV Vaccine Trials: PRISMA and ESCUDDO. NCI notes that the FDA has indicated a high level of evidence would be required to consider changing the HPV vaccine label to one dose. Available at: https://dceg.cancer.gov/research/cancer-types/cervix/single-dose-vaccine-prisma-escuddo-trial

[4] National Cancer Institute, Division of Cancer Epidemiology and Genetics. Single-Dose HPV Vaccine Trials: PRISMA and ESCUDDO. The PRISMA, ESCUDDO, and KenSHE trials enrolled female participants and evaluated cervical and related HPV infection endpoints; they did not include male participants or non-cervical cancer outcomes. Available at: https://dceg.cancer.gov/research/cancer-types/cervix/single-dose-vaccine-prisma-escuddo-trial

[5] Centers for Disease Control and Prevention. HPV-Associated Cancer Statistics. Of the estimated 49,908 annual HPV-associated cancer cases in the U.S., 22,827 occur among males. Oropharyngeal cancer is the most common HPV-associated cancer among men. Available at: https://www.cdc.gov/united-states-cancer-statistics/publications/hpv-associated-cancers.html

[6] Centers for Disease Control and Prevention. HPV and Cancer: Basic Information. There are currently no recommended routine screening tests for oropharyngeal or other head and neck cancers in asymptomatic individuals. Available at: https://www.cdc.gov/cancer/hpv/basic-information.html

[7] Centers for Disease Control and Prevention. National Immunization Survey-Teen (NIS-Teen), 2024. As of 2024, 78.2% of adolescents aged 13-17 had received at least one HPV vaccine dose and 62.9% were up to date. Available at: https://www.cdc.gov/mmwr/volumes/74/wr/mm7430a1.htm

[8] Centers for Disease Control and Prevention. HPV Vaccines. The HPV vaccine has the potential to prevent more than 90% of cancers caused by HPV, including cervical, vaginal, vulvar, penile, anal, and oropharyngeal cancers. Available at: https://www.cdc.gov/hpv/vaccines/index.html

[9] Lewis RM, Naleway AL, Henninger ML, et al. HPV antibody concentrations among male and female adolescents after single-dose 9-valent HPV vaccination. *The Journal of Infectious Diseases*. Published online September 19, 2026. doi:10.1093/infdis/jiag476. Among 111 male and 96 female adolescents, rates of detectable antibodies were similar by sex 12–48 months after vaccination, but geometric mean antibody concentrations were 31%–50% lower among males across all nine HPV types; the clinical significance of these differences remains unknown.Available at: https://academic.oup.com/jid/advance-article/doi/10.1093/infdis/jiag476/8817486

[10] Velicer C, et al. HPV vaccination coverage before and after single-dose schedule adoption in high-income countries. Analysis of publicly available first-dose uptake data from 2018–2024 in six high-income countries with at least two years of data following a switch to a single-dose schedule. Accepted for presentation at the 38th International Papillomavirus Conference (IPVS 2026), Athens, Greece, October 2026.

[11] Vaccine Integrity Project, Center for Infectious Disease Research and Policy, University of Minnesota. *Safety and Effectiveness of Human Papillomavirus (HPV) Vaccine: A Systematic Review and Meta-analysis*. May 2026. The review synthesized 274 studies and concluded that increasing evidence suggests single-dose regimens may offer comparable protection to multidose schedules for key outcomes in females, while further evidence is needed regarding effectiveness against non-cervical cancers and pre-cancers in males. Available at: https://vaxintegrity.cidrap.umn.edu/sites/default/files/FINAL%20REPORT%20HPV%20Vaccine%20Evidence%20Review_0.pdf