



For products that underwent new generic competition in 2022, the average annual estimated savings per product was \$424 million, assuming an average mix of brand and generic utilization.

BACKGROUND & OBJECTIVE

- Savings from generic entry are often overlooked in U.S. policy discussions.
- Analyses often ignore the loss of exclusivity dynamics and comprehensive lifecycle benefits medicines generate both during and after patent protection.
- Limited research examines savings from specific cohorts following transition from brand exclusivity to generic competition.

Objective

To estimate and quantifies the impact of generic entry on annual spending for a cohort of products that were exposed to first-time generic competition in 2022.

METHODS

Study Design: Pre- and post- generic launch brand/generic price comparison.

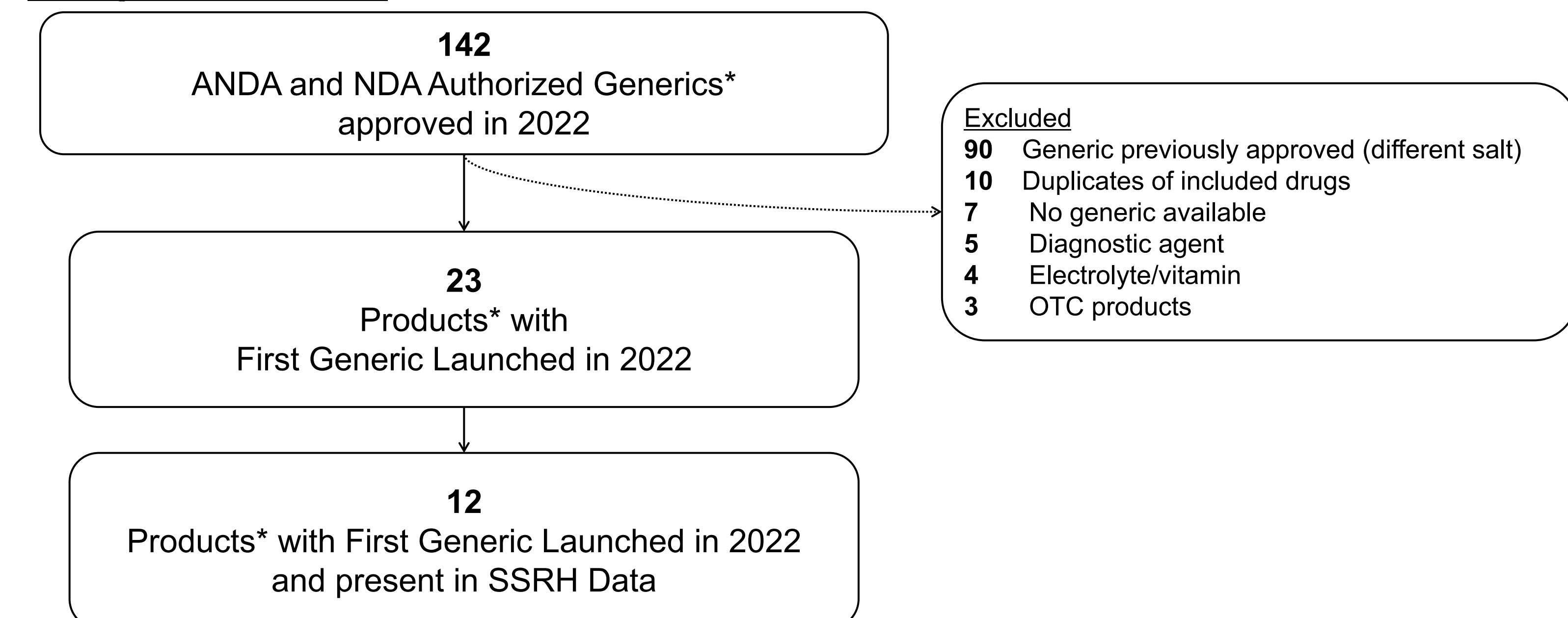
Measures and Analysis:

- Eligible products had an abbreviated new drug application (ANDA) or new drug application (NDA) authorized generic applications with a 'marketing start date' in 2022.
- Brand drug net spending in the year prior to generic entry was compared to the projected 2024 annual generic list spending.
- Different utilization mixes of generic and brand, and associated annual spending differences were reported, holding utilization constant at pre-generic entry levels.
- All costs inflated to 2024 U.S. dollars (via CPI-U).

Data Sources:

- National Drug Code (NDC) Directory and FDA's First Generic Drug Approvals List to identify newly launched generic drugs in 2022.
- Brand net spending was sourced from NAVLIN's Global Pricing and Market Access Database.
- Generic spending was sourced from SSR Health Part D Formulary Tool.

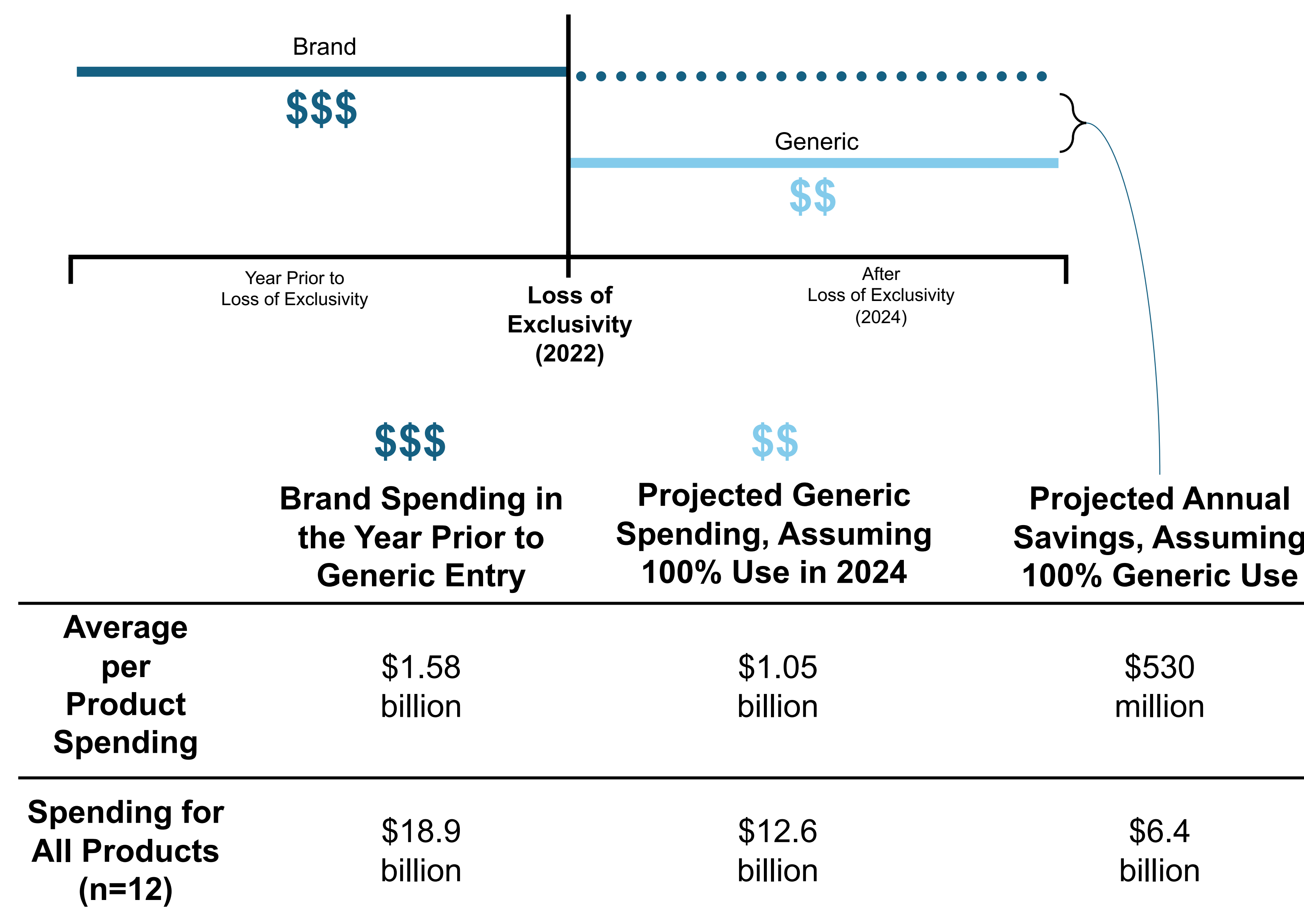
Sample Selection:



*unique active ingredient, dosage form, and route of administration

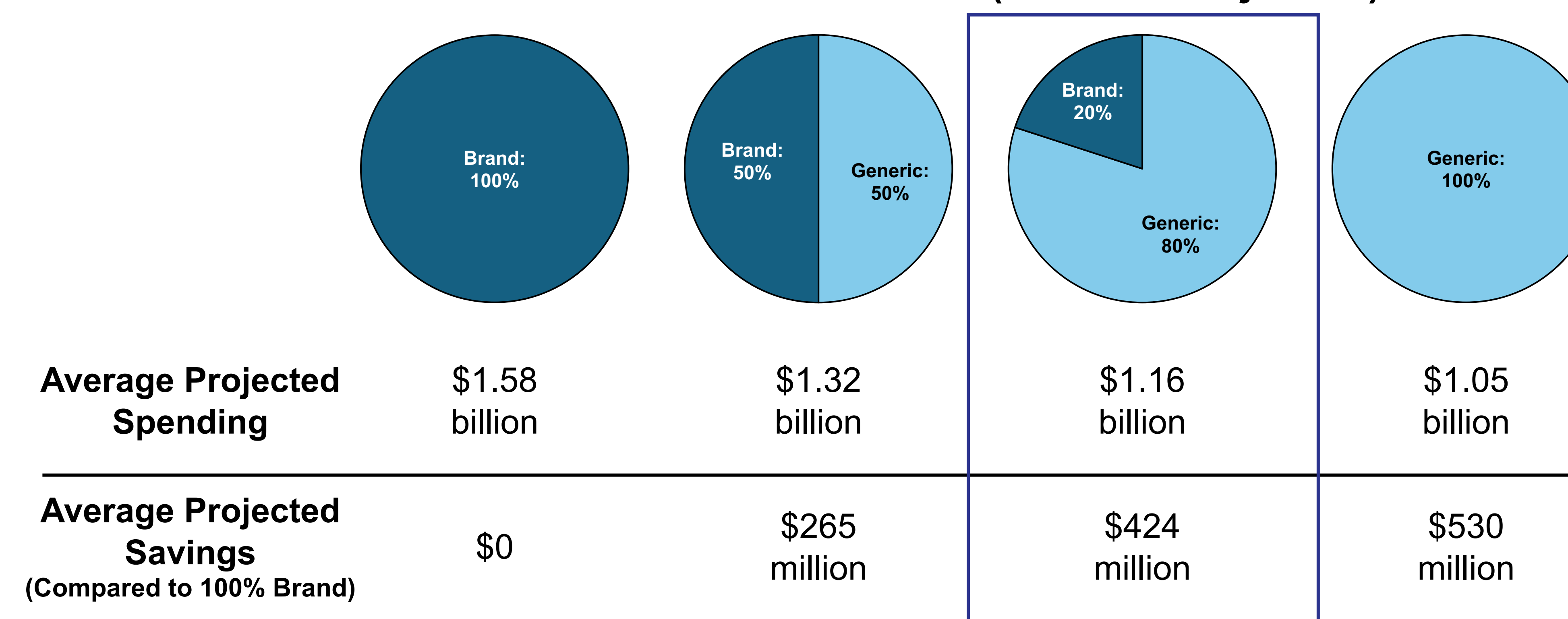
RESULTS

Figure 1:
Annual Projected Brand and Generic Spending and Savings



Dotted line: brand price shown as inflation-adjusted (2024 USD) annual average for the year prior to LOE, due to SSRH reporting limitations.

Figure 2:
Annual Projected Average Cost Savings per Product Associated With Various Brand-Generic Utilization Patterns (Inflation-Adjusted)



Sample Characteristics:

- 12 products (100%) were small-molecule drugs.
- 4 products (33%) had orphan status.
- Routes of administration included oral (5 products, 42%), injection (3, 25%), ophthalmic/transdermal (3, 25%), and respiratory (1, 8%).

Projected Annual Spending (Figure 1)

- Assuming 100% generic utilization, the inflation-adjusted projected average per-product savings was \$530 million per year.
- Across all 12 products, approximately \$6.4 billion in total estimated annual savings.

Varying Brand-Generic Utilization (Figure 2)

- Increasing generic utilization led to increased projected savings.
- At 80% generic / 20% brand (average market adoption), projected annual savings averaged \$424 million per product.

DISCUSSION AND CONCLUSIONS

- We tracked individual product contributions during the transition from brand exclusivity to generic competition of a defined 2022 generic entry cohort.
- Our projected average annual per-product savings aligns with existing market benchmarks while providing cohort-specific context.
 - The Association for Accessible Medicine's 2024 report found that, on average, each product generates ~\$354 million in annual generic savings.
 - Differences in estimated savings may reflect varying measurement timing post generic entry, product characteristics, and utilization.
- Our estimated average annual per-product savings may be conservative as price erosion typically intensifies with additional generic entrants over time.

Limitations

- Utilization was held constant at pre-generic entry levels.
- Absence of estimated net sales data limited inclusion of products.
- The lack of generic rebate data may overestimate generic spending, thus underestimating generic cost savings.

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