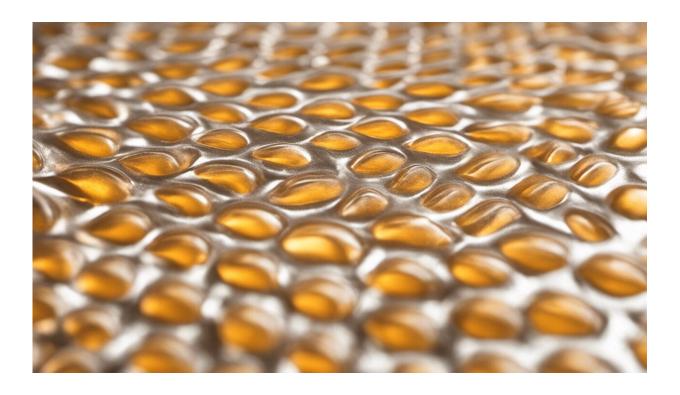


EpiPen's pricing debacle and its impact on patients, insurers

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Credit: AI-generated image (disclaimer)

A firestorm erupted this week in response to the pharmaceutical company Mylan's steep increase in the price of its EpiPen, a life-saving treatment for severe allergic reactions, with consumers and politicians expressing outrage over the device's now \$600-plus price tag. Currently there is no generic version of the medication and just one, infrequently



used, competitor. On Thursday, in response to the furor, the company announced it would issue coupons covering up to \$300 of the cost to users whose insurance plans have high deductibles and also increase the income level for those eligible for its patient assistance program, which provides the EpiPens for free.

We asked three Northeastern faculty members— pharmacist Tayla Rose, healthcare finance expert Steven Pizer, and health policy researcher Gary Young—to explain the EpiPen's role in counteracting allergic reactions and how Mylan's price hike and subsequent discount will affect both the economics of the healthcare system and healthcare policy.

Tayla Rose, assistant clinical professor in the School of Pharmacy

We know that people with severe allergies can go into anaphylactic shock, but what exactly does that mean? What is happening in their bodies?

Anaphylaxis is a severe type of allergy. For any allergy to develop, an individual must first be exposed to a foreign substance, known as an allergen. This allergen could be a medication, food, bee sting, chemical, pet dander, pollen, or many other things. The individual becomes sensitized to that allergen, meaning that the body recognizes it as foreign and primes itself to attack. The next time the person comes into contact with that allergen, the body launches an inappropriate response by releasing chemicals and mediators that have harmful effects. In less severe allergies, this may manifest as a runny nose, itchy eyes, or a rash. However, when anaphylaxis develops, airways swell and spasm, causing difficulty breathing, and blood pressure drops. Other possible symptoms include swelling of the face, especially the mouth and tongue; flushing; an itchy rash or hives; and gastrointestinal issues including nausea,



vomiting, and diarrhea. This all occurs within a few minutes of exposure to the allergen. It is extremely dangerous because individuals can die from not being able to breathe properly or from the body's not being able to circulate blood to its vital organs.

How does the EpiPen counteract the reaction?

The EpiPen contains epinephrine, which is a hormone that occurs naturally in our bodies. People also know it as adrenaline. What makes the EpiPen unique is its delivery system: It is simple, fast, and accurate. It automatically injects the correct dose of the hormone to the sufferer. Epinephrine fights anaphylaxis by relaxing the muscles in the airways so the user can breathe more easily and by tightening the muscles around the blood vessels so that blood can be pumped throughout the body. Epinephrine is a life-saving medication, and should be administered as soon as symptoms of anaphylaxis appear. However, using the EpiPen alone is not enough. Emergency medical services should be called immediately to provide further care.

Steven Pizer, associate professor in the School of Pharmacy and Department of Economics

On Monday The *New York Times* reported that Mylan has raised the price of the EpiPen steadily since it acquired it in 2007, increasing the cost from about \$104 in 2009 to \$461 last May and to more than \$600 this May. Why has the company increased the price so precipitously, and how has it been permitted to do so?

Mylan has been able to raise its price for EpiPens because competition to sell this product is weak. Competition is limited because <u>prices</u> for the device were relatively low before Mylan acquired it, discouraging potential competitors from getting into the business. After Mylan started



hiking prices, competitors had to apply for and receive regulatory approval before they could manufacture alternatives. This regulatory delay has given Mylan a temporary monopoly. I expect Mylan's prices to come down again when alternatives start to hit the market in about a year; Mylan's pricing is definitely attracting competitors. But until then, lots of families will get squeezed.

How will Mylan's price-hiking practices affect the economics of the healthcare system overall and of consumers in particular?

What Mylan is doing is particularly newsworthy because the usual justification for high prices clearly doesn't apply. Manufacturers typically claim that high prices are needed to recover research and development costs, but the EpiPen has been around for a long time and those costs were recovered long ago. The simple truth is that companies generally maximize profits, regardless of whether they are in the healthcare sector, and if they have a monopoly position their profits can be very high.

We rely on a balance between temporary patent protection and market competition across our economy to encourage research and development without permitting excessive profits. In healthcare we also have careful regulations to ensure safety and effectiveness of healthcare products. Unfortunately, there are cases like this one where aggressive companies can exploit the delays inherent in safety and effectiveness regulation to extract monopoly profits without a patent. It's clearly not consistent with the spirit of the law or our broader social and economic goals.

What effect will the company's offering high-value coupons to some people have on ameliorating the



economic damage from the price hikes?

Mylan's announcement that it is increasing rebates to income-qualifying families to cover the cost of their copayments and deductibles is good public relations for the company, but it doesn't solve the problem for the U.S. healthcare system. Rebate programs like these encourage patients to use more expensive products by shifting the entire cost onto their insurance plan, which is ultimately paid for with higher premiums. In the long run, these rebate strategies cost patients and their families more money, not less.

Gary Young, professor, D'Amore Mckim School of Business and the Department of Health Sciences, director of the Northeastern Center for Health Policy and Healthcare Research

Not just consumers but legislators and politicians criticized the EpiPen price increase. What effect might such price hikes and the public response have on healthcare policy and consumer protections?

The price increases for the EpiPen by Mylan fall within a larger controversy over the pricing of medications by pharmaceutical companies. Several months ago, there was a similar reaction to price increases for a drug manufactured by Valeant Pharmaceuticals International. Many policymakers accused Valeant of price gouging.

These controversies typically lead to some policymakers calling for regulating the pricing of medications. The pharmaceutical companies push back by asserting that they make huge financial investments in research and development to bring a drug to market and that price



regulation will stifle future development of drugs that can save lives. A company's decision to sharply raise the price for an existing drug is based on market factors and drug-patent considerations. But when such price increases pertain to life-saving drugs such as the EpiPen or, in the case of Valeant, Mephyton, a blood-clotting medicine, it generates a lot of attention and controversy.

Provided by Northeastern University

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