TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Amphetamine
Amphetamine; Amphetamine aspartate/dextroamphetamine sulfate (multiple reference listed drugs)
Baricitinib
Brimonidine tartrate; Brinzolamide
Brinzolamide
Buprenorphine
Cariprazine hydrochloride
Clindamycin phosphate
Ferric carboxymaltose
Ferumoxytol
Glimepiride
Latanoprost
Letermovir
Leuprolide acetate (multiple reference listed drugs)
Levothyroxine sodium
Lisdexamfetamine dimesylate
Maralixibat chloride
Mirtazapine
Octreotide acetate
Olaparib
Ondansetron
Pitolisant hydrochloride
Sodium phenylbutyrate (multiple reference listed drugs)
Tenapanor hydrochloride
Zolpidem tartrate (multiple reference listed drugs)

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

IV. Paperwork Reduction Act of 1995

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–17222 Filed 8–21–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Docket No. HHS–OS–2026–0332]

RIN: 0991–ZA62

Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice; request for information.

SUMMARY: The Department of Health and Human Services (HHS or the Department), in support of the Task Force on Safer Childhood Vaccines and in furtherance of the Executive Order of August 10, 2026, ''Delivering Gold Standard Childhood Vaccine Recommendations for Americans,'' seeks public comment on whether the categories currently used in Federal vaccine recommendations are adequate. Those categories are routine (universal) recommendations, risk-based recommendations, and recommendations based on shared clinical decision-making, also referred to as individual-based decision-making. The Department seeks comment on these categories and whether additional or different categories should be adopted. The Department further seeks comment on the considerations that should be relied upon in setting vaccine recommendations, including the availability and strength of available scientific evidence, the appropriate approach when randomized controlled trial evidence is limited or absent, a presumption in favor of individual autonomy and religious freedom, the downstream legal and programmatic consequences of category assignment, and the communication practices necessary to earn and maintain public trust.

DATES: To be assured consideration, comments must be received at the address provided below no later than September 20, 2026.

ADDRESSES: Interested persons are invited to submit written comments identified by Docket No. HHS–OS–2026–0332 by either of the following methods: (1) Federal eRulemaking Portal: *https://www.regulations.gov.* Follow the instructions for submitting comments; or (2) Mail: Cynthia Goss, 200 Independence Ave SW, Washington, DC 20201. All submissions received must include the agency name and docket number. Comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Cynthia Goss, Deputy Assistant Secretary for Planning and Evaluation (Health Policy), Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation, Office of the Secretary, Department of Health and Human Services, (202) 690–7858 or by email at: *osaspeinfo@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. The Federal Vaccine Recommendation Framework and its Categories

Federal vaccine recommendations are developed principally through the Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP), and are reflected in the child and adolescent and adult immunization schedules. Current recommendations fall into three principal categories. Under a *routine* (universal) recommendation, the default is to vaccinate all persons in an age group absent contraindications. A *risk-based* recommendation is directed to persons with specified medical, occupational, behavioral, or other risk factors. A recommendation based on *shared clinical decision-making* (SCDM) is individually based and informed by a decision process between the health care provider and the patient or parent/guardian. CDC guidance explains that

for routine, catch-up, and risk-based recommendations ''the default decision should be to vaccinate,'' whereas for SCDM recommendations ''there is no default''; the decision turns on the individual's characteristics, the best available scientific evidence, the clinical discretion of the provider, and the values and preferences of the patient or parent.[1] Since 2025, the Department and ACIP have also used the term *individual-based decision-making* for this category.[2]

ACIP adopted the SCDM terminology in 2019, replacing the earlier ''Category A''/''Category B'' (permissive) framework. It applies the category through an Evidence to Recommendations (EtR) framework, adopted in 2018, that contemplates three outcomes: a recommendation for all persons in an age or risk group; a recommendation for individuals based on shared clinical decision-making; or no recommendation.[3] The EtR framework directs consideration of the public health importance of the problem; the magnitude and balance of benefits and harms, and the certainty of the evidence as assessed under the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach; the values and preferences of the affected population; acceptability to stakeholders; feasibility; and resource use.[4]

[1] Ctrs. for Disease Control & Prevention, *ACIP Shared Clinical Decision-Making Recommendations* (page updated Jan. 7, 2025), *https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.*

[2] See, for example, Ctrs. for Disease Control & Prevention Newsroom, *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID–19 and Standalone Vaccination for Chickenpox in Toddlers* (Oct. 6, 2025),*https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html;* Dep't of Health & Hum. Servs. Press Release, *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus* (Dec. 5, 2025), *https://www.hhs.gov/press-room/acip-recommends-individual-based-decision-making-hepatitis-b-vaccine-birth-dose-infants-born-women-test-negative-virus.html.*

[3] G. Lee & W. Carr, Adv. Comm. on Immunization Practices Evidence-Based Recommendations Work Grp., *Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices,* 67 MMWR Morb. Mortal. Wkly. Rep. 1271 (2018), *available at https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a4.htm;* E. Meites *et al., Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices,* 68 MMWR 698 (2019) (first recommendation issued under the SCDM label).

[4] Adv. Comm. on Immunization Practices, *Evidence to Recommendations Framework;* Ctrs. for Disease Control & Prevention, *Evidence-Based Recommendations for ACIP* (page updated Jan. 7, 2025), *https://www.cdc.gov/acip/evidence-based-recommendations/index.html.*

B. The Executive Order of August 10, 2026, and the Task Force on Safer Childhood Vaccines

On August 14, 2025, the Secretary reinstated the Task Force on Safer Childhood Vaccines, a statutory body established by the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–27) and charged with securing safer childhood vaccines and improved adverse-event surveillance and research.[5]

On August 10, 2026, the President signed the Executive Order ''Delivering Gold Standard Childhood Vaccine Recommendations for Americans.'' [6] The Executive Order states that the policy of the United States is that core childhood vaccine recommendations should be aligned with scientific evidence and best practices of peer nations, as well as that Federal programs should support parental choice consistent with personal autonomy and informed consent. It directs the Secretary, working through the Task Force on Safer Childhood Vaccines, to present plans within 90 days addressing, among other subjects, the timing and sequencing of the Federal immunization schedule and the continuous evaluation of the risk-benefit profile of recommended vaccines. This request for information is issued in furtherance of the Executive Order and in support of the Task Force's work. Public input received in response to this notice will help inform consideration by the Department and the Task Force of whether the current category structure adequately serves the goals of scientific rigor, informed choice, and public trust.

C. Experience With Shared Clinical Decision-Making

The SCDM category was created to clarify the intent of the former permissive ''Category B'' recommendations, which survey evidence indicated were poorly understood. In a 2018 national survey of pediatric primary care providers, only 24 percent could accurately define a Category B recommendation; a majority did not know that such vaccines are covered by private insurance or the Vaccines for Children program; and providers were divided on whether the permissive category should be retained, with 39 percent valuing the leeway it provided and 22 percent favoring its elimination.[7]

Experience with SCDM since 2019 has been mixed, and the Department is aware of both criticisms and defenses of the category. In a national survey of physicians published in 2021, approximately 90 to 95 percent reported that implementing SCDM recommendations requires more time than routine recommendations; fewer than half knew that SCDM vaccines are covered by insurance; many reported that electronic health record and immunization forecasting tools displayed SCDM recommendations inaccurately or not at all; and most agreed that SCDM recommendations create confusion for patients.[8] Some evidence suggests uptake of vaccines recommended under SCDM has been lower than uptake of routinely recommended vaccines.[9]

At the same time, surveyed physicians have expressed support for the existence of an SCDM category for appropriate vaccines, and commenters have defended SCDM as sound, patient-centered clinical practice for vaccines whose benefit-risk balance varies meaningfully with individual circumstances, whose population-level benefit is less clear, or for which the evidence base is limited or evolving.[10] On this view, an intermediate category permits the Federal Government to avoid a binary choice between a universal recommendation and no recommendation at all. This allows for an additional opportunity between patient and provider to discuss the state of the evidence and gives weight to the values and preferences of patients and parents/guardians, including considerations of personal autonomy, informed consent, and religious conviction. These principles apply across all vaccine recommendations, including routine ones. SCDM is

[5] Dep't of Health & Hum. Servs. Press Release, *HHS Revives Task Force on Safer Childhood Vaccines* (Aug. 14, 2025), *https://www.hhs.gov/press-room/hhs-reinstates-task-force-on-safer-childhood-vaccines.html.*

[6] Executive Order No. 14,420, *Delivering Gold Standard Childhood Vaccine Recommendations for Americans,* 91 FR 53,173 (Aug. 14, 2026), *available at https://www.whitehouse.gov/presidential-actions/2026/08/delivering-gold-standard-childhood-vaccine-recommendations-for-americans.*

[7] A. Kempe *et al., Knowledge and Attitudes Regarding Category B ACIP Recommendations Among Primary Care Providers for Children,* 18 Acad. Pediatr. 763 (2018).

[8] A. Kempe *et al., Shared Clinical Decision-Making Recommendations for Adult Immunization: What Do Physicians Think?,* 36 J. Gen. Intern. Med. 2283 (2021), *https://link.springer.com/article/10.1007/s11606-020-06456-z.*

[9] See, for example, J. Vietri *et al., Pneumococcal Vaccine Uptake Among Medicare Beneficiaries Aged ≥65 Years Following the Shared Clinical Decision-Making Recommendation for 13-Valent Pneumococcal Conjugate Vaccine in 2019,* 41 Vaccine 5211 (2023).

[10] A. Kempe *et al., supra* note 8 (majority support for retaining SCDM for certain vaccines); M. Hogue *et al., Shared clinical decision making on vaccines: Nothing has really changed for pharmacists,* 60 J. Am. Pharm. Assoc. e91 (2020).

distinct in that the Federal recommendation provides no default—not because patient or parent decision-making is confined to that category.

The Department seeks information on how the category is understood and applied in practice, whether its risks and benefits have been adequately characterized, and how it could be improved.

D. Considerations in Setting Vaccine Recommendations: Evidence, Freedom, and Trust

The durability of any vaccine recommendation framework depends on the public's trust in the process that produces it. Trust is essential both to public health objectives and to effective, informed individual choice. Several bodies of evidence inform the Department's thinking.

Calibration of recommendations to the strength of the evidence. The GRADE approach used by ACIP recognizes that the certainty of evidence varies, from randomized controlled trials to observational and post-licensure data, and the EtR framework calls for transparency about that certainty.[11] Commentators, including current and former Federal officials, have cautioned that recommendations extending beyond the strength of the underlying evidence can carry costs to institutional credibility.

The Federal COVID–19 vaccination effort shows both the value of calibrating recommendations to the underlying evidence and the cost of departing from that calibration. Operation Warp Speed produced safe and effective vaccines in record time, with first doses administered in December 2020, less than a year after the virus was sequenced. Executive Order 13962 directed that Americans have priority access to those vaccines and framed vaccination as available to ''all Americans who choose to be vaccinated,'' and the initial allocation framework directed limited early supply to those at highest risk of severe disease and exposure.[12] Federal policy thereafter shifted toward progressively broader, population-wide recommendations. That shift drew criticism from within the scientific mainstream. In 2021, an international group of scientists that included senior Food and Drug Administration vaccine officials publicly argued that available evidence did not support COVID–19 booster doses for the general population, and warned that premature deployment could carry risks for vaccine confidence.[13] A 2023 commentary in the New England Journal of Medicine described the broad, all-ages recommendation of the bivalent COVID–19 booster on the basis of limited human data as ''a cautionary tale.'' [14] A 2025 New England Journal of Medicine article by Food and Drug Administration leadership advanced a risk-stratified alternative to universal COVID–19 vaccination recommendations, applying different evidentiary expectations to high-risk and low-risk populations.[15] The Department notes that these positions are contested within the scientific community. That contestation is itself relevant to the questions posed below.

The process by which recommendations are finalized matters as well. In September 2021, ACIP voted against recommending COVID–19 booster doses for adults aged 18 to 64 on the basis of occupational or institutional exposure. Members opposing the recommendation argued that such decisions were better left to individual benefit-risk judgment. The CDC Director set that vote aside and extended the recommendation to the occupational group, a departure from the committee's judgment that was widely reported as extraordinary.[16] In the Department's view, episodes in which the deliberative advisory process reaches a narrower conclusion that is then overridden in favor of a broader, top-down recommendation contribute to public doubt about whether Federal recommendations in fact reflect the process created to produce them, and thereby to mistrust of the system as a whole.

Trust and the effects of mandates. A substantial body of research indicates that top-down mandates and coercive measures can sow distrust and provoke psychological reactance, particularly among persons whose trust in government is already low. A study published in the Proceedings of the National Academy of Sciences found that enforcement can crowd out voluntary support for public health measures, especially where trust in government is weak.[17] Research in Germany and the United States found that mandatory vaccination policies triggered reactance, an anger-driven motivation to reassert restricted freedom, associated with reduced vaccination intentions and increased anti-policy activism.[18] A large United Kingdom survey and modeling study found that the introduction of vaccine passports would likely lower inclination to be vaccinated among some groups.[19] Scholars writing in BMJ Global Health argued that COVID–19-era mandates, passports, and restrictions risked amplifying distrust and proving counterproductive, and urged a return to trust-based public health approaches.[20]

The Department notes that the empirical literature is mixed. Other rigorous studies found that mandate and certification policies measurably increased vaccine uptake in several countries, particularly where baseline uptake was low, and one multi-study United States analysis found that requirements strengthened rather than weakened vaccination intentions.[21] The Department observes, however, that much of the evidence on the effectiveness of compulsory approaches comes from peer countries whose baseline levels of institutional trust differ from those in the United States. The Department acknowledges those differences. But trust is not fixed. It is built, and forfeited, over time through the conduct of institutions. The Department's view is that a

[11] ACIP, *Evidence to Recommendations Framework, supra* note 4.

[12] Exec. Order No. 13,962, *Ensuring Access to United States Government COVID–19 Vaccines,* 85 FR 79,777 (Dec. 11, 2020); K. Dooling *et al., The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID–19 Vaccine—United States, December 2020,* 69 MMWR Morb. Mortal. Wkly. Rep. 1657 (2021).

[13] P.R. Krause *et al., Considerations in boosting COVID–19 vaccine immune responses,* 398 The Lancet 1377 (2021).

[14] P.A. Offit, *Bivalent Covid–19 Vaccines—A Cautionary Tale,* 388 New Eng. J. Med. 481 (2023).

[15] V. Prasad & M.A. Makary, *An Evidence-Based Approach to Covid–19 Vaccination,* 392 New Eng. J. Med. 2484 (2025).

[16] See, for example, CNBC, *The leader of CDC just made a rare call to allow Covid booster shots for more people* (Sept. 24, 2021), *https://www.cnbc.com/2021/09/23/covid-booster-shots-cdc-panel-endorses-third-pfizer-doses-for-millions.html.*

[17] K. Schmelz, *Enforcement may crowd out voluntary support for COVID–19 policies, especially where trust in government is weak and in a liberal society,* 118 Proc. Nat'l Acad. Sci. e2016385118 (2021).

[18] P. Sprengholz *et al., Vaccination policy reactance: Predictors, consequences, and countermeasures,* 27 J. Health Psychol. 1394 (2022).

[19] A. de Figueiredo *et al., The potential impact of vaccine passports on inclination to accept COVID–19 vaccinations in the United Kingdom: evidence from a large cross-sectional survey and modeling study,* 40 EClinicalMedicine 101109 (2021).

[20] K. Bardosh *et al., The unintended consequences of COVID–19 vaccine policy: why mandates, passports and restrictions may cause more harm than good,* 7 BMJ Global Health e008684 (2022).

[21] A. Karaivanov *et al., COVID–19 vaccination mandates and vaccine uptake,* 6 Nature Hum. Behav. 1615 (2022); M.C. Mills & T. Rüttenauer, *The effect of mandatory COVID–19 certificates on vaccine uptake: synthetic-control modelling of six countries,* 7 Lancet Pub. Health e15 (2022); D. Albarracín *et al., Rather than inducing psychological reactance, requiring vaccination strengthens intentions to vaccinate in US populations,* 11 Sci. Rep. 20796 (2021).

recommendation framework should accordingly be judged not only by its immediate effect on uptake but by whether the framework itself builds durable trust. Global guidance on mandatory vaccination counsels that policymakers ''have a duty to carefully consider the effect that mandating vaccination could have on public confidence and public trust,'' and that mandates are not ethically justified where public health goals can be achieved through less coercive means.[22] In the United States, vaccination requirements have historically been creatures of State law within constitutional limits,[23] and Federal recommendations are recommendations, not mandates. The Department believes that distinction should be preserved and made legible to the public.

Trust after COVID–19. Public trust in Federal public health agencies declined measurably during and after the COVID–19 pandemic. In a national survey published in Health Affairs, among adults reporting lower trust in CDC, the most commonly cited reasons were beliefs that recommendations were influenced by politics and that the agency had issued too many conflicting recommendations.[24] Polling has documented declining shares of Americans expressing trust in CDC and other health agencies, a marked partisan divergence,[25] and declining confidence in scientists relative to the early-pandemic peak.[26] Over the same period, routine kindergarten vaccination coverage fell below pre-pandemic levels while exemptions rose to the highest levels reported.[27] In 2022, the CDC Director publicly acknowledged, in announcing an agency reorganization, that the agency was ''responsible for some pretty dramatic, pretty public mistakes, from testing, to data, to communications'' during the COVID–19 response.[28] The Department's working premise is that recommendations perceived as premature, overconfident, or insulated from candor about uncertainty, as many Americans perceived certain COVID–19-era recommendations to be, impose lasting costs on the credibility of all Federal vaccine recommendations, including those resting on the strongest evidence.

Communication science. Risk-communication research bears directly on how recommendation categories are named, explained, and implemented. CDC's Crisis and Emergency Risk Communication framework counsels transparency and candor: tell the public ''what you know when you know it, tell them what you don't know, and tell them if you will know relevant information later.'' [29] Experimental research indicates that communicating uncertainty transparently imposes at most small costs to trust.[30] Transparent communication about negative or uncertain features of vaccines may reduce acceptance in the short term but increases trust in health authorities, whereas vague reassurance fails to increase acceptance and reduces trust.[31] A global behavioral and social drivers framework likewise identifies confidence in vaccines, providers, and institutions as a central determinant of uptake.[32] The names of recommendation categories are themselves communication. As the survey and provider-experience evidence discussed above indicates, categories whose meaning is unclear to clinicians and the public generate confusion about safety, efficacy, coverage, and intent.

II. Request for Information

The Department seeks comment from the public, including parents and patients; clinicians, nurses, pharmacists, and other immunization providers; State, Tribal, local, and territorial health officials; health plans and issuers; researchers in medicine, public health, ethics, law, communication science, and decision science; faith communities; manufacturers; and professional, civil-society, and community-based organizations. Commenters need not address every question. Supporting data, citations, and concrete examples are encouraged.

A. Adequacy of the Current Categories

1. Are the current categories (routine, risk-based, and shared clinical decision-making/individual-based decision-making) adequate, clear, and well understood by clinicians, patients, and parents? What evidence bears on how each category is understood in practice?

2. Do the current categories convey meaningful differences in the strength of the evidence, the magnitude of individual and population benefit, and the room left for individual circumstances and values? If not, how should those differences be conveyed?

3. Do the current categories unintentionally imply that parental permission, individual consent, or meaningful clinical discussion applies only to shared clinical decision-making recommendations? Should the framework expressly distinguish the strength of a Federal recommendation from the consent, parental-permission, and assent processes involved in administering a vaccine?

B. Potential Additional or Modified Categories and Timing and Frequency Recommendations

4. Should additional or different categories be adopted, such as ''recommended, but not during infancy'' (or otherwise age-de-emphasized recommendations); ''recommended with qualification''; or ''shared clinical decision-making with qualification''? For any proposed category, describe its definition, its default (if any), its evidentiary basis, and its intended downstream consequences.

5. What can be learned from the recommendation structures of peer bodies abroad, such as global or

[22] World Health Organization, *COVID–19 and mandatory vaccination: ethical considerations* (policy brief, May 30, 2022), *https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy-brief-Mandatory-vaccination-2022.1.*

[23] See *Jacobson* v. *Massachusetts,* 197 U.S. 11 (1905); CDC, *State Vaccination Requirements, https://www.cdc.gov/vaccines/php/requirements-laws/state-vaccination-requirements.html* (last visited August 17, 2026).

[24] G.K. SteelFisher *et al., Trust In US Federal, State, And Local Public Health Agencies During COVID–19: Responses And Policy Implications,* 42 Health Affairs 328 (2023).

[25] Kaiser Family Found., *Tracking Poll on Health Information and Trust: January 2025* (Jan. 2025), *https://www.kff.org/health-information-trust/kff-tracking-poll-on-health-information-and-trust-january-2025/.*

[26] Pew Rsch. Ctr., *Americans' Trust in Scientists, Positive Views of Science Continue to Decline* (Nov. 14, 2023), *https://www.pewresearch.org/science/2023/11/14/americans-trust-in-scientists-positive-views-of-science-continue-to-decline/.*

[27] R. Seither *et al., Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten—United States, 2023–24 School Year,* 73 MMWR Morb. Mortal. Wkly. Rep. 925 (2024); CDC SchoolVaxView, 2024–25 school year data (released July 31, 2025), *https://www.cdc.gov/schoolvaxview/data/index.html.*

[28] See, for example, CBS News, *CDC director Rochelle Walensky announces shake-up, citing COVID mistakes* (Aug. 19, 2022), *https://www.cbsnews.com/news/cdc-director-rochelle-walensky-announces-organization-shake-up-aimed-at-speed* (quoting CDC Director Rochelle Walensky).

[29] B. Reynolds, Ctrs. for Disease Control & Prevention, Zika Crisis and Emergency Communication (CERC) Discussion (June 14, 2016), *https://stacks.cdc.gov/view/cdc/39966;* see also Ctrs. for Disease Control & Prevention, Crisis and Emergency Risk Communication (CERC) Manual (2014 ed.), *available at https://www.cdc.gov/cerc/php/cerc-manual/index.html.*

[30] A.M. van der Bles *et al., The effects of communicating uncertainty on public trust in facts and numbers,* 117 Proc. Nat'l Acad. Sci. 7672 (2020).

[31] M.B. Petersen *et al., Transparent communication about negative features of COVID–19 vaccines decreases acceptance but increases trust,* 118 Proc. Nat'l Acad. Sci. e2024597118 (2021).

[32] World Health Org., *Understanding the behavioural and social drivers of vaccine uptake: WHO position paper—May 2022,* 97 Wkly. Epidemiological Rec. 209 (2022); see also NE MacDonald & SAGE Working Group on Vaccine Hesitancy, *Vaccine hesitancy: Definition, scope and determinants,* 33 Vaccine 4161 (2015).

international health bodies of peer regulatory bodies?

6. If new categories were adopted, what is needed to preserve access to vaccines currently available to Americans and ensure predictable and consistent treatment under coverage requirements, program eligibility rules, the injury-compensation programs, and State law?

7. If categories remain the same, what modifications to timing and frequency of vaccine administration (for example, clearer presentation of flexible age ranges such as the 12-through-15-month window for the first dose of measles-containing vaccine) or guidance on administering vaccines individually versus at a single visit would help parents and clinicians understand that a vaccine is recommended while affording flexibility in timing of administration?

C. Shared Clinical Decision-Making: Meaning, Risks, and Benefits

8. What does, or what should, ''shared clinical decision-making'' mean in the vaccination context? How, if at all, does ''individual-based decision-making'' differ?

9. Does the term ''shared clinical decision-making'' create an unintended contrast with routine recommendations? Since shared decision-making describes a clinical process applicable to all vaccine decisions, should the Department reserve that phrase for use across all categories and instead adopt ''conditional recommendation'' or ''recommendation based on individualized assessment'' for recommendations whose expected benefit varies materially among individuals?

10. What are the benefits of an SCDM category, including respect for autonomy, informed consent, religious conviction, and individualized clinical judgment, and what evidence supports them?

11. What are the risks of an SCDM category, including confusion, reduced access or uptake, and time burdens in practice, and what evidence supports them?

12. An SCDM recommendation, once adopted by the CDC Director, triggers the same coverage requirements as a routine recommendation, including coverage without cost-sharing under the Affordable Care Act and availability through the Vaccines for Children program. Given evidence that patients and even providers may not understand this, what steps should the Department take to educate the public and the provider community that SCDM-recommended vaccines are covered? What communication formats would most effectively ensure that an SCDM designation is not misread as a lapse in coverage or a signal that a vaccine is unavailable?

13. What supports would make SCDM work as intended, such as decision aids, provider training, documentation standards, coverage clarifications, or category-specific communication materials, and who should develop them?

D. Considerations in Setting Recommendations

14. What considerations should be relied upon in establishing vaccine recommendations and assigning categories, and under what conditions should each predominate? Commenters are specifically invited to address the availability, quality, and strength of evidence; the appropriate approach where randomized controlled trial evidence is absent, infeasible, or unethical to obtain; disease severity and epidemiology; individual versus population benefit; a presumption in favor of individual autonomy, informed consent, and religious freedom; and feasibility and programmatic consequences.

15. When evidence is limited, uncertain, or evolving, how should that uncertainty be reflected in the recommendation itself, whether through category assignment, qualifying language, sunset or re-review provisions, or explicit statements of evidentiary certainty, rather than resolved silently in favor of either a universal recommendation or no recommendation?

E. Trust and Communication

16. What does the evidence show about the effects of mandates and other compulsory or high-pressure approaches on public trust, vaccine confidence, and long-run vaccination behavior? How should Federal recommendation policy account for those effects, consistent with the principle that Federal recommendations are not mandates?

17. What communication practices should accompany vaccine recommendations so that they earn and keep public trust, and what lessons from COVID–19-era communication should inform them?

18. How should the Department measure whether a recommendation framework is succeeding, and what data should be collected and published for that purpose?

III. Scope and Effect of This Notice

This request for information does not constitute a rule, a proposed rule, or a recommendation, and it does not alter any existing vaccine recommendation, coverage requirement, or program obligation. The Department will not respond individually to comments but will consider them in the work described above.

Robert F. Kennedy, Jr.,

Secretary, U.S. Department of Health and Human Services.

[FR Doc. 2026–17250 Filed 8–21–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: T Cell Receptors Targeting HPV 6 or HPV 11

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees for a collection of T cell receptors (TCRs) that specifically target HPV 6 or HPV 11 antigens.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to Suna Gulay French Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: *suna.gulay@nih.gov* or Phone: 240–276–7424.

SUPPLEMENTARY INFORMATION: Recurrent Respiratory Papillomatosis (RRP) and anogenital condyloma arise from chronic infection with human papillomavirus (HPV) 6 or 11. They can cause significant morbidity due to persistent papillomatous growths in the upper aerodigestive or anogenital tract. In RRP, lesions may obstruct the airway (leading to dysphonia), dyspnea, recurrent pneumonia, or pulmonary failure. In rare cases, it may progress to malignancy. Current treatment options for RRP include zopapogene imadenovec (Papzimeos), systemic bevacizumab, and repeated surgical debulking. Papzimeos can lead to durable responses in some patients but remains ineffective against pulmonary disease. Systemic bevacizumab can control disease, but prolonged use can lead to intolerable toxicities. Repeat surgical debulking causes cumulative surgical and anesthetic risks. Therefore, there remains a critical unmet need for