



Post-Approval Impact of Generic Fluticasone Propionate & Salmeterol Inhalation Powder (RLD: Advair Diskus)

***SBIA 2023—Advancing Generic Drug Development:
Translating Science to Approval***

Day 2, Session 5: Noteworthy Complex Generic Drug Approval & Research: Orally Inhaled Products

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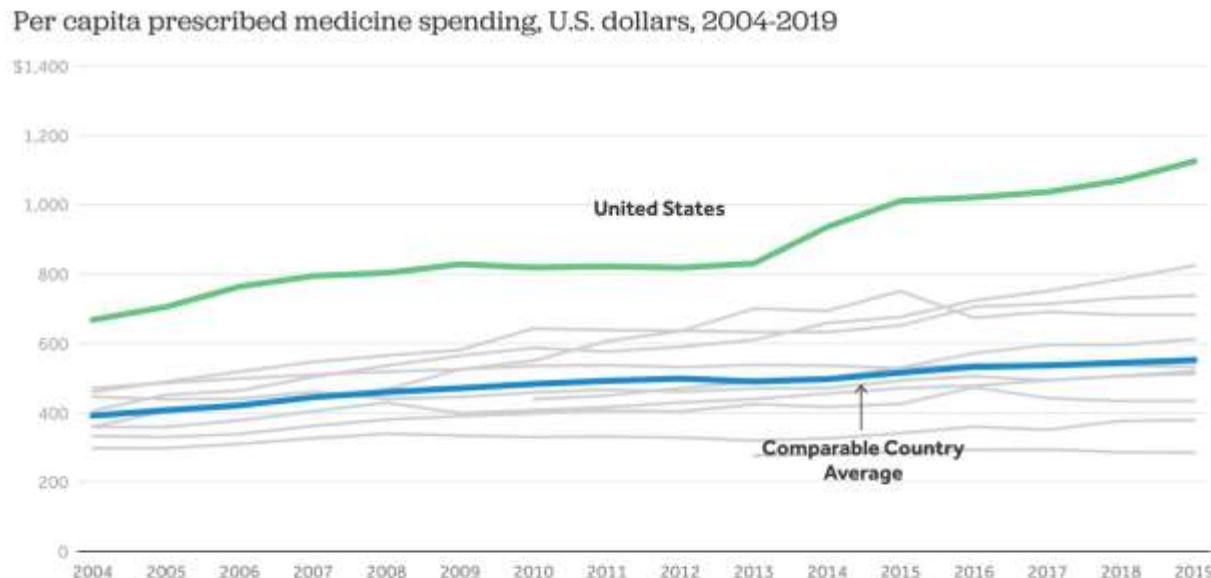
CDER | U.S. FDA

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Learning Objectives

- Describe the high costs of inhalers in the United States and the effect on patient outcomes
- Identify the difference between an approved generic (ANDA) and an authorized generic
- Describe the post-market impact of ANDA approved generic and authorized generic inhalers

U.S. per capita prescription spending is higher than comparable countries



Notes: Data not available for Switzerland from 2004-2009; for the United Kingdom from 2004-2012; Australia and Japan for 2019 (data from 2018 for these two countries are extrapolated for the 2019 comparable country average). Canada's 2019 value is provisional.

Source: OECD

Peterson-KFF
Health System Tracker

Inhalers are a substantial cost to the U.S. healthcare system



- Medicaid spent \$26.2B on inhalers from 2012-2018 with annual spending increasing from \$2.1B to \$4.6B (120%)
- Inhaled corticosteroid/long-acting beta-agonist (ICS/LABA) combination inhalers represented 53% of that spending and increased 607%
- Almost 7% of the \$168B spent by Medicare Part D in 2018 went toward inhalers for asthma or COPD

Sources: Sistani et al. 2021, Feldman et al. 2021

In the United States, cost barriers to obtaining medicine is associated with:



- Uncontrolled asthma in adults and children
- Experiencing at least one asthma-related hospitalization in patients 65 and older
- Higher likelihood of abandoning inhaler therapy in COPD patients



Sources: Zahran et al. 2015, Hsu et al. 2018, Patel et al. 2022

Investigating the impact of generic inhaler approval



- Wixela Inhub, a generic dry powder inhaler (DPI) referencing Advair Diskus, was approved in January 2019 through submission of an ANDA
- An authorized generic of Advair Diskus entered the market in February 2019
- FDA investigators published research investigating the medication cost savings and utilization of generic ICS/LABA products in the United States using IQVIA data
- The investigators hypothesized that introduction of the first approved generic would lead to cost savings compared to an authorized generic

Source: Wang et al. 2022

Authorized generics are distinct from approved generics



- Authorized generics are identical to a brand-name drug and are marketed under the same new drug application (NDA) but do not display a brand name
- Approved generics may have differences from the brand-name drug but are required to demonstrate bioequivalence through an ANDA

Authorized generic market impact



- A 2011 U.S. Federal Trade Commission (FTC) report found that authorized generics impact the marketplace in several ways:
 - Authorized generic competition during the 180-day exclusivity period of an approved generic led to modestly lower prices (4-8%)
 - Authorized generics have a substantial negative effect on the revenues of competing generic firms
 - Brand companies may be using the threat of authorized generics to prompt generic companies to delay their products, leading to limited market competition and higher prices for consumers

Source: U.S. FTC 2011

Key generic products included in FDA's investigation

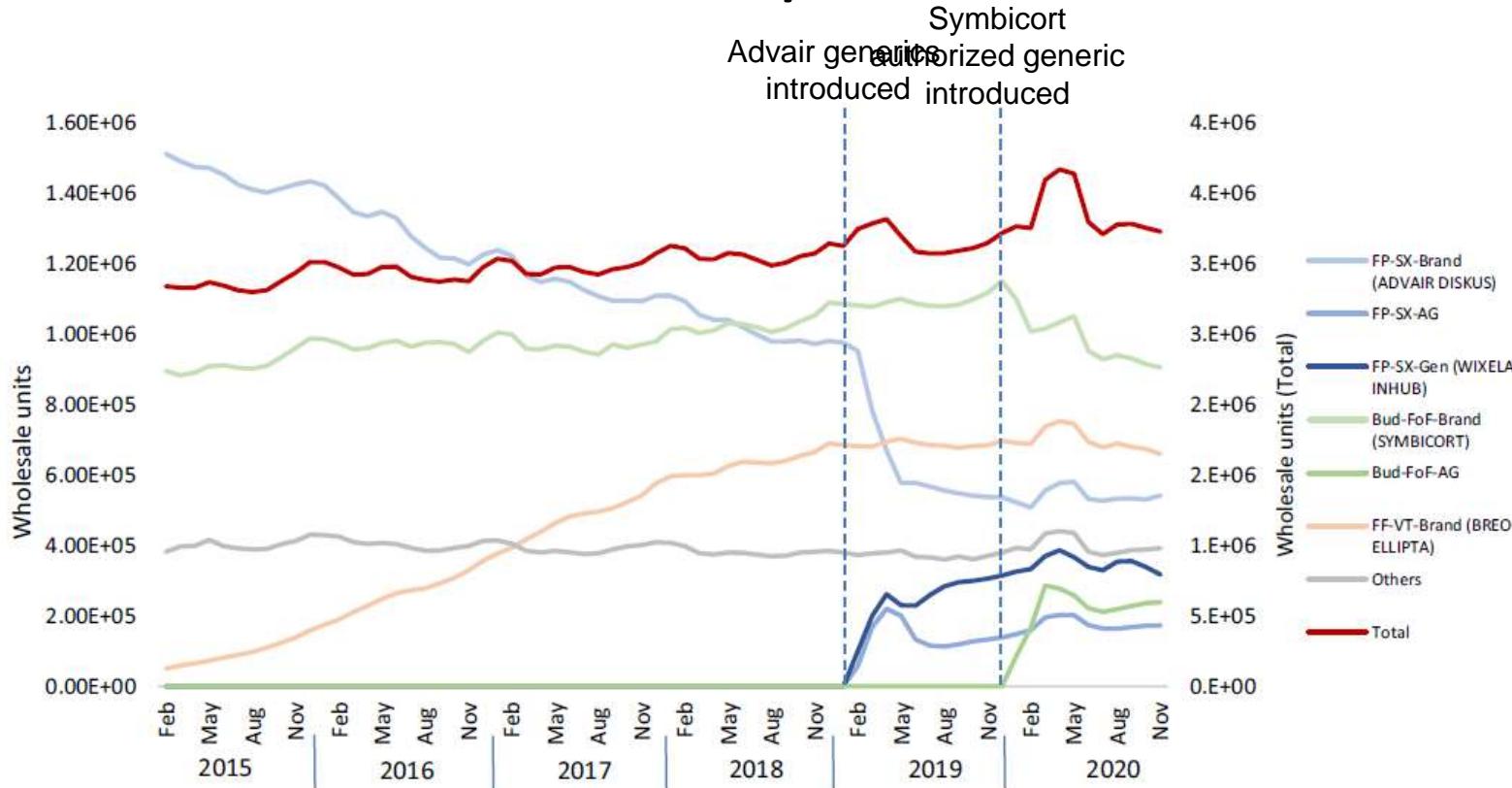


Active ingredient(s)	Dosage form; route	Application number	Category	Company	Approval date or date entered market	Brand name product (application number)
Budesonide; Formoterol Fumarate Dihydrate	Aerosol, Metered; Inhalation	021929	Authorized Generic	Prasco	January 1, 2020	Symbicort (021929)
Fluticasone Propionate; Salmeterol Xinafoate	Powder; Inhalation	208891 ^a	Generic	Mylan Pharmaceuticals Inc	January 30, 2019	Advair Diskus (021077)
Fluticasone Propionate; Salmeterol Xinafoate	Powder; Inhalation	021077	Authorized Generic	GlaxoSmithKline Intellectual Prop. Ltd. England	February 2019	Advair Diskus (021077)

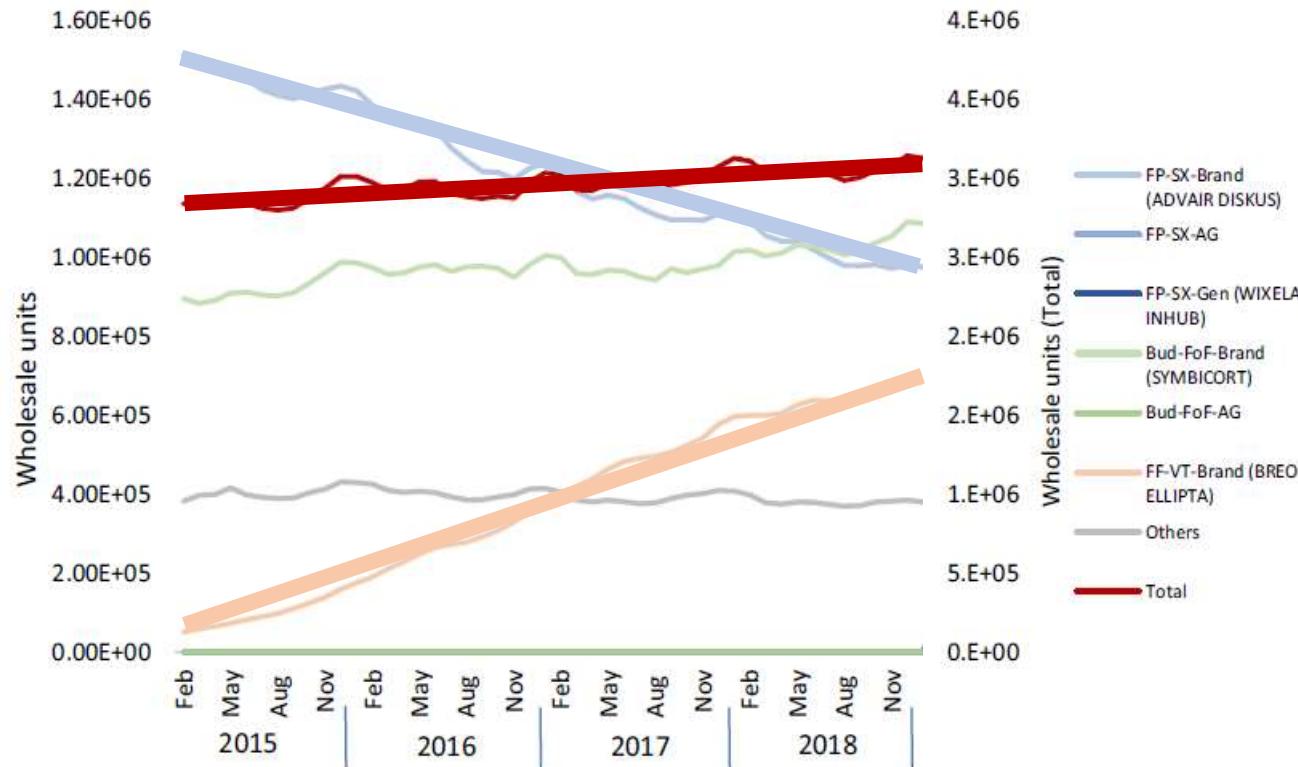
- First approved generic referencing Advair Diskus was introduced in January 2019 following ANDA approval
- Authorized generic of Advair Diskus introduced February 2019
- Authorized generic of Symbicort introduced January 2020

Table modified from: Wang et al. 2022

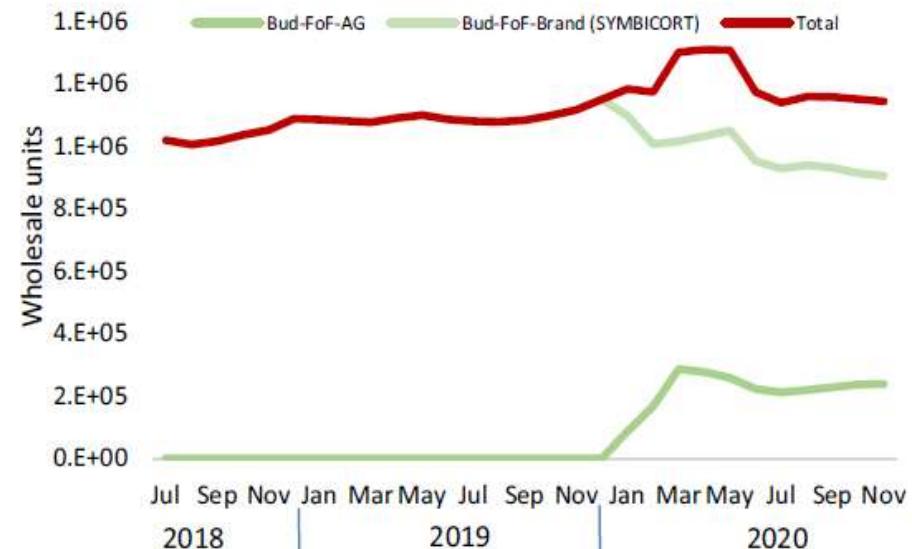
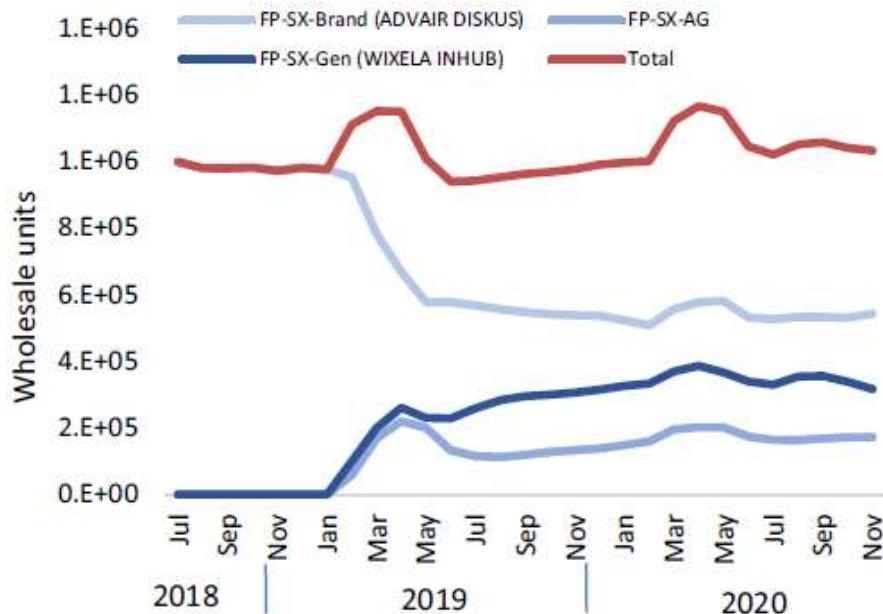
Wholesale units of ICS/LABAs 2015-2020



Before generic approval: Wholesale units 2015-2018

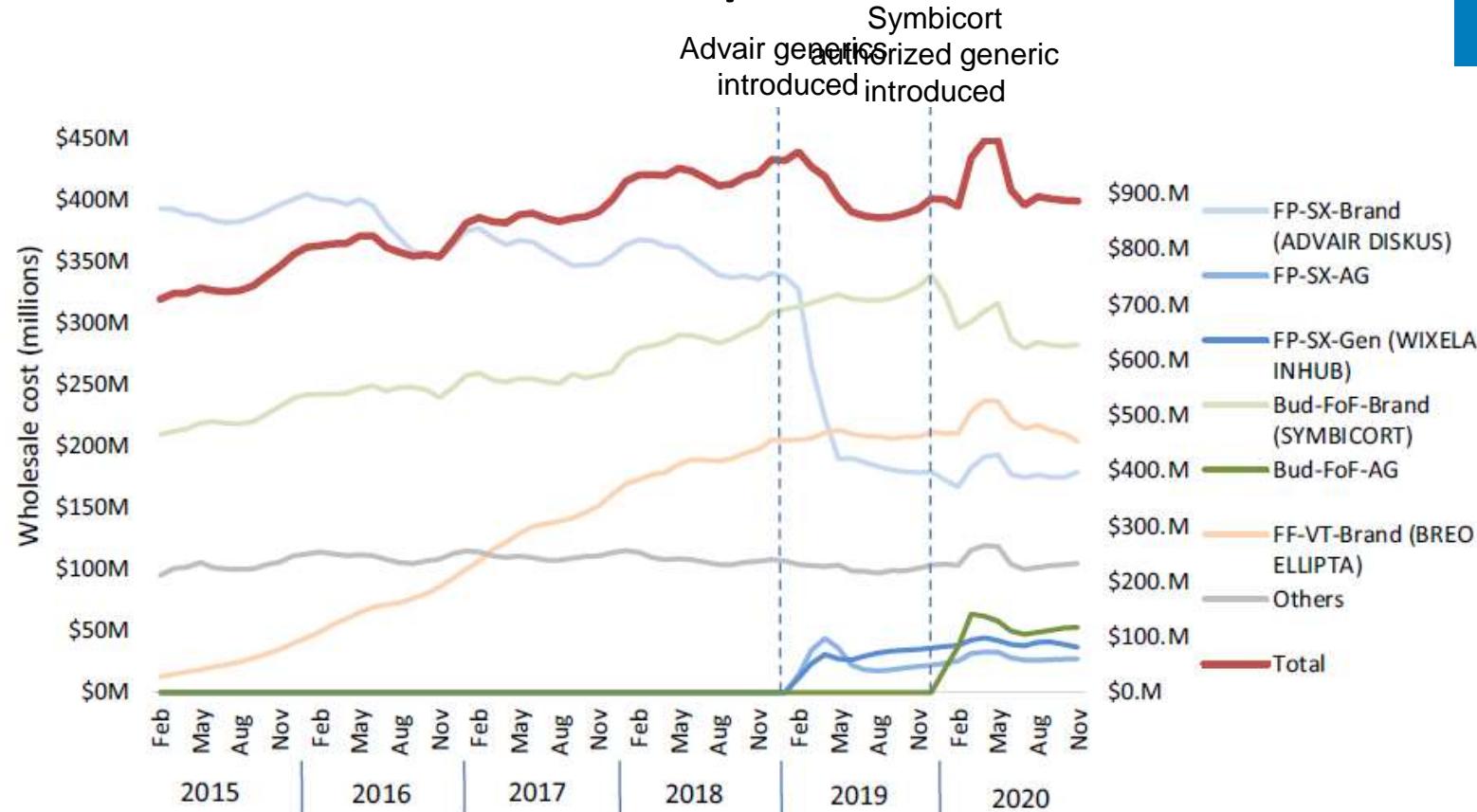


After generic approval: Wholesale units 2019-2020

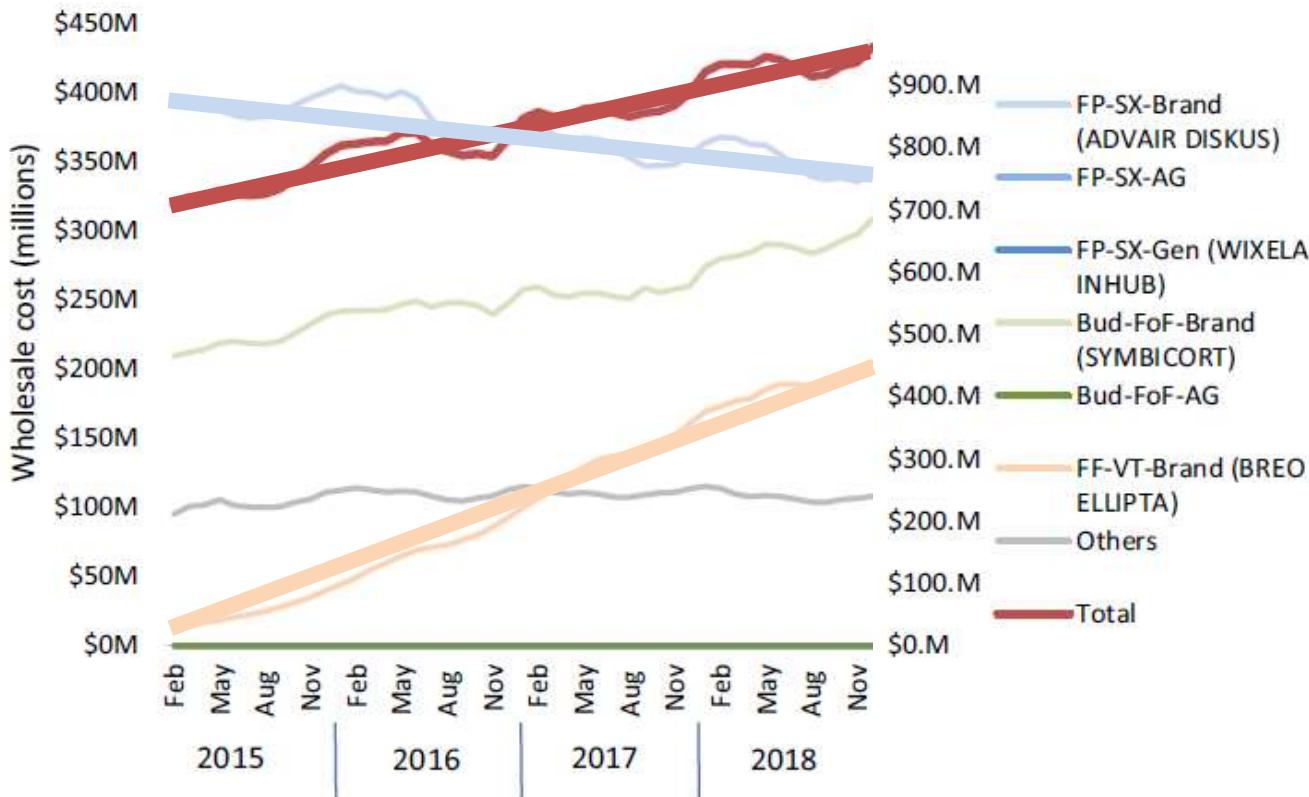


Modified from Wang et al. 2022

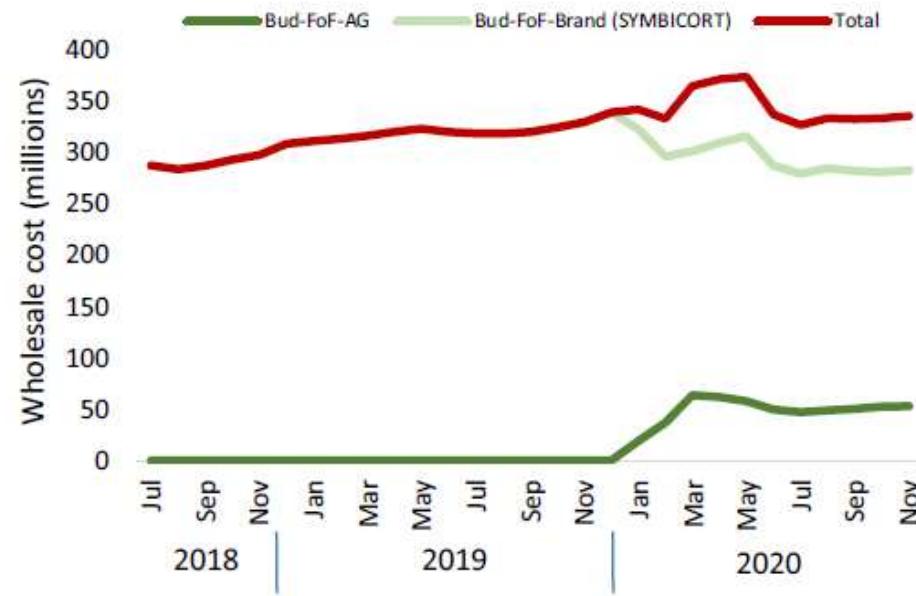
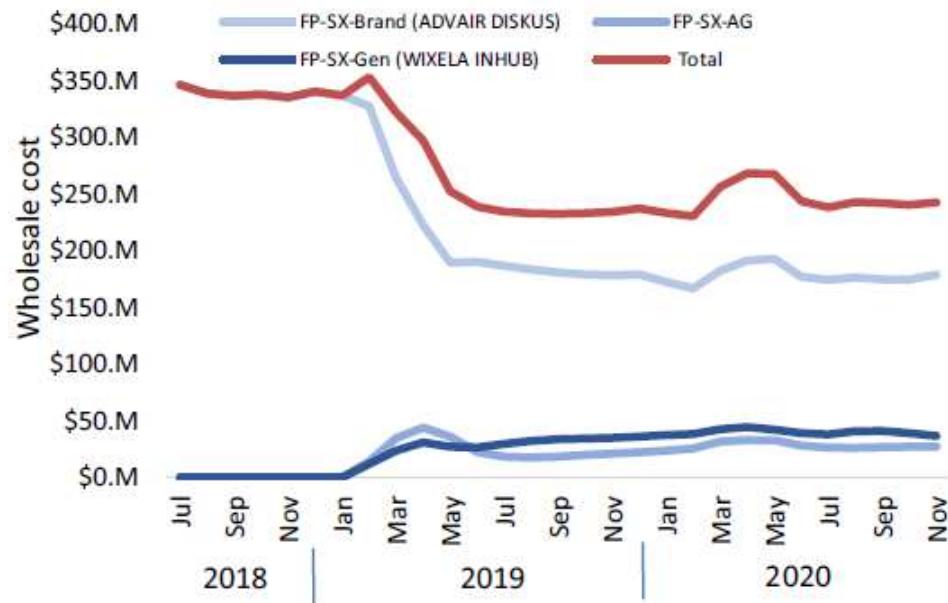
Wholesale cost of ICS/LABAs 2015-2020



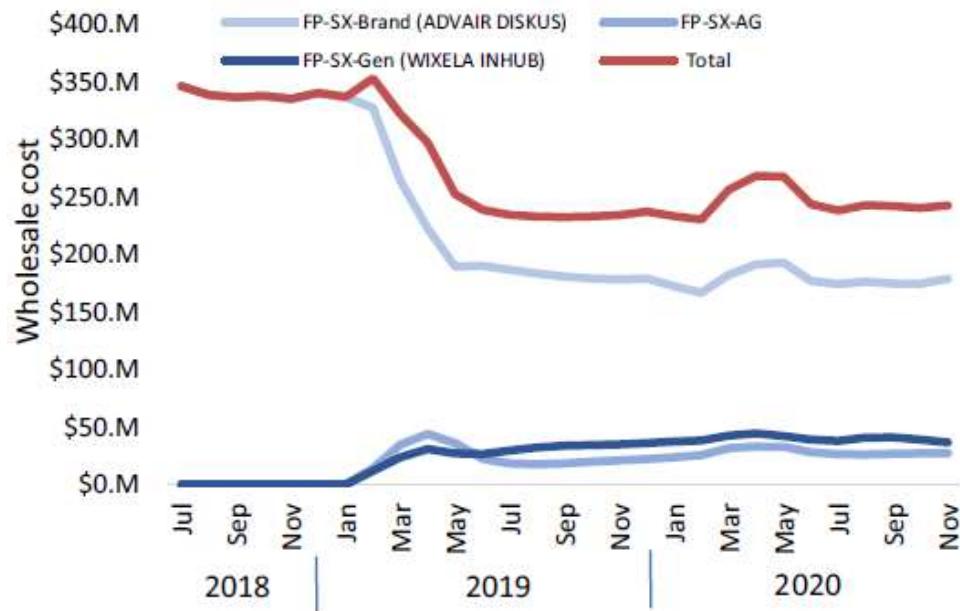
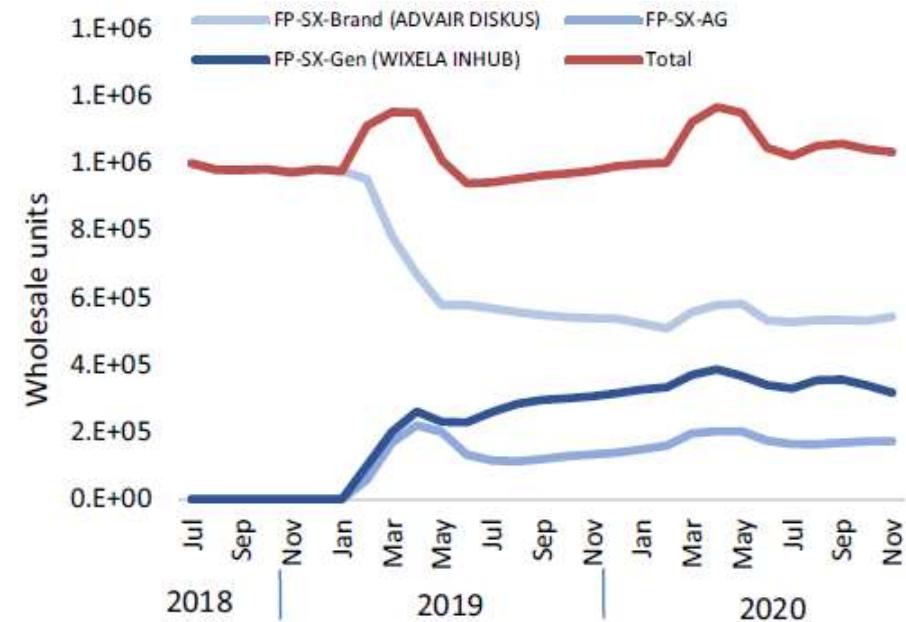
Before generic approval: Wholesale cost 2015-2018



After generic approval: Wholesale cost 2018-2020

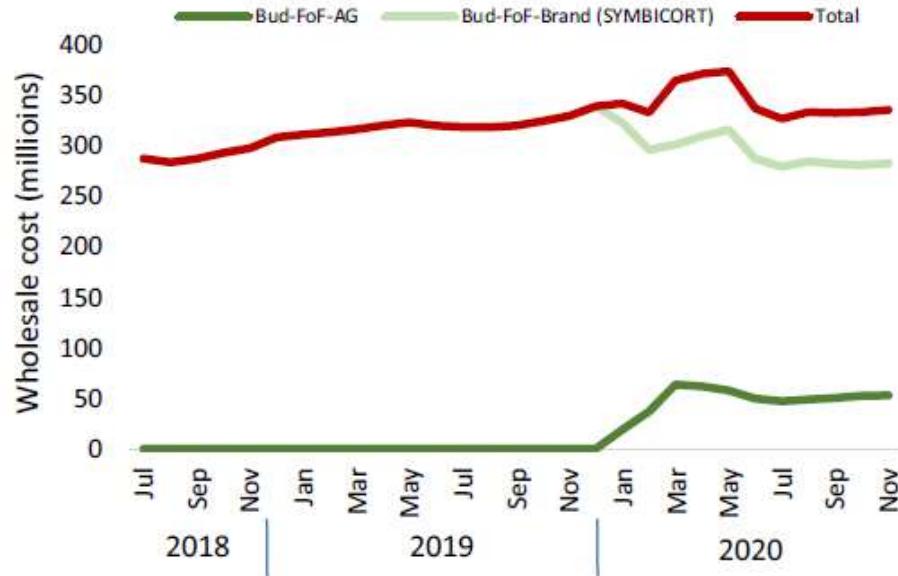
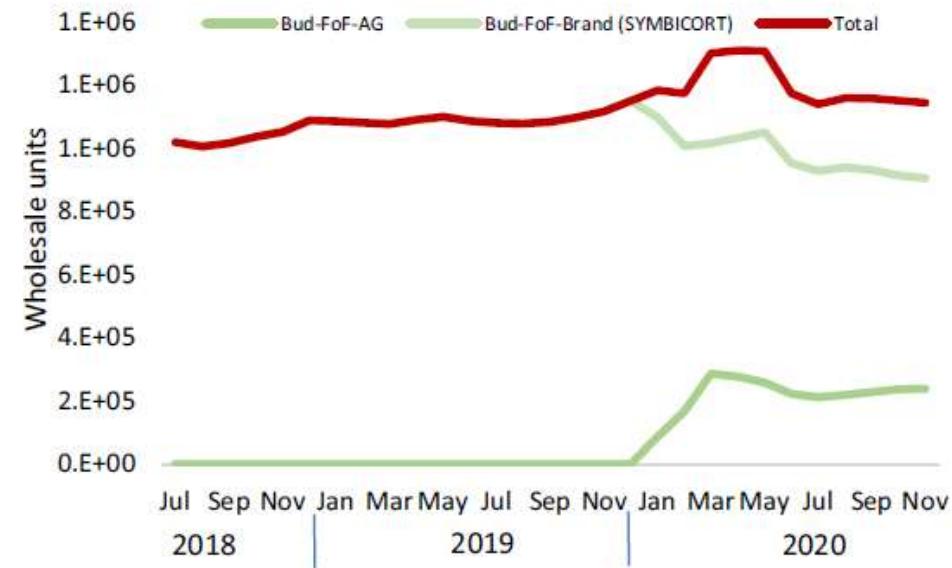


Impact of generic approval on cost



Modified from: Wang et al. 2022

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Impact of generic approval on cost



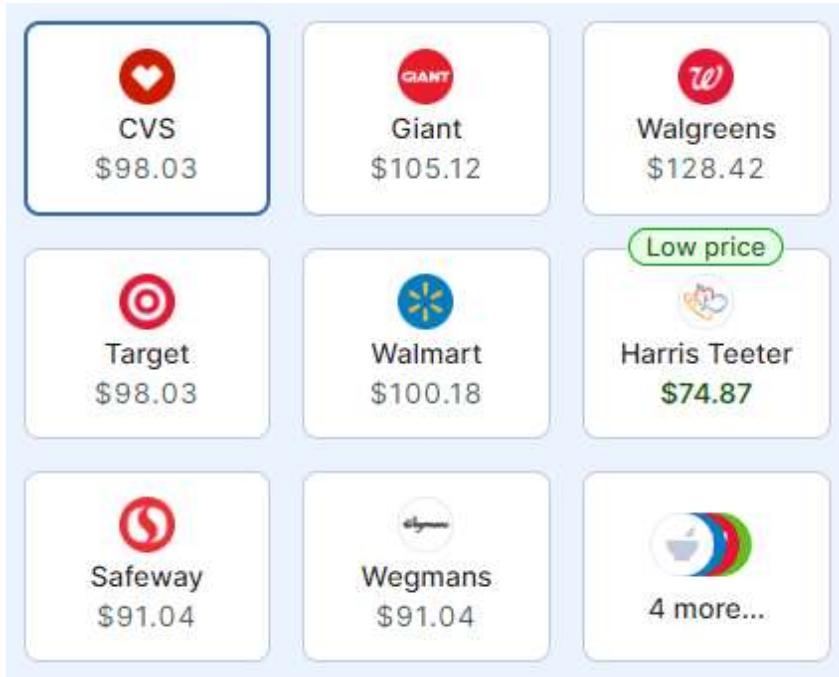
- Total cost for Advair and its generics decreased from \$337M in January 2019 to \$233M in January 2020 despite stable wholesale units
- Averaged unit cost for the approved generic of Advair was \$115 compared to \$169 for the authorized generic and \$334 for the brand name

Source: Wang et al. 2022

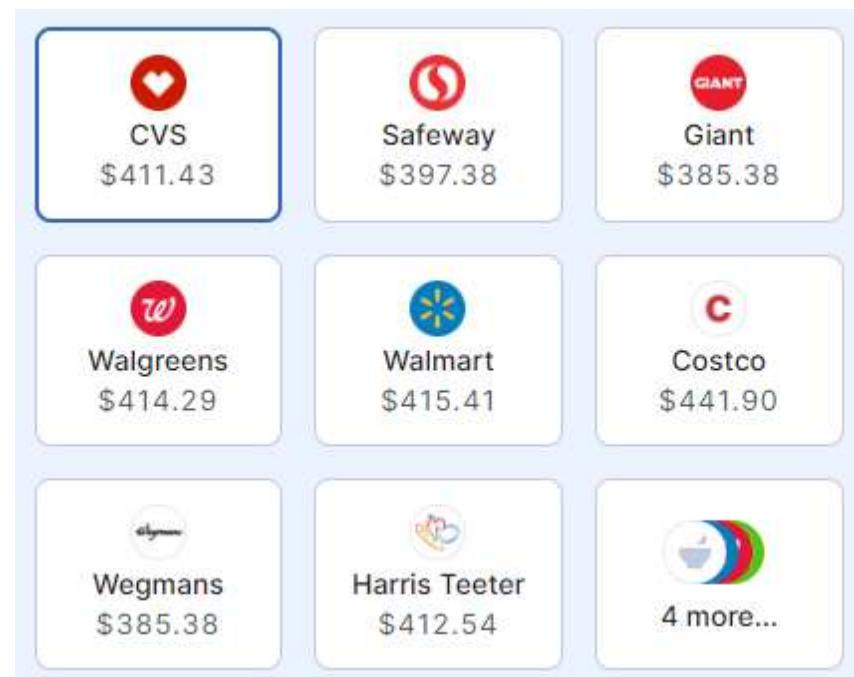
Recent real-world prices



FP/SX approved generic 250mcg/50mcg



Advair Diskus 250mcg/50mcg



Summary



- Inhalers are a substantial cost to the U.S. healthcare system, and high inhaler costs are associated with worse patient outcomes
- An FDA investigation found reduced costs with the ANDA approval of a generic referencing Advair
- Comparatively, introduction of an authorized generic for Symbicort had limited impact on costs

Challenge Question #1

According to a CDC study, U.S. asthma patients 65 years of age and older who had at least one asthma-related hospitalization in the past year were more likely to report:

- A. Pets in the bedroom
- B. Cost barriers to obtaining medication
- C. Secondhand smoke exposure
- D. Obesity

Challenge Question #2

According to an FDA investigation, introduction of an approved generic ICS/LABA through the ANDA pathway resulted in significant cost savings, whereas introduction of a/an _____ did not:

- A. Nebulized formulation
- B. Companion app to monitor inhaler adherence
- C. Authorized generic
- D. Leukotriene receptor antagonist

References

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Questions? Submit for the Q&A Session

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We Are OGD

Ask me why...

"I make sure that the **generic** drug and the **brand** drug work **the same**."

"The first time I was able to buy my son's inhaler as a generic and realized that my out of pocket dropped, I cried and was able to breathe a sigh of relief."

