To prevent another EpiPen controversy, the government should step in

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Mylan, the pharmaceuticals giant, is engulfed in a furor led by parents over dramatic price hikes for its lifesaving EpiPen. The problem, says Mylan CEO Heather Bresch, is a broken health system that has let deductibles and co-pays skyrocket on many insurance policies.

She is half-right. If deductibles had stayed low, the parents wouldn't have noticed that Mylan had increased the price of a two-injector set from around $100 seven years ago to over $600 this spring because only their insurance company was getting gouged.

However, the problem is not really with insurance design, but rather regulatory oversight that does not ensure adequate supply of drugs critical to population health, and opens the door to shocking price increases.

EpiPen is the overwhelming choice to keep kids and others safe from anaphylactic shock that can be triggered by allergies and insect bites. The EpiPen works by being pressed against the thigh, automatically injecting a set dose of epinephrine. Parents usually buy several sets a year to have ready whenever and wherever needed, and to make sure the medicine hasn't expired.

Epinephrine is not a new drug. In fact, its properties were discovered more than 100 years ago, and Parke-Davis — one of the largest pharmaceutical companies at the time — started marketing it under the brand name Adrenalin soon after that.

For maximum benefit, epinephrine should be administered as quickly as possible. For many years we relied upon the use of syringe and vial, wasting precious seconds and risking misdosing. It took the invention of an auto-injector with a predetermined dose to create the EpiPen.

In this case, Mylan could not hold a patent on epinephrine, just the auto-injector. This meant it could exercise its government monopoly when it started marketing the EpiPen in 2007. French competitor Sanofi entered the market with a different type of auto-injector in 2013, but recalled the product in the US and Canada in 2015 after reports of only 26 adverse events, with no fatalities. At that time, Sanofi had already sold 2.8 million units —suggesting a failure rate of less than 0.01%.

But rather than work to keep Sanofi in the game, US officials sat on the sidelines as Mylan's market power grew. Then this spring the FDA rejected a knock-off injector made by Israel-based Teva Pharmaceutical, putting Mylan in position to control 95% or more of the market.

So what can we do? US officials need to get off the sidelines, and understand that sometimes it is worth taking a manageable risk to ensure adequate supply. In fact, such a model already exists for vaccines.

The federal government buys billions of dollars' worth of vaccines annually, stockpiling them for current and future use. The Department of Health and Human Services has several roles in regulating production and availability. In the process, stable markets are created and maintained.

For cases such as auto-injected epinephrine, and essential generic drugs generally, a three stage sequence could emulate the vaccine model.

First, Congress should mandate that the Federal Trade Commission report on the availability of all such drugs and devices by finding the number of manufacturers and how hospitals and pharmacies are being supplied.

Second, the Food and Drug Administration should examine the FTC reports to discover which essential products have competition or supply issues. If the problems are severe, the FDA would have new authorization to allow foreign imports to solve the immediate crisis. In the case of EpiPen, that would result in prices roughly one quarter of Mylan's U.S. listed retail charge.

Finally the Centers for Disease Control and Prevention, which has experience buying vaccines to prevent supply problems, would be authorized to begin buying essential generic drugs and devices on behalf of federal users, including the Veterans Administration, Medicaid, and Medicare.

The purchases would assure potential competitors that a steady market exists worthy of investing in production lines. At the same time, renewed competition and new government stockpiles would act to keep prices from rising.

The current EpiPen imbroglio, which has reached even into the Presidential campaign, may yet force Mylan to cut list prices. But that momentary salve should not delude us into thinking we can solve the problem of unstable drug pricing by shaming one company. Healthy competition among multiple suppliers is the best answer to prevent high prices.

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