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REVIEWING THE RISING PRICE OF EPIPENS

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM HOUSE OF REPRESENTATIVES

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CONTENTS

	Page
Hearing held on September 21, 2016	1

WITNESSES

Dr. Doug Throckmorton, Deputy Director, Center for Drug Evaluation and Research, Food and Drug Administration	
Oral Statement	6
Written Statement	8
Ms. Heather Bresch, Chief Executive Officer, Mylan, Inc	
Oral Statement	17
Written Statement	19

APPENDIX

Statement from Representative Gerald E. Connolly	88

REVIEWING THE RISING PRICE OF EPIPENS

Wednesday, September 21, 2016

HOUSE OF REPRESENTATIVES,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, D.C.

The committee met, pursuant to call, at 3:08 p.m., in Room 2154, Rayburn House Office Building, Hon. Jason Chaffetz [chairman of the committee] presiding.

Present: Representatives Chaffetz, Mica, Duncan, Walberg, Amash, Gosar, DesJarlais, Gowdy, Farenthold, Massie, Meadows, DeSantis, Mulvaney, Buck, Walker, Blum, Hice, Carter, Grothman, Hurd, Palmer, Cummings, Maloney, Norton, Clay, Lynch, Cooper, Connolly, Duckworth, Kelly, Lawrence, Lieu, Plaskett, Boyle, Welch, and Lujan Grisham.

Chairman CHAFFETZ. The Committee on Oversight and Government Reform will come to order. And, without objection, the chair is authorized to declare a recess at any time.

We have an important hearing today, "Reviewing the Rising Price of EpiPens." Anaphylactic shock will kill about 1,500 people a year. Roughly four people a day will die if they don't get the proper dosage of epinephrine. It's one of the ways that you can stop your child or your loved one from dying if they are going into this shock.

This is a generic drug that's been around for about 100 years, and it works, it's a good product. People, parents, they need this. It's not optional for somebody who has severe allergic reactions to a whole variety of things.

But what we're here to discuss today—and believe me, trying to drive into the depths of individual drug pricing was not something I set out to initially do—but it doesn't take very long to talk to parents or talk to people who are afraid that if this EpiPen is not within arm's reach when their young child suddenly needs it, you don't have to talk to somebody very long to figure out that they have to have this. It's not optional.

And so here's the concern. Here you've got a drug that's been on the market for 100 years, costs roughly a dollar, the actual juice that's in here that you need costs about a dollar. But the price of this has gone from, roughly, $99 for one to more than $600 for two in a very short amount of time. You literally see year over year where the price will jump $100 here and $100 there. It's a product that is not available on insurance plans, a lot of insurance plans, it's not mandated like some of the other things in ObamaCare are mandated.

And so suddenly you have people who can't afford what is a 1-year dose, right? There's an expiration date of a year. So you get two of them. Some families I've talked to have 10 of them, because they need them in the car, in the backpack, they have them all over. And now we're talking about more than $600 to the consumer to have two of those. And so we've got a lot of questions.

Now, Mylan, as best I can tell from afar looking at it, has done a lot of good in the world and they offer a lot of good products. But of the 635 products they offer, this generates about 10 percent, about 10 percent of their revenue is found in this one product.

Now, they're here to tell us that they make about $50 profit, which I find a little hard to believe, and that's why I think it's important that the CEO, and I appreciate her willingness to come in and talk to us, is telling us that, well, the middleman makes more than we do. We get less than half of that revenue actually goes to Mylan.

But here's what doesn't add up for a lot of people, and believe me, I'm a person who believes in profit, in profit motivation: You have five executives in 5 years that earned nearly $300 million in compensation. And this is, by all accounts, as best I can tell, one of their biggest revenue drivers and one of the biggest revenue items.

They used to have a competitor. That competitor dropped out of the market, I believe it was 2010. I could stand to be corrected, but I believe it was 2010. When that other product left the market, the product price zoomed. It just went up.

So here's yet but another example of a life-saving drug that you have to have, if you don't have it you're going to die, and there's no competition. Which brings us to why we have Mr. Throckmorton here from the FDA.

One of my concerns, based on the sole economics of it, right, basic economics, you have a generic product that's been on the market for 100 years and suddenly you see this massive rise in the cost, the price to consumers. That would signal to entrepreneurs that there is an ability to make a profit. And when you understand that the cost of goods for the juice is only a dollar, the delivery vehicle, which is unique and it's innovative, there's a cost to that too, but when the juice is a dollar and they're selling it for $600, there's some room for some profit.

But if new market entrants aren't able to submit an application and get it through the FDA, then guess what? You have, in this case, Mylan, who is able to market a product, quickly raise the price, bring home an exorbitant amount of profit, with no competition.

It was actually my brother who said, "Hey, why are you trying get in the business of some private entity and how they price?" I said because the market forces aren't at work. Competition cannot be in there. Competition would be good. It would help drive down the price. So we want to hear about the FDA approvals.

And the last thing I would also mention here along the way: Suddenly, feeling the heat, feeling the pressure, Mylan has offered a generic version and cut the price in half. So that does beg the question, what was happening with that other $300? I mean, driving

the price down is great, but Congress shouldn't be micromanaging that.

But I do think this is worth exploring because we, again, saw one, a different drug earlier this year that we did a hearing, and here we are again. And my guess is, if it's happening in these two instances, it's probably happening in others, maybe not as egregious, maybe not as big of a rapid rise. But I find this to be so extreme.

And we're talking about tens of millions of Americans who have to have it, there's no competition, it's extremely expensive, it's not covered under insurance, there is not the competition, it is driving exorbitant profits, and that's why I think myself and Mr. Cummings are very jointly united in trying to address this, understand it better. We may have different solutions to it.

But let's come back to my original premise: Parents don't have a choice. If your child, your loved one has to have this, it better darn well be in that backpack. It better be there. It better be at school. And we want to try to offer some understanding and some relief to those parents and those people that go through that, because every day four people a day are going to die because they don't have this product handy.

I now recognize the gentleman from Maryland, the ranking member, Mr. Cummings.

Mr. CUMMINGS. Mr. Chairman, I thank you for holding today's hearing. And as you know, this issue of the skyrocketing prices of prescription drugs has been one of my top priorities for several years.

This hearing is critical because yet another drug company, Mylan, has jacked up the price of a life-saving product for no discernible reason.

And I did read your testimony, Ms. Bresch, and I was not impressed.

And they raised the prices, the reason being, I believe, to get filthy rich at the expense of our constituents—at the expense of our constituents.

May I hold your EpiPen?

The EpiPen has been around for decades. It was introduced in 1988. The active ingredient has been around even longer, and it costs just pennies to make, as the chairman said.

So what changed? What changed? What changed is that Mylan acquired EpiPen in 2007. Then they used a simple but corrupt business model that other drug companies have repeatedly used. We've seen it over and over and over again. Find an old, cheap drug that has virtually no competition and raise the price over and over and over again as high as you can. That's what Martin Shkreli did and that's what Valeant's CEO did. They sat at this very witness table earlier this year with absolutely no remorse. None.

In Mylan's case, they had a virtual monopoly over the market, and they decided to take advantage of it. As a result, today a product that used to cost about $100 for two EpiPens now costs more than $600.

To understand why Mylan raised these prices so dramatically, we need to understand how much money they are making off of this drug. According to documents obtained by the committee,

EpiPen generated $184 million in net sales revenue in 2008—$184 million. In 2016, listen to this, in 2016 Mylan expects this number to go up to more than 1.1 billion, as in "B." That's more than a fivefold increase over the 10 years.

What else changed since 2007? The EpiPen became Mylan's first billion-dollar drug. Mylan has received more than $4 billion in net sales revenue on this one drug over the last decade, and that's after rebates and discounts. My, my, my.

The company also engaged in a massive marketing campaign. According to information obtained by the committee, Mylan spent $100 million on advertising and marketing for EpiPens last year alone.

Then came the price increases. When Mylan acquired EpiPen in 2007, the cost for two EpiPens was about $100. In 2012, they raised the price to about $218. Then they, in 2014, they raised it again. You see the pattern? They raised it again, to about $350. In 2015, they were on a roll, they raised it again, to about $460. And now it's $608.

While the price of EpiPens shot up exponentially, so did Ms. Bresch's paycheck and the lavish compensation of her fellow executives at Mylan. In 2007, Ms. Bresch received $2.45 million, according to financial reports. Not bad. By last year, her compensation had soared to more than $18 million, a 671 percent increase. Mylan's chairman, Robert Coury, got even more. He made more than $22.5 million in 2014 alone.

After the public backlash to Mylan's most recent price increase, they announced they would expand their patient assistance program. We've heard that one before. This is the same PR playbook other companies use. When your price increases, finally spark public outrage, just say you're expanding your patient assistance programs and make as much money as you can along the way. That's what Martin Shkreli did, that's what Valeant did, and that's what Mylan is doing.

Here's the bottom line. I begged Martin Shkreli to use whatever influence he still had over his company to lower their prices. I pleaded with Valeant's executives to lower their prices. I called on Mylan to reverse its drastic increases. But they all refused.

They talk about discounts and coupons and rebates, but even with withering bipartisan criticism from Congress and desperate outcries from the American people—and, by the way, the American people that all of these folks up here represent, every single person up here has somebody that's affected by this—they never, ever, never lowered the prices.

I'm concerned that this is a rope-a-dope strategy. Today, we'll hold yet another hearing where the industry will take their punches, but then they go right ahead and keep on raising their prices. I'm sure somebody said to them: You know, look, you just go in there, the Congress is going to be upset with you, but afterwards, you're just going to come out of there, and we'll just keep raising prices, we'll keep doing it.

After Mylan takes our punches, they'll fly back to their mansions in their private jets and laugh all the way to the bank while constituents suffer, file for bankruptcy, and watch their children get sicker or die. That's what we're dealing with today.

Yesterday, someone asked me if I wanted the head of Mylan to apologize today. I had to think about that for a minute. I think it would be more appropriate, it would be nice if she did. But that will not cause Mylan to treat my constituents fairly and bring down the price to where it should be.

We need solutions, I agree, Mr. Chairman, and I'm glad that this is a bipartisan effort. It's time for Congress to act. We will hold today's hearing just like we held our previous hearings.

And to our witnesses, when we had Mr. Shkreli before us, he said something that was very interesting, and for some reason, Mr. Chairman, I think about it over and over and over again. As soon as he got out of the hearing, you know what he called us? Imbeciles. He said every Member of Congress is an imbecile.

You know why he said that? Because he knew they would go back and do the same thing over and over again. So he took his punches. He rope-a-doped. As a matter of fact, he did worse than that, he took the Fifth. And the prices kept on going on up.

And so I beg all of our colleagues to take just a moment. This is our moment. If there's going to be something that we do in a bipartisan way, this is it, as the chairman said, and I watched the chairman in an interview yesterday. And I can tell that he and I were getting a little bit emotional. You know why? Because we were thinking about children. We were thinking about children who may have some kind of spell and need this just to breathe.

So I hope, after the hearing is over, that you just don't go back to the champagne, say: All right, we rope-a-doped it, and now we go on to life as it was. Because our constituents deserve better.

And with that, Mr. Chairman, I yield back.

Chairman CHAFFETZ. I thank the gentleman.

We'll hold the record open for 5 legislative days for any members who wish to submit a written statement.

We'll now recognize our panel of witnesses. We're pleased to welcome Dr. Douglas Throckmorton, deputy director of the Center for Drug Evaluation and Research at the United States Food and Drug Administration, and Ms. Heather Bresch, chief executive officer of Mylan.

We welcome you both, and thank you for being here.

Pursuant to committee rules, all witnesses are to be sworn before they testify. If you will please rise and raise your right hand.

Do you solemnly swear or affirm that the testimony you're about to give will be the truth, the whole truth, and nothing but the truth?

Thank you. You may be seated.

And let the record reflect that both witnesses answered in the affirmative.

We would now like to recognize you each for 5 minutes. We'll be liberal in the time. If you want to go a bit longer than 5 minutes, that's fine. But we want to make sure we maximize the time for members asking questions. Your entire written statement will be entered into the record.

Dr. Throckmorton, you are now recognized for 5 minutes.

WITNESS STATEMENTS

STATEMENT OF DOUG THROCKMORTON

Dr. THROCKMORTON. Thank you, Chairman Chaffetz, Ranking Member Cummings.

Chairman CHAFFETZ. Bring that microphone way up close. We're going to ask you some questions. Bring it uncomfortably close.

Dr. THROCKMORTON. All right.

Chairman Chaffetz, Ranking Member Cummings, members of the committee, I am Dr. Douglas Throckmorton, deputy district for regulatory programs in the Center for Drug Evaluation and Research at the FDA. Thank you for this opportunity to appear before you today to discuss FDA's role in ensuring the safety, efficacy, and availability of epinephrine auto-injectors.

As Chairman Chaffetz said, epinephrine auto-injectors, with the most widely used and recognizable product being Mylan's EpiPen, are critically important and potentially life-saving for patients who suffer from a severe allergic reaction called anaphylaxis. When a patient requires this medication, seconds count, and it must work every time. To ensure this, it is critical that both the medication and the device that delivers it perform as designed.

At the FDA, we are aware of the recent spikes in the price of EpiPen. In fact, I am personally aware of it as my son carries an epinephrine auto-injector for his allergies.

Although FDA does not have a regulatory role in the pricing of drug products, we do play a critical role in ensuring that patients have access to beneficial medicines. We also recognize that when more than one version of a drug, especially a generic version, is approved, it can improve marketplace competition and help to provide additional options for consumers.

With this role in mind, FDA is working hard to support the timely, scientific, and efficient development of new epinephrine auto-injector products.

I should first note that EpiPen is not the only product approved to treat anaphylaxis in an emergency. To date, FDA has approved four products to treat anaphylaxis, two of which are currently on the market.

While doing what we can to support new epinephrine auto-injector product development, FDA cannot approve a product for which we haven't received an application, which is why we're doing all we can to support manufacturers as they work to develop innovative new products, including new epinephrine auto-injector products, and bring them to market faster.

For example, in 2013, the agency provided technical information to industry to design and test auto-injectors. More recently, this year we released draft guidance on how to determine whether these devices can be used effectively by patients.

These efforts can help development by providing a clear roadmap to reduce uncertainty that can slow development.

We also recognize the importance of generic drugs in the United States and are working in this area to support their development. For example, as a part of our larger work to improve the review and development of generic drugs, FDA's Office of Generic Drugs has a prioritization and expedited review policy that allows for cer-

tain products to get priority review, including products that are called, quote, "first generics."

To close, thank you for your interest in this important topic related to the safety, efficacy, and availability of epinephrine autoinjectors. FDA takes our role, our public health mission seriously, and is working hard to fulfill our role as it relates to this issue.

One critical part of this mission is to assure that the medical products on market are safe and effective and that they can be used as needed. In addition, as a part of our mission, FDA is also playing an important role in advancing public health by helping to speed innovation that promotes the wider availability of these products.

For complex medical products, such as epinephrine autoinjectors, this means providing a roadmap to developers seeking to market new products and working with them, whenever possible, in support of new product development. These efforts, coupled with the work of other groups with important roles to play, will help assure access to these important medicines for patients.

I'm happy to answer any questions that I can.

[Prepared statement of Dr. Throckmorton follows:]

Reviewing the Rising Price of EpiPens

Statement of Douglas C. Throckmorton, M.D.

Deputy Director for Regulatory Programs

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

U.S. Department of Health and Human Services

Before the
Committee on Oversight and Government Reform

U.S. House of Representatives

September 21, 2016

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Introduction

Good morning Chairman Chaffetz, Ranking Member Cummings, and members of the Committee. I am Dr. Douglas Throckmorton, Deputy Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to appear today to discuss FDA's role in ensuring the safety, efficacy, and availability of pharmaceutical products, such as epinephrine auto-injectors and generic drugs.

Although FDA does not have a regulatory role in the pricing of drug products, we do play a critical role in ensuring patients have access to beneficial medicines. We also recognize that when more than one version of a drug, especially a generic version, is approved, it can improve marketplace competition and help to provide additional options for consumers. With this role in mind, and as I discuss more fully below, FDA is working hard to support the timely, scientific, and efficient development of new epinephrine auto-injector products.

Overview of the Epinephrine Auto-Injector Market

Epinephrine auto-injectors are a critically important, and potentially life-saving, product for patients who suffer from a severe allergic reaction called anaphylaxis. The most widely used and recognizable product is Mylan's EpiPen. When a patient requires the medication, seconds count, and the epinephrine auto-injector must work every single time. To ensure this, it is critical that both the drug, and the device that delivers the drug, perform as designed.

As a father, I am personally aware of these issues, as my son carries an epinephrine auto-injector for his allergies.

FDA has approved four epinephrine auto-injector products to treat anaphylaxis; two of which are currently on the market. While there are currently no FDA-approved generic epinephrine auto-injectors, we stand ready to quickly review additional applications that come to us from both generic and innovator drug companies. Mylan's EpiPen is the market leader for epinephrine auto-injectors in the United States, and Mylan has recently publicly announced they also will

offer an authorized generic version[1] to be available in the near future. Another firm, Amedra, holds an approval for Adrenaclick, which is also an epinephrine auto-injector. Currently, while the Adrenaclick brand name product is not being marketed, Amedra is marketing its own authorized generic version of the drug. Amedra also previously marketed Twinject under a different approval from FDA, but this product is currently discontinued. Finally, FDA also approved Auvi-Q as an epinephrine auto-injector, although this product was voluntarily recalled from the market in 2015 by Sanofi. We note that Auvi-Q was recently purchased by Kaleo, though this product has not yet returned to the market. In support of increasing the number of safe and effective epinephrine auto-injector products on the market, FDA is working with both Amedra and Kaleo to facilitate the availability of their products.

FDA Efforts In Support Of Epinephrine Auto-Injector Review and Development

In addition to the work that FDA does with individual companies to support their development of specific products, FDA also works to create a publicly-available roadmap describing what companies need to do to bring various types of medical products to market. EpiPen and other epinephrine auto-injector products are considered combination products; that is, these products consist of a drug component and a device component. Because the drug has the primary role in treating the patient, CDER has the lead in regulating these products, with technical input on the device aspects provided by colleagues at the Center for Devices and Radiological Health (CDRH).

FDA understands that development of combination products can be more challenging than for typical drug products, so we have taken a number of steps to help guide industry through the

1. An 'authorized generic' is made under the brand name's existing new drug application using the formulation, process, and manufacturing facilities approved for use by the brand name manufacturer. The labeling is changed to remove the brand name or other trade dress. An authorized generic is not synonymous with an FDA-approved generic, the latter of which requires a separate application and approval from that of the brand name product.

process. First, FDA is continuing to develop, publish, and update guidance documents, which are a kind of roadmap for industry sponsors, explaining FDA's recommendations for the kind of information that should be included in a marketing application.

For example, in February 2016, FDA issued a draft Guidance on *Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development*,[2] which describes the different kinds of human factors studies that may be appropriate for certain combination products, including drugs and biologics delivered by auto-injectors. Human factors studies are conducted to better understand how healthcare providers or patients interact with a product's technology and to understand how the user interface affects the quality, experience, and outcomes of that interaction. These kinds of studies, while not recommended for every product, can be important to FDA's evaluation of the device component of a drug-device combination product by helping to determine whether these complex devices can be used by patients. In addition, in June 2013, the Agency finalized a Guidance that provides technical information to industry about designing and testing auto-injectors.[3]

Guidance documents can provide vital information to drug and device developers for a class of products. FDA recognizes that for more complex products such as epinephrine auto-injectors that contain a drug and a device component, in addition to guidance, one-on-one advice may be needed for sponsors seeking to develop complex products so FDA can address technical and regulatory questions about the pathway to market. Such meetings occur now for both new drugs and generic drugs under development. In addition, FDA regularly responds to specific product-development questions from industry in writing to help companies develop generic drug applications through the process known as Controlled Correspondence. We hope to expand our ability to engage with generic product sponsors through a reauthorization of the Generic Drug

2. *http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM484345.pdf*

3. *http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM147095.pdf*

User Fee Amendments (GDUFA II), where complex product meetings have been described as a key provision of the proposed program.

Further, FDA prioritizes the resources we make available to focus on areas of high public health needs. For example, FDA's Office of Generic Drugs (OGD) has a prioritization and expedited review policy for certain generic drug applications. The policy is set forth in a publicly available document called a Manual of Policy and Procedures (MAPP), which can be found on the FDA website. Pursuant to OGD's prioritization policy, Abbreviated New Drug Applications (ANDAs) for drugs that have "first filer" status or that otherwise are eligible to be the first generic approved are prioritized and given expedited review.

Each of these, and other efforts of FDA, help clarify our expectations and prioritizations concerning specific products so industry can develop and obtain approval of generic versions of branded drugs more quickly.

While FDA is working to lay out a roadmap to support efficient development of complex products like drugs delivered using an auto-injector, consistent with FDA standards, we cannot and will not allow a substandard product, in this or any product area, to come onto the market. For these epinephrine auto-injector products, a patient suffering a life-or-death allergic reaction must be able to pick up and effectively use that device without a moment's hesitation.

The remainder of my statement provides additional information about two factors that influence the development of drug products, including epinephrine auto-injectors, as well as a brief discussion of the limited FDA role in the intellectual property issues that can influence drug development.

Abbreviated Pathways to Approval

There are two abbreviated approval pathways established by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act allowing for the approval of drug products. The first is the approval of ANDAs, and drug products approved under this pathway are commonly

referred to as generics. Unlike an innovator drug application, a generic drug application does not need to independently establish the safety or effectiveness of the drug. Instead, the generic drug has to show that it is the same as an innovator product in several fundamental ways, such as in active ingredient, dosage form, route of administration, strength, and labeling (except for certain permissible differences in labeling); that the generic drug is absorbed and available at the site where it will act in the body at the same rate and to the same extent as the innovator drug (which is known as bioequivalence); and that it meets the same high standards for drug quality and manufacturing as an innovator product. If the ANDA meets these requirements, the generic applicant can rely on FDA's previous finding of safety and effectiveness of the branded drug product, and need not conduct its own clinical investigations to establish safety or effectiveness.

FDA approval of an ANDA indicates that FDA considers the generic product to be therapeutically equivalent to the branded drug product. This means that the Agency has concluded, among other things, that the generic and branded products can be substituted with the full expectation that the generic product will produce the same clinical effect and safety profile as the innovator product when administered under the conditions specified in the labeling. Therapeutic equivalence ratings are published by FDA in what is commonly known as the "Orange Book." Although FDA does not itself determine when a pharmacy would substitute a generic product in filling a prescription, state pharmacy laws and other regulations that determine substitutability often refer to these "Orange Book" ratings.

The Hatch-Waxman Amendments also established a second abbreviated pathway for drug applications. This pathway, commonly referred to as the "(b)(2) pathway," can be thought of as a hybrid between the pathway for an entirely innovative product and the ANDA pathway for a generic drug. In contrast to an ANDA, a (b)(2) application is submitted in a new drug application and can be submitted for a proposed drug product that differs in certain ways from the previously approved branded drug product, differences that are generally outside those permitted for an ANDA product. For example, the drug product can share common attributes like active ingredient and dosage form with an innovator product, but be approved for a new use. This allows for a shorter approval pathway where applicants also have the flexibility to propose drug products that differ from the branded product in ways generally not permitted in the case of

an ANDA. Unlike generic drugs, products approved under the (b)(2) pathway on approval are not presumed to be therapeutically equivalent to the branded product and, if a (b)(2) applicant seeks a determination of therapeutic equivalence, it must demonstrate this separately.

Drug products for which the sponsor has submitted all of the needed safety and effectiveness information, as well as those approved under the (b)(2) pathway, are approved as New Drug Applications (NDAs). None of the currently approved epinephrine auto-injector products have been approved as generic drugs under the ANDA pathway. We also note that none of the currently approved epinephrine auto-injectors have been rated as therapeutically equivalent to EpiPen. Nonetheless, while generic drug products approved under ANDAs may have a greater impact on competition in the marketplace than competing products approved under NDAs, similar products approved under NDAs can also increase competition in the marketplace.

FDA's Role in the Intellectual Property Landscape

Although FDA can and does encourage generic drug development, and has and continues to streamline and improve its review and approval of generic drug applications, the decisions of whether to seek approval for a proposed generic drug and whether to market an approved generic drug are controlled by the generic drug industry. Further, the extent to which the approval or marketing of generic drugs is delayed because of intellectual property rights or marketing exclusivities is largely controlled by branded-drug manufacturers and others that hold those rights.

With respect to patents, FDA has only a "ministerial" role. First, sponsors of innovator products must submit information regarding certain patents related to their products to FDA. FDA lists these patents, such as those for Mylan's EpiPen, in the "Orange Book." In any application that seeks to rely on a previously approved NDA, which includes (b)(2) applications and generic drug applications, the applicant must describe whether it intends to challenge those listed patents in court.

As drug applicants often publicly acknowledge, they routinely take the intellectual property rights of previously approved drug products into account when making determinations regarding the design and development of their proposed drug products. While our approval standards are the same whether or not an applicant designs its proposed product around a competitor's intellectual property rights, the proposed products that FDA receives for review and consideration for approval are no doubt impacted by patent considerations.

Conclusion

Thank you for your interest in the important topic of the safety, efficacy, and availability of epinephrine auto-injectors. FDA takes our public health mission seriously and, as discussed above, is working hard to fulfill our role as it relates to this issue. In addition to working to assure the safety and efficacy of life-saving products like epinephrine auto-injectors, it is critical that they be made to high quality standards to ensure they will work as needed. As a part of our mission, FDA also has an important role to play in advancing public health by helping to speed innovations that make medicines more effective, safer and more affordable. For complex medical products such as epinephrine auto-injectors, this means providing a roadmap to developers seeking to market new products and working with them wherever possible in support of new product development. As a part of this work, FDA understands the importance of generic products in the U.S. marketplace. We hope that our efforts, coupled with the work of other groups that also have roles to play, will continue to ensure medications are readily available to patients. I am happy to answer any questions.

Douglas Throckmorton, M.D., Deputy Center Director for Regulatory Programs

As Deputy Director for Regulatory Programs, Dr. Throckmorton shares the responsibility for overseeing the regulation of research, development, manufacture and marketing of prescription, over-the-counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks.

Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to the FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital. He is a board-certified physician.

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Chairman CHAFFETZ. Thank you.

Ms. Bresch, you're now recognized.

STATEMENT OF HEATHER BRESCH

Ms. BRESCH. Good afternoon, Chairman Chaffetz and Ranking Member Cummings and members of the committee. I'm Heather Bresch, the CEO of Mylan, and I appreciate the chance to be with you today.

Before I answer your questions, I would like to share with you a little information on my background in Mylan and tell you what we have done in the last weeks to address the concerns about the price and the availability of EpiPens.

I grew up in a small town in West Virginia in a close family with a strong work ethic. I joined Mylan in 1992 as an entry-level clerk performing basic administrative tasks in the basement of the company's manufacturing facility and worked through 15 different roles in the company until I reached my current position.

When I started with Mylan, our sales were approximately $100 million with less than 500 employees, and today our sales are in excess of 11 billion with more than 40,000 employees, and 1 in 13 U.S. prescriptions is filled with one of Mylan's medications.

I would like to highlight just two facts about Mylan. First, we aren't the kind of niche pharmaceutical company that offers only a handful of products. In fact, we are the exact opposite. Over the last 55 years, we have grown to offer more than 2,700 products, predominantly generic, made at more than 50 manufacturing facilities capable of producing up to 80 billion doses annually, and we see the need to do more.

This year alone we will invest approximately 1.2 billion in research and development and manufacturing, or roughly 3 million a day, to bring affordable access to many more complex products such as insulins and biosimilars.

Second, our business is predicated on high volumes of hundreds of products. In the U.S. alone, we offer a portfolio of 635 products, which translated last year to more than 21 billion doses available to patients, at an average price to Mylan of 25 cents. Over the last decade, Mylan's medicines have reduced the U.S. healthcare costs by approximately 180 billion.

This is an EpiPen. It may look simple, but it is actually quite complex. In the event of anaphylaxis, a severe allergic reaction, the more than 15 critical components in this device must work every time, and in seconds, to deliver medicine to treat life-threatening symptoms quickly and without fail, many times self-administered by the person in the state of anaphylaxis.

Before Mylan acquired the company that owned EpiPen in 2007, fewer than 1 million of the 43 million people at risk had access to an epinephrine auto-injector. At the same time, it was estimated that anaphylaxis was causing 1,500 deaths annually. We've read stories of children dying at school because they did not have access to an epinephrine auto-injector or due to a lack of education about the need. We saw this as an unacceptable and largely preventable health problem.

We've worked diligently and invested to enhance EpiPen and make it more available. In fact, we have invested more than $1 bil-

lion in these efforts over the last few years and have succeeded on many fronts. We put an improved EpiPen device on the market in 2009. We now reach 80 percent more patients. And today, approximately 85 percent of EpiPen patients pay less than $100 for two and a majority less than $50.

We have made great strides in providing access to EpiPens in public places, starting with schools. In the last 4 years alone, Mylan provided 700,000 free EpiPens to more than 66,000 schools across America with no strings attached. Our pens were used hundreds of times, including on many children who had no known allergies.

I know there is considerable concern and skepticism about the pricing of EpiPens, and I think many people incorrectly assume that we make $600 off of each pen. It's simply not true. Recent EpiPen price increases have not yielded the revenue to Mylan that many assume.

In the complicated world of pharmaceutical pricing, there is something known as the wholesale acquisition cost. Since 2014, the wholesale acquisition cost for two EpiPens increased from 401 to 608, or 51 percent. But the net revenue to Mylan, after rebates and fees, what we actually received, increased from 235 to 274. In other words, the annual increase to Mylan for the last 2 years was approximately 8 percent per year, or 16.6 percent cumulatively, during this period.

From that, you must subtract our cost of goods, which is $69. This leaves a balance of $205. After subtracting EpiPen-related costs, our profit is $100, or approximately $50 per pen.

In the last few weeks, we have confronted the EpiPen issue head on. Our program has four parts. We announced the first-ever generic of the EpiPen product, which will be priced at $300. This unprecedented move is the fastest and most direct way to reduce the price for all patients.

Second, we are creating a direct-ship option, allowing patients to purchase the generic product directly from Mylan.

Third, we increased our EpiPen savings card for the brand product from 100 to 300.

And fourth, we doubled our eligibility of patients receiving free pens from 48,600 to 97,200 for a family of four.

With these changes, our profit per pen will be substantially lower than it is now.

I'm honored and proud to be the CEO of Mylan, and I've spent my entire career working to break down barriers to access and expand access to high-quality medicine and lower healthcare cost. I wish we had better anticipated the magnitude and acceleration of the rising financial issues for a growing minority of patients who may have ended up paying the full wholesale acquisition cost or more. We never intended this. We listened and focused on this issue and came up with an immediate and sustainable solution.

Going forward, we will continue our leadership in developing high-quality medicine and expanding access.

Thank you.

[Prepared statement of Ms. Bresch follows:]

Testimony of Mylan CEO Heather Bresch before the United States House of Representatives Committee on Oversight and Government Reform

Wednesday, September 21, 2016

I'm Heather Bresch, the CEO of Mylan.

I appreciate the chance to be with you today. Before I answer your questions, I would like to share with you some information on my background and Mylan, and tell you what we have done in the last few weeks to address concerns about the price and availability of EpiPen® Auto-Injectors.

I grew up in a small town in West Virginia, in a close family with a strong work ethic. I joined Mylan in 1992 as an entry level clerk, performing basic administrative tasks in the basement of the company's manufacturing facility.

I've worked in 15 different roles since joining the company. When I started with Mylan, our sales were approximately $100 million. Today, our sales are in excess of $11 billion, and 1 in 13 U.S. prescriptions is filled with one of Mylan's medications.

I'm proud to be the CEO of Mylan, but I never expected to be here under these circumstances—discussing the price of EpiPen Auto-Injectors. I've spent my entire career working to break down barriers, expand access to high quality medicines and lower healthcare costs.

As with anyone, our record isn't perfect - and I know you have many important questions you want to ask - but what's also extremely important is the tremendous amount of good Mylan has done for millions of patients in the U.S and around the world.

I want to highlight two facts about Mylan. First, we aren't the kind of niche pharmaceutical company that offers only a handful of products. In fact, we are the exact opposite. Today, we offer more than two thousand, seven hundred different products. Over the last 55 years, we have grown to more than 40,000 employees, with more than 50 manufacturing facilities, capable of producing up to 80 billion doses annually.

As primarily a generic pharmaceutical company, we must invest heavily in research and development and manufacturing in order to produce billions of doses and bring hundreds of new products to market every year. This year, for example, we will spend approximately $1.2 billion on R&D and manufacturing facilities, or roughly $3 million per day.

Second, our business is predicated on high volumes of hundreds of products. In the U.S. alone, we offer a portfolio of 635 products, which translated last year to more than 21 billion doses made available to patients, at an average price to Mylan of 25 cents per

dose. Over the last decade, Mylan's medicines reduced U.S. healthcare costs by approximately $180 billion.

This is the EpiPen device...

It may look simple, but it is actually quite complex. In the event of a severe allergic reaction, the more than 15 critical component parts in this device must work EVERY TIME...IN SECONDS...to deliver medicine to treat life threatening symptoms quickly and without fail.

For millions of families, the presence of an EpiPen Auto-Injector in a purse, briefcase, backpack or medicine cabinet is a source of enormous comfort and an invaluable insurance policy against a potential tragic event.

It troubles me greatly that the EpiPen product has become a source of controversy. I understand the focus of this hearing is primarily about our pricing of EpiPen Auto-Injectors. I'm prepared to address that issue in depth. At the same time, the issue of EpiPens has two equally critical dimensions - price and access. With the current focus on pricing, I'm very 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. At the same time, it was estimated that anaphylaxis was causing 1,500 deaths annually, or more than 4 per day. And many people who suffer a severe allergic reaction requiring epinephrine had no known history of a severe allergy. We read stories of children dying on playgrounds because schools didn't have access to epinephrine to use on children without a prescription in their name. We saw this as an unacceptable and largely preventable health problem.

In the more than 8 years we have owned the EpiPen product, we have worked diligently and invested to enhance the product and make it more available. In fact, we have invested more than one billion dollars in the efforts. On many fronts we have succeeded. We put a much improved EpiPen device on the market in 2009. We've also invested so that we can soon offer a longer shelf life, which means patients will go longer before needing a refill.

We have now reached 80% more patients. And today, approximately 85 percent of EpiPen patients pay less than $100 for a 2 unit package and a majority pay less than $50.

And we've made great strides in providing access to EpiPen Auto-Injectors in public places, starting with schools. In the last four years alone, Mylan provided seven hundred thousand free EpiPen Auto-Injectors to more than 66,000 schools across America, with no strings attached.

I hope these facts will be considered in the larger discussion about price. Price and access exist in a balance, and we believe we have struck that balance. But we don't want to go back to a time - not that long ago - when awareness of anaphylaxis was much lower and epinephrine auto injectors were only available in schools with a prescription for an individual child. Achieving this level of expansion of awareness requires significant investment.

I know there is considerable concern and skepticism about the pricing of EpiPen Auto-Injectors. I think many people incorrectly assume we make $600 off each EpiPen. This is simply not true.

In the complicated world of pharmaceutical pricing there is something known as the Wholesale Acquisition Cost or WAC. The WAC for a 2 unit pack of EpiPen Auto-Injectors 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.

The misconception about our profits is understandable, and at least partly due to the complex environment in which pharmaceutical prices are determined. The pricing of a pharmaceutical product is opaque and frustrating, especially for patients.

In the last few weeks, we've confronted the EpiPen issue head on. Our program has four parts:

We announced the first ever generic version of the EpiPen product, which will be priced at $300. This unprecedented move is the fastest and most direct way to reduce the price for all patients.

Second, we are creating a direct ship option, allowing patients to purchase the generic product directly from Mylan for $300.

Third, we increased our My Epipen Savings Card program benefit for the brand product from $100 to $300.

Fourth, we doubled the eligibility of patients receiving free pens from $48,600 to $97,200 for a family of four.

Looking back, I wish we had better anticipated the magnitude and acceleration of the rising financial issues for a growing minority of patients who may have ended up paying the full WAC price or more. We never intended this. We listened and focused on this issue and came up with a sustainable solution.

I understand your concern about EpiPen Auto-Injectors, but I ask that you look at our overall record for this patient population and our response to the challenge.

Going forward, we will continue our leadership in developing high quality medicines and expanding access.

Chairman CHAFFETZ. Thank you. I'll now recognize myself.

Ms. Bresch, you never anticipated it? You raised the price. What did you think was going to happen?

Ms. BRESCH. Well, thank you, Chairman.

We raised the price over 8 years. And we raised that price, and I think what is incorrectly assumed is that 608 is what Mylan receives. We receive $274 of that 608.

Chairman CHAFFETZ. So here is what I don't understand. Explain to me, when you buy the generic version, what's the difference in the generic version? Is it just the name?

Ms. BRESCH. It will be the same product with epinephrine autoinjector on it. It will be the same product.

Chairman CHAFFETZ. So suddenly it's $608. Now you're going to have a generic of the generic, and that's going to be $300?

Ms. BRESCH. Yes.

Chairman CHAFFETZ. And if they spend 300, I'm sorry, they get two?

Ms. BRESCH. Yes.

Chairman CHAFFETZ. So your revenue is actually going to go up on the direct product because you say you only get $275 now. You're going to get $300, correct?

Ms. BRESCH. Well, I think the direct ship will be a very—we're trying to do that in case—to catch everybody. We're hoping that at least 85 to 80 percent——

Chairman CHAFFETZ. You're actually raising the price. You're actually raising the price.

Ms. BRESCH. No, sir. Our net——

Chairman CHAFFETZ. You're going to have more revenue.

Ms. BRESCH. Our net sales will absolutely go down. Our net per pen will go down dramatically.

Chairman CHAFFETZ. How does your net per pen go down when you're collecting, as you say, I don't know that I believe you, but $274, and under the direct program you're going to collect $300?

Ms. BRESCH. But from that then you take the cost of goods out, which is $69, and then——

Chairman CHAFFETZ. Which is the same on both.

Ms. BRESCH. And then you take out the EpiPen drug-related product.

Chairman CHAFFETZ. Wait a sec, Ms. Bresch, come on, you're very bright here. If you're collecting $274 or $275 for two right now, and you're going to do the generic to save people money, you're going to charge $300, your revenue goes up. How does it go down?

Ms. BRESCH. But that's not—we said that will be the wholesale acquisition cost, is 300. We've cut the wholesale acquisition cost in half from 300——

Chairman CHAFFETZ. And the only thing you changed was the name. The only thing you changed is the name. This is why we don't believe you, is that if the price goes from 608 to 300, your collection on that is actually higher, and you're telling me that your net profit is going to go down?

Ms. BRESCH. Sir, what I'm saying is the wholesale acquisition cost—and I know I've provided this, too, if you want to put it up—the wholesale acquisition cost is what is going to 300. What we will

actually receive we're estimating at 200, we believe it will be less than that, just as what we receive is the 274.

Chairman CHAFFETZ. You said you're going to sell it direct.

Ms. BRESCH. We offer that as an option. There's still——

Chairman CHAFFETZ. How much does that cost to a consumer? $300 is what you told us.

Ms. BRESCH. Sir, we hope that everybody will get it through the channels of the—all of the programs. The patient reduces the cost for everybody across all the channels.

Chairman CHAFFETZ. Wait, wait, the patient reduces the cost. Explain that to me.

Ms. BRESCH. By introducing a generic, which truly is unprecedented, I mean, we cut the price in half, so I know that——

Chairman CHAFFETZ. Well, it's unprecedented to raise the price $500—or 500 percent. So you're raising it to lower it, but your net revenue goes up. How can you claim it goes down?

Ms. BRESCH. What we receive is the 200, and we're estimating that.

Chairman CHAFFETZ. You said you're telling it direct for 300.

Ms. BRESCH. We said that the wholesale acquisition price would be 300.

Chairman CHAFFETZ. You've got to help clarify this for us because this does not make sense. And I don't know how you suddenly offer that generic.

Let me go to Dr. Throckmorton for a second.

What is the current FDA backlog overall, not just for the epinephrine, overall what is the current backlog on the drug approvals at the FDA?

Dr. THROCKMORTON. Currently there are around 2,300 abbreviated new drug applications that we are reviewing. That is not backlog. The backlog I believe you're referring to would be the products that were in the queue prior to 2012, prior to the passage of the——

Chairman CHAFFETZ. And what's that number?

Dr. THROCKMORTON. The number of products that were in the queue in 2012 that remain unreviewed, less than 100. We have reviewed well over 90 percent of those products and provided feedback to the sponsors.

Chairman CHAFFETZ. How many epinephrine-oriented products are in the pipeline right now?

Dr. THROCKMORTON. I can't answer that question, I'm afraid, Congressman. I can tell you that——

Chairman CHAFFETZ. No, no, no, wait. Do you know that number?

Dr. THROCKMORTON. I do not know that number right now, sir.

Chairman CHAFFETZ. We're having a hearing about this. Do you know that number?

Dr. THROCKMORTON. What I can tell you is——

Chairman CHAFFETZ. Look, here's the thing. They may tell you at the FDA: Hey, we don't ever talk about this. I don't care, okay. Congress doesn't care about that. I want to know how many epinephrine-oriented products are in the queue right now.

Dr. THROCKMORTON. I wish that I could answer that question, sir, but——

Chairman CHAFFETZ. When can you give me that answer?

Dr. THROCKMORTON. I can get back whatever information I can to you as quickly as I can.

Chairman CHAFFETZ. Are you going to get back the answer to the question I asked?

Dr. THROCKMORTON. I'll be able to provide whatever information I can.

Chairman CHAFFETZ. Are you going to answer the question that I asked?

Mr. LYNCH. Mr. Chairman.

Chairman CHAFFETZ. Yes. Mr. Lynch.

Mr. LYNCH. Just on a parliamentary inquiry. We've done this before with witnesses, we give them 5 minutes to go out in the hallway there and call the people at his office and get that answer for you. I think it's a pertinent question and you should have an answer.

I yield back.

Chairman CHAFFETZ. How hard is it to get this answer? Who knows that answer?

Dr. THROCKMORTON. It's simply a legal answer. I'm not allowed to——

Chairman CHAFFETZ. It's simply a what?

Dr. THROCKMORTON. A legal answer. I'm not allowed to disclose commercial confidential information in this setting. And my understanding is that——

Chairman CHAFFETZ. Let me talk about it with staff here as this hearing progresses. I don't want to slow it down for just that. But it is a question we want to understand the answer to, and I do think we should be able to get this.

Last question, Ms. Bresch. This came up late in the process. It was a surprise to us. But can you explain or clarify, from your own vantage point, the role that your mother played in this process? I mean, we're reading these articles that seem sensational. I don't know what's true, what's not true. I'm giving you an open-ended opportunity to express your version of what is going on there.

Ms. BRESCH. And I greatly appreciate that. The article is completely inaccurate.

We, Mylan, when we acquired this product and realized the complete lack of awareness and access to the product, and the fact that public places, let's take schools, that if a child at a school or on a playground were to go in and have a severe allergic reaction, go into anaphylaxis, and if that child didn't have a prescription in their name at that school, the school couldn't use it.

So there were deaths in schools happening because there may have been EpiPens or other epinephrine auto-injectors, but they weren't allowed to be used, and children, like I said, tragically died.

We saw this as unacceptable. So there had only been a handful of States that had started to recognize that epinephrine auto-injectors could be in a public place in a school's name, not in a child's name, therefore, the nurses and trained administrators could use it in the case of a tragic event.

We then started helping, and I applaud the Federal legislatures as well as State legislatures who quickly recognized these tragic

events and that they could be largely preventable, and legislation began to get passed to allow schools to stock epinephrine.

We then launched our EpiPen for Schools program, which, as I said, we've given 700,000 free pens to over 66,000 schools with no strings attached, and I hope that one of the benefits of this would be that the other 65,000 schools will participate and receive free EpiPens.

During this period of time, you know the burden on schools from a policy perspective, training perspective, so we gave amounts to various groups, whether it was the National School Board, National Education Association, National School Nurses, that we could help, and only helping to fund them train personnel and educate so that people could recognize an anaphylactic event and know how to use and know how to administer product.

My mother has dedicated her life to education, has been a volunteer for years, and rotated 1 year into the president of the National School Board in 2012, and then rotated out. We have continued to work with these organizations to continue to help train and educate.

So while people may want to criticize Mylan for giving free pens and having access in public places to EpiPens, I certainly thought it was a very cheap shot to bring my mother into this.

Chairman CHAFFETZ. I now recognize Mr. Cummings.

Ms. BRESCH. Thank you.

Mr. CUMMINGS. Thank you very much.

Ms. Bresch, on August 29, the committee sent you a bipartisan request for documents. We included a simple request, and I quote, "We ask for the company's profits from the sales of EpiPen for each year since acquisition," end of quote. Do you recall getting that? Did you see that?

Ms. BRESCH. Yes, sir.

Mr. CUMMINGS. Ma'am?

Ms. BRESCH. Yes, sir.

Mr. CUMMINGS. Your company has started to produce documents, and we appreciate that. We now have information about your marketing expenses and a number of other costs.

But one thing that is absent, Ms. Bresch, from your document production is your profits for each year. Given how much you are now charging for EpiPen, I think the American people have a right to know how much you and your fellow executives are making off of the exorbitant prices you're charging for this drug.

So let's start with last year. I see you've got all kinds of charts, so maybe this is on one of those charts. How much profit did you make in 2015 from the sale of EpiPens? In 2015.

Ms. BRESCH. So, sir, what I think we provided is what I did as in my testimony, is that about $50 per pen is our profit, and that's just direct EpiPen. It's not taking any kind of company allocation or anything else out of that other than just direct related EpiPen cost.

Mr. CUMMINGS. Have you got a number for me? How many did you sell?

Ms. BRESCH. We sold—I'll give you, roughly, over the last 12 months number, roughly, about 4 million packs of two. So 8 million pens, but 4 million packs of two.

Mr. CUMMINGS. Okay. And according to the documents, you had net revenues of $912 million in 2015 for EpiPens, and that was after all rebates and discounts. Is that right?

Ms. BRESCH. Yes, sir. What we recognize is the $274 per pen, and so our revenue is calculated on that average of what Mylan receives.

Mr. CUMMINGS. And so according to these documents, you spent $97 million on marketing in 2015 alone, and that is a huge amount, and that's what the documents say. So that brings you to a number—your number down to about 815 million. Wouldn't you agree?

Ms. BRESCH. Sir, I'm not sure what documents or what you're—what I can confirm is that we absolutely have spent——

Mr. CUMMINGS. You don't know how much you're making off of these pens?

Ms. BRESCH. We've spent about a billion dollars on EpiPen since 2008.

Mr. CUMMINGS. So the next documents say you spent $255 million on costs of goods sold in 2015. So that brings the total to 560 million, and that's pretty simple math. So okay, so you have patient assistance programs and school-based programs for EpiPens, but the documents do not say how much you spent on them last year. So how much did you spend on those programs in 2015 for EpiPens?

Ms. BRESCH. Sir, I don't have the exact breakout, but, like I said, when I took the walk from 274 with cost of goods coming out at $69, which gets you to about the $205, and then down, about $105 for EpiPen-related costs, which is what takes you to the $100 for two or the $50 per pen of profit.

Mr. CUMMINGS. The fellow behind you is getting a chart, and maybe that will help us.

Ms. BRESCH. Okay.

Mr. CUMMINGS. So this is your biggest product. Is that right?

Ms. BRESCH. Yes, sir.

Mr. CUMMINGS. And are you telling me you don't know how much you spent on patient assistance programs and school-based programs last year? Is that what you're saying?

Ms. BRESCH. I just don't have it broken out. I said about $105 would be the EpiPen related, so all of those costs from marketing as well as the patient assistance program, and everything else that we spent on the product.

The disease awareness, we've done quite a bit on just anaphylaxis itself, that because there was such a low awareness of even what anaphylaxis was. Over the last 8 years, the ability to really be able to educate about not only is anaphylaxis something that is obviously life-threatening, but we now know that at least 25 to 30 percent of the time, when someone goes into anaphylaxis, they've never had a known allergy before, whether a child or adult, which really drove our need to want to get it in public places.

Mr. CUMMINGS. So that leads me to the next question. I know we've got some 43 million people that are a possible customer base, but let me ask you this. Let's talk about R&D. How much did Mylan spend on research and development projects that directly related to EpiPens in 2015?

Ms. BRESCH. Sir, actually we've spent over the years trying to do several things that failed and trying to——

Mr. CUMMINGS. Can we talk about 2015?

Ms. BRESCH. And we hope that within the next 12 months we'll have approved a new formulation that will extend the shelf life, which means——

Mr. CUMMINGS. That's not what I asked you. I said, how much did you spend on R&D in 2015? And I think the hearing is about EpiPens. And I've got to tell you, I talked about in my opening statement about rope-a-doping, that's what I'm feeling like. I mean, I feel like you're not giving me answers, ma'am.

And I think, in fairness to us, you knew what this hearing was about, you knew what our concerns were, and I just, I'm asking you questions that—you're the CEO?

Ms. BRESCH. Yes, sir.

Mr. CUMMINGS. That I would think you would know. I mean, seems like this stuff would be jumping out of the top of your head.

Ms. BRESCH. Sir, as a company, Mylan spent $750 million this year, is what we're projected to spend on R&D. For EpiPen it's not broke down so much in products.

What I can tell you is that our overwhelming majority of what we've spent has been on access and awareness programs. We have, like I said, we've been developing over the years, working on smaller different devices due to patient feedback. What we have been successful in is reformulating it so it will have a longer shelf life, and that will extend the time needed between refills.

But the majority of our——

Mr. CUMMINGS. Can we stop right there, right there?

Ms. BRESCH. Sure.

Mr. CUMMINGS. Let's put a pen in that one. This longer shelf life, how are we coming with that? Right now it's about a year. Is that right?

Ms. BRESCH. Eighteen months.

Mr. CUMMINGS. Eighteen months. So how long are we trying to get it up to? Because I heard that it was a year, but I'm glad to hear it's 18 months. But go ahead.

Ms. BRESCH. So——

Mr. CUMMINGS. What are your researchers—what are you projecting?

Ms. BRESCH. Twenty-four months is what we're hopeful for, and maybe even longer, but a minimum of 24 months.

Mr. CUMMINGS. How soon will we know, do you think? What do your researchers—since you're spending all this money on it, what are your researchers telling you, how soon do they say they'll have an answer?

Ms. BRESCH. Sir, we're looking to submit it within days to the FDA. We've been working on this for a couple of years. And it will be with 24 months that you do kind of—you continue to—after you submit it to the FDA, you're able to continue to work on stability, and that there is an opportunity that it could go longer. But we, at a minimum, 24.

Mr. CUMMINGS. I'm running out of time. I only have about a minute left. How about this? Would you agree that you made hun-

dreds of millions of dollars in profit in 2015 based on the sale of EpiPens alone?

Ms. BRESCH. Sir, we have an $11 billion company. I run an $11 billion company. And, yes, EpiPen is our largest product, but by no means driving the entire performance of our company.

Mr. CUMMINGS. Now, you answered my question. So you agree that you made hundreds of millions of dollars in profit in 2015 based on the sale of EpiPens?

Ms. BRESCH. Yes, sir.

Mr. CUMMINGS. Thank you.

Ms. Bresch, here is what—I'm almost finished—Ms. Bresch, here is what I want. I want you to produce to this committee a breakdown for each year for the past 10 years since you acquired this drug in 2007. I want you to include a detailed list of all your costs for each year, all of your expenses for each year, and all of your profits for each year for EpiPen. And that's what we asked for nearly a month ago.

And the chairman is real big on documents, and I am too, and we want to—it makes it—it's very unfair to us when we ask you for documents and we don't get what we want. Because what that means is, is that the hearing is over, as I said before, you go back, you fly back to wherever, you know, your company is, and we are then—we have then lost a chance to get the kind of information we need.

With that, I yield back.

Chairman CHAFFETZ. I thank the gentleman.

I now recognize the gentleman from Florida, Mr. Mica for 5 minutes.

Mr. MICA. Thank you, Mr. Chairman.

Dr. Throckmorton, there is no generic available for competition to the EpiPen, or is there?

Dr. THROCKMORTON. There is no generic product to any auto-injector formulation of epinephrine. The generic form that Ms. Bresch is talking about is a so-called authorized to generic, which, as has been previously characterized, is the brand name product marketed without the brand name on its label. That it is the generic the way we——

Mr. MICA. Do you have under consideration, I guess it would be public knowledge, anyone producing, attempting to produce generic competition?

Dr. THROCKMORTON. I think it's public knowledge that there are companies that are looking at that.

Mr. MICA. You would have to approve them. Do you have any being considered for approval now?

Dr. THROCKMORTON. I can't comment on any specific applications. I can tell you——

Mr. MICA. No, but do you have applications now?

Dr. THROCKMORTON. They would have to be approved by us.

Mr. MICA. How long have you had the applications?

Dr. THROCKMORTON. I'm not—I'm sorry, I can't comment.

Mr. MICA. You can't tell us.

Dr. THROCKMORTON. I'm sorry I can't comment about this.

Mr. MICA. Because we need to know. I mean, one way to bring the price down is to have competition. Wouldn't that be correct?

Dr. THROCKMORTON. I absolutely agree with that.

Mr. MICA. Can you let the committee know for the record how many applications you have—you don't even have to tell us the name—and how long you've had them and how long you've been processing?

Dr. THROCKMORTON. I'm sorry, I can't provide that information to you.

Mr. MICA. I can't—that's not acceptable, to come here on this subject and not have that answer.

So the pen is available, and I understand under the Affordable Care Act there is some exceptions to that. Is that correct?

Dr. THROCKMORTON. I'm sorry, I don't understand.

Mr. MICA. Under the Affordable Care Act, is the EpiPen available?

Dr. THROCKMORTON. Currently, there are two products that are available on the market. Both of them have been approved as new drug products. So the first is the EpiPen. The other is a product called Adrenaclick, which is another epinephrine auto-injector that prescribers can write for and is available through pharmacies.

Mr. MICA. How long would it take to get a generic approved and on the market?

Dr. THROCKMORTON. Beginning in October, on October 1, we've committed to 10-month review times for any new application. Some products——

Mr. MICA. I want to know how long you've had any applications. You can't tell me——

Dr. THROCKMORTON. I'm sorry, I can't provide that information, but I can tell you that in addition to the 10-month clock that we've committed to, beginning on October 1, some products that are particularly high public health value, including so-called first generics, are eligible for priority review. So those things would happen more quickly.

Mr. MICA. Thank you.

Ms. Bresch, in a media interview, you said: "As the health insurance environment has evolved, driven by the implementation of the Affordable Care Act, patients and families enrolled in high-deductible health insurance plans, who are uninsured, or who pay cash at the pharmacy, have faced higher costs for their medicine."

Is that correct?

Ms. BRESCH. Yes.

Mr. MICA. And the chairman talked and the staff had talked about the ingredients cost about a dollar. Is that correct?

Ms. BRESCH. No, sir, we pay $69 for the cost of goods, for the EpiPen.

Mr. MICA. $69.

Ms. BRESCH. For two.

Mr. MICA. For two. Is this your major profit center for the company?

Ms. BRESCH. So, sir, it represents——

Mr. MICA. Is this your major profit center?

Ms. BRESCH. It's our largest product.

Mr. MICA. Is it your major profit center?

Ms. BRESCH. So it's—we have, like I said——

Mr. MICA. It's your major profit center.

Ms. BRESCH. It's our largest product, but we have——

Mr. MICA. And one of the things that concerns us, some people can't get this for their family, their kids, the prices are high. There isn't competition, and then it's also reported that the top five executives within your company earned a collective $292 million from 2011 to 2015. Is that correct?

Ms. BRESCH. Sir, I think that there is——

Mr. MICA. Is that correct?

Ms. BRESCH. I don't——

Mr. MICA. Okay. Well, what's your salary, what was your salary last year?

Ms. BRESCH. About $18 million.

Mr. MICA. About $18 million. Sounds like you're doing pretty well on this.

How does your compensation compare to peers in the industry?

Ms. BRESCH. It's in the middle.

Mr. MICA. It's in the middle. So there are some with even bigger salaries?

Ms. BRESCH. Yes, sir.

Mr. MICA. Okay. Were your payments or executive compensation packages tied to the result of EpiPen sales?

Ms. BRESCH. No, sir. EpiPen's performance is a factor in Mylan's overall performance, but the board sets the compensation based on Mylan's overall performance.

Mr. MICA. My time is up, but I have other questions I'll submit to the witness.

Mr. WALBERG. [Presiding.] I thank the gentleman. The gentleman's time has expired.

I now recognize the gentlelady from the District of Columbia, Ms. Norton.

Ms. NORTON. Thank you, Mr. Chairman. I appreciate this hearing.

Could I ask you, Ms. Bresch, after an avalanche of criticism, perhaps the worst—and that is really saying something—of any pharmaceutical in recent memory, will you reverse the increase in price of EpiPens?

Ms. BRESCH. So, Congresswoman, thank you. We have, by the introduction of a generic, which has never been done before. I mean, an unprecedented event for a brand to cannibalize their own. So we—to $300.

Ms. NORTON. And that you did in response to the criticism. That's your response to the criticism you've gotten from the public long before you came to this hearing, but nothing about the brand-name product. Is that right?

Ms. BRESCH. Because the way that we can make the most immediate impact to the patient——

Ms. NORTON. Would be to reduce the price of the brand-name product.

Ms. BRESCH. But that would not be guaranteed to flow through to the patient. What we did was to give immediate relief to the patients that fall under this——

Ms. NORTON. But that was your concern. You know, this just might not go to the patient, so we will go immediately to——

Ms. BRESCH. Yes. Our concern was absolutely that everyone who needs an EpiPen has one. And so putting a generic into the market would, we believe, be the most effective and efficient way to make that happen.

Ms. NORTON. I asked staff, because there have been some responses from you about this being only one of your products, how much, how substantial was EpiPen. I was amazed by the answer that—and I would ask you to verify this—that Mylan is 0.3 percent of the products, percent of the products you produce, but 10 percent of the revenue.

Ms. BRESCH. EpiPen is less than 10 percent, a little less than 10 percent of our overall——

Ms. NORTON. But only about three one-hundredths of the products you produce?

Ms. BRESCH. Because we absolutely produce billions and billions of doses; in the U.S., 21 billion doses.

Ms. NORTON. Yes, but, you know, this turns out to be a minute amount of the products you produce, yet out of that comes 10 percent of the revenue.

What bothers me, when we try to—what we ought to do is compare you with others, because you're certainly not the only one. The ranking member brought up the names of others who have become notorious. But even in that notorious grouping, Mylan is 11th in revenue in the drug industry. Can you confirm that?

Ms. BRESCH. I'm not—no, I'm not sure.

Ms. NORTON. That is our information. And unless you get back to us with different information, 11th in revenue in the entire drug industry, which is perhaps the most criticized sector of an economy, and 16th by market capitalization, and that Mylan is paying its executives far more, for example.

You have already testified that you earned $18 million. That is last year. I understand you earned $2.45 million in 2007. So you got a hefty increase. But from $2.5, less than 10 years ago, to $18 million last year. That's the figure?

Ms. BRESCH. I am blessed and fortunate, not only financially, but to have worked with this company for 25 years and to——

Ms. NORTON. Could I ask you this: What have you done to earn a 671 percent increase? What have you done to earn that kind of increase?

Ms. BRESCH. Well, I believe Mylan has done a tremendous amount, starting with——

Ms. NORTON. No, I'm asking what you have done. I'm interested in your compensation. What have you done to earn that kind of an increase, 671 percent increase in less than 10 years?

Ms. BRESCH. I would say, starting with saving the U.S. over the last 10 years $180 billion. Our products alone have saved this country $180 billion.

Ms. NORTON. I'm talking about—I'm talking about this product. This product.

Ms. BRESCH. I'm talking about Mylan, but my compensation——

Ms. NORTON. I'm talking about this product, Ms. Bresch, this product. What have you done? Is your compensation based on what you've done with this product, which turns out to be the epicenter of your products for—of the many products you make? So I'm try-

ing to find out what you've done about this product that has earned such an increase.

Ms. BRESCH. First, I would say having 700,000 free EpiPens across 66,000 schools across America, could not be more proud about that, and hope that we can get them in the other 65,000.

Ms. NORTON. For which you will, of course, then want another increase.

Thank you, Mr. Chairman.

Mr. WALBERG. The gentlelady's time has expired.

I now recognize the gentleman from Tennessee.

Mr. DUNCAN. Thank you very much, Mr. Chairman.

And, first of all, I want to associate myself with the opening remarks of both the chairman and the ranking member. And according to MBC, since it's been brought up by the previous question, according to MBC, Ms. Bresch made $18,931,068 in 2015. I suppose when you get to salaries at the level that we're talking about, it's easy to forget an extra $931,000. But the greed is astounding. It's sickening. It's disgusting, almost any words that you can think of and not only by Ms. Bresch but the other executives.

And I am a very conservative pro-business Republican, but I am really sickened by what I've heard here today and what I've read before about this situation. I can tell you that, in my opinion, nobody can really earn or deserve $19 million a year.

And lest anyone be under a misunderstanding that the free market or capitalism hasn't worked here, you don't have a free market. That's the problem. A true free market, you have ease of entry. You certainly don't have that in the drug industry. And, also, you have plenty of competition in a true free market, and you don't have that here. And it's primarily the fault of the FDA. We've let the—I've read article after article, for many years, we've let the Food and Drug Administration become so big and so bureaucratic that it's become almost impossible for a small company to get a drug or a medical device to market. And the cost of getting a drug or a medical device to market, on average, has become in many cases, most cases over a billion dollars to get a drug to market. And because of that, the drug industry has ended up in the hands of a few big giants.

And then I've read article after article that all these giant drug companies and pharmaceutical companies have hired many or most of the former FDA Commissioners and top-level employees, just like the Defense Department—defense contractors have hired so many retired admirals and generals. And what they've done in the drug industry, they've come in and they've manipulated the market.

Now, Ms. Bresch justifies all this, saying that they only get $274 from the EpiPens, but these pens were selling by this other company, this German company, for $100 in 2007. We've only had I think around 30 percent inflation in those years, and yet they have almost tripled the price that this German company was paying.

Then Congress, with good intentions, made the situation worse by giving incentives for the schools in grants to get these pens. And then I understand that the New York State attorney general is getting ready to investigate Mylan, because they have required—

they've given these first pens out for free as marketing devices but then required them to buy the next times they had to buy pens.

But what does concern me, one thing that really concerns me, according to a September 1st story on NPR, the FDA as of July had 4,038 generic drug applications awaiting approval, and the median time it takes for the FDA to approve a generic is now 47 months. That doesn't sound like a very expedited procedure to me, Dr. Throckmorton.

And then it says, in March, generics giant Teva Pharmaceuticals, another giant, told investors that its generic version of EpiPen was rejected by the FDA and that it now wouldn't be able to launch the generic at least until next year. Another pharmaceutical company, Adamas—I'm not sure if I'm pronouncing that correctly—reported a similar rejection from the FDA in June. So that's two pharmaceutical—two giant companies that have been turned down.

Dr. Throckmorton, the FDA needs to speed up its actions, and it needs to allow more competition, and it's not doing that now and in the opinion of I think almost everybody here. And then it's all being done on the backs of sick children, and it's shameful.

Mr. Chairman, thank you.

Mr. WALBERG. I thank the gentleman.

I recognize my colleague Mr. Clay for 5 minutes.

Mr. CLAY. Thank you, Mr. Chairman.

Ms. Bresch, since I have a limited amount of time, I want to ask you a series of yes-and-no questions, and then I will give you an opportunity to respond in more detail if you'd like at the end.

First, epinephrine, obviously, is an essential lifesaving drug, correct?

Ms. BRESCH. Yes.

Mr. CLAY. The formulation of epinephrine, the active drug in the EpiPen, has not changed since 2007, correct?

Ms. BRESCH. The pen has changed. The device has changed. But the epinephrine——

Mr. CLAY. The formulation of the——

Ms. BRESCH. Right.

Mr. CLAY. —drug has not. Do you admit that you have raised the price of EpiPens by more than 400 percent since acquiring it in 2007?

Ms. BRESCH. Yes, the wholesale acquisition cost has increased.

Mr. CLAY. Do you admit that Mylan has spent millions and millions of dollars to expand the EpiPen market?

Ms. BRESCH. Yes, and to expand access.

Mr. CLAY. And according to press reports, on September 17, 2015, you stated at a conference, and I quote: "We are continuing to open up new markets, new access with public entity legislation that would allow restaurants and hotels and really anywhere you are congregating, there should be access to an EpiPen."

Did you make that statement?

Ms. BRESCH. Yes, sir.

Mr. CLAY. In 2012, a settlement agreement was reached with Teva Pharmaceutical Industries, preventing it from putting a generic on the market until 2015 or earlier under certain circumstances. Is that correct? Is that correct?

Ms. BRESCH. Yes. Yes, sir.

Mr. CLAY. Do you admit that by delaying the entry of a generic drug into the marketplace, Mylan has had less competition? Do you admit that, that you had less competition by that delay? Not you-all delaying, but having the delay.

Ms. BRESCH. But we've had competition to EpiPen every year.

Mr. CLAY. Okay. The New York Times reported that although Mylan, and I quote, "was once taking two 10-percent price increases a year, it has made two 15-percent increases annually starting in 2014, when the generic competition seemed imminent."

Do you admit that, in anticipation of generic competition, Mylan raised the price more sharply than it had in the past?

Ms. BRESCH. Not due to generic competition. We did increase the wholesale acquisition cost, but as I've stated, we get 274 out of the 608. So, over that time period, we received an average of 8 percent increase.

Mr. CLAY. So, raising the price, do you admit that these price increases were intended to generate even more significant revenue before generics entered the market? Was that the intent of the raising the price, that you-all receive additional revenues?

Ms. BRESCH. We certainly received additional revenue, but on 274, just not the 608.

Mr. CLAY. Have you ever witnessed an individual having an epileptic seizure? I grew up in the 1960s and 1970s, and I had a friend who I witnessed on a couple of occasions these seizures. Have you ever seen an individual have a seizure?

Ms. BRESCH. Due to anaphylaxis?

Mr. CLAY. Yes.

Ms. BRESCH. No, sir.

Mr. CLAY. Well, it's not a pretty sight. And it's—I mean, look, modern medicine has advanced in a way that's beneficial to patients, but to have companies like yours take advantage of this situation, take advantage of these people who are really in need of this medication, I think it speaks to something that is—that we are better than that.

And I would hope that corporate America, that the pharmaceutical industry is better than that. I mean, look, in the last few seconds, tell me what—you know, how did we get to this point, that we have a culture like this in corporate America that wants to stick it to consumers?

Ms. BRESCH. And, sir, all I can speak to is our culture, which Mylan has for over 50 years spent and invested in being able to produce low-cost pharmaceuticals and provide access. As I mentioned, over 21 billion doses, we've saved this country over $180 billion. So our premise is to provide access. And what we worked on with EpiPen was to be able to give 700,000 free pens to schools with no strings attached, nothing——

Mr. CLAY. But initially you put it out of reach of the average consumer.

Mr. WALBERG. I thank the gentleman. The gentleman's time has expired. I think the question was answered.

I now recognize myself for 5 minutes of questioning.

Recent news articles, Ms. Bresch, have documented a lobbying effort on behalf of Mylan to add the EpiPen to the list of preventative medical services managed by the U.S. Preventive Services Task

Force. Preventive medical services are those that prevent illnesses before they cause symptoms or problems, as I understand it.

Currently, treatments receiving a grade of A or B by the task force are required to be offered to the consumers with no out-of-pocket costs. Supporters of adding the EpiPen to the list of preventive medical services argue that this measure will help consumers get access to EpiPens with no cost-sharing.

So, Ms. Bresch, will adding the EpiPen to the preventive medical services list, will it do anything to lower the actual price of the device, the overall reason for our hearing today?

Ms. BRESCH. So the preventive—the preventative drug list, as you mentioned, would make sure everyone has access. But what we've now done with the generic drug and dropping the price to 300, we believe provides that similar access but believe that, obviously, the importance of epinephrine auto-injectors should be part of the preventative drug list.

Mr. WALBERG. So you are still pushing to have it on that list?

Ms. BRESCH. I absolutely still think it should have——

Mr. WALBERG. Even with the generics?

Ms. BRESCH. Yes.

Mr. WALBERG. Do you believe that spending lobbying resources to add the EpiPen to the preventive medical list and thus shifting the price of the drug to other sectors is a realistic solution to stem rising drug prices?

Ms. BRESCH. But, sir, that's why what we did was so unprecedented. It wasn't to shift. We dropped the price by half by introducing the generic.

Mr. WALBERG. But you still want it on that list?

Ms. BRESCH. Just to ensure that—just showing the importance of epinephrine.

Mr. WALBERG. Why not reduce the price instead of spending those lobbying resources?

Ms. BRESCH. Sir, there has been—the lobbying resources have been primarily about creating access and getting epinephrine in public places, like schools and eventually—just like a defibrillator. I mean, what we recognized is that when you need one, seconds count, and they should be where you are. So——

Mr. WALBERG. Absolutely. We don't disagree with that at all. And we appreciate the fact that the product can be there and can be useful.

But this list also, I think we need to plumb the depths of that. We've gone the generic route; we've had some questions on that. But the list also—won't this, in fact, just shift the full cost of EpiPens to government payers, such as Medicaid, Medicare, health insurers, employers, eventually leading to an overall increase in premiums and other copays on consumers?

Ms. BRESCH. No, sir. We believe, by, one, putting the generic in like we have at 300, over 85 percent of our patients pay minimal out-of-pocket costs. So, by now reducing it by half, it even reduces that further. So this is not all about cost-shifting. It's just making sure everyone has access and understands the importance of epinephrine.

Mr. WALBERG. It certainly takes the pressure off of bad publicity for cost factor to get it paid for by Medicare, Medicaid, et cetera, the process.

Let me shift over to Mr. Throckmorton, because there definitely is a concern about just the delay, the time period, the bureaucratic maze. Some drug companies are taking advantage of your agency's failure to approve more generic drugs. I think we've seen that. We are questioning that today.

What can we do to expedite approvals to ensure we have multiple generic competitors to prevent drastic price spikes? And we heard testimony in our last go-round that said it's a lot of bureaucracy. What are we doing to get to that?

Dr. THROCKMORTON. So thank you for that question. I want to take issue slightly with that characterization of where we are as an agency. There was a time when our resources were not able to keep up with the applications that we were receiving for true generic drug products, not authorized generic but true drug products approved under the abbreviated new drug applications.

There was a time in 2012 when we were—we did have the backlog. We had over 4,400 applications that needed to be reviewed. In 2012, with Congress' help, we got additional resources, allowing us to hire new individuals, put in place new processes. The result of that have been over 2,200 approvals or tentative approvals since 2012. So we have, in fact, made progress in reaching conclusions regarding approvals of true generic products.

Mr. WALBERG. What about the markets? Are you doing anything to identify markets that are at risk of becoming monopolized by a single generic?

Dr. THROCKMORTON. Absolutely. We, first and foremost, agree with everything that has been said today about the power of competition and the importance of us taking that challenge on, us making it possible to develop new products. In particular, when you are talking about products like auto-injectors for epinephrine, the public health value is even higher. And we understand, for those products, we need to put particular work, attention.

We've made several—we've done several things specifically about difficult-to-develop products like the epinephrine auto-injector. I mentioned a couple of them earlier, the guidances that we have put out, talking about how to put these products on the market efficiently, quickly, how we're going to review the data, the kinds of information you need.

In addition, we meet with any company that comes to us with a product that has this public health value. We offer to meet with them individually. We offer to respond to their questions in writing. We have put out——

Mr. WALBERG. I appreciate that. My time is expired. But I would make a statement that if there are companies that are having difficulty, I certainly think that members on this panel would love to hear directly from them and then come directly to you——

Dr. THROCKMORTON. I would welcome——

Mr. WALBERG. —and ask those questions, because we want to deal with this. We want to have the competition. We want to see the price reduced. And we don't want to have hearings like this on a regular price.

Dr. THROCKMORTON. If there is a case, I hope they call.

Mr. WALBERG. My time is now expired.

I now recognize Mr. Lynch of Massachusetts for his 5 minutes of questioning.

Mr. LYNCH. Thank you, Mr. Chairman.

Ms. Bresch, I want to go back to the $50 profit number you've been giving us today. Last year, the price was about $460 per 2–Pak. Is that right? So let's go to your chart there. That's not what I have.

The numbers, the documents you gave us are totally deficient in terms of trying to figure out how much you're charging people and how much it costs you, just so you know. And I know we have some outstanding document requests for your company, so I really hope you can comply with those as soon as possible to help the committee with its work.

So let's even just go off your chart there: $401 one year, that was 2014; 530 in 2015; and then a whopping $608 this year so far. So how much money were you making per EpiPen back in 2014 then when you were charging $400?

Ms. BRESCH. So, sir——

Mr. LYNCH. Please, not another chart. Can you just——

Ms. BRESCH. I'm just saying that the 235——

Mr. LYNCH. I'm not talking about that. I'm talking about the top price.

Ms. BRESCH. We received——

Mr. LYNCH. I'm talking about the overall price.

Ms. BRESCH. We received $235.

Mr. LYNCH. Look, that's not what I'm asking you. Can you just answer the question? When you were charging $400 back in 2014, how much were you making?

Ms. BRESCH. Equivalent to the $50, approximately $50 here.

Mr. LYNCH. Okay. Okay, $50, fair enough.

Ms. BRESCH. I think it was about $40.

Mr. LYNCH. $40?

Ms. BRESCH. Yes.

Mr. LYNCH. Okay. $40 back then?

Ms. BRESCH. I believe it was approximately——

Mr. LYNCH. Okay. 2015, you went up to $500. How much were you making that year?

Ms. BRESCH. Out of the—we received 219 and——

Mr. LYNCH. No, no, no.

Ms. BRESCH. —out of that, the profit was probably about—it was around $38.

Mr. LYNCH. $38. Okay. And now it's up to $50 this year?

Ms. BRESCH. Approximately.

Mr. LYNCH. Okay. So if you're only making $50 this year, you must have been losing money in the previous years, because you've gone up $200 on the overall price, the top price, and you're still only making $50. I just can't understand that. The numbers don't work, based on the documents you've given us.

Ms. BRESCH. So, sir, the 608 is the wholesale acquisition cost. The price to Mylan is 274.

Mr. LYNCH. Yeah, we've done that dance. We've done that dance. I understand that.

Ms. BRESCH. And then it's 50—approximately $50 of profit off of the 274.

Mr. LYNCH. Mr. Throckmorton.

Oh, let me ask you, Ms. Bresch, do you do business with the VA? I know it's a different population and the EpiPens are usually for kids with allergies, but——

Ms. BRESCH. Yes, sir, we do.

Mr. LYNCH. Okay. What is the VA paying?

Ms. BRESCH. I'm not sure of the cost, but I know it's——

Mr. LYNCH. They have the ability to negotiate their own drug prices.

Ms. BRESCH. Yes, sir.

Mr. LYNCH. It's a hell of a lot less, I bet.

Ms. BRESCH. Yes. We've had a——

Mr. LYNCH. So maybe that's what we ought to do for Medicare and Medicaid and everybody else, let them negotiate their own drug prices directly with the pharmaceutical companies. That's what I think should happen here. That's really what—I think maybe—it was not your intention, but I think it might have helped Congress get around an issue by showing the blatant disregard you have and disrespect you have for people who desperately need this medication.

And you talk about expanding the ability for people to have the EpiPen. People in my district can't do it at $608, can't do it. And a lot of those people don't have discounts. They're regular middle class people. They don't have that discount. And Medicare part D, their increase is—I know the access went up by 164 percent since you bought the company from Merck, but the cost increase are up 1,151 percent, based on a study here that I have from Juliette Cubanski and Patricia Neuman. I want to enter this for the record.

Mr. WALBERG. Without objection.

Mr. LYNCH. It's disgraceful what's going on here, but I think, in a way, like I say, you've done us a little bit of a favor here by just showing you what's wrong with this system, what's wrong with our healthcare system. I think it's disgusting.

I'll yield back.

Mr. WALBERG. The gentleman yields.

The chair recognizes the gentleman from Tennessee, Mr. DesJarlais, for 5 minutes.

Mr. DESJARLAIS. Thank you, Mr. Chairman.

Ms. Bresch, I just wanted to try to get inside the mind of a large drug company CEO for a minute. When did you guys sit down and decide after 2008—you acquired the EpiPen—when did you decide to use this model of price increase, and how did you come to that decision?

Ms. BRESCH. It was first recognizing the fact that there's a severe shockingly low understanding of anaphylaxis, and there is a shockingly low number of people who were prepared or protected with EpiPen.

Mr. DESJARLAIS. So you decided you should raise the price?

Ms. BRESCH. No, sir. We committed to investing in this product, which we have about over a billion dollars over this 8 years to provide access.

Mr. DESJARLAIS. And how much have you made over 8 years?

Ms. BRESCH. It is absolutely our largest product, but——

Mr. DESJARLAIS. No. I just said, how much have you made? You said you invested a billion dollars. You know how much you invested. How much did you make?

Ms. BRESCH. I don't have the cumulative number.

Mr. DESJARLAIS. So you know what you spent. Okay. Do you think that you are charging too much? Do you think $600 is too much, or are you going to keep raising the price?

Ms. BRESCH. Sir, which is why we took the unprecedented action of putting the generic in at $300.

Mr. DESJARLAIS. Okay. We'll get to that. But did you plan on increasing the price in 2017?

Ms. BRESCH. No, sir, we did not plan on raising the price.

Mr. DESJARLAIS. Okay. But you did have a plan then to raise it every year for 5 or 6 years?

Ms. BRESCH. And if you look at what we received out of that money——

Mr. DESJARLAIS. I just asked you a question. Did you have a plan to raise the price every year for 6 years and then stop?

Ms. BRESCH. We have raised the price. We have raised the price. And I think managing to—what we received, that 274 out of the 608 is what we were managing.

Mr. DESJARLAIS. You are obviously proud of your company. You think that was fair then to raise the price each year to that point, even though you got a drug at $100, which was probably too much for the drug, considering what the cost is. I know you made a fancy clicker, because I had one of your reps come by my office back in 2009 or 2010 and show me how to use it. So I know that cost a little bit of money. But, generally, when a drug goes to generic, doesn't the price go down?

Ms. BRESCH. Which is why we dropped it to $300.

Mr. DESJARLAIS. Only after you jacked it up to $600. It's like if I go buy this tie and they say it's $600 but were going to sell it to me for $300, that doesn't make it worth $300. You fixed the price on the drug and now you know—when did you know you were going to release the generic?

Ms. BRESCH. We announced it several weeks ago.

Mr. DESJARLAIS. Okay. But when did you know as a company? I mean, you knew it was coming. You've got a gentleman sitting next to you say it takes months, maybe years.

Ms. BRESCH. No, sir. We're putting an authorized generic in the market which is equivalent to EpiPen.

Mr. DESJARLAIS. Okay. So we're supposed to feel good because you've taken a drug that you're overcharging six times what it's worth and you're going to drop the price to 300.

Ms. BRESCH. Sir, we were receiving $274 out of the $608.

Mr. DESJARLAIS. Do you think you were charging too much at $600?

Ms. BRESCH. Sir, we believe it was a fair price, and we've just now lowered that price by half.

Mr. DESJARLAIS. Why did you lower it by half if you thought it was fair? If you thought it was fair, leave it where it's at.

Ms. BRESCH. Because we wanted to make sure we're addressing the patients out there that are facing higher out-of-pocket costs and

paying the wholesale acquisition cost, which was not intended. The system wasn't intended for people to pay the wholesale acquisition cost, and that's what's happening at an alarmingly rising rate, which is—we took the unprecedented step of putting the generic in to sidestep that and be able to lower the cost for——

Mr. DESJARLAIS. You're doing everyone a favor by charging three times what you acquired the drug for as a generic. If you're trying to make us feel good about that, I just don't. I'm not buying your argument. Do you have a guilty conscience about any of this?

Ms. BRESCH. Over that period of time, putting it in public places, giving free—700,000 free EpiPens to 66,000 schools and wanting to get it into all of the public schools across America.

Mr. DESJARLAIS. Well, if it cost 20 bucks, they could afford to buy their own. You wouldn't have to give them to them. But, instead, you chose to jack the prices up and then somehow make everyone want to feel good about you by saying how much you do.

The bottom line is you took a very inexpensive drug and you profited handsomely off it. And I don't have a problem like a lot of my colleagues that you can make money in a free market enterprise, but what I do have a problem with, as a physician, when you take drugs that are lifesaving drugs—and people don't have a choice. They can't go to a different department store to get their tie. They have to have that drug, because, you know, a mother would cut off her right arm to get that dose of drug. You decided to charge 600 bucks instead of cutting off her arm. And now you're saying you're dropping it to $300 and that should make us all feel better when, in fact, that's probably about 10 times what the drug should cost.

And I understand you got to make some money, but you can really sit there with a clear conscience today and say that that's okay and you just decided, because you're such a good company, to cut the price from $600 to $300? I mean, is that your testimony?

Ms. BRESCH. Congressman, we want everyone who needs an EpiPen to have an EpiPen, and we're going to continue to work to expand access.

Mr. DESJARLAIS. Lower the price so they can afford it. Are you going to lower the price so other people can afford it?

Ms. BRESCH. We believe that all the programs that we put in place, from the generic to the higher—patient assistance program to the copay card. So trying to address every facet of patients to make sure they can have access to EpiPens is what we will remain focused on.

Chairman CHAFFETZ. [Presiding.] I thank the gentleman.

I now recognize the gentleman from Virginia, Mr. Connolly, for 5 minutes.

Mr. CONNOLLY. Thank you.

Ms. Bresch, I was listening to your earlier testimony, your formal testimony, and I was just struck with what humanitarians you people of Mylan really are. And if you listen to your testimony, you'd never know what the uproar is about. Do you understand the nature of the uproar?

Ms. BRESCH. I do, sir. And I truly believe it's—the story got ahead of the facts, because I think people had—because of the complexity around the pharmaceutical system, I think that us being

able to now release, put on the record what we're making, what comes to Mylan, in fact, is making $50 a pen.

Mr. CONNOLLY. You will forgive me. I only have 5 minutes, so I have to manage my time like you have to manage yours. I don't mean to cut you off, but I want to get to some questions.

Okay. So let me get this straight in terms of the chronology and sequencing. You took over the previous manufacturer in 2007, Mylan did. Is that correct?

Ms. BRESCH. Correct.

Mr. CONNOLLY. And beginning in that time—the price of EpiPen had been fairly stable up to that point. Is that correct?

Ms. BRESCH. Yes. The product——

Mr. CONNOLLY. Yes. So, since 2007, you've raised the price 15 times, if I understood it correctly. About that?

Ms. BRESCH. Yes, sir.

Mr. CONNOLLY. Yeah. So what happened between 2007 and 2016 different than the previous manufacturer and producer? Did production costs skyrocket for you?

Ms. BRESCH. Cost of goods increased for sure.

Mr. CONNOLLY. Well, how much?

Ms. BRESCH. Almost 100 percent over that period——

Mr. CONNOLLY. 100 percent. And what was the comparable cost on the price of EpiPen in that 100-percent cost increase?

Ms. BRESCH. I'm saying over the last 8 years.

Mr. CONNOLLY. Right. And I'm saying, what did it—you went from what to what in 8 years in what you charged, maximum price? I took your point that not everyone pays that. I understand. We have a medical system where we have all kinds of different layers of pricing.

But, nonetheless, the cost to consumers, at least as pegged at an official cost, what was the comparable increase? While you're absorbing in 8 years 100 percent you say, 100 percent cost to you to produce, what was the comparable cost, in theory, to consumers, maximum cost increase in that time period that you charged by raising costs 15 times, a price?

Ms. BRESCH. And, sir, today that is $274 that we receive for the EpiPen.

Mr. CONNOLLY. Well, I was asking for a percentage increase. Let's do apples and apples. If you're going to contend that production costs went up 100 percent, all right, what is the comparable price increase for consumers during that time period? Your own testimony, you've acknowledged you raised the price 15 times.

Ms. BRESCH. Sir, I believe it's almost 300 percent.

Mr. CONNOLLY. 300 percent. So presumably, that's profit.

Ms. BRESCH. After—I mean, from that——

Mr. CONNOLLY. The delta.

Ms. BRESCH. After the cost of goods come out and then you take out all other EpiPen-related costs.

Mr. CONNOLLY. Well, I got to tell you, unlike some of my colleagues, I don't care what your profit is. I mean, America is built on profits. Profits are an incentive. What I care about is what you charge consumers who have no choice. If I understand it, you've got a stranglehold on the market. You control 94 percent of this market. Is that correct?

Ms. BRESCH. Sir, we have a large market share. We don't control. At any point in time——

Mr. CONNOLLY. All right, I'll withdraw the word "control," Ms. Bresch, if it offends you. You have 94 percent of the market share.

Ms. BRESCH. Correct.

Mr. CONNOLLY. Yeah. I'd call that a stranglehold. I'd call that a lot of control. You don't want to call it control, don't. But consumers are experiencing it a little differently. And so, because you have such a stranglehold on the market, you could do what you want in terms of pricing, and you have.

Ms. BRESCH. Sir, we have had many competitors in and out of this marketplace. In fact, that just underscores the complexity of the product——

Mr. CONNOLLY. Your competitors don't even equal 6 percent of the market, Ms. Bresch. I mean, that doesn't even pass the giggle test, what you're asserting. You virtually have a monopoly and you've used it to your advantage, but, unfortunately, it's at the expense of people who need it.

This is a lifesaving drug in some cases. People who risk anaphylactic shock don't have a choice; they have to use it. And I'm wondering what your sense of social responsibility is to those people. I mean, how do you balance—I'm looking—I could go through for you statements you've made and the company has made in the annual report to investors, and it sure is a different set of statements than what we've heard here today.

I didn't hear the humanism. I didn't hear the philanthropic call. I heard statements about favorable pricing. I heard statements about how EpiPen continues to post strong results and has delivered double-digit growth to date. That's because of your pricing.

Ms. BRESCH. But, sir, it's also because we are reaching almost double the amount of patients in protecting and having the ability to be prepared with an EpiPen. So we absolutely expanded access and reach to patients who are at risk, as well as putting them in public places like our schools program.

Mr. CONNOLLY. During the call to investors, one question asked to you was, what are the prospects for future price increases for EpiPens? This is an investor meeting. And your answer is, and I quote: "You should foresee that just continuing as we continue to maximize the EpiPen franchise." What did that mean if it wasn't reassuring investors that we were going to maximize every opportunity to maximize our profit? And, again, I don't think profitis a bad thing, but I do think it's a bad thing when somebody exploits it at the expense of consumers who live on its price or don't.

Ms. BRESCH. And, sir, that's why we have taken every step to ensure everyone who needs an EpiPen has one. And all of our programs, from whether it's the access program or copay card or the schools program, so that our 700,000 free EpiPens throughout the 65,000 public schools. And we want to reach the other 65,000 public schools.

Mr. CONNOLLY. Well, again, Ms. Bresch, I think my time is running out. But there's sort of this Dr. Jekyll-Mr. Hyde, maybe in this case Dr. Jekyll-Mrs. Hyde, quality to your testimony. There's one message for us here in the public and quite another for investors.

I yield back.

Chairman CHAFFETZ. Thank you.

I now recognize the gentleman from South Carolina, Mr. Gowdy.

Mr. GOWDY. Thank you, Mr. Chairman.

Mr. Chairman, as you know, I'm not a physician, which is why I was consulting with one, and I'm not an expert in economics, like Mr. Meadows and Mr. Mulvaney, but I am trying to understand—Ms. Bresch, maybe you can help me. Walk through the different chains of delivery for name-brand drugs versus authorized generics. From the manufacturer to the patient, what is the difference in the chain of delivery?

Ms. BRESCH. Do you mean in the product or how it's distributed?

Mr. GOWDY. Distributed.

Ms. BRESCH. So the supply chain for a generic is different than the supply chain for a brand. Primarily——

Mr. GOWDY. Authorized generic.

Ms. BRESCH. Authorized generic and a generic would be the same channel.

Mr. GOWDY. Okay.

Ms. BRESCH. So the distribution channels do differ, primarily given the fact that generics are for the retail pharmacy. So there's the supply chain from a pharmacy manager or the formularies differ quite a bit from the brand to the generic.

Mr. GOWDY. Well, that leads me to another question. I'm sure there's a really obvious answer, but given my background, I don't know what it would be. Why don't pharmacies just deal with the manufacturer? If a doctor has to write a prescription and a pharmacist knows what the prescription is for, why is there a middle person in the delivery of drugs?

Ms. BRESCH. So, sir, for many—on the generics, for many, we do deal directly with pharmacies, whether they're large chains or if they're independents and have——

Mr. GOWDY. I guess that's my point. If you can do it for generics and authorized generics, why not for name brands too?

Ms. BRESCH. Because most of America falls under a formulary of payers, and pharmacy benefit managers manage those formularies for insurers or for employers. So they manage what products can be—it's tiered. They decide what products can be on a tier two or a tier three, so whether it's preferred or not preferred. So they serve as an administrator for most employers.

Mr. GOWDY. A drug middleman serves as an administrator?

Ms. BRESCH. As far as deciding what products are on—that they'll reimburse for or at what rate they'll reimburse for them.

Mr. GOWDY. Well, let me ask you this: Is it theoretically possible that your profit margin could increase with an authorized generic as opposed to the name-brand drug?

Ms. BRESCH. No, sir. It will be considerably less.

Mr. GOWDY. Walk me through how that would be. You're cutting out the middleman, but yet you're making less money. How?

Ms. BRESCH. So there still is—there is still—there is still fees and rebates and discounts on the generic side, on the generic channel. They're just not as significant. So we're charging, we set a wholesale acquisition price at 300, and we estimated that our net, what would come to Mylan, would be 200. After you take cost of

goods out of that and EpiPen-related costs, it will certainly be less than the $50 that we talked about today around the profit per pen that Mylan receives on the brand.

Mr. GOWDY. I think you answered this question, but I want you to do it again for me, just because it's important. I want this to be on the record. Tell me what your—walk me through the cost all the way down to what Mylan gets for treating it as a name brand versus treating it as an authorized generic.

Ms. BRESCH. Sure. So this is the math of—you can see the wholesale acquisition, the Mylan revenue of 274 minus the cost of goods minus the direct cost, which is the $100 or $50 per pen. And what we've said for the generic—and what we have said for the generic is that the wholesale acquisition would be at 300. Mylan received 200, less cost of goods, less EpiPen-related cost. So it will be substantially less than the $50 of profit per pen that we receive on the brand.

Mr. GOWDY. Thank you, Mr. Chairman.

Mr. CUMMINGS. Would the gentleman yield just for one question?

Mr. GOWDY. I will be thrilled to yield to the gentleman from Maryland.

Mr. CUMMINGS. Thank you.

Just one question. Just following up on what you just said, it seems like you would be taking a loss, unless I've got my math wrong. When you go to the generic, and you said you've got certain costs, but it seemed like you would be taking a loss on the generic. Am I missing something?

Ms. BRESCH. Not a loss, sir. I just said we would be making less than the $50, substantially less than the $50 per pen we're making today.

Chairman CHAFFETZ. I thank the gentleman from South Carolina.

We're now going to recognize the gentlelady from Illinois, Ms. Duckworth.

Ms. DUCKWORTH. Thank you, Mr. Chairman.

I want to highlight the stories of two families from my district. The Brock family, Lisa and Bob, from Rolling Meadows have an 8-year-old son Brian who was diagnosed with severe food allergies before he turned 1. Lisa carried an EpiPen for 5 years, and one day Brian ate something and began foaming at the mouth and vomiting and her nightmare come true. When he came home from the hospital, he told his mom: "Mom, I don't want to die." Even at 5 years old, Brian knew how serious his body's reaction was. He knew his throat was closing. On this occasion, an EpiPen saved his life.

Then there's Michele Hanson from Schaumburg, Illinois. She is deeply concerned about Mylan's skyrocketing prices. Her husband Mark and her 7-year-old daughter both have life-threatening peanut allergies. So, as a result, their family has to ensure they have two auto-injectors at school, camp, each set of grandparents' homes and mom's purse. The Hanson family knows what it's like to depend on this small device for the safety of their family, and that's why Michelle took the time to write to me and urge me to do everything in my power to ensure everyone, even those less fortunate, can protect their children with the same level of care.

The Brock and Hanson families are lucky; they have good insurance. But, like Lisa shared with me, we don't know we'll always be in this position, and one day they may not be able to afford the EpiPen, whose prices keep going higher and higher. And I agree with Lisa and Michelle. Even a single life lost due to lack of access and affordability to this drug is one life too many.

Now, Ms. Bresch, I'm going to ask you to keep your answers short. I'm going to ask you yes-or-no answers or short one-word answers. Please don't try to filibuster and run up my time. So I need you to answer yes or no.

Earlier, you said that EpiPen has given out over 700,000 EpiPens—Mylan has given out over 700,000 EpiPens to schools across the Nation. Is that correct?

Ms. BRESCH. Yes, we've given free EpiPens.

Ms. DUCKWORTH. Okay. Mylan also offers schools discounted EpiPens through your EpiPens4Schools program. Is that correct?

Ms. BRESCH. Yes, they can purchase additional pens if they want.

Ms. DUCKWORTH. Okay. So this is particularly important in Illinois, States like Illinois that have laws that require schools to stock epinephrine auto-injectors. In fact, this is a program in schools that your own mother was instrumental in getting States to adopt in her capacity as the president of the National Association of State Boards of Education.

So we can better understand the scope of this program, from August '12 through May '16—May of 2016, approximately how many schools signed certification forms purchasing discounted EpiPens at a price of $112.10 per carton?

Ms. BRESCH. Schools that have decided to purchase just additional—besides the four, because we give four free EpiPens——

Ms. DUCKWORTH. So how many schools have done this?

Ms. BRESCH. I think around 5 percent. So I think there has been about 45,000 EpiPens.

Ms. DUCKWORTH. So 45,000 schools?

Ms. BRESCH. No, no, EpiPens purchased.

Ms. DUCKWORTH. Okay. How many schools? So answer my question.

Ms. BRESCH. I'm not sure how many. I don't know how many schools.

Ms. DUCKWORTH. So, as CEO of Mylan, you don't know. You just quoted a number of how many schools you had given them to and how many schools you had not given to and that you wanted to get them to all of these other schools, but you can't tell me how many schools have actually bought EpiPens from you under this program that you are so proud of?

Ms. BRESCH. It's a very small number. It doesn't—it's very small. The 66,000 schools are who we've given free EpiPens to.

Ms. DUCKWORTH. So I'm also not as concerned about your profit making. I believe in the free market. What I am concerned about is your monopolistic practices.

And so there's a little confusion in public reporting. Could you simply confirm, yes or no, whether schools that purchased discounted EpiPens had to make any representation and warrants to

Mylan that they would adhere to certain conditions in order to access the discount price that you give them?

Ms. BRESCH. Schools did not have to purchase any EpiPens.

Ms. DUCKWORTH. No, no. The schools that are trying to get the discounted price from you, did they have to certify or make any representations or warrants to Mylan that they would adhere to certain conditions in order to get that price?

Ms. BRESCH. For people who wanted to buy it at the discounted rate, yes. But that had nothing—the free EpiPens had no——

Ms. DUCKWORTH. I'm not talking about the free EpiPen. So I'm holding here—and, Mr. Chairman, I'd like this entered into the record and please pull this up.

Chairman CHAFFETZ. Without objection, so ordered.

Ms. DUCKWORTH. It's a certification form. Thank you, Mr. Chairman.

It's a certification form where EpiPen—where Mylan has actually said that the school hereby certifies that it will not in the next 12 months purchase any products that are competitive to EpiPen auto-injectors.

So you actually put into practice forcing schools—and you are so concerned about these kids that you actually are limiting the school's ability to buy pens from someone else. And so you're saying here: "We'll sell it to you for 100 bucks. We've raised the price to $600. If you want it for the 100 buck price that it used to be at, you need to sign this and say that you can't buy this from anybody else." Don't answer. I'm not asking you a question. That's what you've done here.

Ms. BRESCH. Well, I disagree with that, because they did not have to buy our pens. Our free EpiPens——

Ms. DUCKWORTH. But if they wanted to get this price.

Ms. BRESCH. If they wanted a heavily discounted price, yes, they bought EpiPens.

Ms. DUCKWORTH. The heavily discounted price is $112.10, which is where it was before you jacked up the price to $600. So it's not a discounted price; it's only discounted because you raised the price on them, and then you say: "Oh, you want it at the old price before we jacked it up for profit; here, you need to sign this and say you will not buy this from anybody else." Don't answer. I'm not asking you a question. This is what you have done. Your own document says it.

Ms. BRESCH. They don't have to buy them, and everyone is eligible for a free one.

Ms. DUCKWORTH. That's right. You don't have to buy them. But your own mother is out there lobbying to make sure that they're in all the schools. And this article says that many members of the board at the NASBE didn't even know that there was a family connection between you and your—between Mylan and your mom through you, as she was out there trying to—passing out your guide from Mylan, as she was out there talking to school boards, as she was pushing for these EpiPens to be put into school districts. And then they can't buy it for a lower price, because——

Ms. BRESCH. I'm sorry, Congressman. That is completely inaccurate.

Ms. DUCKWORTH. —you control 94 percent of the market. And then you tell schools: "You want it at the old price? Sorry, you can't buy it at the old price unless you promise not to buy it from anyone else." That, to me, is an unfair monopoly.

I yield back, Mr. Chairman.

Chairman CHAFFETZ. Thank you.

I now recognize the gentleman from Texas, Mr. Farenthold, for 5 minutes.

Mr. FARENTHOLD. Thank you very much.

Ms. Bresch, I think I now understand why you make $18 million. Trying to figure out the complexities of drug pricing has me really flummoxed. Of course, I won't make $18 million in 100 years serving in Congress.

So let me ask you, you talk about this wholesale acquisition cost of $608. Who pays $608 for an EpiPen? I mean, what is the wholesale? Is that just kind of like the manufacturer's suggested retail price?

Ms. BRESCH. So it certainly was never intended for—the wholesale acquisition cost, the system, we certainly didn't make the system. Mylan didn't make the system.

Mr. FARENTHOLD. No, no. I'm not coming after your company, all right? I'm very tempted to, because I think you all have behaved badly and have invited government regulation. I am a free market person. I'm very much for free market. But this whole drug pricing system that we have right now makes no sense to me, and a free market can't operate in a system where people like me, who are consumers, don't understand it.

So I'm going to lay aside my concern about what your company is doing and why. I think it's wrong, but that's not where I want to get. I want to get to the pricing. You said a $600—I'm going to call it manufacturer's suggested retail price. All right. So, in a free market, you've got a manufacturer, a wholesaler, a retailer and the consumer.

In the drug market, you've got the manufacturer. You've got the insurance company. You've got the pharmacy. You've got the doctor. You've got the benefits manager. And there are probably some more players in there, all who need to take a little bit of money out. So we've created a very complex system. So, basically, you said, manufacturer's suggested retail price is $608. Probably the only sucker who's going to pay that is somebody who doesn't have insurance. I don't know. And then you come up with all these rebate plans that you have to go to the Web site and print something out. You have a discount plan for schools. It's so incredibly complicated; it makes airline pricing look reasonable.

I want to fix this, because it's not just your product that is the problem. Medical prices are skyrocketing. Doctors complain to me they're not making any money. My insurance premiums are going up. My deductibles are going up. How do we fix this, where you can make a reasonable profit and the drug can be available in a way that can—at a price that people understand and that doctors know and I can talk to my doctor about?

I mean, I had—my doctor today: "Great. I got this new pill you can take; you only have to take it once a day instead of twice a day." Instead of being a $10 copay, it was $120 copay. God knows

what my insurance company is paying. I'm going to take two pills to save that kind of money. But in most cases, people and doctors even don't have the information to do that.

How do we simplify this and get the cost of these down, where you can make a profit, the doctor can make some money, the pharmacy can make some money, but people can afford health care? How do we fix this?

Ms. BRESCH. Well, I wish there was a simple answer. The system has been around for decades, and it certainly has not kept pace with the evolving health care that our Nation faces, the crisis, to your point, that health care faces.

I believe that first there needs to be more transparency in the system and certainly welcome the opportunity to sit down in a more holistic way and have the conversation. But the whole supply chain, to your point, has to be involved in that.

Mr. FARENTHOLD. Let me ask, Dr. Throckmorton, with the FDA, it seems like there may be something you guys can do about this. I mean, I see—I had a doctor I was talking to just Monday who said: "Yeah, see this ad for this new drug. Do you realize that it costs over $128,000 a year to do that?"

I mean, if you're not a doctor—and maybe even some doctors don't even know it. Should we be requiring drug companies to disclose the cost of medication in their advertising?

Dr. THROCKMORTON. That would not be a question for me to answer, Congressman, but a very good question. The FDA is not allowed to consider cost when we look at drug approvals.

Mr. FARENTHOLD. Ms. Bresch, would your industry be supportive of that?

Ms. BRESCH. I absolutely believe that if we want consumers to be able to shop and get them engaged in the system, they absolutely have to know how much something costs to be able to make the value proposition.

Mr. FARENTHOLD. I'm almost out of time. I've got one more question for you.

I applaud your company for trying to educate folks about the need for the availability of EpiPens, but what I don't understand is why your marketing costs have to jack up the price that much. If you sell 100 EpiPens and make—what was your profit on—$50 on each pen, and you sell 200 EpiPens at the same price, you're going to make more money—or the same amount of money, you see. I didn't say that correctly.

But what I'm saying is, as your volume goes up, your profit goes up, and you don't have to jack the price up. That ought to pay for the advertising. So if you'd like, I'm out time, I'll let you answer if you want.

Ms. BRESCH. Thank you.

Chairman CHAFFETZ. Did you want to answer?

Ms. BRESCH. Well, I just would say that it's constantly about trying to reach as many patients as we possibly can. So we continue to invest in being able to reach and provide that access.

Chairman CHAFFETZ. I now recognize Ms. Plaskett for 5 minutes.

Ms. PLASKETT. Thank you, Mr. Chairman.

Good afternoon, Ms. Bresch.

It's my understanding, when we talk about Mylan and the eligibility threshold in your patient assistance program, what has that number come to at this point? What is the amount?

Ms. BRESCH. It is, I believe, 97—97—I believe it's right around 97,600 for a family of four.

Ms. PLASKETT. For a family of four.

You know, many of us here, including yourself, come from communities where I don't really know that many of the families that make 97,000 as a family of four. You know, where in the Virgin Islands, the average amount is about 50,000 for a family of four. I would think, you know, in other places that you're familiar with, that would be the case as well.

How do you as a company deal with those individuals who are falling within the margins to be able to afford that?

Ms. BRESCH. So the patient assistant program is for anyone who falls under that 97,200. So it would capture anybody who—a family of four making less than that would be eligible for the free pens.

Ms. PLASKETT. And then what happens to the other families that are below that? Do you have other programs? What are you doing for those?

Ms. BRESCH. Anyone below 97,000 would get the free pens, the eligibility.

Ms. PLASKETT. Anyone below that number that's a family of four?

Ms. BRESCH. Right.

Ms. PLASKETT. Okay. So that would mean, in places like myself, they would pay—how much then would cost be at that point?

Ms. BRESCH. It would be free for any family of four making $97,000 or less.

Ms. PLASKETT. So a family of four then that's above that margin, what happens to those families?

Ms. BRESCH. It could be several. The majority, the overwhelming majority of our patients, 85 percent are paying little to—between $50, $100, it depends on the commercial plan. But we know that about 85 percent or more are paying $100 or less than $50, but that's why we also have the copay card, the savings card that would allow you to put that towards what you're paying at the counter. So it would go against your out-of-pocket cost.

Ms. PLASKETT. So if the individuals, not the companies or not the schools that are buying, individuals who purchase this, what percentage you say fall within the PAP, the patient assistance program?

Ms. BRESCH. It's very small. Most of our—percentage-wise, the majority of our patients are under commercial plans.

Ms. PLASKETT. What percentage would that be?

Ms. BRESCH. About 70 to 75 percent, I believe, are in commercial plans.

Ms. PLASKETT. And of that 70 to 75 percent that are in commercial plans, how much do those individuals pay?

Ms. BRESCH. It varies, depending, because all the plans are different.

Ms. PLASKETT. What is the variation?

Ms. BRESCH. The majority pay $50 or less out of pocket. Some of that group pays $100 or less out of pocket. And you can use—

we also offer a savings card of now $300 that you can use towards any of your out-of-pocket expense.

Ms. PLASKETT. Okay. That does give some kind of—and it would be good if we could get the numbers then of what those individuals are so that we understand what percentage of people are really having to pay the $600, the $400, and the $300 that really seem very outrageous. I'd like to know how many families have to be subjected to that.

Ms. BRESCH. And it's because of that growing minority that we then took the actions we took about putting the generic in place.

Ms. PLASKETT. Then why would you say that minority is growing?

Ms. BRESCH. Because of the higher deductibles that people are faced to pay, the rise of the higher deductible plans, as you know, has grown tremendously, you know, this year alone, and so that is having more out-of-pocket cost. And because of that is why we took the, like I said, unprecedented step to put the generic in that would lower the cost for everybody.

Ms. PLASKETT. Now, you're doing other things as well. I understand that you do have some lobbying efforts to get EpiPens listed as preventative services under the Affordable Care Act. Is that correct?

Mr. BRESCH. Yes. We have definitely said it should be on the preventative drug list.

Ms. PLASKETT. And how much resources have you put towards that?

Ms. BRESCH. Minimal. I mean, it's been internal resources about trying to educate, one, just about the need for epinephrine autoinjectors to certainly make sure everyone has access.

Ms. PLASKETT. When you say education, who would that be towards?

Ms. BRESCH. Towards the formularies who make the decision about whether or not to put a product on the——

Ms. PLASKETT. Who are the formularies, for those of us who are uneducated about these kinds of things?

Ms. BRESCH. So it would be the people that are the large pharmacy managers. So there's several—many companies out there that are the pharmacy managers, and they're the ones that have some decisions around what can go on the preventable drug list or not for the lives they cover.

Ms. PLASKETT. Okay. I'm out of time. I've got a lot more questions, but sorry.

Chairman CHAFFETZ. Thank you.

I now recognize the gentleman from North Carolina, Mr. Meadows.

Mr. MEADOWS. Thank you, Mr. Chairman.

Thank you both for being here.

Ms. Bresch, your new plan, so let me, as a business guy, let me just give you some advice. Parents are upset with the cost of the EpiPen and the potential of not being able to help their children. That's the problem you have.

And what's happened is I started getting calls when I didn't even know it was an issue from people that were saying the out-of-pocket expense was 600, 700, the insurance wouldn't cover it. And now

you've come up with this unbelievable marketing plan that only would suggest that there is unbelievable profits.

I can't imagine anybody in their right mind coming up with a plan like that, instead of just saying: You know what? We screwed up. We knew we had 96 percent of the market, we increased the prices, please forgive us, we'll adjust our prices. So now you're putting out a generic, you're coming up with a different plan for a great product.

And I guess my concern is that as we look at this, you're being thrown in with other witnesses that had sat in your same exact chair who have really stood out to gouge the American people. And I guess my question is, do you believe the increases that you've done with the market share that you have was inappropriate and a mistake from a marketing standpoint?

Ms. BRESCH. We believe that starting 8 years ago, balancing that price and access and making sure that we could not only in public places, but reach more lives and reach more patients, was absolutely critical.

Mr. MEADOWS. So how much is this——

Ms. BRESCH. And, look, that's why we put the generic.

Mr. MEADOWS. How much of this is a——

Ms. BRESCH. That's why we cut.

Mr. MEADOWS. How much of this is a Medicaid, Medicare, private insurance, private pay issue where you're charging different amounts to different people? Because that's another problem I keep hearing, is it depends on what plan you're on and whether you're covered by high deductibles or not. How much of that is just the nature of the pharmaceutical business that you charge different amounts to different people?

Ms. BRESCH. You're correct. I mean, all pharmaceuticals are all different under every different plan.

Mr. MEADOWS. So your pricing model is not, like you say, it cost us X, we make X. You have to come up with all kinds of convoluted ways to make a profit, depending on the coverage for the individual patient. Is that correct?

Mr. BRESCH. Well, and that's why we were giving you what we receive on an average, the 274.

Mr. MEADOWS. So I get that. So how are you affording to give free pens to any family that makes less than $97,000 a year? How are you affording to do that based on the profit margin? I was doing the math. So that just means that if you make $100,000 a year, you're going have to pay a big amount of money, and you're going to give them free to everybody else? Is that what I'm hearing?

Ms. BRESCH. So, obviously, our patient assistant program is to help those families, but the reality is that the majority of the patients fall either with the commercial insurance that have—that aren't facing those huge out-of-pocket costs.

Mr. MEADOWS. So your increased cost is actually being borne by big insurance companies that provide insurance for their employees. Is that what you're saying?

Ms. BRESCH. No, sir, that's what our rebate——

Mr. MEADOWS. Is the giveaway figured into that cost?

Ms. BRESCH. No. The uninsured is really the only person——

Mr. MEADOWS. So you didn't figure the giveaway of giving away free EpiPens to people that make $97,000 or less into the cost of your product?

Ms. BRESCH. What gets factored into the cost of product from free EpiPens to even our EpiPen for School program——

Mr. MEADOWS. It's part of the overall cost.

Ms. BRESCH. —we've given over 700,000 pens. But really the minority of patients, this uninsured patient that was faced with that paying the wholesale acquisition cost or that price is that growing minority is why we took the step we did was to say, hey, we're going to——

Mr. MEADOWS. Well, I would ask you to revisit that. I'm running out of time. I'd ask you to revisit that and make it simpler.

So, Dr. Throckmorton, let me come to you, because this is another hearing with another problem, and part of the problem is, is the FDA has a laborious approval process for any drugs, whether they're orphan drugs or anything else, and your 10-month approval process I don't buy. Is that your testimony today, that you can get drugs approved in 10 months, or just a response?

Dr. THROCKMORTON. Beginning in October 1, we're committing to 10-month review time. If it's a high-quality application——

Mr. MEADOWS. But I've seen some of those reviews. What you do is you send out a letter and say, well, we need more—so you buy time with your letters that may or may not be really in the approval process.

Dr. THROCKMORTON. And we shouldn't be using those letters to do that. Those letters should be——

Mr. MEADOWS. So when did you stop?

Dr. THROCKMORTON. Those letters should be——

Mr. MEADOWS. When did you stop? Because I've got copies of them, if you'd like to see them.

Dr. THROCKMORTON. I'd be happy to look at them.

Mr. MEADOWS. When did you stop?

Dr. THROCKMORTON. What we should be using those letters for is to signal true deficiencies in applications.

Mr. MEADOWS. Mr. Chairman, I just want one answer, and I'll yield back.

When did you stop using those letters as normal practice.

Dr. THROCKMORTON. Since 2012, we have put in place a process——

Mr. MEADOWS. Okay. I've got letters. I've got letters that have been since then. I'll yield back.

Chairman CHAFFETZ. Okay. We'll now recognize the gentlewoman from Michigan, Mrs. Lawrence, for 5 minutes.

Mrs. LAWRENCE. Thank you.

I have a question for you, Ms. Bresch, and thank you for being here. I understand the profitmaking of companies, but under your realm, the EpiPen has become Mylan's first billion-dollar drug. Is that correct?

Ms. BRESCH. Yes.

Mrs. LAWRENCE. In 2014, your company generated 1.19 billion in sales only in their specialty drug section because your company makes a lot more. Is that correct?

Ms. BRESCH. Yes.

Mrs. LAWRENCE. And according to your SEC filing, and this is a quote, as a result of favorable pricing and increased revenue, in 2015, your company generated $1.2 billion in sales revenue, driven largely by the continued strong performance of the EpiPen Auto-Injector.

According to a press release you issued in February of this year, your earnings per share also went up in 2015 by 21 percent. This increase was, and I quote, "at the high end of our previously communicated guidance range." Is that correct?

Ms. BRESCH. Yes.

Mrs. LAWRENCE. Your company is continuing to make incredible profits this year. Is that correct?

Ms. BRESCH. Yes. Our company is strong, and we believe that's the best way to serve our patients.

Mrs. LAWRENCE. Recently, while discussing the EpiPen's massive price increase, you actually said, and I quote, "No one's more frustrated than I am." And so is it true that you're frustrated that you didn't raise it higher, creating a billion-dollar drug was a goal you acquired with the EpiPen, and you're frustrated you didn't raise it more?

Ms. BRESCH. No. What I am frustrated in is that because the system is so opaque, and people—it's hard, it's complicated. I was trying to share today that you don't typically have that transparency of what the company actually receives and what that wholesale acquisition cost is. So that was the frustration.

Mrs. LAWRENCE. So on September 15 you sent a letter to the committee stating that your sales revenue from over 2,700 products is 11 billion this year and your profit from the EpiPen would generate 1.9 billion in net sales. So your company expects to make 9 percent of its revenue this year just off of one of your products. Is that correct?

Ms. BRESCH. Yes. EpiPen is less than 10 percent of our overall revenue.

Mrs. LAWRENCE. But one product can generate 9 percent of your revenue, that one product?

Ms. BRESCH. Yes.

Mrs. LAWRENCE. So this is the frustration. Not that you don't have a product, not that you don't have your free product, but where is the company in responding to this outcry that I have received and every Member of Congress? What do you plan to do with that? Do you hear the cry from the constituents?

And while you and your company and I'm sure the employees enjoy this profitmaking, where is the sensitivity and where is the company in saying, I hear this, we have made a tremendous amount of money?

Is it normal for one product, out of 2,700 drugs, one product is almost 10 percent? And you have increased that. And while if I'm sitting there at the boardroom, I would say, this is great. You're doing a great thing. You're bringing money in. We're making money. Where are you and the company in saying what do we do about the outcry of the people on this situation?

Ms. BRESCH. And we did listen and take immediate action to put a generic in at half the price, and that's truly an unprecedented ac-

tion for a brand to do that. So we did listen, and we believe that we took unprecedented action in getting the generic on the market.

Mrs. LAWRENCE. You control that generic, and you're actually making a higher profit range off of that generic, correct?

Ms. BRESCH. No, we're not making a higher profit off the generic.

Mrs. LAWRENCE. If you raised the——

Chairman CHAFFETZ. I think the gentlewoman's time has expired.

Mrs. LAWRENCE. I yield back.

Chairman CHAFFETZ. Members are advised that there is now a vote on the floor. It is anticipated votes will go between an hour and an hour-and-a-half. It's my intention to recognize Mr. Mulvaney of South Carolina for his 5 minutes and then go into recess. We will reconvene no sooner than 6:30, but it might be later until we get done with the vote series.

We'll now recognize Mr. Mulvaney for 5 minutes.

Mr. MULVANEY. I thank the chairman, and I may not take all 5 minutes.

I've got to tell you, as someone who considers himself to be a free market Republican, a part of me has been uncomfortable with where some of this hearing has gone. I wish we were talking, instead of what we've been talking about, about why Mylan can charge $600 for this or $300 for a generic or whatever, because I think that would be a really good discussion, about why this same exact product costs between $100 and $150 in Europe.

The same exact thing, from the same exact manufacturer, costs 100 to 150 bucks in Europe. In fact, I think you can get it over the counter in Europe for $75. One of the reasons, by the way, is there's nine different people making this stuff in Europe because it's easier to get drugs approved in Europe, Dr. Throckmorton, than it is here.

I've heard you talk today about this new 10-month plan, and you keep telling us, and it's sort of, well, we have a 10-month plan that starts October 1, which makes you wonder how long did it really take before this became a big national deal.

My guess is it takes a long time or to get this stuff approved. And one of the reasons they can charge $300 or $600 is because it's too hard to get new products approved in this country. My understanding is that an EpiPen competitor would be even more difficult to get stuff approved because it's both a drug and a delivery device.

By the way, for those of you, and this hasn't come up, the stuff doesn't cost anything. This is one of the oldest chemicals that we use. I think the stuff is more than 100 years old, and on the Internet it says it costs between, like, 10 cents and 95 cents a vial for the stuff. It's a completely generic—it's adrenaline. It's really easy to make the stuff and really easy to get the stuff. But for some reason in this country there's really only one provider.

So if you can really charge $600 for it and people will pay for it, why aren't more people rushing in to make the stuff so that they can get a piece of this huge market? Because it's too hard to get the darn stuff approved, and that's what I wish we were talking about.

Ms. Bresch, I wish we could talk about what you talked about in your CNBC article, about how crazy the pricing is, because it is bizarre, and we buy stuff in the healthcare market in ways that we don't buy anywhere else.

The reason that this same product is more expensive every single year, with everything else in this room gets less expensive every year, is because it's in the healthcare market, which doesn't function properly, and we could have talked about that and how hard it is to figure out how much stuff costs and the five and six people that touch it between the time it comes out of your product and gets in the hands of the customer. We didn't talk about that.

Instead we talked about your profit margins with people who have no clue what that means. We talked about distribution facilities. We talked about cost of goods sold. We talk about board meetings. We talk about your salary. We talk about a bunch of stuff that tries to make a lot of us look really good. Somebody in my own party said that there's no way you could really earn $18 million a year. That bothers me, okay, and I'm not comfortable with that.

But at the same time, Ms. Bresch, and I've had this conversation with other people who have sat in that same chair, you get what you deserve. Not because you're a bad person, not because you're charging too much or too little for a drug. Nobody here has any clue as to whether or not you are charging too much or too little. We don't like it. We know that. But we don't understand the costs, we don't understand the distribution system, we don't understand how healthcare products get priced and sold and distributed.

I tell you what he we do know, though, is that you've been in these hallways to ask us to make people buy your stuff. In fact, I think there's laws in 11 States now that require schools to have epinephrine in some immediately deliverable fashion. You've lobbied us to make the taxpayer buy your stuff.

At the Federal level, we passed the law here. We did it. By the way, I was here when we did it. Everybody was here when we did it. We did it 2013. It went by voice vote, one of those magical things that happens when we're not on the floor.

The White House called it the EpiPen bill, and it gave this wonderful financial incentive to all of our schools to have this product in the schools. My guess is that didn't happen by magic. It may have happened because your mother works for the State School Boards Association, whatever the group is, it may happen because your dad is a U.S. Senator. But you came and you asked the government to get in your business. So here we are to today.

And I was as uncomfortable with some of these questions as you were, I'm certain, sitting over there. But I have to defend both my Republican and Democratic colleagues because you've asked for it.

So I guess this is my message. If you want to come into Washington, if you want to come into the State capitols and lobby us to make us buy your stuff, this is what you get. You get a level of scrutiny and a level of treatment that would ordinarily curl my hair, but you asked for it.

I wish it weren't like that. I wish you could go off and make your stuff, and I wish the market functioned, and I wish you didn't get government involved, but that's not the world we live in.

And since it is, I have to defend every single question that was asked of you today, and I wish I had questions of my own, and I do, but I've only got 5 seconds left, so I'm not going to get a chance to ask them.

Thank you, Mr. Chairman.

Chairman CHAFFETZ. The gentleman's time has expired.

The committee will stand in recess and reconvene no earlier than 6:30.

[recess.]

Chairman CHAFFETZ. The committee will come to order. We're now back after votes, and we'll go ahead and recognize Mr. DeSaulnier for 5 minutes.

Mr. DESAULNIER. Thank you, Mr. Chairman.

Thank you both for being here.

Ms. Bresch, you talked about your outreach in State legislatures. Did you spend any money or your company on lobbying or helping with that process?

Ms. BRESCH. Yes.

Mr. DESAULNIER. Do you remember how much?

Ms. BRESCH. I don't remember exact number, but I would say minimal in the scope of what we've spent on awareness and access. But that outreach and lobbying was for the epinephrine.

Mr. DESAULNIER. Uh-huh.

Ms. BRESCH. To be able to have it in the school's name and not a child's name——

Mr. DESAULNIER. When those, when that product has reached its life expectancy, do the schools purchase it from you to replace it?

Ms. BRESCH. We give it every year free.

Mr. DESAULNIER. Every year for free.

Ms. BRESCH. Yes.

Mr. DESAULNIER. All right.

Your quote in terms of your accepting some responsibility, and I read here, is, "Looking back, I wish we had better anticipated the magnitude and the acceleration of the rising financial issues for a growing minority of patients. We never intended this."

Is that pretty much your statement in terms of your responsibility? Other than that, are you proud of the actions of your corporation?

Ms. BRESCH. Look, I am absolutely—I don't—I would hope that nobody would want to go back in a period of time to where the awareness was so shockingly low and the access was almost nonexistent for EpiPens. I believe that we have continued to balance that access. It does come at a price, and we've tried to balance that price and access while at the same time continuing to have access in more places. Like I said, I hope the other 65,000 schools, that we can get free EpiPens to them.

I'm also proud of the hearing and understanding this growing minority of patients and the uninsured or people facing that high out of pocket, that we took immediate action to put the generic out there, which is unprecedented, as well as some of the actions from the tripling the copay card or raising the eligibility of the patient assistance.

Mr. DESAULNIER. Okay. I appreciate that. So I'm going to read a couple of quotes from a Los Angeles Times story, August 25, and this is quotes.

"Mylan, the profiteering, tax-dodging"—this is the Los Angeles Times—"drug company currently taking immense heat for jacking up the price of EpiPen by 500 percent, announced Thursday that it will help more patients cover their soaring out-of-pocket costs for their allergy drug device. That's good for some individuals," the LA Time continues, "patients, and families, but at the heart, it's a cynical move that actually protects the company's profits and harms the healthcare system."

As I explained before, the author continues, "That's because such moves are often marketing schemes dressed up to look like altruism," and then he goes on to explain.

Are you familiar with this article in the LA Times?

Ms. BRESCH. No.

Mr. DESAULNIER. Okay. No one ever showed you this?

He goes on to say, "What Mylan is doing is expanding its patient-assistance program by providing eligible patients with a savings card worth up to $500 per prescription and doubling eligibility to households earning up to 400 percent of Federal poverty level," or $97,000. "Many of them, therefore, would pay nothing out of pocket for the device.

"The truth is, however, that these programs are detested by insurers, healthcare economists, and government agencies—with good reason. In fact, they're illegal when applied to Medicare and Medicaid patients because they may violate Federal anti-kickback laws, which bar payments made to induce patients to choose particular services. Insurers and government programs will have to cover everything beyond the copay at a price that can be as much as $600" a pack.

So you're not familiar with any of this, either the article or what he's ascribing to your motives?

Ms. BRESCH. Which is why we went the step of putting a generic in the marketplace, so that we could make sure we touched every patient and tried to make sure every access point was covered. So by putting the generic in and dropping the wholesale cost to 300, we believe went certainly beyond, and again, to reach and provide access to as many patients as we can.

Mr. DESAULNIER. Okay. In this article, he quotes a healthcare economist from Emory University, David Howard, and he talks about what you're doing as programs that are "a triple boom for manufacturers. 'They increase demand, allow companies to charge a higher price, and provide public relations benefits.' The manufacturers' costs look high in absolute terms, but the payoff is even greater. 'Manufacturers can afford to pay a lot of $25 of $50 copayments.'"

So again, the answer to this is the generic? Is it changing the dynamics?

Ms. BRESCH. Completely.

Mr. DESAULNIER. How long did you have the previous practice before you changed to the generic?

Ms. BRESCH. We still have the patient assistant program and the copays for the brand, but by introducing the generic, we hope that

it's—you know, we hope there's 85–88 percent generic utilization of the generic.

Mr. DESAULNIER. How long did you have the profits under the old system before you switched to the generic? It sounds like you did it for altruistic purposes. This article would portray it a different way.

Ms. BRESCH. Well, and, Congressman, at least the parts that you were reading, I think, go to the patient assistant program or the copay as what they were giving their description of versus the generic. They didn't speak about the generic.

Mr. DESAULNIER. Yeah, but my point is that you're making it sound like you introduced the generic for purely altruistic purposes. The way he describes it was it was a business practice that took advantage of the situation for some period of time.

Ms. BRESCH. Putting the generic in is, like I said, an unprecedented move so that we could reach as many patients as——

Mr. DESAULNIER. That's not the question. I believe in redemption, so I'll give you the generic, but prior to that, you were making money off the situation the LA Times described. So my question is, how long did you do that?

Ms. BRESCH. I don't agree with the LA Times' description of the programs or our process, and I don't think they spoke about the generic program that we've now announced.

Like I said, we have invested, and with the point of wanting to reach more patients, if we're now reaching almost 3 million patients, that's 2 million more that are protected and hopefully much better—in a much better position if an anaphylactic event occurs, aside from the school program, again, because so many people have allergic events that had never had a known allergy, so——

Mr. DESAULNIER. My time has gone by, but I'd just say, from this article and other articles, I didn't bother to quote the USA Today article or the Market Watch article, that you had a business practice that was immensely profitable, you've admitted to that, and you have changed it. But it seems as if you've changed it in anticipation of what the public has responded to.

So with that, I'll yield back the balance of my time.

Chairman CHAFFETZ. Thank you.

I'll now recognize the gentleman from Georgia, Mr. Hice, for 5 minutes.

Mr. HICE. Thank you very much.

I think, Ms. Bresch, you've had a lot of questions today and a lot of pressure put on you. I appreciate you coming. I'm personally very hesitant to go down the path of government getting involved in what individuals make and can't make. This is a free enterprise system. And I get very worried when we start going down that tree. My concern is where the bottleneck is occurring.

And, Dr. Throckmorton, I'd like to ask you, an abbreviated new drug application, as I understand it, is an application when companies want to manufacturer a generic drug, that's what they must utilize. Is that correct?

Dr. THROCKMORTON. For a true generic.

Mr. HICE. Sure.

Dr. THROCKMORTON. So an authorized generic like we've been talking about up to now, that's not approved under that——

Mr. HICE. Okay. But a true generic.

Do you know how many abbreviated new drug applications are currently pending with the FDA?

Dr. THROCKMORTON. We have 1,700 responses that we've sent back to sponsors requesting additional information. We're waiting for that information to come back. There are other applications that are in-house that we're reviewing, again, on the timeline that we've discussed earlier.

Mr. HICE. It's my understanding that the generic applications submitted to the FDA are outpacing those applications that are approved three to one. Is that correct?

Dr. THROCKMORTON. I can't verify that number. There are 2,300 applications before the agency and this year——

Mr. HICE. Twenty-four hundred?

Dr. THROCKMORTON. Twenty-three hundred.

Mr. HICE. Okay.

Dr. THROCKMORTON. This year we've approved 600 products through the middle of this year.

Mr. HICE. Okay. Could you verify for me, could you get the numbers back to us, what the number of applications submitted versus those that are being approved?

And, next, can you tell me the median approval time for generic drugs right now?

Dr. THROCKMORTON. I don't have that information before me. It's also changing. So in the period before GDUFA I, before we got the User Fee Act, those times were——

Mr. HICE. I'm talking about now. I would like that information as well.

Dr. THROCKMORTON. I'd offer to get you the trend, if I could. I think that would probably be more useful.

Mr. HICE. Okay. Because the generic pharmaceutical association says it's taking 47 months. It's taking 4 years.

Dr. THROCKMORTON. Yeah, that's simply a misunderstanding. And I'd be happy to——

Mr. HICE. What do you mean that's misunderstanding?

Dr. THROCKMORTON. Forty-seven months is from the beginning of GDUFA I, from the beginning of User Fee Act. So any products that are being approved now that have been——

Mr. HICE. All right. From beginning of the process to the end of the process, are you disputing that it takes 4 years?

Dr. THROCKMORTON. I'm disputing that for products that come in today, it will not make 47 months.

Mr. HICE. Well, I mean, you can make all sorts of promises. I'm talking about realistically, for those who have been trying, have they been trying for 4 years from the time they start till the time they finish?

Dr. THROCKMORTON. There are products that come in and are sometimes insufficient to get approval. Sometimes that's because the data that they've submitted aren't appropriate.

Mr. HICE. Okay. All right. I don't want to run around the bush. I'm trying to find out how long does it take from beginning to end, and from those that have been involved in the process, they're telling us it takes 4 years.

Now, since 2012, the generic manufacturers, of course, they've been paying fees to the tune of billions of dollars to try to speed the process up through the Generic Drug User Fee Agreement. And this past July, as I understand, the FDA actually said that they had acted on more than 90 percent of the generic applications. I assume that's a little bit of what you're referring to now.

Dr. THROCKMORTON. That's the backlog, the applications that have been submitted to us.

Mr. HICE. The backlog is 90 percent?

Dr. THROCKMORTON. Prior to the beginning of GDUFA I, there was a total of around 4,600 applications that we needed to review. We've acted on more than 90 percent of those. In fact, there are fewer than 100 of them that have not gotten a response.

Mr. HICE. All right. So are you saying of the 4,600, there's only 100 left, that 4,500 have been approved?

Dr. THROCKMORTON. Less than 100 of them remain to have a response. Again, some of the—those products that have a full dossier, have given us the data that we need, have been approved or given tentative approval. Products that are not sufficient, that haven't met the data needs for us, I don't think you'd want us to rubber stamp those.

Mr. HICE. No, I don't want to rubber stamp, but the process is bottlenecked. That is the frustration. The free enterprise system works when you've got multiple companies out there offering products and options for people. We have a scenario now that EpiPen basically, you've got 94 percent of the market, whatever, and you're the only major player.

And reason for is because you guys are not processing a host of others who are trying to get in the market, and when it's taking 3, 4, 5 years for that to occur and who knows how many millions of dollars to go through the process, I mean, no wonder the whole system is not working.

Dr. THROCKMORTON. I'd like to show you the trend data. That is not the trend that we're seeing for the cohort that are being—the applications——

Mr. HICE. The European counterpart only has 24 generic drugs awaiting approval, and they do it from beginning to end in less than a year. That is not what we're experiencing here.

Dr. THROCKMORTON. The European system is quite different from ours.

Mr. HICE. Well, it must be because it's not taking nearly as long as ours does.

Dr. THROCKMORTON. I would say they are apples and oranges to try to compare honestly.

Mr. HICE. Well, Mr. Chairman, my time has expired, and I yield back.

But, yes, we've got tremendous concerns with a drug going from $100 to $600, and there's issues that you all have got to deal with. But we can't place all the blame on you. FDA has got to get their act together and start working the process and getting this thing going through.

And I look forward to receiving the information that you said you would send.

Mr. HICE. Thank you, Mr. Chairman.

Chairman CHAFFETZ. Thank you, Mr. Hice.

We'll now recognize the gentleman from Vermont, Mr. Welch, for 5 minutes.

Mr. WELCH. A couple of preliminary matters. First of all, Mr. Chairman and Mr. Ranking Member, thank you for having this hearing. And I thought your opening statements set the right tone: What is it in the market that's broken that is causing these prices to be increased?

Also, Mr. Hice is asking about whether there is something we can do at the FDA in the approval process. I'm all in if there are things we can do that won't compromise safety.

Second, full disclosure. Mylan has an excellent production facility in St. Albans, Vermont. Many Vermonters work there. I'm very proud of it. Good wages and it's a good employer.

And then third, what drug companies do, I totally agree, is vitally important. You know, my first wife had cancer 9 years, and medications extended her life and alleviated her suffering. So it's important to get it right.

But here's the dilemma, and it's best summed up by a letter that I received—we all got a lot of them—from a person in Essex Junction.

"My 4-year-old son has a severe peanut allergy, and I'm a single mother working a low-wage job with little healthcare coverage. I can't afford to pay this much for EpiPens, and I can't afford not to, because that cost is possibly his life."

So the heart of the matter here is that moms and dads are being given a Hobson's choice. They can pay more than they can afford or they can risk a loss they cannot endure. And that's why it's so urgent that we work together to get to the bottom of this.

And I want to focus my questions on some of what I think are the market breakdowns for lack of competition. And again, Mr. Hice, I acknowledge, the FDA, maybe we've got to make some reforms there, but there are some things that are happening.

When your company bought the EpiPen, the company and got the EpiPen, that was in 2007, I think, right?

Ms. BRESCH. Yes.

Mr. WELCH. And how many EpiPens were sold then?

Ms. BRESCH. Much less than today. I think it was—I mean, it was certainly less than half of the——

Mr. WELCH. Probably way less than half, right?

I have a question about the basic economics. Usually when you sell more of something, the per-unit cost goes down. Is that not the case with EpiPen?

Ms. BRESCH. So, no, cost of goods has gone up every year, and our investment has continued—we've continued to invest in the product.

Mr. WELCH. All right. So you're going to give us—you'll give us the figures on that. Because I understand you're saying it's 50 bucks that is the money in your pocket, which sounds like it would be reasonable. But as you can tell from a lot of the questions, there's a lot of head scratching going on here about that.

Ms. BRESCH. I totally appreciate that, and I appreciate there has been a lot of misinformation, understandably so, given the complexity as, you know, many of you have pointed out, in the system.

Mr. WELCH. Well, and I'm going to ask you to get your graph out that you gave us where the wholesale acquisition price is 608 bucks, that's what people are paying. And then you got down to the bottom, it's 50 bucks for the profit per pen.

Ms. BRESCH. Yes.

Mr. WELCH. That 50 bucks sounds reasonable. But the rebates and allowances, who is getting all that money?

Ms. BRESCH. So that goes—that is between the other people in the supply chain, the pharmacy benefit managers, retail pharmacy, wholesalers and insurers.

Mr. WELCH. Okay. Isn't the service that a pharmacy benefit manager provides essentially to negotiate a best price with the pharmaceutical companies to get a given drug? And they get a rebate, right?

Ms. BRESCH. Probably be better to have a PBM.

Mr. WELCH. Well, you work with——

Mr. BRESCH. But, philosophically, I think that the pharmacy manager, the system, that that is——

Mr. WELCH. No, but I'm not talking philosophically. We're all trying to understand, like, how it works.

So the PBM buys huge quantities of drug A, B, or C, and then they get a discount from Pfizer or from you, and they keep some of that, and it's the way they make their money.

And part of their way of negotiating is with the so-called formulary, right? So if you have heart disease, there might be an option of drug A, B, or C, and they put on the formulary drug A, and there's increase volume there and they get a rebate, right?

Ms. BRESCH. Uh-huh.

Mr. WELCH. With respect to epinephrine, there's no formulary. If you're having anaphylactic shock, there's only one thing you need, and it's the product that you sell.

Ms. BRESCH. No. There has been competition, as we've said, throughout the years.

Mr. WELCH. All right, but——

Ms. BRESCH. But I think this is kind of—if I only could just get this point. Auvi-Q, which launched their product at the end of 2013. So we did have to face formulary choices of not even being on the formulary due to the competition in the marketplace.

Mr. WELCH. But somehow you've ended up with 94 percent or 97 percent of the market.

Ms. BRESCH. But I would ask that people recognize our product and that it is more complicated. Auvi-Q was completely recalled off the market for safety reasons, which is a very rare event.

Mr. WELCH. No, I understand that. But in this graph, I mean, what is just impossible to understand is how does something cost $608 when the company that sells it is only making 50 bucks, and that is hard to understand.

Ms. BRESCH. And I understand how complicated and how head scratching that is, which is why, you know, I've said I would welcome the opportunity to sit down—you know, I know this is about EpiPen, but look at the system.

Mr. WELCH. All right. I don't have much time, so I have to keep going.

You know, this is hammering that Vermonter who has that Hobson's choice, but it's also very tough on taxpayers. Our Medicaid program in 2011 was paying $111 per script, and we spent in Vermont—and this is a lot of money for us—we spent then $111. Now it's $557. We went from $256,000 in taxpayer money to $1.7 million. That's tough. I mean, that really is tough.

Ms. BRESCH. And, look, and that's why the generic, being able to put it into the market, that would help lower healthcare costs across the board.

Mr. WELCH. Right. But the generic—what I understand, it used to be the position that you had, Mylan had, is that doing these authorized generics was a real threat to the generic industry. That's the public record of your point of view.

Ms. BRESCH. A decade ago, and I know that this is complicated, but the authorized generics of keeping a first generic or competing with the generic, in this instance, that's not this case, but——

Mr. WELCH. If I can just go on a little bit. One other thing. The cost of EpiPen in the Netherlands is 105 bucks, and that's where your corporate headquarters are. How do they get 105—and you moved your headquarters from the U.S. to the Netherlands—how is it they get to buy it for 105 bucks and we pay 608?

Ms. BRESCH. Sir, one, I'm not sure of the cost, but what I would say is they have a completely different system.

Mr. WELCH. I guess I yield back.

Chairman CHAFFETZ. We would appreciate some clarification on that.

We do have a pharmacist, and I believe the only pharmacist in the House and the Senate, pleased to have him on this committee. We'll now recognize him. Mr. Carter of Georgia.

Mr. CARTER. Thank you, Mr. Chairman. Mr. Chairman, before I start, can I inquire of you, the witnesses took an oath and they're still under oath now?

Chairman CHAFFETZ. Absolutely.

Mr. CARTER. Okay. I just want to make sure.

Ms. Bresch, have you ever seen a child have an anaphylactic shock? You ever witness that?

Ms. BRESCH. I haven't.

Mr. CARTER. Excuse me.

Ms. BRESCH. I have not.

Mr. CARTER. You have not?

Ms. BRESCH. No.

Mr. CARTER. Have you ever gone up to a pharmacy counter and carried a pack of two epinephrines and two EpiPens and told a mother of a child who has had anaphylactic shock, who has an allergy, that the price of that is going to be $600?

Ms. BRESCH. No.

Mr. CARTER. Have you ever seen a mother cry because she can't afford the medication for her child?

Ms. BRESCH. No.

Mr. CARTER. Well, the reason I ask you this, Ms. Bresch, is because I have. I've experienced it. I've seen this. I've seen a mother go out and have to call family members to see if she can get the money together to try and see if she can pay for this medication that she knows her child has to have. I've witnessed that firsthand.

None of us are without blame here, Ms. Bresch, none of us, and I include my profession as well.

Let me ask you a couple of yes-or-no questions. First of all, the 608 wholesale acquisition cost, is that AWP.

Ms. BRESCH. No, sir.

Mr. CARTER. So it's just wholesale acquisition?

Ms. BRESCH. Yes.

Mr. CARTER. Okay. Wholesale acquisition cost is $608. You said that your company receives approximately $274, is that right, after rebates and allowances?

Ms. BRESCH. Correct.

Mr. CARTER. Okay. So after you take out the expenses like manufacturing, acquisition cost, packing, regulatory compliance, all of those things, your profit is even less than that. Is that correct?

Ms. BRESCH. Correct. That would be the $50 per pen.

Mr. CARTER. Okay. So after you do that, Ms. Bresch, do you have any contracts with PBMs? Does Mylan have any contracts with any pharmacy benefit managers, PBMs?

Ms. BRESCH. Yes.

Mr. CARTER. You do have contracts with PBMs?

Ms. BRESCH. Yes.

Mr. CARTER. Okay. Can you describe some of those contracts for me, very briefly?

Ms. BRESCH. Well, the contracts are around products, multiple products. To participate on the formularies, the patients have access to the products.

Mr. CARTER. Okay. So we established earlier that over half of the list price does not go to Mylan. Do you know how much the PBM receives?

Ms. BRESCH. I don't have a breakdown between the channels, but that's where showing that between those——

Mr. CARTER. I understand, but do you know specifically how much the PBM, the pharmacy benefits manager receives?

Ms. BRESCH. I don't specifically know the breakdown between those four buckets, between the PBMs, the pharmacy, the insurers, or the wholesalers.

Mr. CARTER. Nor do I, and I'm the pharmacist, and I don't know either. In fact, nobody knows. That's the problem. Nobody knows how much of this is going to the pharmacy benefits manager, because there is no transparency. That's the problem.

Do you know how much the PBM receives in rebates and other fees that are related to the EpiPen whenever one is adjudicated through a pharmacy?

Ms. BRESCH. I don't.

Mr. CARTER. You don't. Nor do I. All I know is that my computer calls the insurance and they tell me how much I'm supposed to charge a patient. I don't know how much you're getting as a manufacturer. I don't how much the insurance company is getting. I don't know how much the PBM is getting. That's where transparency comes in. That's what we need.

Do you know how much of the EpiPen savings, the related savings and rebates that the PBM gives back to Mylan? You said you had contracts with PBMs. How much do you get back from the PBM?

Ms. BRESCH. I don't know.

Mr. CARTER. All right. Remember you're under oath. Do you know how much you get back in rebates from a PBM?

Ms. BRESCH. I just don't want to give you an inaccurate number. I agree that we have contracts.

Mr. CARTER. Do you know? Can you provide us with that information?

Mr. Chairman, can I ask for that information.

Chairman CHAFFETZ. Absolutely.

Ms. BRESCH. I'll certainly go back and look at that. I'm just saying I don't want to give an inaccurate number to you.

Mr. CARTER. Okay. So you don't know how much the PBM receives or keeps for itself, nor do I, nor does anyone else, whether it's the manufacturer, the insurer, or the pharmacist, none of us know.

What we do know is this. Prescription prices, prescription drug prices have soared, and so have the profits of PBMs. They are in the billions of dollars.

Until we have more transparency in the PBM market, we are going to continue to see these kind of cost increases. We're going to continue to see them.

That's why we need bills like House Resolution 244. My good friend, Representative Doug Collins from Georgia, has introduced this bill dealing with the MAC transparencies. It's called the MAC Transparency Act. This would help us and take a step towards transparency.

Mr. Chairman, I want to thank you. I want to thank you for holding this hearing today. And I want to reiterate my request that I have made to you and to this committee from time to time about further investigating how deceptive practice by PBMs are impacting drug prices.

Would you agree with that, Ms. Bresch?

Ms. BRESCH. I certainly would agree that transparency is needed. The healthcare system has evolved dramatically over the last decade, and I'm sure, as you've seen as a pharmacist, that the system hasn't kept pace with this evolution of the healthcare system.

Mr. CARTER. The system isn't kept pace? PBMs have had billions of dollars, billions of dollars in profits, yet I have to sit there and take a prescription to the counter to a mother whose child has suffered from anaphylactic shock and watch her cry and watch her have to call family members in order to get the money to pay for this medication.

And we don't know where it's going. You say it's not going to you. Where is it going? I need to tell her. I need to tell her where that money is going.

Ms. BRESCH. The most immediate thing I could do was put a generic into the market.

Mr. CARTER. No, don't go there. You know I know better than that. That is wholly—that is just—that is a crock, and you know that I know that. It is. There is no difference whatsoever.

Now, Ms. Bresch, don't——

Ms. BRESCH. We cut the price.

Mr. CARTER. You cut the price in half. Do not do that to me. Don't try to convince me that you are doing us a favor here. You

are not doing a favor by that. You could have dropped the price of EpiPens just as well, but instead you said, no, we're going to make a generic.

Ms. BRESCH. But to the——

Mr. CARTER. Oh, no, no.

Ms. BRESCH. —to the point of the wholesale acquisition cost of getting to those patients and making a difference, to your point, to make sure everyone who needs an EpiPen has one, I couldn't ensure by the wholesale acquisition cost on the branded side of this channel that that would get to all the patients.

Mr. CARTER. You did not want to cut the price on the EpiPen brand, whatever you want to call it, because you wouldn't have gotten your rebates from the PBMs like you get them now. I am waiting for the information that you have promised me that you will send to this committee.

Mr. Chairman, I am going to hold her to that.

Ms. BRESCH. And, sir, what I can tell you is that to bypass this, the most immediate thing that we could do was to put a generic in, because it bypassed the formulary, everything you're just describing.

Mr. CARTER. Are you getting a rebate on those generics from the PBMs? Are you getting a rebate on the generic version of EpiPen from the PBMs?

Ms. BRESCH. I don't—I don't—those are still under—we haven't done those arrangements yet because we're launching——

Mr. CARTER. But are you planning on getting a rebate? Are you planning on getting a rebate from the PBM for the generic version of EpiPen that you are introducing?

Ms. BRESCH. I don't know. I honestly don't know how——

Mr. CARTER. Remember the oath, I'll tell the truth.

Ms. BRESCH. I have not negotiating those—but I can tell you, as you know, the formularies, the PBMs, and the generics, it's very different than on the brand side of the house, the channel.

Mr. CUMMINGS. Would the gentleman yield? I know that he doesn't have any more time, but I just want to help clarify something.

Mr. CARTER. I yield.

Mr. CUMMINGS. And this is to help. I just want to take just one step further.

Do you know what you get from the PBMs for the regular EpiPen, how much rebates? The gentleman was talking about that. Do you?

Ms. BRESCH. That's what I said. I don't want to give an inaccurate number—-

Mr. CUMMINGS. But you can get us that information?

Ms. BRESCH. I absolutely will go back and work on that information.

Mr. CUMMINGS. Okay. And two, you expect to be getting rebates from the generic. Is that right? Yes or no?

Ms. BRESCH. He asked specifically about the PBM, and I don't want to give an inaccurate answer.

Mr. CUMMINGS. But I didn't ask you that. I said are you getting—are you getting——

Ms. BRESCH. We pay rebates. We pay rebates on the generic as well.

Mr. CARTER. That's not what he's talking about. You know what he's talking about.

Ms. BRESCH. I don't—I can't sit here today and tell you what comes back on the generic. What I can tell you is that there's discounts and rebates paid, but it's a much smaller degree on the generic.

Mr. CARTER. Mr. Chairman, reclaiming my time. This is a shell game. That's all it is.

Ms. Bresch, I hope you never have the experience of going to a counter and telling the mother of a child who has suffered from anaphylactic shock that she needs to pony up with $600. I hope you never experience that, Ms. Bresch.

Mr. Chairman, I yield back.

Chairman CHAFFETZ. I thank the gentleman.

Ms. Bresch, when could we expect this committee to have that information that was asked by Mr. Carter? What's reasonable?

Ms. BRESCH. I mean, I have no——

Chairman CHAFFETZ. You're the CEO. You've got how many employees?

Ms. BRESCH. Yeah, no—yes. Just I'm not sure what's asking or how—I don't want to promise something——

Chairman CHAFFETZ. You don't know what he's asking? You want him to ask again?

Ms. BRESCH. No, no, I know what he's asking about what it takes to give you that information, but we will do it as soon as possible.

Chairman CHAFFETZ. I'm asking you what a reasonable date is. A week? Can you get that to us in a week?

Ms. BRESCH. Ten days?

Chairman CHAFFETZ. Okay, 10 days. Yes. Ten days. Thank you. Appreciate it.

Let's now recognize Mrs. Watson Coleman for a generous 5 minutes.

Mrs. WATSON COLEMAN. Thank you, Mr. Chairman.

And I'm really sorry I couldn't be here all day. I may ask you some questions that have already been asked.

So I want to talk about sort of the company and how generous it is and what a good life it seems to be associated with being associated with the company. Your perks, in particular, aren't limited to just an astronomical salary and stock benefits. You also have access to the company jet. Is that true?

Ms. BRESCH. Yes.

Mrs. WATSON COLEMAN. Mylan's public filings list the amount of money that that you spent on the company's jet. In 2015, you spent 310,000, and in 2014, you spent 319,000. Does that sound correct? Does that sound correct?

Ms. BRESCH. I believe that sounds correct.

Mrs. WATSON COLEMAN. Did you fly here today?

Ms. BRESCH. Earlier in the week, not today. Yes, I flew, but just not today.

Mrs. WATSON COLEMAN. And did you fly on the private jet?

Ms. BRESCH. I did.

Mrs. WATSON COLEMAN. And were you accompanied by anybody?

Ms. BRESCH. Other employees.

Mrs. WATSON COLEMAN. That's a yes or you're asking me?

Ms. BRESCH. Yes. No, I'm saying other employees accompanied me.

Mrs. WATSON COLEMAN. Okay. Do you have any idea how much that costs?

Ms. BRESCH. Look, I know that—it's fortunate and it's for efficiency and safety. And, yes, I understand——

Mrs. WATSON COLEMAN. Let me ask you another question. From where did you fly?

Ms. BRESCH. From Pittsburgh.

Mrs. WATSON COLEMAN. From Pittsburgh. Is that where you're located?

Ms. BRESCH. Yes.

Mrs. WATSON COLEMAN. Okay. Yeah, it is a little stunning to see that so much money could be spent on your traveling around in a jet while we're having this discussion here about whether or not Americans are being bilked for a life-saving drug like EpiPen.

I know the importance of EpiPen because when I was a legislator in the State of New Jersey, we voted legislation to make sure that all the schools had it. And so I was sort of very interested in your response to Mr. Welch, if this drug use had increased so very much, wouldn't there have been then an associated decrease in the cost to people because it was so widely used? That's just the economies of scale, but apparently that's not the case.

I want to talk a little bit about the company and some of its tax benefits, because I think I want to participate in the backdrop of a picture here.

We know that you've profited from increasing the price of EpiPens, but you've also—this company has also increased its profits in another way, and that's by taking advantage of a tax loophole, particularly the tax inversion, which involves a company moving its official headquarters abroad to lower the amount of taxes they pay in the United States.

In 2014, Mylan moved its official headquarters to the Netherlands. Is that true?

Ms. BRESCH. Yes.

Mrs. WATSON COLEMAN. You wrote in a letter to shareholders about the tax inversion, and I quote: "The transaction also is expected to lower Mylan's adjusted tax rate, currently forecasted to be approximately 24 to 25 percent in 2014, to approximately 20 to 21 percent in the first full year after the consummation of the transaction and to the high teens thereafter."

What was Mylan's companywide effective tax rate in 2014?

Ms. BRESCH. I believe it was in the mid-20s to low-20s, before we inverted.

Mrs. WATSON COLEMAN. What is it today?

Ms. BRESCH. It's between 15 to 17 percent.

Mrs. WATSON COLEMAN. So, from our perspective, last year, hardworking Americans had to pay 25 percent on all amounts that they've earned over $38,000. But Mylan, which, according to the SEC filings, had earnings in 2014 of close to a billion dollars, you paid a lower tax rate than many individuals who are struggling

and who are possibly parents who need access to those drugs for their children.

Did you lower the cost of the EpiPen since Mylan would be saving so much in taxes by this move?

Ms. BRESCH. So the 15 to 17 percent is our global tax rate. I mean, that's after averaging everything out. So we in the United States are still paying higher taxes on everything that we sell here in the United States.

Mrs. WATSON COLEMAN. So, from the benefit that you derived from moving your headquarters, did you lower the EpiPen cost here in this country?

Ms. BRESCH. We're still paying taxes——

Mrs. WATSON COLEMAN. That's a yes or a no, ma'am.

Ms. BRESCH. —higher taxes.

Mrs. WATSON COLEMAN. So that's a no or a yes? That would be no.

Ms. BRESCH. We did not lower.

Mrs. WATSON COLEMAN. Okay. According to an article in the Washington Post, as a result of this tax inversion, some Mylan executives based in the U.S. faced higher personal tax liability related to stock that they received as part of their compensation. That same article stated that Mylan paid you more than $5 million to cover these taxes.

So, while Mylan skirted its tax liability and left our country, leaving hardworking Americans to foot this bill, you didn't have to worry, because Mylan paid more than $5 million to cover your personal taxes. That's really hard to deal with and hard to believe.

You are the CEO of Mylan, right?

Ms. BRESCH. Yes.

Mrs. WATSON COLEMAN. When Mylan moved its official headquarters abroad, did you move to the Netherlands?

Ms. BRESCH. No.

Mrs. WATSON COLEMAN. According to your Web site, and I quote: "The chief executive officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide business at the company's principal offices in Canonsburg, Pennsylvania." Is that true?

Ms. BRESCH. Yes.

Mrs. WATSON COLEMAN. So is there anything more than a virtual office in the Netherlands so that you could claim to be a tax purposes resident there?

Ms. BRESCH. We are now domiciled in the Netherlands and handle our—and run our global business, but physically, yes, we work out of Canonsburg.

Mrs. WATSON COLEMAN. So, basically, you're running the business out of Canonsburg. So you simply moved your address to another country so that you didn't have to pay at the tax rate in this country at the same time you present this drug, this lifesaving drug at this increased cost to families who can barely afford it. It sounds to me like this is really a sham and a shell, and it's very sad to hear this.

Do you really think that it's fair that you don't have to pay the taxes as a U.S. company?

Ms. BRESCH. So, again, we do pay taxes here in the United States for all of the sales of all the revenue that we receive here in the United States. So we are absolutely paying our taxes for everything that we sell here in the United States.

Mrs. WATSON COLEMAN. The one thing I get is that you all are very smart about avoiding responsibility and straightforwardness, you know, but there is a bill that could close the loophole that you have your virtual office over in the Netherlands and claim to be a resident for tax purposes, and that is the Stop Corporate Inversions Act of 2015, which was introduced in January of last year.

And I'm sorry to say that my Republican colleagues have failed to act on it, but I think that, having had a hearing of this nature, we can expect, I think, to have more attention to this matter.

And, with that, I thank you for the generosity of time, Mr. Chairman, and I yield back.

Chairman CHAFFETZ. Thank you.

We'll now recognize the gentlewoman from New Mexico, Ms. Lujan Grisham.

Ms. LUJAN GRISHAM. Thank you, Mr. Chairman.

And I too want to thank the ranking member and the chairman for bringing this hearing together and having you.

Unfortunately, it's not our first hearing on such matters. I mean, we are talking and dealing with Turing and Valeant and Mylan and Gilead, and seeing a really disturbing pattern where Congress provides a variety of mechanisms to invest in innovation and pharmaceutical companies so that we get the right public health treatments and medicines and that we also have innovations. And we give you patent protections. We give you R&D money. And what we get in return is now a monopoly using your generic aspect in a way that we did not intend and have a hearing where we're not going to get any relief. You've made it clear that you're following the rules, you're completely justified, and the amount of money that you are both spending on salaries and bonuses and infrastructure and acquisitions is all justified while you're making a billion dollars on a drug that most people can't afford, with a patient assistance program that most drug companies created in the 1990s so that as drug prices went up, policymakers would hesitate before dealing with price legislation that would make it fair to consumers. Because the problem is, if you're a consumer and you have to have it because it's lifesaving, it's already unfair, because we're going to have to do whatever we need.

And, quite frankly, my constituents aren't so happy about a prescription drug assistance program. Nobody wants to give you their tax returns or their Social Security number or tell you over the phone what their income is or provide you those income statements. And I don't know what you pay for those staff to provide those—to do that evaluation. The reality is: Just don't do it. Make the drugs affordable. And you create an environment where you have preferences and you make sure that it's on a preventative drug list. So I think, instead of having any more conversations—I mean, I don't think that we've gotten very many of our questions answered, because, in fact, Mr. Chairman, it is true it is very complicated. We've created an environment where they don't have to be transparent, so they aren't.

Let me give you an example where what we thought, what we intended in terms of policymaking with generics and competition worked. In 10 years, when we decided that, as a public health issue, we should have, to your point, have defibrillators in all public places, because we want to save people's lives. We know that vehicle creates an opportunity where laypersons can help administer that level of care and prevent a person from dying from a heart attack. And in 10 years, by having six companies effectively compete, we've dropped those prices of defibrillators by about two-thirds.

Unfortunately, that's an anomaly. Today, we are seeing price increases in therapeutic equivalents, in generics. We're seeing longer patent protections. We negotiated longer patent protections in 21st Century Cures. So I would suggest that, today, while we have bipartisan now support and real interest in protecting our consumers, that maybe it's time that this committee lead the effort. Let's join up with Ways and Means, and Energy and Commerce, and here's some ideas: I think it's time to consider allowing FDA to look at price increases and then ask them to include that when they prioritize generic applications.

I propose that maybe we need a price protection program for public health drugs, and that we need to decide a public formulary. There's no formulary for the EpiPen. You've got it. A formulary works when there's competition. There are different drugs on that formulary for high blood pressure or insulin. You don't need a formulary; you're it. And you're it, except that, in Canada and all over Europe, your drug is much cheaper. So I think we should import those drugs right back.

We paid you to figure out the device, the application, the drug. Now we're protecting you with a generic. We're allowing you to do patient assistance programs under the guise of trying to make sure that it's affordable. We create rebates and very complicated. You pay them; they pay you back. I say: Let's demystify it. Let's make sure that Congress puts in a real patient protection program to prevent companies like yours from taking advantage of every policy aspect that was intended to make affordable health care.

And, quite frankly, as long as I'm on this rant, I'm tired of paying prescription drug companies and drug manufacturers and device companies to treak these issues. If we put the same kind of money that we're allowing you to keep to deal with curing allergies, we wouldn't be having this conversation about EpiPen, would we? So I say we shift it, instead of trying to, you know, pull out information where I agree; I think you've been far less than transparent. And I think we ought to do transparency legislation. I think there's a whole host of ideas where we could lead instead of being dragged down this path where we're upset for our constituents when none of these prices on their own at these company's hands will shift. They certainly haven't.

Pharmaceutical companies and insurance companies and PBMs where you tried to shift to PBMs, they are all making incredible profits in an environment where that profit-making environment has all been at the hands of policymakers trying to create a competitive, innovative, private sector, high-quality investment to protect Americans.

And, instead, we've created that access around the world, and we've left Americans holding, if you will, the financial bag. And I for one am tired of that. So I don't need any answers because I won't get any that are fair from you or your company, but I am expecting Congress now to take a much different leadership role.

And I thank my colleagues on this committee and the leadership by the ranking member and the chairman, because maybe, because of your greed and the other companies, maybe you finally put Congress into a position where, bipartisan, we will have the courage to finally do what's right for our constituents. I have that courage. I believe my colleagues do too.

I yield back.

Chairman CHAFFETZ. I thank the gentlewoman.

We'll now recognize the gentleman from Wisconsin, Mr. Grothman.

Mr. GROTHMAN. I'm out of breath. I just got here.

Okay. First of all, for you, Mr. Throckmorton, and maybe somebody's asked this question. If they've asked it, just say, "Go to the next question."

Have we figured out why the market is not working and why other companies are not marketing these things and undercutting Mylan?

Dr. THROCKMORTON. There is another product that's being marketed. Why it's not marketed more broadly, why these increases in prices I think is the question you are asking. Isn't it?

Mr. GROTHMAN. Right, right. Is the other product at a lower cost?

Dr. THROCKMORTON. I'm told that that product is lower price, yes.

Mr. GROTHMAN. Okay. Maybe we don't want Ms. Bresch to pitch the competition. But you do have competition. You've only got 94 or 96 percent of the market, right?

Ms. BRESCH. That's our current market share, but there's been products in and out of this marketplace over the years. And as——

Mr. GROTHMAN. Are there products in the marketplace today?

Ms. BRESCH. Pardon me?

Mr. GROTHMAN. Are there products in the marketplace today?

Ms. BRESCH. Yes, yes.

Mr. GROTHMAN. And are they lower priced than your product?

Ms. BRESCH. There's an Adrenaclick authorized generic, and I'm not sure of its exact price, but I believe it's in the $450 range.

Mr. GROTHMAN. Okay. Is there anywhere—I'll ask Mr. Throckmorton, because I don't mean to ask you to pitch your competition. Is there any reason why there—there are generics available—why people aren't producing this stuff for substantially less?

Dr. THROCKMORTON. There are no generics in the way that I think you are speaking of them. The generics that are available are so-called authorized generics, which are branded name products that have chosen to remove their name from their label. Otherwise, they are——

Mr. GROTHMAN. So that's not what this is.

Dr. THROCKMORTON. Our interest, I would say the broader interest that we have is in encouraging real competition, which means multiple manufacturers creating many different versions of epi-

nephrine auto-injectors, including true generics, generics approved under the Abbreviated New Drug Application.

Mr. GROTHMAN. So so-called competition for EpiPen, you would really argue, is not as good or is not the same thing?

Dr. THROCKMORTON. If you were looking just simply at the numbers of manufacturers in the area, there are two manufacturers currently making epinephrine auto-injectors for prescription in the U.S. There's a third product that's approved that was voluntarily withdrawn last fall because of some manufacturing issues. If they address those manufacturing issues, they would be able to come back onto the market also.

Mr. GROTHMAN. And do you expect them to, given, I presume, there's a high markup here?

Dr. THROCKMORTON. We are offering any assistance that we can to them to do exactly that.

Mr. GROTHMAN. Now, my next question for Ms. Bresch, kind of a more difficult question, and I'm not suggesting any governmental problem, but I read a book a little while ago by Charles Murray. I don't know if you're familiar with him, a famous author. He talked about the moral decline of America. And a lot of that moral decline, he focused on what I'll call the underclass and a lifestyle is not something that many people in my age group had when we were growing up, but he focused a little bit on the upper class. And one of the things he focused on, which I think maybe collectively isn't a huge amount of money—maybe it adds, you know, a penny to each prescription drug you have, but I think it's bad for the fabric of society. Now, I realize it's legal, and I'm not just targeting you, because it's common across the board.

It came up earlier that, you know, you're making whatever, $19 million or $20 million a year. And that's fine. Maybe that's a half cent off of every prescription you guys make. But the point Murray made is there was a time in this country where chief executives got along making a lot less. And they apparently make a lot less in sizable companies around the globe. And I think the point he made was this is a sign of greed. And while, you know, it may be a relatively small amount for every person in the country, it probably tears a little bit at the moral fabric as people who work for companies and make relatively small amounts of money look at the chief executive making more money than anybody could possibly imagine.

Do you ever feel guilty or have pangs of guilt making such a large sum of money, not as somebody who founded the company but as an employee who really doesn't have a lot of risk yourself?

Ms. BRESCH. Look, I am blessed and fortunate. I've been working at this company for 25 years and representing 40,000 employees. So what—Mylan has continued to provide access to multiple medications here in the U.S., over 600 products.

Mr. GROTHMAN. I know, and I'm sure there are many employees who work for you who do wonderful things, valuable scientists who are saving people's lives. I'm just saying, as you walk around the cubicles and see all the people making $40,000 or $50,000 or $60,000 a year, do you ever feel guilty that you and the board of directors and such have arranged to have you make $20 million a year?

Ms. BRESCH. I am—I love that Mylan is trying to make a difference every day in what we do and how much product and how much access we are bringing and the savings to this country alone, which, over the last decade, have been $180 billion.

Mr. GROTHMAN. Probably more the scientists who work for you than you. But you understand what I'm saying? Maybe you don't understand. And maybe you are very good and maybe you're worth it. I think one of the things that frustrates a lot of Americans is there are a lot of people who even run their companies into the ground and make tens of millions of dollars.

But I'm just going to ask you to comment again. Do you think it's good for the moral fabric of society and the idea of we want people to believe in the free economy system when, in a business, some people make $20 million a year?

Ms. BRESCH. I think to your point, the free market system and delivering—being a well-run company and delivering great shareholder value is part of that free market system.

Mr. GROTHMAN. I'm sure they're getting good value. You see what I'm saying? Maybe you don't understand what I'm saying. There are a lot of people out there—we're going into election season here. There are a lot of people out there who think the system is, in part, broke, and in part, it's broke because they're working their butt off and doing very valuable things, and maybe they're even told to take cuts in pay, and they see a chief executive making a huge amount of money, way more proportionately, even adjusting for inflation, than chief executives made 50 years ago and, as I understand it, more than they make in other Western countries. And I think it grates at some people. I think it causes distrust in our system.

I'm not suggesting we take away your freedom to make that amount of money. I'm just saying, in all walks of life, there are people that have the capability of making more and voluntarily say, "I don't need that amount of money." And I just wondered if you had any comments on the system that we have in America where so many chief executives, not just you, seem to be making far more money than I think anybody would even know what to do with. And that's my only question.

Ms. BRESCH. And I—other than commenting that, yeah, the free market system and—is—I hope that there are companies that are definitely giving back, giving back and creating access and providing—providing many things. And, like I said, I go back to Mylan and what we have been able to create and with 80 billion doses capacity and building up to lower those healthcare costs. So——

Mr. GROTHMAN. I'll take it you're not answering the question because a little bit deep inside, you are embarrassed at what you're making.

Chairman CHAFFETZ. Thank you.

I will now recognize myself for 5 minutes.

Your last comment about reducing the price I find offensive and inaccurate, but let me go first. Is EpiPen, is it a brand drug, or is it a generic drug?

Ms. BRESCH. EpiPen is a brand drug.

Chairman CHAFFETZ. Does that mean it's an innovator drug?

Ms. BRESCH. You mean based on CMS classification. It's a noninnovator drug.

Chairman CHAFFETZ. Wait, wait, wait. Noninnovator drugs are really generics, correct?

Ms. BRESCH. The definition, CMS has a statutory definition for innovator and noninnovator drugs.

Chairman CHAFFETZ. So you think it's a branded product, but it's a noninnovator drug for the purpose of CMS?

Ms. BRESCH. Yes, that's how it's classified.

Chairman CHAFFETZ. And you're familiar that Mylan had to settle a $118 million settlement with the Department of Justice back in 2009, right? Yes?

Ms. BRESCH. I'm not familiar. I'm trying to—what settlement?

Chairman CHAFFETZ. With the Department of Justice to resolve allegations that Mylan had underpaid the rebate obligations in the Medicaid prescription drug rebate program with respect to several other Mylan products, not EpiPen. But you're familiar with that?

Ms. BRESCH. I'm not recalling the settlement that you are speaking of.

Chairman CHAFFETZ. This is the Justice Department. I'll ask unanimous consent to enter this into the record, dated Monday, October 19, 2009, Justice News, "Four Pharmaceutical Companies Pay $124 Million for Submissions of False Claims to Medicaid."

Without objection, so ordered.

Chairman CHAFFETZ. Have you or anybody at Mylan spoken with CMS?

Ms. BRESCH. Yes, there has been conversations with CMS.

Chairman CHAFFETZ. Have you had any of those conversations with CMS about EpiPen or the generic EpiPen?

Ms. BRESCH. I have not.

Chairman CHAFFETZ. Have you spoken with anybody at Health and Human Services about EpiPen?

Ms. BRESCH. I have not.

Chairman CHAFFETZ. Nobody?

Ms. BRESCH. No.

Chairman CHAFFETZ. Has anybody at your company been in negotiations or discussions with CMS regarding EpiPen?

Ms. BRESCH. Yes. People at the company have talked. Staff has talked back and forth.

Chairman CHAFFETZ. Who at your company has done that?

Ms. BRESCH. I think there's been several people, I mean, several people within the company that have had conversations.

Chairman CHAFFETZ. Can you get us the names of those people?

Ms. BRESCH. I'm sure we could tell you—yes, I'm sure we——

Chairman CHAFFETZ. Within that 10 days?

Ms. BRESCH. I'm sure that we can do that.

Chairman CHAFFETZ. We would also like the names of the people at CMS they've been in discussions with. Can you give us the names of the CMS people that your staff has been working with?

Ms. BRESCH. I'm sure we can. Like I said, I've not had any of——

Chairman CHAFFETZ. Is 10 days reasonable?

Ms. BRESCH. Sure.

Chairman CHAFFETZ. Because the concern here is that and the question really is, why is Mylan classifying EpiPen as a noninnovator drug?

Ms. BRESCH. When we acquired the product, it had been designated as a noninnovator drug. And there's been several points throughout time that have confirmed that status.

Chairman CHAFFETZ. Do you believe that the generic that you are planning to introduce—when, by the way, do you hope to introduce the generic?

Ms. BRESCH. Certainly before the end of the year. Over the next——

Chairman CHAFFETZ. In the next 90 days or something?

Ms. BRESCH. Couple of months, yes.

Chairman CHAFFETZ. Okay. And are you going to work to classify that as a noninnovator drug or an innovator drug?

Ms. BRESCH. I'm not sure what that classification—we haven't submitted that document. We haven't submitted yet, because we haven't launched the product.

Chairman CHAFFETZ. Okay. I need to spend a few minutes going through this, this chart that's right next to you. And I also need the help with you—and it's going to take a few minutes; I appreciate the indulgence of the committee—to understand some of the definitions. Mr. Carter pointed out there's a revenue line here that seems to be missing, correct? Let me go first to the Mylan revenue, 274. Define that for me. Is that the average revenue per—what is that? 274, define that.

Ms. BRESCH. The average revenue that Mylan receives for a 2–Pak of EpiPens.

Chairman CHAFFETZ. So, in your letter to me and Mr. Cummings of September 15, page 2, at the very top of the paragraph—I'll read here—you write: "Approximately 85 percent of consumers who are prescribed an EpiPen auto-injector pay less than $200 for a two-unit pack and a majority pay less than $50."

Is that accurate?

Ms. BRESCH. I actually thought it was lower than the 200. I actually thought the majority of patients pay less than 100, and then many pay less than 50.

Chairman CHAFFETZ. Well, they're both in the majority, right? Eighty-five percent of consumers who are prescribed an EpiPen auto-injector pay less than $100 for a two-unit pack and a majority pay less than $50.

Ms. BRESCH. Yes.

Chairman CHAFFETZ. So, of those that purchase the EpiPen, how many do it as a prescription? Do you have to have a prescription?

Ms. BRESCH. Yes, you have to have a prescription.

Chairman CHAFFETZ. So 100 percent of that universe?

Ms. BRESCH. Yes.

Chairman CHAFFETZ. So, if your average revenue to Mylan, your Mylan revenue is $274 and the majority of people are paying less than $50, the minority is paying what to get it?

Ms. BRESCH. Well, it could range from—it could be anything, because all the plans—if you're uninsured or if you're—it would range, because every plan is different.

Chairman CHAFFETZ. So what's the highest number? Is 608 low?

Ms. BRESCH. It could—because we don't set the price that's—that when the patient walks up to the pharmacy counter——

Chairman CHAFFETZ. I'm talking about your revenue.

Ms. BRESCH. Our revenue is the 274 per pen, on average.

Chairman CHAFFETZ. Okay. So that's the average number.

Ms. BRESCH. Right.

Chairman CHAFFETZ. And you just told me that the majority pay less than 50 bucks. So I'm trying to figure out with the remainder, what are they paying?

Ms. BRESCH. But the cost to the patient is different than what we're receiving.

Chairman CHAFFETZ. Yes.

Ms. BRESCH. And I think that—and when——

Chairman CHAFFETZ. But you just told me—look, you told me that you sell 4 million 2–Paks, right? Eight million individual, 4 million 2–Paks.

Ms. BRESCH. Correct.

Chairman CHAFFETZ. If you multiply 4 million 2–Paks times the $274, you miraculously get to roughly $1.1 billion.

Ms. BRESCH. Correct.

Chairman CHAFFETZ. So how is it that the majority, according to what you wrote us, pay less than $50 if the majority of 4 million people, just more than 2 million people, are paying less than 50 bucks, how do you get to an average of $274?

Ms. BRESCH. Because the patient—what the patient is paying is not—is not coming back to Mylan. And when we were speaking earlier of the people, the middlemen in the system, so that's either the pharmacy benefit managers, retailers, wholesalers, insurers, is where—because I'm not—I'm not interfacing directly, from a price perspective or a pay perspective, to the patient.

Chairman CHAFFETZ. But you are representing to us that 85 percent of consumers are paying less than 100 bucks and that a majority are paying less than $50. The reason you're having this hearing is not because the public thinks they're getting a good deal. Look, I got a $600 product, and I only had to pay $48. That's not why you're here. They're telling us they are having to pay much greater numbers.

Ms. BRESCH. And it's that growing minority that I spoke of earlier that is being faced now with the wholesale acquisition cost or more at the counter.

Chairman CHAFFETZ. How do you define "profit"? What is profit to you?

Ms. BRESCH. So the $50-per-pen profit is for the direct EpiPen-related cost. We didn't—there's no company allocation or anything like that off of that.

Chairman CHAFFETZ. Well, but that's not what you wrote me. You wrote this letter less than a week ago. Here's what you said: "Among other things, this profit is used to fund research and development and to maintain and improve our facilities across Mylan, in which we invest $1.2 billion this year alone or more than $3 million every day." That's not the definition of profit.

Ms. BRESCH. No. I think what we were saying in there is that's how we reinvest the profit that we make. But I thought you were asking me how the $50——

Chairman CHAFFETZ. When there are five executives over 5 years that take out $300 million, where in your P&L does that show up? Does it show up in your profit line? Does it show up in EBITDA? Where does it show up?

Ms. BRESCH. Well, it's not coming out of—the $50 number I'm showing you per pen is taking no company allocation to that whatsoever.

Chairman CHAFFETZ. But that's what you just wrote to me. You said, "This profit is used for our"—we're supposed to believe that your $50 profit is funding R&D and facilities and all that, because that's exactly—I just read to you verbatim what you wrote to me.

Ms. BRESCH. And we absolutely take our profits and reinvest in our business. I mean, to your point, we're—this year alone, 750 million in R&D we're spending across bringing hundreds of products to the market.

Chairman CHAFFETZ. When you take the $300 million that the five executives got, where on your P&L does that show up?

Ms. BRESCH. And I'm saying it's not—we didn't take any of that out of this $50. When we're showing you this $50 profit——

Chairman CHAFFETZ. I'm not talking about the $50, the whole thing. Come on, you amortized your fixed expenses and your operating expenses over everything, correct?

Ms. BRESCH. Correct. But——

Chairman CHAFFETZ. Where does that show up in that spreadsheet? Tell me where that number is.

Ms. BRESCH. It's not. It's not on here. $50 would be lower if we were taking those company allocations, like running the business, out of this. This is straight just EpiPen.

Chairman CHAFFETZ. I've gone way past. I'm going to come back to this, because your numbers are so askew. It just—it really is troublesome.

Let me recognize the ranking member, Mr. Cummings.

Mr. CUMMINGS. Thank you very much. You know, when Mr. Shkreli appeared before us, he took the Fifth. And to be frank with you, you might as well have taken the Fifth too, with the kind of information that we've gotten here today, because I don't think that we—I tell you: This reminds me of a game when it's like hiding the ball. And it's like a shell game, and we can't—you know, you seem—it seems like we can never figure out where the ball is.

And as I said from the very beginning, I was concerned that we would be here in a rope-a-dope situation. It's worse. It is worse. In the rope-a-dope situation, the boxer sort of holds on and tries to get through, and then, at the end, he comes back and he wins.

In this situation, not only are you holding on and trying to win, but in the end, you are placing us in a position where we're not making very much progress here at all. I'm saying I've listened to—I've been here 99 percent of this hearing, and I've practiced law for many years, and I'll tell you: I don't know what your lawyers are telling you, but I don't think that you have been frank with us. And I could understand it a little bit better if you didn't know what this hearing was all about. And I don't say those words lightly.

Let me ask you a few questions to see if we might be able to move forward here a little bit. You know, your numbers just don't add up. And I think that's what's happened. I mean, if I could sum

up this hearing, it would be "the numbers don't add up." And it is extremely difficult to believe that you are making only $50 in profit when you just increased the price by more than $100 per pen.

Do you have any internal company documents that track the total profits you have made off of EpiPen from 2007, when you acquired it, until today? Do you have any of those documents?

Ms. BRESCH. Well, we certainly could—I, sitting here today, don't have the cumulative number, but I totally understand and had—I know if I had only read everything that's been out there around the price, I can totally understand how perplexing it is and the system. And I would hope that, while I don't have answers how to fix all of it, I think that I couldn't agree more: the transparency of the 608 down is needed across the board, because patients have no visibility, pharmacists—nobody's got a visibility of the value or where—what's being paid for what. And I think——

Mr. CUMMINGS. Can we hold on for that one little thing you just said? You talk about the value of the medication, right? You know, you can take that—I mean, when you talk about the value of a medication, I guess you're saying, well, if you have a certain medication, it will keep you out of the hospital. A certain medication will save your life. I mean, where does that end? In other words, how do you put value on life? Are you following what I'm saying? I could go on and on and on. So is that the measurement?

Ms. BRESCH. No. That's why I was saying——

Mr. CUMMINGS. I mean, but you've said it 50 million times in this hearing. And it sounds like you're saying: "Because I'm able to save somebody from possibly going to the hospital or whatever, that's supposed to be incorporated into the value, and that's partly why we are able to charge these prices." And are you telling us that you are doing us a favor, that you're doing our constituents a favor by raising these prices?

Ms. BRESCH. I think hopefully what you'll see with the generic coming to the market is a——

Mr. CUMMINGS. I'm talking about right now. Right now. Right now. I've got—the other night I was at a PTA meeting in my district, and I had a mother who has three children, and all of them use EpiPen. She has to have one set at home, and she has one at the school. And she stood there in tears, because she's only making maybe $50,000 a year or less, and she's trying to figure out how she's going to afford this.

And as I listen to you more and more and you talk about—I think I wouldn't be so—I think I might be a little bit more trustful if I hadn't heard some of this before, if I hadn't read some of it before from people like Shkreli, who called us imbeciles.

But now—but when you present to me that you've got these assistance programs, as I see the assistance programs—and by the way, everybody comes in with the same story. There must be some playbook that you all use. And they say: "Oh, we've got an assistance program. We're going to help some people." And the next thing you know they then use that to justify not bringing the prices down.

Do you understand that?

Ms. BRESCH. I do. And I——

Mr. CUMMINGS. And that's exactly what you've come in here to do—you've done. You've done it. That's what you're doing. Are you going to go down on the price? Are you going to come back down on the price at all? Put aside the generic stuff. What about coming down on the price?

Ms. BRESCH. We believe that the generic was much more meaningful to make sure we're reaching those patients, so that—across all the access points. And one thing I would say—and I know you've had other companies in here, and I know orphan drugs. There has been conversations across this. I would say, just as an example, Mylan's had an orphan drug product called Cystagon on the market for years, years and years. And at—it treats a very small number of patients, cystinosis, less than—I believe it's now 500. It's a very, very rare disorder. And that price has stayed around $1,200 to $2,000 annually to provide the medicine needed every day, where a company came on the market 3 years ago at $300,000 to treat that same patient population with just a more convenient dose.

So I understand that there are the things that you've seen and companies that you've spoken to, but I would hope that you would be able to look at Mylan and the role that we've played with generics, the role that I play if I talk about our Cystagon experience, or trying to make sure that the access point for people who are both carrying it but in schools and in other public places, so that there is an EpiPen there or an epinephrine auto-injector there for anyone who needs it whenever——

Mr. CUMMINGS. You know, we appreciate all of that, but do you all, does Mylan have a slogan of "Seeing is Believing"?

Ms. BRESCH. Yes.

Mr. CUMMINGS. You do?

Ms. BRESCH. Yes.

Mr. CUMMINGS. "Seeing is Believing." That's what we want to do. We want to see the records. We want to see the records. You are refusing to say how much profit your company makes. You are repeating industry talking points with no substance whatsoever. You are trying to claim that your massive price increases are actually a good thing for American families. Our committee requested documents from Mylan, but so far, you failed to produce everything we've asked for. As you just said, Mylan's slogan is "Seeing is Believing."

So, in summary, Ms. Bresch, will you agree today—I know the chairman has asked you to produce some documents within the next 10 days and some information in the next 10 days. Will you agree today to produce all the documents the committee has requested so we can confirm what's going on here?

Ms. BRESCH. We will certainly produce everything that we can.

Mr. CUMMINGS. What does that mean? I don't know what that means. We've given you—we've asked for specific documents.

Ms. BRESCH. And I know we've been responsive, and I know that we're still—I mean, this has been real time. I understand that we've produced thousands of documents, a couple thousand documents. And I know that there's more—there's more that we have to produce. And I'm saying that I'm sure we will produce every-

thing that we possibly can to give you the visibility and the transparency to the numbers that I'm showing you here today.

Mr. CUMMINGS. And so that we will be clear, we want your agreements and your contracts with manufacturers and suppliers, distributors, PBMs, and any of your other partners in the distribution channel for EpiPen.

Will you produce those?

Ms. BRESCH. I can't speak to all of those contracts, from the confidentiality agreements in some of those, the competitive information in some of those. But that's why I've got to rely on the lawyers who are producing these documents to make sure we're staying compliant with some of the other provisions in the contracts.

Mr. CUMMINGS. So you will get us what you got. I know you're all lawyered up back there, but you're going to make sure that you consult with your lawyers to get us what you can?

Ms. BRESCH. Yes.

Mr. CUMMINGS. All right. Thank you.

Chairman CHAFFETZ. I now recognize the gentleman from Georgia, Mr. Carter.

Mr. CARTER. Thank you, Mr. Chairman.

I'll be very brief. I find the chart very interesting. Can you hold it up a little more? I can't see the very bottom of it. Okay. So we've got wholesale acquisition costs at $608, rebates and allowances. This is what you give back to patients. And so that's minus $334?

Ms. BRESCH. No, no. This rebates and allowances are all the things that you were speaking of, the PBM, retail. That's all the rebates and things that flow to all the——

Mr. CARTER. So you're giving a rebate to a PBM?

Ms. BRESCH. Yes.

Mr. CARTER. You're giving a rebate to a PBM?

Ms. BRESCH. Yes.

Mr. CARTER. That's where that comes in there.

Ms. BRESCH. It's part of it.

Mr. CARTER. It's part of it.

Ms. BRESCH. It's in there.

Mr. CARTER. Okay. So you're giving a—what are allowances?

Ms. BRESCH. That's—so all of the fees, there's wholesaler fees, discounts, rebates. That's just capturing everything that's between the 608 and the 274, which is what Mylan receives.

Mr. CARTER. Okay. Are you getting any rebates from PBMs?

Ms. BRESCH. And that's what I said I didn't want to give you an inaccurate number. There's——

Mr. CARTER. Okay. I understand that, but that was not my question. I didn't ask you for a number. I said, are you getting rebates from a PBM?

Ms. BRESCH. And across our business?

Mr. CARTER. Yes or no, are you getting rebates from a PBM?

Ms. BRESCH. But for EpiPen, we are paying rebates to the PBM.

Mr. CARTER. Are you getting rebates from a PBM?

Ms. BRESCH. I don't—we're not getting EpiPen-specific rebates from an EpiPen from being the manufacturer.

Mr. CARTER. So you are not getting——

Ms. BRESCH. I don't believe——

Mr. CARTER. —rebates from a PBM?

Ms. BRESCH. I don't believe so on—like, for instance, if we're just talking about EpiPen.

Mr. CARTER. You just told me earlier you were going to produce documents that would give us your numbers.

Ms. BRESCH. But—so we—what I don't want to confuse is we're a manufacturer. We're also an employer. So we have a PBM that is managing, say, all of employees in the U.S. So what I didn't want to give you is an inaccurate number. If there was rebates that come from the PBM as an employer versus the manufacturing, we're paying the rebates for the products.

Mr. CARTER. This is amazing. This is amazing. I have never in my life seen such a shell game. I'm speechless, and that doesn't happen very often.

Ms. BRESCH. And that's why we have said and encouraged, to your point, that transparency and where that's flowing and how it works, so that you do know what the cost is.

Mr. CARTER. Okay. Let me ask one more question, and then I'll stop. Can you hold it up again?

Ms. BRESCH. Sure.

Mr. CARTER. You took an oath earlier today saying you would tell the truth.

Ms. BRESCH. Yes.

Mr. CARTER. Is that the truth, $50 per pen?

Ms. BRESCH. Yes.

Mr. CARTER. That is the truth?

Ms. BRESCH. Our profit is approximately $50 per pen.

Mr. CARTER. Mr. Chairman, I yield.

Chairman CHAFFETZ. Thank you.

Just a few questions as we wrap up. On that chart again, I would like to see a definition of "rebates and allowances." I'd like to see a definition for each of those numbers. For instance, cost of goods sold, what do you include and not include in that number?

Ms. BRESCH. That's everything that we're paying to our partner for the cost of goods sold.

Chairman CHAFFETZ. So that's it? What else is in the cost of goods sold?

Ms. BRESCH. Because we are—we have a partner on the product.

Chairman CHAFFETZ. Yes.

Ms. BRESCH. So we pay a price to——

Chairman CHAFFETZ. Do you buy it as a finished product?

Ms. BRESCH. Yes.

Chairman CHAFFETZ. So you don't manufacture it?

Ms. BRESCH. No. We're partnered on the product.

Chairman CHAFFETZ. And so you pay them $69 per——

Ms. BRESCH. Per 2–Pak.

Chairman CHAFFETZ. Per 2–Pak.

Ms. BRESCH. For two EpiPens.

Chairman CHAFFETZ. For two EpiPens. So that's your turnkey price?

Ms. BRESCH. Yes.

Chairman CHAFFETZ. When you call "direct EpiPen auto-injector costs" of $105, what is in that number?

Ms. BRESCH. So sales, marketing, the disease awareness. So everything that would be directed to EpiPen or around anaphylaxis

awareness. All the access programs. So that would be all-inclusive of everything directly related to EpiPen.

Chairman CHAFFETZ. And the number for research and development, your fixed costs, your variable costs at your company, where does that number show up?

Ms. BRESCH. So that's not on here. These are just direct EpiPen-related costs. So, I mean, if you look at our—the entire company, obviously, that was the point I was trying to just say earlier, that this doesn't—this is looking at a product on a standalone basis versus saying it takes a company or human resources or other entities to sell the product. So this doesn't take any of that into consideration. This is just giving you an approximate profit on just from an EpiPen-related perspective.

Chairman CHAFFETZ. And not to pick so much on your own personal compensation, none of that comes out of this number, these numbers? You want us to believe that your profit is less than $50?

Ms. BRESCH. If you took company allocation and all that in, yes.

Chairman CHAFFETZ. I don't know who the investors of this company are, but, man, I'm telling you: this is some fishy business, because these things do not add up. We would expect a very professional presentation on your P&L, and these dumbed-down versions here do not make sense without the definitions in here. It just feels like you're not being candid and honest with Congress, who is asking you for some very basic information.

Ms. BRESCH. And we——

Chairman CHAFFETZ. And your attorneys are over there scrambling. They're all uncomfortable. But you know what? We just want some basic information. You dug this hole for yourself. You guys dug this hole for yourself. We asked for some simple basic information. Don't tell me that you're pulling all your R&D costs and all of your fixed expenses and all your facilities and all of that out of your profit line.

Any responsible P&L, it would lay this out for us. You can make this thing go away by being honest and candid, and we just don't think you are. That's why we're on I don't know what number hour here and we're asking you to provide more information.

And don't come here and tell us that, you know, you're doing the world a favor by increasing the price from $125 to over $600 and everybody else is making money but poor old Mylan. It just doesn't smell right. It doesn't pass the basic sniff test.

Ms. BRESCH. And, Chairman, I don't think we said we weren't making money. I think all we were trying to set the record straight as to the dollar amounts that have been out there around the 608 price to show that what we actually receive is the 274 and to walk down that. And we will happily provide the definitions and that transparency to show you the $50.

Chairman CHAFFETZ. And I just don't buy the idea that the majority of consumers are paying less than 50 bucks. I mean, that's what you're telling us.

Ms. BRESCH. Right. And that's what——

Chairman CHAFFETZ. Trust but verify. Seeing is believing, the Mylan way. Show it to us. Show it to us.

Ms. BRESCH. And that is what our data shows, and we will.

Chairman CHAFFETZ. I know. Well, we haven't seen it. So I appreciate you providing that to us.

I have two quick FDA questions here.

Dr. Throckmorton, how many Abbreviated New Drug Applications are pending before the FDA right now?

Dr. THROCKMORTON. 2,300 actions are currently before us.

Chairman CHAFFETZ. And how long is the average wait time for an approval of a generic drug?

Dr. THROCKMORTON. I'd like to get that information and get it back to you as soon as I can.

Chairman CHAFFETZ. Can you define what—in fairness, what I asked Ms. Bresch, what's a reasonable time before we start raising the red flag here?

Dr. THROCKMORTON. Can I——

Chairman CHAFFETZ. Ten days, is that——

Dr. THROCKMORTON. Ten days sounds like a common number, if that would be good enough for you.

Chairman CHAFFETZ. We would appreciate that.

Mr. Cummings.

Mr. CUMMINGS. Just briefly. Ms. Bresch, you mentioned that you've got some confidentiality agreements. That doesn't apply to us, Congress, you know that, right? Hello.

Ms. BRESCH. No, I didn't know that if there's confidentiality——

Mr. CUMMINGS. Now you know. That doesn't apply to us. And I'm sure your attorneys will work that through.

I just hope that—I just want to go back and briefly as I close with what I said before. I've asked you every kind of way, would the prices come down? And you've basically made it clear—basically, you fall in the same category of Shkreli and the Valeant people. They come to the hearing, they go through the motions. At least you tried to answer some questions.

But in the end, our constituents still suffer. And I hope that, when you fly back on your jet, you'll think about that mother that I told you about or the people that Mr. Carter talked about a few minutes ago trying to just take care of their families. And, you know, I don't—I try to really look at things from a very—in a way, a very balanced way. But I can tell you that I've been on this committee for 20 years, and very rarely have I seen a situation where it seems that we could not get the answers that we were looking for to this degree.

And what that does is it goes against credibility, and that's a very, very difficult hurdle. And so that's why we really do need to see the documents. And what we're trying to do—you know, you can make all the money you want. I just don't like the idea of it being done in a way that's not transparent, and I don't like it being done on the backs of people who can least afford it.

And you keep trying to convince us that Mylan is doing a great favor, but Mylan's making money. Mylan's doing fine. But to come in and to say some of the things that you've said, it just makes me, you know, feel that maybe you don't think we're that bright, and that's a sad commentary.

So thank you very much, and we'll look forward to receiving your answers and documents.

Chairman CHAFFETZ. Yes, we'll be following up with both of you within 10 days.

The committee stands adjourned.

[Whereupon, at 8:28 p.m., the committee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

OCT 0 4 2016

McDermott
Will & Emery

Boston Brussels Chicago Dallas Düsseldorf Frankfurt Houston London Los Angeles Miami
Milan Munich New York Orange County Paris Rome Seoul Silicon Valley Washington, D.C.
Strategic alliance with MWE China Law Offices (Shanghai)

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October 4, 2016

The Honorable Jason Chaffetz
Chairman
Committee on Oversight and
Government Reform
Attn: Sarah Vance
2157 Rayburn House Office Building
Washington, DC 20515-6155

The Honorable Elijah E. Cummings
Ranking Member
Committee on Oversight and
Government Reform
Attn: Alexandra Golden
2471 Rayburn House Office Building
Washington, DC 20515-6155

Dear Chairman Chaffetz and Ranking Member Cummings:

I am responding today on behalf of my client, Mylan, to additional requests for information that you directed to the company at the hearing conducted by the Committee on Oversight and Government Reform on September 21, 2016. Enclosed is a disk containing the following documents:

1. An Excel spreadsheet containing a Managed Care Rebate Report Summary report from Mylan at MYLAN-HOGRC-002393. This is responsive to Requests 5, 6, 9 and 15 in your September 30, 2016, letter.

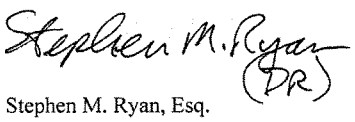
2. A Form 8-K filed by the company with the SEC on September 26, 2016 and enclosed here at MYLAN-HOGRC-0002387 through MYLAN-HOGRC-0002392. This is responsive to Request 3 in your September 30, 2016, letter. Please note that the Bates range in this letter supersedes the range in my letter last night.

3. Copies of product supply and services agreements with Meridian Medical Technologies, a subsidiary of Pfizer Inc. Copies are enclosed here at MYLAN-HOGRC-0002067 through MYLAN-HOGRC-0002386. This is responsive, in part, to Request 6 in your September 30, 2016, letter.

Much of the information contained in this submission is highly proprietary and business sensitive, and is labeled as such. I respectfully would request that Members and staff treat such information as confidential, and not publicly disclose it. To the extent the Committee does intend to disclose such confidential information, I would request that the Committee notify the company in advance so that appropriate communications and business measures may be put in place to protect the company's business.

If you have any questions regarding this submission, please do not hesitate to contact me or my partner T. Reed Stephens at McDermott Will & Emery at 202-756-8129.

Sincerely,



Stephen M. Ryan, Esq.

September 20, 2016

The Honorable Jason Chaffetz
Chairman
Committee on Oversight and
Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Elijah Cummings
Ranking Member
Committee on Oversight and
Government Reform
U.S. House of Representatives
2471 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Chaffetz and Ranking Member Cummings:

As your committee prepares to hold a hearing on the EpiPen price increases, the Healthcare Leadership Council (HLC) appreciates the opportunity to share our thoughts on the important topic of healthcare pricing.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC—hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies—believe that the issue of healthcare costs needs to be addressed. As leaders from the full spectrum of American healthcare, we have long maintained that affordability and accessibility must be health system priorities. We also believe that, for the good of patients and consumers, affordability and innovation can, and must, co-exist.

Earlier this year, through our National Dialogue for Healthcare Innovation (NDHI) initiative, HLC publicly released a set of proposed actions to reduce costs while maintaining, and even improving, access to high-quality care. They include:

- Improving care coordination and patient engagement and adherence
- Accelerating data interoperability
- Modernizing existing statues to accommodate the movement toward value-based care
- Commonsense Food and Drug Administration (FDA) reforms that will speed therapies to consumers and strengthen competition in the marketplace

More information on these ideas and examples on how they can result in reduced costs and improved care can be found in NDHI's report on *Viable Solutions: Six Steps to Transform Healthcare Now.* These proposals, if adopted, will help to ensure improved

access to therapies in the long-term, as opposed to price controls or excessive regulations that will slow the development of needed cures for devastating illnesses. Price controls may affect costs in the short-term but could reduce access over time to current and new cures.

As your committee investigates the EpiPen price increases, we hope that you will keep HLC's thoughts in mind. We look forward to continuing to work with you in support of a healthcare system that is affordable, accessible, and innovative.

Sincerely,

Mary Grealy
President

ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

September 21, 2016

The Honorable Jason Chaffetz, Chairman
The Honorable Elijah Cummings, Ranking Member
Committee on Oversight & Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Chaffetz and Ranking Member Cummings:

Consumers Union, the policy and mobilization arm of Consumer Reports,[1] appreciates your Committee's continuing work to look for reasons behind, and solutions to, rising prescription drug prices and their impact on consumers. High drug costs impose a significant burden on the health and financial security of millions of Americans – nearly 60% of adults regularly take a prescription drug.[2]

Consumer Reports is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers. We have a particular focus on the drug marketplace. As part of our work to help consumers find the best value when purchasing prescription drugs, in 2004 we launched Consumer Reports Best Buy Drugs. This program uses evidence-based, systematic reviews of prescription drugs to clearly demonstrate the efficacy and safety of commonly used medicines in over 30 categories.[3] We combine this information with reliable cost information, enabling consumers to truly identify the "best buy" for many drugs.

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[1] Founded in 1936, Consumer Reports is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers, and to empower consumers to protect themselves. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Consumer Reports has over 7 million subscribers to its magazine, website, and other publications. Its policy and mobilization arm, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and the marketplace. It employs a dedicated staff of policy analysts, lobbyists, grassroots organizers, and outreach specialists who work with the organization's more than 1 million online activists to change legislation and the marketplace in favor of the consumer interest.
[2] As of 2011-12, nearly 3 in 5 Americans over age 20 take at least one prescription drug. As of 2012, those taking five or more drugs has doubled since 1999-2000 to 15% of all Americans. Elizabeth D. Kantor et al., *Trends in Prescription Drug Use Among Adults in the United States From 1999-2012, JAMA. 2015;314(17):1818-1830.*
[3] http://www.consumerreports.org/health/best-buy-drugs/index.htm. Note: Best Buy Drugs does not do cost-effectiveness analysis. Instead, we present price data alongside the effectiveness, safety, and side-effect data. And then we let consumers—in consultation with their doctors—interpret and adapt these data according to individual preferences, clinical circumstances, and priorities (including budgetary).

Rampant High Drug Prices

A feature article in the August 2016 issue of Consumer Reports asks in its title: "Is There a Cure for High Drug Prices?"[4] The article reports on the results of a nationally representative telephone poll of more than 2,000 consumers who take a prescription medication, conducted by Best Buy Drugs in March, finding that high drug prices are taking a serious toll on consumers.

We found that 45 percent of people regularly take a prescription drug, and on average take between four and five medications. Three in ten people told us their out-of-pocket costs for one of their prescriptions has gone up in the past 12 months, costing them an average of $63 more for a drug they routinely take – with a few being hit with increases of $500 or more. And for those consumers:

- 47 percent took less of the drug than the prescription called for, to save money, with 17 percent skipping or splitting doses, and 30 percent not filling the prescription at all.
- 28 percent put off a doctor's visit.
- 19 percent took an expired medication.
- 19 percent postponed paying other bills to pay for their medications.

As we noted in that article, one reason drug manufacturers are charging high, even exorbitant, prices is "because they can." Fundamentally, it is the lack of competition – the lack of consumer choice.

The Mylan Example

The focus of today's hearing, Mylan's five-fold hike in the price charged to consumers for a life-saving product, the EpiPen, is a glaring example.[5] Because our review of the facts has produced no legitimate justification for this inordinate price hike for EpiPens, this appears to be a calculated decision by Mylan to exploit the monopoly power that the company holds to enrich itself and its corporate executives[6] at the expense of the millions of consumers – including families and children dealing with serious allergies and the possibility of life-threatening anaphylaxis – who use this life-saving drug and delivery system as a failsafe.

Moreover, there are indications that a further marketplace abuse may also be at work here, an anticompetitive abuse that could be in violation of the antitrust laws. Although a company's exploitation of monopoly power, even to the extent that may be involved here by Mylan, may not by itself violate antitrust laws, it *is* a violation for a company to *maintain* monopoly power by sabotaging or undercutting efforts by competitors to provide consumers more choice.

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[4] http://www.consumerreports.org/drugs/cure-for-high-drug-prices/

[5] *See, e.g.*, Solving the Problem of High Drug Costs, Consumer Reports, June 21, 2016, http://www.consumerreports.org/drugs/solving-the-problem-of-high-drug-costs/.

[6] *See., e.g.*, EpiPen Price Rises Could Mean More Riches for Mylan Executives, NY Times, Sept. 1, 2016, http://www.nytimes.com/2016/09/04/business/at-mylan-lets-pretend-is-more-than-a-game.html.

There are a number of troubling reports that Mylan may have engaged in such anticompetitive conduct. These include:

- Reports that Mylan attempted to influence the FDA to derail approval of Teva's competing delivery system.[7]

- Reports that Mylan had earlier persuaded the same competitor, Teva, to delay its application for FDA approval, perhaps in an anticompetitive "pay for delay" scheme. In fact, Mylan reportedly began its campaign to derail the application only as this delay was set to expire.[8]

- Reports that Mylan included restrictions in its contracts with schools purchasing the EpiPen at a discount under its EpiPen4Schools program, requiring these schools to agree not to purchase competing delivery systems.[9]

Engaging in any of these practices to maintain a monopoly by blocking competition could very well run afoul of the antitrust laws. Accordingly, we have asked the Federal Trade Commission to investigate, and to take appropriate enforcement action as supported by the facts.

On a related note, a year ago, Teva was seeking to *acquire* Mylan. The acquisition was abandoned in the midst of active antitrust investigation by the FTC, with a number of serious concerns being raised about the harms to competition that would result. The implications of a combined Teva/Mylan corporation under the current circumstances highlight the critical importance of vigorous merger enforcement in the health care marketplace—to protect both existing competition and the possibility of even greater competition—so that consumers have meaningful choices and can access life-saving drugs and devices.

Exploring Solutions

Our health care system is multifaceted, and the solutions go beyond antitrust. Among the steps worth considering are:

- Limiting monthly out-of-pocket costs and addressing concerns about discriminatory formulary designs.[10]

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[7] *See, e.g.*, I-Team: Company Behind EpiPen Fought to Keep Cheaper Generic off Market, http://www.nbcnewyork.com/investigations/EpiPen-Cheap-Generic-Teva-Product-Mylan-Investigation-Drug-Cost-391758871.html.
[8] *See, e.g., id.*
[9] *See, e.g.*, Mylan May Have Violated Antitrust Law in Its EpiPen Sales to Schools, Legal Experts Say, http://www.pbs.org/newshour/rundown/mylan-may-violated-antitrust-law-epipen-sales-schools-legal-experts-say/.
[10] For example, Consumers Union recently helped pass legislation enacted in California which caps a consumer's share of payment at no more than $250 for a 30-day prescription on all metals tiers except bronze, on which it is capped at $500.

- Increasing transparency, by requiring Pharmacy Benefit Managers (PBMs) to reveal the negotiated cost of medications to employers.

- Prohibiting Medicare Part D plans from using gag clauses that prevent pharmacists from offering drugs at a lower price, if a lower price exists.

- Publishing the prices that the Veterans Administration pays, and that other countries pay, for drugs, so consumers and employers could use those prices as a benchmark.

Measures that could more directly address the underlying causes of high prices and are worthy of consideration include:

- Patent Reform – Patent terms should be reasonable, and granted only for real pharmaceutical advances. More selectively granting this legal monopoly, and more carefully limiting the monopoly period, could speed up the entry of new competing drugs that would provide choices and bring prices down.

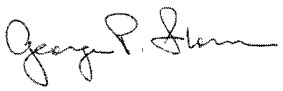
- Increased Comparative Effectiveness Research – Expensive new drugs may provide significant consumer benefits that are worth the higher cost, but it is often difficult for payers to know if the benefits truly justify the costs when a cheaper, slightly different alternative is available. Increasing funding for comparative effectiveness research, especially targeting expensive new drugs and drugs targeting a large patient population, could bring significant savings.

- Medicare Negotiation -- Allowing Medicare to negotiate prices directly if the prices paid by Part D beneficiaries exceed the weighted average of what other developed countries pay, could bring down prices significantly in some cases.

- Drug Re-importation -- Study solutions that would legalize re-importation from Canada, in a way that is overseen by FDA and ensures consumer safety, could reduce the cost for a number of drugs.

Ensuring that consumers can afford the drugs they need and that they have access to reliable information on the comparative effectiveness of treatments will provide to a better consumer experience, better treatment compliance, and better health outcomes. We appreciate the Oversight and Government Reform Committee's continued attention to this issue of profound importance to our health care system and to consumers.

Respectfully,



Victoria L. Burack
Health Policy Analyst

George P. Slover
Senior Policy Counsel

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