INSTITUTE #HEALTH POLICY FORUM

### ADDRESSING HIGH DRUG PRICING





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### **The Physician Perspective**



# Elisa Choi, MD, FACP Governor-Elect, Massachusetts Chapter American College of Physicians





### **American College of Physicians**

- https://www.acponline.org/
- The American College of Physicians (ACP) is a diverse community of internal medicine specialists and subspecialists united by a commitment to excellence. Internists apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. With 152,000 members in countries across the globe, ACP is the largest medical-specialty society in the world. ACP and its physician members lead the profession in education, standard-setting, and the sharing of knowledge to advance the science and practice of internal medicine.

### **American College of Physicians**

- Mission: To enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine.
- Vision: To be the recognized leader in quality patient care, <u>advocacy</u>, education and enhancing career satisfaction for internal medicine and its subspecialties.





#### **Annals of Internal Medicine**

- POSITION PAPERS | 5 JULY 2016
- Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians
- Hilary Daniel, BS; for the Health and Public Policy Committee of the American College of Physicians
- Ann Intern Med. 2016;165(1):50-52.





### S. 974 / H.R. 2212 - Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act

- Main Sponsor(s): Sen. Leahy (VT)
- Summary: Promotes drug competition by addressing abuses of the risk mitigation and evaluation (REMS) process that keep generic manufacturers from obtaining the samples necessary to establish bioequivalence required by the FDA for approval. The bill allows for generic manufacturers to sue brand manufacturers to compel the brand to provide it with the drug samples. The bill takes a narrow approach and allows this action on a case-by-case basis.
- Action: There is considerable bipartisan support for the bill from a variety of groups and the bill has attracted a lot of attention in light of continued interest in drug pricing and the FDA's emphasis on increasing access to generics, however, there has been little legislative movement.





### S. 1131 / H.R. 2439 - Fair Accountability and Innovative Research (FAIR) Pricing Act

- Main Sponsor(s): Sens. Baldwin (WI) and McCain (AZ)
- Summary: This bill requires drug manufacturers to disclose and provide more information about planned drug price increases, including research and development costs. The bill requires manufacturers to notify HHS and submit a transparency and justification report 30 days before they increase the price of certain drugs that cost more than \$100 by 10% in one year or 25% over three years. Justification reports will require justification for the price increase, manufacturing and research and development costs for the drugs, net profits attributable to the drug, and marketing/advertising spending.
- Action: None.





#### S. 41 / H.R. 242 - Medicare Part D Negotiation Act

- Main Sponsor(s): Sen. Klobuchar (MN) and 8 other Sens.
- Summary: Authorizes the Centers for Medicare and Medicaid Services to negotiate directly with pharmaceutical manufacturers regarding prices for drugs covered under the Medicare prescription drug benefit.
- Action: None. ACP has longstanding policy supporting Medicare Part D negotiation; however, with the current makeup of Congress, it is unlikely this bill will garner any traction.

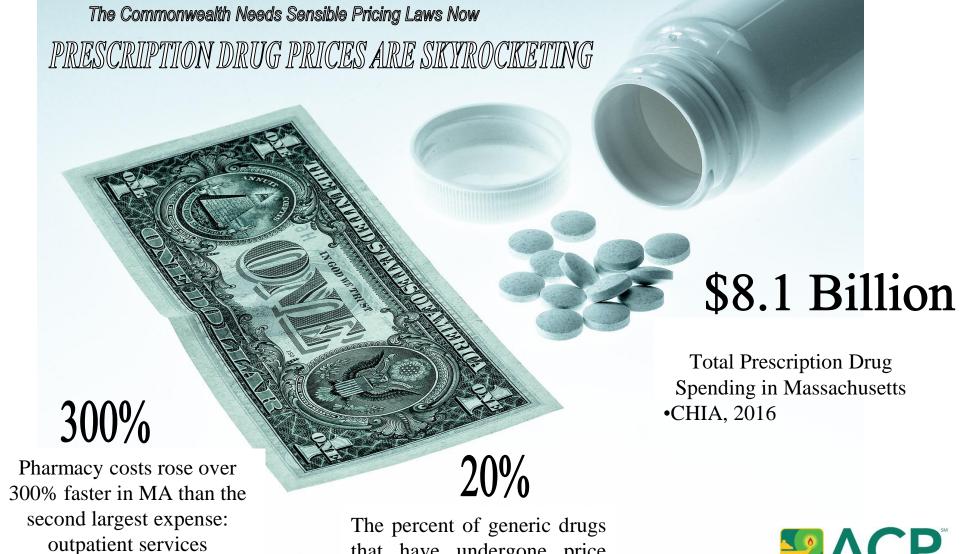
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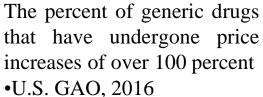
### S. 2157 - The Drug-price Transparency in Communications Act

- Main Sponsor(s): Sen. Durbin (IL) and 5 other Sens.
- House Companion: None.
- Summary: Requires the disclosure of the wholesale acquisition cost (WAC) of prescription drug in direct-to-consumer advertising materials such as television ads, as well as communications provided to health care practitioners. The bill also directs the FDA to issue guidance on the amount of time a manufacturer has to update disclosures after price increases as well as the manner in which such disclosures should be made.
- Action: None.













•HPC, 2017

## MA S.652 - An Act to promote transparency and prevent price gouging of pharmaceutical drug prices (Senator Mark Montigny)

- Requires manufacturers, PBMs and insurers to report prescription drug pricing information to CHIA for the costliest prescription drugs.
- HPC will identify critical prescription drugs whose cost are excessively higher than justified and jeopardize the Commonwealth's ability to meet heath care cost growth benchmarks.
- Cost excessively higher than justified:
- Notice provided to manufacturers, Attorney General, Secretary of Health and Human Services, and registered providers and payers in the Commonwealth.
- Attorney General may bring Chapter 93A (Regulation of Business Practices for Consumers Protection) action.

#### **Acknowledgments and Thanks**

- Hilary Daniel
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### **Acknowledgments and Thanks**

- Audra Riding
- Deputy Counsel
- Office of MA Senator Mark Montigny
- MA State House, Room 312-C





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