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AMERICA FIRST MEANS PATIENTS FIRST

Aimed Alliance convened international patient stakeholders to understand best practices in international reference pricing and solutions that ensure meaningful affordability changes for consumers. The recommendations are as follows:

PRIORITIZE U.S.-BASED SOLUTIONS THAT ADDRESS OUR UNIQUE HEALTH INSURANCE SYSTEM

Investigate International Pharmacy Benefit Manager (PBM) Aggregators: The U.S. Trade Representative (USTR) should examine whether PBM aggregators are operating internationally to circumvent U.S. laws requiring prescription drug rebates to be passed to payers and employers. USTR should investigate these practices and take appropriate actions to ensure all savings reach consumers.

Consider Medicaid Carve-Outs for Prescription Drugs: States should explore carving out Medicaid prescription drug benefits from managed care contracts to increase savings and improve affordability. Eight states have already implemented carve-outs, generating substantial savings. For example, New York saved an estimated $400 million in 2024 by independently managing its formulary and rebates.

Strengthen Pharmacy Benefit Manager Oversight: PBMs are third-party middlemen that play a major role in the U.S. drug pricing system yet remain largely unregulated by state or federal authorities. Reform should include increasing transparency on drug costs, prices, markups, and discounts; banning spread pricing; implementing delinking practices; and imposing fiduciary duty obligations.

Prioritize Systematic Reform over Individual Manufacturer Agreements: While individual arrangements between the White House and pharmaceutical companies demonstrate good-faith efforts, long-term affordability improvements require reform addressing institutional challenges such as PBM practices, insurer practices, and other U.S. specific third-party cost drivers.

Address Consumer Out-of-Pocket Costs: Reforms that directly lower out-of-pocket costs will have the greatest impact on consumers. Options include annual out-of-pocket caps similar to those in the IRA or banning copay accumulator programs.

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INTERNATIONAL REFERENCE PRICING ESSENTIAL PATIENT PROTECTIONS

While the alternatives outlined above could more directly address prescription drug spending and affordability in the United States, if the Trump Administration moves forward with international reference pricing, the following recommendations should be implemented to ensure patients, caregivers, and providers have a meaningful opportunity to engage in the process.

Use IRP as a Benchmark, Not a Baseline: Any use of an international reference price should supplement, not replace, an independent U.S. pricing assessment that reflects federal law and anti-discrimination protections, U.S. patient values, and U.S. patient populations.

Prohibit the Use of Discriminatory QALYs: Federal law bans the direct and indirect use of QALY data in federal programs governed by the Social Security Act. Policymakers should ensure this prohibition is upheld in any international reference pricing program and applies to all federal programs, given the discriminatory nature of these assessments.

Ensure Patient Engagement from the Earliest Stages: Developing a pricing system that accurately reflects patient needs requires involving patients, providers and caregivers from the beginning. Early engagement substantially improves the process and leads to more equitable and accurate outcomes. As one participant noted, "patients should be placed at the center of the healthcare system and that this participation should be structural, early and binding, not just consultative." Engaging patients from the outset prevents the need to later overhaul systems to better reflect U.S. patient values, views, and communities.

Provide Opportunities for Patient Feedback and Reconcile Feedback in Decisions: A persistent global challenge is the lack of transparency around how decision-makers use patient, caregiver, and provider feedback. Any IRP programs should allow patients to comment on drug value and should require decision-makers to explain how input and insight informed final pricing decisions.

Protect Rare Disorders: Treatments for rare diseases, disorders, and orphan drugs should be carved out from IRP models. Rare disease therapies often fail QALY thresholds due to the small patient population sizes. Participants noted that, given these distinct challenges and needs of the rare disease community, additional research is needed to establish value-assessment best practices for these communities.

Protect Innovation: The U.S. is a global leader in biotechnology and pharmaceutical innovation, with many novel treatments launching in the U.S. before other countries. This leadership is critical for U.S. patients who depend on timely access to cutting-edge treatments. An IRP program could unintentionally hinder research, development, and access. Safeguards to protect this infrastructure could include:

- **Create a small biotech exemption:** Similar to the IRA, an exemption could reiterate Congress's concerns about small biotechnology companies and the need to safeguard these stakeholders to ensure continued investing in research and development for new treatments.
- **Delay the application of international reference pricing:** Under the Inflation Reduction Act, Medicare price negotiations are delayed for seven years after FDA approval for small-molecule drugs and 11 years for large-molecule drugs. However, health policy experts have raised concerns that these differing timelines may disadvantage investment in small-molecule drugs. Congress is therefore considering legislation to establish a single, uniform negotiation timeline and legislation that clarifies how niche technologies, like genetically targeted therapies, fall within these timeframes. If policymakers adopt an IRP program, they should similarly consider implementing a uniform negotiation timeline across all therapeutics.
  - Without such safeguards, manufacturers may choose to launch certain products exclusively in the U.S. and delay introductions in other countries to avoid triggering reference pricing benchmarks.
- **Create pricing control exceptions:** IRP operates with the understanding that one pharmaceutical company controls global pricing for a product. In practice, many smaller companies license or sell the rights to manufacture and market their products to international companies. Under these circumstances, it would be difficult for the original company to be held accountable for IRPs it cannot influence. Policymakers should therefore consider whether and how such companies should be subject to an IRP requirements and whether targeted exceptions are appropriate.