## **Introduced by Senator Hernandez** (Coauthors: Senators Hall and Leno)

August 29, 2016

Senate Joint Resolution No. 29-Relative to EpiPen.

## LEGISLATIVE COUNSEL'S DIGEST

SJR 29, as introduced, Hernandez. EpiPen: pricing.

This measure would urge the United States Food and Drug Administration to reconsider its denial of approval for generic alternatives to the epinephrine auto-injector EpiPen, would urge the Congress of the United States to investigate the impact that Mylan NV's monopoly has had on price increases for EpiPen, and would urge the Congress and the President of the United States to take action to limit the unrestrained ability of drug manufacturers to increase prices based on what the market can bear.

Fiscal committee: no.

1 WHEREAS, Millions benefit from life-saving drugs and devices,

2 including Americans with allergies that can be treated by epinephrine; and 3

4 WHEREAS, Last year, doctors wrote 3.6 million prescriptions

5 for EpiPen, which stops allergic reactions by quickly and safely injecting epinephrine; and

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WHEREAS, In 2007 Mylan NV purchased the rights to EpiPen 7

8 and immediately began raising its price. In 2008 and 2009, Mylan

raised the price by 5 percent, and at the end of 2009 it raised the 9

price by another 19 percent. From 2010 to 2013, Mylan imposed 10

a series of 10-percent price hikes. And from the fourth quarter of 11

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1 2013 to the second quarter of 2016, Mylan raised EpiPen prices

2 15 percent every other quarter; and

3 WHEREAS, A pack of two EpiPen devices now has a list price

4 of over \$600, an increase of 548 percent since Mylan began selling
5 the drug, according to Truven Health Analytics; and

6 WHEREAS, The formula of EpiPen did not change, and it is

7 no more effective in protecting against allergic reactions in 2016 8 than it was in 2007; and

9 WHEREAS, During the same time, Mylan began an aggressive

10 marketing and lobbying effort to increase demand for EpiPen,

11 which included the passage of federal and state legislation. The 12 United States Congress passed the School Access to Emergency

12 United States Congress passed the School Access to Emergency13 Epinephrine Act in 2013 to provide an incentive to states to boost

13 Epinephrine Act in 2013 to provide an incentive to states to boost 14 the stockpile of epinephrine at schools. A number of states,

15 including California, passed laws requiring public schools to have

16 epinephrine. In 2010, the United States Food and Drug

17 Administration (FDA) changed its recommendations so that two

18 EpiPen devices be sold in a package instead of one and that they

19 be prescribed for at-risk patients, not just those with confirmed

20 allergies; and

21 WHEREAS, The rising cost of EpiPen has implications for

22 taxpayers. Over half of California's children are insured through

23 Medi-Cal, therefore the taxpayers are paying a large share of the 24 cost of this medication; and

WHEREAS, Mylan has an effective monopoly that it is using to maximize profit because there is no equivalent generic competitor; and

WHEREAS, Patients who have to pay retail prices are being forced to buy EpiPen abroad, where it is cheaper, and are resorting to other devices that deliver epinephrine, including do-it-yourself syringes; and

32 WHEREAS, Even some ambulance providers in California have 33 stopped the use of EpiPen to treat allergic shock and instead are 34 drawing from a vial and injecting epinephrine by syringe. First 35 responders in Seattle have developed such a kit and have sold them to public health agencies in five other states. There is a 36 37 demonstration project in New York called "Check and Inject New 38 York" that trains first responders to use syringe epinephrine kits 39 in place of EpiPen to save money; and

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1 WHEREAS, After recent widespread criticism, Mylan said it 2 would expand access and increase benefits to programs that it uses 3 to help consumers pay less, but those changes do not alter the 4 prices that insurers and employers pay. Those institutions will still 5 face the brunt of the impact from the price hikes; and

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6 WHEREAS, Offering co-payment assistance and free product

7 to consumers is part of the standard playbook for manufacturers8 of expensive drugs. Efforts by drug makers to shield consumers

9 from the out-of-pocket costs associated with the rapidly increasing

10 cost of their medications ignores the fact that insurance companies

11 bear the brunt of these unreasonable price increases, which results

12 in higher premiums for all consumers; now, therefore, be it

13 Resolved by the Senate and the Assembly of the State of

14 *California, jointly,* That the Legislature declares unnecessary and 15 unexplained increases in pharmaceutical pricing is a harm to our

16 health care system that will no longer be tolerated because the

17 system cannot sustain it; and be it further

18 *Resolved*, That the Legislature urges the United States Food and

19 Drug Administration to reconsider its denial of approval for generic

20 alternatives to EpiPen; and be it further

*Resolved*, That the Legislature urges the Congress of the United
 States to investigate the impact that Mylan's monopoly has had
 on the price hikes for EpiPen; and be it further

24 *Resolved*, That the Legislature urges the Congress and President

of the United States to take action to limit the unrestrained ability
of drug manufacturers to increase prices based only on what the
market can bear rather than on providing a fair return on

28 investment; and be it further

*Resolved,* That the Secretary of the Senate transmit copies of this resolution to the President and Vice President of the United

31 States, to the Speaker of the House of Representatives, to the

32 Majority Leader of the Senate, to each Senator and Representative

33 from California in the Congress of the United States, to the

34 Secretary of the United States Department of Health and Human

35 Services, and to the Commissioner of Food and Drugs, and to the

36 author for appropriate distribution.

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