

**AFFORDABLE DRUG MANUFACTURING ACT**  
Senator Elizabeth Warren and Representative Jan Schakowsky

Generic drugs – which now account for nearly 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.<sup>1</sup> But the generic drug market is plagued by numerous market failures. Forty percent of generic drugs are now made by a single manufacturer, and a majority are made by only one or two companies.<sup>2</sup>

Industry consolidation harms consumers by allowing drug makers to jack up prices.<sup>3</sup> A 2016 GAO report on generic drugs in the Medicare program found that more than 20% of generic drugs analyzed “had at least one extraordinary price increase of 100 percent or more” during the study period.<sup>4</sup> Hospitals and emergency room physicians also report persistent shortages of generic drugs, including painkillers, saline, and other essential medicines.<sup>5</sup> And forty-seven states are now investigating top generic drug makers for allegedly conspiring to fix the prices of hundreds of generic drugs, in what one investigator called “most likely the largest cartel in the history of the United States.”<sup>6</sup>

***Affordable Drug Manufacturing Act***

Public 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 with the public 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 three key conditions:
  - No company is manufacturing the drug,
  - Only one or two companies produce the drug, and the price has spiked or the drug is in shortage,
  - Only one or two companies produce 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 publicly-manufactured drugs at a fair price that covers manufacturing costs while ensuring patients have access to these drugs;
- Requires the Office to begin public production of insulin within one year;
- Improves the ability of new companies to enter the generic drug market by authorizing the public manufacturing of active pharmaceutical ingredients;
- Requires the Office to offer to sell the rights to publicly-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 Public Citizen, Social Security Works, Open Markets Institute, Physicians for a National Health Program, Housing Works, Knowledge Ecology International, Center for Medicare Advocacy, CREDO, National Physician’s Alliance, AIDS Healthcare Foundation, American Federation of Teachers, and the Business Initiative for Health Policy.**

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<sup>1</sup> Association for Accessible Medicines, “Generic Drug Access and Savings in the U.S.,” 2017, <https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>.

<sup>2</sup> Ernst. R. Berndt, Rena M. Conti, and Stephen J. Murphy, “The Landscape of U.S. Prescription Drug Markets, 2004-2016,” 2017, NBER Working Paper # 23640, <https://www.nber.org/papers/w23640>.

<sup>3</sup> Carolyn Y. Johnson, “The Generic Drug Industry Has Brought Huge Cost Savings. That May Be Changing,” *The Washington Post*, August 1, 2017, [https://www.washingtonpost.com/business/economy/the-generic-drug-industry-has-brought-huge-cost-savings-that-may-be-changing/2017/08/01/ee128d0a-68cf-11e7-8eb5-cbccc2e7bfbf\\_story.html?utm\\_term=.20b7bd6d4a9d](https://www.washingtonpost.com/business/economy/the-generic-drug-industry-has-brought-huge-cost-savings-that-may-be-changing/2017/08/01/ee128d0a-68cf-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.20b7bd6d4a9d).

Chintan V. Dave et al., “High Generic Drug Prices and Market Competition,” *Annals of Internal Medicine*, 2017. Andrew Pollack and Sabrina Tavernise, “Valeant’s Drug Price Strategy Enriches It, but Infuriates Patients and Lawmakers,” *The New York Times*, October 4, 2015, <https://www.nytimes.com/2015/10/05/business/valeants-drug-price-strategy-enriches-it-but-infuriates-patients-and-lawmakers.html>.

<sup>4</sup> Government Accountability Office, “Generic Drugs under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases,” August 2016, <https://www.gao.gov/assets/680/679022.pdf>.

<sup>5</sup> Katie Thomas, “Emergency Rooms Run Out of Vital Drugs, and Patients Are Feeling It,” *The New York Times*, July 1, 2018, <https://www.nytimes.com/2018/07/01/health/emergency-rooms-run-out-of-vital-drugs-and-patients-are-feeling-it.html>.

<sup>6</sup> Christopher Rowland, “Investigation of Generic ‘Cartel’ Expands to 300 Drugs,” *The Washington Post*, December 9, 2018, [https://www.washingtonpost.com/business/economy/investigation-of-generic-cartel-expands-to-300-drugs/2018/12/09/fb900e80-f708-11e8-863c-9e2f864d47e7\\_story.html?noredirect=on&utm\\_term=.6f175b79be6e](https://www.washingtonpost.com/business/economy/investigation-of-generic-cartel-expands-to-300-drugs/2018/12/09/fb900e80-f708-11e8-863c-9e2f864d47e7_story.html?noredirect=on&utm_term=.6f175b79be6e).