

GENERICS

Category Audit



Dec 2019

GENERICs

Dominate
The Market¹

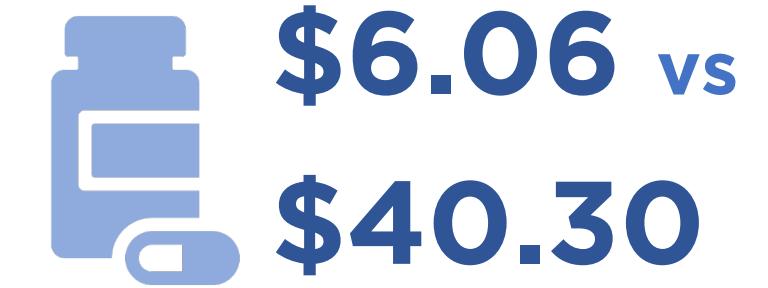


Of US medication prescriptions in 2018 were generic



\$20
or less

The cost of 93% of all generic drug prescriptions filled



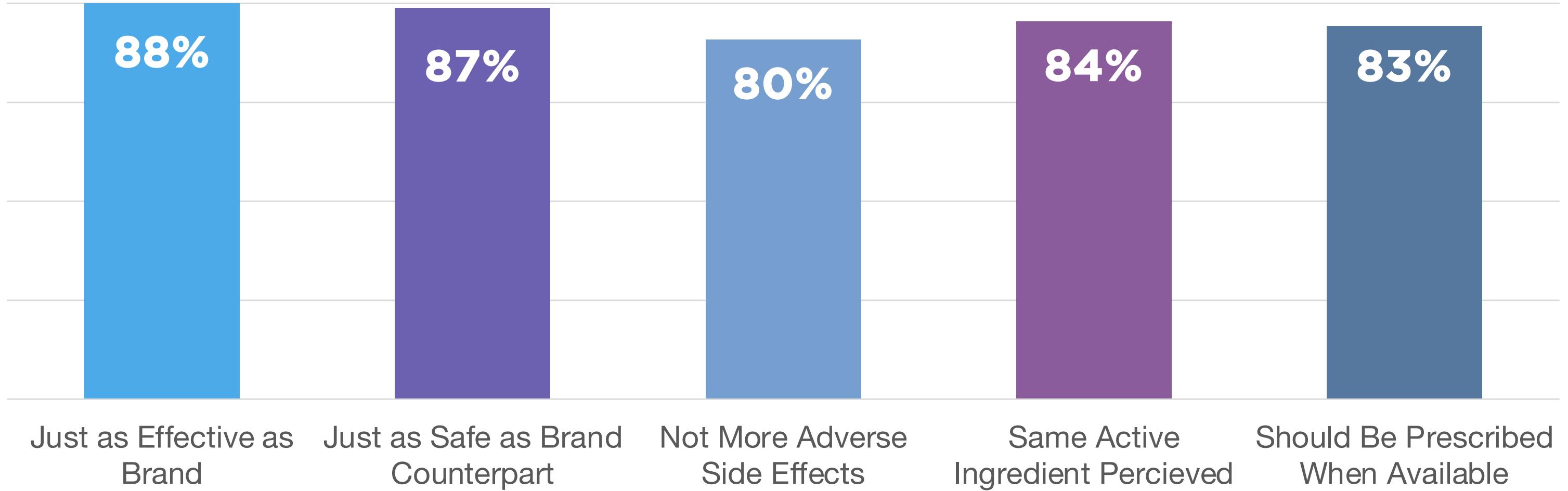
\$6.06 vs
\$40.30

Average co-pay for generic drugs versus branded

GENERICS

Are Widely
Favored²

National Patient Sentiment



GENERICS

Demographic Preferences

Non-Caucasians

- More likely to request brand over generic (56% vs. 43%)
- More skeptical of generic's clinical equivalence (43% vs. 29%)

Social Class Differences³

- Lower income, less educated individuals held more negative attitudes toward generics
 - Wealthiest patients (\$100k+ yearly income) more likely to report they preferred generic medications*
- *variance may depend on drug⁴

DO PATIENTS

Trust the FDA?

Perception of FDA Approval Process⁵

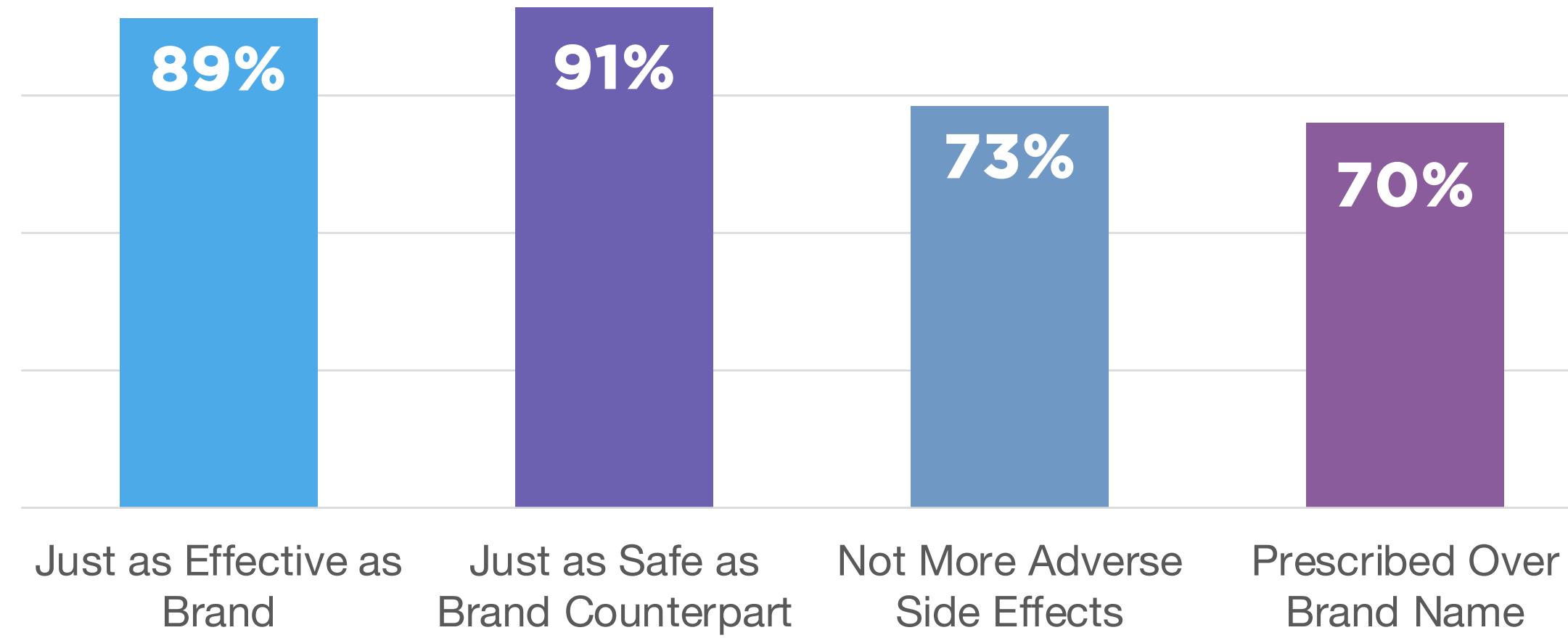
- 753 patients with chronic diseases surveyed (2017)
- 74% unsure of the process
- 89% believed FDA approval ensures safety & effectiveness
- 1 in 5 heard concerns about their generics, mostly from physicians (35 to 36%) & the Internet (32 to 38%)

Generally uninformed & unconcerned

GENERICS

Favored By
Experts⁶

National Physician Sentiment



32% were general skeptics

Heightened among physicians who learned about generics through pharma sales reps

AUTHORIZED Generics

Identical Formula to Brands

- From a '99 – '14 study of 7 drugs, 93.6% of 5,234 patients switched to generic⁷
- After 1 year, outcomes (visits, outpatient care) medically similar
- By Nov '14, of FDA approved drug combos⁸:
 - 1 in 5 patent protected or discontinued (no generic competition)
 - Around half had generic competition
 - 36.4% had at least one Authorized Generic competitor

MANDATORY Generics



38 states require mandatory substitution of **therapeutically equivalent generic** to save on capital \$\$\$⁹

Sometimes physicians can still prescribe “brand medically necessary/prescribe as written”

POLICY Concerns

The Industry's Turning Tides

- For past 3 years, multiple state AGs have sued nation's biggest generics manufacturers¹⁰, scathing report from Senate¹¹
- Current 2019 suit: 43 states allege price fixing on 100+ drugs
- Price inflation of up to 1000%¹²

"We have hard evidence that shows the generic drug industry perpetrated a multi-billion dollar fraud on the American people."

—Connecticut AG William Tong

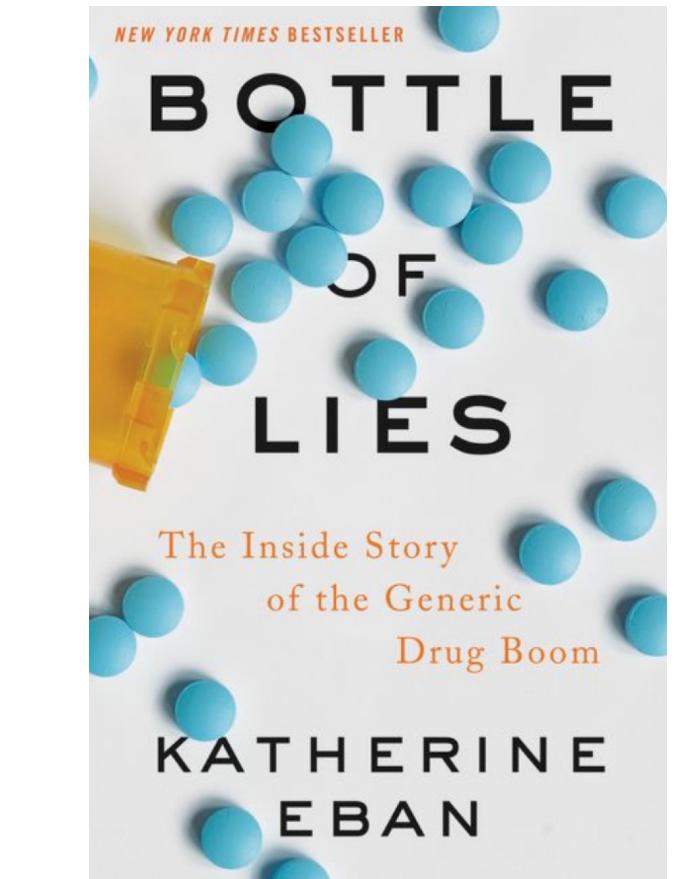
DAMAGING Public Opinion

Bottle of Lies: The Inside Story of the Generic Drug Boom Hardcover – May 14, 2019

by Katherine Eban (Author)

★★★★★ 35 customer reviews

#1 Best Seller in Pharmaceutical & Biotechnology Industry



Thomas R



★★★★★ Excellent book - Raises serious questions about generic drugs

May 18, 2019

Format: Hardcover | **Verified Purchase**

As a pharmacist, I was looking forward to reading Katherine Eban's new book about generic drugs. I know her to be an excellent researcher and a great author. Having just finished the book, I can say I was not disappointed. At least I was not disappointed in the author. She did a wonderful job as usual! The book is well researched and documented, and it reads like a novel. It would make a great movie as well!

It was, however, very disappointing (shocking, disturbing!), to learn about the negligence and outright fraud associated with the manufacture of many generic drugs and the lack of oversight and public protection provided by the federal agency that is supposed to regulate these products, the U.S. Food and Drug Administration (FDA). About 90% of medications consumed in the United States are generics and the vast majority of these are made in India and China.

ONLINE Pharmacies

More Growing Concerns

- Increasing in number
- Regulatory & health risks¹³
- Some illegal, questionnaires ≠ prescription
- Dangerous drug interactions possible
- “Very often” wrong labeling & chemical composition

Tramadol Example



Prescriptions motivated by pain management, not managed through legitimate channels

Experienced significantly more, severe adverse events, including life-threatening seizures: 7% compared to 0%¹⁴

CATEGORY

Recommendations

Online Pharmacies

1. Enhance benefits and minimize risk
2. Focus on policy & improve an individual's health literacy

Physician Approval

1. Limiting interactions with pharmaceutical marketing
2. Direct educational outreach to ensure generics' success

Emerging Market Leader

1. Bold, unafraid, transparent brand
2. Empowering and educational content

1. National Conference of State Legislatures (2014-2018): Generic Prescription Drugs and Brand-Name Discounts & Prescription Agreements and Volume Purchasing- Health Cost Containment ([LINK](#))
2. Journal of General Internal Medicine (2016): Variations in Patients' Perceptions and Use of Generic Drugs: Results of a National Survey ([LINK](#))
3. Health Affairs (2009): Patients' Perception of Generic Medications: Although most Americans appreciate the cost-saving value of generics, few are eager to use generics themselves ([LINK](#))
4. The European Journal of Health Economics (2012): Patient socioeconomic determinants of the choice of generic versus brand name drugs in the context of a reference price system: evidence from Belgian prescription data ([LINK](#))
5. Pharmaeconomics & Drug Safety (2017): Do patients trust the FDA? a survey assessing how patients view the generic drug approval process ([LINK](#))
6. JAMA Internal Med (2016): Prevalence & Predictors of Generic Drug Skepticism Among Physicians ([LINK](#))
7. Clinical Psychology & Therapeutics (2016): Comparison of Outcomes Following a Switch from a Brand to an Authorized Versus Independent Generic Drug ([LINK](#))
8. 1. Value in Health (2015): *Generic Competition and Authorized Generics in the United States* ([LINK](#))
9. Matrix Healthcare Services (2017) *Mandatory Generics Chart* ([LINK](#))
10. PBS (5/11/19): *States bring price fixing suit against generic drug makers* ([LINK](#))
11. US Senate Special Committee on Aging (2016): *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* ([LINK](#))
12. New York Times (5/11/19): *Teva and Other Generic Drugmakers Inflated Prices Up to 1,000%, State Prosecutors Say* ([LINK](#))
13. Journal of Medical Internet Research (2011): *Quality of Online Pharmacies and Websites Selling Prescription Drugs: A Systematic Review* ([LINK](#))
14. Journal of Medical Internet Research (2012): *Health Outcomes in Patients Using No-Prescription Online Pharmacies to Purchase Prescription Drugs* ([LINK](#))

REFERENCES & Web Citations