Fact Checking Mylan Claims They Raised The EpiPen Price Because of Improvements

By Hank Campbell — August 25, 2016

On August 17th I got an email from a concerned reader, the parent of a child with an allergy, who was shocked by their family bill for EpiPens for this year. She could still afford it, she noted, but the increase of nearly 400 percent was surely going to be an issue for families with less money, especially when schools require one, and most families keep them at places they often visit, like grandparents. Wasn't that the kind of thing we liked to examine, as consumer advocates?

Yes, indeed. One puzzle we have long been unable to solve is why generic drug makers have such a health halo among politicians, the media and the public, who uniformly believe that Big Pharma should spend 12 years and $1 billion on new drug discovery only to have to sell it for a dollar. (1) Somehow with both Valeant and Turing showing the public how generic drug companies should not be run, Big Pharma still has the bad reputation.

Yet generic prices haven't really been anything special. Turing bought a niche toxoplasmosis drug, for example, and immediately raised the price, because they said it was not profitable, and they could use the new money to improve it. The blowback was immediate. Valeant is almost a running joke for how not to manage your brand. And now Mylan with the EpiPen.

If you aren't familiar with them, EpiPen is the brand name for the most popular epinephrine autoinjector. If needed, such as during a serious allergic reaction, an autoinjector provides a measured dose of epinephrine. You could do the same thing with a needle and epinephrine, but that is obviously going to be more risky. Yet you can bet some people are being forced to do just
that and hope for the best because of the new price hike.

So why did they boost its price so much this year? They claimed they had improved the product [1].

So we had a researcher here look into what that meant:

In May of 2016 they changed the label [2]. It had read the same since 2008. Yes, there is cost in that, we are dealing with the government and parents worried about anaphylactic shock and side effects so these have to be careful and clear, but hardly worth a 400-plus percent boost in price.

In October of 2015 they showed that they had done post-market testing to make sure the product met quality standards [3]. Also not a big deal, manufacturing needs to be consistent, so hire some secret shoppers and they buy it and you test it.

Other than that, not much has been done. They pulled an advertisement because of an FDA warning about exaggerated claims in 2012, but that didn't cost them anything.

Really, there is no justification other than that they can do it because the market has grown while competitors have faded away.

There are two key reasons why that has happened, and it points to the weaknesses in breaking into the generic market, even if an existing company is making a billion dollars on something:

1. Generics have never realized their promise in many ways because the regulatory process is still pretty onerous. Want to be a small entrepreneur and make a $50 competitor to EpiPen? You need to have millions of dollars in the bank for testing first [4], and also be able to survive for years without selling a product. What venture capitalist is going to give you money when you are making a generic and just want to charge less?

2. The autoinjector market used to be pretty crowded, but since 2010 there has been a lot of consolidation. And there was a recall of the biggest competitor to EpiPen, implemented by the FDA.

Those things mean what is obvious to most; generic or not, Mylan basically has a monopoly on allergic kids and it's enabled by the FDA. That, coupled with more allergy prescriptions and a brand that, doctors say, is basically equivalent to having "Kleenex" in the epinephrine market, made it an easy way to charge some extra cash.

It may also be worth considering that CEO Heather Bresch thought she was untouchable, and the company by association. Her father is Senator Joe Manchin and he was Governor of West Virginia when she got the job running Mylan. She obviously knows politics because she somehow got an MBA she never earned [5]. When you can pull that off, and get handed the keys to a multi-billion organization just the same, you might get a little arrogant about your ability to sell anything. Using her political instincts now, she is savvy enough to blame ObamaCare for their price boost during election season [6]. That part, she learned from the best. Her dad, a Democrat, was the guy who took a rifle and shot a hole in President Obama's cap-and-trade plan during his election campaign and West Virginians cheered.
In response to the controversy, Mylan has said they will roll out new ways to make their product more affordable. But they have not said they are going to lower the price.

People are going to pay. They have to pay. There's no new competitor even beginning the regulatory approval process.

NOTE:

(1) Technically, it's still Big Pharma. Pfizer bought King Pharmaceuticals and its EpiPen in 2010, and Mylan had the US licensing agreement for it. At the time the concern was that Pfizer would want to kill it and promote its own Greenstone unit. That would have been as crazy as Google buying YouTube and then killing it so people would have to use Google Video instead. So when Mylan does something wrong, like when they engage in aggressive marketing claims, the CEO of Pfizer still gets a letter from FDA.


Links