

Case Study: Demand Study for Pipeline Agent in Major Depressive Disorder (MDD)



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Outcome of Our Study: Product X's Post-Project History



1. The target of the project, **Product X**, was a new mechanism of action that was a unique antidepressant because it had a dual mechanism of action.
2. Product X's eventual performance could be considered “mixed”, at best.

Outcome of Product X Assessment

Our client was assessing **Product X** as part of a potential acquisition of a company where **Product X** was the primary agent in the target company's pipeline.

Product X and the company were eventually acquired, for over \$1 billion.

Product X was launched soon after.

Due to increasing competition, **Product X** was capturing only \$80+ million five years after launch.

Due to our “conditional” recommendation, our client **did not** pursue the acquisition of the company nor **Product X**.

Product X only attained a peak of \$160+ million in annual revenues three years after launch.

Product X was generic ten years after launching and cumulatively did not recoup the initial \$1 billion investment.

MDD Demand Study Project Approach



- Project was a Demand Study for a pipeline agent (**Product X**) in Phase 3 clinical trials to treat major depressive disorder (MDD).
- Our client wanted to assess whether **Product X** was a potential acquisition candidate.
- Overall engagement included:



Qualitative Phase

- 4 PSYCH KOLs
- 6 non-KOLs: 3 PSYCHs, 3 PCPs
- 60-minute web-based telephone interviews
- Standard MDD treatment screening criteria
- Respondents viewed a product profile, which was shown to them by the moderator, who controlled exposure during the interviews
- MDD agent was blinded as “Product X”



Quantitative Phase

- 49 PSYCHs, 70 PCPs
- 15-minute web survey
- Standard MDD treatment screening criteria
- Respondents viewed a product profile for the MDD agent that was blinded as “Product X”



Forecast Phase

- Integration of quant phase share estimates with MDD TRx market data
- Includes adjustment for MDD as 60% of all antidepressant prescribing
- Apply rate of change from quant phase to existing TRx share
- Adjustment for promotional impact/effectiveness = 1.0

Summary of Our Conclusions & Recommendations



We rated the Product X Opportunity “conditional”, at best.

Qualitative Phase

- Optimistic results, as Product X’s perceived efficacy and lower rates of sexual and weight gain side effects were considered attractive.
- The MOA was seen to have a potential “halo” effect on comorbidities of MDD such as anxiety.

Quantitative Phase Reaction

- Quantitative phase painted a neutral picture of the opportunity:
 - Likelihood to prescribe of 5.9 points on a scale of 10.
 - One quarter of respondents indicated no Product X prescribing.
 - Patient share was 8% for newly diagnosed patients and slightly more than 7% for existing patients.

Quantitative Phase Access

- Quantitative phase valued the challenges that a new branded therapy would have in an increasingly generic MDD market:
 - Tier 3 copay levels were estimated to cut expected Product X prescribing significantly.
 - Any type of prior authorization or step therapy would further erode prescribing estimates.

Quantitative Phase Recommendation

- Based on the results of the quantitative phase and the resulting forecast, our recommendation was for the client to be cautious in proceeding and to seek more advantageous terms.

Sample Analyses from Quantitative Phase

Impact of Product X on Future MDD Market – Newly Diagnosed

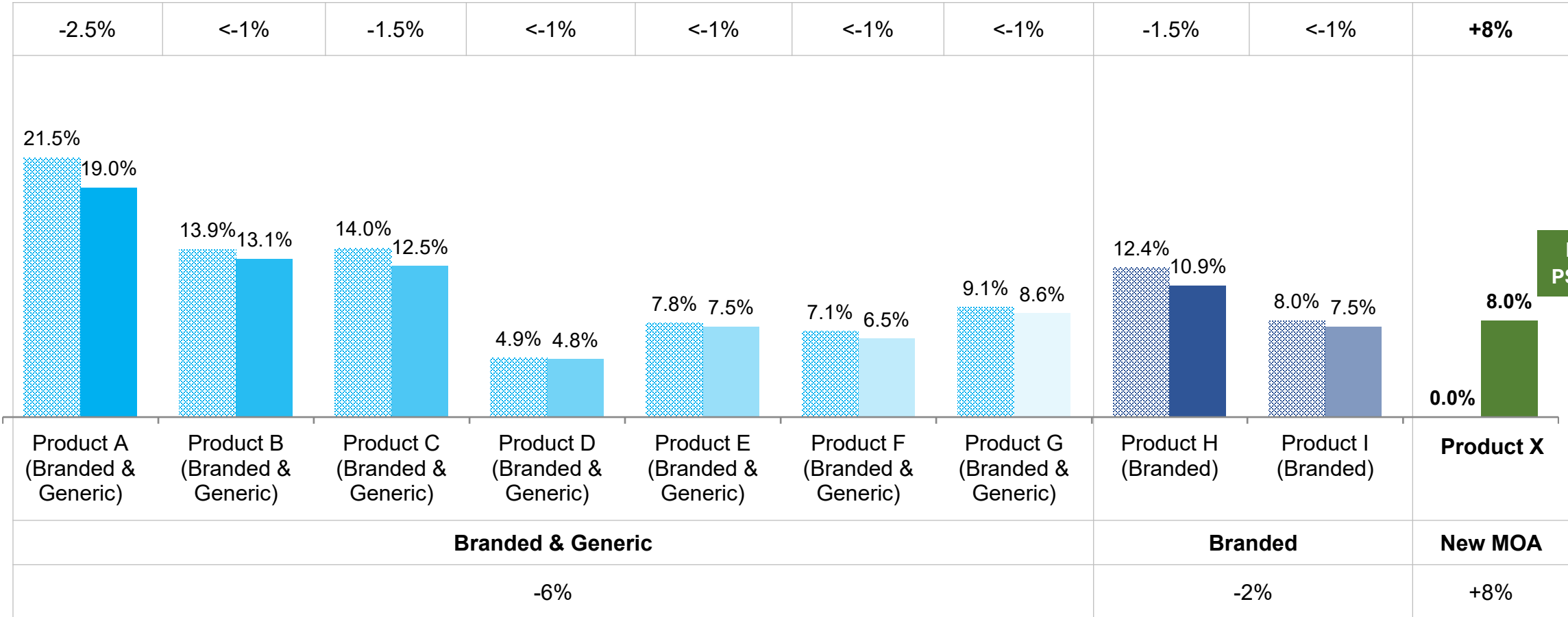


- Given the current generic domination of the newly diagnosed MDD market, Product X is expected to primarily capture share (8%) from branded/generic medications versus those agents that are just branded.

Future MDD Prescribing Newly Diagnosed – Post Product X Launch

PCPs/PSYCHs (n=119)

Current Future with **Product X**



Impact of Product X on Future MDD Market – Existing

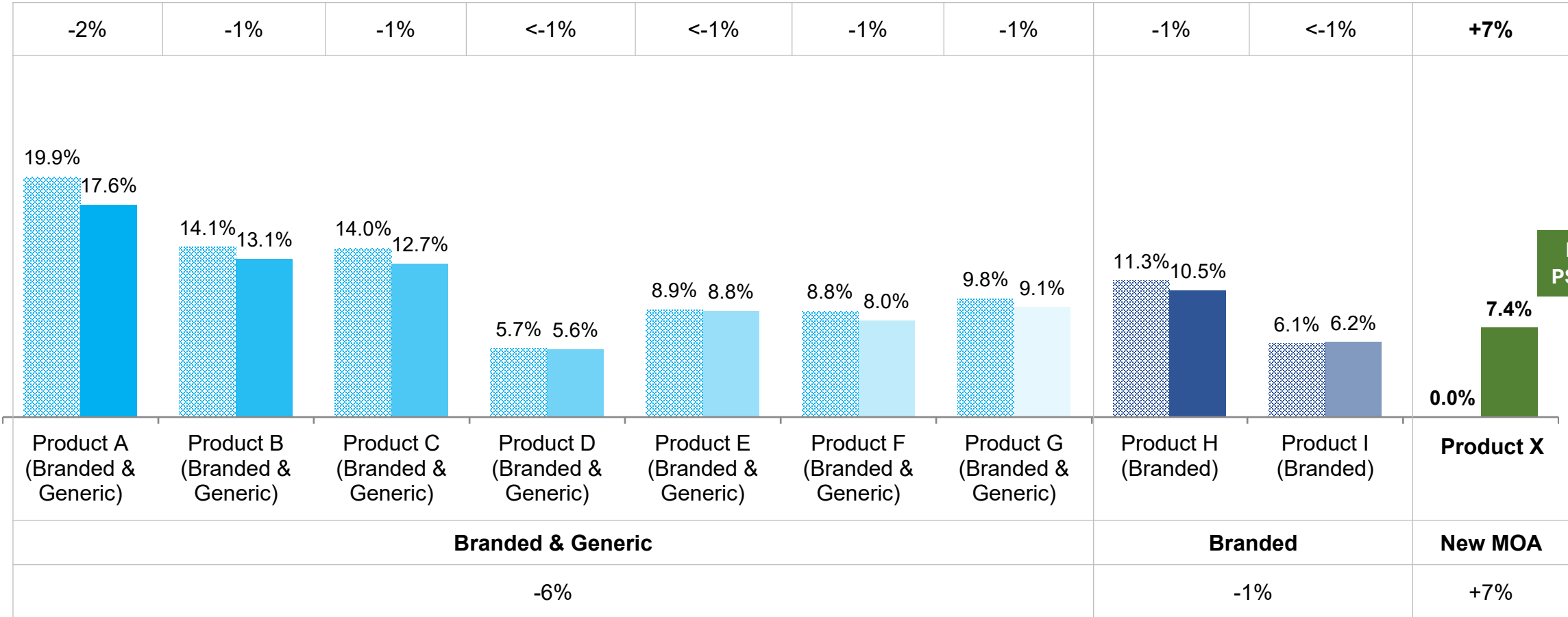


- Similar to the newly diagnosed MDD patient market, the current domination of the existing MDD market by generics lead to a Product X forecast of 7.4% primarily from branded/generic medications versus those that are just branded.

Future MDD Prescribing Existing – Post Product X Launch

PCPs/PSYCHs (n=119)

Current Future with **Product X**



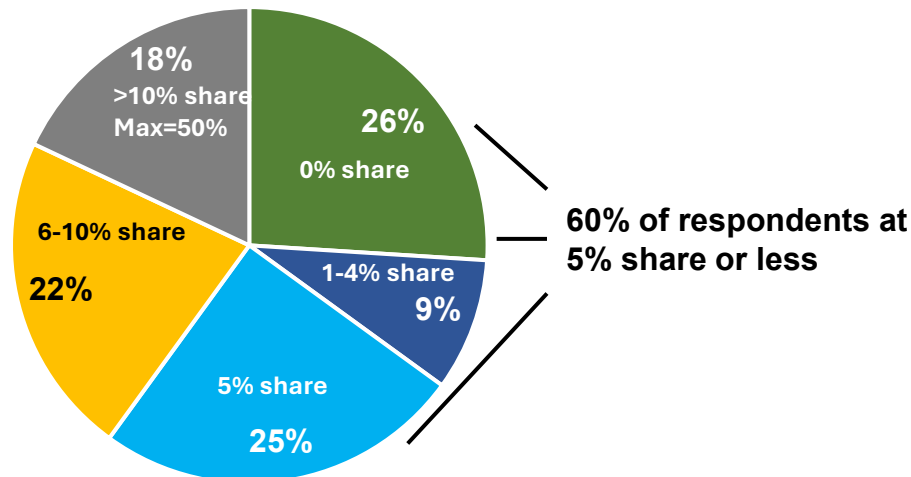
PCPs 7.4%
PSYCHs 7.5%

Expected Levels of Product X MDD Prescribing – Newly Diagnosed & Existing

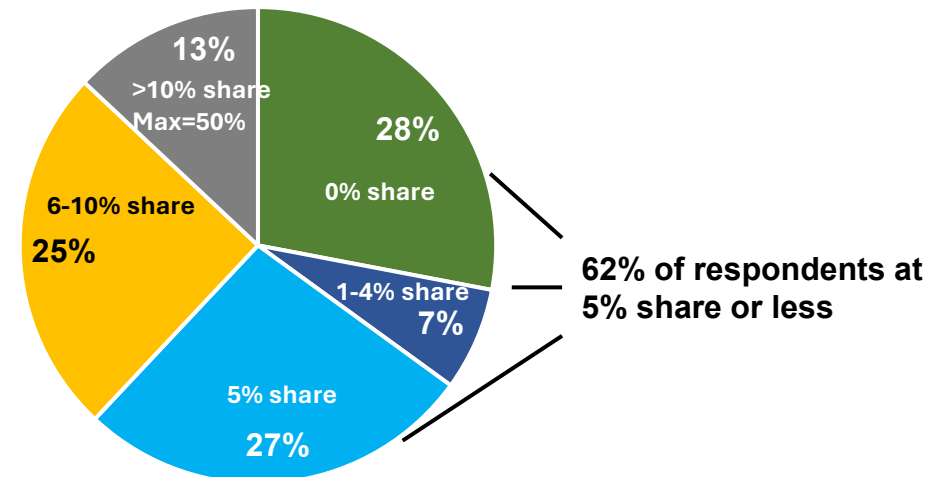
- A key reason for the “conditional” recommendation for **Product X** was the lack of broad-based physician interest in the product:
 - At least one quarter of respondents would not prescribe **Product X** for either newly diagnosed or existing MDD patients.
 - Another quarter of respondents would prescribe **Product X** to 5% or less of their newly diagnosed or existing MDD patients.

Summary of Range of Product X Use – Total Sample (n=119)

% of Respondents at Each Product X Newly Diagnosed Share Level



% of Respondents at Each Product X Existing Share Level



Comparison of Heavy Product X Prescribers to Light/Non-Product X Prescribers

Heavy Product X prescribers also currently prescribe fewer generics for MDD (more brands) and are asked about medications much more often than respondents unlikely to prescribe **Product X**.



Key Differences Between Product X Heavy and Light/Non-Prescribers

	Heavy Product X >5% Share (n=36)	Light Product X 0-4% Share (n=31)	Implication
Avg. patient share for generics combined	38%	 51%	Product X Light/Non-Prescribers are already heavily invested in prescribing generics, so they are less interested in new therapies.
# of times/month asked by a patient about a medication after DTC ad	 Avg. 12.3	Avg. 3.3	Product X Heavy Prescribers get many more questions about therapies, so they are more interested in the potential for Product X.
Level of impact from sole indication	 Avg. 7.3 out of 10	Avg. 5.1 out of 10	Product X Heavy Prescribers are already looking for new options for their patients, so new agent with just one indication is less likely to be an issue for them.
Familiarity with MOA	 Avg. 6.5 out of 10	Avg. 5.2 out of 10	Because they are already trying to address the higher level of MDD patient questions, Product X Heavy Prescribers are more likely to be familiar with the Product X MOA.
Positivity about serotonergic advantage	 Avg. 7.6 out of 10	Avg. 6.0 out of 10	Because they are already trying to address the higher level of MDD patient questions, Product X Heavy Prescribers are more likely to be about Product X's serotonergic advantage.

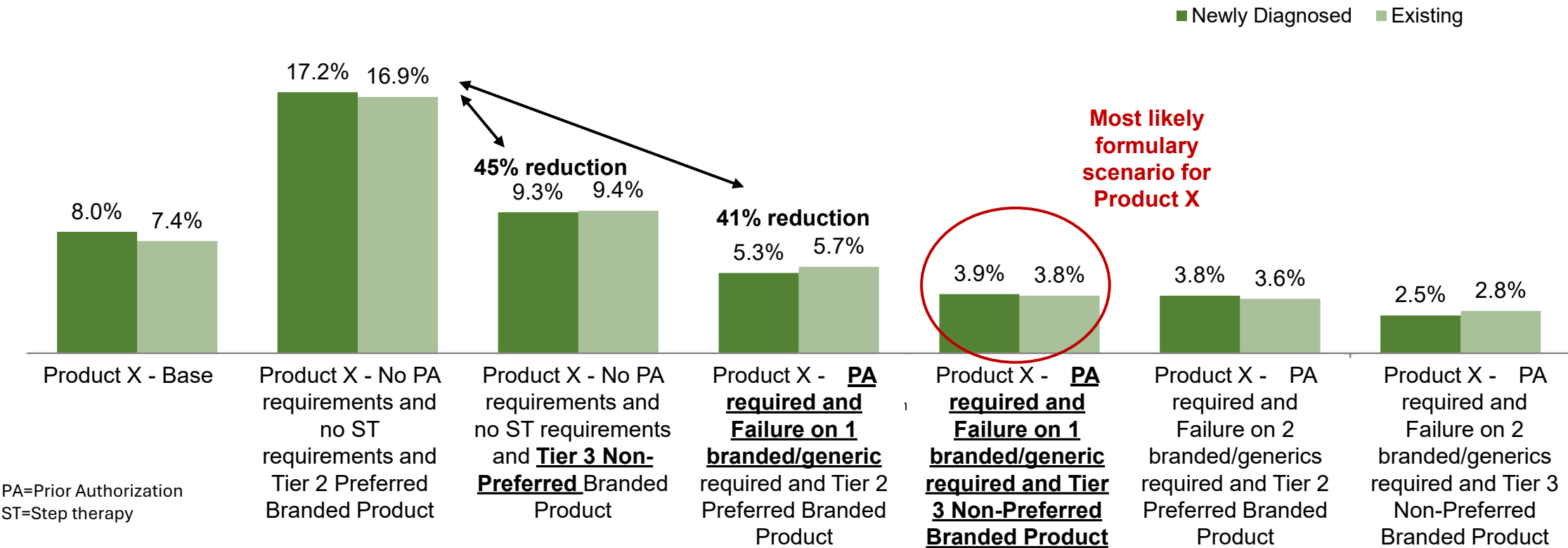
Impact of PA, ST and Tier Status on Potential Product X Prescribing

Formulary tier, prior authorization and step therapy requirements all have significant negative impacts on **Product X** prescribing.

- An increase in patient cost from Tier 2 to Tier 3 would reduce potential **Product X** prescribing by almost half.
- Likewise, requiring prior authorization or one branded/generic failure would reduce potential prescribing by around 40%.
- **Product X** was likely to have both challenges, at least initially upon approval; this would lead to less than a 4% share in newly diagnosed and existing patients

Future MDD Prescribing Existing – Post Product X Launch – Across PA, Step Therapy & Formulary Tier Levels

PCPs/PSYCHs (n=119)

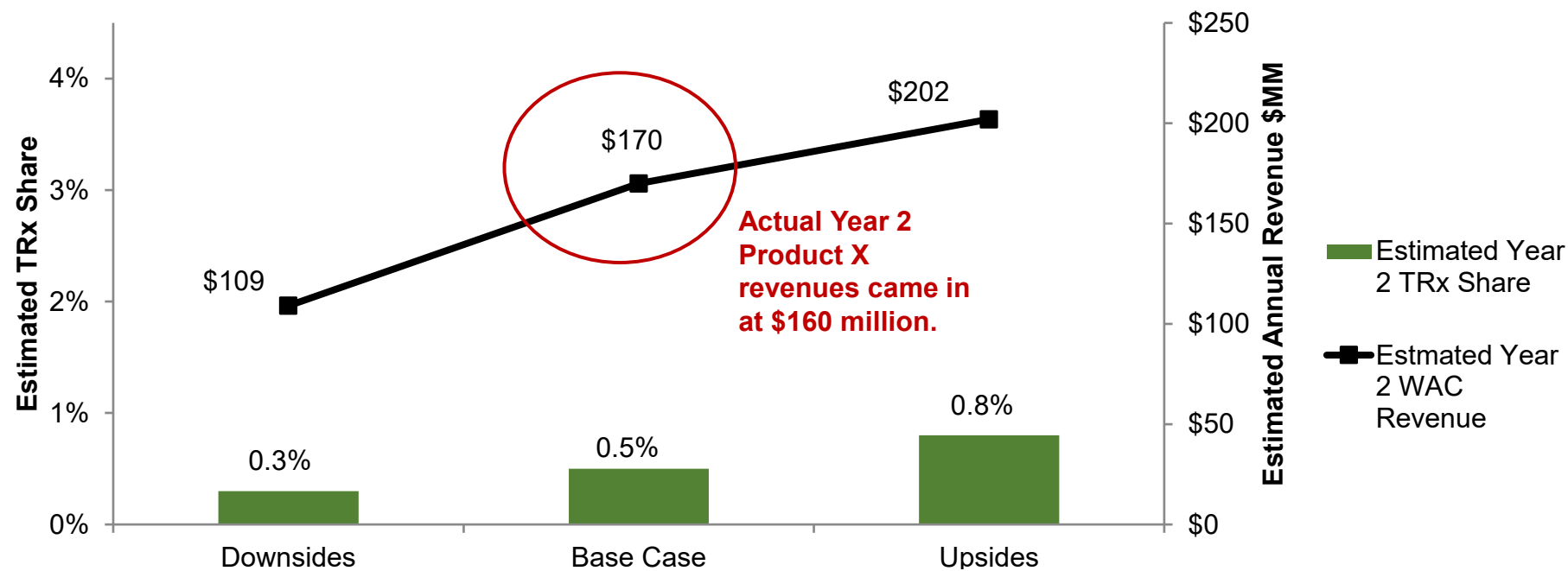


Product Year 2 MDD Forecast (Revenue and Patient Share)



- Base Case estimates half a share point in the MDD market and **\$170MM** in Year 2 WAC revenue.
- Year 2 revenue actually came in at **\$160MM**.

Summary of Product X Year 2 MDD Revenue and Shares by Across Cases



Product X Share Adjusted for:	Downsides	Base Case	Upsides
Standard Adjustments to Share	Yes	Yes	Yes
Payer Probability Adjustment	Full	Partial	Partial
Ability to Capture Share from Product A Generic	No	Yes	Yes
\$ WAC/Tablet	\$5.00	\$4.33	\$3.33



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