AFFORDABLE DRUG MANUFACTURING ACT

Senator Elizabeth Warren and Representative Jan Schakowsky

Generic drugs – which account for over 90 percent of all U.S. prescriptions – can generate substantial savings for the health care system and patients by introducing price competition once patents and other legal protections for brand-name drugs expire. But the generic drug market is plagued by numerous market failures. 40 percent of generic drugs are now made by a single manufacturer, and a majority are made by only one or two companies. Industry consolidation harms consumers by allowing drug makers to jack up prices. In recent years, generic drug manufacturers have been engaging in anticompetitive behavior that has led to higher prices. Generic drugs made up 67 percent of the drugs that went into shortage from 2013 and 2017, and drug shortages have hit a five-year high with nearly 300 drugs in shortage at the end of 2022.

Affordable Drug Manufacturing Act

Domestic manufacturing of pharmaceuticals will lower drug prices for millions while improving competition. The *Affordable Drug Manufacturing Act* tasks the Department of Health and Human Services (HHS) with the manufacturing of generic drugs in cases where the market has failed and strengthens the generic market for the long term by jump-starting competition. The Act:

- Establishes an Office of Drug Manufacturing within HHS charged with lowering prices, increasing competition, and addressing shortages in the market for prescription drugs;
- Authorizes the Office to manufacture generic drugs under one of the following key conditions:
    - No company is marketing the drug,
    - Three or fewer companies are marketing the drug, and the price has spiked;
    - Three or fewer companies are marketing the drug, and the drug is in shortage; or
    - Three or fewer companies are marketing the drug, the price is a barrier to patient access, and the drug is listed as an "essential medicine" by the World Health Organization
- Authorizes the Office to manufacture any drug that the federal government has licensed, including under existing compulsory licensing authorities;
- Allows the government to sell manufactured drugs at a fair price that covers manufacturing costs while ensuring patients have access to these drugs;
- Requires the Office to begin production of insulin, asthma and chronic obstructive pulmonary disease inhalers, naloxone, epinephrine auto-injectors, and antibiotics within one year;
- Improves the ability of new companies to enter the generic drug market by authorizing the manufacturing of active pharmaceutical ingredients;
- Requires the Office to offer to sell the rights to manufactured drugs to manufacturers who commit to keep the drug on the market at a fair price, but authorizes the Office to resume production if a manufacturer violates these commitments.

The *Affordable Drug Manufacturing Act* is endorsed by the Democracy Collaborative, Social Security Works, Public Citizen, FamiliesUSA, Center for Medicare Advocacy, T1 International, Indivisible, Alliance for Retired Americans, People's Action, MomsRising, Main Street Alliance, Physicians for a National Health Program, PrEP4All, Action Center on Race and the Economy, American Federation of Teachers, U.S. PIRG, NETWORK Lobby for Catholic Social Justice, Knowledge Ecology International, Center for Popular Democracy, Treatment Action Group, National Consumer Voice for Quality Long-Term Care, Universities Allied for Essential Medicines, CASA, Center for Common Ground, Health Care Voices, Citizen Action of Wisconsin, Beta Cell Action, ACA Consumer Advocacy, Oregonizers, Seventh Generation Interfaith Coalition for Responsible Investments, Tennessee Health Care Campaign, Coalition on Human Needs, and Metro New York Health Care for All.