Dr. Marty Makary
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Support for FDA Action to Address Unapproved and Misleading Compounded GLP-1 Drugs

Dear Commissioner Makary:

We write to applaud the FDA's February 6, 2026 announcement to take decisive action against mass-marketed, non-FDA-approved GLP-1 drugs that put patients at risk. The Agency's clear signal that it intends to use its enforcement authority was a welcome development in the face of so many flagrant violations by compounders.

Your statement reinforces a foundational principle: companies may not mass-produce and mass-market, either online or in-person, unapproved products as substitutes for FDA-approved medicines. Nor may they promote compounded products as "clinically proven to produce results" or "the same as" FDA-approved drugs.

When practiced within the narrow boundaries Congress established, compounding can serve an important role by meeting unique, individualized patient needs that cannot be met by FDA-approved drugs. We share FDA's concern, however, that certain actors are exploiting these exceptions to mass-produce and aggressively advertise knockoffs of FDA-approved medicines without regard to any individualized patient needs.

Particularly troubling are claims that these products are "generic," are backed by "the same science" as FDA-approved drugs, contain the same active ingredient as approved drugs, or are clinically proven to deliver comparable results. Such representations mislead patients about products that are not clinically proven and are never reviewed by the Agency for safety, effectiveness, or quality, undermine physician decision-making, and erode public confidence in the nation's drug approval framework.

We support FDA moving swiftly on the following:

- Restricting GLP-1 APIs intended for use in mass-marketed, non-FDA-approved compounded products that fall outside statutory limits.
- Increasing inspections of compounders and entities that supply API used in compounding.
- Taking public enforcement action against misleading direct-to-consumer advertising and promotional claims, including those claims identified in FDA's February 6 statement.
- Clarifying — through guidance and enforcement — what constitutes "essentially a copy" of an FDA-approved drug.
- Deploying all available compliance and enforcement tools under the federal Food, Drug, and Cosmetic Act (FDCA) to address violations that threaten public health.

Clear, consistent enforcement will protect patients and provide needed certainty to pharmacists and physicians seeking to practice within lawful guardrails. What patients need now is safe, effective, and transparent access to medicines — and confidence that products promoted as

alternatives have met FDA's rigorous, gold-standard review. Patients and providers alike depend on the agency to follow through with durable, enforceable steps that preserve these protections.

We appreciate and commend you for your leadership in safeguarding the integrity of the U.S. drug approval system and stand ready to support full and prompt implementation of these enforcement priorities.

Sincerely,

- Alliance for Patient Access
- Aimed Alliance
- Alliance for Safe Online Pharmacies (ASOP Global)
- Alliance for Women's Health and Prevention
- Alliance of Sleep Apnea Partners (ASAP)
- American Medical Women's Association
- Association of Black Cardiologists
- Diabetes Leadership Council
- Diabetes Patient Advocacy Coalition
- Gerontological Society of America
- John Hertig, PharmD
- League of United Latin American Citizens (LULAC)
- Dr. Lyn Behnke
- National Alliance for Caregiving
- National Black Nurses Association, Inc.
- National Consumers League
- National Council on Aging
- National Hispanic Health Foundation
- Obesity Medicine Association
- Partnership for Safe Medicines
- Peter J. Pitts
- RetireSafe
- The Alliance for Safe Biologic Medicines
- The Mended Hearts, Inc.
- The Obesity Society