



Authorized Generics and Their Role in Mental Health Treatment

Joe & Terry Graedon
The People's Pharmacy

MHA
Mental Health America
B4Stage4

What are authorized generic drugs?

- *JAMA Internal Medicine*, Jan. 25, 2021: “Authorized Generics and Their Evolving Role in Prescription Drug Pricing and Access”
- FDA definition: “approved brand name drug that is marketed without the brand name on its label” as of 12/28/2020
- Licensed under original brand name application (NDA) by brand-name maker or licensee

What is the difference between generic drugs and authorized generics?

- Generic drugs and the FDA
- Same active ingredient as brand-name drug
- Actual formulation is proprietary
- Generic companies do reverse engineering
- Authorized generic marketers hold a license from the patent holder

Requirements for a Generic Drug

- Must be “bioequivalent”
 - Gets into bloodstream in a comparable manner to brand-name drug
- Part of approval process ANDA
- This is where the reverse engineering is tested

Price Differences Between Brand & Generic

- Xanax XR Pfizer 30 tabs, 1mg \$415
 - Alprazolam \$15-\$30
- Zoloft Pfizer 30 tabs, 100mg \$450
 - Sertraline \$15-\$33
- Wellbutrin XL 30 tabs, 300mg \$2350
 - Bupropion XL \$98
 - Buying from Canada, brand name is approximately \$50

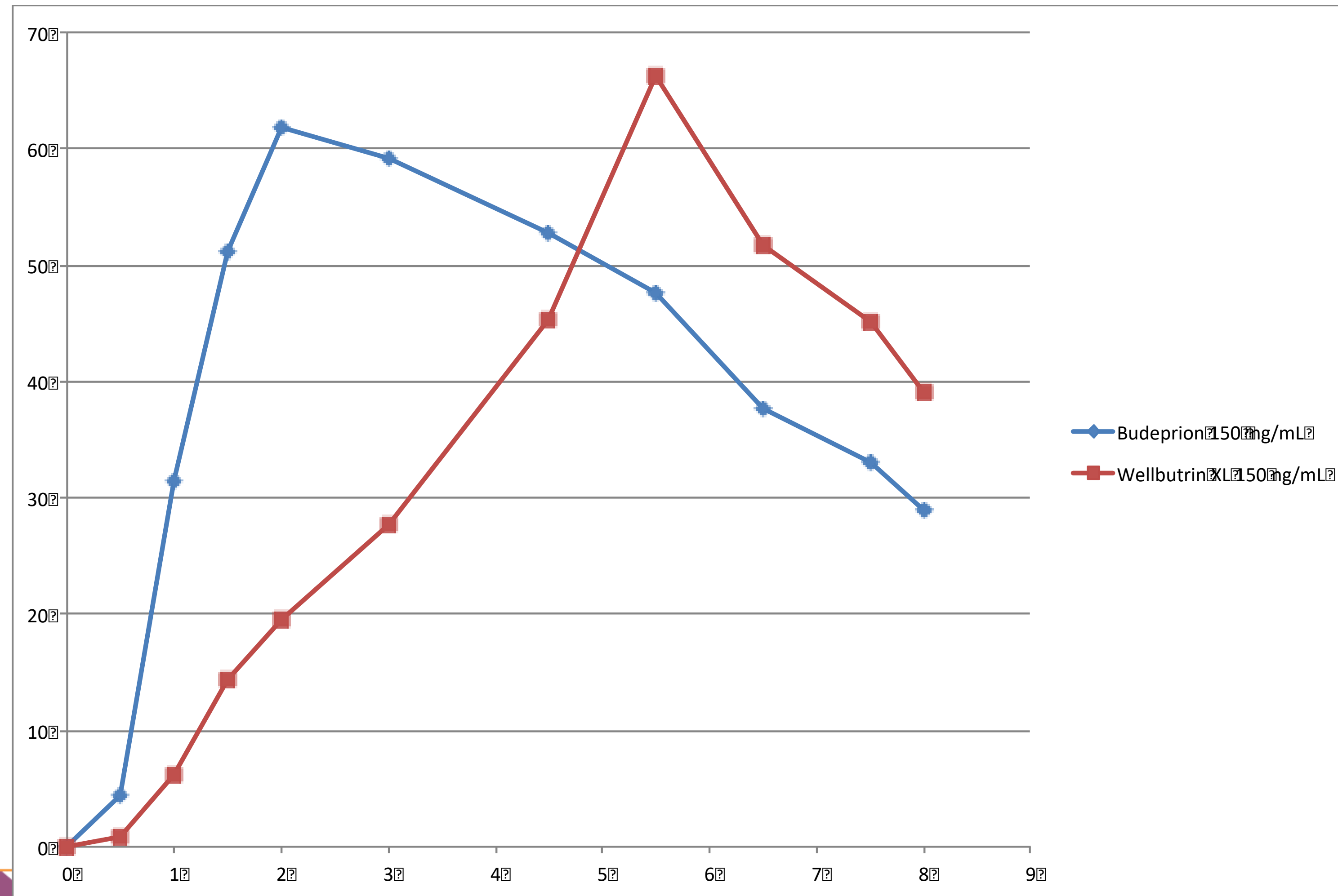
Why do companies offer authorized generic drugs?

- Retain market share
- Avoid public censure (EpiPen, Humalog)

Why would consumers want authorized generics?

- Quality concerns
- Questions about foreign manufacturers
- FDA oversight
- Bioequivalence testing

Wellbutrin XL 150 vs Budeprion XL 150



Pros & Cons of Authorized Generics

- Quality is assured
- Price is lower than brand-name product
- Price may be higher than ordinary generic
- Authorized generic may be difficult to access
- Not available for every drug

How to Find an Authorized Generic

Coalition for Authorized Generics:

<https://www.authorizedgenericmedicines.org/>

Q & A

Joe & Terry Graedon
The People's Pharmacy
www.peoplespharmacy.com

