Tackling the Rise of Prescription Medications Prices
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Opportunity

Abstract
Objective: To advocate for policies that control the price of medications by evaluating policy proposals.
Methods: A literature search was conducted to collect policy proposals that address medication price increases.
Results: Analysis of the literature reveals an absence of policies in the United States that impose price controls measures on pharmaceuticals. Some feel that pharmaceutical manufacturers take advantage of the lack of price controls. We have analyzed current proposals and advocate that the FDA develop criteria to address this issue. This will require pharmaceutical manufacturers to justify significant price increases for existing medications.
Conclusion: The high cost of medications is not a new problem. However, it has gained attention in the media lately due to the enormous price hikes of medications such as Mylan’s EpiPens. Although many ideas have been proposed to this end an issue that applies to both newly available medications as well as medications that have already been on the market. Eliminating manufacturer coupons, allowing government funded insurance to have more price-negotiating power with manufacturers, and allowing medication imports from other countries are amongst the ideas that have been proposed to alleviate this problem. However, each has strengths and weaknesses. While it is clear that there is no easy or quick way to resolve the issue, potential solutions, are evaluated and we make recommendations on how to proceed to deal with this issue.

Background
- Pharmaceutical manufacturers may set and manipulate their prices in the US market
- There is no single, unified body that negotiates medication prices on behalf of private and public healthcare sectors.
- Some proposals for lowering medication prices include: medication reimportation, accelerated introduction of generics, manufacturer coupons, and strict formularies.
Stemming the increase in medication prices through the use of an application to the FDA with a strict criteria may provide an equitable solution to the government, manufacturers, and patients.

Solution
- Incorporation of an additional section into the New Drug Application, Therapeutic Biologics Applications, or Abbreviated New Drug Application that regulates prices based on:
  - Disclosure of Research and Development (R&D) Costs
  - Proof of effectiveness for a treatment of an indication that it was not originally approved for
  - Decreased availability of ingredients
  - Presence of me-too drugs
- Implementation:
  - Price shall not increase >150% at a time once every 5 years
- Purposes of the Application:
  - Allow pharmaceutical companies to justify the price they want to charge
  - Indicate what measures manufacturers used to come up with that price
  - Demonstrate transparency from pharmaceutical companies to justify price increases

Table 1. Components of Applications for Innovator Drugs (NDA) and Generic Drugs (ANDA)

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<tr>
<th>Component</th>
<th>NDA</th>
<th>ANDA</th>
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<tr>
<td>1. Labeling</td>
<td>1. Labeling</td>
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<td>2. Pharmacology/toxicity</td>
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<td>3. CMC</td>
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<td>4. Microbiology</td>
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<td>5. Inspection/testing</td>
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<td>6. Preclinical studies</td>
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<td>7. Clinical studies</td>
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Conclusions
- An FDA approval for price increases would
  - prevent sudden unexpected price increases that would limit patient access.
  - increase oversight in an unrestricted area of the pharmaceutical industry
  - Price increases would also justify the entry of generic manufacturers to enter the market for more competition.
- With the various proposals and anticipated changes to the healthcare system under Trump’s presidency, such as direct price negotiations by Medicare and repeal of the Affordable Care Act, this situation bears continued monitoring and analysis.
- It is in the interest of all parties for the FDA to provide more regulation over prescription drug prices in order to maintain an equitable market.

Approach

Methods
- A literature search was conducted to collect policy proposals that address medication price increases.
- Databases: PubMed and Google Scholar
- Information pertaining to medication price increases were extracted from Cochrane, American Pharmaceutical Association (APhA), general medicine journals, manufacturer websites, as well as government websites (i.e. FDA).
- Articles were reviewed on Google Scholar to ensure we have the most relevant and up to date discussion.

Impact

Value Proposition
- The unique feature about our innovation is it addresses a healthcare issue relevant to everybody.
- This addresses the problem of high prescription prices.

Limitations
- Putting a restriction cap stating that price shall not increase >150% at a time once every 5 years of the current AWP may allow manufacturers to still increase the price of their medication within limits to remain in accord.
- Medications are expensive to offset costs spent for R&D, advertising, and expenses. Putting a price cap on medications will affect a company’s revenue and may discourage investment in research and development for new drugs.
- This new application may place the FDA at odds with the FTC
  - The FDA would be able to regulate drug prices while the FTC lacks the power to explicitly control prices.
  - FTC already has the authority to maintain fair competition.
- FDA would require more time and personnel to review these applications effectively

References:

Resources: