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October 18th, 2024

Advisory Committee on Immunization Practices (ACIP)
Centers for Disease Control and Prevention
Department of Health and Human Services
Atlanta, Georgia 30329

RE: GHLF Comments on ACIP proposed RSV guidelines

Hello Committee Members,

Thank you for allowing me to speak today. The Global Healthy Living Foundation fully supports widespread access to vaccines and initiatives to enhance public trust in the safety and effectiveness of vaccines. However, we have reservations about certain guidelines for the RSV and PCV vaccines that have been put forward by the committee, and we hope to see these revised before finalization.

By way of background, the Global Healthy Living Foundation (GHLF) is a 501(c)(3) patient group that works to improve the quality of life for people with chronic disease, often focusing on those least able to advocate for themselves. Through our websites, social media channels, and conventional media, GHLF reaches more than 10 million chronically ill people monthly in the United States – in English and Spanish. Our community comprises some of the most vulnerable patient groups to non-communicable diseases, and vaccine access is crucial for them to lead their daily lives.

The clinical risk criteria identified by ACIP for patients aged 60 to 74 who may require an RSV vaccine pose significant challenges for implementation, especially for community pharmacists and non-primary care providers. Conditions such as end-stage renal disease, dependence on hemodialysis or other renal replacement therapies, severe obesity, liver disorders, neurologic or neuromuscular conditions, and moderate to severe immune compromise require thorough clinical evaluation. However, these evaluations often depend on comprehensive medical records or specialty medication data, which are not easily accessible in community settings.

ACIP's guidance suggests that "patient attestation is sufficient evidence of the presence of a risk factor." However, this puts healthcare professionals in a difficult position. Pharmacists and non-primary care providers are required to disregard their clinical judgment based on available evidence, which goes against the fundamental principles of healthcare practice. It is crucial for ACIP to acknowledge that healthcare providers should not be in a position where their clinical decisions conflict with practical limitations or put patients at risk due to incomplete medical information.

Furthermore, community pharmacies are one of the most easily accessible healthcare points in the U.S., especially for seniors in low-income areas where ethnic and racial minorities are overrepresented. Pharmacies play a crucial role in providing access to RSV vaccination, and it's important to empower pharmacists to make sound clinical decisions. The Advisory Committee on Immunization Practices (ACIP) should reassess the current risk criteria to ensure that pharmacists can apply them accurately and confidently without compromising their professional integrity.

One possible solution is for ACIP to align its recommendations with the FDA-labeled indications. Healthcare professionals are accustomed to adhering to the FDA-approved package insert, which offers clear, actionable guidance for prescribing or administering medications and vaccines. By aligning the criteria with FDA guidelines, ACIP can more effectively assist healthcare professionals in efficiently and safely delivering vaccines, while also ensuring broader access for the high-risk populations most in need of protection against RSV. We understand this vote will not occur today, but we would like these issues to be considered when it does.

We also have some thoughts on the guidelines related to the PCV vaccine guidelines. Pneumococcal vaccination rates in the U.S. are alarmingly low. Only 23% of adults aged 19 to 64 and 64% of those aged 65 and older have received at least one dose. These figures are significantly below the CDC's Healthy People 2020 immunization goals.

We urge ACIP to make a routine recommendation for the pneumococcal vaccine for all adults 50 and older. This will reduce burdensome and unworkable clinical risk-based recommendations for a significant portion of the adult population most in need of protection. In addition, the routine recommendation aligns, to a certain degree, with the FDA-indicated label of the vaccines currently approved in the U.S.

To further improve pneumococcal immunization rates for vulnerable populations, we also urge ACIP to include all FDA-approved pneumococcal vaccines as part of the routine guidance thus improving vaccine access for providers and patients.

Thank you once more for the chance to comment on these regulatory changes. We hope that ACIP will implement the recommended changes above to safeguard patient access.

Sincerely,



Corey Greenblatt, MPH
Director of State Policy & Advocacy
Global Healthy Living Foundation

