

## Background

While pharmaceutical innovation can be rewarded with high revenue generating blockbuster drugs, patent expiration can lead to generic competition that reduces the revenue of these drugs by as much as 90%.<sup>1</sup> Hence, patent expiration is an event that pharmaceutical companies must plan for in advance, using strategies designed to mitigate the impending revenue loss. A variety of mitigation strategies exist that companies use for life cycle management including authorized generics, reformulation, pricing incentives, prescription to over-the-counter (OTC) switch, and pediatric exclusivity. These strategies impact the amount of revenue loss, however, no descriptive research has been conducted to evaluate the extent of this impact. A successful mitigation strategy can prevent the loss of millions of dollars in revenue for a blockbuster drug.<sup>2</sup>

## Objectives

The purpose of this study was to determine the most common patent cliff mitigation strategies that were utilized when blockbuster drugs lost patent protection in the past decade, and the relationship between each mitigation strategy and revenue.

## Methods

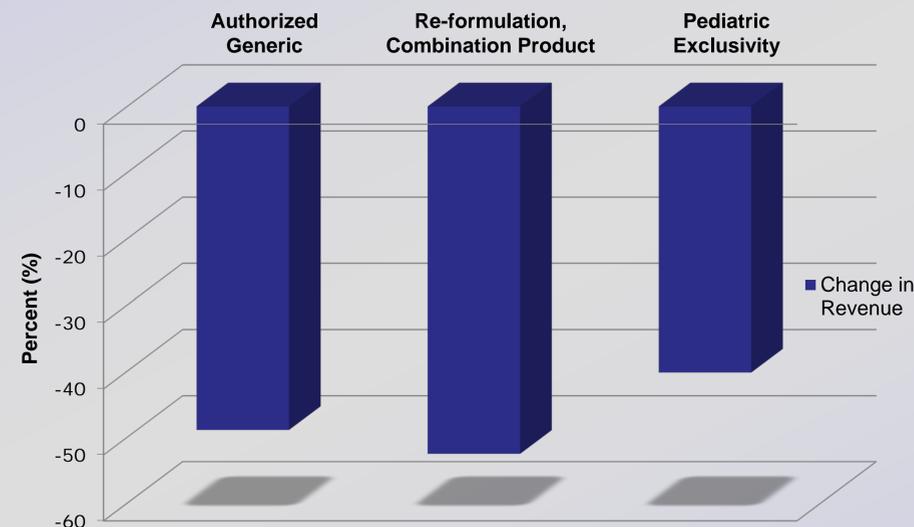
Blockbusters were defined as prescription drugs that generated revenue greater than or equal to one billion dollars in the United States (U.S.). Drugs that were blockbuster for at least one year between 2001 and 2010 were included in the analysis. Exclusion criteria included blockbuster drugs withdrawn from the market during this time period, biologics, and drugs with unclear mitigation strategies. Patent expiration dates, U.S. revenues, and global revenues were identified utilizing each company's U.S. Securities and Exchange Commission (SEC) Form 10-K, annual reports and financial reports. Publicly available mitigation strategies were searched through press releases, company websites and external websites for each drug. For drugs that used reformulation as a mitigation strategy, the revenue of the reformulated product was added onto the revenue of the original product. If the patent expired in the first half of the year, the percent change in revenue from the year before through the end of the patent expiration year was calculated for each drug. If the patent expired in the second half of the year, the percent change in revenue from the patent expiration year through the end of the year after patent expiration was calculated. Percent change in revenue for each drug was stratified by mitigation strategies. The average change in revenue for each strategy was then calculated.

## Results

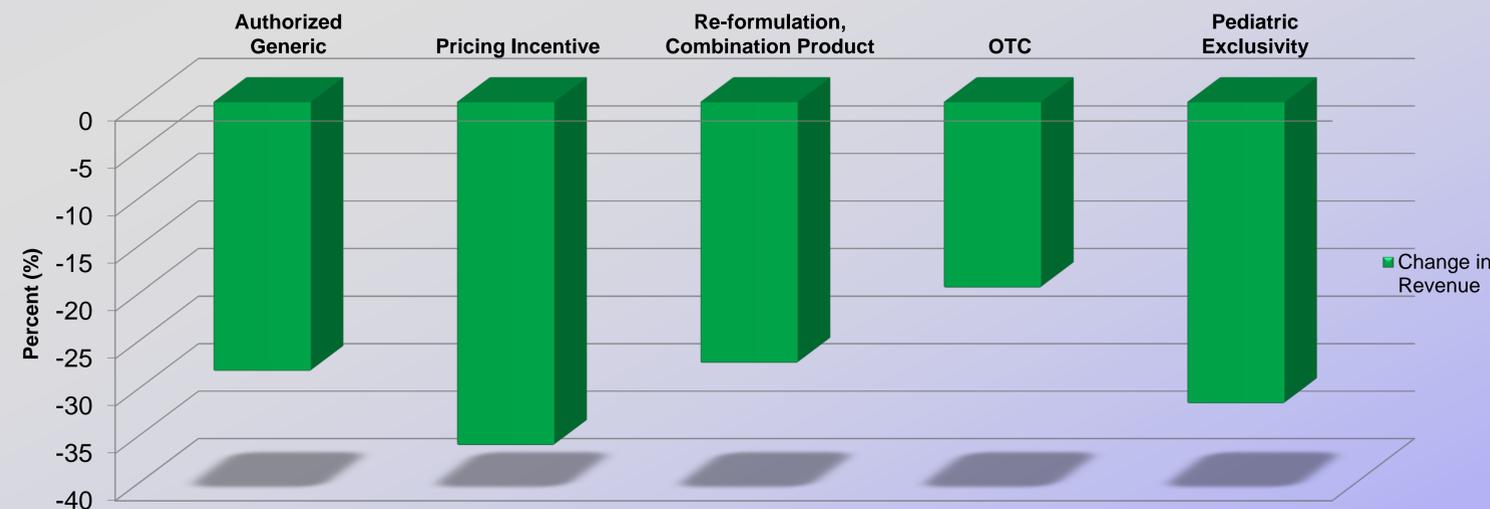
### Mitigation Strategies Utilized

Mitigation Strategy	Times Strategy Used (n = 15)
Authorized Generic	12 (80%)
Pricing Incentive (e.g. Copay Card)	3 (20%)
Re-formulation, Combination Product	7 (47%)
OTC	1 (7%)
Pediatric Exclusivity	13 (87%)

### Impact of Mitigation Strategies on Annual Revenue (U.S.)



### Impact of Mitigation Strategies on Annual Revenue (Global)



## Discussion

A decrease in revenue loss was predicted in both the U.S. and Global analysis since loss of patent protection in the U.S., the largest market, impacts worldwide revenues. Mitigation strategies utilized most commonly were authorized generics (80%) and pediatric exclusivity (87%). These two strategies are only designed to reduce short-term revenue loss (6 months). Incentives and pricing was used for 20% of products, however additional incentives (such as incentives to payers) may not have been accounted for. The data shows that OTC switch is the most effective mitigation strategy, however the sample size was limited.

Each strategy appeared to be similarly effective at mitigating revenue loss from patent expiration (average decrease in revenue of 29%) versus the potential decrease in revenue resulting from generic competition.

## Limitations

- Variability of publicly available data resulted in a smaller than anticipated sample size.
- Some drugs were excluded from the analysis because generic manufacturers engaged in at-risk launch of generics, potentially affecting mitigation strategies implemented by the innovator companies.
- Only mitigation strategies implemented at the time of patent expiration were included in the analysis.

## Conclusions

- The most common mitigation strategies utilized were pediatric exclusivity and authorized generics though these two strategies only addressed short-term revenue loss.
- Based on this analysis, similar results were seen with all mitigation strategies in terms of the impact on revenue loss.

## Disclosure

All authors are affiliated with the Rutgers Institute for Pharmaceutical Industry Fellowship Program and are paid employees of Rutgers, the State University of New Jersey.

## References

1. Slovick S. Strategies for Drugs Going Off Patent. PriceSpective, Value Strategy Consultants - Gerson Lehrman Group. April 2011. <http://pricespective.com/wp/wp-content/uploads/2012/01/Strategies-for-Drugs-Going-Off-Patent.pdf>. Accessed 8/13/2013.
2. Tuttle E, et al. Beyond Lifecycle Management – Optimizing Performance Following Patent Expiry. Economic, Financial and Strategy Consultants - Analysis Group, INC. July 2004. [http://www.analysisgroup.com/uploadedFiles/Publishing/Articles/Patent\\_Expiry.pdf](http://www.analysisgroup.com/uploadedFiles/Publishing/Articles/Patent_Expiry.pdf). Accessed 8/15/2013.
3. FDA Listing of Authorized Generics as of July 22, 2013. FDA Website. Updated July 22, 2013. <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM183605.pdf>. Accessed 10/31/2013.
4. Pediatric Exclusivity Granted. FDA Website. Updated October 2013. <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM223058.pdf>. Accessed 10/31/2013.