ASTCT®
American Society for
Transplantation and Cellular Therapy

September 20, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary of Health and Human Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Secretary Kennedy:

The American Society for Transplantation and Cellular Therapy (ASTCT) appreciates the opportunity to comment on the U.S. Health and Human Services Department's (HHS) "Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Decision-Making." ASTCT is a professional membership association of more than 3,900 physicians, investigators, and other healthcare professionals. Our mission is to advance hematopoietic cell transplantation and cellular therapies through groundbreaking research, high-quality education, impactful advocacy, and clinical excellence.

ASTCT Position
ASTCT encourages HHS to adhere to peer-reviewed literature that has guided the United States' childhood vaccine recommendations for decades. This literature demonstrates the safety and effectiveness of the U.S. childhood vaccine schedule, which can be credited with eradicating many infectious diseases and protecting the youngest and most vulnerable populations. Because of the existing evidence base, ASTCT recommends that HHS keep the current decision categories that exist within the Federal vaccine recommendations.

ASTCT's members care for critically ill patients of all ages who suffer from hematologic cancers, bone marrow failure diseases, other hematological abnormalities, or immune deficiencies only cured by a transplantation or cellular therapy. These treatments require a reset of the patient's immunity which can take one-two years or longer after the transplant has occurred. During this period, these immunocompromised patients have no defense against everyday germs and even the most minor infection can be life-threatening.

Importantly transplant patients cannot receive vaccinations until their immune system is stronger, which can take at least six months or longer after transplantation. They will not be fully immunized until at least two years after transplantation.

Developing and making available effective and safe vaccines for infectious disease is one of the greatest medical achievements in history. Based on decades of systematic evidence and continuous research, America's schedule has saved millions of lives and has significantly reduced global morbidity rates. Emulated by countries from across the globe, America's vaccine schedule is safe, effective, and continuously assessed.

The public's adherence to evidence-based vaccine recommendations is critical for bone marrow transplant and cellular therapy patients who rely on herd immunity to reduce exposure to common and infectious pathogens while they rebuild their own immunity. Patient's adherence to evidence-based vaccine recommendations is critical for their health, recovery, and even survival. Weakening this schedule and/or casting public doubt on the safety of these vaccines would increase U.S. morbidity rates and threaten the lives of Americans, especially cancer and transplant patients with compromised immune systems.

ASTCT appreciates the opportunity to answer the following questions posed in the RFI:

A. Adequacy of the Current Categories

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?

Promoting shared decision-making for safe and effective vaccine recommendations puts the public at risk, not just the individual making the decision. Unlike other areas of medicine, compliance with recommended vaccines enables herd-immunity status that keeps infectious diseases at bay for all Americans. Each individual decision for forgo a vaccination threatens a community's herd immunity against an infectious disease.

In many cases in medicine, individual medical decisions have little effect on the health of others. An individual's decision not to follow recommendations for a heart condition or for managing diabetes affects the health outcomes of that individual alone. An individual's decision to decline a recommended vaccine based on the premise of shared decision-making, however, affects the health of that individual and of countless others.

This individual decision to be vaccinated puts others at risk and threatens herd-immunity status that has helped reduce morbidity and mortality rates of diseases that otherwise pose significant threats. Higher rates of infectious disease spread creates an unnecessary risk to everyone, especially for immunocompromised patients who rely on herd-immunity status to stay healthy and safe.

Herd immunity is especially critical for the immunocompromised patients that ASTCT members care for every day. Many of these patients beat cancer and other life-threatening diseases only to succumb to an infectious diseases that they acquire due to individuals in their communities choosing not to vaccinate. In these cases, they are at the mercy of healthy individuals making individual decisions about vaccine compliance.

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.

No, because these categories are not supported by scientific evidence.

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

Countries and organizations from across the world emulate America's vaccine schedule because it is the most rigorous and comprehensively tested set of recommendations. Data continues to support their safety, as well as their efficacy in preventing the spread of infectious disease.

America's vaccine schedule is the gold standard for promoting and protecting the public's health that has led to the eradication of many fatal diseases. Countries that deviate from this schedule do so because of differing epidemiological needs or resource limitations—not because of disagreements with the evidence.

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?

Adopting new categories, especially ones that are not based on systematic evidence, would undermine patients' predictable and consistent treatment schedules. These new categories would also reduce adherence to recommended vaccines, cast doubt on existing evidence, and facilitate the spread of infectious diseases that vaccine adherence largely controls today.

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?

Everything in medicine is shared clinical decision-making. However, the strength of and importance of physicians' recommendations for various instances changes depending on the importance of the treatment, the potential for harm, and the level of evidence available to support that decision.

The criteria for adding vaccines to the recommended schedules has been so incredibly rigorous—and the U.S. vaccine schedule as it recently stood was very strong and effective. Equating the strength of these recommendations with smaller and less consequential medical decisions that depend on patient preferences is dishonest and cheapens the expertise of medical professionals.

Conclusion

HHS has the opportunity and the responsibility to use peer-reviewed data to guide public health recommendations and decisions. Casting doubt on existing evidence, or on vaccines that have strong evidence bases for safety and efficacy, will create distrust in the scientific process, put our transplant and cell therapy patients as well as countless more Americans at risk, and place a greater strain on America's public health system.

ASTCT respectfully asks that HHS preserve the current categories within Federal vaccine recommendations and so that we can collectively keep ourselves and each other safe from preventable infectious disease.

ASTCT appreciates your consideration of this letter. Please contact Molly Ford, ASTCT's Director of Government Relations at mford@astct.org with any questions.

Sincerely,



Margaret L. MacMillan, MD, MSc, FRCPC
ASTCT President
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