Authorized Generics and Their Role in Mental Health Treatment

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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

![Graph comparing Wellbutrin XL 150 vs Budeprion XL 150](chart.png)
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

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