Quantifying Annual Medical Economic Burden of Patents and Regulatory Exclusivities on ICS/LABA Inhalers Among End-Stage COPD Patients

Farideh Sistani, Fadia T. Shaya, Magaly Rodriguez de Bittner, Zafar Zafari

Department of Practice, Sciences, and Health Outcomes Research, University of Maryland Baltimore

Introduction

- COPD imposes a substantial societal health and economic burden in the United States (US).[1]
- Patent protection and limited generic availability, can lead to inhalers' high out-of-pocket (OOP) costs, lower adherence and more frequent exacerbations.[2,3]

Objectives

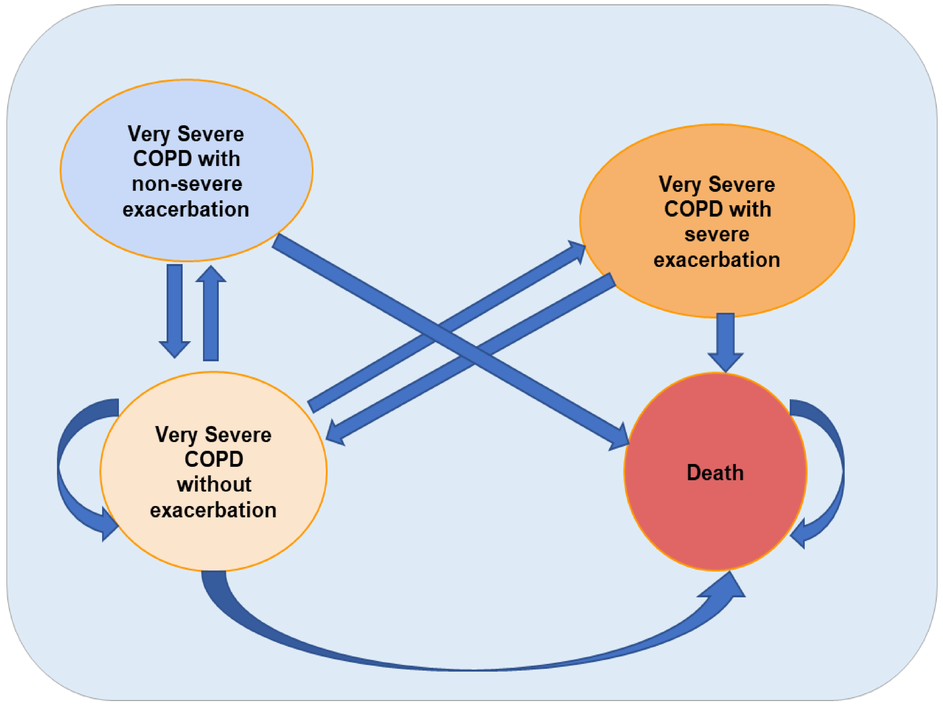
- To model one-year economic burden of market exclusivity for inhaled corticosteroids (ICS) combined with long-acting beta2 agonists (LABA) among end-stage COPD patients.

Methods

- A Markov model was developed to assess the increase in the level of adherence and its impacts on exacerbations associated with lower OOP costs of generic equivalents in the absence of long patent protection.
- Levels of adherence based on the proportion of days covered (PDC)included: adherent (PDC ≥0.8); mildly nonadherent (0.5 ≤ PDC <0.8); moderately nonadherent (0.3 ≤ PDC <0.5); and highly nonadherent (PDC <0.3).
- Mortality rates were assumed to be irrespective to the level of adherence.
- All input parameters were obtained from published literature.
- Model Cycle length: one week
- Model included four health states **(Figure 1)**
- All analyses were done using TreeAge Pro software

Methods

Figure 1: The illustration of the Markov model of very severe COPD



Results

- Annual medical cost attributable to the branded ICS/LABA inhalers was estimated to be $14K per patient with very severe COPD
- Medical cost attributable to the branded ICS/LABA inhalers was 1.7 times greater than the estimated cost attributed to a generic ICS/LABA inhaler.
- A $6K savings in annual costs for a patient with very severe COPD after lifting the patent exclusivities of branded inhaler and availability of generic equivalents

Conclusion

- This study projects the substantial annual burden of patent protection for an ICS/LABA inhaler on the US healthcare system.
- Future studies are needed to examine the impact of market exclusivities for other classes of inhalers across all severity stages of COPD patients.

References

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Contact

Farideh Sistani, PharmD
Ellen H. Yankellow Health Outcomes Postdoctoral Fellow
Email: Fsistani@rx.umaryland.edu