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The Honorable David McCormick
United States Senate
Washington, DC 20510

Dear Senator McCormick,

On behalf of the Global Healthy Living Foundation (GHLF) and the thousands of patients and caregivers we represent across Pennsylvania through our 50-State Network, I am writing to share concerns regarding the recent decision by the U.S. Food and Drug Administration to decline review of Moderna's mRNA influenza vaccine application.

GHLF is a non-profit, non-partisan patient advocacy organization that works with individuals living with autoimmune and chronic inflammatory diseases. Many of these Pennsylvanians are immunocompromised or medically vulnerable, placing them at heightened risk of severe complications from influenza. For these individuals, timely access to the most advanced preventive tools is not theoretical. It is essential.

We respect and support the FDA's responsibility to apply rigorous scientific standards. Strong oversight protects patients and sustains public confidence. At the same time, regulatory consistency and transparency are equally vital to maintaining public trust and sustaining biomedical innovation.

Public recording indicates that the agency's decision was based on questions related to trial design rather than safety or efficacy findings. While technical regulatory decisions are part of the normal review process, clarity around standards and expectations is important to patients, clinicians, and researchers alike. Predictability in regulatory pathways supports preparedness and long-term public health planning.

The implications extend beyond a single product.

Influenza remains a serious public health threat, particularly for medically vulnerable populations. Traditional flu vaccines require strain selection many months in advance. mRNA platforms offer the potential for faster adaptation to emerging strains, strengthening preparedness and responsiveness. Delays in evaluating such technologies may have downstream consequences for both innovation and public health readiness.

Equally important is public confidence. Headlines stating that an mRNA flu vaccine was "rejected" can contribute to confusion at a time when vaccine confidence is already fragile. Clear communication and consistent regulatory processes are central to preserving trust in institutions that protect public health.

Pennsylvania is home to world-class research institutions, life sciences employers, and a large population of medically vulnerable residents. Policies that affect vaccine development and review processes carry direct implications for both the health of Pennsylvanians and the state's role as a leader in biomedical innovation.

Through our national vaccine education platform (www.ghlf.org/vaccines), GHLF provides evidence-based resources and state-specific awareness efforts to help patients and caregivers make informed decisions. We see firsthand how federal regulatory signals influence public perception at the local level, including here in Pennsylvania.

We respectfully encourage continued oversight and dialogue to ensure that regulatory standards remain rigorous, transparent, and stable, and that decisions are communicated in ways that reinforce public trust while preserving America's leadership in medical innovation.

Thank you for your leadership on issues affecting the health and well-being of Pennsylvanians.

Respectfully,

Seth Ginsberg
Co-Founder & President
Global Healthy Living Foundation

Steven Newmark
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