EpiPen and the Pricing Debate – Congressional Oversight and Campaign Proposals

The chorus of disapproval about the cost of EpiPen prescriptions reached a crescendo last week after the maker of the drug, Mylan, was widely lambasted for drastic price increases in the product which is widely used to combat potentially life-threatening allergic reactions. Over the past decade, the list price for a package of two injectors has jumped from $94 to $608; Mylan raised the price by 15 percent three separate times since 2014. The EpiPen has garnered more attention recently thanks, in part, to timing: with the beginning of the school year, many parents suddenly found that the device cost more than ever before.

EpiPen has become the latest focal point for national outrage over prescription drug costs, which has also been directed at new drugs for hard-to-treat diseases, such as cancer and hepatitis C, as well as some generics. While Mylan took immediate actions in an attempt to ameliorate the public outcry, legislators have promised strict federal oversight of the company. Meanwhile, the issue is also having an impact on the campaign trail, where Hillary Clinton has invoked Mylan in her renewed calls for federal investments in comparative effectiveness research to determine the "value" of prescription drugs.

For now, Mylan has supplanted other pharmaceutical makers – such as Turing, Valeant, and Gilead – as the poster child for high drug prices and excessive company profits. This brief update provides an overview of the pending congressional oversight into Mylan, as well as the policy solutions that have been proffered from the presidential campaign trail.

Mylan's Response

- Following the public outcry, Mylan took immediate steps last week to make its EpiPen device more affordable. Specifically, the company is increasing the amount of money on a copay assistance card from $100 to $300, and is also widening eligibility for patients to receive the device through that assistance program.
- Earlier today, Mylan announced it plans to launch the first generic version of its EpiPen at a 50 percent discount from the branded version in "several weeks." At $300, the so-called "authorized-generic" will still be more than three times the price of the EpiPen when Mylan acquired the product in 2007. Unlike Mylan's plan to increase patient co-pay assistance, today's announcement will directly impact the price paid by insurers
- Mylan CEO Heather Bresch struggled to justify the repeated price hikes for EpiPen in a series of interviews last week, arguing that the problem of drug prices is not with Mylan or even the pharmaceutical industry, but instead with a health-care system that often requires consumers to pay out-of-pocket for prescription medications. Bresch said there are "four or five hands that the product touches and companies that it goes through before it ever gets to that patient at the counter." She was referring to the fact that intermediaries – including

wholesalers, retailers and pharmacy benefit managers add to the ultimate cost, and can increase the amount paid by patients.

- Most legislators were far from impressed by Mylan's initial response last week. "This step seems like a PR fix more than a real remedy, masking an exorbitant and callous price hike. This baby step should be followed by actual robust action," Sen. Richard Blumenthal (D-CT) said in a statement. As detailed below, legislators on several key committees have promised oversight of Mylan's actions.

Congressional Oversight

- ***Senate Judiciary Committee.*** Chairman Chuck Grassley (R-IA) sent a letter to Mylan seeking additional information on the company's decision to increase the price of the drug. Grassley asked about what analysis went into determining the price increases, the company's advertising budget, the changes Mylan has made to the treatment since its acquisition, and what sort of patient assistance programs exist. Committee members Amy Klobuchar (D-MN) and Richard Blumenthal have called for a hearing on the issues, as well as a Federal Trade Commission (FTC) investigation into the increased price of EpiPen packs. Grassley is expected to decide whether to hold a hearing once he receives a response from the company and his offices concludes their review.
- ***Senate Committee on Aging.*** Chair Susan Collins (R-ME) and Ranking Member Claire McCaskill (D-MO), wrote a letter to Mylan seeking information on the company's pricing practices. The senators are asking Mylan to provide any analysis relating to pricing or market share of EpiPen dating back to 2007, the year Mylan acquired the rights to the device from Merck. It also asks Mylan to provide a briefing to the committee's staff by September 7.
- ***House Oversight Committee.*** Ranking Member Eijah Cummings (D-MD) has called for a hearing featuring the makers of EpiPens and controversial former pharmaceutical executive Martin Shkreli. In February, Shkreli appeared at a hearing about his company's price hikes but cited his Fifth Amendment right not to incriminate himself. "The tactics we have seen recently with Mylan are not limited to a few 'bad apples,' but are prevalent throughout the entire drug industry," Cummings said. It is unclear whether the Republican majority will agree to hold the hearing.
- ***Sen. Manchin, Father of Mylan CEO.*** Sen. Joe Manchin (D-WV), the father of Mylan CEO Heather Bresch, said Thursday that he shares his colleagues' concerns about the recent price hike. "I am aware of the questions my colleagues and many parents are asking, and frankly I share their concerns about the skyrocketing prices of prescription drugs," Manchin said in a statement. "I look forward to reviewing their response in detail and working with my colleagues and all interested parties to lower the price of prescription drugs and to continue to improve our health care system."

Clinton's Response: More Comparative Effectiveness Research

- Democratic Presidential Nominee Hillary Clinton weighed in on Mylan's controversial price increase by touting her plan to invest in private comparative value and benefits research. Clinton has said the results could be used to hold drug companies accountable for justifying their price hikes and ensure patients pay drug prices that reflect the improved value new treatments provide. Under her plan, Clinton has said "pharmaceutical manufacturers should be required to explain significant price increases, and prove that any additional costs are linked to additional patient benefits and better value."
    - Clinton has promised to "build on the Affordable Care Act (ACA)," which notably established the Patient-Centered Outcomes Research Institute (PCORI) to assist patients, clinicians, purchasers and lawmakers in making informed health decisions

by advancing the quality and relevance of evidence concerning the manner in which diseases can be prevented, diagnosed, treated and managed through research and evidence synthesis. Under the law, PCORI is prohibited from considering cost when comparing treatment options.

  - Some left-leaning policy groups have touted "value frameworks" such as those advanced by the Institute for Clinical and Economic Review (ICER) as a means to determine a fair market price for pharmaceuticals. President Obama's administration recently invoked ICER's cost analysis reports in a controversial proposal, the Medicare Part B Drugs Payment Model.

- Clinton's approach echoes calls by other policy and stakeholder groups for more comparative effectiveness research.
  - Rep. Lloyd Doggett (D-TX) said earlier this year that FDA could be doing more to ensure that drugs coming to market have clear evidence of effectiveness by testing whether products going through the pipeline are better than existing therapies. Doggett has said he wants the data on comparative drug research to be available, but not necessarily affect FDA approval.
  - The Campaign for Sustainable Rx Pricing (CSRxP) included comparative effectiveness in its list of drug pricing proposals, which call for requiring drug companies to conduct comparisons of new products to existing products, saying many other countries currently require manufacturers to provide a dossier of comparative effectiveness research.
  - The Center for American Progress (CAP) has also called for additional comparative effectiveness research is needed to properly inform payment policy. CAP called for HHS to certify a research-based, independent entity to aggregate this data to assess independently industry-sponsored CER and to conduct additional, independent CER to supplement existing studies.
- Patient groups and the pharmaceutical industry have been widely opposed to the application of comparative effectiveness research in reimbursement policy, citing President Obama's emphasis on "personalized medicine" and suggesting that relying on such studies fails to account for the differences in patient preferences and how individuals may react to unique drug combinations.

Presidential Candidates' Policy Priorities

- Aside from her focus last week on comparative effectiveness research, Secretary Clinton has released a number of other policy proposals targeted at the pharmaceutical industry, several of which are designed to target the rising cost of prescription drugs:
  - Regulate the percentage of revenues a pharmaceutical company that receives federal support must spend on research and development and require manufacturers to increase their R&D or pay rebates if they do not meet targets;
  - Cap the out-of-pocket cost of many drugs for chronic and serious health conditions;
  - Allocate additional funding to increase the number of generic drugs on the market, including clearing the FDA's Office of Generic Drugs backlog;
  - Cap the out-of-pocket amount insurers can ask individuals to pay for specialty drugs;
  - Increase competition for specialty drugs, including decreasing the exclusivity period for biologics from twelve to seven years and authorizing the FDA to give expedited review to biosimilar applications when there are only one or two competitors in the market;
  - Allow Americans to import lower-cost drugs from abroad;
  - Prohibit "pay for delay" arrangements that keep generic drugs off the market;

- Eliminate deductions for direct-to-consumer ("DTC") advertising and devote those funds to making permanent and simplifying the R&D tax credit;
- Establish a mandatory FDA pre-clearance procedure for DTC advertising, funded through manufacturer-paid user fees;
- Give HHS the authority to negotiate drug prices under the Medicare Part D program; and
- Require drug companies to provide higher rebates (equivalent to Medicaid rebates) under Part D for low-income Medicare enrollees.

- Republican presidential nominee Donald Trump, who hasn't addressed the EpiPen price increase, has offered far less detailed health care reform ideas than Secretary Clinton. Trump has not presented a plan specific to prescription drug pricing, though he has called for the government to negotiate drug prices with pharmaceutical manufacturers under Medicare Part D. The idea of repealing the "non-interference" provision of the Medicare Part D statute has long been opposed by Republicans. Trump has also said he supports importation of prescription drugs from other countries.