California Legislature

SENATE COMMITTEE ON HEALTH

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Informational Hearing: Mylan's EpiPen and Drug Pricing
September 29, 2016 - 10:30 am

Background

Purpose. The purpose of this hearing is to inform the members of the Senate Committee on Health about the history and impact of EpiPen pricing in California. The Committee will hear from patients, families, and health care providers on how price increases over the past decade, coupled with changes to state and federal policies, have affected access to this life-saving drug. The Committee will also explore some of the ways that Mylan helped increase awareness of their product among the public and promote policies that attempt to ensure its purchase by individuals and institutions while shielding the public from the true costs.

This hearing is one in a series of hearings of the Committee to examine health care costs. In March of 2014, the Senate Committee on Health convened health care experts to discuss factors that contribute to the growing cost of health care in California and efforts to make care more affordable. At a second hearing in February of 2015, the Committee heard testimony related to some of the major cost drivers in the health care system, including pharmaceuticals, hospital costs, and the effects of geographic location on contracting. On March 18, 2015, the Committee met to educate members and the public about the effect of health care costs on consumers. Finally, on March 16, 2016, the Committee discussed the impact of health care mergers and concentration on California's health care market. A link to materials from these hearings can be found at http://shea.senate.ca.gov/informationalhearings.

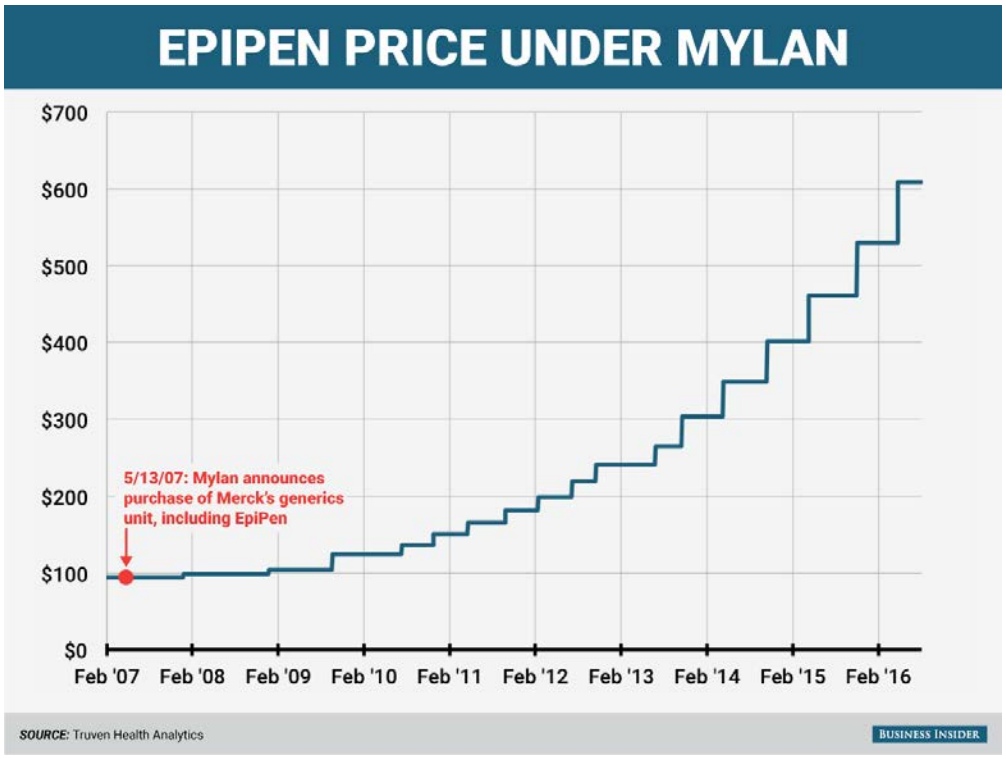
Anaphylaxis. According to the National Institutes of Health, anaphylaxis is a severe, whole-body allergic reaction to a chemical that has become an allergen. After being exposed to a substance, such as bee sting venom, the person's immune system becomes sensitized to it. When the person is exposed to that allergen again, an allergic reaction may occur. Anaphylaxis happens quickly after the exposure, is severe, and involves the whole body. Tissues in different parts of the body release histamine and other substances. This causes the airways to tighten and leads to other symptoms. Some drugs and substances (such as morphine, x-ray dye, and aspirin) may cause an anaphylactic-like reaction when people are first exposed to them. These reactions are not the same as the immune system response that occurs with true anaphylaxis. However, the symptoms, risk for complications, and treatment are the same for both types of reactions. Risks include a history of any type of allergic reaction. According to a study of anaphylaxis prevalence published in the Journal of Allergy and Clinical Immunology in February 2014, the rate is approximately 1.6% in the general population. Another study, published in September 2014, conducted by researchers at Montefiore Medical Center and Albert Einstein College of Medicine of Yeshiva University found that medications are the leading cause of allergy-related sudden deaths in the U.S. Medication reactions account for nearly 60% of the deaths, venom accounts for 15%, food accounted for 7%, and 19% of deaths were caused by unspecified reactions.

Epinephrine auto-injector (EAI). An EAI is a medical device used to deliver a measured dose of epinephrine using auto-injector technology, most frequently for the treatment of acute allergic reactions to avoid or treat the onset of anaphylaxis. According to the Food Allergy Research and Education Web site, epinephrine is a highly effective medication that can reverse severe symptoms of anaphylaxis but must be administered promptly to be most effective. EpiPen and EpiPen Jr. (the version for smaller children) are commonly used EAIs. According to Mylan, which makes the two products, EpiPen contains 0.3mg of epinephrine and is intended for those who weigh 66 pounds or more, while EpiPen Jr. contains 0.15mg and is intended for patients weighing between 33 to 66 pounds. Mylan's product information states that it is not known if EpiPen and EpiPen Jr. are safe and effective in children who weigh less than 33 pounds. The devices are intended to be injected into the middle of the outer thigh, and patients are directed not to inject the device into a vein, buttock, fingers, toe, hand, or foot.

EpiPens and generic alternatives. Epinephrine on its own is extremely cheap, just a few cents per dose. The auto-injecting device (EpiPen) is the product that is protected under patent in this case (Mylan's current patent does not run out until 2025*).* Mylan "owns" the EpiPen auto-injector device design, so competitors must find work-arounds in their devices to deliver the epinephrine into the patient's body. This task has proven to be difficult for EpiPen competitors. In 2015, Sanofi US issued a voluntary nationwide recall of its Auvi-Q due to potential inaccurate dosage delivery. In 2016, the U.S. Food and Drug Administration (FDA) rejected Teva Pharmaceutical's generic epinephrine injector because it had reliability issues and therefore was not medically equivalent. Another company, Twinject, also discontinued their injector in 2012. A generic product called Adrenaclick is on the market, but is not very popular and is not always covered by insurers. Last year, approximately 3.6 million prescriptions for EpiPen were written.

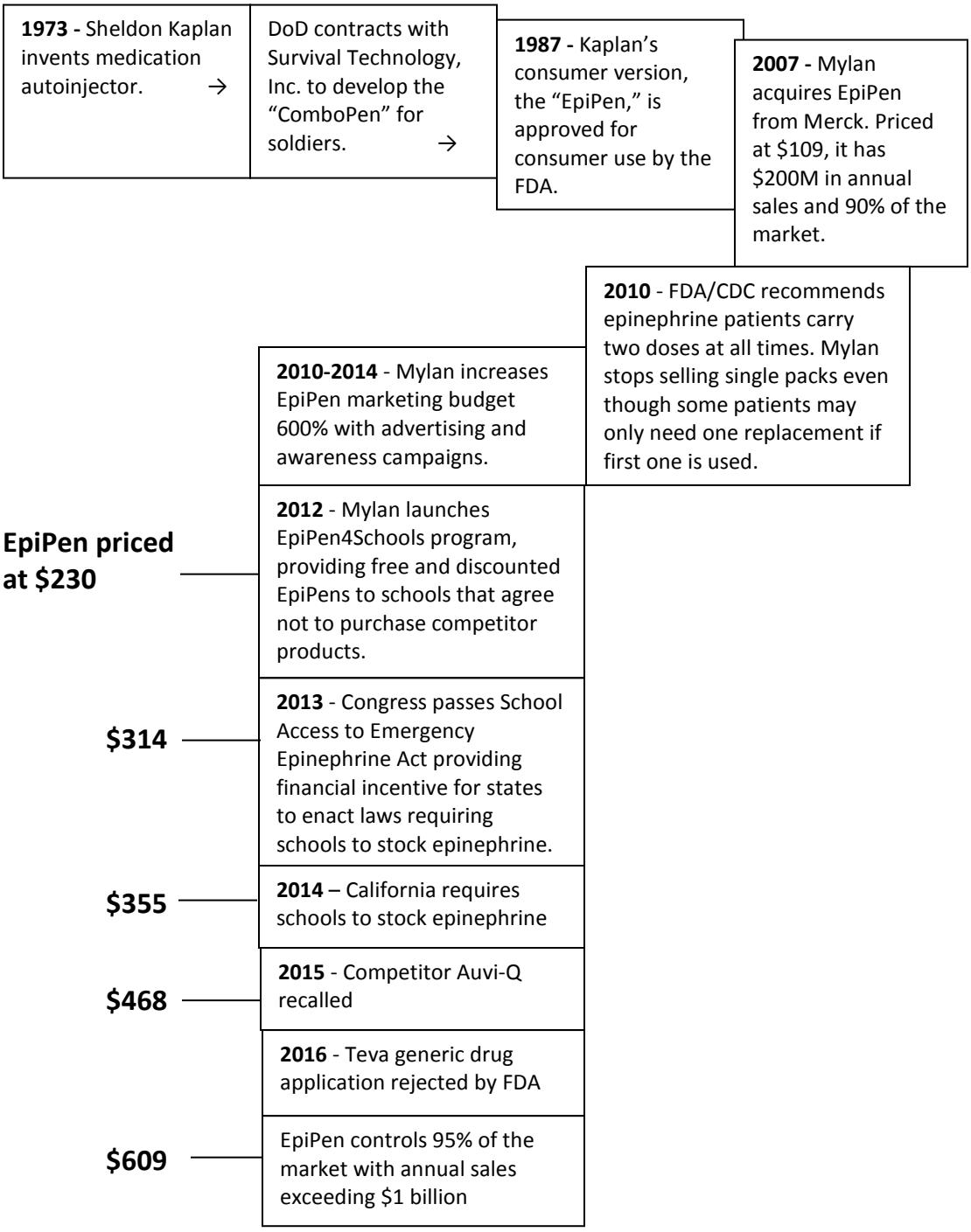
EpiPen history and pricing. The medication autoinjector was invented in 1973, and was developed, in part, to be a tool to deliver a nerve gas antidote to soldiers in the field. It was first approved by the FDA for consumer use in 1987 for epinephrine. In 2007, Mylan NV purchased the rights to EpiPen from Merck, and began steadily raising the price of the device. In 2008 and 2009, Mylan raised the price by 5% and at the end of 2009 by another 19%. Between 2010 and 2013, Mylan imposed a series of 10% increases. From the fourth quarter of 2013 to the second quarter of

2016, the price of EpiPen rose 15% every other quarter. A pack of two EpiPen devices now has a list price of over $600, an increase of 548% since Mylan began selling the drug, according to Truven Health Analytics. On August 29, 2016, Mylan announced it would offer the first generic to the EpiPen for $300, a 50% discount from the brand price, but still about 175% above the 2007 price.



Advocacy for EpiPen. According to data from the Center for Responsive Politics, marketing and lobbying efforts by Mylan increased during this same time period after the acquisition of EpiPen. In 2007, Mylan's reported spending on lobbying was $270,000. In 2008, that number had jumped to $1.2 million and marginally increased each year until it peaked at $1.8 million in 2012. These efforts were aimed at increasing the demand for EpiPen through changes in federal and state policies. Examples of changes during that time period include in 2010, the FDA changed its recommendations so that two EpiPen devices could be sold in a package instead of one, and that they could be prescribed for at-risk patients, not just those with confirmed allergies. The United States Congress passed, and President Obama signed into law, the School Access to Emergency Epinephrine Act in 2013 to provide an incentive to states to boost the supply of epinephrine at schools. A number of states, including California, passed laws requiring public schools to have epinephrine on hand to treat anaphylaxis.

A Timeline of EpiPen



The company also employs unbranded advocacy to increase public awareness. According to a STAT News report published on August 29, 2016, unbranded ads are a "stealthy and lightly regulated form of drug marketing" that focuses on educating the public about a health condition, hosted by a pharmaceutical company, for which that company has a product to treat. The ads are not required to disclose side effects, and often direct patients to a website about the disease. Once on the unbranded disease page, there are links to pages promoting the branded treatment. STAT News also reported that for EpiPen, Mylan spent millions on television ads and celebrity testimonials that promote the EpiPen without mentioning it by name, and on their face, only intend to increase awareness of anaphylaxis.

Spending on EpiPen. According to a report released earlier this month by the Kaiser Family Foundation (KFF), while EpiPen can be a lifesaver for children with serious food allergies, it is also used to treat life-threatening allergic reactions in older adults and people with disabilities who are covered by Medicare. EpiPen is covered under Medicare Part D, which provides outpatient prescription drug coverage to beneficiaries who enroll in private drug plans. The KFF analysis, which was based on retail claims data that do not take into account manufacturer rebates, found a stunning increase in spending. According to the analysis, total Medicare Part D spending for the EpiPen increased from $7 million in 2007 to $87.9 million in 2014, an increase of 1151%. Part D rebate information is confidential; therefore, no data on rebates for the EpiPen to Part D plans is publicly available, but those rebates range from an average of 9.6% of total Medicare Part D spending in 2007 to 14.3% in 2014. According to the Department of Health Care Services (DHCS), in California the number of Medi-Cal beneficiaries in fee-for-service (FFS) receiving filled prescriptions for EpiPen increased by about 5% between Fiscal Year (FY) 2011-12 and FY 2014-15 (from 5,349 to 5,737 during the four-year period). Medi-Cal FFS payments, excluding rebates, went from $1.08 million to $2.4 million during the same time period (a 125% increase). During the first nine months of FY 2014-15, that spending had jumped to $3.09 million, an increase of 187% from 2011-12. These amounts do not take into account spending in EpiPen by Medi-Cal managed care, which accounts for 3/4 of Medi-Cal enrollment. As is the case with Medicare data, rebate information is confidential. However, DHCS states that the net cost to the State for the drug, taking into account rebates, has more than doubled over the last five years.

Congressional action. Several letters from members of the U.S. Congress have been sent to the Chief Executive Officer of Mylan in the past several weeks, following the most recent increase to the price of EpiPen. These letters include one from the House of Representative's Committee on Oversight and Government Reform, signed by the chair as well as the ranking member; a letter signed by 20 Democratic members of the U.S. Senate; and, a letter from Senator Charles Grassley, Chairman of the Committee on the Judiciary. The letter from the House Committee on Oversight and Government Reform requested a number of documents from Mylan, including documents relating to the company's gross and net revenues from the sales of the EpiPen since its acquisition, documents relating to the company's expenses from the manufacture and sale of the EpiPen, and any cost estimates, profit projections, or other analyses relating to the company's current and future sales of the EpiPen. Senator Grassley's letter requested that Mylan explain the changes it has made to EpiPen since the acquisition that have caused it to increase the price, any analyses conducted by Mylan in determining the price of EpiPens, and Mylan's advertising budget for the product. The letter signed by the Democratic members of the U.S. Senate requested answers to a number of questions, including the number of consumers who have used certain consumer savings assistance programs offered by Mylan, and how Mylan justifies charging $600 for the branded product when it claims that the new generic alternative it will offer at $300 will be identical to the brand name version. On September 15, 2016, Senators Tammy Baldwin (D-Wisconsin) and John

McCain (R-Arizona) introduced S.3335, the Fair Accountability and Innovative Research Drug Pricing Act of 2016. The bill requires that drug manufacturers submit a report to the federal Health and Human Services Secretary for drug price increases of 10% percent or more in a 12-month period. The report would be required to include a justification for the price increase, expenditures related to the manufacturing of the drug, research and development derived from federal funds, revenue and profit from the drug, and marketing costs.

On September 21, 2016, Mylan's CEO, Heather Bresch, appeared before the House Oversight Committee. In her testimony, she focused on the efforts the company has made to increase availability and awareness of the devices, but did not give a reason for the incredible increase in price over the past decade. She stated that with the current focus on pricing, she is concerned that "the access part of the equation is being minimized. When Mylan acquired the company that owned EpiPen Auto-Injectors in 2007, not only was there low awareness of anaphylaxis, but fewer than 1 million of the 43 million people at risk had access to an epinephrine auto injector." According to Ms. Bresch's testimony, Mylan has "reached 80% more patients" than when they first acquired EpiPen. With regard to profits, Ms. Bresch stated that while the Wholesale Acquisition Cost (WAC) for a 2-unit pack of EpiPen is $608, "…after rebates and various fees, Mylan actually receives $274. Then you must subtract our cost of goods which is $69. This leaves a balance of $205. After subtracting all EpiPen Auto-Injector related costs our profit is $100, or approximately $50 per pen." Mylan did not produce all the documentation requested by the Committee prior to the hearing, and Ms. Bresch was asked to fulfill that request and follow up with answers to questions raised at the hearing within ten days.

Related legislation. SJR 29 (Hernandez, 2016) makes various legislative findings related to the increase in the price of the EpiPen by Mylan, urges the FDA to reconsider its denial of generic alternatives to EpiPen, and urges Congress to investigate the impact that Mylan's monopoly has had on the price hikes for EpiPen and to take action to limit the unrestrained ability of drug manufacturers to increase prices based only on what the market will bear.

AB 1386 (Low, Chapter 374, Statutes of 2016) permits a health care provider to issue a prescription for, and a pharmacy to dispense, an EAI to an authorized entity, which is defined as any entity or organization that employs at least one person that has completed an approved training course on the emergency use of EAIs. AB 1386 also revises the definition of "epinephrine auto-injector" to eliminate the reference to a spring-activated needle, and instead defines this term as a "disposable delivery device designed for automatic injection of a premeasured dose of epinephrine into the human body to prevent or treat a life-threatening allergic reaction. Governor Brown included a signing message criticizing Mylan, who sponsored the bill, for "unconscionable price increases" and "rapacious corporate behavior." He also sent a letter to Congress urging "swift and strong" action to "rein in this kind of predatory pricing."

SB 1266 (Huff, Chapter 321, Statutes of 2014) requires school districts, County Office of Education (COE), and charter schools to provide emergency EAIs to school nurses or trained personnel who have volunteered, as specified. SB 1266 also authorizes school nurses or trained personnel to use the EAIs to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction.

SB 669 (Huff, Chapter 725, Statutes of 2013) permits a prehospital emergency medical care person or lay rescuer to obtain and use an EAI in emergency situations with certification of training, as specified.

SB 1069 (Pavley, Chapter 512, Statutes of 2010) in addition to expanding the scope of practice for physician assistants in other instances, allowed pupils to obtain a written statement from a physician assistant in order to carry and self-administer a prescription EAI.

SB 1912 (Ashburn, Chapter 846, Statutes of 2004) permits pupils to carry and self-administered inhaled asthma medication or an EAI at school, as specified.

AB 559 (Wiggins, Chapter 458, Statutes of 2001) was identical to AB 1791 (see below).

AB 1791 (Wiggins, 2000) would have established provisions of law that permit a school district or COE to provide emergency EAIs to trained personnel, and permit trained personnel to utilize these EAIs to provide emergency medical aid to persons suffering from an anaphylactic reaction at a school or during a school activity. The bill was vetoed by Governor Davis who stated that the shortage of school nurses with the knowledge necessary to administer medications would assure that the bulk of school personnel administering epinephrine in emergencies would be lay personnel. The Governor further stated that lay persons cannot receive the necessary background in a limited training program that would provide the essential medical judgment skills required to administer medication in an emergency situation.

Conclusion. Mylan and EpiPen pricing is a focus of this hearing because it is an example of a common strategy wherein pharmaceutical companies increase the demand for their products through marketing and advocacy to consumers, health care providers, and policymakers. In addition, the company increases the price exponentially, while shielding consumers who have to pay out of pocket through coupon programs. Efforts to expand access to health insurance under the Affordable Care Act, such as mandating employers and individuals purchase insurance, is making the prices that Americans pay for health care treatment more real. While efforts to shield individual consumers from unjustified price increases are made by these companies, ultimately, individual purchasers, employers, and government are paying the price through higher health care premiums. These increases cannot be sustained and must be reined in.