

How to Talk About High Drug Costs in a Time of Economic Insecurity

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How to Talk About High Drug Costs in a Time of Economic Insecurity

Health care and the cost of prescription drugs are top issues for voters across the country. Patients and their families confront difficult choices when faced with the high cost of brand-name drugs. Seniors with Medicare coverage are experiencing higher drug costs due to anticompetitive tactics that limit access to FDA-approved generics and biosimilars. Voters want Congress to act and are paying attention to what you have to say on the issue.

The COVID-19 pandemic has only heightened voters' anxiety over the cost of brand-name drugs. A June 2020 Gallup survey found...

“9 out of 10 adults are concerned that the pharmaceutical industry will leverage the COVID-19 pandemic to raise drug prices.”¹

The same survey found that 23 percent of Americans did not have the money to fill a doctor's prescription in the last 12 months.²

^{1,2} <https://news.gallup.com/poll/312641/nine-concerned-rising-drug-costs-due-covid.aspx>

Competition from generic drugs is a proven way to lower drug prices. Too often, however, anti-competitive practices by brand-name pharmaceutical companies keep generic drugs out of the hands of patients, allowing prices to be raised year after year.



Humira

BY THE NUMBERS (2018)

\$19.9 billion in sales

\$38,000 price for patients

\$5 billion cost to taxpayers

\$483 million spent on advertising

120 patents filed to delay competition from more affordable alternatives

50% increase in price from 2014 to 2018



AbbVie, already famous for its Humira strategy, forms another 'patent wall' around Imbruvica: report

Source: New York Times. "Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher." January 2018. <https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html>; CMS Medicare Part D Drug Spending Dashboard. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD>

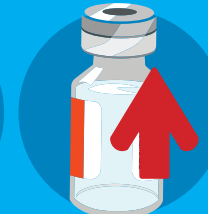
ARE GENERICS AND BIOSIMILARS THE SAME AS BRAND-NAME DRUGS?

Generic and biosimilar medicines are FDA-approved alternatives to expensive brand drugs. Generics contain the same active ingredients, in the same strength, as brand drugs. Biosimilars are highly similar to and have no clinically meaningful differences from an existing FDA-approved reference product. By law, most brand drugs have some period of monopoly protection, in the form of exclusivity and/or patents, that delay the FDA's approval of the generic or biosimilar version of the drug.

Generic medicines produce patient and system savings while brand drugs drive costs



Generic drug prices have **declined by more than 40%** since 2014



Brand-name drug prices have **risen by over 70%**³

³ <https://www.express-scripts.com/corporate/drug-trend-report#2019-by-the-numbers>

Cost to patients affects access



Around \$5 for a generic



More than \$40 for brand-name drugs

Generic medicines save billions of dollars for patients and taxpayers



90%
PRESCRIPTIONS FILLED

20%
OF TOTAL SPENDING



10%
PRESCRIPTIONS FILLED

80%
OF TOTAL SPENDING

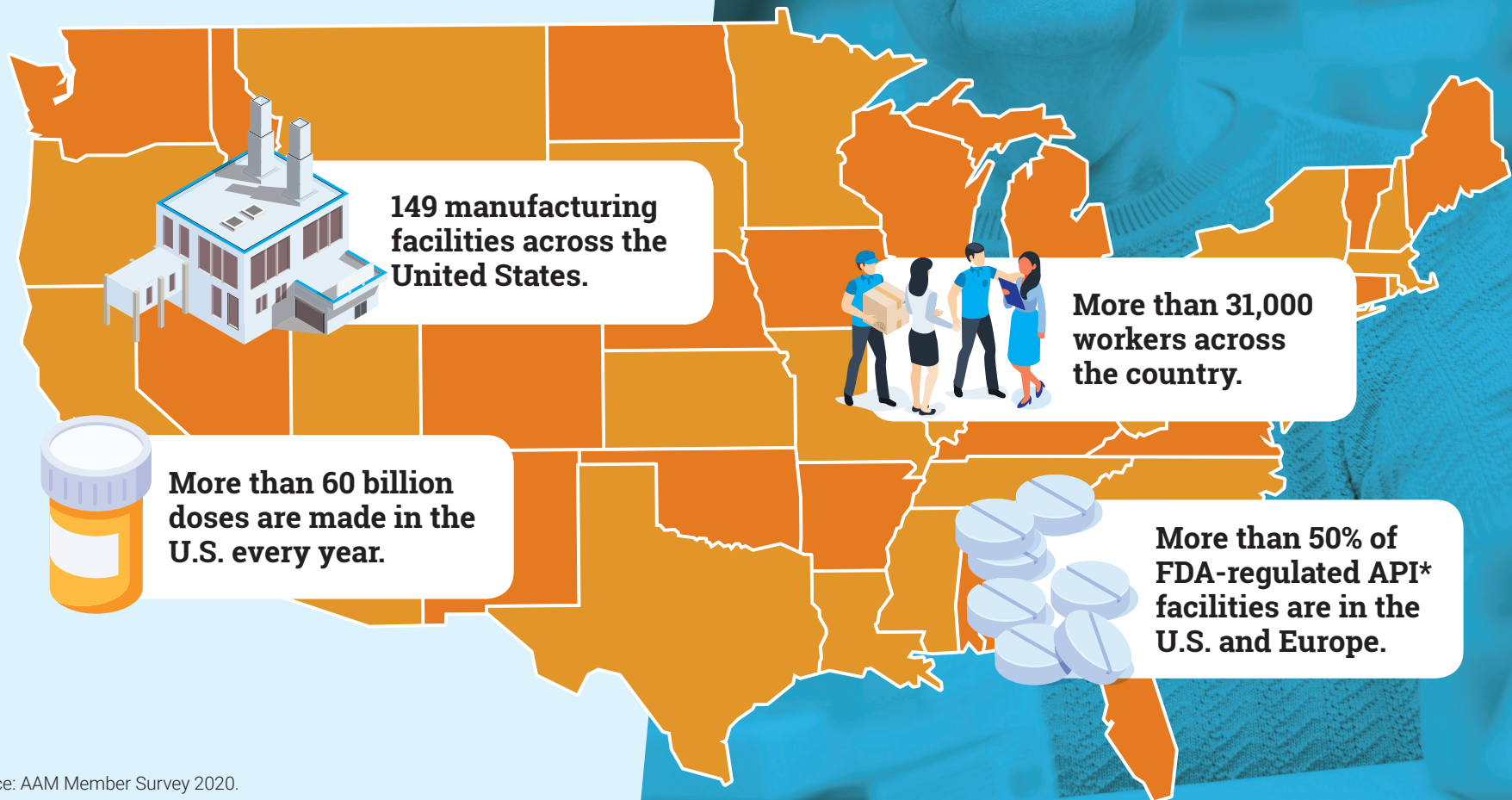
Generics are 90% of prescriptions filled yet account for 20% of overall drug spending

Brand-name drugs are 10% of prescriptions filled but account for 80% of overall drug spending

GENERIC MEDICINES: MADE IN THE U.S.A.

Generic and biosimilar manufacturers contribute to the U.S. economy by providing over 31,000 jobs across the country and paying state, local and national taxes.

They do all this while ensuring patient access to safe, effective and lower-cost medicines.



Source: AAM Member Survey 2020.

*Active Pharmaceutical Ingredient.

How to Talk About Drug Prices

Voters are asking questions about the rising cost of prescription drugs. Below are some suggested answers to commonly asked questions.

WHAT IS A GENERIC DRUG?

- Generic medicines are FDA-approved alternatives to brand-name drugs. Generics contain the same active ingredients, in the same strength, as the brand-name drug, and meet the same FDA quality and effectiveness standards as the brand product.

WHY DO DRUG PRICES CONTINUE TO GO UP?

- **Monopoly pricing:** When brand-name drugs and biologics are approved, current law provides market exclusivity (monopoly) for five and 12 years, respectively, and up to 20 years of patent protection for most products. However, abuse of the patent system often delays competition well beyond what Congress intended. During this time, brand-name pharmaceutical companies are able to raise prices without threat of competition.
- **Patent abuse:** The initial patent of a prescription drug expires 20 years after filing. Toward the end of this period, brand-name pharmaceutical companies sometimes file late-stage patents to extend patent protections and increase the barriers to competition. In order to introduce competition and make a more affordable option available to patients, generic manufacturers often need to engage in lengthy and expensive patent litigation or wait until all patents expire.

WHAT DO SOME BRAND-NAME PHARMACEUTICAL COMPANIES DO TO THWART COMPETITION?

- Far too often, some brand-name pharmaceutical companies request and obtain late-stage patents that serve only to delay generic and biosimilar competition and do not provide patients with a clinically meaningful improvement.
- Once a generic or biosimilar is able to come to market, some brands block competition through “rebate traps” that reward coverage of higher-priced brand drugs instead of generics or biosimilars.

WHAT POLICIES SHOULD BE SUPPORTED TO DECREASE DRUG PRICES?

There is one proven way to reduce drug prices: competition. When multiple generics are competing against brand-name drugs, the cost to patients falls by 85%, according to the FDA.

The following policies enhance competition:

- Establish a regulatory and legislative climate in the United States that encourages generic and biosimilar entry.
- Strengthen patent law to ensure only true innovation is rewarded and anticompetitive tactics are eliminated.
- Align Medicare policies to encourage use of lower-priced generic and biosimilar medicines.

CAN BIOSIMILARS HELP LOWER DRUG PRICES AND INCREASE PATIENT ACCESS?

- The most expensive prescription drugs on the market are brand-name biologics. Biologics comprise more complex molecules than standard small-molecule drugs and are more complicated to manufacture. **Although biologics are roughly 2% of prescriptions filled in the United States, these expensive brand-name biologic medicines, like the heavily advertised Humira and Trulicity, are responsible for nearly half of all spending on drugs in this country.**
- Biosimilars are highly similar to and have no clinically meaningful differences from an existing FDA-approved reference product.
- Currently, the FDA has approved 28 biosimilars, 18 of which are on the market. Biosimilars promise significant savings – more than \$54 billion – if policies are enacted that ensure entry and coverage of these important medicines.⁴

I'VE HEARD THAT MEDICINES AND THEIR INGREDIENTS ARE OFTEN MADE IN CHINA. SHOULD PATIENTS IN THE U.S. BE CONCERNED?

- FDA oversees the manufacturing of medicines for the U.S. market and ensures that – regardless of where the medicine is made and sourced from – the same stringent standards for safety and efficacy are adhered to. The FDA is the gold standard for safety and its officials declare the U.S. drug supply is the safest that it has ever been.⁵

⁴ <https://www.rand.org/pubs/perspectives/PE264.html>

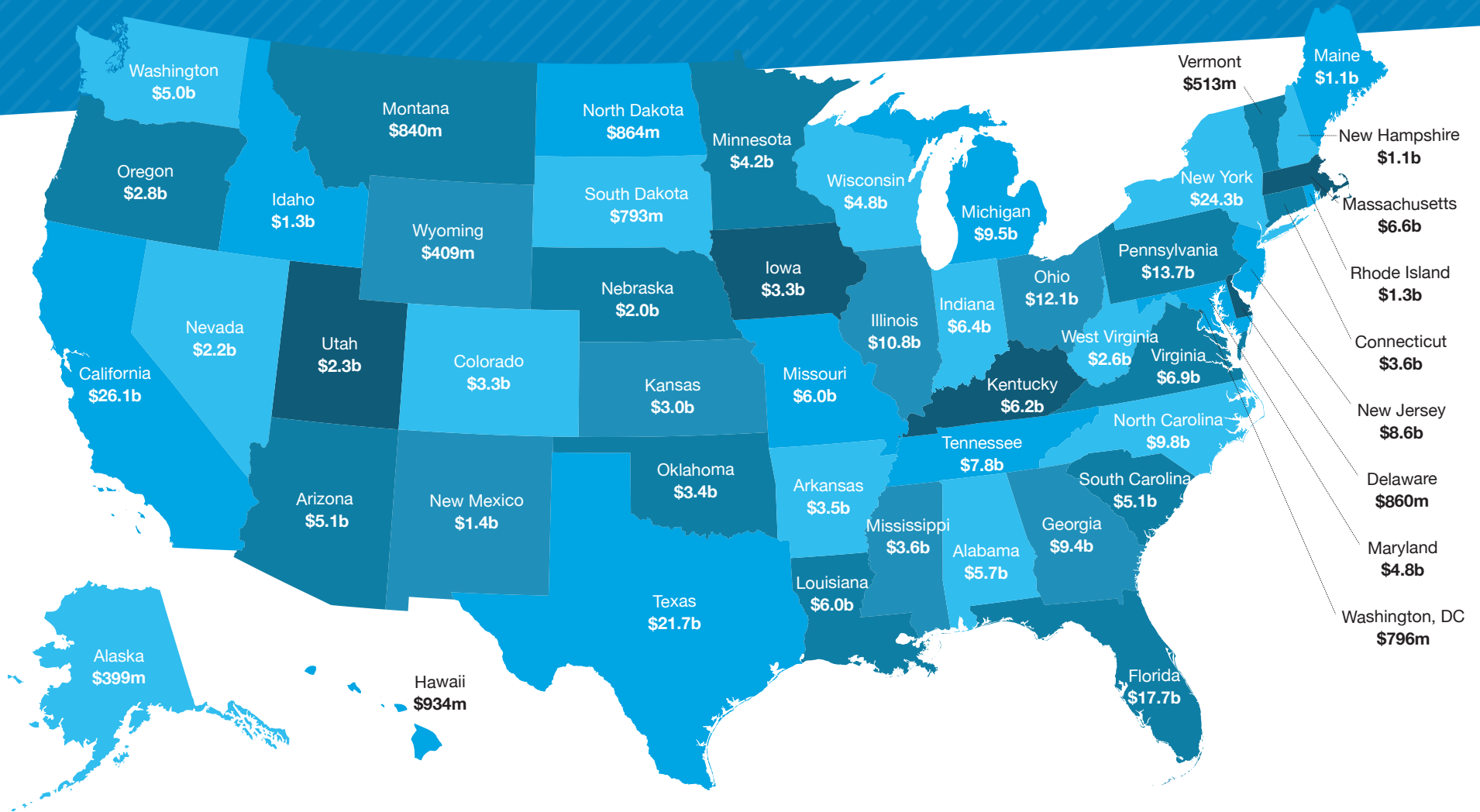
⁵ Michael Kopcha, Ph.D., R.Ph., director of CDER Office of Pharmaceutical Quality <https://www.fda.gov/drugs/news-events-human-drugs/cder-conversation-assuring-drug-quality-around-globe>

- According to the FDA, more than 50% of FDA-regulated active pharmaceutical ingredient facilities are located in the U.S. and Europe. Seven percent are located in China.
- Moreover, more than 60 billion doses of generic medicines are manufactured in the U.S. each year.

WHAT CAN BE DONE TO STRENGTHEN THE U.S. SUPPLY OF GENERIC MEDICINES?

- Policies need to be enacted to ensure a stable and sustainable market and price for U.S.-made medicines, including harnessing the purchase power of the federal government.
- Congress must act to incentivize additional U.S.-based manufacturing – including grants and tax credits – in order to ensure a more diversified and resilient supply chain.
- The U.S. should establish a list of essential medicines – those drugs most critical to public health and national security – to prioritize for domestic production.

Generic Drug Savings By State



Source: IQVIA 2019



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For more information, contact:
Kristin Murphy
Director, Federal Affairs
Association for Accessible Medicines
202.249.7102
Kristin.Murphy@accessiblemeds.org



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