National Health Federation
P.O. Box 288
Mossyrock, WA 98564

September 10, 2025

Martin A. Makary, M.D., M.P.H.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Kennedy and Commissioner Makary,

We write to express our deep concern regarding the Food and Drug Administration's July 3, 2025 draft guidance, *"Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations."*

The draft guidance, as written, would weaken long-standing safety standards for premature infants, undermine the United States' successful generic drug framework, and further erode Americans' already faltering trust in the FDA.

On behalf of the patient communities we serve and the principles we fight to uphold, we urge you to withdraw this guidance.

Parenteral nutrition (PN), or intravenous feeding, is essential to the survival of premature infants, who account for one in 10 births in the United States. It delivers the nutrients they need, but cannot yet take in orally.

The FDA plays a critical role in limiting impurities in PN -- notably, aluminum. Premature infants are particularly vulnerable because they lack mature kidneys capable of filtering aluminum out, allowing it to accumulate in their bodies. Studies routinely show that excess exposure to aluminum can cause serious, long-term harm -- including neurological damage, developmental delays, and bone disorders.

For decades, the FDA appropriately recognized this risk. The agency maintained that total aluminum exposure from PN -- which consists of both small volume parenteral (SVPs), like amino acids and lipids, and large volume parenterals (LVPs) like electrolytes -- should not exceed four to five micrograms per kilogram per day.[1]

[1] *Id.* p. 4 / Figure 1.

In 2022, however, the FDA issued draft guidance that would have permitted an SVP to contain aluminum concentrations nearly 17 times higher than previously approved levels for branded products on the market.[2] That proposal rightly drew strong opposition from patient advocates, pediatric experts, and members of Congress.

Now, the FDA has released a revised draft that -- while less extreme -- still poses significant risks. The updated guidance moves away from strict per-product ceilings in favor of a looser framework focused on Individual Aluminum Exposure (IAE).[3]

Under the IAE system, the FDA assumes LVPs contribute two mcg/kg/day of aluminum.[4] This leaves three mcg/kg/day to be divided among an assumed five SVPs, which each then have a recommended allowance of 0.6 mcg/kg/day.[5]

In theory, this holds exposure at five mcg/kg/day -- the very upper edge of what the FDA has deemed safe. In practice, this breaks down.

As the agency's draft guidance acknowledges, premature infants receive PN as a compounded mix of SVPs and LVPs, not as isolated components.[6] Real-world PN mixtures often contain more than five SVPs as well -- and some components approach the top of their allowance. Once combined, the totals could very easily exceed the daily cap that the FDA insists it is preserving.

The FDA would be lowering the bar and distorting the market without any scientific justification. Rather than requiring generics to meet the same strict aluminum ceilings as the branded injections, the draft guidance allows higher-aluminum versions into the market. That would break the guarantee that generics are true equivalents.

This runs counter to the Hatch-Waxman framework that underpins the United States' world-leading generic drug system. Hatch-Waxman was founded on a non-negotiable principle: generics must fully measure up to branded counterparts in strength, dosage form, route of administration, active ingredient, clinical effect, and safety profile. This standard has long ensured that patients can trust a lower-cost generic to be every bit as safe and effective as the original. Loosening aluminum standards would make a mockery of that principle.

The result would be a market with backwards incentives. Manufacturers that invested in cleaner processes to minimize aluminum would be penalized, while those willing to produce cheaper -- but more dangerous -- higher-aluminum products would be rewarded. Over time, this dynamic would discourage innovation, drive out higher-quality competitors, and leave patients with fewer and riskier choices.

The consequences would fall hardest on the most vulnerable. Fragile premature infants, who depend on parenteral nutrition for survival, could be needlessly exposed to higher aluminum levels in their daily nutrition. That kind of preventable harm defies common sense, erodes public trust in the FDA, and signals a broader willingness to weaken safeguards in the name of market intervention.

---

[2] Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations" (Dec. 2022) p. 8, Table 1; p. 12, Table 2.
[3] Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations" (Jul 2025) p. 2.
[4] *Id.* p. 6.
[5] *Id.* p. 6.
[6] *Id.* p. 4 / Figure 1.

We urge the administration to withdraw this draft guidance. High safety standards for vulnerable patients should not be negotiable, and unelected regulators must not be allowed to rewrite the rules to favor inferior products -- particularly not at the expense of infant health.

Thank you for your time and consideration.

Sincerely,

Scott C. Tips, JD – President and General Counsel, National Health Federation

Cathie Adams – 2nd Vice President, Eagle Forum
Demetrio J. Aguila, III, MD – Leader, Nebraska Chapter, Free Market Medical Association
David Aucoin – Executive Director, Rhode Island Family Institute
Lindsey Berning – Spokesperson, Kansans for Health Freedom
Julie Booras – Co-Founder, Health Rights MA Advocacy
C. D. Casscells, M.D. – Director, Center for Health Policy, Caesar Rodney Institute (DE)
Cindi Castilla – President, Texas Eagle Forum
Cait Corrigan – National Ambassador, Veterans for Trump
Rebekah DeWitt – Grassroots Activist, Lincoln County (AR) Patriots
Michelle Flowers – Founder, Oncology Managers of Florida
Larry J. Ford – Attorney and Conservative Columnist, Clay County (NC)
Paul Gessing – President, Rio Grande Foundation (N M)
Simone Gold, MD, JD – Chairman and Founder, America's Frontline Doctors
Janine Hansen – President, Nevada Families for Freedom
George Harris – Publisher, Liberty Watch Magazine
John Hinderaker – President, Center of the American Experiment
Mary Holland – President, Children's Health Defense
Nancy Hone – Founder, South Dakota Natural Health Coalition
Drew Johnson – Senior Fellow, National Center for Public Policy Research
Jonathan Keller – President and CEO, California Family Council
Leslie Manookian – President and Founder, Health Freedom Defense Fund
Bethany Marcum – Former CEO, Alaska Policy Forum
Gene Mills – President, Louisiana Family Forum
Annette Olson – CEO, The John K. MacIver Institute for Public Policy (WI)
Bryan Perry – Spokesman, Colorado Chapter of the Free Market Medical Association
Erin Phillips – President & CEO, Power 2 Parent
Scott Pullins – Founder, Ohio Taxpayers Association
Samuel Pascal Redfern – President and Founder, Montana Conservative Liberty Alliance
Laurence Schiff, MD – Chairman, Conservative Club of Kingman
Stephanie Smith – President and CEO, Alabama Policy Institute
Christopher B. Summers – President and CEO, The Maryland Public Policy Institute
Mary Kelly Sutton, M.D. – Co-Founder, Physicians and Patients Reclaiming Medicine
Nicole Theis – President, Delaware Family Policy Council
Paul Thomas, MD – Founder, Kids First 4 Ever
Regina Thomson – Chairman and President, Americans For America
Dr. Michelle Veneziano – Founding Member, Physicians for Informed Consent
Kenneth Wallis – Founder, Keep Arkansas Legal
Stacy Washington – CEO, ShareNet Ministries
Leah Wilson – Executive Director and Co-Founder, Stand for Health Freedom
Allan Wright – Executive Director, New Jersey Family Policy Center