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# DEVELOPMENTS IN THE PRESCRIPTION DRUG MARKET: OVERSIGHT

## HEARING

BEFORE THE

## COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM HOUSE OF REPRESENTATIVES

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# DEVELOPMENTS IN THE PRESCRIPTION DRUG MARKET: OVERSIGHT

**Thursday, February 4, 2016**

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

The committee met, pursuant to call, at 9:02 a.m., in Room 2154, Rayburn House Office Building, Hon. Jason Chaffetz [chairman of the committee] presiding.

Present: Representatives Chaffetz, Mica, Duncan, Jordan, Walberg, Amash, Gosar, DesJarlais, Gowdy, Farenthold, Lummis, Massie, Meadows, DeSantis, Mulvaney, Buck, Walker, Hice, Carter, Grothman, Hurd, Palmer, Cummings, Maloney, Norton, Lynch, Connolly, Cartwright, Duckworth, Kelly, Lawrence, Lieu, Watson Coleman, DeSaulnier, Boyle, Welch, and Lujan Grisham.

Chairman CHAFFETZ. Welcome, everybody. The Committee on Oversight and Government Reform will come to order.

Without objection, the chair is authorized to declare a recess at any time. The chairman is responsible, under the rules of the House and the rules of the committee, to maintain order and preserve decorum in the committee room, and I will do that.

We have an important hearing today. We have had an important week. We have had a number of hearings that have been very important.

Today, we are talking about the cost of health care in our country, because it is growing at an unsustainable rate. The Congressional Budget Office reported the Federal Government will spend $1 trillion—trillion—on Medicare and Medicaid and other health care programs. The CBO also reported that, in 10 years' time, that cost will double to roughly $2 trillion.

The cost for prescription drugs are a substantial portion of the Federal health care expenditures. In 2014, the Federal Government paid out just over $77 billion in Medicare Part D prescription drug benefits. Clearly, it is very difficult to sustain this.

One way that affects the cost of prescription drugs is to increase access to generic drugs and drugs that have been on the market for some time.

Our committee is very fortunate to have one pharmacist. I think there is one pharmacist in the United States Congress. He happens to sit on our panel. I would like to yield a minute to Mr. Buddy Carter from Georgia.

Mr. CARTER. Thank you, Mr. Chairman.

I am disgusted that we are here today to talk about drug price increases. As a pharmacist for over 30 years, I have owned and op-

erated numerous pharmacies in Southeast Georgia. As the only pharmacist in Congress, I know free-market principles are the best way to provide quality, affordable health care to the American people. But what was done here is different.

Perverse business practices were employed to exploit a patient group trying to do nothing more than to extend their lives. None of the witnesses here today have had to look into the eyes of someone who is trying to make a decision between buying groceries and buying medication. No one here today has seen the look on a mother's face when she realizes that she can't afford to buy her child's medication. I have.

But as a health care professional, I have worked with these people in order to make sure that they can get their medications, and to make sure that my business and my employees stay afloat. So some here today may hide behind their shareholders or their corporate boards and say that this is just free-market principles. But I, for one, don't agree with that. I will tell you that you can meet your shareholders' needs, that you can meet your board's needs, and still take care of the American public.

But then again, I am not sure that those who are hiding behind their shareholders and their boards really care about that.

Mr. Chairman, I yield back.

Chairman CHAFFETZ. I thank the gentleman.

The FDA, the Food and Drug Administration, is responsible for approving applications to manufacture generic drugs, but it is drowning in a backlog of applications. In an attempt to deal with the backlog, Congress passed unanimously out of the House by voice vote, and with only one dissenting vote in the Senate, as I recall, the Generic Drug User Fee Act in 2012. The act promised shorter wait times but required applicants to pay $1.5 billion in user fees over a 5-year period.

Despite these fees and their promises, the FDA still has a backlog of more than 3,700 generic drug applications.

The basic premise here I think is one of basic economics. If you have somebody who rapidly increases or dramatically increases the price of a prescription drug, that is going to invite more competition. But if that competition can't get the approval from the FDA, then there is no competition, and the price will be inelastic, and it will continue to rise.

So most of my questions today are actually for the FDA and what they are doing to accelerate that process. I believe that the FDA has failed to meet its statutory responsibility and is dramatically behind in its processing.

A good example of how valuable a shortened FDA review process has become is the program that offers priority review vouchers. Because the FDA review process can be so time-consuming, drug companies have been paying outrageous sums for these vouchers.

Last year, one of these vouchers sold for $350 million, but these vouchers only speed up the process by roughly 4 months. That means at least one applicant was willing to pay $2 million a day just for an additional 120 days.

Given these facts, it is pretty obvious our current review process for generic drug applications is too slow.

Along with the FDA, we have representatives from two drug manufacturers. Turing Pharmaceuticals purchased the prescription drug Daraprim and raised the price per pill from $13.50 to $750. Valeant Pharmaceuticals' CEO is also here to explain how his company bought heart drugs Nitropress and Isuprel, and raised their prices 525 percent and 212 percent, respectively.

All three of these drugs lacked any generic competition, even though the patent had expired and they are available for generic versions.

I look forward to hearing from all witnesses today.

I also want to thank Ranking Member Cummings, who has been very passionate on this issue and very insistent that we have this hearing. And I think I am glad that we did this together.

I now yield the time and recognize Mr. Cummings for 5 minutes.

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

From the depths of my heart, I thank you again and again for holding this hearing.

The issue has been my number one—number one—investigative priority for several years. I am so grateful that we are holding this hearing today and that drug companies, the FDA, and other stakeholders have been called here.

Thank you also for sending joint document requests to these companies, Turing and Valeant. They both refused my previous requests and obstructed our ability to investigate their actions. The fact is we would not have the documents we have today without your action, and I thank you again for that.

We have now obtained more than 300,000 pages of internal documents from these companies after they stonewalled. They include emails, analysis on revenues and profits, communications with hospitals and other providers, and public relations strategy documents.

Earlier this week, I circulated two memos summarizing these documents. I now ask unanimous consent that they be made part of the official hearing record.

Chairman CHAFFETZ. Without objection, so ordered.

Mr. CUMMINGS. These new documents provide an insider's view into how drug company executives are lining their pockets at the expense of some of the most vulnerable families in our Nation. Their basic strategy has been to buy drugs that are already on the market and then raise the prices astronomically for a temporary period of time before other competitors enter the market.

These companies did not invest funds to research or developed these drugs. They bought them; jacked up the prices; took as much money as they could out of the pockets of patients, hospitals, and others; and put those funds into their own coffers. I call this money blood money.

How much money are we talking about? Valeant reported gross revenues of more than $547 million on Nitropress and Isuprel, just two drugs. That is more than a half billion dollars in 1 year coming out of the pockets of hardworking Americans. The company reported profits of $351 million on just these two drugs in 2015 alone.

These stunning returns by Valeant CEO J. Michael Pearson, on the Forbes list of billionaires, according to press reports, these massive profits allowed Mr. Schiller, who is here today on behalf of

Valeant, to collect a salary of $400,000 per month—per month—out of the pockets of our constituents.

For Turing, the company reported $98 million in revenue for Daraprim in 2015 with manufacturing costs of only $1 million. Yet, Turing actually tried to claim that it took a $44 million loss last year.

The company reported that it spent $22 million on research and development. This money apparently went to donations to unnamed entities, "contributions to foundations," and vague "other research and development costs."

But the documents we have obtained indicate that these expenditures were just as much about PR as R&D. Like a Ponzi scheme, it appears that Turing may be using revenues from Daraprim to research and identify the next drug it will acquire and then impose similarly massive price increases on future victims.

It is not funny, Mr. Shkreli. People are dying, and they are getting sicker and sicker.

Based on the documents obtained by the committee, we know exactly what these companies will say as part of their public relations strategy. They will try to distract from their massive price increases by talking about their R&D. They will downplay their massive profits by claiming that they help patients who can't afford their exorbitant prices.

The testimony from the drug companies today will be the same. But the difference now is that we have been behind their smokescreen.

These tactics are not limited to a few bad apples. They are prominent throughout the entire industry. Lannett, Pfizer, Horizon, Teva, Amphastar, Allergan, Endo, all of these companies have taken significant price increases on their drugs.

The reason I care so much about this issue is because it directly—directly—affects my constituents and the constituents of every member of this committee, every Member of this Congress.

The people in my district are not on the Forbes billionaire list. They do not buy Wu-Tang Clan albums for $2 million. They can't liquidate assets to free up millions of dollars. They work hard. They get the early bus. And many take home decent salaries. But like many Americans, they struggle every single month to support their families and to pay for the increasing costs of housing, education, and health care. They live from paycheck to paycheck, and sometimes from no check to no check.

Hardworking American families should not be forced to pay increases of 10 percent, 100 percent, or 1,000 percent, just to subsidize the lavish lifestyles of hedge fund managers and corporate executives.

As I conclude, I hope we can also talk about solutions today.

For example, Secretary of State Hillary Clinton has sent letters to the FDA and FTC proposing stronger regulatory action to crack down on companies that engage in price gouging. I think this is an interesting approach that could be significant in bipartisan support.

On the legislative side, I have introduced the Prescription Drug Affordability Act with Senator Bernie Sanders. One provision in

this bill would allow HHS to negotiate drug prices for Medicare. This is something that even Donald Trump supports.

There is significant bipartisan agreement on the need to address this crisis. According to the nonpartisan Kaiser Family Foundation, rising prescription prices are the top health care concern for all Americans, including Democrats, Republicans, and independents.

I hope today's hearing is the beginning of a sustained effort to address this issue in a bipartisan way. It should be addressed in a bipartisan way that brings much-needed relief to American families.

Again, Mr. Chairman, I truly and sincerely thank you for this hearing.

Mr. Chairman, may I ask unanimous consent to take care of some business before we continue?

Chairman CHAFFETZ. Yes.

Mr. CUMMINGS. Mr. Chairman, since I started this investigation several years ago, I have literally been inundated with letters from families, hospitals, and patient groups begging—not asking, begging—for relief from these astronomical price increases.

I have 12 letters here that I would like to include in the official record of today's hearing, and they have been signed by more than 100 different organizations. Obviously, I won't go through all of them, but some of them include the American Association of Poison Control Centers, the American Federation of Teachers, the California Poison Control System, Consumers Union, Fair Pricing Coalition, HIV Medicine Association, Infectious Diseases Society of America, Human Rights Campaign, National Alliance of State and Territorial AIDS Directors, National Multiple Sclerosis Society.

Finally, Mr. Chairman, there is one more letter I would like to submit, and it is one of the first letters I received on this issue way back in 2011 when I started this journey. This is a heartfelt letter I received from Brenda Frese, the coach of the women's basketball team at the University of Maryland. Coach Frese's son was diagnosed with leukemia and treated with a drug called cytarabine.

Now, the interesting thing is what the coach wrote: "My son, Tyler, would not be alive today if we did not have access to the drugs that rid his body of cancer. Every family should have access to these drugs, and it is a shame that they are either not available or only available to the highest bidder."

I kept that letter with me for the past 5 years, and it has motivated me every day on this journey.

So I ask unanimous consent that all of these letters be included in the record.

Chairman CHAFFETZ. Without objection, so ordered.

[The information follows:]

Mr. CUMMINGS. With that, I yield back.

Chairman CHAFFETZ. I thank the gentleman.

I will hold the record open for 5 legislative days for any members who would like to submit a written statement.

[The information follows:]

Chairman CHAFFETZ. We will now recognize our witnesses. We are now pleased to welcome our panel.

Mr. Mark Merritt is the president and chief executive officer of the Pharmaceutical Care Management Association.

Dr. Janet Woodcock is the director of the Center for Drug Evaluation and Research of the United States Food and Drug Administration. Ms. Woodcock is accompanied by Mr. Keith Flanagan, director of the Office of Generic Drug Policy at the United States Food and Drug Administration, whose expertise might be needed during questioning.

By prior arrangement, we are going to release and excuse Dr. Woodcock at roughly 10:30 a.m., as she is testifying at another committee. In order to accommodate this, we are squeezing it in.

We appreciate your participation in both hearings, but you will be excused at 10:30, as we previously had agreed upon.

She will be replaced by Mr. Keith Flanagan, and we will swear him in at the same time.

Mr. Howard Schiller as the interim chief executive officer of Valeant Pharmaceuticals International.

I appreciate you being here.

Ms. Nancy Retzlaff is the chief commercial officer at Turing Pharmaceuticals.

And we have Mr. Martin Shkreli, former chief executive officer of Turing Pharmaceuticals.

We appreciate you being here. Pursuant to committee rules, all witnesses are to be sworn before they testify. We will also be swearing in Mr. Flanagan.

If you would please all rise and raise your right hand?

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

Thank you. Please be seated.

Let the record reflect that the witnesses all answered in the affirmative.

In order to allow time for discussion, we would appreciate you limiting your oral statements to 5 minutes.

Mr. Merritt, you are now recognized for 5 minutes.

## WITNESS STATEMENTS

### STATEMENT OF MARK MERRITT

Mr. MERRITT. Thank you, Mr. Chairman, Ranking Member Cummings, and other members of the committee.

I am Mark Merritt, president and CEO of the Pharmaceutical Care Management Association, the group representing America's pharmacy benefit managers, or PBMs. PBMs administer drug benefits for more than 260 million Americans with health coverage through employers, unions, Medicare Part D, FEHBP, State Government plans, and other sources.

Over the next decade, PBMs are projected to save $654 billion, or up to 30 percent, on drug costs, while still offering consumers broad choice and access.

PBMs reduce drug costs in several ways. They negotiate price concessions from drug manufacturers, negotiate discounts from drugstores. They offer more affordable pharmacy options, including home delivery. They encourage the use of generics and more affordable brand medications. They manage high-cost specialty medica-

tions. And they improve accountability up and down the pharmacy supply chain.

PBMs are perhaps most notable for their role in administering Medicare Part D plans. Since its launch, Part D has come in under CBO projections year after year, delivering countless choices to patients, and been perhaps the most popular health program in America. As the GAO reports, one way Medicare Part D plans reduce costs is through their ability to negotiate prices with drug manufacturers and pharmacies.

PBMs do that by pitting competing drugs and drugstores against one another and using differential copays and other tools to encourage patients to choose the more affordable options.

Competition is the key, as you can see from a recent high-profile example of high-priced drugs that treat hepatitis C. According to news reports, the price of these drugs has been cut nearly in half over the past year as new brand competitors have entered the marketplace. PBMs will demand even greater discounts as other competitors enter the space.

The pricing tactics we are here to discuss today are just one piece of a much larger puzzle, and that is important to note. They highlight how you can't separate drug company pricing strategies from marketing strategies to promote those drugs. Many drug companies use marketing strategies to reduce awareness and resistance to higher prices, the higher prices that ultimately increase the cost of care.

One of the most prevalent of these tactics is the use of bait-and-switch copay assistance programs to encourage patients to ignore generics and start on the most expensive brand instead. Unlike programs for the poor and uninsured, copay assistance programs specifically target patients with drug benefits and encourage them to bypass less expensive drugs for higher cost branded drugs.

Copay coupons are different than normal coupons for groceries and other products where consumers pay 100 percent of the cost and get 100 percent of the benefit because copay coupons pay only the cost of the copay, say $25 or $50, in order to make the third-party payers that offer coverage—the employers, unions, and others—to pay hundreds or thousands more for the most expensive brands on the formulary.

Such practices are considered illegal kickbacks in Federal programs and have long been under scrutiny by the HHS Office of the Inspector General. However, copay marketing programs are widespread in the commercial marketplace, and they play a key role in increasing costs there.

Now that I have outlined the problem, what can policymakers do about it? Well, there are a few solutions.

First, we do need to accelerate FDA approvals of me-too brands against competitors that face no competition.

Second, we need to accelerate FDA approvals of generics to compete with off-patent brands that face no competition. Of course, I defer to Dr. Woodcock on how to do this. She is, certainly, the expert on this, and I know it is not an easy task.

Third, Congress should create a government watch list of all the off-patent brands that don't face competition, so potential acquirers are aware that policymakers are monitoring these situations.

Finally, copay coupons should be considered illegal kickbacks in any Federal program or program that receives Federal subsidies.

Thank you very much, and I look forward to any questions you might have.

[Prepared statement of Mr. Merritt follows:]

**Introduction**

Good morning. My name is Mark Merritt, President and CEO of the Pharmaceutical Care Management Association (PCMA). I appreciate this opportunity to appear before the Committee to contribute our suggestions for ways to increase competition to better manage drug spending. PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, managed Medicaid plans, and others.

PBMs reduce drug costs by:

- Negotiating rebates from drug manufacturers;
- Negotiating discounts from drugstores;
- Offering more affordable pharmacy channels;
- Encouraging use of generics and more affordable brand medications;
- Managing high-cost specialty medications; and
- Reducing waste and improving adherence.

From 2016 to 2025, the use of PBM tools will save employers, unions, government programs, and consumers $654 billion—or up to 30%—compared with programs that make little use of proven PBM tools.[1]

PBMs are the key industry in America addressing the challenge of reducing costs, expanding access, and improving the quality of pharmacy benefits. Potential solutions that will enhance competition and help lower drug prices include:

- Getting speedier approval of drugs based on economic need;
- Solving the problem of off-patent drugs not subject to competition;
- Removing the generic drug backlog;
- Ensuring access to brand drug and biologic samples for development of generics and biosimilars; and
- Unlocking more innovative pricing arrangements.

This testimony will outline how PCMA's member companies harness competition to get lower prices from manufacturers and pharmacies. It will also discuss PBMs' role in combatting fraud and abuse, raise concerns about use of copay coupon programs, and offer policy solutions to increase competition among drug manufacturers to bring down drug costs, especially where drugs are long off patent.

**PBMs Create Market Competition Among Drug Manufacturers**

The PBMs competing in the marketplace, across all lines of business, represent total patient populations of tens of millions of individuals, bringing significant negotiating leverage to the table with brand manufacturers.[ii]

Recent events demonstrate how competition in the marketplace can drive significant savings on expensive drugs. A few months ago, a drug manufacturer reported that PBMs were able to negotiate a 46 percent rebate discount for one new hepatitis C drug—saving billions—when a direct competitor drug was introduced into the market.[iii] Indeed, while some PBMs preferred the first drug in their formulary, competing PBMs opted to prefer a competing manufacturer's drug, realizing equally large discounts. Other PBMs chose to keep both on their formulary, and ultimately, the market competition has allowed for this steep discount as compared with when the first drug was originally introduced.

Commercial clients and PBMs negotiate the proportion of rebate savings returned to the plan and the proportion used by the PBM in lieu of other fees to pay for their services. As passed through to clients, rebates reduce the cost that they pay for their prescription drug benefit. In Medicare, the rebate is largely applied to reduce premiums for beneficiaries.

**Using Competition to Make Medicare Part D a Success**

Medicare Part D was designed to encourage private health plans—MA-PDs and PDPs—to compete for beneficiaries, on the principle that competition keeps costs lower. The private plans in turn have engaged PBMs to negotiate with drug manufacturers and pharmacies, administer the benefits, recommend formularies, and otherwise implement Part D. Over the past 10 years, Part D has realized costs well under the original projections, benefiting beneficiaries and taxpayers alike, as PBMs have innovated to keep costs as low as possible.

Just as in the commercial sector, Medicare Part D plans negotiate to capture the largest possible discounts and rebates by using cost sharing and utilization management tools to encourage patients to choose preferred drugs where appropriate. CBO has found that Part D plans "have secured rebates somewhat larger than the average rebates observed in commercial health plans."[iv] Further, the Medicare Trustees note that "many brand-name prescription drugs carry substantial rebates, often as much as 20-30 percent."[v] Analysis of Medicare Trustee data shows that negotiated rebates have increased in each year of the program, repeatedly exceeding projected levels.[vi]

Indeed, the Government Accountability Office (GAO) reported that Medicare Part D plans lowered costs for beneficiaries, "through their ability to negotiate prices with drug manufacturers and pharmacies...Sponsors must . . . pass price concessions on to beneficiaries and the program through lower cost sharing, lower drug prices, or lower premiums."[vii] Growth in the reported average levels of negotiated rebates in Part D show competition at work, and competition among Part D plans to attract enrollees translates into savings for Medicare beneficiaries.

**PBMs have Innovated Preferred Pharmacy Networks in Part D**

PBMs have innovated in Medicare Part D by negotiating with pharmacies to offer lower costs in exchange for higher volume, as well as better value and higher quality, as part of preferred pharmacy networks. These networks comprise all types of pharmacies, including independent pharmacies. Plans using pharmacies offering preferred cost sharing have proven enormously popular—currently 75 percent of Medicare Part D beneficiaries have chosen these types of plans. While not every pharmacy achieves preferred status in every plan, the vast majority of pharmacies are in at least one plan as a preferred pharmacy, giving beneficiaries the opportunity to stay with a pharmacy with preferred cost sharing by carefully choosing their Part D plan every year.

Evidence shows Part D enrollees have embraced the savings that preferred pharmacies bring. A national poll conducted by Hart Research Associates shows that seniors in plans with preferred pharmacy networks are overwhelmingly satisfied, citing lower costs and convenient access to pharmacies, among other benefits. The survey revealed that 80 percent of those in preferred pharmacy plans—which translates to over 7 million seniors—would be very upset if their plan was no longer available.[viii]

For Part D overall, 89 percent of Americans age 65 and older are satisfied with their coverage and 85 percent say that they consider their Medicare drug plan to be a good value.[ix]

**PBMs Drive Efficiency through MAC Reimbursement**

Maximum allowable cost (MAC) is one of the most common methodologies used in paying pharmacies for dispensing generic drugs. By definition, MAC is the maximum allowable reimbursement by a PBM for a particular generic drug that is available from multiple manufacturers and sold at different prices. Each manufacturer has its own price for a particular generic drug and these prices can differ extensively by manufacturer. The use of MAC encourages competition: the purpose of MAC pricing is to encourage pharmacies to obtain the lowest-cost generic from among identical products from various manufacturers.

PBMs use MAC lists to balance providing fair compensation to pharmacies with being able to provide a cost-effective drug benefit plan to their health plan and employer clients. MAC pricing has become the industry standard—it is used by 79 percent of private employer prescription drug plans for retail generic prescriptions. In addition, 45 state Medicaid programs now use MAC lists. States adopted MAC lists after government audits showed that Medicaid reimbursements based on cost-plus reimbursement for generic drugs far exceeded a pharmacy's acquisition costs.

MAC reimbursement is a negotiated point in contracts between pharmacies and PBMs. Far from being at a contract negotiating disadvantage, independent pharmacies typically pool their collective purchasing power to increase leverage. More than 80 percent of independent pharmacies (18,103 of the 21,511 pharmacies identified by National Council for Prescription Drug Programs data) use large third-party organizations known as pharmacy services administrative organizations or group purchasing organizations to increase their leverage in negotiating their payment terms and conditions with PBMs. [x]

**PBMs Fight Fraud and Abuse**

PBMs exert great efforts to combat fraud, waste, and abuse with respect to prescription drugs. Pharmacy fraud, waste, and abuse costs the overall Medicare program billions. PBMs use data analytics to identify fraudulent pharmacies and fraudulent patients and then go after the perpetrators. PBMs also perform audits, where records from pharmacies are compared to claims data records. Additionally, PBMs make site visits to ensure that a pharmacy reporting claims is actually occupying physical space and has customers.

To address increasing opioid abuse, PBMs are using sophisticated analytics to uncover patterns of potential fraud or abuse, and scanning for behavioral red flags to identify when someone may be inappropriately seeking opioids. To further combat opioid abuse, PCMA strongly supports creation of a lock-in program in Medicare Part D, to allow Part D plans to work with at-risk Part D beneficiaries to choose a single pharmacy to dispense their controlled substances. Such a policy would maintain beneficiary access to needed medications, but prevent inappropriate shopping for opioids.

PCMA also supports requiring drugstores and pharmacists to register with state prescription drug monitoring programs; allowing payers to coordinate with state drug monitoring databases; and allowing Part D plans to use the same fraud prevention tools for pharmacies—including predictive analytics and suspension of payment upon a credible allegation of fraud—as are used in Medicare Parts A and B.

**Copay Coupons Undermine Efforts to Incent Patients to Take Cost-Effective Drugs**

Drug companies now offer copay coupons to undermine efforts by employers, unions and state governments to reduce costs by assigning higher consumer copays to expensive drugs and lower copays to more affordable drugs. The economics of brand copay coupons are simple: each time a drug company can sell a $150 product by helping cover a $50 copay, it gains $100 in revenue, which is paid by the employer, union, or state government that offers coverage.

By definition, copay promotions target those who already have prescription drug coverage (i.e., those who pay copays). These programs are not means tested or designed to help the poor or uninsured. Instead, they are designed to encourage insured patients to bypass less expensive drugs (which typically have lower copays) when multiple options are on the formulary, raising the cost of drug coverage.

Such practices are illegal in federal programs and have long been under scrutiny by the Health and Human Services Office of Inspector General because they are viewed as "kickbacks" that encourage wasteful spending for the profit of an outside third-party. Copay offset programs are estimated to increase pharmacy spending by $32 billion.[xi] To help cover the $4 billion spent annually on copay coupons, manufacturers can simply raise prices. Manufacturers reportedly earn as much as a six-to-one return on investment on copay coupon programs. Because insurers and plan sponsors foot this bill, these programs increase premiums.

Additionally, drug companies often require consumers to submit confidential, personal information in order to redeem copay coupons. Manufacturers have long sought (but found difficult to obtain) such sensitive patient data, which enables them to identify and directly target individual patients with brand-loyalty marketing programs.

**Increasing Competition in the Marketplace**

While PBMs can negotiate significant discounts and rebates when drugs are subject to competition, the options to achieve lower prices are limited when there is an absence of it. When a sole-source brand drug with no close substitutes enters the market, often similar competing brand drugs will subsequently enter the market, and eventually the original drug's patent will expire and generic versions of it will be produced. However, for various reasons, generic versions of brand drugs do not always come to market after the original drug's market exclusivity has expired. A number of policy changes to enhance competition could lower the cost of drugs generally.

**Getting Speedier Approval of Drugs Based on Economic Need:** A number of recently approved drug and biologic therapies have entered the market with historically high manufacturer prices. While many of these drugs represent needed breakthroughs to fight devastating and debilitating illness, their cost can be a barrier to access for patients who need these drugs and strain health budgets in both the public and private sectors. Additionally, although drug trend has been historically low in recent years, current projections show that the greater availability and use of specialty drugs and clinical guidelines encouraging drug use at earlier stages are poised to dramatically increase overall drug trend. According to FDA, 16 of the 45 novel drugs approved in 2015 (36 percent) were first-in-class, implying they will face little if any competition in the marketplace.[xii] Rather than directly intervening in manufacturer pricing, policymakers could better encourage price competition in the marketplace by accelerating approval of drugs in development for conditions where the cost of existing medications is a barrier to treatment and where manufacturers of current therapies have little incentive to compete on price. For example, in classes where there are only one or two drugs, new brand applications could be fast-tracked.

**Solving the Problem of Off-Patent Drugs not Subject to Competition:** As a first step, the FDA or other qualified entity should compile a list of all drugs and concomitant indications for which market exclusivity has expired, but do not currently have generic or other brand substitutes. This initial indexing will allow stakeholders to understand the number and types of such products. Additionally, policymakers and stakeholders alike should explore ways to encourage competition for such drugs, to help prevent the kinds of pricing actions discussed in

this hearing. This might be accomplished through providing accelerated review of abbreviated new drug applications (ANDAs) for these products.

**Removing the Generic Drug Backlog:** PBMs could bring additional competition to the market for other drugs, but FDA prioritizes breakthrough therapies, leaving generic and "me-too" brand drugs languishing on the approval sidelines. FDA argues that it has largely cleared the historic 42-month generic backlog.[xiii] However, a mid-year industry estimate places the median approval time for 2015 at 48 months,[xiv] and, the agency's GDUFA goal of a 15-month review for new ANDAs is substantially longer than the 10-month PDUFA goal currently in place for new non-generic drugs. In addition, there are still over 1,000 applications that have received a complete response and therefore will soon be back in the agency's hands after the sponsor addresses the identified deficiencies.[xv]

This is still a significant backlog, and it will likely take the agency years to process. FDA says that the filing backlog has been virtually eliminated, but it should be noted that this does not mean the entire backlog has been resolved. This only means that there is no longer a backlog of applications waiting to be formally accepted for filing. There remains a substantial backlog of applications already accepted for filing, which are now pending review. Resolving the filing backlog is akin to eliminating the line to take a number at the deli counter—though patrons are no longer waiting in line to get in the queue, they still must wait for their turn to be served (or in this case, for FDA to review their application). Finally, it is critically important to examine FDA's ability to work with generic manufacturers toward successful applications in judging FDA's progress on the backlog, and indeed on getting generics to market timely.

**Ensuring Access to Brand Drug and Biologic Samples for Development of Generics and Biosimilars:** Some drug manufacturers, including some manufacturing off-patent brand drugs, have made it extremely difficult for potential generic competitors to obtain samples needed for bioequivalence testing, sometimes by invoking FDA Risk Evaluation and Mitigation Strategies (REMS) but other times simply using extremely limited distribution schemes.[xvi] The use of such schemes to thwart generic competition has gotten the notice of the Federal Trade Commission (FTC), which has expressed concern over "the possibility that procedures intended to ensure the safe distribution of certain prescription drugs may be exploited by brand drug companies to thwart generic competition."[xvii] Further, survey results indicate that brand manufacturers are indeed using REMS or similar systems to deny generic manufacturers' access to brand drug samples.[xviii] In addition, brand manufacturers have also begun applying these anticompetitive distribution practices to drugs carrying no notable safety concerns, and for which the FDA has not required a REMS program.[xix]

In the House, there is bipartisan legislation (FAST Act, "Fair Access for Safe and Timely Generics," introduced by Steve Stivers (R-OH) and Peter Welch (D-VT)) that would require brand manufacturers to allow competitors access to samples of their product as a condition of FDA approval. We are supportive of these kinds of ideas.

**Unlocking More Innovative Pricing Arrangements:** The rapid increase in the cost of specialty drugs is driving the market to begin to consider alternative ways of paying for expensive therapies. The move to bundled payments, accountable care, comparative effectiveness research,

evidence-based medicine, and payments linked to performance are the direct result of regulatory and market pressures to reduce health costs without compromising safety and quality. For PBMs and drug manufacturers, these trends will demand innovative approaches to pricing. To enable more creative, value-based arrangements, however, our laws and regulations will need to be updated. For example, Medicaid best price rules make drug manufacturers reluctant to offer pricing arrangements that could, in theory, result in very low unit prices for some groups of patients, because manufacturers must then give that price to all Medicaid enrollees.[xx]

**Price Controls and Cost Sharing Limits Are Not the Answers**

The U.S. drug manufacturing and distribution system is the best in the world because it relies on market forces and competition to deliver high quality benefits and services to patients who need them. I urge the Committee to pursue policies that foster and encourage competition to keep drug costs and pharmacy benefits affordable. I especially urge the Committee to consider carefully the likely harm of certain proposals that would impose federal price controls on drug products and pharmacy services, impose limits on patient cost sharing, or expand coverage mandates. Such policies do not address the underlying problem at hand—rising drug costs and spending—and only serve to shift costs or reduce availability. In particular, limits on cost sharing may only serve to allow drug manufacturers to further increase prices on drugs. Those increased costs are borne by employers, governments, and patients themselves in the form of higher premiums.

**Conclusion**

PBMs were created because they increase the value of prescription drug benefits. PCMA's member companies harness market forces and competition to corral drugs costs and deliver high-quality benefits and services to their health plan clients and enrollees. In its search for solutions to what appear to be unusually high drug price increases, PCMA believes the Committee would be best served to pursue policies that foster and encourage competition to keep prescription drug costs and pharmacy benefits more affordable for employers, enrollees, taxpayers, and government programs. Improving drug approval times and encouraging competition, as well as resisting the urge to unduly regulate PBMs and prescription drug benefits, will go a long way toward helping to constrain drug manufacturers' demonstrated impulses[xxi] to price their products high.

As just one part of the prescription drug marketplace, our companies welcome continuing discussion among all stakeholders in the drug distribution system to create a robust, sustainable market that will continue to deliver needed cures and treatments for patients who suffer through disease and chronic illness. Additionally, PCMA looks forward to working with Congress to find additional ways to promote savings while continuing to deliver the highest quality, highest value prescription drug benefits for all.

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[i] Visante: Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, February 2016.
[ii] Health Strategies Group, "Pharmacy Benefit Manager Research Agenda 2015," http://www.healthstrategies.com/download/file/fid/1892
[iii] New York Times, "Costly Hepatitis C Drugs for Everyone?" September 2, 2015.
[iv] CBO, Letter to the Honorable Joe Barton and the Honorable Jim McCrery, March 12, 2007, Page 3.
[v] Medicare Trustees, "2014 Medicare Trustees Report," p.150, footnote 63.
[vi] Medicare Trustees, "2015 Medicare Trustees Report," p. 144, Table IV.B8.

[vii] GAO, "Overview of Approaches to Control Prescription Drug Spending in Federal Programs." Statement of John E. Dicken, Director, Health Care, Government Accountability Office, before the Subcommittee on Federal Workforce, Postal Service, and the District of Columbia, Committee on Oversight and Government Reform, House of Representatives, June 24, 2009. http://www.gao.gov/new.items/d09819t.pdf
[viii] Hart Research Associates, "A Survey of Seniors on Their Medicare Part D Preferred Pharmacy Network Plan: Key findings from quantitative research", September 2014, Prepared for PCMA.
http://www.pcmanet.org/images/stories/uploads/2014/medicare%20part%20d%20preferred%20pharmacy%20network%20survey_complete_hart%20associates.pdf
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http://www.pcmanet.org/images/stories/uploads/2011/Nov2011/visante%20copay%20coupon%20study.pdf
[xii] FDA, "Novel Drugs Summary 2015," January 12, 2016.
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm
[xiii] HHS, "Department of Health and Human Services, Fiscal Year 2016 Justification of Estimates for Appropriations Committees, Food and Drug Administration." http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM432322.pdf
[xiv] http://www.gphaonline.org/gpha-media/press/statement-by-ralph-g-neas-president-and-ceo-gpha-on-the-june-15th-fda-public-meeting-on-gdufa
[xv] Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA).Testimony of Janet Woodcock, M.D. Before the Committee on Health, Education, Labor and Pensions. January 28, 2016, Page 5
[xvi] Michael Carrier and Aaron Kesselheim "The Daraprim Price Hike And A Role For Antitrust," *Health Affairs* Blog, October 21, 2015.
[xvii] Federal Trade Commission's Brief as Amicus Curiae, Actelion Pharmaceuticals Ltd. v. Apotex Inc., (No. 1:12-cv-05743-NLHAMD), (D.N.J. Mar. 2013), available at www.ftc.gov/os/2013/03/130311actelionamicusbrief.pdf.
[xviii] Alex Brill, "Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry," July 2014.
http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf
[xix] Alex Brill, "Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry," July 2014.
http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf [ This could just be ibid]
[xx] Dana Goldman and Darius Lakdawalla, "Moving Beyond Price-Per-Dose In The Pharmaceutical Industry," *Health Affairs* Blog, September 30, 2015.
[xxi] *See, e.g.*, The Staffs of Ranking Member Ron Wyden and Committee Member Charles E. Grassley, Committee On Finance, United States Senate "The Price Of Sovaldi And Its Impact On The U.S. Health Care System," December 2015, pp. 45-46.

Chairman CHAFFETZ. Thank you.

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

**STATEMENT OF JANET WOODCOCK**

Dr. WOODCOCK. Thank you. Good morning, Mr. Chairman, ranking member, and members of the committee. I am Janet Woodcock. I am head of the drug center at the FDA. We regulate generic drugs as well as brand drugs.

The Hatch-Waxman legislation that established the generic drug program has been extraordinarily successful. Today, about 88 percent of prescriptions that are given out or dispensed in the United States are generic drugs, saving the public an estimated almost $1.7 trillion recently.

In the last decade, the generic drug industry grew very rapidly and globalized its operations. FDA's generic drug review program did not grow significantly and fell behind both in our review and our inspection capacity. And a large backlog accrued.

To resolve this, in 2012, Congress enacted the Generic Drug User Fee Act, reflecting a negotiated agreement between the generic drug industry and the FDA. This was a 5-year program during which industry would pay $300 million per year in fees and FDA would attempt to meet a progressively more difficult series of performance measures over that time.

In the 3 years since that was enacted, FDA has met or exceeded all GDUFA performance goals. This has been a formidable task. In these 3 years, we have been managing over 6,000 generic applications, 2,500 that were piled up at the start of the program and almost 3,000 that have been submitted in the 3 years since the program started.

But the good news is over 90 percent of these applications have received review at the FDA or review communications, and over 1,700 have been approved or tentatively approved. Tentative approval means they are waiting for their patent exclusivity to expire. Over 1,000 have been sent back to industry because they had deficiencies.

This means there are only about 600 applications out of the 6,200 that are awaiting review, and many of these have been submitted recently.

The generic drug backlog was a big problem. It was caused by rapid growth in industry submissions not matched by corresponding investment in the FDA generic review program. This was ultimately fixed by the user fee act that was passed by Congress, but it takes some time for us to dig out of this hole. And it will take a bit more time before we are fully caught up.

Nevertheless, applications that have been submitted in the past 2 years, 2014 and fiscal year 2015, have a 15-month review clock that we expect to make. And by this October, we will have a 10-month review clock. So an application submitted this October or beyond, we would expect to completely finish the review and get back to the sponsor in 10 months.

It is the older applications that we need to clean up, and we are working very hard and very successfully at doing that.

The purpose of Hatch-Waxman was to introduce high-quality, FDA-approved competition into the market to improve access for

patients. Sixty-five percent of drugs have generic competition right now, and another 24 percent are still protected by patents or exclusivity, so they are not yet eligible for generic competition. Ten percent have no protection, either patent or exclusivity, but lack generic competition and lack applications submitted to the FDA. Two percent have applications with the FDA awaiting approval. Those are all expedited. We expedite all first generics, and those are all moving through the process and getting review and so forth.

Under the GDUFA system, we have the potential to get on the market very fast, because these first generics are prioritized and all applications will have a 10-month review clock.

Now I am, as you said, scheduled to testify at a second hearing this morning beginning at 10:30, and I may need to depart before all committee questions have been answered, so Mr. Keith Flanagan, who is director of the Office of Generic Policy, will be able to answer any technical questions about the generic program after I leave.

So I thank you very much for your attention, and I look forward to answering your questions.

[Prepared statement of Dr. Woodcock follows:]

# Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA)

**Testimony of Janet Woodcock, M.D.**

Director, Center for Drug Evaluation and Research

U.S. Food and Drug Administration

**Before the Committee on Oversight and Government Reform**

United States House of Representatives

February 4, 2016

U.S. Department of Health and Human Services

**U.S. Food and Drug Administration**

Center for Drug Evaluation and Research

www.fda.gov/drugs

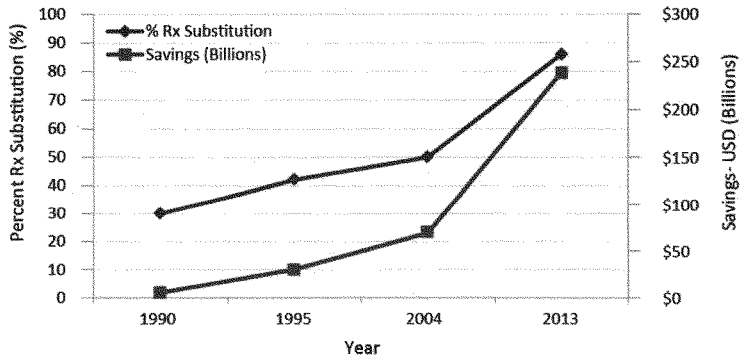
## Introduction

Chairman Chaffetz, Ranking Member Cummings and Members of the Committee, I am Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss FDA's implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA).

## Historically, the generic drug program has been a great success.

The generic drug industry has grown from modest beginnings into a major force in health care. According to the IMS Institute for Healthcare Informatics, generic drugs now account for 88% of prescriptions dispensed in the United States, and saved the U.S. health system $1.68 trillion from 2005 to 2014.

**Chart 1. Generic Substitution and Annual Savings[1]**

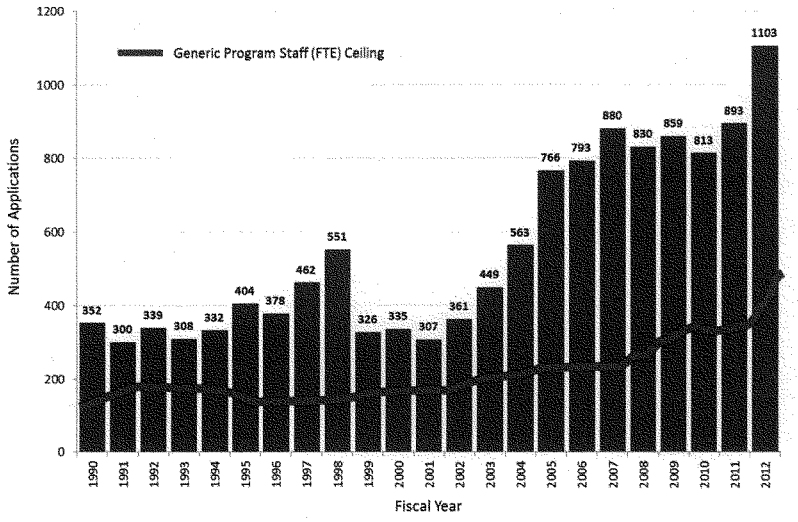



1. Annual generic utilization and savings data compiled from IMS Health, the Generic Pharmaceutical Association, and the Congressional Budget Office.

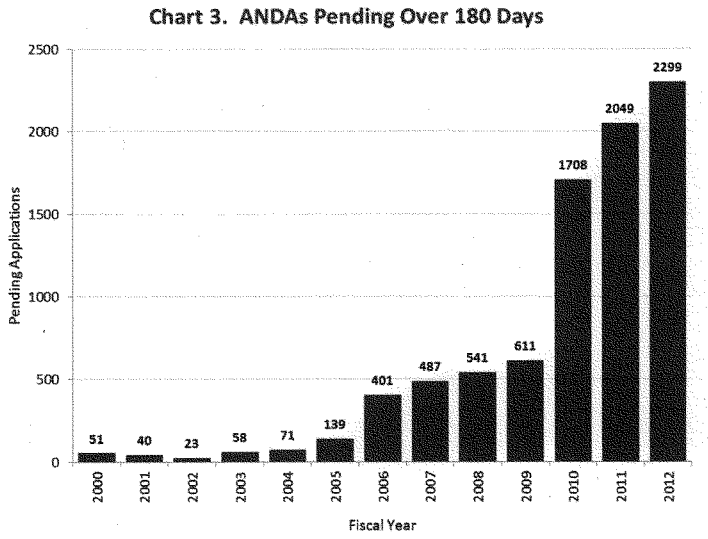
## This success brought new challenges.

Over the last several decades, the generic industry, the number of generic drug applications (known as "Abbreviated New Drug Applications" or "ANDAs") submitted to FDA for review, and the number of foreign facilities making generic drugs grew substantially. As a result, FDA's generic drug program became increasingly under-resourced. Its staffing did not keep pace with the growth of the industry.

**Chart 2. Number of ANDAs Submitted Per Year and Number of Staff Over Time**




Because the program could not keep up with its workload, a backlog of submitted ANDAs developed and grew. It overwhelmed the FDA staff and created unpredictability and delay for industry.




## Solution: GDUFA

After multiple attempts, FDA and the generic industry developed a proposal for a generic drug user fee program and submitted it to Congress. Congress enacted it as part of the Food and Drug Administration Safety and Innovation Act of 2012.

Under GDUFA, industry agreed to pay approximately $300 million in fees each year of the 5 year program. In exchange, FDA committed to performance goals, the specifics of which are contained in the Generic Drug User Fee Act Program Performance Goals and Procedures agreement that was negotiated with industry ("GDUFA Commitment Letter")[1]. Because of the amount of hiring, restructuring, and catch-up needed, performance goals were set to commence in the later years of the program. The GDUFA performance goals with respect to ANDAs, amendments to ANDAs, and prior approval supplements (PAS)[2] are timeframes by which FDA

1. http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf

2. A prior approval supplement is a post approval change requiring supplemental submission and approval prior to distribution of the product made using the change.

is to take a "first action" on an application, by either granting an approval or tentative approval[3], or, if there are deficiencies that prevent approval, identifying those deficiencies to the applicant in a complete response letter or in a refusal to receive[4] the application. When deficiencies are identified, industry usually responds by correcting them and resubmitting the application.

**Chart 4. Major GDUFA Performance Goals****

| Goals | FY2015 | FY2016 | FY2017 |
|---|---|---|---|
| Original ANDA | 60% in 15 months | **75% in 15 months** | 90% in 10 months |
| Tier 1 first major amendment | 60% in 10 months | **75% in 10 months** | 90% in 10 months |
| Tier 1 minor amendments (1st - 3rd) | 60% in 3 months* | **75% in 3 months*** | 90% in 3 months* |
| Tier 1 minor amendments (4th - 5th) | 60% in 6 months* | **75% in 6 months*** | 90% in 6 months* |
| Tier 2 amendment | 60% in 12 months | **75% in 12 months** | 90% in 12 months |
| Prior approval supplements | 60% in 6 months* | **75% in 6 months*** | 90% in 6 months* |
| ANDA teleconference requests | Close-out 200 | **Close-out 250** | Close-out 300 |
| Controlled correspondences | 60% in four months* | **70% in two months*** | 90% in two months* |
| ANDA, amendment and PAS in backlog on Oct 1, 2012 | Act on 90% by end of FY 2017 | | |

*10 months if inspection required

**Performance goals in the chart means FDA should take an action on a certain percent of applications, etc. within the timeframes listed; it does not mean FDA should approve applications, etc. within such timeframes.

To date, FDA has met or exceeded all performance goals outlined in the GDUFA Commitment Letter.

3. Tentative approval applies if a generic drug product is otherwise ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product. In such instances, FDA issues a tentative approval letter to the applicant. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved. A tentative approval does not allow the applicant to market the generic drug product.

4. A "refuse-to-receive" decision indicates that FDA determined that an ANDA is not sufficiently complete to permit a substantive review.

## Actions on Pre-GDUFA ("Backlog") Applications

A major commitment of GDUFA was to take a "first action" on 90% of the "backlog" applications, defined as pre-GDUFA applications pending before the Agency on October 1, 2012, by the end of Fiscal Year 2017. As of October 1, 2012, the backlog included 2866 ANDAs and 1873 PASs. As Chart 5 indicates, to date, FDA has completed first actions on 84% of ANDAs and 88% of PASs. And so, FDA is well ahead of schedule in achieving the GDUFA goal to significantly reduce the backlog, and our ultimate goal of eliminating it.

### Chart 5. Percentage of Backlog Applications with First Action

**First Actions 10/1/2012 to 12/31/2015**

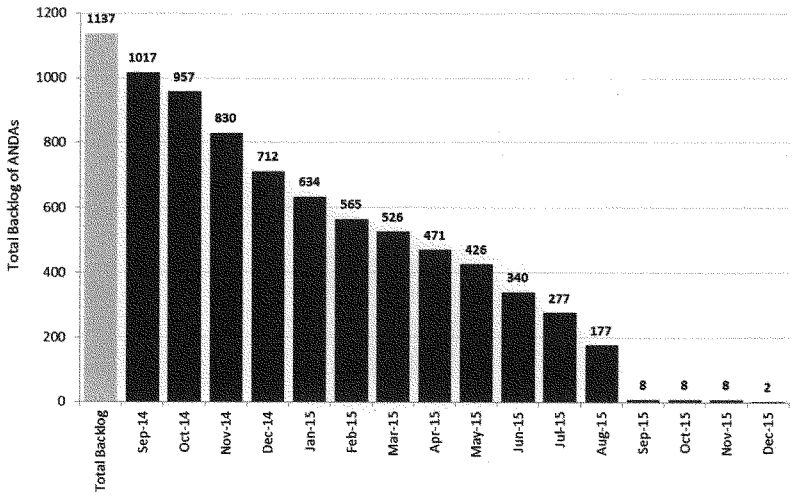
| Actions | ANDAs | PAS |
|---|---|---|
| Number with First Action** | 2414 | 1666 |
| **Percentage Complete** | **84%** | **88%** |
| Approval | 609 | 959 |
| Tentative Approval | 151 | 4 |
| Complete Response with Inspection* | 1384 | 465 |
| Refuse to Receive | 69 | 2 |
| Withdrawn Applications | 201 | 236 |

*Complete Response with an Inspection is a written FDA communication to an applicant usually describing all of the deficiencies that the agency has identified in an application that must be satisfactorily addressed before it can be approved.
**Numbers are based on current data and will be further scrubbed for formal reporting purposes.

Some of these backlog applications had been pending or in review for a long time prior to GDUFA. At this point in time, as FDA acts on one of the outstanding backlog applications, the "time to approval" of such application will be recorded as, at minimum, 40 months (i.e., we now are three years and four months (40 months) into GDUFA implementation). This helps to explain the often-quoted 42 month approval time, which does not apply to post-GDUFA applications as explained below.

Moreover, the filing backlog for ANDAs has been eliminated. "Filing" is where we evaluate if a drug sponsor's submitted application is sufficiently complete to permit FDA's substantive review. In August 2014, we had a filing backlog of over 1,100 applications. Now that backlog is gone.

**Chart 6. ANDA Filing Backlog**




## Actions on Post-GDUFA Original Applications[5]

In addition to the pre-GDUFA backlog applications, nearly 2,500 applications were submitted in FY 2013 and FY 2014 after GDUFA had commenced. Per the GDUFA Commitment Letter, these FY 2013 and FY 2014 applications have no GDUFA goal dates. Notwithstanding this, FDA assigned internal goals, called "Target Action Dates" (TADs), to both the pre-GDUFA backlog applications and to the FY 2013 and FY 2014 applications and has been aggressively reviewing them.

5. In this context, "Original Applications" refer to the first ANDA submitted, as opposed to a subsequent amendment or supplement to the ANDA."

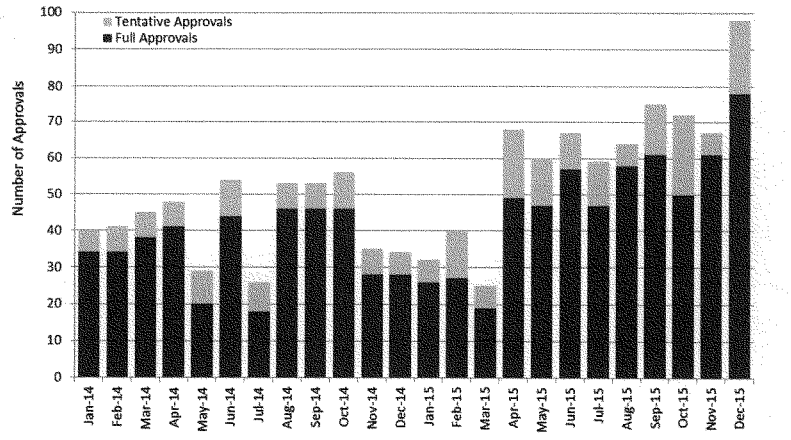
Under the GDUFA Commitment Letter, applications submitted in FY 2015 have a 15 month "first-action" goal date. Goal dates represent a paradigm shift. They substantially improve the speed and predictability of review. So, any concerns about delayed competition in the generic space pertain to prior years, when our backlog was accumulating, and not to applications with GDUFA goal dates.

Importantly, if the ANDA submission is a potential "first generic" or could mitigate a drug shortage, its review is expedited. The performance goals for those generic applications submitted in the first few months of FY 2015 are just coming due. We are on track to meet or exceed our obligations under the GDUFA Commitment Letter relative to these applications and already have approved or otherwise acted on some applications submitted in FY 2015.

Applications submitted in Fiscal Year 2016 also have a first-action goal date of 15 months, with the Agency committed to reviewing a greater percentage of generic applications within the timeframe specified.

The cumulative result of all this effort is a huge increase in the productivity of the generics program. As Chart 7 indicates, we ended last year at a new monthly high of 99 approvals and tentative approvals in December.

**Chart 7. Approvals and Tentative Approvals**



Of course, a major goal of GDUFA is timely approval of affordable, high-quality generic drugs. FDA's success in implementing the Prescription Drug User Fee Amendments (PDUFA) program–the user fee program for new drugs begun in 1992–provided the Agency with valuable experience that enabled us to rapidly build a modern generic drug review process once sufficient resources were made available through user fees. FDA is now on track to achieve the throughput needed, with sustained levels of record or near-record approvals in the third and fourth quarter of 2015.

## Prioritization of First Generics Applications

We recognize that certain types of applications merit priority attention based on their public health significance.

For example, we consider "first generics" to be public health priorities, as they can lead to increased patient access. First generics are just what they sound like–the first generic versions of a drug to enter the market. Under GDUFA, beginning in FY 2015, each of these first generic submissions automatically receives a 15 month goal date. FDA has worked hard to provide an even faster review for potential first generics. Because they are public health priorities, we expedite their review, like an express lane at the supermarket.

Thanks to GDUFA, we made substantial first generic program improvements. We opened a docket to solicit technical input; issued a public-facing, transparent prioritization policy;[6] formed a team to expedite the review of first generics; trained review staff; and enhanced our computer systems to streamline the process.

Potential first generics are approximately 15% of our overall workload. All of these have been going in the "express lane." Over the past 3 years we have approved hundreds of first generics for over 200 new drug products. Significant first generic approvals for 2015, and the indications (abbreviated) for which these products were approved, are listed on the next page.

6. http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf

## Significant First Generic Approvals for 2015

| Brand (Generic name) | Indications (Abbreviated) |
|---|---|
| Abilify® (aripiprazole) | Schizophrenia, Bipolar Disorder |
| Fusilev® (levoleucovorin) | Supports cancer treatment |
| Enablex® (darifenacin) | Overactive bladder |
| Lotronex® (alosetron) | Irritable bowel syndrome |
| Zyvox® (linezolid) | Pneumonia, serious infections |
| Tygacil® (tigecycline) | Pneumonia, serious infections |
| Vagifem® (estradiol) | Menopause |
| Integrelin® (eptifibatide) | Heart attack |
| Xenazine® (tetrabenazine) | Huntington's Disease |

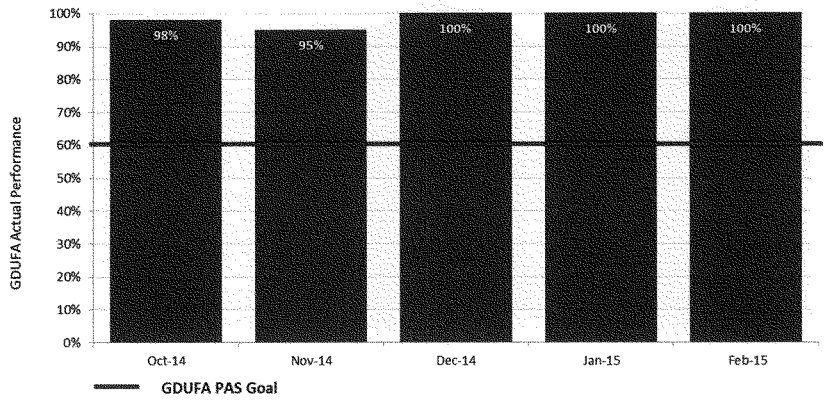
## Progress on Additional Important GDUFA Goals

In addition to reducing the backlog, acting on post-GDUFA applications, and approving first generics, FDA is also achieving other important GDUFA goals.

One goal addressed risk-based inspection parity for foreign and domestic facilities. Before 2012, the law required us to inspect domestic facilities at a two-year interval, but was silent on frequency for foreign establishments, regardless of their relative risk. GDUFA directs us to target inspections globally on the basis of risk. We are on track to achieve the goal of risk-based inspection parity between foreign and domestic facilities by the end of FY 2017.

GDUFA also established goals for our review of PASs. PASs are important because they enable flexibility and improvements for generic drug manufacturing. To date, we have substantially exceeded GDUFA PAS goal of 60% reviewed within 6 months if an inspection is not required and 10 months if an inspection is required.

**Chart 8. Exceeding Prior Approval Supplements (PAS) Review Goals***

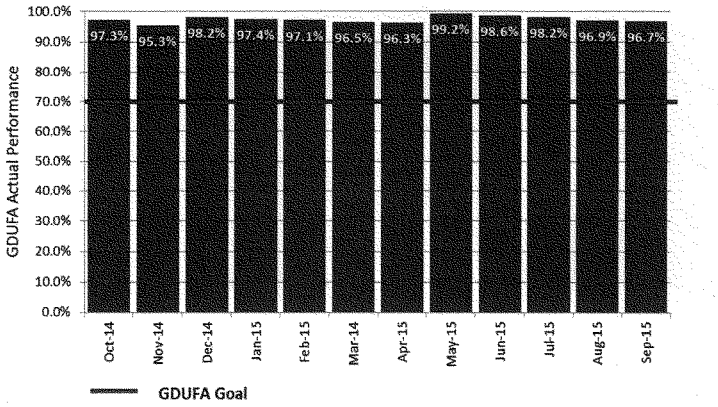



*Goal dates provided through February 2015, as those are the goal dates that have actually accrued. The cohort data is not mature enough to report on whole year data

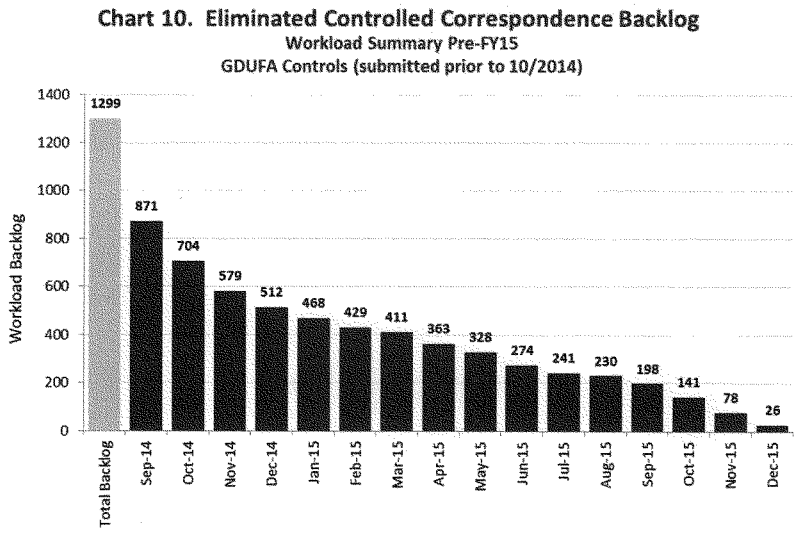
There are also GDUFA goals for responding to controlled correspondence. Controlled correspondences are product development questions that FDA answers to help companies develop applications. The GDUFA goal for FY 2015 was to respond to 70% within 4 months of submission. As noted in Chart 9, we substantially exceeded our commitments in this area.

**Chart 9. Exceeding Controlled Correspondence Goals**

**FY15 GDUFA Performance by FDA Receipt Date - All Disciplines**



We also had a significant backlog of controlled correspondence from before goal dates started. We have eliminated that backlog.




## How did FDA achieve these results?

***Deep, foundational restructuring.***

We achieved these results by building a modern generic drug program.

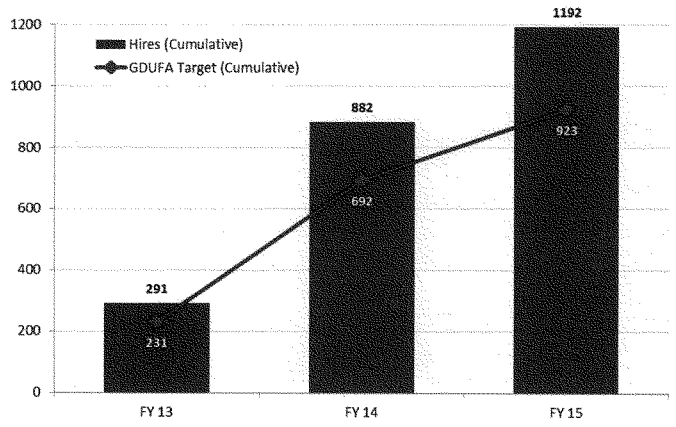
This involved major reorganizations. We reorganized the Office of Generic Drugs and elevated it to "Super-Office" status, on par with the Office of New Drugs. We established a new Office of Pharmaceutical Quality[7] to integrate the quality components of the review.

7. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm418347.htm

We developed an integrated informatics platform to support the generic drug review process. It is a significant improvement over our fragmented, legacy systems, and has enhanced our productivity.

We hired and trained over 1,000 new employees, achieving our GDUFA hiring goals well ahead of schedule.

**Chart 11. GDUFA Hiring Progress**



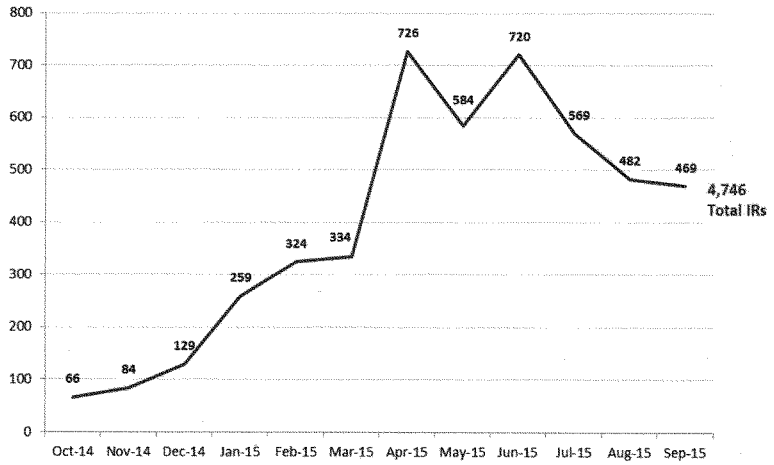

***Flexible Approach: Communications and Transparency***

We also took a flexible approach to managing the program in ways that benefit generic drug sponsors and, ultimately, patients.

One example of fine-tuning the process to speed approvals is the "Information Request" process. As originally agreed during the GDUFA negotiations, FDA was to package all deficiencies found in the review of an application and provide them to the applicant in a complete response letter. But that turned out not to be a helpful approach and industry asked us to send them information concerning individual deficiencies on a rolling basis, instead of

consolidating them all into one package. This would help industry correct deficiencies in "real time." We agreed. In FY 2015, we issued over 4,700 Information Requests.

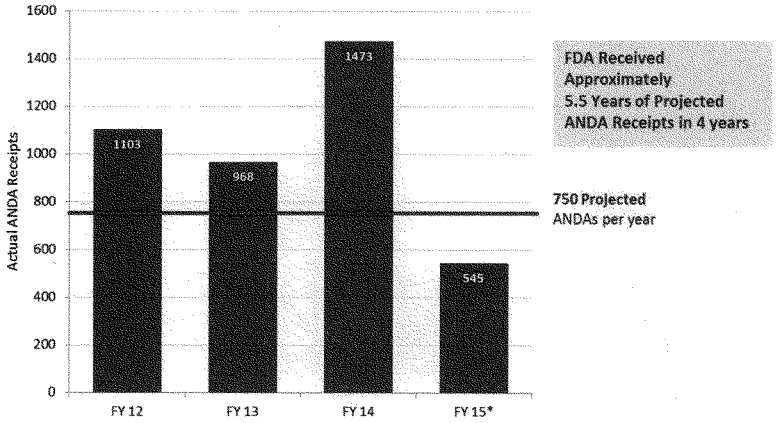
**Chart 12. Communications with Industry**
**FY15 Trends (ANDA Originals)**
**Information Requests (IRs) Issued by Month *excluding filing**




At industry's request, we communicated "Target Action Dates" (TADs). As previously described, TADs are our internal deadlines for action on all applications without goal dates. Although GDUFA did not require the Agency to develop TADs or communicate them to industry, we understand that they help companies plan product launches, spurring timely access to generics.

We also reacted to much larger than expected ANDA submission volume. As the GDUFA Commitment Letter stated, GDUFA review goals and planning were based on the assumption that the Agency would receive approximately 750 ANDAs per year. We budgeted and planned with this projection in mind. However, in FYs 2012, 2013 and 2014, we received over 1,000, nearly 1,000, and nearly 1,500 applications, respectively. We had to modify our planning and execution accordingly.

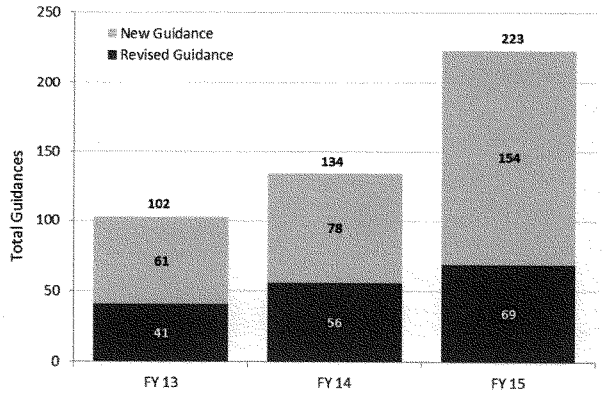
**Chart 13. Projected vs. Actual ANDA Receipts**




*Numbers are based on current data and will be further scrubbed for formal reporting purposes.

In addition, we increased our output of product-specific guidances. These guidances clarify our expectations concerning specific products so industry can develop and obtain approval of generic versions of branded drugs more quickly.

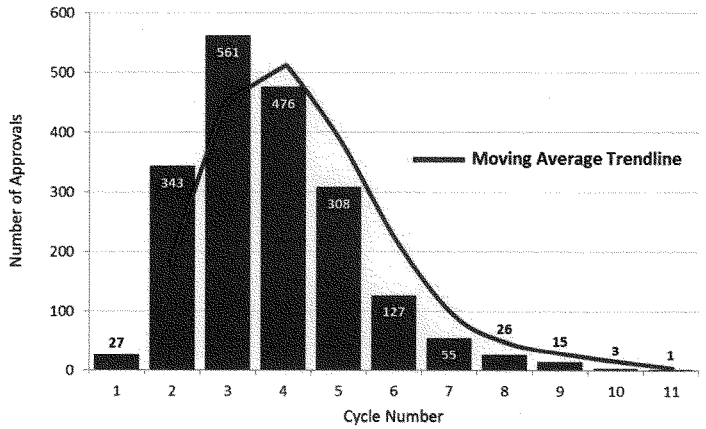
**Chart 14. Product-Specific ANDA Guidances**



## Ongoing Challenges

We do have some ongoing challenges. The first relates to submission quality. Historically, it has taken on average about 4 review cycles to approve an ANDA as a result of deficiencies by generic drug sponsors in submitting complete and quality applications (see Chart 15). This has resulted in the submission of numerous amendments to correct deficiencies in the original ANDAs and comprises a huge amount of re-work for FDA and industry alike. Currently, for example, nearly 900 applications are back with industry awaiting resubmission to correct deficiencies in the original applications. New filing policies will help, but more work by both the Agency and industry will be necessary to have the filings be "right the first time."

**Chart 15. Review Cycles for ANDAs**
**2009 through July 2014**



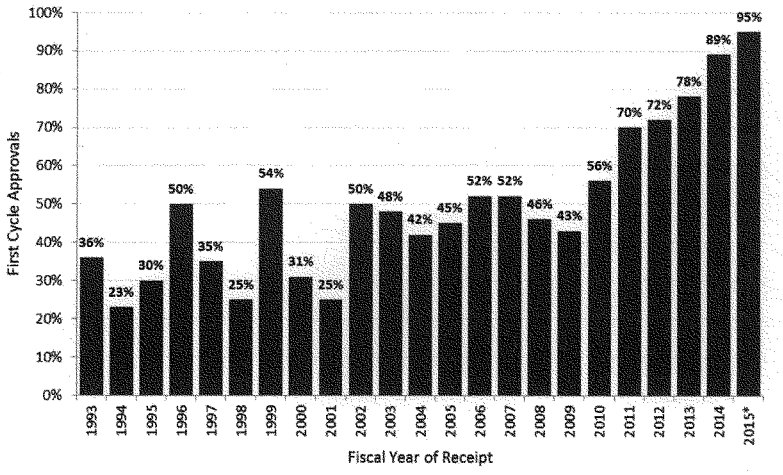

As noted in the public minutes[8] published as part of the GDUFA II negotiations now underway, FDA and industry are discussing a pre-ANDA process by which FDA and industry would address approval challenges for particular drugs prior to ANDA submissions, which could make a big difference in the completeness and quality of applications.

8. http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm256662.htm

**Chart 16. First Cycle Approval Rate Under PDUFA**

CDER NME NDAs/BLAs†

First Action Approval Rate




Improvement may take some time. As Chart 16 shows, in the first few years of the PDUFA program, the first cycle approval rate dropped as low as 23%. Now it is 95%. Achieving this was the result of many years of work on standards and expectations.

Second, there is a need for more research in the generics space. Some drugs lack generic competition because there is no convincing bioequivalence test method available. In these instances, a more extensive clinical study is needed to show equivalence of a generic to a brand name drug. Similarly, methods for showing chemical sameness for certain complex drugs are not available. GDUFA provided funding for research efforts to work out these problems. So far, GDUFA has funded $34.9 million in research programs that will open up previously blocked pathways. However, scientific research takes time, and results will need to be translated into guidance for industry.

Third, shared system Risk Evaluation and Mitigation Strategies–or REMS–pose challenges. REMS are used to ensure that the benefits of drugs outweigh their risks. The statutory requirement that REMS programs that include elements to assure safe use (ETASU) be

implemented through a "single shared system" relies on brand and generic companies to agree on such a system before generic drugs may come to market. This is challenging to implement and frequently results in blocking generic competition. We would welcome the opportunity to discuss possible solutions to this problem with you.

Fourth, to better assure quality in an increasingly globalized industry, FDA is undertaking major changes in quality regulation. CDER's Office of Pharmaceutical Quality, FDA's Program Alignment Group[9] and the International Council for Harmonisation[10] are all driving major changes, and FDA is pursuing mutual reliance discussions with the European Union. As a result of this work and collaborative effort, the public can be assured that FDA will hold generic products to the same quality standards as brand drugs, no matter where they are manufactured or tested.

## Conclusion

I am extremely proud of what the FDA staff has accomplished in implementing GDUFA. Getting to where we are today has taken an enormous amount of work and above-and-beyond dedication by many people over the past three years. I have no doubt that we will exceed the goals initially established for this program.

GDUFA II discussions between the Agency and Industry are underway and constructive. We are excited and positive about the opportunity to make significant program improvements.

Thank you for the opportunity to describe what we've accomplished over the past three years. I look forward to your questions.

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9. http://www.fda.gov/AboutFDA/CentersOffices/ucm392733.htm
10. http://www.ich.org/home.html

Chairman CHAFFETZ. Thank you.

Mr. Schiller, you are now recognized for 5 minutes.

**STATEMENT OF HOWARD B. SCHILLER**

Mr. SCHILLER. Chairman Chaffetz, Congressman Cummings, members of the committee, thank you for the opportunity to testify. I have been with Valeant since 2011, first as CFO, then on the board, and now as interim CEO.

Over this time, Valeant has grown substantially. Today, we are a large, innovative pharmaceutical company that employs 22,000 people around the world, including 6,000 in the United States. We have about 1,800 products, including 200 prescription drugs in the U.S. We are a leading dermatology, gastroenterology, ophthalmology, and consumer health care company.

Our flagship brands, like Bausch + Lomb, Jublia, and CeraVe, are known to many Americans. We have a large U.S. presence, including 16 manufacturing sites, and we are making significant investments in the United States.

In Rochester, New York, alone, we have invested more than a quarter of $1 billion to upgrade the plant and added nearly 200 jobs. And we expect to invest $500 million more over the coming years and add 630 jobs.

We have heard very clearly Congress' and the public's concerns about drug prices and the industry generally, and Valeant's increases in prices, including for two of our drugs, Nitropress and Isuprel, and we are responding to those concerns. We created a volume-based rebate program providing up to a 30 percent discount for Nitropress and Isuprel. And we just launched a 20-year partnership with Walgreens that will provide a 10 percent average price reduction for branded dermatology and ophthalmology products, and a price reduction for up to 95 percent on branded drugs where there is a generic.

These steps are in addition to the existing patient-assistance programs, which help ensure that out-of-pocket expenses don't prevent eligible patients from receiving the medicines they need. We expect to spend more than $1 billion in 2016 on patient assistance.

I would like to specifically address the pricing of Nitropress and Isuprel, which are cardiac drugs used in hospital procedures, which there is a fixed rate of reimbursement by payers.

These are not drugs purchased by patients in a pharmacy. When we acquired them, we commissioned an outside pricing consultant to review the market. They concluded that Nitropress and Isuprel were clinically very valuable to hospitals and patients, and that the fixed reimbursement rates allowed for significant price increases without eliminating a hospital's profits. Based on these findings, we implemented significant price increases.

Since then, we have experienced about a 30 percent reduction in volume as hospitals moved to alternative drugs. The volume discounts we implemented will help address the needs of those hospitals that are large users of these drugs.

Now let me say a word about commitment to research and development. Valeant's R&D results make us a leader in the industry. Our productivity drugs approved for R&D dollars spent is 7 times higher than the average of the 15 companies with the most new

drug approvals. In just the last 2 years, Valeant has launched 76 new prescription drugs, generic drugs, medical devices, and other products in the United States. And there is more to come from our robust U.S. pipeline, which has more than 200 active programs. We expect approvals this year of a significant novel treatment for glaucoma and a biologic for the treatment of moderate to severe plaque psoriasis.

We believe that R&D should focus on outputs and should not be judged by spending alone. Nonetheless, our R&D spending is significant, expected to exceed $400 million in 2016. We have 43 R&D facilities with 1,000 R&D employees worldwide.

In addition to internal development, we have followed the successful model of the technology industry by acquiring valuable R&D assets.

Mr. Chairman, where we have made mistakes, we are listening and we are changing. Our Walgreens partnership is a key step forward, but we have more to do.

Through internal development and acquisitions, we developed a portfolio of world-class franchises. Like other pharmaceutical companies, we will sometimes adjust our prices but our price increases in the future will be well within industry norms and much more modest than the ones that drew your legitimate concerns.

Mr. Chairman, thank you for the opportunity to appear today, and I look forward to answering your questions.

[Prepared statement of Mr. Schiller follows:]

Statement of
Howard B. Schiller
Interim Chief Executive Officer and Director,
Valeant Pharmaceuticals International, Inc.
before the
Committee on Oversight and Government Reform
U.S. House of Representatives

February 4, 2016

Chairman Chaffetz, Congressman Cummings, and Members of the Committee, thank you for the opportunity to testify on behalf of Valeant and address your questions about the company, our products, the prices of our prescription drugs, and our approach to pharmaceutical research and development.

I have worked for Valeant since 2011, first as the company's chief financial officer, then as a member of the Board of Directors, and now as interim CEO during the medical leave of Michael Pearson. Over this time, I have watched Valeant grow quickly and substantially. Today, we are a robust and innovative specialty pharmaceutical and medical device company that employs about 22,000 people around the world, including 6,000 in the United States, and generates more than $10 billion in annual revenue. We have a collection of world-class franchises that we use to meet our mission of delivering life-changing drugs to doctors and patients who depend on them. In the United States, we are a leading dermatology, gastrointestinal, ophthalmology, and consumer healthcare company, with growing dental, oncology, and women's health businesses, among others. Valeant makes and markets approximately 1,800 products, including more than 200 prescription drug products in the United States. Our flagship products and brands – such as Bausch + Lomb, Jublia, and CeraVe – are familiar to many Americans, and I am sure to many of you as well.

I hope that today's hearing will permit me to address some of these broader aspects of Valeant's business, although I recognize that I am here today primarily because of the Committee's interest in two issues: The pricing of our drugs and our investment in research and development. I would like to address each of these issues directly.

First, we understand, and have heard very clearly, Congress's and the public's concerns about drug prices in the pharmaceutical industry and Valeant's increases to the list prices of certain drugs, including two cardiac medicines used in hospital procedures, Nitropress and Isuprel. We are responding to these concerns and have already taken steps to address them. We have, for example, created a volume-based price rebate program providing up to a 30% discount for Nitropress and Isuprel through arrangements with the leading hospital group purchasing organizations in the United States. For prescription products purchased by consumers at retail, we have just launched a 20-year program with Walgreens, one of the most well-known and well-respected pharmacies in the nation, that will provide substantial savings for patients purchasing both branded and generic prescription drugs – averaging a 10% reduction for a majority of our branded dermatology, ophthalmology, and women's health products and up to a 95% reduction

on certain branded products for which there is a generic alternative. These actions together offer new and innovative ways to deliver prescription medicines to patients, doctors, and hospitals at lower costs. Valeant takes pride in its innovation, which extends both to the development of new medicines and treatments, and to the development of innovative business approaches that increase patient access to medicines. These new innovations are in addition to our existing patient assistance programs that help ensure that out-of-pocket expenses do not prevent eligible patients from receiving the medicines they need. Valeant offers patient assistance programs for more than 55 products, and we expect to spend more than $1 billion on patient assistance in 2016.

Second, Valeant's history of innovation is also evident in our approach to research and development. We have consciously avoided building a large, fixed-cost research infrastructure focused on open-ended research, which often proves inefficient. We believe innovation should be judged not by how much a company spends on R&D, but by the new products and innovation that a company is actually able to bring to market.

Valeant's R&D outputs make us a leader in the industry:

- Over the past five years, our productivity – measured by drugs approved per dollar spent – is seven times higher than the average of the fifteen pharmaceutical companies with the most new drug approvals. In the dermatological sector, where we are a market leader, our clinical research success rates exceed the industry in each of the three research phases, and our phase II and phase III success rates are significantly better than industry averages.

- In the last three years, the FDA has approved 6 new drug applications and issued 13 device approvals to Valeant. In the past two years, Valeant has launched 76 new prescription drugs, generic drugs, medical devices, and other products in the United States.

- Our U.S. R&D pipeline contains more than 200 active programs, more than 100 of which we consider significant, including programs for 32 surgical products, 26 consumer products, and 15 dermatology products.

Although, as I noted, we do not believe that dollars spent on R&D alone are the most useful measure of effectiveness, our R&D spending is significant. Valeant's U.S. pharmaceutical R&D spending is about 8% of our U.S. branded pharmaceutical revenue, and we estimate that total U.S. R&D spending will exceed $400 million in 2016. We have 43 R&D facilities and employ more than 1,000 R&D employees worldwide.

In addition to our internal development, we have looked outside the company to bolster our R&D pipeline, and we have made a strategic choice to pursue valuable R&D through corporate acquisitions, in-licensing, and partnerships. From an economic standpoint, a dollar spent to buy the output from another company's R&D is the same as a dollar spent on in-house R&D. The economic effects may even be greater when acquisitions have the effect of providing capital to small startups that are uniquely positioned to engage in further research and innovation in particular therapeutic spaces. This transformation in the pharmaceutical industry – from large

internal R&D expenditures to entrepreneurial acquisitions – is similar to the transformation that occurred in the technology sector. The large internal R&D operations at traditional technology companies have been supplemented by an ecosystem of incubators, startups, and entrepreneurial specialization. The larger technology companies in Silicon Valley and elsewhere now frequently pursue R&D through the acquisition of start-up companies and their products. Following such an acquisition, the large companies can bring innovations to the market more quickly. At the same time, the companies' acquisition expenditures provide capital to the innovators, spurring further research and new product development. The pharmaceutical sector is following this same trend.

A few weeks ago, the Deloitte Center for Health Solutions, which is the research division of Deloitte's life sciences and healthcare practice, released its sixth annual report examining the pharmaceutical industry's return on R&D investment. The conclusions were dramatic, and very consistent with Valeant's experience and strategy. Deloitte found that, in the past two years, "smaller companies are delivering higher R&D returns" than 12 of the largest research-based life science companies. These smaller companies reported a 25% lower average cost to develop a new product and a 340% higher internal rate of return on their R&D spending. In contrast, the R&D internal rates of return for the 12 large research-based life science companies declined from 10.1% in 2010 to 4.2% in 2015.

Deloitte concluded that smaller companies "may be better at integrating the most innovative science due to their smaller and more nimble R&D organizations." This is certainly true at Valeant. We have purposely created a streamlined, nimble in-house R&D operation that efficiently brings promising products to market, both from our internal R&D and from our acquisition of external R&D assets. This model is helping to serve patients, as Valeant brings new and better products to market. As the Deloitte study highlights, the pharmaceutical industry is moving in this direction as well.

Finally, the Deloitte study noted that given the weakening performance of their internal R&D operations, large life science companies "are now more likely to return cash generated to shareholders via a combination of dividends and share buybacks than they are to invest in company acquisitions, product licenses and internal R&D." In contrast, Valeant has not paid a dividend to shareholders in more than five years. We have chosen instead to reinvest our profits in R&D, manufacturing expansion, and acquisitions of new products.

For example, Valeant is investing substantially in manufacturing in the United States. Valeant has 16 manufacturing sites throughout the United States, with our largest facilities in Rochester, New York; Greenville, South Carolina; St. Louis, Missouri; Tampa, Florida; and Clearwater, Florida. We are currently expanding our investments in Rochester, Greenville, and St. Louis.

Before its acquisition by Valeant, it is our understanding that Bausch + Lomb intended, over time, to move its contact lens manufacturing facilities from Rochester to Ireland. Valeant took a different approach. Given its talented workforce and strong contact lens R&D group, we decided to retain our contact lens manufacturing facility in Rochester and also to expand our investment. Since that decision, we have invested more than $250 million in capital and expanded our manufacturing work force by nearly 200 employees in Rochester. To provide

additional support for four new product lines for Bausch + Lomb's popular Ultra contact lenses and other contact lens projects, over the next five years we expect to invest almost $500 million more and add approximately 630 jobs in Rochester, including many highly skilled engineering and manufacturing jobs.

Last fall, our Greenville plant celebrated the production of its four billionth bottle of eye care solution. In Greenville, we expect to spend approximately $150 million over the next five years, creating between 150 and 200 jobs. The jobs that Valeant is creating are the result of our growing sales, both within and outside of the United States. In St. Louis, since acquiring Bausch + Lomb, we have made significant capital investments, and we expect to develop the next generation of our cataract and retina surgery equipment at the facility.

From the United States, Valeant exports to more than 100 countries, including countries like China that are traditionally viewed as lower-cost manufacturing centers rather than export markets. As a percentage of revenue, the products we manufacture in the United States and Canada represent more than twice the revenue generated by products we manufacture in the rest of the world, and this share is increasing. We are proud to be reinvesting our earnings to strengthen American exports while expanding skilled manufacturing and R&D jobs in the United States.

**Nitropress and Isuprel**

I would like to address the Committee's specific concerns regarding Nitropress and Isuprel, which are two of the approximately 1,800 products sold by Valeant (comprising about 4% of our 2015 revenue). Although broad conclusions about Valeant cannot be drawn from the pricing history of any one drug or set of drugs, I understand your concerns, and I therefore want to provide the Committee with detailed information concerning these two drugs. In addition to this written testimony, we have produced thousands of pages of supporting data to the Committee concerning the two drugs.

Nitropress and Isuprel are used in cardiac care. Nitropress is an antihypertensive (it lowers blood pressure) that immediately addresses blood pressure for patients in hypertensive crisis or acute congestive heart failure. Sodium nitroprusside, the active ingredient in Nitropress, was first introduced during the nineteenth century, and the product is therefore not on patent.

Isuprel is indicated for mild or transient episodes of heart block that do not require shock or pacemaker therapy and for certain serious episodes of heart block and Adams-Stokes attacks, among other uses specified in its label. Isoproterenol, the active ingredient in Isuprel, was patented in 1943, and therefore has been off patent for several decades.

It is important to note that Nitropress and Isuprel are administered by healthcare professionals in clinical settings, primarily hospitals. They are not sold to patients at a traditional consumer pharmacy. Moreover, Nitropress and Isuprel are mostly used as part of a larger hospital procedure. They normally are not administered as stand-alone treatments.

Valeant acquired Nitropress and Isuprel from Marathon Pharmaceuticals in February 2015. Prior to that acquisition, Marathon had engaged an outside pricing consultant to study the market for these two drugs. We understand that the pricing consultant examined the uses of the

drugs, interviewed healthcare professionals, studied the then-current pricing and reimbursement rates for hospital procedures in which these drugs may be used, and reviewed the drugs' price history. In a report to Marathon in 2013, the consultant concluded that the prices of Nitropress and Isuprel, even after prior price increases, were still substantially below their true value to hospitals and patients. The "bundled" rates at which hospitals were being reimbursed by health insurance payers for the procedures in which they were used were substantially higher than the price of either drug. The consultant recommended a 250% increase in the list price of Nitropress and a 350% increase in the list price of Isuprel. Marathon took overall price increases totaling 350% for each of Nitropress and Isuprel in 2013.

In the case of a hospital-administered drug like Nitropress and Isuprel, a pharmaceutical manufacturer typically will sell to a wholesaler and the wholesaler will sell to a hospital pharmacy (or other buyer, such as a hospital group purchasing organization, which typically negotiates a discount on behalf of the hospitals). Following a medical procedure, the hospital typically will seek reimbursement from the patient's health insurance provider, such as a commercial payer or a federal healthcare program. In many cases, there are separate limitations on the amount that the payer, whether an insurance company or federal program, pays for a drug. For example, an insurance company may have a contract with the pharmaceutical manufacturer that limits the amount that the pharmaceutical company can charge for its product. If the reimbursed price is greater than this contracted amount, the pharmaceutical company will "rebate" the difference to the insurance company, with the effect of lowering the net cost of the drug.

Certain federal programs are likewise subject to a variety of limitations that restrain the price that a pharmaceutical company can actually charge for a drug, regardless of the list price. The short-term changes in the price of any input for the procedure – whether it is a drug, the hospital's overhead, or the cost of doctors and technicians – often does not immediately change the reimbursement amount, although the amount may be adjusted over time.

In the specific case of Nitropress and Isuprel, we understand that the drugs most often are used by hospitals and other care providers as part of procedures that are subject to their own overall pricing caps. The specific price that a hospital is reimbursed for the procedure – often referred to as a "bundled" rate – is derived from an approximation of the wide variety of costs associated with the products and services, including the costs of various drugs, personnel, equipment, and overhead typically incurred in the average procedure. Those bundled reimbursement rates may vary by patient condition, procedure, and payer. Importantly, however, the amount that a hospital is reimbursed for a procedure that includes Nitropress or Isuprel generally will be the same regardless of short-term changes to the prices of the individual drugs. Of course, the reimbursement amount to hospitals may change over time as commercial insurance companies and federal programs adjust their formulas, including the Centers for Medicare & Medicaid Services' ("CMS") "Ambulatory Payment Classification" rates for outpatient services and "Diagnosis-Related Group" rates for inpatient treatments. Even then, however, the reimbursement rates continue to be adjusted based on the average cost of the procedure as a whole, not the price of any particular drug.

A price increase or decrease for a drug that is a component in a larger procedure therefore may have an attenuated impact, if any, on the reimbursement rates approved by CMS and other

payers for that procedure. Those rates are adjusted gradually over time based on many factors. In the case of Nitropress and Isuprel, which face likely near-term competition from generic versions of both drugs that will place downward pressure on average prices, it is far from clear that the increase in the price of the branded versions of those drugs ultimately would increase hospital reimbursement rates for the procedures in which they are used.

During the acquisition of Nitropress and Isuprel from Marathon, Valeant commissioned an update of the pricing consultant's earlier review of the market, which was nearly two years old at that point, along with other assessments of the market and hospital practices. These analyses showed that Nitropress and Isuprel continued to be very valuable to hospitals and patients, including following the price increases instituted by Marathon. The pricing consultant found, for example, that the volume of Nitropress and Isuprel used by hospitals had been relatively constant over one year of data, indicating that the hospitals continued to value the products highly at the new list prices.

The consultant also confirmed that, under the existing CMS-established hospital reimbursement rates for the procedures in which Nitropress and Isuprel are used, there was considerable room to increase the price of both drugs. In other words, the consultant found that hospitals were receiving from federal payers, and likely commercial payers, payment amounts for the typical procedures in question that were significantly higher than the cost of the drugs used, and they had been doing so for some time. Because these drugs are hospital-administered, and not purchased by patients directly, increasing the cost of the drugs to hospitals would affect the hospital's profits on these procedures, but it should not reduce patient access.

Because most institutions use only a limited number of Nitropress and Isuprel doses, Valeant's increases in the list prices would have had a limited impact on most hospitals. A few institutions that specialize in cardiac care, however, use a larger share of the volume. For this reason, and in response to the concerns that Congress and others raised, Valeant has created a volume-based price rebate program for Nitropress and Isuprel through arrangements with the leading hospital group purchasing organizations in the United States. We recently concluded agreements with two major national group purchasing organizations – one representing approximately 3,600 U.S. hospitals, the other representing about 4,500 U.S. hospitals. These agreements provide volume rebates for Nitropress and Isuprel up to 30% (for 500 units or more of Nitropress and 20 units or more of Isuprel). Our goal is to provide tiered rebates on half of the volume of Nitropress and Isuprel that we sell. This means that hospitals that have an atypical need for Nitropress and Isuprel because of the size of their cardiac practices will have access to significant volume discounts.

**Drug Pricing in the United States**

In the U.S. healthcare system, the list price of a drug is not the same price that a drug manufacturer receives from selling the drug, or even that the hospital, pharmacy, or consumer pays for the drug. The list price operates much like the manufacturer's suggested retail price of a new car. It is a useful reference, but it reflects neither the price that is actually paid by any given car buyer nor the amount that is ultimately received by the car manufacturer for the sale. Like MSRP, the list price of drugs is typically much higher than the amount that a buyer pays.

In the pharmaceutical industry, this difference can be substantial – far more than the difference between a car's MSRP and its sales price. For Valeant's overall U.S. prescription products, the difference between our gross and net sales is approximately 50%. That is, for each dollar of sales, about half is given back in discounts, rebates, chargebacks, and the like to wholesalers, managed care organizations, pharmacy benefit managers, federal and state healthcare programs, and others. In dermatology, one of the company's most significant market segments, the overall effective discount is even higher – about 60% and some individual drugs have discounts up to 90%.

In certain federal healthcare programs, Congress has established requirements that restrict the prices that drug companies can charge. These restrictions lower drug company margins and sometimes result in drugs being sold at a loss. For example, as of September 2015, Valeant's gross sales of Isuprel in the VA's Federal Supply Schedule were $10.8 million, but the discounts totaled $9.9 million. After accounting for applicable distribution costs, Valeant's total net revenue was only about $300,000. In the same period, gross sales of Isuprel to the Public Health Service were $48.7 million, with discounts of $47.7 million. After distribution costs, Valeant realized negative net revenue of approximately $2.2 million on these sales. Similarly, Valeant had negative net revenue of $3.5 million on the sales of Wellbutrin XL to the Public Health Service, and negative net revenue of $4.5 million on sales of Glumetza to Medicaid.

Although the pharmaceutical pricing and reimbursement system in the United States is complex, the pharmaceutical companies, health insurance providers, hospitals, pharmacy benefit managers, group purchasing organizations, and federal administrators are all sophisticated participants in the healthcare market. If a pharmaceutical company, for example, were to price a drug above its true value to healthcare providers and patients, the company would see market-based responses, including increased pressure for rebates from the payers, decreased sales volumes from hospitals, increased substitution of alternative products, and heightened competition from new generic or branded drugs.

Indeed, Nitropress and Isuprel sales volumes have fallen by a greater degree – about 30% for each drug – than was anticipated at the time of the price increase. The available data suggests that hospitals are in some cases substituting other drugs. In response to these changes and the public's and Congress's concerns, we are calibrating our pricing through volume rebates, which should help address budgetary concerns at hospitals that frequently use these drugs. Even with the volume rebates, some hospitals may choose to substitute other drugs to protect their profit margins on cardiac procedures or for other reasons.

Off-patent drugs like Nitropress and Isuprel also face market pressure from generic drugs, and Valeant expects that both drugs will likely be subject to generic competition in the not-too-distant future. It appears that this generic competition was spurred by the price increases taken by Marathon Pharmaceuticals on Nitropress and Isuprel, which highlighted the value of these drugs to hospitals even before their acquisition by Valeant. As Congress has recognized, there is a degree of inefficiency in the generic drug market, and competition from generics is not always immediate. These inefficiencies sometimes cause instances, such as currently exists with Nitropress and Isuprel, where clinically valuable drugs are subject to little price competition despite being off-patent. This is probably most true in the case of drugs for which the market is relatively small, as is true of Nitropress and Isuprel. Because Valeant itself files applications for

new branded drugs as well as generic drugs, we too would benefit from faster FDA drug approvals. We also recognize that the benefits of faster drug approvals must be balanced with the exceedingly important process that the FDA undertakes to ensure the safety and efficacy of drugs in the U.S. market, and we support ensuring that the FDA has sufficient resources for this important work.

While there is widespread criticism in the media and in Congress of price increases for older, off-patent drugs – and we understand why – it is important to recognize that patients, doctors, and the entire U.S. healthcare system are best served by a system that permits drugs to be priced based on their clinical value. Older drugs sometimes languish for long periods at prices that do not reflect their value to doctors and patients. When these drugs are priced to reflect more closely their true clinical value, the more accurate price signals incentivize generic competition and innovation. Higher prices draw generic competitors into the market, which in turn tends to put significant downward pressure on prices.

This is exactly what we have seen happening in the case of Nitropress and Isuprel. The rising prices of these drugs over the past decade, including by Marathon before Valeant acquired the products, have stimulated market competition and innovation. We expect that multiple generic alternatives could be approved within the next year or two. These generic alternatives can be expected to put significant downward pressure on the cost of hospital procedures in which Nitropress and Isuprel are currently used.

**Patients' Access to Medicines and Valeant's Partnership with Walgreens**

Nitropress and Isuprel are hospital drugs, typically administered in a clinical setting, as part of a procedure with a set, bundled reimbursement rate. Patients' out-of-pocket expenses, therefore, generally are not affected directly by price changes. Valeant, however, recognizes that many of its products are purchased directly by patients at a retail or mail-order pharmacy. We have therefore implemented a number of strategies that are designed to ensure that patients' out-of-pocket expenses are not an impediment to getting access to the medicines that they need.

First, Valeant offers patient assistance programs for more than 55 different products in the United States. One of our larger programs, Valeant Coverage Plus, provides extensive aid to patients needing financial assistance to purchase Syprine or Cuprimine, medications that treat the genetic disorder Wilson's Disease. Valeant Coverage Plus provides a capped co-pay for patients with commercial insurance ($25 co-pay), subsidized prescriptions for patients without insurance or with low incomes (maximum patient cost of $200 per month above 400% of poverty line; $0 co-pay below 400% of poverty line), and referrals to a foundation that provides prescription support for patients in federal health programs. The foundation, which is supported in part by a Valeant grant, independently determines a patient's eligibility for support, pursuant to its own criteria. Valeant also provides hardship exceptions in certain cases. With fewer than 1,000 patients in the United States taking these drugs, we seek to ensure that out-of-pocket costs are not a barrier to a patient's access to these needed medicines.

It is an unfortunate reality of U.S. healthcare laws that pharmaceutical companies cannot provide co-pay assistance to individuals on government programs – some of the patients with the

most acute need for assistance. We encourage Congress to re-examine this policy and consider whether changes are warranted.

In 2014, Valeant spent approximately $544,000,000 on patient assistance programs. As of September 2015, the company had spent approximately $476,000,000 on patient assistance, and we estimate that our total expenditure for patient assistance for 2015 will be more than $630,000,000. In the years ahead, we expect our spending on patient assistance programs to continue increasing at double-digit annual percentage rates. With our expected continued growth and launches of brodalumab, Addyi (flibanserin), and latanoprostene bunod, we expect to spend more than $1 billion on patient assistance in 2016 in the United States.

Second, almost a month ago, we launched a major new program with Walgreens, one of the largest, best known, and most well-respected pharmacy chains in the nation. The Valeant Access Program with Walgreens will provide substantial savings for eligible patients purchasing both branded and generic prescription drugs at pharmacies throughout the United States. The program with Walgreens is a 20-year partnership designed to increase affordable access to Valeant products that doctors choose to prescribe to eligible patients. This innovative program will improve patients' access to medicines and reduce costs to the healthcare system. Independently, Walgreens has retained Leavitt Partners, headed by former Health and Human Services Secretary, and former Utah Governor, Michael Leavitt, to assess the model and evaluate its benefits to patients and markets to ensure it is delivering value.

Our partnership with Walgreens has two distinct components:

The U.S. Branded Access Program, which became active last month, will enable consumers to access a majority of Valeant's dermatology, ophthalmology, and women's health products at a lower out-of-pocket cost from more than 8,000 Walgreens retail pharmacy locations in the United States. The program will also be open to independent retail pharmacies, in addition to Walgreens. The program will initially cover a majority of Valeant's branded dermatology, ophthalmology, and women's health products, including popular medicines such as Jublia, Solodyn, Retin-A Micro 0.08, Besivance, Lotemax, and Alrex, along with Addyi.

This program is designed to lower patients' costs and ensure that patients have access to the products their doctors prescribe. Patients with commercial insurance can benefit from lower out-of-pocket costs, such as reduced co-pays, and the program will provide access for patients who lack coverage for these products. The program will provide a price reduction of approximately 10% from the list price, on a weighted average basis, over the next six to nine months. Like our other patient assistance programs, the program will not be available to patients with government insurance because of government restrictions relating to federal healthcare programs.

The U.S. Brand for Generic Program is a separate initiative with Walgreens, in which Valeant will make certain branded products available at generic prices. A number of branded products in the dermatology, ophthalmology, gastrointestinal, neurological, and other therapeutic areas will potentially be included in the program, which we expect to launch in the second half of this year. We expect that the discount off of list price for these products will be up to 95%, with

a weighted average discount of approximately 50%. I'm pleased that we can make this program available to all patients, including those in federal healthcare programs, under current law.

When fully implemented, Valeant expects that the price decreases across both programs will result in significant savings to the U.S. healthcare system. Our agreement with Walgreens is another example of Valeant's efforts to innovate in ways that benefit patients and doctors.

Finally, Mr. Chairman, I would like to address some of Valeant's critics who have suggested that the company should be subject to a different set of standards because it does not always operate like a traditional pharmaceutical company. I noted recently that a pharmaceutical trade group proposed five criteria by which it suggested pharmaceutical companies should be judged: 1. Whether the company is developing life-changing medicines for patients. 2. Whether the company has a commitment to discovering new treatments and cures. 3. Whether the company is fueling economic growth and job creation. 4. Whether the company maintains a robust pipeline of new medicines. 5. Whether the company helps patients access needed medicines.

As demonstrated in the many examples cited in my testimony today, Valeant passes each of these five tests easily. Let me summarize my testimony with reference to these five tests:

1. In the last three years, the FDA has approved 6 new drug applications for Valeant and issued 13 new device approvals. In the past two years, Valeant has launched 76 new prescription drugs, generic drugs, medical devices, and other products in the United States.

2. We have 43 R&D facilities and employ more than 1,000 R&D employees.

3. We are investing hundreds of millions of dollars in manufacturing facilities in New York, South Carolina, and Missouri. These investments are generating hundreds of new jobs in the United States.

4. Our development pipeline in the United States contains more than 200 active programs, more than 100 of which are significant, including programs for 32 surgical products, 26 consumer products, and 15 dermatology products.

5. We offer patient assistance programs for more than 55 different products in the United States, and we expect to spend more than $1 billion on patient assistance in 2016 in the United States. We are currently launching an innovative distribution model with Walgreens.

Valeant is helping to improve access to drugs at affordable prices and seeking better outcomes for our R&D investments. My Valeant colleagues and I are proud of these innovations, as we believe strongly that they will define the future for innovative, research-based companies in the pharmaceutical industry. As Deloitte's recent R&D study shows, the industry is moving in this same direction.

At the same time, we recognize that being an innovator also means that some of our assumptions and choices will not always prove to be correct. Where we have made mistakes, we

have listened to the criticism and are taking steps to change. We have more to do. We continue to listen and adapt. Our Walgreens partnership is evidence of that. I also expect that after years of rapid growth, which included significant price increases, we will no longer rely on such significant increases in price. Through internal development and acquisitions, we have developed a portfolio of world class franchises. While, like most other pharmaceutical companies, we will from time to time raise prices, I expect those price increases to be within industry norms and much more modest than the ones that drew this Committee's legitimate concern.

Thank you again for the opportunity to testify today. I would be happy to answer any questions that you may have.

Chairman CHAFFETZ. Thank you.

Ms. Retzlaff, you are now recognized for 5 minutes.

**STATEMENT OF NANCY RETZLAFF**

Ms. RETZLAFF. Thank you, Chairman Chaffetz, Ranking Member Cummings, and distinguished members of the committee. I appreciate the opportunity to provide Turing's perspective on the issues before this committee today.

Turing is a small research-focused pharmaceutical company founded just 1 year ago. We invest in developing and commercializing important drug treatments for patients who suffer from serious and often neglected diseases.

Daraprim is our principal current product. It is a prescription drug used to treat a serious parasitic infection called toxoplasmosis, which most often affects patients with compromised immune systems.

Daraprim was on the market for more than 60 years before Turing acquired it last August. In the preceding 5 decades, there was no significant pharmaceutical innovation in the treatment of toxoplasmosis, and Daraprim remains the only FDA-approved treatment for this disease. Perhaps that is not surprising, since only about 3,000 patients are prescribed Daraprim each year.

Daraprim presented an investment opportunity for Turing because it was priced far below its market value in comparison to other similar drug treatments for rare and serious diseases. After considering the pricing of comparable drugs, the value Daraprim provides in the treatment of a potentially life-threatening disease, a small patient population for Daraprim, and the mandatory discounts and rebates that applied to many who receive the drug, Turing made the decision to raise the wholesale list price, or WAC, for Daraprim to $750 per pill.

As Turing's chief commercial officer, I was comfortable with that decision, first, because of our company's commitment to ensure access to Daraprim for every single patient who needs the drug, regardless of ability to pay; and, second, because of our commitment to invest a large portion of net revenues generated from Daraprim in R&D for new and improved drug treatments.

Let me address patient access. Most fundamentally, in terms of cost, it is important to realize that the wholesale list price of a drug is not the same as the price paid by patients, hospitals, health plans, or government programs. To our knowledge, no patient needs to pay $750 per pill for Daraprim. In fact, about two-thirds of patients get the drug through government programs that receive a discounted price of one penny per pill.

Beyond the discounts available through government programs, Turing has taken several additional steps to ensure affordable access to Daraprim. We fund a patient assistance program that offers Daraprim free of charge to qualified uninsured patients with incomes at or below 500 percent of the Federal poverty level, well above industry standard for patient assistance eligibility. We provide copay support to help insured patients meet their copay obligations. And we fund a bridge program to give those with commercial insurance a supply of Daraprim at no charge, if there are delays in coverage.

In response to concerns about cost, and after consulting with key stakeholders, Turing announced in November that we would discount the price of Daraprim to hospitals by up to 50 percent. That is especially important because hospitals are the first to treat 80 percent of patients with the most common form of toxoplasmosis. We have also begun offering Daraprim to hospitals in a smaller, 30-pill bottle, which can help to ensure availability and lower the cost burden for hospitals.

There have been challenges with patient access, particularly in the first weeks after Turing acquired the drug. To the best of our knowledge, most of those challenges involved deficiencies in distribution that were unrelated to our pricing of Daraprim. Since then, we have worked hard to improve and expand the distribution system, including through the engagement of a new specialty distributor providing streamlined access to more than 90 percent of hospitals.

Of course, Turing expects to generate profits from Daraprim, but our net income is not simply passed on to shareholders. Turing is committed to bringing innovation to the treatment of neglected diseases. We invest nearly 60 percent of net revenue into R&D, a percentage far higher than most other companies. Thirty-six of our 139 employees are dedicated to R&D. And our pipeline of research includes candidates for innovation.

We are proud of our investment in innovation, just as we are as proud of our commitment to patient access. I believe the decisions made by the company have been appropriate and strike the right balance between patient access, innovation, and shareholder value. Thank you.

[Prepared statement of Ms. Retzlaff follows:]

HEARING BEFORE THE HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

"DEVELOPMENTS IN THE PRESCRIPTION DRUG MARKET: OVERSIGHT"
JANUARY 26, 2016
TESTIMONY OF NANCY RETZLAFF
CHIEF COMMERCIAL OFFICER, TURING PHARMACEUTICALS

Chairman Chaffetz, Ranking Member Cummings, and members of the Committee, thank you for giving me the opportunity to share with you additional information regarding Turing's business practices, its product Daraprim®, and its commitment to ensuring that every patient in need has access to Daraprim®. I am Nancy Retzlaff, the Chief Commercial Officer of Turing Pharmaceuticals LLC. Turing is a small, research-focused, pharmaceutical company that began commercial operations on February 24, 2015. It is committed to helping patients who often have limited or no effective treatment options by investing in and developing pharmaceuticals that treat serious and neglected diseases. As the Committee is aware, since this fall, Turing has received significant attention about its decision to raise the price of a recently acquired drug, Daraprim®, which is primarily used to treat a parasitic infection called toxoplasmosis that most often affects patients with compromised immune systems. Toxoplasmosis is considered a "neglected" parasitic infection by the CDC, and a priority for public health action based on the number of people infected, the severity of the disease, and the ability to prevent and treat it. It is important to highlight that there has been no pharmaceutical innovation or research in the treatment of toxoplasmosis for over 50 years. With my testimony today, I hope to dispel certain misconceptions of Turing's business practices and provide any additional details that the Committee may find helpful.

Turing purchased the sole rights to manufacture and sell Daraprim® in the United States and Puerto Rico from Impax Laboratories on August 7, 2015, for $55 million. Impax had owned Daraprim® since March 2015. During its time of ownership, Impax raised the wholesale acquisition price, or WAC, of the drug from $13.55 to $17.63 per pill. In connection with the acquisition of Daraprim®, Turing assessed the market for similarly situated pharmaceuticals and found that despite Impax's decision to increase the price, Daraprim® was still being sold for a price that was well below its market value. Daraprim® is a lifesaving medication that is not only widely accepted as the preeminent treatment for toxoplasmosis, but also the only approved treatment (in conjunction with a sulfonamide) for toxoplasmosis in this country. After considering the extremely small patient population of approximately 3,000 patients per year, mandatory statutory discounts and rebates like those in the 340B and Medicaid programs, and the costs to manufacture and distribute Daraprim®, Turing made the decision to raise the WAC to $750 per pill. This decision also reflected Turing's business goals of funding improved access programs and services for patients in need, and importantly, research and development into alternative treatments for the disease that Daraprim® is used to treat, as well as other diseases that have been neglected by the pharmaceutical industry. To reiterate, there has been no new pharmaceutical approved for treatment of toxoplasmosis in over 50 years. This pricing decision was spearheaded by Turing's then-Chief Executive Officer.

As this Committee knows, pricing of pharmaceuticals is complex, given the many participants in the distribution and payment system. The WAC is only the published price and does not reflect the actual net cost of Daraprim® or any other drug to patients, hospitals, health plans, or government programs. Significant discounts or rebates are customary, or often mandatory, but are not typically disclosed to the public. The actual net price of Daraprim® ranges from $0.01 (one cent) per pill ("penny-pricing") to $750 per pill. Less than a quarter of the sales occur at the higher-end of this range. Although actual patient out-of-pocket costs are typically set by insurers and government programs and therefore may vary, the vast majority of Daraprim® sales (over 60 percent) are associated with either Medicaid or the 340B program. Those programs receive penny-pricing and have the ability to pass these savings through to patients. However, these penny-pricing programs do not lower our overhead, manufacturing, or distribution costs. Rather, Turing voluntarily participates in these programs because it wants to ensure that all patients who need Daraprim®, particularly the most vulnerable who need this life-saving drug, are able to access it.

At this point, I would like to discuss various steps that Turing has taken to improve patient access to Daraprim®, as well as the programs that are funded, in part, by Turing's sales of the drug.

## I. Further Changes in Pricing

After consulting with patient advocacy groups and toxoplasmosis thought leaders around the country about how to strike the appropriate balance between the cost of treatment and the need for innovation in toxoplasmosis therapies, and in response to concerns raised about the cost of Daraprim®, Turing announced on November 24, 2015 that it had discounted the price of the drug by up to 50 percent for hospitals. This is in addition to the "penny pricing" that many hospitals already enjoy as covered entity participants in the 340B program. Notably, hospitals are the first to treat about 80 percent of patients with toxoplasmosis encephalitis – the most common form of toxoplasmosis in the United States – which means that a significant number of patients will benefit from this decrease.

Turing also learned that another major barrier to keeping Daraprim® stocked in hospital pharmacies was that it was only offered in bottles of 100 tablets for purchase. After learning of this issue, the company worked quickly to make available a new 30-pill bottle, which allows hospitals to purchase a more manageable volume of Daraprim® if needed. To be clear, hospitals may still receive a 50 percent discount on the new 30-pill bottles.

*Patient Access and Affordability Programs*

Ensuring patient access is, and always has been, our top priority– regardless of a patient's ability to pay. To this end, Turing has implemented and/or expanded several programs that make Daraprim® available to all patients, including the most vulnerable.

*First*, as previously noted, approximately two-thirds of Daraprim® sales are associated with federal and state government programs like Medicaid and the Public Health Service Section

340B programs. These programs have access to Daraprim® at penny-pricing. Turing also offers Daraprim® at a reduced price of $2,216.26 per bottle, or $22.16 per pill, to the Department of Veterans Affairs and Department of Defense under the Veterans Health Care Act for distribution to their patients.

*Second*, the Daraprim® Patient Assistance Program ("PAP") provides Daraprim® free of charge to qualified, uninsured patients with demonstrated income that is at or below 500 percent of the federal poverty level. Until recently, the assistance income limit for the Daraprim® PAP was only 150 percent of the federal poverty level. Therefore, Turing has substantially expanded the qualifying income eligibility for this PAP, and increased it to a level that is well-above industry standards.

*Third*, Turing supports patients who have commercial insurance through a co-pay support program, under which eligible patients may receive cost sharing support under which they are not obligated to pay more than $10 out of pocket for Daraprim® prescriptions.

*Fourth,* Turing offers a "bridge" program that provides patients who have commercial insurance with a supply of Daraprim® at no charge during the period of a benefits investigation by their commercial insurer, or during the pendency of their appeal from a commercial insurer's denial of coverage. This ensures that a patient will have timely access to Daraprim®.

*Fifth*, Turing contributes to Patient Services, Inc. ("PSI"), a longstanding independent charity that provides financial assistance to help cover the cost-sharing obligations of financially needy patients for toxoplasmosis therapies in a manner consistent with PSI's advisory opinion from the HHS Office of Inspector General.

Turing actively supports these programs now, and is committed to continuing and expanding these programs in the future, because patient access is Turing's top priority.

## II. Disease Awareness and Education

In addition to its assistance programs, Turing also supports people at risk from toxoplasmosis by making a significant investment in a national team of health educators.

Toxoplasmosis is a rarely-seen, sometimes forgotten disease, so diagnosis can be delayed or missed. Time lost allows the infection to progress towards harmful, and sometimes life-threatening consequences. Recognizing this danger, Turing's team offers unbranded, non-promotional education to allied healthcare professionals, who are then able to use this information to raise awareness of toxoplasmosis, and more effectively screen patients for changes in health related to this disease in order to allow for early diagnosis.

The educators, and their well-referenced, simple-to-follow programs, have been welcomed at many hospitals, health centers and community-based organizations. Just last week at a major inner-city hospital, one of our team members learned of a patient whose toxoplasmosis had initially been missed. With this in mind, the hospital has recognized the urgency to improve

their caregivers' understanding of toxoplasmosis and has adjusted its training schedule to allow prompt delivery of toxoplasmosis education by Turing.

### III. Distribution

When Turing acquired Daraprim®, it also assumed the distribution channels, organizational decisions, and contracts that its predecessor, Impax, had put in place. Some of these decisions and operations were perceived to have limited, or at least changed, patient access to the drug. To address customers' concerns, Turing took decisive action within a few weeks of acquiring Daraprim®, including initiating a broad, multi-channel communication initiative to ensure providers were aware of how to access Daraprim®. Further, Turing engaged and hired experts to expand and alleviate access issues.

Turing engaged a specialty distributor to improve access with institutions and hospitals. Before the acquisition, Impax used a third party logistics provider to handle all institutional sales. This led to unnecessary bureaucratic inefficiencies in the distribution system that resulted from the third-party logistics provider's need to register each hospital as a new account. Turing's new specialty distributor has pre-existing contracts with upwards of 90% of hospitals in the United States, which affords institutions more streamlined access. This distributor is also able to quickly establish agreements with the few entities with which it does not have a pre-existing relationship. Simply adding a third party logistics provider to an experienced specialty distributor has greatly improved Turing's ability to get Daraprim® to those in need. Let me point out that this distribution change primarily benefits recipients of the 340B program that Turing participates in at a financial loss.

To further improve the distribution system, Turing also began proactive outreach to state AIDS Drug Assistance Programs (ADAPs) and other patient advocacy organizations within weeks of acquiring Daraprim®. These patient advocacy organizations expressed dissatisfaction with the access issues caused by the Impax model. Turing representatives have been traveling the country to meet with various ADAPs, HIVMA, and other organizations in order to ensure state-by-state access for patients who comprise a large percentage of severe toxoplasmosis population.

Through this outreach, Turing was made aware that Walgreens Specialty Pharmacy ("WSP") was not able to facilitate access to 340B pricing under the original agreement with Impax. When Turing learned of this obstacle on September 15, 2015, it immediately met with WSP, and within 48 hours, it had the necessary distribution channels and chargeback procedures in place to offer 340B through WSP. This process normally takes months to finalize, but Turing was able to make the necessary changes in a matter of days. That very weekend, the New York ADAP was able to fill an order through WSP, which would not have been possible previously.

### IV. Research and Development

Turing Pharmaceuticals is focused on developing and commercializing innovative treatments for serious diseases and neglected conditions. I want to take this opportunity to

emphasize Turing is a research-based company that is committed to innovation and reinvests 60 percent of its net income from the sale of Daraprim® into research and development – a figure that far exceeds industry standards. Toxoplasmosis research is particularly important to Turing, and the company's current pipeline includes product candidates that might be the only advance in toxoplasmosis treatment in 50 years. I would like to highlight that among our R&D programs, is one specifically focused on addressing a main adverse event of current treatment for toxoplasmosis. This program has advanced to a stage that gives us confidence in our ability to potentially improve patient outcomes in the not too distant future. As of December 2015, Turing had 13 research and development programs in its pipeline. For your reference, I have supplied as attachments to our written testimony both: (1) a summary of our R&D pipeline as of December 2015; and (2) our 2015 Quarter 3 report, which discusses our R&D philosophy and several efforts.

## V. Conclusion

On behalf of the dedicated employees of Turing who strive to bring new advances to rare and neglected diseases, and fulfill our pledge "that no patient needing Daraprim® will ever be denied access," I thank you for the opportunity to testify today. I hope that my testimony has helped show the Committee that Turing's business practices have found a way to fund innovative research for a neglected disease. At the same time, the company has and will continue to offer comprehensive patient assistance programs to ensure all patients can access Daraprim® regardless of ability to pay. Turing looks forward to providing improved treatments for patients in the future.

As Turing has done over the past several months, it will continue to work with the Committee and its members to answer any additional questions that it may have. Thank you for your time.

TURING
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Press Release

# Turing Pharmaceuticals AG Announces Third Quarter Business Highlights and Financial Results

Zug, Switzerland, November 12, 2015 - Turing Pharmaceuticals AG, a privately-held biopharmaceutical company focused on developing and commercializing innovative treatments for serious diseases and conditions, today announced financial results and operational highlights for the quarter ended September 30, 2015.

**Research and Development**

- Toxoplasmosis is on the Center for Disease Controls' list of neglected parasitic infections (NPIs) as a priority for public health action. We intend to file Investigational New Drug applications with the FDA for new candidate medications, currently in preclinical studies. The most advanced pipeline products are dihydrofolate reductase (DHFR) inhibitors with improved pharmacological profiles relative to pyrimethamine. Turing is also actively engaged in licensing opportunities for toxoplasmosis therapeutics.
- Epileptic encephalopathies are a diverse group of severe epilepsy disorders in which uncontrolled epileptic activity contributes to a progressive decline in cognitive and motor function. Beginning in November, we are initiating the Phase I clinical program for TUR-004, our new candidate for this group of disorders. The first trial will be a randomized, double-blind, placebo-controlled, single ascending dose study to evaluate the safety, tolerability and pharmacokinetics of an oral

formulation of TUR-004 in healthy young adult subjects. TUR-004 has received Fast Tack Designation from the FDA.

- We are developing, TUR-002, an intranasal formulation of ketamine for the treatment of Posttraumatic Stress Disorder (PTSD) and Major Depressive Disorder (MDD). Ketamine, which has been extensively used as an anesthetic, may also be used as rapid treatment for these disorders as suggested by experimental studies. It is estimated that more than fifteen million adults in the United States suffer from MDD and more than seven million from PTSD over a given year, many of whom will experience suicidal ideation. In addition, a World Health Organization report indicates that by 2030 depression will be the leading cause of disease burden globally. We plan to initiate Phase I trials for TUR-002 by the first quarter of 2016.
- TUR-007 is a preclinical drug candidate targeting pathological mechanisms associated with Canavan Disease. Canavan is a neurological disorder that manifests in early infancy and is caused by an inherited genetic abnormality. This genetic aberration leads to a deterioration of myelin in the brain, thereby preventing proper transmission of nerve signals. Symptoms include intellectual disability and the inability to crawl, walk, sit or talk. Some patients suffer from paralysis, blindness and seizures with a life expectancy limited to early adolescence. There is currently no approved treatment. Turing has initiated preclinical work in Q3 '15 at an industry-leading CRO to aid in the development of TUR-007.
- TUR-005 is a preclinical drug candidate for Lafora Disease, a fatal autosomal recessive neurological disorder typically diagnosed in adolescents. Dysfunction of one or more key proteins involved in glycogen processing leads to the presence of hallmark Lafora bodies and is associated with neurodegenerative myoclonic epilepsy for which no disease-modifying treatments exist. Turing also initiated preclinical work in Q3 '15 at an industry-leading CRO to aid in the development of TUR-005.
- Cross reacting material 197 (CRM197) is a non-toxic variant of diphtheria toxin, which we believe is an ideal platform technology capable of intracellular delivery of cargo proteins into cytosol and across the blood-brain-barrier. We are developing CRM197 fusion constructs with therapeutic proteins of up to 1,000 amino acids in length as a proof of concept before assessing even larger delivery systems. Our initial focus is on monogenic diseases with validated animal

models and a firmly established connection between the defective protein and associated disorder. Turing entered a Sponsored Research Agreement in Q2 '15 with the Hospital for Sick Children in Toronto to discover and develop new treatments based on this technology.

Due to the high cost of pursuing these development objectives, Turing expects to spend at least 60% of its revenue on research and development for the foreseeable future.

Martin Shkreli, founder and CEO of Turing said, "Our Research and Development organization, led by Dr. Eliseo Salinas, has surpassed my expectations in advancing TUR-004 for epileptic encephalopathies and TUR-002 for depression with the FDA." Dr. Salinas remarked, "We are very excited about the potential for Turing's pipeline of new drug candidates to help patients in need of better medications."

With respect to Daraprim®, after consulting with patient advocacy groups and infectious disease doctors, Turing understands that toxoplasmosis patients are primarily concerned with timely access and minimal out-of-pocket costs. We are committed to continuing the expansion of our distribution partnerships in order to facilitate optimal patient access. In addition to participation in federal and state programs with costs as low as 1 penny per pill, and patient savings programs under which patients' out-of-pocket expenses do not exceed $10 per prescription, Turing contributes to Patient Services, Inc. (PSI), a longstanding independent charity that provides support for financially needy patients' cost-sharing obligations for any toxoplasmosis therapies, consistent with PSI's advisory opinion from the HHS Office of Inspector General. In order to better address the needs of physicians and patients, Turing will be introducing a 30-count bottle to address the needs of hospitals as well as a sample package to ensure physicians have timely and affordable access to therapy in emergency situations.

**Financial Update: Quarter Ended September 30, 2015**

For the third quarter of 2015, net revenue was $5.6 million representing Daraprim® and Vecamyl® sales. Research and development spending of approximately $7 million reflects Turing's progress advancing TUR-002 and TUR-004 with the FDA and multiple preclinical programs.

The following represents expectations for selected financial figures in the quarter ended September 30, 2015.

**Turing Pharmaceuticals AG and Subsidiaries**

(amounts in thousands, unaudited)

| | **Three Months Ended 30-Sept-15** | **Nine Months Ended 30-Sept-15** |
|---|---|---|
| Net revenues | $5,657 | $5,975 |
| Research and Development | 6,969 | 11,467 |
| Net loss | **($14,590)** | **($27,729)** |

The September 30, 2015 financial information is subject to independent auditor review. Accordingly, the amounts set forth above are estimates based solely on currently available information, which is subject to change and has not been reviewed by our independent auditors. We have not finalized our review of financial statements for the quarter ended September 30, 2015 and during the course of our review we may identify items that would require us to make adjustment to our preliminary operating results described above. As a result, the discussion above constitutes forward-looking statements and, therefore, we caution you that these statements are subject to risks and uncertainties, including possible adjustments to our preliminary operating results. Unless otherwise noted, Turing is providing this information as of November 12, 2015 and disclaims any duty to update the information contained herein.

**About Turing**

**Turing Pharmaceuticals AG** is a privately-held biopharmaceutical company with offices in Zug Switzerland and New York, New York. Turing focuses on developing and commercializing innovative treatments for serious diseases and conditions across a broad range of therapeutic areas, for which there are currently limited or no treatment options. Products being developed include intranasal ketamine for a variety of mood

disorders and Syntocinon® (oxytocin nasal solution) for multiple indications. Daraprim® (pyrimethamine) for the treatment of Toxoplasmosis in combination with sulfonamide and Vecamyl® (mecamylamine HCl tablets) for hypertension are Turing's first commercial products.

For more, visit www.turingpharma.com (http://www.turingpharma.com).

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**Safe Harbor**

In addition to historical facts or statements of current condition, this press release contains forward-looking statements within the meaning of "Safe Harbor" provisions of The Private Securities Litigation Reform Act of 1995, including statements regarding the initiation of product development activities, including but not necessarily limited to clinical trials. Forward-looking statements provide Turing Pharmaceuticals' current expectations and forecasts of future events. Turing Pharmaceuticals' performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, regulatory and political conditions affecting the biotechnology and pharmaceutical industries. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Turing Pharmaceuticals undertakes no obligation to update publicly any forward-looking statements.

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TURING
PHARMACEUTICALS

# R&D PIPELINE – FOR DISTRIBUTION

October 19, 2015

# Turing Pharmaceuticals' R&D Pipeline – For Distribution

| Product | Indication | Preclinical | Phase I | Phase II | Phase III | Marketed | |
|---|---|---|---|---|---|---|---|
| DARAPRIM® | Toxoplasmosis | | | | | | |
| VECAMYL® | Hypertension | | | | | | |
| VECAMYL® | New Indication | | | | | | |
| TUR-001 (Syntocinon)™ | Lactation | | | | | | |
| TUR-001 (Syntocinon)™ | New Indication | | | | | | |
| TUR-002 (IN Ketamine) | Suicidality | | | | | | (Ph3 estimated Q3, 2016) |
| TUR-002 (IN Ketamine) | New Indication | | | | | | (Ph3 estimated Q3, 2016) |
| TUR-004 | Epileptic Encephalopathy | | | | | | (Ph3 estimated Q2, 2016) |
| TUR-004 | Epilepsy | | | | | | |
| TRP-001 | Glycogen Storage Disorders | | | | | | |
| TRP-002 | Rare Genetic CNS Disorder | | | | | | |
| TRP-003 | Pediatric Leukodystrophy | | | | | | |
| TRP-004 | Toxoplasmosis | | | | | | |
| TRP-005 | Next Generation Epilepsy | | | | | | |
| TRP-011 | Congenital Metabolic Disorder | | | | | | |

Chairman CHAFFETZ. Thank you.

Mr. Shkreli, you did not provide the committee any written testimony. Do you wish to make an opening statement?

Mr. SHKRELI. On the advice of counsel, I will not be giving an opening statement.

Chairman CHAFFETZ. I want to ask you a few questions.

What do you say to that single, pregnant woman who might have AIDS, no income, and she needs Daraprim in order to survive? What do you say to her when she has to make that choice? Would do you say to her?

Mr. SHKRELI. On the advice of counsel, I invoke my Fifth Amendment privilege against self-incrimination and respectfully decline to answer your question.

Chairman CHAFFETZ. You were quoted as saying, on Fox 5 in New York, you were quoted as saying, "If you raise prices, and you don't take that cash and put it back into research, I think it is despicable. I think you should not be in the drug business. We take all of our cash, all of our extra profit, and spend it on research for these patients and other patients who have terrible, life-threatening, life-ending illnesses."

Did you say that?

Mr. SHKRELI. On the advice of counsel, I invoke my Fifth Amendment privilege against self-incrimination and respectfully decline to answer your question.

Chairman CHAFFETZ. Do you think you have done anything wrong?

Mr. SHKRELI. On the advice of counsel, I invoke my Fifth Amendment privilege against self-incrimination and respectfully decline to answer your question.

Chairman CHAFFETZ. I would like to yield time to Congressman Gowdy of South Carolina.

Mr. GOWDY. Thank you, Mr. Chairman.

Is it pronounced "Shkreli"?

Mr. SHKRELI. Yes, sir.

Mr. GOWDY. See there, you can answer some questions. That one didn't incriminate you. I just want to make sure you understand that you are welcome to answer questions and not all of your answers are going to subject you to incrimination. You understand that, don't you?

Mr. SHKRELI. I intend to follow the advice of my counsel, not yours.

Mr. GOWDY. I just want to make sure you are getting the right advice. You do know that not every disclosure can be subject to the Fifth Amendment assertion, only those that you reasonably believe could be used in a criminal prosecution or could lead to other evidence.

Mr. SHKRELI. I intend—I intend to use the advice of my counsel, not yours.

Mr. GOWDY. Do you also understand that you can waive your Fifth Amendment right? You gave an interview to a television station in New York where, if I understood you correctly, you couldn't wait to come educate the Members of Congress on drug pricing. And this would be a great opportunity to do it. So do you understand you can waive your Fifth Amendment right?

Mr. SHKRELI. On the advice of counsel, I invoke my Fifth Amendment privilege against self-incrimination and respectfully decline to answer your question.

Mr. GOWDY. Well, Mr. Chairman, I am vexed. He has been willing to answer at least one question this morning. That one did not subject him to incrimination. I don't think he is under indictment for the subject matter of his hearing.

So the Fifth Amendment actually doesn't apply to answers that are not reasonably calculated to expose you to incrimination. And even if it did apply, he is welcome to waive it.

And I listened to his interview, and he didn't have to be prodded to talk during that interview. He doesn't have to be prodded to tweet a whole lot, or to show us his life on that little Web cam he's got.

So this is a great opportunity, if you want to educate the Members of Congress about drug pricing or what you call the fictitious case against you.

Or we can even talk about the purchase of—is it Wu-Tang Clan? Is that the name of the album? The name of the group?

Mr. SHKRELI. On the advice of counsel, I invoke my Fifth Amendment privilege against self-incrimination and respectfully decline to answer your question.

Mr. GOWDY. Mr. Chairman, I am stunned that a conversation about an album he purchased could possibly subject him to incrimination.

Chairman CHAFFETZ. The gentleman is correct. I understand that Mr. Shkreli is under indictment, but it is not the intention to ask him questions about that topic.

Mr. GOWDY. So if I understand it correctly, we are not going to ask him questions that are going to be on the subject matter of his current pending criminal charges. And if we were to get close to one or in a gray area, he is welcome to assert his Fifth Amendment privilege there. And if we stay away from the subject matter of this indictment, some could argue he has a legal obligation to answer, under Kastigar v. United States. But he, certainly, has the right to do so, as he did in the television interview and as he does quite frequently on social media.

Chairman CHAFFETZ. Correct.

Mr. BRAFMAN. Mr. Chairman, may I be recognized for a moment?

Chairman CHAFFETZ. No. No, you are not allowed to. Under the House rules, you have not been sworn in.

Mr. BRAFMAN. I understand, but he is making ——

Chairman CHAFFETZ. You are not recognized. You are not recognized, and you will be seated.

The gentleman from South Carolina is correct. We were trying to provide an opportunity to have a candid discussion about issues related to drug pricing.

We now recognize Mr. Cummings for any questions he may have.

Mr. CUMMINGS. Thank you very much. Mr. Chairman, let me say for the record that I completely support your decision to bring Mr. Shkreli to make sure that he asserted his Fifth Amendment right before this committee.

Normally, Democrats on our committee have accepted the assertions of a witness's attorney that his or her client is going to take

the Fifth. But in this case, Mr. Shkreli made a number of public comments himself, raising legitimate questions about his intentions.

Honestly, I did not know whether he was even going to show up today, so it is nice to see you.

But now that he has invoked his constitutional rights, of course, I will respect his decision.

To Mr. Shkreli, since I have you in front of me, after trying to get you in front of this committee for so long, let me say this. I want to ask you to—no, I want to plead with you to use any remaining influence you have over your former company to press them to lower the price of these drugs.

You can look away if you like, but I wish you could see the faces of people, no matter what Ms. Retzlaff says, who cannot get the drugs that they need.

By the way, it is the taxpayer—somebody is paying for these drugs. Somebody is paying. It is the taxpayers who end up paying for some of them. And those are our constituents.

People's lives are at stake, because of the price increases you imposed and the access problems that have been created.

You are in a unique position. You really are, sir. Rightly or wrongly, you have been viewed as the so-called "bad boy of pharma." You have a spotlight, and you have a platform. You could use that attention to come clean, to right your wrongs, and to become one of the most effective patient advocates in the country, and one who can make a big difference in so many people's lives.

I know you are smiling, but I am very serious, sir.

The way I see it, you can go down in history as the poster boy for greedy drug company executives, or you can change the system. Yes, you.

You have detailed knowledge about drug companies and the system we have today, and I truly believe—I truly believe—are you listening?

Mr. SHKRELI. Yes.

Mr. CUMMINGS. Thank you.

I truly believe you could become a force of tremendous good. Of course, you can ignore this, if you like. But all I ask is that you reflect on it.

No, I don't ask, Mr. Shkreli. I beg that you reflect on it. There are so many people that could use your help. May God bless you.

Thank you. I yield back.

Chairman CHAFFETZ. The gentleman yields back.

Mr. Shkreli, it is your intention to decline all answers to the questions and invoke your Fifth Amendment right?

Mr. SHKRELI. Yes.

Chairman CHAFFETZ. Given that the witness has indicated that he does not intend to answer any questions, and out of respect for his constitutional rights, I ask now that the committee excuse the witness from the table.

Without objection, so ordered.

We will pause for a moment as Mr. Shkreli is escorted out.

We will continue and now recognize the gentleman from Florida, Mr. Mica, for 5 minutes.

Mr. MICA. Thank you, Mr. Chairman.

Mr. Chairman, Mr. Cummings has been around this committee for a long time. I don't think I have ever seen the committee treated with such contempt. In fact, Mr. Chairman, I would like to know if, based on his response today and his actions, if he could be held in contempt.

Chairman CHAFFETZ. It is not my intention to hold him in contempt. We had heard multiple statements from Mr. Shkreli prior to this hearing, everything from I can't wait to school Congress to I will invoke my Fifth Amendment rights.

It is important for us to have a person like that come explain that and answer those questions in person. I wish he would have answered those questions. We had no intention of asking him things for which he was under indictment.

But I will entertain any suggestions that there might be. But at this point, no.

Mr. MICA. Well, at some appropriate time, I may move to hold the gentleman in contempt.

It is very sad, you know? Mr. Cummings said he may be the poster child for greed and unfair pricing. It is a very serious matter.

While he is the focus of attention, and he is the villain, we have a lot of blame to go around.

The pricing for drugs from all of these companies has skyrocketed. Some of the information I have is that prices have more than doubled for 60 drugs in the past year. And a survey of about 3,000 brand-name prescription drugs found that prices have more than doubled for 60 and at least quadrupled for 20 since 2014.

Is that correct, Dr. Woodcock?

Dr. WOODCOCK. Congress has not really invested any authority for FDA on pricing.

Mr. MICA. On pricing. Yes, we know that.

Dr. WOODCOCK. We do not follow that.

Mr. MICA. And you said about 88 percent of the drugs that are consumed out there are generic today?

Dr. WOODCOCK. That are dispensed by pharmacists are generics, that is correct.

Mr. MICA. And the situation with their pricing, has that increased or decreased? What did you testify to?

Dr. WOODCOCK. The HHS recently released a report that showed for Medicare about two-thirds of the drugs over the last several years, the generic drugs, decreased, the prices had decreased. But there are a few where prices have increased. So there is a group that has increased. And this may have to do with the amount of competition for those drugs.

Mr. MICA. One of the problems is the approval process, and you spoke of getting drugs out there. When you have competition, the price can come down. You have made some progress you cited today.

Ms. Retzlaff, is the company you work for owned by Mr. Shkreli?

Ms. RETZLAFF. He is a shareholder, yes—a shareholder.

Mr. MICA. Does he own what share? Do you know?

Ms. RETZLAFF. I'm not sure what share he owns of the company, but I can check that out.

Mr. MICA. Well, you described a little bit different scenario on what has been publicized as Daraprim's cost.

Ms. RETZLAFF. Yes.

Mr. MICA. It is pretty sad that your shareholder would take that attitude. At least you did explain to the committee some of the pricing.

But again, there are other companies and drugs. Alcortin A, a 1,860 percent increase. Is that correct? Does anyone know? That is not your drug, is it?

So it is another manufacturer who is just as guilty. Maybe not as arrogant, but just as guilty.

But millions of Americans depend on medication. I brought mine, and I am pretty fortunate. I have coverage. But a lot of people's lives depend on it. Mine is not that situation.

But what we have seen here is an unprecedented arrogance, and what we see is a situation where people who need these drugs are denied these drugs because of pricing and lack of competition. And I think we are going to see more of this, because people take advantage of the system.

I yield back.

Chairman CHAFFETZ. I thank the gentleman.

I now recognize the gentlewoman from New York, Ms. Maloney, for 5 minutes.

Ms. MALONEY. When you read the emails between Valeant and Turing, after you finish, you would not describe your business as a business, but as an exploitation machine.

Your basic business model was to buy a company, fire people to save money, and then jack up prices to reach revenue goals. You set a revenue goal, and then you jacked up the price.

Now, Ms. Retzlaff, when you talk about discounts, it is really disingenuous when you raise the prices 5,000 percent.

So my first question to Mr. Schiller is, when you were jacking these prices and sending your emails back and forth, did you ever think about the impact on patients, on hospitals, on public health payers? Did you ever think about it?

And how can you justify raising prices by thousands of percent on lifesaving orphan drugs for which there are no competing manufacturers, no generic, no manufacturers. People are going to die if they can't get the drug. Did you ever think about how hiking the price on Daraprim, which is important in treating life-threatening infections and AIDS, did you ever think about the people who would not be able to afford it? Did you ever think about it? Or the impact on the hospitals and the payers?

Your memos just show, the internal memos, you just said this is the price we need to make, this is the goal and the profits we need to make.

Mr. SCHILLER. I can't comment on Daraprim. It is not our drug. But I will ——

Ms. MALONEY. Well, then let me ask you another question, since you mentioned that it is from someone else. How is Valeant's conduct any different than the conduct of Mr. Shkreli's company? Is the conduct of your company and your business model any different?

Mr. SCHILLER. Well, I'm not that familiar with their company, other than reading newspaper articles. But as far as Valeant is concerned, Valeant is a global company. We operate in 100 countries. We have over 1,800 products.

Ms. MALONEY. We are not looking at the company. We are looking at you strategy, which from your own memos, that I would like to place into the record, show the business model was to set a goal, a revenue goal, the profit you would make, and that was all you did.

Now yesterday, in response to questions that were put forward by this committee and memos about Valeant's price increases, your company said Mr. Pearson made an inaccurate statement during Valeant's first quarter of 2015 earnings conference call where they were clearly setting the goal, and let's raise the price to that goal.

In light of this, why should this committee have confidence in the accuracy of your testimony today?

Mr. SCHILLER. Well, the statement you are referring to I think related to an email that I sent to Mr. Pearson, which was 100 percent correct. Our SEC filings were 100 percent correct. I can't tell you what Mr. Pearson's intent was, what question he thought he was answering. But as a company, yesterday, we chose to clarify, make sure it was clear, and we put out that press release.

Ms. MALONEY. Well, he talked about increasing prices on Isuprel in July 2015 to meet goals of revenue.

Well, did you increase the price of Isuprel on July 2015?

Mr. SCHILLER. I believe yes.

Ms. MALONEY. You did increase the price. So on May 21, 2015, you wrote an email to him stating, Pearson, and I quote, "Last night, one of the investors asked about price versus volume for Q1. Excluding Marathon, price represented about 60 percent of our growth. If you include Marathon, price represents about 80 percent."

So, Mr. Schiller, price increases represented 80 percent of your company's growth for the first quarter of 2015. Is that correct?

Mr. SCHILLER. That is correct.

Ms. MALONEY. And most of your growth is attributed to one strategy, and that is increasing the price of your drugs. In all of your memos, the only strategy I saw was: Let's increase the price of the drugs to increase revenue.

That was your strategy, correct?

Mr. SCHILLER. No, in the past, there were examples where we blocked older drugs.

Ms. MALONEY. Okay, I would like you to place that in the record, any strategy that was different from just increasing prices.

Chairman CHAFFETZ. I thank the gentlewoman for her time. Her time is now expired.

Ms. MALONEY. I just would like to say, Mr. Chairman, increasing revenue and profits was their strategy, regardless of cost and impact. It is a terrible example of American business, and, I would say, the American people are tired of paying the price for it.

Chairman CHAFFETZ. I thank the gentlewoman.

Ms. MALONEY. Thank you for this hearing, Mr. Chairman.

Chairman CHAFFETZ. Thank you.

We will now recognize the gentleman from Tennessee, Mr. Duncan, for 5 minutes.

Mr. DUNCAN. Thank you, Mr. Chairman.

Dr. Woodcock, I have a report here from Tufts University, their Center for the Study of Drug Development. It is dated November 2014. It says cost to develop and win marketing approval for a new drug is $2.6 billion and average out-of-pocket cost is $1.395 million.

What do you say about that, $2.6 billion? And it says it takes an average of 10 years to get a drug to market? What do you have to say about that? Is that anyplace close to being accurate?

Dr. WOODCOCK. Well, the economics community has various estimates of these costs, so those costs are in dispute. But it is agreed that it costs a great deal of money, and it takes a long time to get an innovative drug to the market.

Some of the recent advances in science are shortening this time frame for targeted therapies and breakthrough therapies. However, in general, that time frame is accurate, and it does take a large investment to first find and then develop a new drug.

Mr. DUNCAN. Don't you see that if a small company or an individual comes up with some miraculous drug, that they would be forced to sell out to some big drug giant to get a drug to market with those kinds of costs? That is what many people think has led to this overconsolidation of the drug business, how it has ended up in the hands of a few big giants.

Dr. WOODCOCK. Well, the industry is changing rapidly because of the new science. Last year, we approved—a large proportion of our new drugs were orphans and a number of them came from small companies, so it is doable.

And the drug development paradigm is in flux, because of the new scientific findings.

Mr. DUNCAN. Mr. Merritt, what do you say about that?

Mr. MERRITT. Well, as Dr. Woodcock says, the market has been changing toward more specialized drugs that are developed differently and marketed differently than drugs traditionally have been.

I know, from our perspective, we know the best way to get costs down is through competition. So the more products we can get on the market, the faster we can get them on the market, whether they are competing me-too brands or generic competitors, the better it is for consumers and the employer unions and government programs that we serve.

Mr. DUNCAN. We all believe that there should be some testing to make sure that drugs are safe, but you can go ridiculously overboard on anything. And it seems to me that when it is taking 10 or 12 years to get a drug to market, and it is costing $2.6 billion as the Tufts study says, that that is going a little bit overboard.

Mr. Schiller, I have a very detailed letter from one of my constituents that I would like to place in the record. But she sends to me her costs of a drug that your company put out, Aplenzin. And her costs, for 30 pills in December 2013, a total annual cost of $13,566. The cost per pill was $37. Less than 2 years later, the cost for the same pills had gone to the $106.74, a 224 percent increase in 2 years' time.

And also, I have a letter from another individual, a state representative in Tennessee, who says that the average pharmaceutical company averages spending over 20 percent on research and development, but that your company averages less than 3 percent.

What do you say about this 224 percent increase in less than 2 years' time, and the 3 percent on research and development?

Mr. SCHILLER. Sure. When we price our drugs, we try to take into account the clinical value, the alternative therapies, patient access, among other factors. It is not an exact science.

In a number of cases, we have been too aggressive. We are also trying to manage a bottom line to be able to invest in our research and development pipeline, and make investments in expanding our manufacturing. I mentioned Rochester, New York, where we are going to put another half billion dollars to increase the capacity in that facility as well, as patient access. And patient ——

Mr. DUNCAN. My time is running out. Let me just add that I think you need to do much more to hold down these costs.

But I would also like to say that, in all my time in Congress—I have served on four committees, been here 28 years. I have seen hundreds of witnesses and some very heated confrontations. I have never seen an individual act with such arrogance as Mr. Shkreli a while ago, with such childish, smart-alecky smirks, even turning away from Ranking Member Cummings to pose for pictures while the ranking member was speaking. I think it was just totally ridiculous.

I can tell you this, his lawyer better advise him a little bit, because a jury would love to convict somebody if he acts that same way while he is on trial.

Thank you, Mr. Chairman.

Chairman CHAFFETZ. I thank the gentleman.

We will now recognize Ms. Norton for 5 minutes.

Ms. NORTON. Thank you very much, Mr. Chairman. It may have been Mr. Shkreli's antics that drew the kind of attention that gets us this very important hearing today.

And I understand your testimony, Mr. Merritt, about competition and encouraging patients to go to less expensive drugs. I also appreciate what you said about more specialized drugs.

And let me say this about pharmaceuticals. I think pharmaceuticals, the work of our companies, is most extraordinary. It has not only saved lives, kept people out of the hospital, so I want you to know that I think there is great appreciation for the industry here, even for what is often given as the reason for the price of drugs. We do understand R&D. We do understand that more of the R&D is done here than done abroad. And then, of course, it costs less abroad, all of that.

And I think Dr. Woodstock's last testimony in response to a question made it clear that the government understands it.

That understood, let us go to a kind of paradigm here, Daraprim. This is a lifesaving drug that is used for parasitic or, indeed, what could be fatal parasitic infection. It is known, Ms. Retzlaff, who took over from Mr. Shkreli, it is known as toxoplasmosis. It is used by cancer patients, by patients with HIV. It has a relatively small patient market.

Now, Ms. Retzlaff, Turing purchased this drug. I just said that I give all credit to the industry for R&D, but it is true, Ms. Retzlaff, is it not, that you did not do the R&D for Daraprim? You purchased Daraprim?

Ms. RETZLAFF. It is true, yes, we purchased Daraprim. Now, Daraprim was on the market for 60 years, and even after 60 years, it is still the only FDA-approved treatment for toxoplasmosis.

Ms. NORTON. Now, isn't it interesting that for 60 years somehow, a company had been able to manufacture this drug for $13.50 per tablet, but when you purchased it, the tablet overnight went to $750 per tablet. To do the math, Ms. Retzlaff, that is a 5,000 percent increase.

Is there any conceivable justification for a company that had nothing to do with the R&D, taking over a company, and then overnight raising the price so that it is, let's be fair, out of reach for patients and even some hospitals? What is your justification for that?

Ms. RETZLAFF. My justification is that there has been no new innovation, no new treatments, which we believe are critically needed. And we are reinvesting much of the revenue ——

Ms. NORTON. How much are you ——

Ms. RETZLAFF.—60 percent.

Ms. NORTON. So you bought it. You immediately began to reinvest. And the reinvestment was so large that you had to increase for those who are now using—not talking about future users—who are now using the drug, you needed to increase it 5,000 percent?

Ms. RETZLAFF. And we are also investing in other serious and neglected diseases.

Ms. NORTON. Now, in spite of—yes, you are putting it all on this one lifesaving drug?

Ms. RETZLAFF. It is not uncustomary for pharmaceutical companies to use revenues from one product to fund multiple programs.

Ms. NORTON. Well, it certainly isn't. But why is it when the committee—I drew some of the testimony from the committee. The documents obtained by the committee indicated that, in response to this very widespread concern about this huge increase, Turing employed a public relations strategy to try to divert attention to patient assistance programs and research and development efforts.

In other words, instead of keeping the price so that it could be purchased by patients in hospitals, you went to what I think even some of your testimony was about, and that is to patient assistance programs to try to obscure the price.

Is that your strategy for raising prices and then essentially trying to obscure those raises by telling people that is all right, we will give you a 50 percent increase—sorry, discount. But to the rest of you, we are using this money ourselves for R&D? Is that your strategy?

Ms. RETZLAFF. No, it is not. Our intent behind our public relations strategy was to correct any miscommunication.

Again, as I said in my testimony, two-thirds of patients, the most vulnerable toxoplasmosis patients, can access our product for a penny a pill. That is two-thirds.

Twenty-three percent are covered by commercial insurance. For those patients, we capped their copays at $10.

We are absolutely committed, and always have been, to ensuring every single patient who needs Daraprim gets it.

Chairman CHAFFETZ. That ain't true, but we will talk some more about that.

We will now recognize the gentleman from Michigan, Mr. Walberg, for 5 minutes.

Mr. WALBERG. Thank you, Mr. Chairman, and thank you for having this hearing.

I think we can all agree on the importance to pursue lifesaving treatments and cures to illnesses like cancer, et cetera, that affect our communities, our neighbors, our families, our friends. We can also agree that we want individuals to have access to these treatments at an affordable price.

The question, of course, today is, how do we do that? Unfortunately, under the President's health care law, we have seen drug costs spike. We have all heard that back in our districts. Congress needs to push back. It needs to create an environment that promotes innovation, increases competition, which will bring down costs and increase access to prescription drugs. We have our fault in the process.

But so far, we have acted to approve more than $2 billion in additional funding for NIH—a good thing—the first big raise in over 12 years to boost medical research.

Additionally, the House, we the House, have acted responsibly and passed 21st Century Cures Act, which reforms the FDA approval process. It would accelerate the discovery and development of treatments and cures. The Senate has not allowed that to go through yet or the President to push for it.

So, Dr. Woodcock, it is my understanding, and I guess I just want to delve a little more deeply into your responses so far, it is my understanding that the FDA currently has a backlog of over 4,000 new drug applications, at a median process rate of over 42 months.

Can you explain to our committee why your agency is so far behind?

Dr. WOODCOCK. We were far behind when we started the Generic Drug User Fee program. At this point, the number of applications where the manufacturer hasn't heard from us, where we haven't picked them up, is 600. We have approved and ——

Mr. WALBERG. Let me understand. They haven't heard from you, but I guess we are talking approvals.

Dr. WOODCOCK. Well, in the past generic program, before we reformed it, generic drugs went through four cycles of review and back to the company and review. This is a very inefficient process. We are trying to streamline that process, so we can get it right the first time. The company sends in an application, it is an approvable application.

Under that scenario, as I said, this year, 15 months. Starting in October, 10 months.

We still have to deal with the backlog, which we are cranking out approvals of the backlog. But they started in 2012. When the program starts, they are already 40 months old. They are not going to get any younger.

So for the backlog applications, when we approve them, their time to approval will be more than 40 months. But these newer ones, we have approved drugs in 10 months, under the new program, generic drugs.

Mr. WALBERG. Well, I wish you well on that, and that is the direction we want to see going, because we very clearly have seen here—we have seen efforts in the pharmaceuticals as well to try to get away from that perception. But we have also seen that they have used this backlog to really capitalize on a system that allows them to pillage the market.

Dr. WOODCOCK. The drugs under discussion have been on the market for decades, times when there were no backlogs and there was still no generic competition to them. There are other reasons that, for a very small segment of generic drugs, the 88 percent is out there, but for a small segment of generic drugs, there is no generic competition.

When we, at the end of the first GDUFA program, will have eliminated this backlog and be in a steady-state type of activity, there will still be problems with drugs that don't have generic competition, because there are other reasons for that.

Mr. WALBERG. Probably expediting that will ultimately help have more competition as well.

Let me ask you about biosimilars. Do you think that biosimilars can play a part in addressing affordability and patient access to the drugs they need?

Dr. WOODCOCK. Absolutely. And that is what they are intended to do, and we are very vigorously enacting that program. We've had a very vigorous response to the legislation that Congress passed.

Mr. WALBERG. So it is bumping up there. Do you believe that patient and health care professional confidence in biosimilars is essential for savings from biosimilars to occur?

Dr. WOODCOCK. I believe that is the number one issue. We just recently completed with generics some studies of seizure drugs, because, after all these years, the neurologists still didn't believe that the generics were equivalent. Those studies showed no difference between the generics and brand name seizure drugs.

Mr. WALBERG. Well, your efforts in moving that forward will assist that, I am sure, so thank you.

Dr. WOODCOCK. Thank you.

Chairman CHAFFETZ. I thank the gentleman.

We will now recognize the gentleman from Massachusetts, Mr. Lynch, for 5 minutes.

Mr. LYNCH. Thank you, Mr. Chairman.

I do want to follow up on the gentleman from Tennessee's line of questioning. I thought it was very good.

The costs are prohibitive in terms of trying to develop some of these drugs. In Massachusetts and in the Boston area, we have been blessed. We have had 29 IPOs, small pharmaceutical companies, come to market in the last 2 years. So we do have some growth in the industry. And so those few big players are not dominating like they were before, so that is good for change.

But in the case of Turing here, they just bought the drug, didn't do a lick of research. Bought the drug, and as the gentlelady from the District of Columbia pointed out, the next day went from

$13.50 a pill to $750 a pill overnight. And that is disgraceful. There is not a lot of shame at the table today, but this is disgraceful. It was well known that the impact would be great harm on the public.

So, Ms. Retzlaff, after you in August increased the price of the drug by 5,000 percent for people who had no alternative, on August 18, Tina Ghorban, a Turing employee, sent an email that you were CCed on regarding the increase in the price. And she wrote, and I quote, "There are patients waiting now for product who have a $6,000 copay."

Now, you just said, and you are under oath—you are under oath. You are subject to perjury charges, if you don't answer correctly. She is saying that these patients had a $6,000 copay, and you are saying they never had to pay more than a penny for a pill.

Ms. RETZLAFF. So allow me to provide some context. Yes, she did say there was a $6,000 copay. However, we paid the majority of the copay. The patient did not pay ——

Mr. LYNCH. Everything but a penny?

Ms. RETZLAFF. We paid the copay up to $10.

Mr. LYNCH. Okay. I am glad to get you on the record on that.

Ms. RETZLAFF. I can show you the data.

Mr. LYNCH. This email also shows that you were aware that your Daraprim price increase was resulting in incredibly high copays. Isn't that correct?

Ms. RETZLAFF. It's correct, which is why we introduced a very generous copay program to ensure the price increase did not hurt patients.

Mr. LYNCH. So this is another email from Ms. Ghorban. She sent another email to you and the director of special pharmacy development at Walgreens asking whether Turing would, and I quote, "grant an exception for those patients with a copay over the approved amount of $10,000."

Ms. RETZLAFF. Our policy was to ensure that the price increase did not impair access for patients. So, yes, we subsidized that copay.

Mr. LYNCH. You didn't want to impair access so you raised the price to $750 a pill.

Ms. RETZLAFF. The access issues with Daraprim had nothing to do with the price. To our knowledge, they were based on gaps in the distribution network, which, by the way, we inherited from the previous manufacturer.

Mr. LYNCH. I reclaim my time. She asked the question because there was patient in North Carolina who had a copay of $16,830.

Ms. RETZLAFF. Yes.

Mr. LYNCH. That is what the patient was being asked for.

Ms. RETZLAFF. Yes, and we paid that down for the patient.

Mr. LYNCH. Four days later, on August 24, the same outrageous copay was reflected in an internal Turing presentation on patient access, and this is your presentation: Patients with commercial private insurance experience increased copays and delays in claims approval and rejections. One has a 50 percent coinsurance resulting in a copay of $16,830.

That is your own company and your own presentation on what the patient is being charged.

Ms. RETZLAFF. Yes. Again, we put that in the presentation to inform leadership that that—those were the subsidies that we were offering patients.

Mr. LYNCH. So I think we have a solution here. I think we have a solution. Congress has the power. I would suggest in our pharmaceutical regulatory procedure, our regulations, that we adopt a poison pill amendment that when anybody acts like Turing is acting in increasing the price from $13.50 to $750 a pill, Congress can suspend the exclusivity period for you to produce that drug. We can eliminate it the next day and contract with DARPA, our government research labs, to produce your drugs at no cost to the consumer. That is what we can do.

The problem is that it will impact the good companies that are actually doing research, not the hedge funds that come in and buy a company and pump up the prices.

Ms. RETZLAFF. If I may, we are ——

Mr. LYNCH. I didn't ask you a question. I didn't ask you a question. I am telling you what we can do. If Congress has the willpower, we can do that.

Unfortunately, it will hurt a lot of good companies. And you are trashing—you are trashing—the pharmaceutical industry that is doing a great job on a lot of different drugs, from organ transplants to cystic fibrosis. Good researchers who are out there doing great work, you are trashing that industry. And you are going to cause us to have to put heavy, heavy regulations on good companies. And you are probably going to choke off other drugs that will come into the pipeline.

So look at the impact you are having.

Ms. RETZLAFF. May I speak?

Chairman CHAFFETZ. I thank the gentleman.

Mr. LYNCH. Thank you for your indulgence.

Chairman CHAFFETZ. Thank you.

We are going to excuse Dr. Woodcock, per our previous arrangement. We will allow her to hopefully make her next hearing without any hesitation. As we change this nameplate, we will now have Mr. Flanagan join us, also from the FDA, as was previously introduced and was also sworn in. So he, too, is under oath.

We have Dr. DesJarlais, who is now recognized for 5 minutes.

Mr. DESJARLAIS. Thank you, Mr. Chairman.

Good morning, panel.

Mr. Schiller, could you explain to us a little further how you determined the new price for Isuprel and Nitropress?

Mr. SCHILLER. Sure. After we signed the contract to purchase the assets, we reengaged a pricing consultant that had been engaged previously by the prior owners. They made a presentation to the head of our neurology division where this product was going to sit. The conclusion was that, given the reimbursements for the procedures where Isuprel was used, which were as high as $12,000 or $14,000, in some cases, that there was significant opportunity to increase the price of Isuprel without impacting—without making it unprofitable for the hospitals.

Mr. DESJARLAIS. Excuse me. Why were cardiology drugs put with neurology?

Mr. SCHILLER. It's—I apologize. It's our neurology and other division. So it is our neurology and we have another a number of other smaller therapeutic categories that are underneath that.

Mr. DESJARLAIS. Both of these drugs are generic, right? They have lost their patents?

Mr. SCHILLER. They have lost their patents, but there is not generic competition.

Mr. DESJARLAIS. Okay. So this isn't a drug that a patient can go to their doctor and say, "Hey, Doc, I need some Nitropress. I need some Isuprel." Is that correct?

Mr. SCHILLER. It's in a hospital setting, part of a procedure, or in a clinic.

Mr. DESJARLAIS. Right. So it is not the patient that is getting out their wallet and paying for this drug. They are actually in a hospital and either their blood pressure is going through the roof and the doctor has really no other choice but to use your drug.

In several cases, this comes in a vial, right? And you raised the price of Nitropress 252 percent, is that right? $257 for a 2 mL vial to $805?

Mr. SCHILLER. Correct.

Mr. DESJARLAIS. So if you are laying there in the ICU, and your blood pressure is going sky-high, the doctor doesn't ask you if you want to pay for this drug. He just has to use it. And whatever you charge the hospital for, they have to pay it, right?

Mr. SCHILLER. That is correct. It is used in emergency situations.

Mr. DESJARLAIS. And Isuprel, the same way? It is not a pill. This is a vial. And you raised the price 525 percent from $215 to $1,346 a vial?

Mr. SCHILLER. That is correct.

Mr. DESJARLAIS. And you don't asked the doctor, "Hey, I need some Isuprel." You have an arrhythmia in your heart and things are circling the drain in a hurry, the doctor doesn't have a choice. He is kind of over a barrel, because there is no other competition here, so he has to get that drug. He doesn't have another choice.

Mr. SCHILLER. Well, there are substitutes, and the volumes have gone over down over 30 percent since we acquired those drugs.

Mr. DESJARLAIS. So you are saying that you raised one 212 percent and one 525 percent, but you have been so gracious as to drop the price 30 percent?

Mr. SCHILLER. Well, we have gone to the hospitals that have the largest users, they have large cardiac departments, who would be the most impacted, to make sure that they have a significant discount. I think also, when you look at our overall portfolio, we have tried to address the issue of price by reducing the prices on our dermatology and ophthalmology products by 10 percent, and by dramatically increasing the amount of patient ——

Mr. DESJARLAIS. Well, that is probably falling on deaf ears. I did pick up on something in your opening statement when you said the patient doesn't really pay this, so they don't really feel the sting. But I don't think anyone who has been a patient comes up from the hospital—they know they get a really big bill. And somewhere in that bill is Isuprel or Nitropress, if it was used. So the patient does end up paying for that drug in the end, correct?

Mr. SCHILLER. It is paid as part of the procedure, so somebody at the end pays it. I would add, though, that these types of transactions, Isuprel and Nitropress, in the past, we have purchased some drugs like this, where there was no generic competition. We raised the price, as you mentioned. We were too aggressive and we are not ——

Mr. DESJARLAIS. Maybe way too aggressive.

Mr. SCHILLER. We are not going to be looking for those kinds of acquisitions going forward.

Mr. SCHILLER. Yes.

Ms. Retzlaff, you also kind of did the same thing with your drug. It is a unique drug and people don't have much of a choice.

In your opening statement, it sounded like maybe you were doing people a favor. You were giving it to them for a penny, or they were getting it free. You are making a lot of money. I mean Mr. Shkreli wouldn't even answer a question, he was so ashamed of himself.

And you are basically saying that you are doing these people a favor, you are knocking off their $10 copays and all that. But the bottom line is that your company made a heck of a lot of money on this drug, and there is only a handful of patients who need it. Don't you think that maybe you can do a little better?

Ms. RETZLAFF. We didn't make a lot of money on the drug, actually.

Mr. DESJARLAIS. Okay.

Ms. RETZLAFF. I believe the committee has our financial statements. I don't want to share that information, because it is confidential. But you will see that Turing is operating at a loss.

Mr. DESJARLAIS. I would just say that people are really hurting right now. They are seeing increased premiums. They are seeing increased deductibles. And this type of thing doesn't help.

It is like if one gas station has gas and all the other ones run out, that gas station can jack the price and people have to pay it. But they are not going to think much of that gas station. I think you guys are at risk of the same thing.

Ms. RETZLAFF. Yes, I ——

Mr. DESJARLAIS. I yield back.

Chairman CHAFFETZ. I thank the gentlemen.

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

Mr. WELCH. Thank you, Mr. Chairman. Thanks for calling this hearing to go over this astonishing and unsustainable situation with the price of prescription drugs.

A couple things. One, Ms. Retzlaff, if Springfield Hospital in Vermont wanted to buy Daraprim, what would they have to pay you?

Ms. RETZLAFF. So we have introduced a hospital discount program.

Mr. WELCH. Yes. Give me a number. What would they have to pay?

Ms. RETZLAFF. So for a 100-count bottle, it would be roughly $35,000. For a 30 count-bottle, it would be roughly $11,000.

Mr. WELCH. So how much does that come to a pill? So $1,100 a bill?

Ms. RETZLAFF. So $750 is the list price. We are offering discounts up to 50 percent for hospitals.

Mr. WELCH. $1,100 is the discount?

Ms. RETZLAFF. No, no, no. $1,100 is not the discount. It is 50 percent off of $750.

Mr. WELCH. Okay, so if Springfield Hospital ——

Ms. RETZLAFF. It is $375.

Mr. WELCH. So if Springfield Hospital wanted to buy a pill, it would be $350?

Ms. RETZLAFF. Correct.

Mr. WELCH. All right. What about if I had Blue Cross Blue Shield and it was covered? What would Blue Cross Blue Shield pay?

Ms. RETZLAFF. So that would depend on what the copayment and coinsurance was. About 25 percent of patients on Daraprim have commercial insurance. So in the examples that were mentioned above, the patient would be asked to pay a copay of say $5,000, in which case we would pay down that copay, so they didn't have to pay any more than $10 out-of-pocket.

Mr. WELCH. So your financial statement, you are saying, if I had to buy that, and I had a $5,000 copay, you would pay all of it except a penny?

Ms. RETZLAFF. Except $10.

Mr. WELCH. Except $10. And we can confirm that?

Ms. RETZLAFF. Yes, you can.

Mr. WELCH. All right. What if they had—what if they were on Obamacare? What would be the cost for that pill?

Ms. RETZLAFF. On Obamacare, so, well, if they are a Medicaid patient, for instance ——

Mr. WELCH. Well, Medicaid, tell me Medicaid and tell me Medicare.

Ms. RETZLAFF. Medicaid patients, so for Medicaid patients, as well as patients that are treated through the 340B programs, they can get the medicine for one penny per pill, and that actually represents two-thirds of Daraprim's business.

Mr. WELCH. And so who pays the rest of that, if the patient gets it for one penny?

Ms. RETZLAFF. That is the price. Nobody pays.

Mr. WELCH. All right. Why isn't it possible to just have a price where anybody who wants to know what that price is can go to a Web site and see? Do you do that? Do you provide that?

Ms. RETZLAFF. We provide, as you know, a list price, but the list price does not reflect the price that patients pay, that hospitals pay, that other government programs pay.

Mr. WELCH. Let me ——

Ms. RETZLAFF. From a government program perspective, there are often mandatory, statutory rebates, which is why it costs a penny.

Mr. WELCH. Reclaiming my time, the list price is just a starting point.

Ms. RETZLAFF. Yes. That is correct.

Mr. WELCH. So most people have no idea what the actual price will be after you go through the gymnastics that you just described.

Ms. RETZLAFF. That is correct. That is the way pharmaceutical pricing works in the industry.

Mr. WELCH. That is a mess in the industry. We have had a lot of outrage at the outrageous conduct here, and none—we can't underdo it.

But the bottom line here is, we have a broken market. And there is a real challenge for us, as members who represent the public who are getting hammered with this, to deal with that broken market.

I think Mr. Duncan has a really good idea. Anything we can do with the FDA to streamline, we should do that.

But on the other hand, you have market power without competition, and it is resulting in ripoffs, most glaringly represented by Mr. Shkreli.

I hope, Mr. Chairman, Mr. Ranking Member, we can have an action plan to include what Mr. Duncan is talking about. It would streamline getting the drugs to the market. It would deal with these ripoff approaches where the companies are oftentimes extending the life of the patent to prevent generic competition, doing me-too evergreening to imitate a drug that is on the market with slight changes that don't really increase the efficacy but increase the cost. Work on Mr. Stivers' bill to get generics to markets faster.

And, actually, let's have some transparency in pricing. There is all this talk about how much cost goes into research, and that is a legitimate cost. We all support it. Incidentally, taxpayers, $30 billion to NIH, we mutually support. That is our contribution.

But the bottom line here is that we know prescription drugs are life-extending and pain-relieving. They are good. But we are getting killed with the price.

Mr. CUMMINGS. Will the gentleman yield?

Mr. WELCH. I do yield.

Mr. CUMMINGS. Five seconds. Hospitals are getting killed, too, big time.

Mr. WELCH. And employers trying to do the right thing.

So I guess my time is up, but I think we have a lot more work to do. And I thank the ranking member and the chairman of the committee for setting up this hearing.

Chairman CHAFFETZ. I thank the gentleman.

Mr. WELCH. I just have one item to submit for the record, if I can, Mr. Chairman.

Chairman CHAFFETZ. Without objection. I'm not sure what it is.

Mr. WELCH. It concerns regarding the pharmacy benefit management industry, a paper by Applied Policy. Thank you.

Chairman CHAFFETZ. Without objection, so ordered.

[The information follows:]

Chairman CHAFFETZ. We will now recognize the gentleman from Florida, Mr. DeSantis, for 5 minutes.

Mr. DESANTIS. I will yield back my time.

Chairman CHAFFETZ. Mr. Walker. Let's recognize Mr. Walker for 5 minutes.

Mr. WALKER. Thank you, Mr. Chairman. I appreciate the time today.

I thank you folks are being here and testifying on this panel.

I want to go back a little bit, Ms. Retzlaff, and talk a little bit about what you said about shareholders.

Ms. RETZLAFF. Yes.

Mr. WALKER. As far as Mr. Shkreli, you said that he is a shareholder, but you were unaware as far as how much he owned in the shares?

Ms. RETZLAFF. Yes, I can't remember off the top my head. That's correct.

Mr. WALKER. Okay, according to our information, he is your largest shareholder of Turing.

Would you dispute that? You are just not aware of that? You don't know?

Ms. RETZLAFF. I knew he was a major shareholder. I wasn't aware that he was the largest shareholder.

Mr. WALKER. Okay, as far as code of conduct, you know, most organizations—I recently remember the LA Clippers with Donald Sterling got set down because of the way he behaved. I was a minister for 20 years. There are codes of conduct that we have to follow.

Is that ever part of the discussion, as far as the outrageous conduct that he is representing your company? Do you have anything in your bylaws or constitution, if you will, that would prevent somebody from being so outlandish in his behavior?

Ms. RETZLAFF. Thank you for the question. So, first, as you know, Mr. Shkreli is no longer the CEO of the company. And, subsequently, our chief commercial—or our chief compliance officer just published a code of conduct for the organization, which, again, is customary for pharmaceutical companies.

Mr. WALKER. But you just said he just published it. When was the date that he just published it?

Ms. RETZLAFF. She published it a few weeks ago. I can't remember the exact date.

Mr. WALKER. And was that code of conduct published to push back a little bit on Mr. Shkreli's behavior?

Ms. RETZLAFF. Again, Mr. Shkreli is no longer a party to the organization. The code of conduct was put in place to ensure that, you know, our current employees behaved in a manner that reflected our values.

Mr. WALKER. Would you find it—I mean, I don't know. For me, I just find it odd that all of a sudden you have a code of conduct. But you say, as far as you know, there is no link with her institution of this code of conduct with the behavior of Mr. Shkreli?

Ms. RETZLAFF. Turing is a very young company. We are just a year old. We brought on our chief compliance officer not long ago. We are still in the process of putting together all of our policies and procedures, and we just happened to get the code of conduct out a few weeks ago.

Mr. WALKER. A mere 5 days after acquiring Daraprim, Mr. Shkreli was sending emails about the timing of the price increase. In emails dated August 12, Mr. Shkreli asked when the price of Daraprim will be updated in Red Book, which is a compendium of drug pricing used by health care, as we all know.

Ms. RETZLAFF. Right.

Mr. WALKER. He said: I need an answer ASAP. It took 3 days too long the last time I did it—what he is referring to. When he says the last time I did this, was he referring to the 2,000 percent price hike of Thiola that he implemented at his former company, Retrophin?

Ms. RETZLAFF. I'm not sure, but I'd be happy to check that out.

Mr. WALKER. So when could you get that information back?

Ms. RETZLAFF. Yes, I can get that information back to you.

Mr. WALKER. By the end of the week, next week?

Ms. RETZLAFF. Sure, absolutely.

Mr. WALKER. I appreciate that.

I do want to come back and make sure I am clear with something with the FDA, Mr. Flanagan, if I could. Earlier Dr. Woodstock said there were 600 manufacturers waiting to hear back from the FDA on approval. My question is, is that 600 manufacturers part of the backlog? Are those all new? There is 40 months' backlog that you are waiting to get to, and you are trying to reduce it from 15 months to 10 months.

Can you explain what number and what column? Who are the new manufacturers versus the old ones? Can you use the microphone, too, please?

Mr. FLANAGAN. So, Representative, let me see if this answers most of the question. There is basically two big buckets of work. An incoming submission, something that comes in right now, that is going to get a 15-month goal state. Beginning in October, it will have a 10-month goal. Then there is a big pot of much older submissions. A lot of those had been at FDA before the user fee agreement started.

Mr. WALKER. Sure. When we say "big pot," can you give me a number value of what a big pot is?

Mr. FLANAGAN. Yes, sir. It was 2,866 Abbreviated New Drug Applications in October 2012.

Mr. WALKER. And those rank back as far as 40 months or nearly 3.5 years?

Mr. FLANAGAN. So those were like 40 months after October 2012. And many of those had been very long pending at FDA before the user fee agreement even started, like 2011, 2010, 2009. So now, when we clear out the backlog, the way that everyone wants, any time we approve one of those old ones that has been sitting around, the approval time is very high.

Mr. WALKER. Sure. And what makes you think you are going to go from 15 months to 10 months?

My time has expired, but if you can answer that?

And I will yield back. Thank you.

Mr. FLANAGAN. We made very substantial improvements to the program, like rebuilt the factory, and it is described in Dr. Woodcock's written testimony.

Chairman CHAFFETZ. I thank the gentleman.

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

Mr. CONNOLLY. Thank you, Mr. Chairman.

Well, Lord Almighty.

Mr. Flanagan, just to try to understand how pharmacological, pharmaceutical research works, basic research, a lot of it is done by the government, isn't it?

Mr. FLANAGAN. Yes. Representative, I am here ——

Mr. CONNOLLY. I understand. But, I mean, your understanding of where research is done as a precursor to the development of approved drugs, it is usually done by the government, is it not?

Mr. FLANAGAN. I'm really a technical expert just concerning the Generic Drug User Fee Act. I'm sorry, I'm just not the right person to answer that kind of question.

Mr. CONNOLLY. Ms. Retzlaff—have I got that name right?

Ms. RETZLAFF. You have.

Mr. CONNOLLY. Thank you.

You, in testimony, in response to Ms. Norton's question, about how could you go from $13.73, whatever it was, per pill, to $750 in your new company—and you have had a hell of a first year as a company. It is a model for everyone. You said, well, we need to use it, that revenue, to help finance research on other life-threatening conditions, for drugs that address other kinds of diseases and life-threatening conditions. That was your testimony.

Ms. RETZLAFF. Other conditions as well as toxoplasmosis, yes.

Mr. CONNOLLY. Is it your testimony that the company you bought this drug from was not doing that?

Ms. RETZLAFF. The company we bought the drug from was not doing any research, pharmaceutical innovation research, for toxoplasmosis.

Mr. CONNOLLY. Are you doing basic research?

Ms. RETZLAFF. Yes. We are doing early research right now on toxoplasmosis.

Mr. CONNOLLY. Well, but you said other conditions as well.

Ms. RETZLAFF. Yes. Yes, we have a ——

Mr. CONNOLLY. So can you provide the committee with a list of these basic research efforts that this revenue is financing?

Ms. RETZLAFF. I believe we can. I'm not involved in the day-to-day operations of research and development, but I can, certainly, check with our president of research and development.

Mr. CONNOLLY. But it is your testimony on behalf of your company, that that is what you are doing with this revenue.

Ms. RETZLAFF. That is correct.

Mr. CONNOLLY. And that was the rationale, or part of the rationale, for jumping the price up 5,000 percent.

Ms. RETZLAFF. Yes, I believe we've provided the committee with our research and development spend. Is that correct?

Mr. CONNOLLY. Well, I am being a little bit more specific.

Ms. RETZLAFF. Okay.

Mr. CONNOLLY. In answer to Ms. Norton's question, I would like to see that correlation. I would like to see where that revenue is, in fact, going from this increase.

Ms. RETZLAFF. Yes.

Mr. CONNOLLY. Because that was your testimony, that it is funding other good things.

Ms. RETZLAFF. That is correct.

Mr. CONNOLLY. And the only way, presumably, we can do that is this $5,000 price increase.

Let me ask you a question, a corny question. In your company, in Turing, did the public interest ever come up in terms of, by jacking up the price, we really could affect access, we could have unintended consequence on people's health, especially since the sacred trust we have is a drug no one else produces? It is only drug for this condition that exists on the planet, and we just bought it, we control it, and we just increased the price by 5,000 percent.

Was there any discussion at the corporate level about the morality, the ethics, of that, in terms of impact on people's health and lives?

Ms. RETZLAFF. So as I said in my testimony, I was comfortable with that price increase, first, because of the company's commitment to invest generously in patient access programs. Those are important. We didn't want the price increase to disadvantaged patients in any way. And second, the company's commitment to reinvest into research and development. And I will just say that we believe that there is a need for a new and better treatment for toxoplasmosis.

Mr. CONNOLLY. Would you agree, whatever your motivation and your altruistic instincts, that from a public relations point of view, it didn't work out so well?

Ms. RETZLAFF. We had challenges from a public relations point of view, and I believe it is because there was a lot of misinformation, and there continues to be a lot of misinformation out there.

Mr. CONNOLLY. Well, I would suggest to you, and I know he is no longer your CEO, but when you have an individual behave the way Mr. Shkreli did when he was CEO, and in a public appearance today, and in his tweets, he has put a pretty ugly face in front of the public in terms of the industry, its motivation, its profit motivation, its concern for patients, any sense of ethical responsibility.

And I would echo what Mr. Lynch said. It has unfairly damaged a whole industry, because of the practice of one CEO at one company.

I just think—I would hope—it would cause a very profound reexamination about the practice of jacking up prices the way Turing did with this one.

I yield back.

Chairman CHAFFETZ. I thank the gentleman.

We will now recognize the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. CARTER. Thank you, Mr. Chairman.

Mr. Merritt, isn't it true that your organization, PBMs, pharmacy benefit managers, isn't it true that three of your member companies control over 75 percent of the PBM market?

Mr. MERRITT. I don't have exact numbers, but there are ——

Mr. CARTER. I have it. It is 78 percent, to be exact.

Mr. MERRITT. Yes.

Mr. CARTER. Seventy-eight percent are controlled by three different companies.

Mr. MERRITT. Yes, and they get discounts for their customers, too.

Mr. CARTER. Mr. Merritt, are you aware of the term MAC, maximum allowable cost?

Mr. MERRITT. Yes.

Mr. CARTER. You are aware that. And you understand that that is a PBM-generated list of drugs that determines the maximum amount that an insurance sponsor will pay for a medication. In other words, they tell the pharmacy what you are going to pay.

Mr. MERRITT. Yes, it was actually created ——

Mr. CARTER. That is what MAC is.

Mr. MERRITT. It was created by Medicare, not PBMs.

Mr. CARTER. And there are no two MAC lists that are the same. Each PBM generates their own separate list, correct?

Mr. MERRITT. Right, kind of like PSAOs have their own list for how much they ——

Mr. CARTER. They choose the products they want on it, and they are the ones who dictate that.

So, on the other side, PBMs also have a MAC list on how much they will charge the insurance company, and that is a different MAC list. Is that correct?

Mr. MERRITT. Sometimes. All the different companies are different.

Mr. CARTER. All the different companies are different, but they have one list here that they are going to reimburse the dispenser at. They have another list here that they are going to charge the insurance company that they are representing. So you have two different lists here.

Don't you find that somewhat awkward? And don't you find that to be a situation where a PBM could distort the market greatly?

Mr. MERRITT. No, because that is a decision negotiated in a contract between a client and a PBM, and there are a million different kinds of contracts, including those. And if the client thinks it is in their interest to have that ——

Mr. CARTER. But the point is, Mr. Merritt, that you are deciding what you are going to reimburse the dispenser for it, and you are deciding what you are going to charge the insurance company for it. Therein lies the difference.

Are you familiar with the term spread pricing?

Mr. MERRITT. Yes.

Mr. CARTER. You are familiar with that?

Mr. MERRITT. I am.

Mr. CARTER. And you understand what spread pricing is?

Mr. MERRITT. Yes.

Mr. CARTER. That is when the price of the drug goes up. It costs the pharmacy more to buy it, but yet, you are still reimbursing at the lower rate.

For instance, in Turing, when Daraprim was $13.50 a pill, if you had it on the MAC at $13.50, if you didn't increase that MAC and she went up to $750 a pill, you would still be reimbursing that dispenser $13.50, yet you would be charging the insurance company $750.

Mr. MERRITT. No.

Mr. CARTER. That is spread pricing. That is what is happening, because you are not increasing—you are not updating—the PBMs are not updating their MAC lists.

Mr. MERRITT. That is inaccurate. MAC lists are updated ——

Mr. CARTER. That is accurate. If that is inaccurate, the let me ask you, Mr. Merritt, why is it that just recently—and let me quote here.

At a recent hearing of the Judiciary Committee, one of your largest member companies, who I notice aren't here today, and I am very disappointed by that. I am sorry that you have to represent them.

We invited them, I believe, Mr. Chairman. They decided not to come.

Anyway, at the Judiciary Committee, one of your largest member companies testified in December that they have teams of people who constantly update MAC lists. Is that correct?

Mr. MERRITT. I don't know about that specific company, but industrywide, PBMs update MAC lists regularly.

Mr. CARTER. They update them regularly, and that was the testimony in the Judiciary Committee.

If that is true, don't you find it somewhat odd that CMS found it necessary to mandate, to require, that these MAC lists be updated every 7 days and that 26 States have passed laws requiring PBMs to update their MAC lists? Don't you find that somewhat odd, if you have teams of companies doing this?

Mr. MERRITT. You just don't know why that happened. Drugstores want higher payments, and they lobbied for those changes and got them.

Mr. CARTER. Drugstores just want to get paid what they are paying for it. When companies go up from $13.50 to $750, that is a problem, when we are only getting reimbursed—when they are only getting reimbursed $13.50. That is where the spread pricing comes in.

I noticed that the profits of the PBMs have increased enormously over the past few years, in fact, almost doubled. I find that very disturbing, particularly when you are talking about spread pricing.

Mr. MERRITT. Going back to Turing ——

Mr. CARTER. Let me ask you something, Mr. Merritt, and I want to switch gears here real quick, okay? Just let me ask you something.

As you know, I formerly owned three independent retail pharmacies. I had a family member who got a prescription filled at my pharmacy. She got it filled at my pharmacy. Later on that night, she got a call at home from the insurance company, encouraging her to use mail-order pharmacy, a mail-order pharmacy that is owned by the PBM.

Now don't you find that a conflict of interest, when a PBM not only owns the pharmacy, but they are reimbursing here, they are setting the reimbursement? Is that not a conflict of interest? How can it not be a conflict of interest?

Mr. MERRITT. The Federal Trade Commission looked into that and said there are no conflicts and these benefit patients.

Mr. CARTER. Mr. Merritt, that is a conflict of interest. I have actually had experiences where I have adjudicated a claim—for those of you who do not know, adjudicate means my computer calls his computer. It tells me what they are going to pay me. I have adjudicated a claim, and it told me they weren't going to pay for it. They weren't going to cover it. While this patient was still in my

lobby, they got a call from the PBM saying, hey, you can use our mail-order pharmacy.

That is a conflict of interest.

Thank you, Mr. Chairman.

Chairman CHAFFETZ. I thank the gentlemen.

We will now recognize the gentleman from Pennsylvania, Mr. Cartwright, for 5 minutes.

Mr. CARTWRIGHT. Thank you, Mr. Chairman. And I thank you for calling this hearing.

I am obviously concerned about these price increases on a number of levels, but one of the levels is as a former hospital director myself.

Mr. Schiller, because Isuprel and Nitropress are hospital-administered drugs, hospitals, it is hospitals that are bearing the biggest burden of your price increases. Am I correct in that?

Mr. SCHILLER. That is correct.

Mr. CARTWRIGHT. So last year, the Cleveland Clinic reported that price increases for Isuprel and Nitropress added $8.6 million to its budget.

And Isuprel and Nitropress are both heart medications. Am I correct in that?

Mr. SCHILLER. Correct.

Mr. CARTWRIGHT. Given the choice between paying higher prices and risking the lives of their patients, most hospitals choose to knuckle under and pay the price. Am I correct in that?

Mr. SCHILLER. I assume that is correct, yes.

Mr. CARTWRIGHT. So by raising the price of these medications exponentially, you are forcing hospitals to make that decision between their budgets and, essentially, their patient's life and well-being, almost like holding the hospitals own patients as hostages against them.

Of course, Valeant was not the first company to raise prices. Valeant actually bought Isuprel and Nitropress from a company called Marathon Pharmaceuticals, correct?

Mr. SCHILLER. Correct.

Mr. CARTWRIGHT. And Marathon Pharmaceuticals acquired the drugs in 2013 from another manufacturer. Marathon also raised prices in the 2 years it owned Isuprel and Nitropress by about 400 percent each. Marathon's price, its increase, had a net impact to the Cleveland Clinic at that time of $2.8 million.

And the Cleveland Clinic is not alone in bearing the burden of rising prescription drug prices. Johns Hopkins Hospital up in Baltimore sustained an impact of $20 million last year, of which $4 million was attributed to price increases for injectable drugs like Isuprel and Nitropress.

These price increases hurt hospitals in ways that reach far beyond the immediate care of patients. They also divert much needed funding from research and other programs and technologies that improve care.

Look, the truth is hospitals are struggling in this country. We have to keep hospitals alive.

There is no greater impact to your health care than when your local community hospital has to close. I have seen this. They trim their budgets. They trim their budgets. They absorb these price in-

creases. They absorb the cost of uninsured care. And they absorb it, and they absorb it, and they absorb it until they can't absorb it anymore, and they can't cut back nursing and staff anymore, and patients lives become endangered, and they have to close.

There is no greater impact to you than when your local hospital closes. So when you are having a heart attack, it is not a 10- or 15-minute drive to the hospital. It is a 40- or 50-minute drive to the hospital. And that can be the difference between life and death.

So, Mr. Schiller, I understand from information your company has provided to this committee that Valeant has spent a "nominal amount of money on research and development for Isuprel and Nitropress." Am I correct in that?

Mr. SCHILLER. That is correct.

Mr. CARTWRIGHT. Well, that is the usual vindication of these exponential drug price increases, that we need to do this because it is funding research. But you have admitted there is a nominal amount of money on research and development for Isuprel and Nitropress, the very drugs that are experiencing this exponential price increase.

Let me ask you this, Mr. Schiller. Isn't it also true that one of the "key elements" of your company's operating philosophy is, and I quote, "Do not bet on science. Bet on management." Have I quoted that correctly?

Mr. SCHILLER. That is a quote from Mike Pearson. I don't know what the date is on that. But I would say that this company has changed quite a bit.

Mr. CARTWRIGHT. Mike Pearson is at your company?

Mr. SCHILLER. Yes, he is.

Mr. CARTWRIGHT. And you have turned over a new leaf since him? Is that it?

Mr. SCHILLER. No. I think if Mike were here, if you look at his quotes over the last year or 2, he has changed the way he has described the company, and our focus and emphasis on research and development.

I would also add, in the pharmaceutical industry, it is very rare to trace a dollar of revenue to a dollar of R&D. It is almost ——

Mr. CARTWRIGHT. Mr. Schiller, I understand that shareholder return is your primary concern and objective, but I say it is unconscionable to deprive hospitals of the resources they need to fulfill their primary objectives —caring for patients and developing new and better treatments for the future.

Again, Mr. Chairman, I appreciate you bringing this hearing and calling all of this information to light, and I yield back.

Chairman CHAFFETZ. I thank the gentleman.

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

Mr. FARENTHOLD. Thank you, Mr. Chairman.

Ms. Retzlaff, you testified that your $750 drug, nobody pays that. Some people get it for a penny. Some people get it for $20. How much am I paying for that? Because the rest of that is either coming from the Federal Government in Medicare, Medicaid; State Governments; or it is coming from an insurance company that is being funded by the premiums that I pay, and hopefully will never need that drug.

So I mean, you make it sound like nobody is getting hurt by this, but everybody in this room is actually getting hurt by these prices, are they not?

Ms. RETZLAFF. So there are only 3,000 patients in the United States that are treated with Daraprim. Twenty-five percent of them are covered by commercial insurance.

Mr. FARENTHOLD. Right. So that is my insurance rates, which have gone greatly up under Obamacare.

Ms. RETZLAFF. So the overall impact, in terms of the budget for any health care plan, is very, very small. It is in the pennies.

Mr. FARENTHOLD. All right, but you guys are potentially setting another trend in the industry. Buy these orphan drugs and jack up the price, or go and buy a generic manufacturer that is the only manufacturer of a generic drug, which brings me to the FDA.

You are saying you are getting down to 10 and 15 months, but you have basically created a 10- and 15-month monopoly for anybody who is a single source of a generic drug to do that kind of price increase and name their price for that drug. Is that not correct, Mr. Flanagan?

Mr. FLANAGAN. Can you ask the question a different way? Can you clarify, please?

Mr. FARENTHOLD. All right. So the amount of time it takes the FDA to approve a generic drug manufacturer, if there is only one manufacturer in the generic market, they basically have the 15 months it takes—and I am going to argue that number with you. They have an exclusive ability to sell that drug for 15 months at $1 million a pill, if they choose to do that.

Mr. FLANAGAN. Right.

Mr. FARENTHOLD. So what takes so long to do this? I am not an expert in what is involved in approving a place to manufacture drugs. I assume if you can manufacture XYZ drug in a place, you have a clean facility, there are no roaches on the assembly line. If you want to add another product, why should it take 15 months to get that approved? I assume you can test whatever drug they make and see if it is what they say.

What else is involved there? And if they do screw up making it, 1–800–BAD–DRUG is going to bankrupt the company.

Mr. FLANAGAN. So, basically, to review a generic drug, there is the scientific and technical review, bioequivalence, chemistry, and manufacturing controls, stuff like that.

Mr. FARENTHOLD. How much of this is really necessary and how much of it is regulations that are what color is the toilet paper?

Mr. FLANAGAN. So the reason we have 88 percent prescription penetration in the United States is because when you or your family go to the pharmacy to get a generic drug, that you can be confident that it is the same as the brand. A review ——

Mr. FARENTHOLD. Why does it have to take 15 months? How difficult is it to get their output, analyze it, and see what it is? I can't believe that takes 15 months. The TSA can, in a matter of seconds, tell whether or not I have an explosive in my bag by just swiping something on it. I mean, isn't there technology there that will make it faster and better? Why aren't we using it?

Every day you delay getting a competitor on the market is a day companies can screw the consumer.

All right, so let me ask you one other question on your numbers. Before at a time when Dr. Woodcock was testifying, my B.S. detector went off when she said, oh, we have our number of applications way down. But she also mentioned that a great many of them were, and I think her words were returned due to technical defect.

So are you artificially decreasing your numbers and wait time as a result of somebody turning something in without a t crossed or i dotted?

Mr. FLANAGAN. No.

Mr. FARENTHOLD. All right, so give me an example of what one of those technical defects is going to be.

I see it with the VA all the time in the casework I do. "Well, you don't have this piece of paper, or you don't have that. You go to the back of the line."

My fear is that we have a bureaucracy at work here that is costing the taxpayers money, and the amount we have to reimburse Medicare and Medicaid for. And it is costing the insured money based on higher rates they have to pay for their premiums. And the taxpayers are having to pay premium supplements under Obamacare.

Mr. FLANAGAN. Mr. Chairman, do I have time ——

Mr. FARENTHOLD. Yes, you have the time to answer. I am done after this question.

Chairman CHAFFETZ. Please, answer the question.

Mr. FLANAGAN. So you asked for two examples. One example would be if the application doesn't show that the generic drug would be bioequivalent to the brand. So we want to make sure it is going to work the same as the brand.

Another example would be that if the facility it is manufactured in is substandard and can't produce a safe, quality drug.

Mr. FARENTHOLD. Again, the amount of time this takes is, I think, criminal. And add to that we have a tort system with plenty of attorneys willing to go after any company that screws up even the slightest. This has to be fixed.

Thank you. I yield back.

Chairman CHAFFETZ. The gentleman makes a good point, and I plan to ask some further questions on this.

But we will now recognize the ranking member, Mr. Cummings, for 5 minutes.

Mr. CUMMINGS. Ms. Retzlaff, when Turing—and I am going to remind you that you are under oath, by the way—when Turing increased the price of Daraprim by more than 5,000 percent on August 11, 2015, you were hoping to avoid attracting attention from the media and the public. Is that right?

Ms. RETZLAFF. Yes, of course.

Mr. CUMMINGS. Yes, you were. Despite your best efforts, the price increase soon became a major news story. On October 8, an outside consultant sent an email to a member of Turing's board of directors laying out a PR strategy—I am sure you paid a lot for PR here—for Turing to respond to this unwanted attention.

The consultant suggested that the board remove Mr. Shkreli as CEO and, and I quote, "as early as next week." The consultant also suggested that Turing reduce the price of Daraprim. Is that correct? Come on, talk to me.

Ms. RETZLAFF. I believe that is correct, yes.

Mr. CUMMINGS. You don't know? You have these memos in regard—do you have an answer for me?

Ms. RETZLAFF. Yes, that is correct.

Mr. CUMMINGS. All right, so, okay. So he wrote, and I quote, "The price drop has to be significant and tied to something. ...This cannot be seen as something that appears to be as arbitrary as the price hike in the first place."

Do you remember that?

Ms. RETZLAFF. Yes, I do.

Mr. CUMMINGS. All right. The consultant recommended that Turing issue a press release announcing "a package of assistance programs for patients." Do you remember that?

Ms. RETZLAFF. Yes, I do.

Mr. CUMMINGS. Did you follow those instructions?

Ms. RETZLAFF. Not all of them.

Mr. CUMMINGS. All right. We are going to talk about that.

The consultant also recommended that Turing "specifically tie profits from Daraprim to the research and development of a new and more effective treatment for Daraprim patients." Do you remember that?

Ms. RETZLAFF. Yes, I do.

Mr. CUMMINGS. And that is exactly what you are doing today. And the consultant also suggested a long-term strategy of "forcing a focus on Turing as a research and development company, not a pharma-hedge fund hybrid." Do you remember that?

Ms. RETZLAFF. Yes, I do.

Mr. CUMMINGS. Now, Ms. Retzlaff, this email was forwarded to you by a board member. Do you recall receiving it?

Ms. RETZLAFF. I believe I did, yes.

Mr. CUMMINGS. Okay. It seems that Turing followed most of the consultant's advice with one glaring exception. You never lowered the price of Daraprim.

Let me read another email you received from a Turing marketing executive on October 2, 2015, since you are so concerned about patients and discounts. She wrote, and I quote, "The cause of the inpatient hospital issue is pretty clear now—it's price."

She continued to quote, and this is what she said, "We all realize that we need a solution ASAP, but we also don't want to commit to something beyond the smaller pack that will potentially debilitate the business and risk future revenues."

Do you remember that?

Ms. RETZLAFF. Yes, I do.

Mr. CUMMINGS. Now, Ms. Retzlaff, this email indicates that Turing was aware that its price increase had created issues for inpatient hospitals, as Mr. Cartwright was just saying. It also indicates that Turing was unwilling to do anything to risk future revenues, including actually lowering the price for everyone.

Is that fair? Is that a fair reading?

Ms. RETZLAFF. No, it is not a fair reading.

Mr. CUMMINGS. Well, give me what is a fair reading.

Ms. RETZLAFF. So, yes, we did learn that price seemed to be an issue with hospitals. So then, in November, we actually announced a discounting program for hospitals of up to 50 percent. And then,

based on feedback from hospitals, we also introduced a smaller count bottle, to alleviate their financial burden.

Mr. CUMMINGS. I am glad you said that. Now let's move on.

Let me read an excerpt from an email that Ed Painter, Turing's head of investor relations, said to Patrick Crutcher, the director of business development, on September 26, 2015. Mr. Painter asked if there was a lower price Turing could announce that would discourage generics from entering the market and generate positive PR. Mr. Crutcher replied, and I quote, "It's best we don't PR something like that unless it's something we're willing to commit to doing." He added, "Only thing to PR is the PAP and R&D."

Mr. Painter replied jokingly, and this is the quote—and maybe you can interpret this for me. Maybe it is millennial talk, I don't know. But it says, "My Rs bangen D and my PAP can't rap."

Ms. Retzlaff, do you know what that meant, what he was saying?

Ms. RETZLAFF. I'm sorry, I do not.

Mr. CUMMINGS. But this was sent to you. You didn't read it? You didn't ask him?

Ms. RETZLAFF. I read it, but I don't what that last sentence means.

Mr. CUMMINGS. Okay. There are very real issues for people with compromised immune systems. And this email indicates that, despite the promises of lowering the price internally, Turing has no desire to actually fix what it has broken.

And the thing that really gets to me, Mr. Shkreli, who just sat there, your former CEO—is that right?

Ms. RETZLAFF. That is right.

Mr. CUMMINGS. He walked out of this hearing a few minutes ago, and before he probably got out of the door, he sends a tweet calling everybody on this committee imbeciles. Did you know that?

Ms. RETZLAFF. I was not aware of that.

Mr. CUMMINGS. So instead, you all spent all of your time strategizing about how to hide your price increase behind positive PR and coming up with stupid jokes—no, no, no—while other people were sitting there trying to figure out how they were going to survive.

Ms. RETZLAFF. No, that is not true.

Mr. CUMMINGS. I have said it before. This is about—a lot of this is about blood money.

And, Mr. Schiller, one question for you. You said, and I quote, a few minutes ago, you said, "In some cases, we have been too aggressive in increasing prices." Do you remember saying that?

Mr. SCHILLER. Yes, I did.

Mr. CUMMINGS. Now, just so that we can be effective and efficient in what we do, are you all going to be reducing prices?

Mr. SCHILLER. We have looked across our portfolio, and we have reduced prices.

Mr. CUMMINGS. Are you going to continue to reduce prices?

Mr. SCHILLER. We're ——

Mr. CUMMINGS. You said that you are learning your lesson. You said that Pearson apparently now has a new attitude. I want people watching this to know that they are not being ripped off.

Mr. SCHILLER. We looked across our portfolio. We took a 10 percent reduction in two of our largest business units, our dermatology

division and our ophthalmology division. We reduced by 10—up to 30 percent, Nitropress and Isuprel. We increased our patient assistance programs. We're going to continue to look at ways to improve access at affordable prices. At the same time, manage our business so we can invest in R&D, and manufacturing in places like Rochester and Greenville, South Carolina.

We have made mistakes. We grew very quickly. We are acknowledging those mistakes. We are going to change. We are going to be a responsible corporate citizen and part of the health care community. And we have made changes.

Mr. CUMMINGS. So you are going to continue to make those changes? You will continue to make changes?

Mr. SCHILLER. We are always going to look to do the right thing, but we have made significant changes.

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

Chairman CHAFFETZ. Thank you.

I now recognize myself.

Ms. Retzlaff?

Ms. RETZLAFF. Yes.

Chairman CHAFFETZ. The proper role of Congress is not to micromanage a private company. It is not my role. And I do believe in the right to profit. I think profit is a motivator that does a lot of good.

But I also do believe that it is imperative that people tell the truth, that they are ethical, that they not mislead the public, that they properly represent the truth.

Would you disagree with that or agree with that?

Ms. RETZLAFF. I agree with that.

Chairman CHAFFETZ. All right, let me show you video. This is just a couple weeks ago. This is, I believe, on channel 5. This is Mr. Shkreli.

[Video shown.]

Chairman CHAFFETZ. Is that true?

Ms. RETZLAFF. We invest 60 percent of our net revenues into research and development.

Chairman CHAFFETZ. That is not all of it, is it?

Ms. RETZLAFF. He may have meant profits. He may have misquoted, but we ——

Chairman CHAFFETZ. No. He said, "We take all of our cash, all of our extra profit."What is "extra profit"?

Ms. RETZLAFF. I'm not sure what he meant by extra profit. What he could—what he could've meant is that once we deal with expenses, just operational, administrative expenses, then we take that money and we reinvest in R&D.

Chairman CHAFFETZ. Are you really testifying that you are losing money?

Ms. RETZLAFF. Yes. I think you have seen our financial statements.

Chairman CHAFFETZ. Yes. You are not losing money. You are raking it in hand over fist as fast as you can.

Let me ask you about some of that.

Ms. RETZLAFF. Sure.

Chairman CHAFFETZ. And first, let me ask you, are you planning another price increase?

Ms. RETZLAFF. No, I am not.

Chairman CHAFFETZ. That is not what the documents show. We will release them to the media, and you can fight that one in the public.

But based on this—do we know who Adam Stone is?

Ms. RETZLAFF. He's an investor.

Chairman CHAFFETZ. Yes. And he wrote to Mr. Martin Shkreli. He wanted the public relations to calm down. He wanted the politicians to slow down a little bit.

Mr. Shkreli said, "We can wait a few months for sure."

That sounds like a planned price increase to me.

Ms. RETZLAFF. What was the timing of that email?

Chairman CHAFFETZ. December.

Ms. RETZLAFF. December. Well, subsequent to that, Mr. Shkreli is no longer the CEO. So I will have final call on those business decisions.

Chairman CHAFFETZ. And we will see what happens with that.

The company has been in business how long?

Ms. RETZLAFF. We started operations in February of last year.

Chairman CHAFFETZ. So about a year.

Ms. RETZLAFF. Yes, close to a year.

Chairman CHAFFETZ. And within the first year, you have given out raises?

Ms. RETZLAFF. Yes, we have.

Chairman CHAFFETZ. Given out bonuses?

Ms. RETZLAFF. I don't believe we've given out bonuses as of yet.

Chairman CHAFFETZ. Your spreadsheet says 30 percent across-the-board, everybody gets a bonus.

Ms. RETZLAFF. But we haven't paid out any bonuses.

Chairman CHAFFETZ. We have this document from the agenda of October 14, 2015. One person had a pay increase of $250,000 to $600,000, correct?

Ms. RETZLAFF. Correct.

Chairman CHAFFETZ. Another person had a pay increase of $275,000 to $600,000, correct?

Ms. RETZLAFF. Correct.

Chairman CHAFFETZ. Another person had a pay increase of $160,000 to an annual salary of $800,000, correct?

Ms. RETZLAFF. I'm sorry, what was that one?

Chairman CHAFFETZ. It went from an additional $160,000 to $800,000.

Ms. RETZLAFF. I'm not aware of that one.

Chairman CHAFFETZ. We will release it. You can look at it. It is from your agenda in October.

Now, again, people can make a profit. They can pay exorbitant salaries. But don't come before the American people and cry and shed a tear and say, "Well, we are not making any money." And don't have the person who is the major investor into the company come and say we invest all of our cash into research and development.

We have emails here that show they are not even sure if they are going to invest in research and development. A person wanted to check off and make sure that was even part of the plan. And it sounds like a contrived PR plan in order to do that.

Do you know who Metro Yacht Charters is?

Ms. RETZLAFF. Yes, I do.

Chairman CHAFFETZ. Why would you know them?

Ms. RETZLAFF. I believe we rented Metro Yacht Charters for a sales force meeting.

Chairman CHAFFETZ. Yes, for party, $23,000.

Did you spend money on fireworks?

Ms. RETZLAFF. Yes.

Chairman CHAFFETZ. Did you spend money on a cigar roller for the yacht night, 800 bucks?

Ms. RETZLAFF. Yes, we did.

Chairman CHAFFETZ. Okay, so don't tell me that you are losing money. Don't try to pretend and tell us that this $750 is justified when you have a woman who has AIDS and what is she supposed to do? Is she supposed to tweet Martin and try to get that for a penny? Is that how that works?

Ms. RETZLAFF. No, that doesn't work—that is not how it works.

Chairman CHAFFETZ. It doesn't work, I get it.

Ms. RETZLAFF. That is not how it works.

Chairman CHAFFETZ. So who pays the $750?

Ms. RETZLAFF. You know, $750 is paid primarily by commercial insurers. That represents the minority of patients, about 25 percent. Again, that is a very small number of patients. There are only 3,000 patients.

Chairman CHAFFETZ. But it generates a lot of revenue, doesn't it?

And who pays those insurers? Are they just the big, bad insurance companies that are raking in all these profits? Who are these insurers? Who pays them their money who then have to pay you?

Ms. RETZLAFF. I suppose it is big companies that are insuring their employees, for the most part.

Chairman CHAFFETZ. No, it is people.

Ms. RETZLAFF. And, again, because there are so few patients treated with Daraprim, the impact on their budgets, the budget impact, is very, very small. It is in the pennies.

Chairman CHAFFETZ. What is your first year revenue?

Ms. RETZLAFF. This year's revenue? Our gross sales were $98. Our net sales were $20.

Chairman CHAFFETZ. They were what? $20 million, right?

Ms. RETZLAFF. $20 million, yes.

Chairman CHAFFETZ. Yes. And this is one drug that just services about 3,000 people.

Ms. RETZLAFF. Yes.

Chairman CHAFFETZ. And then you wonder why the average person who is trying and scraping by, and they see their insurance rates go up double digits, screaming high, it is because of people like you. That is why they are going up. It is one of the key reasons.

Ms. RETZLAFF. I will add, and I think I need to be clear here, that Turing is a specialty pharmaceutical company. We are 139 employees, 36 of which are dedicated to R&D. We are absolutely committed to taking that revenue that we generate from Daraprim and investing it in next-generation treatments, as well as other neglected diseases. That is a fact.

Chairman CHAFFETZ. I think that is legitimately part of what you are doing, but what Mr. Shkreli is saying publicly, what you are putting out to the public, to say that you are losing money, it is not true. And if you are going to continue to lie to the American people, the Congress is going to continue to probe. I can investigate under the House rules, the House of Representatives, the Oversight Committee can investigate anything at any time.

Ms. RETZLAFF. Right. I am being truthful. I am looking at our income statement right now and our operating profit for 2015.

Chairman CHAFFETZ. I have additional questions. I have gone far past my time.

Let's recognize the gentlewoman from Michigan, Ms. Lawrence, for 5 minutes.

Ms. LAWRENCE. Thank you, Mr. Chairman.

I just wanted to, before I start my questions, just state that heart disease and stroke kill one in three women, more than all the cancers combined. I personally experience the miracle of medicine and the need when my husband had a heart attack.

So I really want to talk about R&D. In the 2014 proxy statement filed with the SEC, Valeant reported that one of the key elements of the company's operating philosophy is, and I quote, "Do not bet on science. Bet on management."

And it has been reported, financial reports, that Valeant R&D was equal to only 3 percent of sales between 2014 and 2015.

Mr. Schiller, is this correct? Three percent of sales is R&D?

Mr. SCHILLER. This past year, it would have been about 4 percent of total sales, but a big chunk of our portfolio are consumer products or generics, which don't require R&D. If you look at our branded pharmaceuticals, the number is 8 percent. And then last year, if you look at what we spent to acquire late-stage projects, which we later commercialized, it was over $1 billion.

So we have a significant commitment. We have over 200 active programs in R&D. We expect this year to get approval for a significant new glaucoma drug and a new biologic for the treatment of moderate to severe plaque psoriasis. And we have projects in phase 1, 2, and 3, which we hope would bring fruit and new products in the future.

There is tons of risk associated with it, but that comes with the territory. And we will continue to invest in that portfolio.

Ms. LAWRENCE. Three percent for R&D. You said it was $1 billion? What is 3 percent?

Mr. SCHILLER. If you look at our total revenue, we spent around 4 percent of revenue. But again, we have a very significant percentage of our revenue which is consumer products or generics, where there is no R&D required. So it is about 8 percent on our branded pharmaceutical business, which does require R&D. And then in addition, we spent $1 billion on acquiring late-stage products last year, over $1 billion.

Ms. LAWRENCE. Committee staff received an email from Dr. Benjamin Levine, who is conducting NIH-funded research on exercise intolerance and heart failure. Isuprel—Isuprel, am I saying that correct?

Mr. SCHILLER. Isuprel.

Ms. LAWRENCE. Isuprel is a drug that stimulates the beta receptors of the heart, natural pacemakers, and causes the heart rate to go up using the same biological pathways.

Now, Dr. Levine uses this drug to conduct his research and has been impeded in meeting his commitments to NIH because of the increase of cost of this drug. He has attempted to reach out directly to your company to no avail.

Here we have a doctor who is focused on doing real research for people's lives. Mr. Schiller, what should Dr. Levine do so that he can use this drug in his research to fulfill the requirements, to perhaps extend the lives of individuals? What do you recommend?

Mr. SCHILLER. I'm not aware of that, but now that you have made me aware of it, if you would give me his number, I will call him tomorrow and make sure that we help him wherever we can, make sure that it is in a compliant fashion.

Ms. LAWRENCE. Because, sir, you have to know the connection, your research that you are funding. But also, if you are increasing the drugs that are being used in research, you must recognize the impact you are having.

Mr. SCHILLER. Well, of course, we do. And if there is ever a situation where we need to do something about access, that is something we are going to do. So I am happy to talk to him tomorrow and see if we can rectify that situation. I am assuming it is all compliant. I am assuming we can take care of that tomorrow.

Ms. LAWRENCE. I just want to say this, before my time runs out. In America, while we are a leader in the world of R&D and medical research in some areas, we have turned the focus from medicine being a part of healing of people to a profit-making industry. Every business should make a profit, but it has turned from profit to greed.

And this is why this is so important to me. I know there are senior citizens who are making decisions between food and drugs, the medicine that they need to live. And then there is someone in your industry that is buying a yacht. And I want you to be able to be part of the American economy and pay salaries that will allow a basic and even an advanced, based on education, quality-of-life. But we are at the point where greed is not acceptable in America, and I am very concerned about that.

Chairman CHAFFETZ. Thank you. The gentlewoman's time has expired.

We now recognize the gentleman from North Carolina, Mr. Meadows, for 5 minutes.

Mr. MEADOWS. Thank you, Mr. Chairman.

Thank you for holding this hearing, and, further, thanking the staff for bringing this to the attention of the American people. It was obviously the work of this committee, both majority and the minority, where we have highlighted this issue.

But it is truly an issue that must be addressed. And the best way to address it is to put companies that do the kind of, to use a tweeted-out word, imbecile pricing strategy, is to put you out of business.

So the barrier to putting you out of the business, obviously, Mr. Flanagan, the FDA plays a role in that. And let me tell you why I am concerned, because I hear from a number of stakeholders that

they are afraid to even give me the details for fear of retribution from FDA, in terms of the potential approval process that we go through.

And the reason why companies like this can compete is because there is no one to compete against them. They are small little drugs, orphan drugs. They are things that for the average company don't pay. For the big pharmaceutical company, it doesn't pay. But there are a thousand—I mean, to have $20 million sales, $90-some million sales that was just testified, lots of companies that would be willing to take that on, smaller companies.

So Dr. Woodcock gave her testimony. Did you agree with all of her testimony, Mr. Flanagan?

Mr. FLANAGAN. Yes, sir.

Mr. MEADOWS. Okay. So you agreed with her. She testified also in the Senate just a few days ago. Are you familiar with her testimony there?

Mr. FLANAGAN. Yes, sir.

Mr. MEADOWS. So I guess the question, with that Senate testimony, we are talking about all the progress we are making and how we are 90 percent, and we made great progress. But I look at her testimony, and it looks like you have only approved 25 percent of the applications over a 3-year period. Do you call that a winning percentage?

Mr. FLANAGAN. So right now, it usually ——

Mr. MEADOWS. Yes or no, a winning percentage? Twenty-five percent over 3 years, is that a good track record?

Mr. FLANAGAN. I can't answer the question yes or no. It usually takes, on average, four review cycles to approve a generic drug submission. So it is not that way for the brand side. On the brand side, there is about a 90 percent ——

Mr. MEADOWS. I am talking about generics. So let's look at this. If you would put up the first slide for me, one of the concerns I have is with the ambiguity, and we have this particular letter, which actually is a letter from Dr. Woodcock. It says that, in terms of the application process, that with certain types, that they will go ahead and allow that application to be filled out with less than 12 months of stability data. It says, generally, we will allow it to happen with 6 months. And on ANDA drugs, we will actually allow the application process to be started with 3 months of stability. Would you agree with that?

Mr. FLANAGAN. I'm actually not the expert on stability. That is out of the Office of Pharmaceutical ——

Mr. MEADOWS. So you are an expert on ——

Mr. FLANAGAN. It is a different office than me.

Mr. MEADOWS. All right. I thought you were the technical expert, is what you just said a few minutes ago.

Mr. FLANAGAN. Unhappily, just in my little space.

Mr. MEADOWS. Okay. So would you agree that this is typically the way the FDA does business, that they give faster approval for generics in the application process?

Mr. FLANAGAN. I don't think that our approval ——

Mr. MEADOWS. Okay, let me cut to the chase. I have 1 minute left.

Put up the other slide, which actually—go on to the case 2 slide, if you would?

Here is my concern. I have a number of stakeholders throughout North Carolina and across the country who are willing to compete with these two companies, and they are willing to provide the drug to compete with them. And they have been told by the FDA, "Well, we have to get a little bit more information. We have to wait for 12 months of stability data," instead of going with their own internal data. If you look, it says a company initially submitted 3-month-long term, accelerated process for three batches.

Can you do that consistently for all of these that want to compete with these kinds of companies?

Mr. FLANAGAN. So I understand your question, it is the same issue. The stability issues are out of the Office of Pharmaceutical Quality, which is just a different office.

Mr. MEADOWS. All right. So let me close with this, is there anything the FDA can do to make sure that we can speed up the process, so we can compete with companies who are willing to price gouge on a regular basis? Can you speed up your process, Mr. Flanagan?

Mr. FLANAGAN. Mr. Chairman, can I answer? I don't know how the rules work.

Chairman CHAFFETZ. Please, yes.

Mr. FLANAGAN. So two things. First is if a submission comes in the door and it is for a product for which there isn't generic competition or for which there is a drug shortage, we consider those to be priorities, and we expedite their review, like a ——

Mr. MEADOWS. Well, that is interesting, because I have a letter that basically is from Dr. Woodcock that would just that shortage is not part of your decision-making process. So you are saying her letter is wrong?

Mr. FLANAGAN. Well, I would need to see the letter. We for sure consider drugs ——

Mr. MEADOWS. We will follow up on a number of other questions. I am way beyond my time.

Chairman CHAFFETZ. The gentleman's time is expired.

We do expect votes on the floor soon, so we will now recognize the gentlewoman from New Mexico, Ms. Lujan Grisham, for 5 minutes.

Ms. LUJAN GRISHAM. Thank you, Mr. Chairman. I really appreciate you holding this hearing, and, quite frankly, I share my colleagues' outrage. I think outrage is actually too soft a word, given what we have heard today, what we knew before today, what we still don't know after today, about what is really going on to make sure that there is fair pricing, protected access from the patient's perspective to lifesaving drugs and treatments.

I want to talk a little bit in my statement and get to my question about FDA approval and making sure that we do everything we can here to give the right opportunity so that we are focused on the right thing here, which are patients. That is the right thing to focus on here.

But in all the emails that you have had members read to you—and I have the email of my own, if I have time, that I am going to read—that make it very clear, particularly from Turing, that

FDA approval and that R&D, that none of those issues were issues that caused the price gouging that we are talking about today.

So as we sort of figure out what we can do better, I am really interested in what we ought to be doing to make sure that there is real accountability into an entire industry that has made it their practice to put profits and not small profits, outrageous profits, before the patient.

And, actually, Ms. Retzlaff, you, certainly, indicated that really it is not patients who pay. It is hospitals and insurance companies. There are a lot of people that don't love insurance companies and hospitals, so we will just shift, try to shift the focus.

Where do you suppose the majority of their reimbursements come from, Ms. Retzlaff?

Ms. RETZLAFF. Again, as I said, there are so few patients treated with Daraprim, and only about—very few that are covered by commercial insurance. The overall ——

Ms. LUJAN GRISHAM. When you are dying ——

Ms. RETZLAFF. The overall impact is very, very small. And to our knowledge, no commercial insurers ——

Ms. LUJAN GRISHAM. I am going to interrupt you. So when 3,000 people have their HIV/AIDS drugs shifted someplace else, and my copays go up, and my out-of-pocket costs go up, my hospital access goes up, and this country is under-bedded in the hospitals—and do you know who is paying them? Medicare and Medicaid and veterans and TRICARE. And guess who pays for those? I do. Every member in this audience does. Every member of this committee does.

I cannot believe that your indication here is that the cost really, in terms of the number of people who are impacted, is so small that that is really not the issue. It is the issue.

Let's talk about a couple other drugs. Let's talk about another company. Let's talk about Gilead. Let's talk about hepatitis C drugs, Sovaldi and Harvoni, which retail at $84,000 and $94,000, respectively, for a 12-week course.

So we can treat with this drug. We can cure hepatitis C. But because of profit, we are not going to cure it. Instead, we are going to create an environment where people are going to have to have liver transplants.

So I see a pattern here that is incredibly frightening for the overall aspect of getting a handle on health care costs and clearly is a shift from protecting patients in this design.

And it is not a result of R&D. We have many emails from your company that would indicate that directly.

We just passed 21st Century Cures, which is another indication that Congress is very interested in making sure that innovation and research and development, and that the FDA approval without minimizing patient safety, is as streamlined as we can.

And yet, that is not an indication, at least not as a result of this hearing, that that is really an issue about how we determine what drug costs are. Greed is how we determine what drug costs are.

So here is my question. Given what you have stated today, and given the questions and emails that we have provided during this hearing about Turing, would you say that the practices at Turing

are the same practices for all pharmaceutical companies? Or is this just really an issue for your company?

Ms. RETZLAFF. Turing Pharmaceuticals is a research-based pharmaceutical company that invests, is committed to developing and commercializing treatments for rare and neglected diseases. As I said in my testimony ——

Ms. LUJAN GRISHAM. So this is not the practice of everyone else. This is just your practice.

Ms. RETZLAFF. I cannot speak on behalf of other companies. But what I can tell you is that we are an ethical pharmaceutical company. As I said in my testimony, I was comfortable with the price increase of Daraprim provided the company was willing, and it was, to invest in ——

Ms. LUJAN GRISHAM. I am going to reclaim my ——

Ms. RETZLAFF.—generously in patient assistance programs—if I may finish ——

Ms. LUJAN GRISHAM. This is how this works in this hearing. I get to reclaim my time.

Ms. RETZLAFF.—and research.

Ms. LUJAN GRISHAM. The issue is that I think it is clear today that that is not your intent or your motive. We have provided plenty of information here that would not just suggest but clearly identify the opposite of that.

Ms. RETZLAFF. I disagree with you ——

Ms. LUJAN GRISHAM. Mr. Chairman, thanks for exposing these issues.

Ms. RETZLAFF.—respectfully.

Chairman CHAFFETZ. I now recognize the gentleman from Georgia, Mr. Hice, for 5 minutes.

Mr. HICE. Thank you, Mr. Chairman.

I want to go realquickly to you, Mr. Flanagan, regarding the generic backlog and what Mr. Meadows was talking about. Can you provide a little bit more clarity as to how the FDA is prioritizing applications to expedite the review process?

Mr. FLANAGAN. Yes, sir. So there's a policy that's available online. You can find it on the Web site. Basically, certain categories of submissions, like first generics that could potentially open the market to competition, drugs that can mitigate shortage, PEPFAR or HIV drugs, and a couple other specific categories ——

Mr. HICE. So it is based on the disease, the prioritizing, is that what you are saying?

Mr. FLANAGAN. The PEPFAR ones are based on the disease. The shortage is just based on whether—kind of whether there's a shortage out there in providers. And first generics depends on whether the market has already been, you know, opened up to generics.

Mr. HICE. So there is no real standard policy.

Mr. FLANAGAN. There is a standard policy.

Mr. HICE. All right. How long is four review cycles?

Mr. FLANAGAN. It is hard to answer that question, because it depends on how long it takes the applicant to respond back to us.

Mr. HICE. Okay. The targeted action dates, they are assigned, and yet they are aspirational, noncommittal. What is the point of having a targeted action date, if it basically means nothing?

Mr. FLANAGAN. Well, industry very strongly requested them for the following reason. So we have this new user fee program. Beginning in year three of it, you get a goal date that tells you when we are going to act on your submission. But for everything prior to year three, there were no goal dates. Industry needed some kind of information so they could plan product launches and conduct other types of business planning, and they strongly requested that we disclose to them what are aspirational ——

Mr. HICE. But is it true that these dates really are virtually meaningless, because there is no commitment there?

Mr. FLANAGAN. No.

Mr. HICE. All right. Well, according to what you said, they are aspirational. They are noncommittal. And it appears we have months and months and months, 15 months-plus before we ever get these prioritized and get something going, so the targeted action dates basically are meaningless.

Mr. FLANAGAN. Well, again, Congressman, industry strongly requested that we do this ——

Mr. HICE. We are all requesting something be done. That is the problem. You have these targeted dates, but the backlog is not getting any better. It is getting worse.

Mr. FLANAGAN. No. The target action dates say when we are going to take action on each of the submissions in the backlog. It is a way of organizing the backlog and disclosing to all the companies who have submissions in there, here is when we think we are going to move on your submission.

Mr. HICE. Okay, Mr. Chairman, I would like—I have other questions, but I would like to yield the remainder of my time to my colleague from Georgia, Mr. Carter.

Mr. CARTER. I thank the gentleman from Georgia.

Ms. Retzlaff, when Turing bought Daraprim, was it a specialty medication then? No, it was not.

Ms. RETZLAFF. It depends on how you define a specialty medication.

Mr. CARTER. No. I define a specialty medication as one that is available only through specialty pharmacies. You said yourself that access to Daraprim was a problem when the price went up.

Ms. RETZLAFF. When we—when we ——

Mr. CARTER. I reclaim my time.

When the price went up, it became distributed only through specialty pharmacies. I cannot, at my pharmacy ——

Ms. RETZLAFF. That is not true.

Mr. CARTER. It did. You created a specialty medication, and you did it intentionally, because you had a limited market of only 3,000 patients, and you knew you weren't going to be able to make a profit unless you went up on that drug, and it became a specialty medication. You abused the system, is what you did. A PBM owns a specialty pharmacy, and now you are using it only through specialty pharmacies.

Ms. RETZLAFF. May I correct ——

Mr. CARTER. Ms. Retzlaff, Mr. Schiller, let me tell you, I have been practicing pharmacy for many years. I have spent my adult life dispensing medications to help people get well. I find it repulsive what you have done.

I have seen advances in medicine that have been amazing to me. Since I started practicing, we have had advances that are just amazing, and I have always been amazed at the pharmaceutical companies. And when you come in and you rape the public, and you give this a black eye, I find it repulsive.

Mr. Chairman, I want to thank you and your staff for bringing this hearing here, and for all those involved. You have been most cooperative, and I thank you for this.

Ms. RETZLAFF. May I correct a statement?

Chairman CHAFFETZ. Sure. Go ahead.

Ms. RETZLAFF. So when we purchased Daraprim, it was already in a closed distribution model, so we inherited that model from the previous manufacturer. And subsequent ——

Mr. CARTER. Then why did you say that access to Daraprim was a problem when the price went up? You said that yourself.

Ms. RETZLAFF. Access to Daraprim was a problem because of the distribution model that we inherited from the previous manufacturer. That is what I said. And subsequent to that, we have made—we have taken action. We have added ——

Mr. CARTER. You said, when the price went up, it became a problem.

Ms. RETZLAFF. I don't believe that price was the driver of the access problem.

Mr. CARTER. That is not what you said earlier.

Mr. Chairman, earlier ——

Chairman CHAFFETZ. I thank the gentleman.

We will now recognize the gentlewoman from New Jersey, Ms. Watson Coleman.

Ms. WATSON COLEMAN. Thank you, Mr. Chairman.

I think I want to follow up on Mr. Carter's line of questioning, because I think I don't quite understand now.

Before you acquired the drug ——

Ms. RETZLAFF. Yes.

Ms. WATSON COLEMAN.—was there a problem with access to it?

Ms. RETZLAFF. Yes, there was.

Ms. WATSON COLEMAN. So your desire to acquire this drug, for which there was supposedly a problem with access, does that mean that those people who were suffering from—what is it?—infections associated with HIV and AIDS did not have access to it the way they needed it?

Ms. RETZLAFF. So in June, that was 3 months before we acquired the asset, the previous manufacturer did what they—they went to a specialty distribution model. They closed distribution.

Ms. WATSON COLEMAN. That was 3 months before you purchased it.

Ms. RETZLAFF. Three months before we purchased it. After ——

Ms. WATSON COLEMAN. What was going on before those 3 months? Was it still that closed distribution?

Ms. RETZLAFF. No, it wasn't. It was broader distribution.

Ms. WATSON COLEMAN. So was that as a result of perhaps conversations with your company in anticipation of your company buying the drug?

Ms. RETZLAFF. Absolutely not. Absolutely not.

Ms. WATSON COLEMAN. How are we to believe that?

Ms. RETZLAFF. Absolutely not. There is plenty of proof that arrangement with the specialty pharmacy originated, in fact, not with the previous manufacture but the manufacturer before that.

Ms. WATSON COLEMAN. Walgreens, which is the closed distribution, right?

Ms. RETZLAFF. Yes.

Ms. WATSON COLEMAN. Walgreens informed you all they were concerned about access, this drug's access to other patients, to other pharmacies, et cetera. Is that correct?

Ms. RETZLAFF. Yes.

Ms. WATSON COLEMAN. What did you all do in response to that?

Ms. RETZLAFF. So we have added a specialty distributor that addresses—that eliminates a lot of the red tape and distributes the product to roughly 90 percent of hospitals. We are in the process of adding additional specialty pharmacies to the network. We have worked with the different State ADAPs to make sure that all the processes are in place, so they can access Daraprim seamlessly. These are the most vulnerable patients, by the way, who are covered by ADAP.

Ms. WATSON COLEMAN. So once you acquired this drug and you increased the costs associated with this drug—which still eludes me why this was done other than to make somebody very, very, very wealthy—you all anticipated that there was going to be push back from human rights organizations, from advocacy organizations. So from what I have read, and I believe some of this is obviously from internal memos, it didn't seem that your company was at all concerned about ensuring that people who needed this drug could have access to it. It was about managing the message for your company.

Ms. RETZLAFF. No, that is not true. In fact, the actions—the actions we took reflect differently. We put in place multiple patient access programs ——

Ms. WATSON COLEMAN. Yes. It seems that you all ——

Ms. RETZLAFF.—to ensure that they had access.

Ms. WATSON COLEMAN. Thank you very much. It seems to me that you all responded to a whole bunch of pressure. And you have your serious issues that you have to contend with now. Your company has a very bad physical, public image right now, if you care to know that.

I come from a State, New Jersey. We have large pharmaceutical companies. We have large universities. We do a lot of R&D. And the people that engage in research and development, they are not trying to make somebody a billionaire. They are trying to cure people.

That is not even the issue here, because you all weren't trying to do R&D. You were manipulating access to a medicine that already showed the benefits of treating a very dangerous disease.

And with that, I yield my time back to you, sir.

Chairman CHAFFETZ. Thank you.

We now recognize the gentlewoman from Illinois, Ms. Duckworth, for 5 minutes.

Ms. DUCKWORTH. Thanks, Mr. Chairman.

I want to thank both you and the ranking member for your collaborative efforts to raise this issue today.

I want to start off by talking about a couple in my district. They are 73 and 74 years old, respectively, and they are stretched every single month to cover their expenses. The wife is diabetic, and she has a number of medical conditions, and for 2016, will probably lead to an out-of-pocket prescription price tag of around $4,600. Her husband's out-of-pocket expenses for prescriptions are going to be about $1,900 a year.

Now, since they retired, they are seriously anxious about their finances, how they are going to continue to afford to pay for their health care. And get this, the wife feels endlessly guilty because her medications are the most expensive. And even with some coverage, they, together, face overwhelming pressure of having to manage the family's budget, which after medical expenses is only about $20,000 a year. This is to pay their home loan, property taxes, as well as food and utilities. This is a crisis that is far too common across the country.

And when I hear about stories like this from my constituents in the Eighth Congressional District, and then I hear about $200,000 bonuses for executives at a pharmaceutical company that purposely shut down distribution of a lifesaving drug so that they could make that money, it disgusts me. It is absolutely disgusting.

The Valeant and Turing witnesses who have testified today have used many different tactics to downplay the harmful effects of their price increases. They want to shift the blame, and they want to shift the attention and say that, "Oh, the patient population is so small that the price increases don't affect the larger health care system. And individuals that pay on the more mainstream drugs, you're not being affected. It is just those 3,000 people, because there are only a few of them. And it is actually the large insurance companies, not individual patients, that bear this burden."

But let me tell you, every one of us pay those insurance companies. My entire office is in Obamacare. We pay those insurance companies.

So this hearing has really shown that this is hardly the case.

And, Ms. Retzlaff, isn't it true that Turing's price increase led to astronomically higher copays for many of your privately insured patients?

Ms. RETZLAFF. Yes, it did. But through our copay program, we capped them at $10.

Ms. DUCKWORTH. Really.

Ms. RETZLAFF. Yes, that's true.

Ms. DUCKWORTH. Well, you know, your internal memo identified that one patient had an insurance copay raised, up to a 50 percent increase, to $16,000. And others have copays ranging from $1,000 to $6,000.

Ms. RETZLAFF. Correct.

Ms. DUCKWORTH. Ms. Retzlaff, is it true that some doctors treating patients in hospital settings were forced to switch to secondary alternative therapies because they could not access Daraprim?

Ms. RETZLAFF. I suppose that's true, but in response to that, we have discounted Daraprim by 50 percent and introduced a smaller bottle to better meet their needs. That seems to have resolved the issue.

Ms. DUCKWORTH. Well, you know, doctors are saying that they had to switch, and it was not their preference for what they would treat their patients.

Ms. RETZLAFF. Again, in the hospital setting, we are offering discounts now so that Daraprim can be available for those patients.

Ms. DUCKWORTH. Can you confirm that before Turing owned Daraprim, it was widely available, covered by most insurance, and affordable, before you owned it?

Ms. RETZLAFF. Yes, it was covered by most insurance. I don't know what you mean by widely available.

Ms. DUCKWORTH. Okay.

Mr. Schiller, isn't it true that your price increases and on Isuprel and Nitropress have cut into hospital budgets?

Mr. SCHILLER. Yes, it, certainly, would have hit—cut into their budgets. The price increases were meant to stay underneath the reimbursements for the bundled rates, but it would've, certainly, hit their budgets.

Ms. DUCKWORTH. Yes, it absolutely did. In fact, at Johns Hopkins Hospital, their chief pharmacy officer in Baltimore said these expenses deplete important savings and result in less funding for research programs and technologies that improve care. This is Daniel Ashby. And he further says that the high cost threatens patient access to critical treatments and creates financial burdens on low- and middle-income patients.

Mr. Schiller, these are only two of the many drugs your company owns and has increased the price on. Is that correct?

Mr. SCHILLER. That is correct.

Ms. DUCKWORTH. How many other drugs have you increased the price of?

Mr. SCHILLER. I don't know offhand.

Ms. DUCKWORTH. So you have so many that you don't even know how many other drugs you have jacked up the prices on, everyday, hardworking Americans who are suffering from diseases. I mean, that boggles the mind.

You are coming to testify before Congress, and you don't even know how badly you have socked it to the American public.

Mr. SCHILLER. We have 1,800 products around the world.

Ms. DUCKWORTH. Okay.

Mr. SCHILLER. We, certainly, raised the price on some, and the number that you all have mentioned. We have acknowledge mistakes. We have also acknowledged that, going forward, we would no longer be looking for those opportunities to purchase these older drugs.

When I took over at the beginning of this year, we froze all price increases.

Ms. DUCKWORTH. Have you returned the price increases back to where they before where you raised them? That is the important question.

I yield back, Mr. Chairman.

Chairman CHAFFETZ. The time is expired.

There is a vote on the floor. The committee is going to go into recess with the intention of coming back no sooner than 12:15.

The committee stands in recess until that time.

[Recess.]

Chairman CHAFFETZ. The committee will come to order.

We will resume now. Thank you for your patience and understanding. Votes happen, and I appreciate your understanding that.

Dr. Woodcock has rejoined us. We appreciate you being here. We know you were testifying with us, testified in another hearing, and now you are back. I appreciate you toggling back and forth.

In consultation with the minority, we are going to go ahead and start. We are now going to recognize the gentleman from Texas, Mr. Will Hurd, for 5 minutes.

Mr. HURD. Thank you, Mr. Chairman.

My first question, Ms. Retzlaff, when you all made the decision to go from $13.50 to $750 a pill, who made that decision?

Ms. RETZLAFF. The final decision was made by the former CEO.

Mr. HURD. All by himself?

Ms. RETZLAFF. Yes, he made the final call.

Mr. HURD. There was no conversation? You didn't know in advance? You all found out after the fact? He made the decision and told you all?

Ms. RETZLAFF. No, there were, certainly, conversations about it.

Mr. HURD. Who was involved in those conversations?

Ms. RETZLAFF. The senior leadership team.

Mr. HURD. Which would be?

Ms. RETZLAFF. Myself, our president of R&D ——

Mr. HURD. And that person's name?

Ms. RETZLAFF. Dr. Eliseo Salinas.

Mr. HURD. Okay.

Ms. RETZLAFF. Our chief people officer, which would have been Peter Myall. Let's see, I'm not recalling all ——

Mr. HURD. Can you furnish us a list of the people who were involved in that conversation?

Ms. RETZLAFF. Yes, yes. I will, certainly, do that.

Mr. HURD. Because, to be frank, I don't think you should be the only one enjoying the fun up here answering these conversations.

Did anyone raise their hand and say, "Y'all, this may not be a good idea"?

Ms. RETZLAFF. So I think the conversations we had were around ensuring that if the price went up, that we would have the appropriate programs in place to ensure that no patients were left behind.

Mr. HURD. So nobody thought an increase of 5,000 percent was a bad idea?

Ms. RETZLAFF. And—and we provided that we had the mechanisms in place to ensure patients did not suffer from the price increase; and second, that we were absolutely committed to investing in R&D for next-generation toxoplasmosis treatment, which we are doing currently.

Mr. HURD. So help other people on the backs of those folks who had a 5,000 percent increase. Interesting.

Mr. Schiller, my question for you, when you all made the decision to go from $215 to $1,356, a 525 percent increase, on the drug Isuprel, who made the decision?

Mr. SCHILLER. Our neurology and other division, where these products sat, initially did the review.

Mr. HURD. The review of the price?

Mr. SCHILLER. The review of the pricing, the market for that drug.

Mr. HURD. And who are those people? Give me some names.

Mr. SCHILLER. Well, Steve Sembler is the gentleman who ran that division at that time.

Mr. HURD. So he made the decision by himself?

Mr. SCHILLER. No, he brought—he organized a meeting for senior management, which Mike Pearson and myself were included in that meeting, where it was discussed and the price was decided.

Mr. HURD. Did anybody raise their hand and say, "Y'all, an increase of 525 percent may not be a good idea"?

Mr. SCHILLER. There is always discussions and dissent, but the bottom line is that the decision was made and ——

Mr. HURD. So was the decision made at an actual meeting? Was there everybody vote, all those in favor, say aye, opposed, nay?

Mr. SCHILLER. It definitely was not a meeting where there was a vote. I can't recall how the final decision was made. But as I have mentioned, we acknowledge that it was too aggressive and ——

Mr. HURD. So can you send us a list by next week of all the people that were involved in making the decision?

Mr. SCHILLER. I can try. If that list exists, I can get it to you.

Mr. HURD. Best effort.

And, Ms. Retzlaff, again, in the next week, it would be great to have a list of people involved in that.

Also, Mr. Schiller, for Nitropress, going from $257 to $800, a 212 percent increase, were the same individuals involved in making that decision?

Mr. SCHILLER. It was the same meeting.

Mr. HURD. Excellent.

I yield the balance of my time to the chairman.

Chairman CHAFFETZ. Thank you.

I actually would like now to recognize the gentleman from Alabama, Mr. Palmer, for 5 minutes.

Mr. PALMER. Mr. Schiller, how large is Valeant's work force?

Mr. SCHILLER. Twenty-two thousand people, plus or minus.

Mr. PALMER. How many do you have engaged in R&D?

Mr. SCHILLER. There are roughly 1,000 people.

Mr. PALMER. How much do you spend on your own in-house R&D?

Mr. SCHILLER. This year, we will spend in excess of $400 million.

Mr. PALMER. How many products are in Valeant's development pipeline?

Mr. SCHILLER. We have over 200 active programs, 100 of which we would consider significant. And we expect and hope to get an approval for a novel glaucoma drug and a biologic for the treatment of moderate to severe psoriasis ——

Mr. PALMER. I don't need a list. I just want to get an idea of how much you are investing in R&D versus what you are doing in terms of buying other branded drugs. There is some suggestion that you operate your models more along the lines of a hedge fund in that regard. How would you respond to that?

Mr. SCHILLER. I would disagree with that characterization. We have, as I mentioned, 22,000 people. We operate in 100 countries. We have 1,800 products. We have a vibrant R&D effort. We have

16 manufacturing facilities in the United States that we are investing heavily in. And we have launched 76 products in the last 2 years, and invest heavily in patient assistance programs. So I think we are just like any other pharmaceutical company.

Mr. PALMER. I want to raise some questions to Dr. Woodcock.

Where there is no competition, prices are high. I think we all understand that. Do you agree that you have all these generic drugs in the pipeline, that if we can get those 4,000 generic drugs into the marketplace, it would have an impact on pricing?

Dr. WOODCOCK. Yes.

Mr. PALMER. Well, let me ask you this. Does the FDA prioritize reviews for first generic drugs? There is an issue that the FDA blames sloppy applications for the current backlog. Have you considered compiling a preferred providers list of generics to try to move some of these drugs up and get them approved quicker?

Dr. WOODCOCK. We fast track all first generics, so we give them special attention. We move them through. We recognize the consequences.

In the last several years, a first generic, there might be 14 applicants who would be the potential first generic. We don't know who is going to get over the finish line first, so we expedite that class of filings, that set of applications.

Mr. PALMER. Well, 10 years ago, the median approval time for a generic drug was about 16 months. And now it is 42 months. It is almost four times as long. Can you explain why that takes so long, if these are generic drugs are coming from a brand drug that has already been approved?

Dr. WOODCOCK. Yes. As I said in my oral testimony, we were a victim of our own success. Eighty-eight percent of dispensed prescriptions are generics, so there are thousands of generics on the market, and they have been very successful.

But the industry grew as a response to that, just like a factory that had a great product. And we got many, many more applications, but our resources against that workload did not grow and we built up a backlog. As a result, we were able to negotiate the user fee program with the industry to provide the resources to get it done.

But we had that backlog. And that 42 months is a reaction to that, because we had 2,500 applications waiting when we started the user fee program, and that was 40 months ago. They are not going to get any younger when we approve them. They are at least 40 months.

The new ones have a much shorter clock.

Mr. PALMER. You are talking about the first generic drugs or the new applications?

Dr. WOODCOCK. The new applications. The first generics in that 2,500 are very few, and we are expediting those.

Mr. PALMER. Okay.

Of the current backlog, can you tell me what percentage of those are first generics?

Dr. WOODCOCK. Very, very, very—it depends on how you define the backlog. If you're talking about the 2,500 that were there when we started the user fee program, it is a very small percentage.

Mr. PALMER. Well, you had 1,400 submissions in fiscal year 2014, but only approved 409 of those, so you are adding to that.

Dr. WOODCOCK. Under the agreement, that has a 15-month clock for getting back to the sponsor. So we are planning to meet those goals and get back to the sponsor and complete the review in 15 months. Now, because generics typically have multiple cycles of review, the time to approval may be longer.

In my testimony, I think you see that in the prescription drug world, the new drug world, we are up to 95 percent last year, first cycle approval. But that took a lot of work and effort to get it right the first time. That is what we need. We need a "right the first time" application. Then starting in October, when we get those, we will approve them in 10 months.

Mr. PALMER. And you expect to do that in what time frame? When do you expect to be at 10 months approval?

Dr. WOODCOCK. The applications submitted October 1, 2016, and beyond, if they are right the first time, they will get approved in 10 months. If they are deficient, they will get an answer in 10 months to tell them what they have to do. We get some where we go out and we find that the bioequivalence data has been falsified or some of the manufacturing has been falsified. So we have to have time to make sure that these meet the standards for the U.S., because people are going to be forced to take these, if we approve them. They have to be right.

Mr. PALMER. My time has expired, but I have one last quick question. Is the FDA catching up or falling further behind?

Dr. WOODCOCK. We are definitely catching up. We are doing a great job.

Mr. PALMER. My time has expired.

Thank you, Mr. Chairman.

Chairman CHAFFETZ. Thank you.

I have some unanimous consent requests.

The first one is a statement from Congressman Doug Collins of Georgia. Without objection, I will enter this into the record. So ordered.

[The information follows:]

Chairman CHAFFETZ. I also have Congressman Duncan who has a letter of December 15, 2015, that he had received from a Joy Macklin. I ask unanimous consent to enter that in the record.

Without objection, so ordered.

[The information follows:]

Chairman CHAFFETZ. Congressman Blum also has a statement for the record.

Without objection, we will enter his as well. So ordered on that.

Chairman CHAFFETZ. I have a few questions as we start the second round here.

Dr. Woodcock, again, thank you for joining us.

Since the passage of the Generic Drug User Fee Act of 2012 has passed, the intention here was to generate roughly $1.5 billion. This is user fee money coming out.

In the Office of Generics, the people working on this, tell me what has happened to the staffing level since 2012.

Dr. WOODCOCK. Well, across the program, we have hired over 1,000 people.

Chairman CHAFFETZ. Working specifically on the approval process for generics?

Dr. WOODCOCK. That is correct.

Chairman CHAFFETZ. Okay, can you give us the very specific number. I would really like to see that line. Not right here in this hearing, as a follow-up. I just really want to be able to see that.

Dr. WOODCOCK. I need to understand your question. I don't understand your question.

Chairman CHAFFETZ. I want to see which offices they are actually working in and what they are doing, if you could break that down. I don't expect you to do it verbally of the top your head. What I am suggesting is, as a follow-up to this hearing, can you provide the committee that information?

Dr. WOODCOCK. Yes.

Chairman CHAFFETZ. Okay, perfect.

I want to get into these priority review vouchers. These were intended to incentivize treatment for rare pediatric and tropical diseases. The vouchers were supposed to shorten the FDA review time by roughly 4 months. But companies have figured out how valuable these are. I think it demonstrates the frustration with the FDA and the timing.

Recently, there was one voucher in August that was sold for $350 million. That means, roughly, they were willing to pay—they thought it was a good business transaction to pay roughly $2 million a day just to get in line a little bit quicker. I am concerned that not everybody can buy their way to the front of the line. But this does demonstrate how backlogged and how problematic the demand is at the FDA.

Does FDA have the necessary authority to prevent the alleged abuse of the PRV system? Do you think there is any abuse of the PRV system? Should they be sold the way they are being sold?

Dr. WOODCOCK. Again, this is an economic issue. It was intended to incentivize development. These recent vouchers applied to products that were already being in development because it's early.

Chairman CHAFFETZ. But they don't have to actually sell those drugs. They don't have to actually market those drugs. Correct?

Dr. WOODCOCK. Correct. They need to be approved.

Chairman CHAFFETZ. Again, so they could be used for a variety of different things. They don't necessarily—because if you develop one, you are going to get this priority review voucher, but you can use the priority review voucher for something other than that category, correct?

Dr. WOODCOCK. Yes. And that is what has been done. And I do have to comment on what you said.

The priority review vouchers are applied to novel drugs. They have nothing to do with the generic drug review process. That program is completely on time.

And the reason people use priority review vouchers is to move in front of competitors and reach the marker faster than a competitor who may be developing a drug in the same space, because for a new drug, a novel drug, being first on the market—and I know nothing about this—but apparently, it must have a great deal of value.

So it does not apply to generic drugs or the generic drug process.

Chairman CHAFFETZ. But you can see how this could be manipulated. Do you see any evidence of manipulation here?

Dr. WOODCOCK. I don't know—it depends on how you define manipulation.

Chairman CHAFFETZ. Well, are they eating these up in order to get the voucher with no real intention of actually marketing, producing, or investing in the smaller drug?

Dr. WOODCOCK. The companies that we have awarded vouchers to have fulfilled the requirements of the statute for being eligible to be awarded a priority review voucher.

Chairman CHAFFETZ. The worry is that the statute is inadequate. It has provided the market a way that people can get in line sooner. They are willing to pay hundreds of millions of dollars in order to do so. We are concerned about spurring innovation and actual drug development.

Dr. WOODCOCK. It was supposed to—the existence of the PRV was supposed to spur those developers of tropical diseases or rare pediatric diseases to enter that space because they would get this reward at the end for ——

Chairman CHAFFETZ. I think that is one our questions. Are they actually spurring innovations? Should there be limitation on the resale of those vouchers?

Again, when you have a difficult disease that affects such a small population, it is difficult—not everybody can just act altruistically. There has to be some degree of profit motivation.

But this rise has gone from tens of millions dollars to hundreds of millions of dollars just to get that 4-month edge. When I see $350 million transactions for a 4-month edge, that catches a lot of people's attention.

I am just asking the FDA if they see it fulfilling its original mission? And are you seeing any abuse?

Dr. WOODCOCK. All right. Well, there are two sides to this. Is it stimulating development in rare pediatric diseases or tropical diseases? I think it is too early to say, because it takes a long time to develop one of these products.

Chairman CHAFFETZ. So let me read a quote here real quick. I am sorry to cut you off, but I have gone past my time.

John Jenkins, the director of FDA's Office of New Drugs, has publicly criticized the PRV program as diverting "time and resources away from other important public health work, such as reviewing other applications for potentially much more serious conditions or drafting of guidance documents on issues related to drug development."

Is he, in your opinion, right or wrong?

Dr. WOODCOCK. Yes, that is true. But we have to implement—this program is established by Congress, and we will implement it.

Chairman CHAFFETZ. Okay. I appreciate that.

We are going to continue to have this discussion, because I do think it is not going to solve all problems, but it is an interesting thing.

My basic concern here is Turing or Valeant or any other company has the right, I believe, to come in and enter the marketplace. But when you have a rapid rise in pricing, a dramatic rise in pricing, natural economics would suggest that that would create oppor-

tunity for others to come in and create more of a balance to the true market pricing, if there was competition. But if they can't get through the process with the FDA in order to enter the marketplace and compete with somebody who was rapidly rising the price of goods, then the market factors are out of balance.

And I think it is incumbent upon us to accelerate the process, so that if somebody is taking advantage of price elasticity, the only way to make it more elastic is to provide some competition.

What I don't want to do is have government controls or government price controlling, but it is difficult when you see patients who are suffering and they don't have access and they don't know how to go through the convoluted process. They look at that equation and say, you know, "Do I buy food for my kids or do I just suffer myself?" So that is why it is so pertinent.

I have gone well beyond my time.

We will now recognize Mr. DeSaulnier for 5 minutes.

Sorry, I was thinking DesJarlais over here. We have a DesJarlais and a DeSaulnier, so I apologize.

Mr. DESAULNIER. That is all right. As long as you said from California, I am fine.

Chairman CHAFFETZ. The gentleman from California.

Mr. DESAULNIER. Thank you, both to the chair and the ranking member, for having this hearing.

I just want to say, just as an observer and as somebody who is not young, the history of this industry, I think it is fascinating. And, certainly, the gentleman to my left, given his professional experience, Mr. Carter understands this better than I do. But as an observer, 30, 40 years ago, people invested in pharmaceutical companies because it was a relatively low rate of return, but it was a different culture.

I, certainly, don't think that the addition of more capital into this industry is necessarily a bad thing, and meeting with people in the public sector in my district in the Bay Area and the private sector, particularly at UCSF, and hearing all the amazing things we are on the verge of doing, whether it is cancer or cardiovascular disease, because of some of these investments, but also because of the public investment.

But the concern I have is that although your companies and an individual are getting a lot of press in an extreme example, that in a transition of the pharmaceutical industry, although there has been benefit to increased capital into the marketplace, that this is more a symptom of an overall culture problem.

And if I was a free marketeer, which to some degree I can be, you would be a symbol of what is wrong with my philosophy, because as Madison once said, if people were angels, there would be no need for government. And this is an example of, certainly, less than angelic behavior.

So, Ms. Retzlaff, I would just ask you to sort of comment on, we have examples of the quotes. For instance, a Reuters headline, "Pfizer hikes U.S. prices over 100 drugs"; the Washington Post, "Prescription drug prices jumped more than 10 percent in 2015"; from Bloomberg, "Everyone is hiking drug prices," is a quote from your former CEO.

So you have PR that the ranking member has talked about, that you have emails on. There are emails from your former CEO, who refused to speak on the record here.

It is my impression that you are doing what companies to do, in terms of controlling what was a bad episode in your company. But it seems like you are on a track to maybe repeating the same mistake because of market pressures, but that is also indicative to the whole industry.

So tell me that you have learned your lesson and that there is a place where shareholders can be satisfied, but that consumers can be fairly full of confidence that this isn't going to repeat itself. Because it, certainly, seems like, following some of the comments by the ranking member, that you may retire, but we are set up for failure again here again, that this is just a symptom of a larger problem.

Ms. RETZLAFF. Right, so you weren't here, but Turing is a research-based pharmaceutical company. We have 139 employees. Thirty-six are dedicated to research and development. The increased revenues from Daraprim, 60 percent of them, actually, are reinvested into research and development, which is critical for a pharma company, and I believe essential.

And then we also invest very aggressively and generously in patient access programs. So our goal with patients is to ensure that they don't incur any incremental, out-of-pocket costs, because of our price increase.

Another thing I will note is that almost two-thirds of patients who are on Daraprim benefit from government program pricing, which is one penny per pill. Those are your most vulnerable patient populations.

What I will say is I am proud of the work that we are doing for toxoplasmosis. It is the second-leading cause of death in the United States due to foodborne illness. Seven hundred and fifty patients still die each year. Not all patients respond to Daraprim. Some of them don't tolerate it. Daraprim is not active on the—or doesn't behave on the parasite when it is in its dormant phase. You know, many people go blind ——

Mr. DESAULNIER. Can I ask you to wrap up, because I don't want to use on my time?

Ms. RETZLAFF. Yes. So, you know, I don't believe my company has done anything wrong. I believe that the decisions we made struck the right balance between the need to ensure patient access, innovation, as well as shareholder value.

Mr. DESAULNIER. I don't think you answered my question partially.

So, Mr. Schiller, I will try with you.

There are a lot of people in your industry that do practice what I would describe as responsible consumer practices, historically. Yours, I would not include in that group. But they have market pressures that, if you have a higher return on investment, because of these practices that would skirt what I think is in the best interest of the consumers, they are forced to come down to a level in the marketplace.

So tell me how your company is never going to be in this situation again, absent, as best you can, from a public relations re-

sponse. Personally, how are you going to look back and tell your grandkids that you were part of a solution?

Mr. SCHILLER. So we grew very, very quickly. We did a lot of good things. We made a lot of mistakes.

In the past, we have looked for situations with older drugs, where there wasn't generic competition, where we could increase revenue by increasing price. You should not expect that those are opportunities that we will be looking for in the future.

We have taken aggressive steps in terms of our partnership with Walgreens where we are reducing our prices by 10 percent on average in two of our largest franchises, dermatology and ophthalmology prescription drugs.

We went to a 30 percent volume-based discount structure on Isuprel and Nitropress.

We significantly increased our patient assistance program.

Going forward, as it has been in the past, our focus is going to be on developing our franchises around dermatology, gastrointestinal diseases, ophthalmology, women's health, and some of our other smaller franchises. We will continue to invest in R&D, and bring innovative products to the market, and continue to invest in expanding our manufacturing.

Mr. DESAULNIER. Thank you.

Thank you, Mr. Chairman.

I appreciate those responses. I would say that although I understand why you respond that way, it does suggest to me that the cultural changes I think we need within your company, your industry, I hesitate to have confidence that you have actually learned the necessary lessons that I think you need to learn for the chairman's question about avoiding more government regulation.

So with that, I will return to you.

Chairman CHAFFETZ. Thank you. Thank you.

We will now recognize the gentleman, again, from Georgia, Mr. Carter, for 5 minutes.

Mr. CARTER. Thank you, Mr. Chairman.

I would like to follow up on a couple questions from colleagues earlier.

Dr. Woodcock, you weren't here, but one of my colleagues, Representative Meadows from North Carolina, was asking about the process of drug approval in the FDA. And I would like to ask you something, or like for you to clarify something.

It is my understanding that FDA can expedite a new drug application, abbreviate a new drug application, to help with the drug shortage problems, if there is such a thing. But I understand, right now, that you are putting more emphasis on the approval and the quality standards, which we all applaud. But you can, in fact, approve a drug if, indeed, there is a drug shortage there, and that has been done before. There has been precedent with that.

Now, let me ask you, you could address an issue of drug shortage with compounding, could you not? Yes or no?

Dr. WOODCOCK. We wouldn't overtly do that but the compounders could potentially may offer ——

Mr. CARTER. Dr. Woodcock, you ——

Dr. WOODCOCK. Yes.

Mr. CARTER. You control the list of ingredients that they are allowed to compound, correct?

Dr. WOODCOCK. Yes.

Mr. CARTER. So you could add one to that, if there was a drug shortage. In fact, you have done that before in the past. You set precedent with that, correct?

Dr. WOODCOCK. I don't know about ——

Mr. CARTER. If you will, in 2012, the FDA waived its authority of an enforcement action against a compounded version of a hormone cream—yes, I see your staff nodding here—that is prescribed to lower the risk to women of premature birth, when the approved version became too expensive.

This could have helped us in this situation. This could have helped the American public in this situation.

Dr. WOODCOCK. The situation you refer to was enforcement discretion. Usually when a new drug is approved, then other versions are not supposed to be marketed and ——

Mr. CARTER. But through compounding, we could have addressed this issue of the drug shortage because of a significant price increase. And that has been done before. There is precedent there.

Dr. Woodcock, just one other thing, through the omnibus that was recently passed by Congress, we instituted a rule on office use compounding. I know that there was language in the bill that directed the FDA to issue guidance on that. Can you give me an idea, are you still working on that? Do you have any idea when that will be?

Dr. WOODCOCK. We are working on a set of guidances to implement the recent statutory changes, and I would hope that they would come out within this year in draft.

Mr. CARTER. Okay, thank you for that.

Another question that was asked by one of my colleagues from New Mexico, Ms. Retzlaff—and in fact, she just repeated again. She asked you a question, and you stated that Turing is a research pharmaceutical company.

How many drugs has Turing taken from research to development? How many drugs have you—microphone.

Ms. RETZLAFF. We have 13 products in development right now. We are a new company. We are ——

Mr. CARTER. You are new company, so have had none, but you are calling yourself a research pharmaceutical company. I think it is a stretch to even call you a pharmaceutical company, because I think it is a shell of a company.

And I will tell you that when a company that calls themselves a research pharmaceutical company only puts in 5 percent of their profits back into research and development, I think that that proves the point that they are, indeed, not one.

And I know what you have said, that no, 60 percent. Yes, when things went south, you increased it to 60 percent, to increase your public relations. But before that, it was only 5 percent. So I beg to differ with you on that.

Now, you said that your drug Daraprim was being distributed through specialty pharmacies. Any of those special pharmacies owned by PBMs?

Ms. RETZLAFF. I think Walgreens.

Mr. CARTER. The answer is yes.

Ms. RETZLAFF. Yes.

Mr. CARTER. Yes, they are, which brings us to the PBM problem, which is a great problem that we have in our country, particularly in the medical field.

Mr. Merritt, I want to ask you, over the past week or so, there has been much in the press about a problem between one of the largest health insurers and one of the largest PBMs in our country, that they cannot reach negotiations. They are trying to negotiate. They cannot reach a deal in a $3 billion settlement.

If that is the case with one of the largest PBMs and one of the largest insurance companies, how do you expect a small pharmacy, a small, independent pharmacy, to stand a chance against a giant PBM when one of the largest insurance companies in the world can't even negotiate with you?

Mr. MERRITT. Well, on that particular issue, that is a dispute, a contract dispute, between two companies. But I do know that pharmacies, independent pharmacies ——

Mr. CARTER. Can you imagine a contract dispute between a company that is one of the smallest in the United States and one of the giant PBMs?

Mr. MERRITT. That is true, but drugstores, independent drugstores, typically work with PSAOs that are a part of giant companies, and they negotiate with PBMs on behalf of independent drugstores.

Mr. CARTER. Mr. Merritt, I am really concerned about the current marketplace, because I believe it creates perverse incentives for PBMs to shut out independent pharmacies at the expense of the American public.

And I say that because, as competition decreases, price is going to increase. That is what we are finding now. That is one of the worst things about the Affordable Care Act. Look at how many health insurance companies we have left. Only three or four. That is what is going to lead us to destroy what I believe is the greatest health care system in the world.

Now, Mr. Merritt, I know that you are not specifically the problem. I know that you represent an association. But I can tell you, we have to have transparency in the PBM world.

Now, Representative Collins just introduced a letter for the record, and I can tell you he has a bill that deals with transparency.

Mr. Chairman, I hope that this is something that we will continue to deal with in this committee. It is vitally important that we do.

And, again, Mr. Chairman, I want to thank you, the ranking member, and all your staff, for this hearing today.

Chairman CHAFFETZ. I thank the gentleman.

We will now recognize the ranking member.

Mr. CUMMINGS. Thank you, Mr. Chairman.

I want the witnesses to know that I fully support Mr. Carter in his efforts, because I have a lot of people in my district that are very, very concerned about that issue.

And, Mr. Carter, I plan to join you in your efforts, because you are absolutely right.

Not going on, Mr. Schiller, I have been interested in Isuprel and Nitropress since Marathon Pharmaceuticals, the company that owned these drugs before you, dramatically increased their prices by roughly 400 percent each.

The Johns Hopkins Hospital—by the way, which is smack dab in the middle of my district, 5 minutes from where I live—their hospital budget was significantly impacted by Marathon's price increases. That is why I wrote a letter to Marathon asking about the drugs in October 2014.

Then in February 2015, your company came along and jacked up the prices of these critical medicines even more, 525 percent and 212 percent. Your price increase stretched the Hopkins pharmacy budget even further.

You have testified today that Valeant is offering a 30 percent discount to some hospitals that use these products.

From what we have heard, it is unclear whether hospitals are actually able to access this discount. But even if they are, a 30 percent discount on a 500 percent price increase hardly makes a dent.

You are a businessman, Mr. Schiller. Does that sound like a good deal to you?

Mr. SCHILLER. What we try to do is address the issue from a portfolio point of view.

Mr. CUMMINGS. Do you realize how much that hurts Hopkins? I don't know whether you heard the testimony, the questions of Mr. Cartwright a little bit earlier. These hospitals are suffering big time. And that means for some of them, they are not like Johns Hopkins, one of the best in the world. But they are suffering big.

My father, who only had a third grade education, a former sharecropper, used to say, and I didn't understand it then, but I understand it now. He said, "Somebody is going to pay. Somebody has got to pay." And hospitals are paying big time.

Now going back to you, Ms. Retzlaff, I am very concerned about the documents the committee has obtained showing that your company was more concerned about managing the PR backlash of your price increase then ensuring patients had access to Daraprim.

An internal Turing presentation—and again, these are not my documents; these are your documents—from 2015, stated, and I quote—listen to this; this is incredible to me. "HIV patient advocacy may react to price increase. ...HIV community is highly organized, sensitive, and action-oriented."

"Significant price increases that disproportionately affect this community could result in backlash from patient advocacy groups, particularly if payers increase cost sharing with patients."

I am concerned about this because in the district that I live in, the ZIP Code has one of the worst HIV situations in the world—in the world. And so that is why you are going to hear me talk about this. It would be legislative malpractice for me not to.

It appears Turing was aware this price increase was going to adversely affect the HIV/AIDS community, yet the company still chose to increase the price by 5,000 percent.

You can sit here now until forever and tell me about all your little discounts, $1, and all this. You are raising the price, all right?

So, Ms. Retzlaff, did anyone at Turing stop and think about the effect this price increase would have on such a vulnerable population, beyond the anticipated bad PR?

Ms. RETZLAFF. Yes, we did, and we took action on it. So that is why, again, and it's important, that we participate in Medicaid 340B. We offer Daraprim to the most vulnerable patients at one penny per pill.

Mr. CUMMINGS. You were worried about the AIDS community, weren't you?

Ms. RETZLAFF. Absolutely.

Mr. CUMMINGS. Oh, yes. You were really worried. You were worried about the PR, not the patients, the PR.

Ms. RETZLAFF. We were worried that there would be misinformation in the public domain, and that is exactly what happened.

So our efforts from a PR perspective were intended to correct the misinformation and make sure that patients understood that we have these programs in place that they could access Daraprim at a very affordable price.

Mr. CUMMINGS. Well, one thing, there was a memo from October 12, 2015, and this should give advocacy groups like the Human Rights Campaign—I am sure it is going to invigorate them to continue to fight for the people that they represent. But this is a quote, it says, the Human Rights Campaign "has been vocal and in the media about the pricing issue and is potentially the most vocal organization able to garner media coverage. While their motivation is primarily political given their actions we feel it would be important to get a meeting with CEO Chad Griffin in an attempt to slow their aggressive stance and work with them to better understand the company."

So you thought it was political that they were trying to make sure that people suffering from AIDS get the proper medication that they need. So it is a political problem?

Ms. RETZLAFF. No. We thought we needed to engage all important stakeholders to make sure they were aware that the most vulnerable patients suffering from toxoplasmosis, over two-thirds of Daraprim's use, can access that product at a penny per pill.

Mr. CUMMINGS. Now, Mr. Schiller, I just have a—I just have a few more questions, Mr. Chairman. I know you are trying to close this down.

It has been reported that in 2014 Valeant led the industry in price hikes, raising prices on 62—so you acted like it was just a few drugs you raised prices on—62 of its drugs by an average of 50 percent. In 2015, Valeant continued that pattern with the highest average increase in the industry, 65 percent across 50 drugs.

According to CMS data compiled by CQ Roll Call, five of the 10 brand name drugs that had the largest price increases between April 2013 and July 2015 are Valeant drugs. Of those five drugs, two increased by more than 500 percent. One increased by over 600 percent, and one by 800 percent. And one skyrocketed over 1,000 percent in just 15 months.

One drug, in particular, Glumetza, a drug used to treat patients with type 2 diabetes, increased by a whopping 800 percent over a mere 6-week period.

Is that true, Mr. Schiller?

Mr. SCHILLER. I'm not familiar with all those numbers, but directionally, that is true.

Mr. CUMMINGS. The massive price jump was so preposterous that it caused pharmacy benefit manager Express Scripts to announce on January 29, 2016, that it intended to remove Glumetza from its formulary.

And this is what they said. They said, "To protect clients and patients from wasteful, unnecessary drug spending, Express Scripts will exclude Glumetza from our 2016 national preferred formulary pending FDA approval of a generic equivalent."

I asked you a little bit earlier—and you danced around it very nicely, you did a great dance—what were you going to do—you admitted under oath that you all had gone too far.

I am asking you, are you going to tell the public, which is watching this, by the way, what you are going to do further. You talked about what you have done. What are you going to do, because as far as I am concerned, we still have problems?

Mr. SCHILLER. First of all, you are right. We made some mistakes. I acknowledge ——

Mr. CUMMINGS. You said that before. I got that.

Mr. SCHILLER. I knowledge that.

We have frozen all price increases other than for our gastrointestinal drugs this year, and it's been ——

Mr. CUMMINGS. Whoa, whoa, whoa. How long will that price freeze last? Until what? The end of the year?

Mr. SCHILLER. I can't commit. I mean, we raised it at the board level, and at the board level, we decided to freeze any price increases that had been proposed for 2016.

We also rolled out our Walgreens program where we took a 10 percent average price discount off of ophthalmology and dermatology drugs. The 30 percent volume discount on Isuprel and Nitropress has been rolled out. And any of the significant users of that will be availing themselves of the 30 percent price increase—price decrease.

Going forward, we are not going to be looking for those opportunities, such as Isuprel and Nitropress. Our focus is going to be on our core franchises, as it always has been, around dermatology, ophthalmology, gastro, women's health, consumer health care. And that is where our focus is going to be, on our pipeline, on our manufacturing, and delivering innovative drugs.

We have to do a better job of getting the balance right, between being shareholder-friendly, being a good corporate citizen, and being a good partner in the health care system. And we will work very hard to get that balance right.

Mr. CUMMINGS. Take you very much, Mr. Chairman. I really appreciate—Mr. Chairman, I have to say this. I really cannot tell you how much I appreciate this hearing.

Chairman CHAFFETZ. Thank you.

Mr. CUMMINGS. Thank you.

Chairman CHAFFETZ. We now recognize the gentlewoman from New York, Ms. Maloney.

Ms. MALONEY. Thank you. I join the ranking member in thanking you for this hearing. It is an important one.

Mr. Schiller, how much compensation have you received since joining Valeant, including salary, bonuses, stock-based compensation? Is it more than $20 million, including your current stock holdings?

Mr. SCHILLER. It is.

Ms. MALONEY. So basically, how much is it?

Mr. SCHILLER. I have not added it up. In 2014, it was $27 million. I am incredibly fortunate and well compensated.

Ms. MALONEY. Well, if you could get it back to us in writing, we would appreciate it.

Mr. SCHILLER. We will do so.

Ms. MALONEY. Now, throughout this hearing, everyone is citing consultants as the cover, I would say, of increasing prices. Would you please identify those consultants, Mr. Schiller?

Mr. SCHILLER. First of all, while we mentioned consultants, we do not want to cast blame on anyone. We accept responsibility for our own actions. The consultants we referred to for Nitropress and Isuprel I believe was a firm called MME.

Ms. MALONEY. Could you get back to us in writing the consultants that you used in all of these price hikes in your business?

Also, Ms. Retzlaff, what consultants did you use for these price hikes?

Ms. RETZLAFF. We didn't use any consultants.

Ms. MALONEY. Okay. I was stunned by the internal documents that actually the majority secured. In particular, an exchange with Mr. Pearson, where he shows in three different graphs that the increase in earnings for your company, Mr. Schiller, was almost completely and totally price increases. And I refer to the Q15. He cites everything except the U.S. grew a total of $26 million. So these other firms overseas didn't grow your growth, according to his graph. The remaining $305 million in growth came totally from the United States.

He goes on further. He says, out of this, he says, $61 million of that growth came from volume, where as the remaining $244 million of growth came from price increases.

My question is, how do you justify these price increases, particularly on drugs that are the sole source of treatment, there is no other manufacturer? How do you justify these price increases? And did you ever think about the impact on patients, on hospitals, on other providers, on the government, on the taxpayers?

You say, very blithely, that this is going to be covered by health care or Medicaid or Medicare or whatever. That comes from the American taxpayer. And the copayments, many people tell me their copayments have gone to thousands of dollars, which they cannot afford.

How do you justify that? How does your company justify that?

Mr. SCHILLER. When we have decided on prices for drugs in the past, we have taken in a number of factors, including clinical value, alternative therapies, and patient access, which is obviously critical.

Ms. MALONEY. May I add that in our memos that we got from you, that patient access was decreased after these price increases, that major hospitals, like Mass General in Boston, a major hos-

pital, couldn't even get access to these drugs. They weren't covered by any other form. People could not get treatment.

Mr. SCHILLER. I am not aware that people weren't able to get access to Isuprel and Nitropress, if that is what you're referring to.

Ms. MALONEY. I will send you the memos that we read. I started reading them last night, and I couldn't go to sleep.

I tell you, I don't even think this is a hearing. This is a scandal, an absolute abuse of power, abuse of the pharmaceutical industry. And it is a scandal.

I would like the permission to put into the record additional questions in writing for you to answer for us, both of you.

And I yield back the balance of my time.

Chairman CHAFFETZ. Thank you.

As we wrap up here, Mr. Schiller, tell me again the factors that you take into consideration when pricing a drug.

Mr. SCHILLER. It is a number of factors, including clinical value, alternative therapies, patient access, and, obviously, it is quite subjective. In some of these situations that we have talked about, we have clearly gotten it wrong.

Chairman CHAFFETZ. Anything else? I'm just trying to make a little checklist. Anything else on that list?

Mr. SCHILLER. That ——

Chairman CHAFFETZ. Ms. Retzlaff—I'm sorry if I'm not pronouncing your name properly—but what considerations does Turing take in place when considering the pricing of the drug?

Ms. RETZLAFF. So, I think, first, you take into account the value of the medicine, or the clinical value of the medicine. We took into—we take into account the size of the patient population, other products in the category, the need to invest in innovation, the assessment of whether or not there are mandatory rebates and things like that associated with the product. And then I think I mentioned innovation, and the need to fund patient access programs.

Chairman CHAFFETZ. Can I just tell you candidly—again, I am a conservative guy.

Ms. RETZLAFF. Yes.

Chairman CHAFFETZ. I want people to make a profit. But you know why I feel like you are both lying to us? You didn't write in there—you didn't say profit. And if you don't include that as a factor in how you price a drug, you are lying. You are not telling the full and complete truth.

You can tell me about access and all the other things, but profit is a motivator. I happen to not think it is an evil thing, but I think you are purposely avoiding it. I don't think you are telling the full and complete truth.

We want people to make money. You can't be in business and not make money.

Ms. RETZLAFF. May I make a comment?

Chairman CHAFFETZ. Sure.

Ms. RETZLAFF. Of course, we expect to make a profit.

Chairman CHAFFETZ. Then when you price a drug, is that part of the consideration?

Ms. RETZLAFF. It is part of the ——

Chairman CHAFFETZ. Then why didn't you list it out?

Ms. RETZLAFF. Again, we expect to make a profit. I think what is critical, and I did mention it in the form of the need for innovation, because in a research-based pharmaceutical company ——

Chairman CHAFFETZ. And I don't believe you.

Ms. RETZLAFF.—we reinvest that into research.

Chairman CHAFFETZ. That is not the history of Turing. You have ——

Ms. RETZLAFF. Turing is a brand-new company.

Chairman CHAFFETZ. Exactly. And it is a better model to understand, because Valeant has literally over 1,000 different items. They have a long history here.

Ms. RETZLAFF. Right.

Chairman CHAFFETZ. And we can be fairly critical of certain things, but when you have a drug that is acquired that has been on the market since I believe 1953 or so ——

Ms. RETZLAFF. Something like that.

Chairman CHAFFETZ.—then you start to understand what happened here.

And, again, when it gets abused and it goes too far and you are taking advantage of and you lie to the public, you go on television—and I am not saying you personally, but I am saying that the person who owns the plurality of the company here lies, it appears as if you are cheating the American people.

And I think you are both being disingenuous and incomplete in your answer, and I want you to reconsider in the future. Profit is, of course, a motivator. It is, of course, part of your calculation. You don't have CFOs that sit in there and don't calculate out the profit line. You don't go out and rent yachts and fireworks and all that kind of stuff unless you are able to jack up the price.

And what I am worried about is you are out there marketing a drug that is now $750 and you are telling me, "Oh, well, the majority of the people, they can just discount that down to a dollar." Who is paying the 750 bucks? Suckers. And you know the suckers are? The American public, because we all pay our insurance premiums, we do the right things, we go to the hospitals, we pay our bills, and your—your—extravagance is something we all have to pay for.

Ms. RETZLAFF. It's pennies.

Chairman CHAFFETZ. Pennies.

Ms. RETZLAFF. Pennies.

Chairman CHAFFETZ. Pennies.

Ms. RETZLAFF. It's pennies, and I actually think ——

Chairman CHAFFETZ. And that is why it makes us sick.

Ms. RETZLAFF. And I actually think ——

Chairman CHAFFETZ. Don't tell me that it is pennies, because you are right, you have a drug that affects less than 3,000 people out of 330 million people. But you multiply what you are doing out over the long course of everybody else, and you are taking advantage of the system.

And that is why, again, the pressure comes back to the government and the FDA to increase the competition, so that there is a proper balance here. You can find the right amount of profit, not have Congress dictate or set up price controls. And that is why we will continue to do this.

This has been a very fruitful and enlightening hearing. I appreciate it.

Did the ranking member want to—yes?

Mr. CUMMINGS. A few questions.

Ms. Retzlaff, you have a research department?

Ms. RETZLAFF. A research department?

Mr. CUMMINGS. Yes. You said you are spending all this money on research.

Ms. RETZLAFF. Yes, yes. We have an R&D department.

Mr. CUMMINGS. All right—no, no, no. Research.

Ms. RETZLAFF. Research.

Mr. CUMMINGS. Okay, I am going to get to development in a minute.

Ms. RETZLAFF. Yes.

Mr. CUMMINGS. Research. How many people, how many scientists do you have in the research department?

Ms. RETZLAFF. We have 36 people in our research department of the 139 employees.

Mr. CUMMINGS. You have 36 ——

Ms. RETZLAFF. Thirty-six ——

Mr. CUMMINGS. Whoa, whoa, whoa. You have 36 scientist types?

Ms. RETZLAFF. Thirty-six people in research and development. Generally having a science background is a requirement to work in R&D.

Mr. CUMMINGS. So you have 36 science-type folk doing research.

Ms. RETZLAFF. Yes, we do.

Mr. CUMMINGS. So of the money that you are spending on R&D, how much of that, what percentage of that is development? Again, we have separated it. I am putting development to the side and putting research over here.

Ms. RETZLAFF. Yes. I don't know—I don't know if I have that exact number, but I think I can go back to our president of R&D and get you that information.

Mr. CUMMINGS. How soon can I get that?

Ms. RETZLAFF. As soon as possible. I can call him when we are finished here.

Mr. CUMMINGS. All right, we will get it by—Mr. Schiller, just one question for you.

Do you all ever meet with the hospital associations, because there are a lot of hospitals, probably almost every hospital in this country, that need those drugs that we were talking about, that you have gone up on so much, that are suffering. Do you all meet with hospitals?

It probably affects everybody. I know it affects Hopkins. So you know if it affects Hopkins, it is affecting a lot of other hospitals. Do you meet with them? Do you at all?

Mr. SCHILLER. We—I have not personally. The head of the division where those drugs sit has reached out to all the major users of Nitropress and Isuprel, and had discussions. We have also reached agreement with the large group purchasing organizations that buy for the hospitals to make sure that those who need the discount are getting the discount.

Mr. CUMMINGS. When you say those who need the discount, you mean to tell me that there are some people who come up and say,

"Hey, we can spend those millions extra. It is no big problem. We don't need the discount." Is that what you are trying to tell me?

Mr. SCHILLER. No. That was a poor choice of words.

Mr. CUMMINGS. Well, why don't you tell me what you mean?

Mr. SCHILLER. We wanted to make sure that the heavy users of Isuprel and Nitropress did not have a big burden from the price increase. That is why we tiered it toward heavy volume users, so the largest users will get a 30 percent discount. Lighter users would get a smaller discount.

Mr. CUMMINGS. Well, if you have a hospital that is a small hospital but needs those drugs desperately, then they don't get as much of a discount. Maybe some small town in South Carolina or wherever, as opposed to a Hopkins, right?

Mr. SCHILLER. They—we ——

Mr. CUMMINGS. So in other words, it might hurt them even more.

Hopkins is a big, international hospital, and they are complaining big time. So they would qualify, I guess, for the big hospital discount, right? Come on, man.

Mr. SCHILLER. I don't know off—I would assume so, but I can't tell you specifically.

Mr. CUMMINGS. So my point is that you know—and then I am finished with this, Mr. Chairman.

But Mr. Cartwright I think made some good points about these hospitals. Our community hospitals, hospitals doing the best they can with what they have, and this is all cutting into their bottom line.

But the chairman is absolutely right. You know, I absolutely have no problem with folk making money. But when it gets to a point where basically it is about greed, so that—what did you make? $26 million? What was it, 26, Mr. Schiller?

Mr. SCHILLER. It was 27.

Mr. CUMMINGS. And what about you, Ms. Retzlaff?

Ms. RETZLAFF. I'm sorry?

Mr. CUMMINGS. How much money do you make? That is what I asked you.

Ms. RETZLAFF. I'm with a private company. I don't know that I have to disclose that.

Mr. CUMMINGS. Okay. All right. Well, I am sure you are making a nice sum.

Ms. RETZLAFF. Not as much as Mr. Schiller.

Mr. CUMMINGS. Yes, I am sure.

Well, guess what, the people in my district are making like $30,000 a year, $40,000 a year. Probably the money that you spend in a day or a week, they make in a year. Yet and still they have to get drugs to stay alive.

So are you in contact with Mr. Shkreli?

Ms. RETZLAFF. On occasion, yes.

Mr. CUMMINGS. Okay.

Again, I want to thank you all for being here. Bye-bye.

Chairman CHAFFETZ. Thank you. It has been very illuminating.

The committee stands adjourned. Thank you.

[Whereupon, at 1:22 p.m., the committee was adjourned.]

# APPENDIX

Material Submitted for the Hearing Record

EARL L. "BUDDY" CARTER
1ST DISTRICT, GEORGIA

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COMMITTEE ON HOMELAND SECURITY
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**Statement for the Record**

**House Committee on Oversight and Government Reform**

**Developments in the Prescription Drug Market: Oversight**

Thursday, February 4, 2015

Chairman Chaffetz, Ranking Member Cummings, and Members of the Committee, thank you for allowing me to offer this Statement for the Record and for holding this important hearing. As a pharmacist with over 30 years of experience, I have witnessed and participated in the ever evolving world of pharmaceuticals. I can remember when a computer was first used in my pharmacy business to help with inventory and processing of patient prescriptions. I can remember the development of life saving drugs like Lipitor and Crestor that have helped to decrease heart disease deaths by over 40 percent, and I witnessed the creation and evolution of pharmacy benefit managers (PBMs). Now, I am honored to be the only pharmacist serving in the United States House of Representatives.

Over the last 50 years, much advancement has been achieved by the pharmaceutical industry. In the United States, life expectancy is now 78 years old compared to 47 over a century ago. Five-year cancer survival rates are up 39 percent across all cancers. New therapies like the new Hepatitis C therapies have cure rates of more than 90 percent, and, on average, 70 percent of drugs are potential first-in-class therapies, meaning they use a completely new approach to fighting a disease. With these types of advancements and achievements, some would assume that the cost of health care in the U.S. would have significantly increased. However, according to the Center for Medicare and Medicaid Services' data on national health expenditures by type of service and source, prescription medication costs account for only 10% of total health care spending in the U.S. This is the same percentage of spending on prescription medication costs as in 1960.[1]

Many point to a competitive U.S. marketplace for these results. Generally, brand-name pharmaceutical manufacturers have another brand-name competitor in the market within two years of initial introduction of a pharmaceutical. In addition, many patients are prescribed a generic form of a medication. Ninety percent of all medicines prescribed to U.S. patients are generics, and the cost of a generic drug is usually 80 percent less than that of a brand name

[1] Centers for Medicaid and Medicare Services. National Health Expenditures by type of service and source of funds, CY 1960-2014. 2015. Raw data. Https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-report/nationalhealthexpenddata/nationalhealthaccountshistorical.html, Washington.

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medicine. In fact, in regards to the new hepatitis C treatment, the New York Times Editorial Board stated in September 2015 that "competitive market forces and hard-nosed bargaining make tremendously effective new hepatitis C medicines not just more accessible to ailing patients- but also offer good value to the U.S. health care system."[2] If national data and market response are used as indicators, it is clear that pharmaceutical companies are not the driving force behind making medications unaffordable.

With this in mind, I would like to draw a distinction between legitimate pharmaceutical companies and the two companies testifying before the committee today. Many pharmaceutical companies have one major principle at their core- letting research and development drive their business model. In fact, the majority of pharmaceutical companies invest an average of 20 percent of total revenue in research and development. This equates to more than $51 billion used for researching and developing new therapies for patients, which is more than the entire operating budget of the National Institutes of Health. Many agree that this dedication to R&D by many pharmaceutical companies is the reason why cancer death rates are down 22 percent, 99 percent of patients with early detected melanoma survive, and HIV/AIDs is now a chronic condition. In comparison, according to Valeant's income statement, it spends just 3 percent of its revenue on R&D. While Turing has boasted that they plan to invest 60 percent of their 2016 revenues into R&D past business practices indicate differently. Instead of working to better our industry and the health of Americans, both companies have demonstrated they will instead exploit the sick and seek to make a profit off those in dire need of medications. Valeant's CEO, Mr. Michael Pearson, made this very clear when he stated that Valeant's strategy for market growth is quite different from traditional pharmaceutical companies and has consistently pursued profitable growth through diversification, strong execution, and financial discipline.[3] In turn, some have referred to Valeant as a "shell company" created for the sole purpose of buying other companies. Similarly, Turing's former CEO, Mr. Martin Shkreli, has a long history of creating hedge fund companies and has continuously faced legal proceedings with his companies claiming breach of loyalty and securities fraud. I ask my colleagues to please draw the distinction between who is part of the pharmaceutical industry and who are taking advantage of a vulnerable sector of the American population.

Disregarding these two companies, who should be excluded from all conversations and investigated by all relevant law enforcement, I would like to bring attention to the real issue that drives pharmaceutical costs. Since the 1980s, Pharmacy Benefit Managers (PBMs) have evolved from fiscal intermediaries who adjudicate prescription drug claims to companies that manage pharmacy benefits, negotiate drug discounts with pharmaceutical companies, and require patients to use preferred providers and products to treat medical conditions. Over time, this evolution by PBMs has resulted in fewer choices in care for patients and ever-restricting access to community pharmacists. Action must be taken to ensure that consumers and independent health care providers alike do not suffer from an industry that hides negotiations, manipulates pricing data, and continues to funnel consumers into a system that has no government oversight and leaves Americans with no choice of service or care.

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[2] Boffey, P. M. (2015, September 2). Costly Hepatitis C Drugs for Everyone? *The New York Times*.
[3] Ubl, Stephen J. (2015, December 11). Turing and Valeant do not represent biopharmaceutical industry. *The Hill*.

For there to be fair pricing for pharmaceutical products, there must be a fair and competitive market. I believe there are three essential elements that must exist for the creation of a competitive market transparency, choice, and a level playing field for patients and providers alike that is devoid of conflicts of interest. Without these three elements, patients will see fewer choices and higher costs as providers are not forced to compete by offering fair prices and better services. Without transparency, consumers would not be able to evaluate products, make informed choices, and participate in the full range of services the market could offer. The lack of transparency of PBMs continues to make it difficult for consumers and pharmacists to take part in the benefits they deserve. According to the Pharmaceutical Care Management Association, PBMs manage over 250 million Americans' pharmacy benefits. The three largest PBMs alone cover more than 180 million patients in the United States, roughly 78% of all Americans who have pharmacy benefits.

Evidence to the lack of transparency was made apparent with the recent case involving Meridian Health Systems (Meridian). In 2008, Meridian was experiencing surging medication costs for its employees. In turn, they hired a PBM to help reduce their costs. In the beginning, the PBM projected that they would save Meridian at least $763,000. However, just three months into the contract with the PBM, Meridian was on pace to spend an additional $1.3 million than previously spent before hiring the PBM. On the brink of the largest medication bill Meridian had ever experienced, the officer in charge of Meridian's medication spending began to investigate where all the money was going. After review of Meridian's employee prescription data, he was shocked to find that the PBM was inflating their bills to play "the spread" (billing the company for larger amounts than what it costs to actually fill the prescription). Rather than the PBM acting a fiduciary for Meridian like they were supposed to, the PBM padded its profits by taking advantage of a complicated and opaque system.

PBMs are supposed to be "honest brokers." They are supposed to act as a fiduciary to the plans they serve, bargaining to secure the lowest price for prescription drugs and dispensing services. I ask the committee: When a company owns the "independent" arbitrator, how can any action by the arbitrator be independent? When a PBM owns a drug company or has a mail order pharmacy, how can the PBM be an honest broker while serving two masters?

As a practicing pharmacist, I consistently helped customers navigate their pharmacy benefits. I had to do this because PBMs create barriers for consumers and the only way for my patients to receive the care they needed was for me to help them understand what the PBM allowed and didn't allow. The majority of consumers never deal with the PBM or their insurance company to negotiate benefits. Most of the time, pharmacists are the professional who help consumers with the vast array of complex rules and agreements that define prescription drug benefits. Pharmacists are health care providers and I did everything I could to provide my patients with the information to make informed decisions and receive the medications they needed for the best possible health care.

Due to its lack of transparency and under-regulated market, PBMs have grown substantially since 2003. In just over ten years, the two largest PBMs have increased their profit margins by almost 600%. This increase alone is impressive without considering within those 10 years that the U.S. suffered the worst financial crisis since the Great Depression. A 600% increase in

profits during some of the slowest overall economic growth this country has seen in a century only suggests the PBM market is not competitive and consumers are being footed with the bill.

While there are bad actors in any profession or field, the lack of transparency in PBMs limits our ability to separate the wheat from the chafe or enact much needed reforms. Some PBMs have frequently faced a wide range of claims concerning deceptive business practices and anticompetitive conduct that has been shown to harm consumers and deny medication benefits. These acts can range from receiving kickbacks or rebates in exchange for exclusive arrangements to keep cheaper medications off the market to diverting patients to more expensive medications to take advantage of rebated that PBMs receive from drug manufacturers. From the pharmacy perspective, pharmacists are consistently squeezed out of the market when PBMs manipulate drug reimbursement rates or Maximum Allowable Cost (MAC) pricing as a method of increasing their profits.

Moving forward, greater attention should be paid to legislative action that brings transparency and competitiveness back into the PBM market. I encourage the Committee to look at every possible angle to address these issues and bring transparency and choice back into the market while eliminating the existence of conflicts of interest.

I ran for Congress to serve the people of the First Congressional District of Georgia and my country. As the only pharmacist in Congress, it is my responsibility to help and protect consumers, providing them with an environment where they can decide for themselves how they wish to live their lives. As a lifelong medical professional, I know that addressing the questionable practices of PBMs would be a step to ensuring that Americans are provided the best possible quality of care in an affordable and accessible manner. Importantly, this would be achieved by allowing the free market to perform in the way it was intended.

I want to again thank Chairman Chaffetz, Ranking Member Cummings, and the members of this Committee for holding this hearing today. This is a perfect opportunity to show the American people that we care about them and are working towards patient-centered solutions for health care.

Earl L. 'Buddy' Carter
Member of Congress
First District of Georgia

Statement of Congressman Doug Collins (GA-09)
As Submitted for the Record
Committee on Oversight and Government Reform Hearing on:
Developments in the Prescription Drug Market: Oversight
February 4, 2016

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Thank you, Mr. Chairman and Members of the Committee, for holding this important oversight hearing addressing Developments in the Prescription Drug Market. Given the state of healthcare in this country, Congress' responsibility to conduct oversight of all areas of the healthcare ecosystem, including the prescription drug market, is more important than ever.

I appreciate the opportunity to submit this statement for the record. As a former Member of the Oversight and Government Reform Committee, I have great respect for the work of this Committee and the leadership of Chairman Chaffetz. While there are a number of topics related to the prescription drug market that are of great importance to Northeast Georgia, I will focus on one in particular: the role of Pharmacy Benefit Managers (PBMs) in negotiating drug prices, and the need for transparency in pricing contracts.

Independent community pharmacies dispense more than 40 percent of prescriptions nationwide and are a crucial part of the healthcare system. They provide invaluable support and guidance, particularly to seniors. There is a pressing need for transparency and openness in the federal government's substantial business partnership with PBMs and their reimbursement practices. As you well know, PBMs serve as the mediator between health plans and all pharmacies - some chains and all independents. They play a vital role in the system, but over time, PBMs have transformed far beyond their original form. Many large PBMs also own mail order pharmacies and are therefore are in direct competition with their clients – the pharmacies. The PBMs negotiate two things with pharmacists the total amount that the pharmacy can charge a customer for a given drug, and the amount the pharmacy will be reimbursed by the PBM for that same drug.

Today, community pharmacists routinely incur losses of approximately $100 - in some cases, much more - on individual prescriptions because it is not uncommon for PBMs to reimburse pharmacies well below their cost to acquire and dispense generic prescription drugs that have skyrocketed in price. PBMs may wait weeks or months to update the reimbursement benchmarks they use to compensate pharmacies while drug prices increase virtually overnight. This situation jeopardizes community pharmacists' ability to continue serving patients because it leaves these small businesses with unsustainable losses.

PBMs like to talk about making healthcare affordable. But in doing so, they fail to realize that we must also make healthcare accessible. Unlike my local pharmacist in Hall County, and those across the nation, PBMs do not have a real relationship with patients. In fact, it is not uncommon for them to secretly retain most manufacturer payments – rebates, discounts and other fees – instead of passing the savings on to patients. Additionally, PBMs have been known to switch plan members from low-to-high cost drugs and manipulate generic pricing. This is why I support strong PBM transparency requirements. I believe these policies are the key to delivering real savings to patients.

Community pharmacies should have access to up-to-date pricing information so when they dispense a drug, they know their reimbursement rate reflects current market prices. PBMs have been padding their bottom lines at the expense of our local pharmacies. Predictability and transparency should exist in every industry, for every company, regardless of their size or market power. In Northeast Georgia and across the nation, many pharmacists have to choose between keeping their business open, or giving their patients the services and care they need. This isn't a choice they should be forced to make.

The American Antitrust Institute notes that, "considering the substantial number of enforcement actions and the severity of the PBM conduct, we believe these efforts at regulating PBMs are well founded and that the FTC's advocacy has been ill-advised." Many states have acted where the federal government has failed to, and we should learn from them. Most recently, we've seen state laws enacted to increase transparency and reform within the generic drug pricing and reimbursement system. To date, 24 states have enacted such laws. The goal of these laws is to increase transparency and provide structure around the generic drug pricing and reimbursement system. But when community pharmacies speak out in support of these reasonable reforms, the PBM community has retaliated through baseless lawsuits against the states.

If PBMs were truly acting in the best interests of consumers, as they claim, then why do they oppose virtually every transparency reform effort at the state and federal level? PBMs come to Congress and say one thing to Members, then turn around and behave however they wish in the pharmacy marketplace without fear of enforcement or oversight. It's time for that to change. We must preserve pharmacy access for patients - especially those in rural areas like Northeast Georgia.

Supporting strong PBM transparency requirements is the cornerstone to delivering real savings to patients. To achieve this goal and return the focus of the prescription drug industry to patients, I introduced H.R. 244, the MAC Transparency Act. H.R. 244 would preserve pharmacy access for patients by requiring PBMs to update their "maximum

allowable cost" (MAC) benchmarks every seven days to better reflect market costs and allow pharmacists to know the source by which PBMs set reimbursement for his or her community pharmacy. My legislation will also give patients greater choice of pharmacy, as patients would not be forced by PBMs to use a PBM-owned pharmacy – an obvious conflict of interest. According to Medicare data, PBM-owned mail order pharmacies may charge plans more – as much as 83 percent more – to fill prescriptions than community pharmacies. Operating within the law and operating transparently are two very different things. The behavior that several large PBMs have been able to get away with in the marketplace has left me with no option but to pursue a legislative solution in the form of H.R. 244. With soaring healthcare costs at the forefront of everyone's minds, we need to make sure small pharmacies have the tools they need to appropriately deal with large PBMs.

I thank the Chairman for holding this hearing and urge prompt congressional consideration of H.R. 244, the MAC Transparency Act, and other PBM reform legislation.

Statement for the record:

# DEVELOPMENTS IN THE PRESCRIPTION DRUG MARKET: OVERSIGHT

Before the Full House Committee on Oversight and Government Reform

February 4, 2016

David A. Balto
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Dear Chairman Chaffetz, Ranking Member Cummings, and Members of the Committee,

Please accept this statement for the record. The following statement documents substantial concern over pharmacy benefit managers and the lack of market transparency, which is a concern of this Committee and part of today's hearing.

I write the below statement based on my expertise as a private sector antitrust attorney and an antitrust enforcer for both the Department of Justice and the Federal Trade Commission ("FTC"). From 1995 to 2001, I served as the Policy Director for the FTC's Bureau of Competition and the attorney advisor to Chairman Robert Pitofsky. I have testified before Congress and eleven state legislatures on PBM regulation, and was an expert witness for the State of Maine on its PBM legislation.

PBMs have a profound impact upon drug costs. If PBMs are unregulated, which they mainly are, they can continue to engage in conduct that is deceptive, anticompetitive, and egregious. For the healthcare system to work effectively PBMs must be free of conflicts of interest that arise from owning their own pharmacies. What health plans and employers are fundamentally purchasing is the services of an "honest broker" to secure the lowest prices and best services from both pharmaceutical manufacturers and from pharmacies. When the PBM is owned by the entity it is supposed to bargain with or has its own mail order operations there is an inherent conflict of interest, which can lead to fraud, deception, anticompetitive conduct, and higher prices. The three major PBMs clearly face that conflict since they own mail order operations, specialty pharmacies, and in the case of CVS Caremark – the second largest retail pharmacy chain and the dominant long-term care pharmacy.

Conflicts of interest raise severe concerns in the health care system. Where a payor is also a provider they can manipulate the relationship to raise health care costs. That is why, when pharmaceutical manufacturers obtained PBMs in the 1990's, the FTC acted to eliminate those conflicts of interest. The FTC challenged the acquisition of PCS by Lilly and Medco by Merck, because of the concern that having a manufacturer own a PBM would be giving the "fox the keys to the hen house door"—and would lead to higher prices for consumers.

**A Broken Market Leads to Escalating Drug Costs and Rapidly Increasing PBM Profits**

PBMs entered the health care market as "honest brokers" or intermediaries between heath care entities. However, the role of the PBM has evolved over time and increasingly PBMs are able to — "play the spread" – by not fully sharing the savings they purportedly secure from drug manufacturers. As a result PBM profits have skyrocketed over the past dozen years. Since 2003, the two largest PBMs—Express Scripts/Medco and CVS Caremark— have seen their profits increase by almost 600% from $900 million to almost $6 billion.

There is tremendous concern over rapidly increasing drug prices which threaten our nation's ability to control the cost of health care. While PBMs suggest that they are there to control these costs these claims must be carefully scrutinized. The concern of a PBM is to maximize profits and that means maximizing the amount of rebates they receive. Since rebates

are not disclosed this is an incredibly attractive source of revenue. PBMs can actually profit from higher drug prices, since this will lead to higher rebates. While PBMs tout their ability to lower drug costs, the gross profit the major PBMs reap on each prescription covered is increasing year after year. For example, Express Scripts' gross profit on an adjusted prescription increased from an average of $4.16 in 2012 to $6.68 in 2015 to an estimated $7.00 by 2017. In other words the gross profits have increased by almost 75% since Express Scripts acquired its biggest rival Medco.

Would PBMs withhold their negotiating punch to secure higher rebates? We do not have to guess that this is occurring. PBMs have used similar strategies in the past. Indeed, state enforcers have attacked sweetheart deals PBMs arranged with drug manufacturers to force consumers to use higher cost, less efficacious drugs, in order to maximize rebates and secure kickbacks. They held back their negotiating muscle to allow prices to escalate to maximize rebates.

Facing weak transparency standards, the largest PBMs frequently engage in a wide range of deceptive and anticompetitive conduct that ultimately harms and denies benefits to consumers. Some PBMs secure rebates and kickbacks from drug manufacturers in exchange for exclusivity arrangements that may keep lower priced drugs off the market. PBMs may switch patients from prescribed drugs to an often more expensive drug to take advantage of rebates that the PBM receives from drug manufacturers. PBMs often do not pass through to payors rebates secured from drug manufacturers, and instead are accounted for as a reduction in cost of revenues, allowing the PBMs to hide profits. In fact, Medco was the last PBM to publicly disclose rebates in 2012. In short, PBMs derive enormous profits at the expense of the health care system from the ability to "play the spread" between pharmaceutical manufacturers, pharmacies and health care plans.

No other segment of the health care market has such an egregious record of consumer protection violations as the PBM market. Between 2004 and 2008, Express Scripts and CVS were the subject of six major federal or multidistrict cases over allegations of fraud; misrepresentation to plan sponsors, patients, and providers; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. One of the most common forms of egregious conduct identified was PBMs switching consumers to higher cost drugs, that often were less efficacious, in order to maximize rebates. These cases appended to this testimony, resulted in over $371.9 million in damages to states, plans, and patients so far.

Unfortunately the provisions in the orders in each of these cases have expired increasing the need for greater regulation and enforcement to ensure that the market functions with transparency, consumer choice, and free of conflicts of interest.[1]

These problems are only getting worse. Case in point are the number of recent cases which are either ongoing or have settled in 2015. In 2015 alone, Express Scripts and CVS have

[1] For a more detailed analysis of the federal and state cases against the PBMs, *see* David A. Balto, *Federal and State Litigation Regarding Pharmacy Benefit Managers*. http://www.dcantitrustlaw.com/assets/content/documents/PBM/PBM%20Litigation%20Updated%20Outline%20-%201-2011.pdf.

paid settlement fines to the federal government and to numerous states of over $129 million for illegal prescription dispensing and various violations of the false claims and anti-kickback laws.[2] In 2014 CVS was responsible for over $30 million in penalties concerning violations of the false claims act and SEC violations.[3] And currently pending before the Delaware federal district court is a false claims act brought against Medco (now Express Scripts) on behalf of the U.S., California, Florida and New Jersey over claims the company defrauded state and federal health insurance programs by accepting undisclosed discounts from drug manufacturers and not passing on the savings to its clients, according to a recently amended complaint.[4]

Moreover, substantial private litigation is pending against major PBMs. For example, Catamaran Rx, a recent acquisition of Optum Rx, has several separate pending suits against it. One by retail chain Kmart alleging failure to pay reimbursements for dispensed drugs equating to $38 million in damages;[5] and the other by 55 independent pharmacies alleging illegal conduct serving to inflate patient costs while simultaneously underpaying pharmacies.[6] Additionally, Express Scripts is facing an antitrust conspiracy suit in which the plaintiff has alleged Express Scripts engaged in a conspiracy with other major PBMs to exclude competing compounding pharmacies from their network, effectively forcing the competition to close and routing patients to the PBMs captive pharmacies. The case has survived a motion to dismiss.[7]

As a general matter it is essential to provide transparency in the healthcare sector, which helps all participants adequately evaluate products carefully, to make informed choices, and to secure the full range of services they desire. In these respects the PBM market is fragile at best. PBM operations are very obscure and a lack of transparency makes it difficult for plan sponsors, including the federal government, to make sure they are getting the benefits they deserve.

Responding to the numerous enforcement actions, both a handful of states and Congress have taken measures to enact transparency provisions by requiring some degree of disclosure of rebates and other revenue. In the multistate enforcement action against CVS Caremark, 30 state attorneys generals required rebate disclosure. Additionally, the Department of Labor ERISA Advisory Council recommended PBMs be required to disclose fees and compensation to sponsors of ERISA health plans.[8]

Unclear and inadequate disclosure of rebates and discounts undermine the ability of plan sponsors to compare competing proposals. Because rebates, discounts, and other fee structures remain undisclosed, plan sponsors cannot clearly identify and choose PBMs offering the highest value services. PBMs' promise of controlling pharmaceutical costs has been undercut by a pattern of conflicts of interest, self-dealing, deception, and anticompetitive conduct. The dominant PBMs have been characterized by opaque business practices, limited market competition, and widespread allegations of fraud.

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[2] See Appendix A.
[3] Id.
[4] *John Doe v. Medco Health Solutions Inc., et al.*, Case No. 1:11-cv-00684 (D. Del.).
[5] *Kmart Co. v. Catamaran Co.*, Case No. 2015-L-008290 (Ill. Ct. Cl. Aug. 31, 2015).
[6] *Albert's Pharmacy, Inc. et al v. Catamaran Corporation*, Case No. 3:15-cv-00290 (M.D. Pa. Feb. 9, 2015).
[7] *HM Compounding Services v. Express Scripts*, Case No. 14-cv-01858 (E.D. Mo.).
[8] *See* PBM Compensation and Fee Disclosure, Report by the ERISA Advisory Council, Department of Labor (2014), *available at* http://www.dol.gov/ebsa/publications/2014ACreport1.html.

Increased disclosures by PBMs have resulted in price decreases and significant savings for health plans. Increasingly larger health plans are negotiating for transparency and securing significant savings. Large plan sponsors, such as universities, states, and federal programs have recently learned that they can achieve substantial cost savings by requiring transparency – i.e. requiring PBMs to disclose their negotiations and financial interactions with drug manufacturers.

**In considering the role of PBMs in negotiating drug prices and concerns about the lack of transparency in pricing contracts we remind the Committee that where transparency and consistency are absent there is a significant opportunity for providers and plan sponsors to be harmed by deceptive and unfair conduct.**

Thank you for your consideration of this statement.

To Caroline
From: V.F.
2 pages Drug Cost

December 15, 2015

Congressman John J. Duncan
Attn: Ms Vickie Flynn
331 Court St
Maryville, TN 37804

Dear Vickie,

The purpose of this letter is to request the Congressman's help to understand the justification for the incredible increase in the cost of one of my Medicare prescription drugs, Aplenzin. I am a very healthy woman, but due to a chemical imbalance in my system, I have been treated for depression for many years. In 2013, my female gynecologist, working with a female medical psychiatrist, prescribed the drug Aplenzin. For the first time in a long while, I really began to feel much better. The only negative was Aplenzin was very expensive. Both doctors also commented that while Aplenzin was really helping a lot of their patients, they could not understand its high cost. Their understanding was that Aplenzin was only a slight variation from the very popular drug Buprion, which I used for many years, and is a generic drug available at Wal-Mart for $10 for a 90-day supply.

I understand the business models of many drug companies and their need to recover their R & D costs, and also the economic laws of supply and demand when a product provides better results than its competitor. But after doing some research on the Internet, there appears to be a lot more in play here with the drug Aplenzin (and many others as well).

Valeant Pharmaceuticals International Inc. manufactures Aplenzin, and is a publically traded Canadian company that is managed out of Bridgewater, New Jersery by a controversal CEO J. Michael Pearson. The US Senate recently was very critical of Valeant for predatory pricing policies and the Center for Medicare has also begun an investigation. In several of the articles on the Internet, several drugs were highlighted as examples of Valeant's extreme drug cost increases and Mr. Pearson's business strategy of price gauging their customers, who are sick people needing help either through hospital care or prescription drugs. In none of the articles was the drug Aplenzin mentioned. So perhaps the data below will add yet another log to the blazing fire hopefully about to burn Valeant and Mr. Pearson.

My first prescription for Aplenzin was in late 2013 and I have been taking one 522 mg pill a day ever since. As a member of a United Health Care (UHC) AARP Medicare Advantage Plan since I turned 65, have had the option to purchase prescription drugs through local pharmacies or through UHC's mail order pharmacy, OptumRx. The normal purchase has been a 90 supply by mail order from OptumRx, since it is supposed to be less expensive than retail pharmacies. Outlined below is my drug cost for Aplenzin since December 2013. The table shows the date of purchase, the pharmacy provider, numbers of pills purchased, the total cost of the pills, the unit cost per pill, and the annual cost for 365 Aplenzin pills at that date's cost per pill. Only purchase dates with a drug cost change are shown for clarity. It should be noted that Medicare provides the total drug cost of the Aplenzin on a monthly summary that identifies the total cost of the drug and the distribution of the total cost between UHC, Medicare, and me. Since starting

Aplenzin, I have blown through the prescription drug donut hole and into the catastrophic area in both 2014 and 2015. As a result, my personal cost has varied with almost every purchase, and depends on each year's UHC prescription drug plan rules, and in which of the four Medicare drug tiers I am in at the time. All documentation for these purchases is readily available if needed. Needless to say, my personal cost for Aplenzin has increased at the same rate as the total cost. If my math is correct, in less than two years (Jan 2014 to Sep 2015), the cost of Valeant Aplenzin has increased by an incredible 224%. That should make Mr. Pearson's shareholders very pleased, but obviously not his customers.

| Date | Provider | # of Pills | Total Cost | Cost/pill | Annual cost |
|---|---|---|---|---|---|
| 12/13/2013 | Wal-Mart | 30 | $1115 | $37.17 | $13,566 |
| 1/10/2014 | OptumRx | 90 | $2964 | $32.93 | $12,021 |
| 10/16/2014 | OptumRx | 90 | $3660 | $40.67 | $14,843 |
| 3/14/2015 | OptumRx | 90 | $5,848 | $64.98 | $23,717 |
| 6/21/2015 | OptumRx | 90 | $7390 | $82.11 | $29,971 |
| 9/24/15 | OptumRx | 90 | $9607 | $106.74 | $38,962 |

In September, an appeal was made to UHC to understand the unimaginable cost increase for Aplenzin. Although a case was opened, there has been no response from UHC in several months Needless to say; I received no information when I tried to communicate directly with Valeant. I spoke with both the pharmacy and with customer service, and neither were willing to discuss their drug costs. My husband, who is a mechanical engineer and spent his entire career in pulp and paper manufacturing for a Fortune 500 company, estimates it costs Valeant pennies to produce an Aplenzin pill, based on the cost and similar chemical formulation (bromine vs. chlorine base) to its biggest competitor Buprion.

To summarize, I would sincerely appreciate Congressman Duncan's help in understanding the justification of Valeant Pharmaceuticals International Inc for the incredible increase in the cost of my Medicare prescription drug, Aplenzin. My social security check has certainly not increased by 224%. Understanding the reality of our world I will not be surprised if your answer is simply greed, or some other catch phase like pressure from Wall Street to produce results. I believe in the free market, and my husband and I spent his 30-year career with a Fortune 500 corporation that was able to successfully balance all its stakeholders (customers, employees, financial markets, etc). I also find it is interesting to discover the US is one of the few countries that does not regulate its drug industry. So perhaps his answer to me could also include what his thoughts are, and even what those of Congress as a whole are, on the subject of how to identify and control those drug companies who appear to be taking advantage of their customers with significant medical needs during their particularly difficult times.

Thank you in advance for your help.

Yours truly,

Joy A. Macklem

Joy A. Macklem

**Statement for the Record: National Community Pharmacists Association (NCPA)**

**House Committee on Oversight and Government Reform**

**"Developments in the Prescription Drug Market: Oversight"**

**Thursday, February 4, 2016**

Chairman Chaffetz, Ranking Member Cummings, and Members of the Committee:

Thank you for conducting this hearing on the current state of the prescription drug market and the potential need for oversight. In this statement, NCPA would like to present our thoughts on how increasing transparency into the business practices and potential conflicts of interest of Pharmacy Benefits Managers (PBMs) could provide tangible benefits to health plans/payers, pharmacists, and patients. NCPA represents the pharmacist owners, managers and employees of nearly 23,000 independent community pharmacies across the United States. These pharmacies dispense approximately 40 percent of all community pharmacy prescriptions and are typically located in rural or very urban areas.

Community pharmacies represent the most accessible point in patient-centered health care where typically consumers do not need an appointment to talk with a pharmacist about their prescription medication, over-the-counter products or really any health-related concern. In this way, community pharmacies serve as safety-net health care providers in their communities—not only when patients need help with their medications. Community pharmacists provide expert medication counseling and other cost-saving services that help mitigate the $290 billion annual cost of treating patients who do not adhere to their medication regimen.

**Concentrated and Powerful PBM Marketplace**

According to the Pharmaceutical Care Management Association (PCMA), the trade group that represents the PBM industry, PBMs manage pharmacy benefits for over 253 million Americans.[1]

[1] Testimony of Mark Merritt, President and CEO of the Pharmaceutical Care Management Association before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health, October 21, 2015.

Three large companies lead the PBM market: ExpressScripts, CVS Health (formerly CVS Caremark), and OptumRx. In total, they cover more than 180 million lives in the United States, or roughly 78% of Americans whose pharmacy benefits are managed by a PBM.[2] In addition, the annual revenues for these three entities are staggering. In 2014, annual revenues for ExpressScripts were approximately $100.9 billion, annual revenues for CVS Health were $139.4 billion and annual revenues for OptumRx were $31.97 billion. (In 2015, OptumRx acquired Catamaran, which reported annual revenues of $21.6 billion).

**Current Lack of Transparency Regarding PBM "Spread" Profits**

PBMs serve as the "middleman" in the majority of all prescription drug transactions in the United States. They are able to leverage the number of beneficiaries in a particular plan to negotiate lucrative rebates from pharmaceutical manufacturers. They also formulate pharmacy provider networks that will supply or dispense these drugs to the plans' beneficiaries and in turn, charge the plan sponsor for these products. What most plan sponsors and consumers alike do not realize is that PBMs extract "spread" profits from both of these activities. Unless a plan has negotiated a "pass through" contract with its PBM—and typically only the largest and most sophisticated plans are able to do so—the PBM will keep a significant percentage of the rebate dollars that they have obtained by virtue of the number of plan beneficiaries for themselves. In addition, the amount that the PBM reimburses the pharmacy for dispensing the drug is rarely the same amount that the PBM "charges" the plan for the same drug. Typically, the PBM "marks up" the cost of the drug, charging the plan more than the pharmacy is reimbursed, keeping the difference as profit for the PBM. It is precisely these hidden spread amounts that should be disclosed in some way to plan sponsors.

It is also through these activities that PBMs wield immense power in influencing precisely which prescription drug products will be considered to be "on formulary" or that will be actually covered by a specific health plan. Typically, the actual drug products selected and plan design

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[2] Health Strategies Group, "Research Agenda 2015: Pharmacy Benefit Managers," available online: http://www.healthstrategies.com/sites.default.files:PBM_Research_Agenda_PBM_RA101513.pdf

are largely calculated by the PBM to garner the greatest amount of rebate dollars—that may or may not be passed along to the actual plan sponsor.

**Cost Savings to Health Plan Sponsors Could be Realized With Increased PBM Transparency**

This type of information—about the vast sums of money that PBMs are making by virtue of the drug spend of a particular plan—should not be "proprietary" on the part of the PBM—but rather should belong to the plan. These disclosures could easily be protected by confidentiality agreements to address possible PBM concerns about such information weakening their negotiating stance with manufacturers. If plan sponsors have a clearer picture about the amount of money that is being made by their vendor by virtue of handling the plan's business—this may provide them with a greater ability to negotiate more competitive contracts with these vendors in the first place. In this way, plan sponsors could save money and realize actual savings in today's increasingly difficult prescription drug marketplace.

**Community Pharmacies Lack Effective Negotiating Power**

Small business pharmacy owners are faced on a daily basis with the difficulties of dealing with the PBM's disproportionate market power. Community pharmacies routinely must agree to "take it or leave it" contracts from the PBMs just to be able to continue to serve their longstanding patients. Such contracts often include blind price terms, onerous obligations including gag clauses that restrict their ability to communicate with patients and other provisions that disadvantage both community pharmacies and patients. PBMs also directly set the ever-shrinking reimbursement rates for retail pharmacies—the very same pharmacies that stand in direct competition to the PBM-owned retail (in the case of CVS Health) and PBM-owned mail order and specialty pharmacies. Therefore, it should come as no surprise when PBMs present both employer and government payers with carefully tailored suggested plan designs that steer beneficiaries to PBM owned mail order and specialty pharmacies.

Although many independent community pharmacies rely on a Pharmacy Services Administrative Organization or PSAO to contract on their behalf, these PSAOs are no match for the PBMs. In 2013, the Government Accountability Office (GAO) conducted a study on the role and ownership of PSAOs and stated that "over half of the PSAOs we spoke with reported having

little success in modifying certain contract terms as a result of negotiations. This may be due to the PBMs' use of standard contract terms and the dominant market share of the largest PBMs. Many PBM contracts contain standard contract terms and conditions that are largely non-negotiable."[3]

**Lack of Transparency in Generic Drug Reimbursement**

In today's marketplace, generic drugs currently comprise approximately eight-six percent of all prescriptions dispensed in the United States. [4] Given this fact, it is somewhat surprising that there is no standardized method for determining how pharmacies are reimbursed for generic drugs. PBMs create and maintain "Maximum Allowable Cost" or MAC lists that set the upper limit or maximum amount that a PBM/plan will pay for most generic drugs. Pharmacies are not provided any insight into how drug products are selected to be put onto this list or how exactly these prices are determined or updated. In short, contracted pharmacies have zero insight or transparency into the MAC process and sign contracts without having any idea of the rate at which they will be reimbursed for the majority of the prescriptions they fill. In response to PBM secrecy surrounding the creation and maintenance of these lists, twenty-six states have enacted legislation to try to compel greater transparency into this system. The PBM industry in general has vigorously opposed these efforts and in fact is currently engaged in litigation with a number of individual states that have sought to compel their compliance.

**PBM Industry Largely Unregulated**

Given the immense market influence that PBMs exert, one would expect these entities to be subject to the same type of comprehensive regulation that is currently required of commercial health insurers. However, PBMs are **not** subject to industry-wide regulation similar to what is generally required of commercial health insurers. There are no federal laws or regulations that are specific to the PBM industry. Instead, PBMs face a patchwork of regulations at the state level that are designed to curtail some of the more onerous PBM business practices such as

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[3] GAO-13-176 Pharmacy Services Administrative Organizations

[4] PhRMA; The Reality of Prescription Medicine Costs in Three Charts; 5/27/14: available online: http://www.phrma.org.catalyst.the-reality-of-prescription-medicine-costs-in-three-charts

abusive PBM audits of pharmacies and requirements related to timely MAC updates. However, even in states that have been able to pass these limited reforms, PBMs typically resist complying and have recently filed lawsuits against two such states.

**Conclusion**

In conclusion, the prescription drug marketplace continues to grow at an alarming pace. Large mergers continue to be announced every day while at the same time—healthcare costs—and particularly prescription drug costs—are at an all-time high. The current business climate seems to be one in which market power is increasingly concentrated in an ever-shrinking number of corporate entities. In particular, the overly concentrated and largely unregulated PBM industry exerts immense influence over how prescription drugs are accessed by the majority of Americans. Given the fact that the federal government is the largest single payer of health care in the United States,[5] it makes financial sense for Congress to demand increased transparency into this aspect of the prescription drug marketplace in order to identify potential savings.

[5] Troy, Tevi D., 2015 "How the Government As a Payer Shapes the Health Care Marketplace" *American Health Policy Institute.*

# UNIVERSITY OF MARYLAND

*Women's Basketball*

**2006 NATIONAL CHAMPIONS**

April 21, 2011

Dear Congressman Cummings,

I hope this communication finds you doing well. As always, I want to thank you for the support you've offered our terrific university, as well as me personally. We take great pride in wearing "Maryland" across our uniform and strive to represent our state the best way possible.

This is the first time I've ever been moved to write you or anyone in a similar position. What triggered this letter really is a matter of life and death. It's explained more in an article in the Washington Post on April 18, 2011 entitled "When the drug you need to cure cancer is nowhere to be found". It's an article I find disgraceful and heartbreaking on every level. Link: *http://www.washingtonpost.com/national/health/when-the-drug-you-need-to-cure-a-cancer-is-nowhere-to-be-found/2011/04/11/AFH802zD_story.html*

The point of the article is that there is a shortage of a crucial drug (cytarabine) used in the treatment of leukemia. To get to the point, without cytarabine, many leukemia patients won't be cured and will die. What makes this hit home even more for me and my family is that my three year old son Tyler is a leukemia patient who has benefited from cytarabine. We are lucky that some of the drug was available for him to receive at the time his treatments called for it. Even with that good fortune, it makes me feel outraged that other families are being told that this vital drug isn't available.

From what I understand, the shortage isn't the result of a lack of natural resources or research dollars, but simply a choice by pharmaceutical companies because their profit margin on the drug isn't high enough. This is wrong on every level and I don't want to believe it is allowed to happen.

Time is critical in this matter because lives are hanging in the balance. I urge you to bring the pharmaceutical companies before congress to expedite a resolution and explain their sorry and shameful business practices. Moreover, they should have to address leukemia patients and their families, who have seen their living hell get worse and have quite literally been issued a death sentence by the pharmaceutical companies.

To use the vernacular of our sport, solving this problem is a lay-up and everyone wins. I know there is a workable solution to this inexcusable, marginalizing of human lives. My family and I have first hand experience that the medical teams in places like Maryland's own Johns Hopkins are incredible. My son Tyler wouldn't be alive today if they didn't have access to the drugs that rid his body of cancer. Because of that, I feel incredibly passionate about making sure every other patient has the best possible chance to beat cancer too.

Time is running out on people who must have cytarabine to defeat leukemia. Please take action. If you need more info, there are brilliant people at Hopkins that can be great resources to you. I recommend reaching out to Dr. Pat Brown [redacted] Head of Pediatric Leukemia or Dr. Ken Cohen, Clinical Director of Pediatric Oncology [redacted]

Thank you for your time and Go Maryland!

Best Regards,

Brenda Frese

Brenda Frese

[redacted]

0726 Comcast Center, College Park, MD 20742

[redacted]

www.umterps.com • www.marylandwomensbasketball.com

ACC

ATLANTIC COAST CONFERENCE

Released: October 22, 2015

# An Open Appeal to Turing Pharmaceuticals:

We, the under-signed organizations, are concerned that despite a commitment by Turing Pharmaceuticals to lower the price of Daraprim (pyrimethamine) more than a month ago, the price has not been reduced nor have distribution issues been sufficiently addressed.

The controlled distribution system requiring purchase of Daraprim (pyrimethamine) through Walgreen's Specialty Pharmacy and its classification as a "specialty drug" also continues to create high and unreasonable hurdles for a medication that previously was widely available through local pharmacies to providers and their patients.

As a result, many individuals with toxoplasmosis in the United States are left without access to the preferred treatment for a condition that if not effectively treated can cause blindness, brain and organ damage or death. Patients already affected by the failure of Turing Pharmaceuticals to act on its commitment include pregnant women, children, infants, people with HIV and others with compromised immune systems across the country, for example:

> ***Within the last month I was seeing a child recently diagnosed with toxoplasmosis and was unable to obtain pyrimethamine as all contacted pharmacies had it listed as discontinued by their distributors. I had to change to trimethoprim/sulfamethoxazole despite the fact that data on that therapy in pediatrics is thin. – Reported by a physician***
>
> ***A patient with toxoplasmosis retinitis was quoted a price of $26,000 so we had to change his medication to Bactrim. A second patient had cerebral toxoplasmosis and was unable to get medications refilled by Medicaid. The patient was switched to a second line therapy. Neither therapy is ideal. – Reported by a physician***
>
> ***Currently, we have two inpatients on pyrimethamine for cerebral toxoplasmosis. We have two days left of pyrimethamine. A single bottle of 100 pills is the smallest the hospital can buy and will thus cost $75,000. Both patients will have to be switched to trimethoprim/ sulfamethoxazole.[1 2] – Reported by a physician***
>
> ***Yes, we have had a major issue getting pyrimethamine initially for a pregnant woman, and then for her baby following delivery. – Reported by a physician***

We call on Turing Pharmaceuticals to take the following immediate actions regarding Daraprim (pyrimethamine):

1. Lower the price to a level comparable to the price prior to the August 5000% increase.
2. Provide parity on pricing for inpatient and outpatient settings.

[1] The Department of Health and Human Services guidelines on the Prevention and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents were updated on October 19th to offer guidance on the use of alternative therapies due to limited access to pyrimethamine.
[2] The Department of Health and Human Services guidelines on the Prevention and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents recommend a course of acute therapy for a minimum of six weeks followed by maintenance therapy for at least six months. Following their treatment recommendations, a minimum of 486 pyrimethamine tablets are required to effectively treat immunocompromised patients. Available online at: https://aidsinfo.nih.gov/contentfiles/lvguidelines/Adult_OI.pdf.

*For more information, contact Andrea Weddle with the HIV Medicine Association at aweddle@hivma.org.*

3. Offer support under the patient assistance program to patients with incomes at the level of at least 500 percent of the federal poverty level.[3]
4. Provide complete transparency regarding eligibility and documentation requirements for the patient assistance and co-pay assistance programs.
5. Cover the maximum out-of-pocket costs ($6,600 for an individual plan and $13,200 for a family plan in 2015) on co-insurance and copayments allowable under the Affordable Care Act. The co-pay assistance program should be front-loaded to ensure that coinsurance amounts, which can be between 25 and 50 percent of the retail drug cost, are fully covered until the out-of-pocket limit is reached.[4]
6. Ensure same day and direct access to the drug in the communities where patients live.

The unjustifiable actions taken to leverage the value of an effective 70-year old medication are jeopardizing the health of individuals with a serious, life-threatening condition. These individuals do not have the luxury of time to wait for promised new treatments – which also will likely be priced out of reach.

Endorsed by the 152 organizations listed below representing 29 states, the District of Columbia and Puerto Rico:

**Alabama**
AIDS Alabama
AIDS Alabama South
Blue Faery: The Adrienne Wilson Liver Cancer Association
Health Services Center
University of Alabama at Birmingham, 1917 Outpatient HIV/AIDS Clinic
Selma AIR
West Alabama AIDS Outreach
**Arizona**
El Rio Special Immunology Associates
HIV/AIDS Law Project
**California**
AIDS Healthcare Foundation
AIDS Project Los Angeles
Berkeley Free Clinic
Correlia Biosystems, Inc.
Cure for AIDS Coalition
Infectious Diseases Associates Medical Group, Inc.
Natural Wholistic Health & Wellness Research Center
Pangaea Global AIDS
Positive Life Series Palm Springs
Positive Women's Network - USA
Project Inform
San Francisco AIDS Foundation
San Francisco Hepatitis C Task Force
SumOfUs.org
The Ihangane Project
Tom Waddell Urban Health Center
WEB.PsyD
**Colorado**
Colorado AIDS Project
THRIVE!: The Persons Living With HIV/AIDS Initiative of
**Colorado**
Treatment Educat1on Network
**Connecticut**
Liberty Community Services, Inc.
**District of Columbia**
340B Health
ADAP Advocacy Association (aaa+)
AIDS United
Alliance for Retired Americans
American Academy of HIV Medicine
American Federation of State, County and Municipal Employees
Community Access National Network (CANN)
DC Fights Back
Fair Pricing Coalition
GLMA: Health Professionals Advancing LGBT Equality
HealthHIV
Human Rights Campaign
National Alliance of State and Territorial AIDS Directors
National Black Justice Coalition (NBJC)
National Center for Lesbian Rights
National Center for Transgender Equality
National Coalition for LGBT Health
National Latina Institute for Reproductive Health
National Latino AIDS Action Network (NLAAN)
NMAC
Pozitively Healthy
The AIDS Institute
Woodhull Freedom Foundation
**Florida**
Dab the AIDS Bear Project
Okaloosa AIDS Support & Informational Services, Inc. (OASIS)

[3] This is in line with the policies of manufacturers of other HIV-related medications. See National Alliance of State and Territorial AIDS Directors. Pharmaceutical Company Patient Assistance Programs and Cost-sharing Assistance Programs. Online at: https://www.nastad.org/sites/default/files/HIV-PAPs-CAPs-Resource-Document.pdf.
[4] IBID.

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**Georgia**
AIDS Research Consortium of Atlanta
Emory University
Georgia AIDS Coalition
Georgia Equality
HIV Dental Alliance
HOPE CARE FOUNDATION
**Hawaii**
The CHOW Project
**Illinois**
AIDS Foundation of Chicago
HIV Prevention Justice Alliance
Howard Brown Health Center
Recovery 2000, Inc.
TACTS-The Association of Clinical Trial Services
Test Positive Aware Network
The Legal Council for Health Justice
University of Chicago Infectious Disease
**Indiana**
Mohammad Sharief, MD
**Louisiana**
Aspirations
**Massachusetts**
Boston Healthcare for the Homeless Program
Community Research Initiative
David Morris Nutritionist
Fenway Health
Search For A Cure
Treatment Access Expansion Project
**Maryland**
AIDS Action Baltimore
LIGHT Health & Wellness Comprehensive Services, Inc.
PeterCares House
Racial and Ethnic Health Disparities Coalition
The Veterans Health Council of Vietnam Veterans of America
**Misouri**
Hep C Alliance
**Minnesota**
Positive Care Center, Hennepin County Medical Center
**New Jersey**
Buddies of NJ, Inc
New Jersey Association on Correction
Sandra Paileja, MD
**New Mexico**
Albuquerque Pride
H.O.P.E. Alliance
New Mexico Hepatitis C Coalition
Southwest CARE Center
**Nevada**
Amy Keller and Associates Consulting
**New York**
ACRIA
AIDS Treatment Activists Coalition (ATAC)
Albany Damien Center
American Association for the Treatment of Opioid Dependence
AVAC
COPE
Division of Infectious Diseases, New York University School of Medicine
Doctors of the World USA Inc.
End AIDS Now
GHAP
GMHC
Marriage Equality USA
National Queer Asian Pacific Islander Alliance (NQAPIA)
The Center for HIV Law and Policy
The Hepatitis C Mentor and Support Group
Treatment Action Group
Unity Fellowship of Christ Church NYC
VOCAL-NY
**North Carolina**
Division of Infectious Diseases, Department of Pediatrics, Duke University Medical Center
Southern HIV/AIDS Strategy Initiative
Warren-Vance Community Health Center, Inc.
**Ohio**
Association of Nurses in AIDS Care
Cincinnati Exchange Project
Nightsweats & T-cells, Co
**Oregon**
Caring Ambassadors Program
Cascade AIDS Project
Health Education Network
**Pennsylvania**
ACT UP Philadelphia
AIDS Resource Alliance
ALPHA Pittsburgh, Inc.
Prison Health News
Reading Health System
**Puerto Rico**
Pacientes de SIDA pro Política Sana
**Rhode Island**
American Academy of Addiction Psychiatry
The Center for Prisoner Health and Human Rights
The Miriam Hospital Immunology Center
**Tennessee**
National Health Care for the Homeless Council
Vanderbilt Comprehensive Care Center
**Texas**
Gordon Crofoot, MD PA
Migrant Clinicians Network
**Virginia**
American Medical Student Association
HIV Medicine Association
Infectious Diseases Society of America
Pediatric Infectious Diseases Society
Ryan White Medical Providers Coalition
**Washington**
defeatHIV Community Advisory Board
Fred Hutch- defeatHIV CAB
Hepatitis Education Project
Point Defiance Aids Projects
Young Activists Against AIDS
**Wisconsin**
AIDS Resource Center of Wisconsin
Steven Schwimmer, DO, SC
**No State Affiliation**
Engender Rights Centre for Justice (ERCJ)
FAM-CRU, Stellenbosch University
JAPETI
Public Union Against AIDS
Southern AIDS Coalition
Stop Tuberculose Bouaké

# IDSA

Infectious Diseases Society of America

2015-2016
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January 21, 2016

The Honorable Jason Chaffetz
Chairman
Committee on Oversight and Government Reform
2236 Rayburn House Office Building
Washington, DC 20515

The Honorable Elijah Cummings
Ranking Member
Committee on Oversight and Government Reform
2230 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Chaffetz and Ranking Member Cummings:

On behalf of the Infectious Diseases Society of America (IDSA), thank you for scheduling the U.S. House of Representatives Committee on Government Oversight and Reform hearing, "Developments in the Prescription Drug Market: Oversight," on January 26, 2016. As you know, patients with serious infections (toxoplasmosis and cryptococcal meningitis) have recently faced serious barriers in accessing their previously affordable, decades-old treatments due to sudden and dramatic price increases. We greatly appreciate the Committee's attention to this serious issue. We hope you also will consider broader, related issues regarding access to existing and new therapies for preventing and treating infectious diseases (ID) as well as serious areas of unmet medical need for which innovation is sorely lacking, such as emerging infections and increasing antimicrobial resistance. We look forward to helping the Committee understand the specific ID patient needs regarding pharmaceutical accessibility and innovation as we all strive to achieve balanced policies that will best serve patients and public health.

In this letter, we describe examples that we believe help illustrate different aspects of the complex issues of pharmaceutical accessibility and innovation: (1) accessibility of older generic medications with little competition; (2) accessibility of novel therapies for hepatitis C virus (HCV); and (3) incentives for new antibiotics to address unmet medical needs. We hope these cases will help the Committee better understand ID patient needs. While we advocate for necessary economic incentives in situations where there is unmet medical need in order to recoup innovation costs for truly novel products that have a significant clinical impact, we believe that checks and balances are necessary to prevent the inappropriately high prices that severely limit patient access to needed treatments.

**Decades-old Off-Patent Drugs Priced Out of Reach**

Daraprim: Sudden, Dramatic Price Increase of a 62 Year-Old Drug Severely Hampers Accessibility: Acquired by Turing Pharmaceuticals in August 2015, Daraprim (pyrimethamine) is part of the first-line treatment regimen for the

parasitic disease toxoplasmosis, a serious and potentially life-threatening infection that most commonly affects immune-compromised individuals such as those with HIV. The drug was approved by the FDA in 1953. Shortly after acquiring Daraprim, Turing raised the price of this drug from $13.50 per tablet to $750 (Wholesale Acquisition Cost) per tablet. The price increase and a controlled distribution strategy implemented earlier in the summer have left hospitals without the ability to stock the medication, and prompted physicians to prescribe alternative therapies with limited data supporting their use.[1] This has required adding alternative strategies to the federal guidelines for preventing and treating opportunistic infections[2] for situations where first line agents may not be available. Under the new price, it is estimated that the annual cost of treatment for toxoplasmosis, for the pyrimethamine component alone, will be $342,750 for patients who weigh less than 60 kg (or approximately 130 pounds) and $648,000 for patients who weigh more than 60 kg. Interestingly, the $342,750 figure is more than quadruple the initial cost of Sovaldi (the first of the new HCV cures whose price came under public criticism) despite the fact that pyrimethamine (the active ingredient in Daraprim) is a decades-old drug that should be available as a generic.

In response to the public outcry concerning the 5000% price hike of Daraprim and resulting significant patient access issues, Turing promised in late September to lower the price of the drug. One month later, no change had been made, prompting more than 150 organizations to urge Turing to take immediate action regarding Daraprim's price and accessibility. In early November, IDSA joined HIV advocacy organizations in a meeting with Turing executives. At this meeting, Turing executives described a complex network of assistance programs and suggested making the drug more accessible to hospitals by distributing tablets in 30 rather than 100 tablet bottles in addition to addressing access issues experienced by health care facilities participating in the 340B program. It was subsequently reported that the company intends to modestly lower (by around 10 percent) the price of the drug by the end of the year.[3] Unfortunately, later in November, Turing reneged on its promise to lower the list price of the drug. Instead, Turing will offer discounts of up to 50% to hospitals. Unfortunately, the reduced hospital pricing is still significantly higher than what hospitals paid for Daraprim prior to Turing's acquisition of the drug and will still present access barriers. Further, patients must typically take Daraprim for 8 to 12 months, most of the time on an outpatient basis. These persisting barriers to accessing Daraprim underscore the need for new options for patients with toxoplasmosis and their medical providers. On December 22nd, IDSA, the HIV Medicine Association, and the Pediatric Infectious Diseases Society wrote to the Turing Interim CEO Ron Tilles to urge him to place patient interests and lives ahead of short-term profits by returning the price of pyrimethamine to $13.50. The company has not yet responded to the request.

We remain very concerned that a significant disruption in treatment for a life-threatening condition has occurred due to a dramatic price increase of a decades-old drug initiated by a company that had not assumed any of the risk nor provided any of the investment necessary to

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[1] See HIVClinician.Org Access to Daraprim (Pyrimethamine) Blog. Available at http://hivclinician.org/pyrimethamine/.

[2] The Department of Health and Human Services guidelines on the *Prevention and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents* were updated on October 19th to offer guidance on the use of alternative therapies due to limited access to pyrimethamine.

[3] *New York Times*. Turing Commits to Modest Price Reduction on a Drug. Nov 3, 2015. Available at: http://www.nytimes.com/2015/11/04/business/turing-commits-to-modest-price-reduction-on-a-drug.html?_r=2&mtrref=undefined.

develop this medication. In addition, the controlled distribution system precludes competition that could result in lower prices and greater accessibility by limiting access to the compounds necessary for other manufacturers to conduct the necessary testing to develop an approved other generic version of this drug. Similar to the situation with cryptococcal meningitis (see below under Flucytosine), toxoplasmosis is an infection for which effective treatment has been available for decades but has recently been priced out of reach of patients who need it. These are unlike other life-threatening infections caused by multi-drug resistant pathogens for which no effective treatment options are available.

Flucytosine: Significant Price Increase on a Drug Critical in Treating a Serious Infection: In another case that has not received much attention outside of the infectious diseases community, Valeant increased the price of flucytosine from $10 per 500 mg tablet to $110 per 500 mg tablet, raising the price of a 100 tablet bottle from $1000 to $11,000. Flucytosine was initially approved by the FDA in 1971 and is a key component of the preferred treatment for cryptococcal meningitis—a serious infection of the brain and spinal cord that typically affects patients with compromised immune systems. The price increase also has forced providers to deviate from the preferred treatment for this life-threatening and potentially debilitating infection.

**Hepatitis C Virus (HCV): Innovation Victories and Accessibility Challenges**
IDSA has been extremely encouraged by the development of new therapies that can cure HCV—a significant clinical advancement over prior HCV therapies. In the U.S., nearly 4 million persons are estimated to be infected with HCV and approximately half are unaware of their status. Approximately 20,000 individuals are newly infected each year.[4,5] New cures for this virus, which if not treated can lead to debilitating and costly conditions including cirrhosis, liver cancer, and liver transplants, represent a tremendous new scientific advancement with the potential to improve and save the lives of millions of patients. It is critical that federal policies continue to stimulate this type of innovation, given how it helped fulfill an unmet medical need. It is equally critical that patients be able to have access to these promising new therapies so that scientific advancements can achieve their life-saving potential.

IDSA applauded the Centers for Medicare and Medicaid Services (CMS) for the guidance sent in November to state Medicaid programs and pharmaceutical companies to urge them to improve accessibility to new HCV medications. CMS expressed concern, shared by ID physicians, that many states are limiting access to these drugs only to patients with late stage liver disease, and to those abstinent from drug or alcohol use, and is limiting the types of providers who can prescribe these therapies.

We appreciate that CMS highlighted the IDSA and the American Association for the Study of Liver Diseases (AASLD) guidance in the communication to state Medicaid programs. As you may know, IDSA and AASLD continue to update our guidance at www.HCVguidelines.org, as new therapies and evidence on existing therapies become available. In October 2015, the

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[4] Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. Ann Intern Med 2006; 144:705–14.

[5] CDC. Surveillance for acute viral hepatitis—United States, 2008. Available at: http://www.cdc.gov/hepatitis/Statistics/2008Surveillance/index.htm.

recommendation for initiating treatment in nearly all patients with hepatitis C was strengthened and the recommendations on how to prioritize patients for treatment were removed based on "real world" experience with the tolerability and efficacy of newer HCV medications.[6] Successful HCV treatment results in sustained virologic response—in other words, cure of the HCV infection—and benefits nearly all of those chronically infected with HCV. We urge continued engagement from CMS and Congress on this important issue, and we look forward to continuing to work with all stakeholders to ensure appropriate patient access to these important new therapies.

**Incentives for New Antibiotics to Address Unmet Medical Needs**

Despite tremendous scientific advances in a wide variety of disease areas, there remain some patients—such as those suffering from serious or life-threatening infections caused by multi-drug resistant pathogens—who have few or no safe and effective treatment options. The Centers for Disease Control and Prevention (CDC) conservatively estimated in 2013 that at least 2 million individuals in the U.S. are sickened by antibiotic-resistant bacteria every year and that at least 23,000 die as a result. Further, CDC found that infections caused by resistant bacteria cost the health care system approximately $20 billion annually, with a total societal cost of about $35 billion each year.[7]

IDSA greatly appreciates that Congress has prioritized this issue by enacting the Generating Antibiotic Incentives Now (GAIN) Act as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012. GAIN provides an additional 5 years of exclusivity for new antibiotics that treat a serious or life-threatening infection and represents a key first step toward addressing the urgent unmet need for new antibiotics. We also greatly appreciate that the House passed the 21st Century Cures Act (H.R. 6) last July by an overwhelming bipartisan margin. This bill contained a provision authored by Representatives John Shimkus (R-IL) and Gene Green (D-TX) to address a key regulatory barrier to antibiotic research and development (R&D) by allowing antibiotics that treat a serious or life-threatening infection and address a truly unmet medical need to be studied in smaller, more rapid clinical trials and approved only for the limited population of patients who need them and for whom they have been proven safe and effective. However, experts agree that additional incentives in this space are necessary to bring forth the new antibiotics that patients need.

Antibiotic R&D has failed to keep pace with increasing patient need due to rising rates of antibiotic resistance. As more and more patients contract and succumb to these serious infections, R&D of new antibiotics to treat these infections has dwindled. Unfortunately, unique significant economic barriers continue to hamper antibiotic R&D. Antibiotics are typically taken for a much shorter course than other drugs, tend to be inexpensive, and are held in reserve to protect their utility from the rapid development of resistance. These factors have driven most pharmaceutical companies away from antibiotic R&D entirely and left the few who remain struggling to develop the antibiotics that patients need most, representing a failure of the normal market forces.

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[6] AASLD and IDSA. Hepatitis C Guidance Underscores the Importance of Treating HCV Infection: Panel Recommends Direct-Acting Drugs for Nearly All Patients with Chronic Hepatitis C. October 2015. Available at: http://hcvguidelines.org/sites/default/files/when-and-in-whom-to-treat-press-release-october-2015.pdf.

[7] CDC. Antibiotic Resistance Threats in the United States, 2013. Available at: http://www.cdc.gov/drugresistance/threat-report-2013/

Representatives Charles Boustany (R-LA) and Mike Thompson (D-CA) have sponsored legislation to provide a new tax credit for new antibiotics to treat serious or life-threatening infections and address an unmet medical need—the Reinvigorating Antibiotic and Diagnostic Innovation (READI) Act, H.R. 3231, which is garnering strong bipartisan support among members of the Ways and Means and Energy and Commerce Committees. This bill is modeled off of the successful Orphan Drug Act and would provide a much needed incentive to address the economic obstacles to antibiotic R&D and spur the development of the antibiotics patients need most.

**Conclusion**

As this Committee investigates recent price spikes of off-patent drugs, we hope you will consider strategies to help prevent future disruptions to care, such as those caused by the sudden and dramatic price increases for Daraprim and flucytosine. We also urge you to balance the need for accessibility for both new and old medications with the need for innovation to help those patients who still face significant unmet medical needs, such as those with infections caused by resistant pathogens. Further, we urge you to consider how new antibiotics can help reduce the significant excess health care costs associated with antibiotic resistance. New federal incentives are necessary to stimulate the innovation needed to bring forth new life-saving therapies for these patients.

Striking balanced federal policies that provide appropriate patient access to needed treatments and incentivize innovation to address truly unmet medical needs is a complex endeavor in which many factors must be considered. These factors include: patient access; defining the areas of unmet medical need; barriers to R&D; the role of Medicare, Medicaid, and private payers; and access to generic drugs for uncommon conditions. IDSA is a committed partner with the federal government and other stakeholders in examining these issues and considering appropriate policy solutions. We are committed to continuing to raise awareness regarding both accessibility and innovation to benefit patients with infectious diseases, and to providing feedback on the impact of federal policies and proposals on our patients' needs and the public health.

We welcome the opportunity to continue discussing these issues with you and your staff and can be reached through the IDSA Director of Government Relations, Jonathan Nurse at jnurse@idsociety.org or 703-299-0202.

Sincerely,

Johan S. Bakken MD, PhD

Johan S. Bakken, MD, PhD, FIDSA
President, IDSA

***About IDSA***

IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant Staphylococcus aureus (MRSA) vancomycin-resistant enterococci (VRE), and Gram-negative bacterial infections such as Acinetobacter baumannii, Klebsiella pneumoniae, and Pseudomonas aeruginosa, and, finally, emerging infectious syndromes such as Ebola virus fever, enterovirus D68 infection, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), and infections caused by bacteria containing the New Delhi metallo-betalactamase (NDM) enzyme that makes them resistant to a broad range of antibacterial drugs.

January 22, 2016

Congressman Jason Chaffetz, Chair
Congressman Elijah Cummings, Ranking Member
House Committee on Oversight & Government Reform
U.S. House of Representatives
Washington, DC

Re: Developments in the Prescription Drug Market – Oversight

Dear Chairman Chaffetz and Ranking Member Cummings:

The Fair Pricing Coalition (FPC) commends the House Committee on Oversight & Government Reform for holding a hearing on drug price increases for older, off-patent medications. Founded by the late Martin Delaney of Project Inform, FPC is a national coalition of activists who work on HIV and viral hepatitis drug pricing issues, and to help control drug costs for patients who are privately insured, underinsured and uninsured. The FPC also works to ensure access for individuals covered by state AIDS Drug Assistance Programs (ADAPs), Medicare, and Medicaid.

FPC members have been actively engaged in challenging Turing Pharmaceuticals on the exorbitant price increase the company enacted for pyrimethamine upon acquiring this lifesaving medication in August 2015. An FPC letter to Turing's new interim CEO submitted at the end of December 2015 urging the company to return pyrimethamine to its original $13.50 per pill has gone unacknowledged, with no action taken. We hope the committee's hearing leads to policy actions that prevent companies from having free rein in pricing older drugs with little or no competition.

**Prices for HIV Treatment Continue to Rise**

As the committee examines unjustified price increases for older medications, we also urge investigation of HIV antiretroviral (ARV) and hepatitis C virus (HCV) direct-acting antiviral (DAA) costs. In 2016, we are already seeing exorbitant price increases for some of the antiretrovirals most frequently prescribed. The trend in price increases for ARVs is unsustainable and will continue to hinder patient access to life-saving HIV treatment and prevention, as well as curative hepatitis C regimens. In letters to industry executives in December, the FPC urged all major manufacturers to refrain from enacting price increases in 2016 or at a minimum to limit increases to the medical Consumer Price Index (CPI) measure of medical inflation.

On average, the WAC prices for antiretrovirals increased in the range of 7 to 8 percent despite already being priced at the upper limit of any conceivable justification (see attached table). While the January 2016 CPIs have not yet been announced, the 2016 WAC increases for leading antiretrovirals are approximately three times higher than the ten-year CPI average of 2.5 percent. They are also higher than all medical CPI categories, which average 2 to 3 percent and are driven in part by unrestrained drug pricing.

**High Drug Prices Creating Barriers to Treatment**

High drug prices have led to the increased use of specialty tiers that require consumers to pay a percentage of the drug's cost, and HIV antiretrovirals and the new HCV DAAs are frequently placed on the highest cost sharing or specialty tiers.[1 2] These practices have a greater impact on individuals in fair or poor health. Those who rely on four or more medications – which is not uncommon for people living with HIV – are more likely to skip doses due to cost.[3]

HIV care providers also report an uptick in Medicaid and private plans requiring prior authorization for antiretroviral drugs, particularly for preferred standard-of-care single tablet regimens. Most concerning are provider reports that some insurance coverage requests are being denied outright. While denials are presently rare, it is disturbing that people living with HIV may not have access to the treatment recommended by their physician.

Egregious drug pricing has also resulted in a clear inability of people living with hepatitis C to access the DAAs available from Gilead Sciences, Bristol Myers-Squibb, Janssen Therapeutics, and AbbVie that achieve as much as a 99% cure rate with minimal side effects. Many health plans, both public and private, have instituted treatment utilization polices and prior authorization processes that are based on cost-containment concerns, rather than on the best and most current clinical science. Nowhere is this more apparent than in state Medicaid programs, many of which cover DAAs only for patients with advanced fibrosis or cirrhosis, contrary to published guidelines. Many of these programs also have policies that deny curative therapy to people who use drugs or alcohol, despite guidelines and clinical evidence that this population should be prioritized for treatment, both for their personal health and to prevent ongoing transmission of the virus. We have the tools to end the HCV epidemic, but current pricing of the best new DAAs and concomitant treatment access restrictions make this goal impossible.

We appreciate the Committee's attention to drug pricing. FPC looks forward to working with policymakers on solutions that ensure lifesaving medications – both old and new – are accessible and affordable for those who need them. Please contact the FPC co-chairs Lynda Dee at Lyndamdee@aol.com or Murray Penner at mpenner@nastad.org if we can be of assistance.

Respectfully submitted,

The Fair Pricing Coalition

cc: Kelly Christl, Congressional Staffer
Brian Lattanzi, Congressional Staffer
Christy Gamble, Congressional Staffer
Alexandra Golden, Congressional Staffer

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[1] Avalere. Patient Access to HIV Drugs in the Exchange Plans Is Limited Compared to Other Sources of Coverage. November 2015. Online at: http://avalere-health-

[2] Kaiser Family Foundation. Medicare Part D in its Ninth Year: The Marketplace and Key Trends, 2006-2014, August 2014. Online at http://files.kff.org/attachment/medicare-part-d-in-its-ninth-year-the-2014-marketplace-and-key-trends-2006-2014-report.

[3] Drew Altman. *How High Drug Prices Weigh on the Sickest Americans*. The Wall Street Journal. December 28, 2015, Online at: http://blogs.wsj.com/washwire/2015/12/28/how-high-drug-prices-weigh-on-the-sickest-americans/.

| WAC Price Increases for Antiretroviral Drug Products | | | | |
|---|---|---|---|---|
| **Company** | Product | 2016 | 2015 | Since Approval |
| **Abbvie** | Kaletra | 6.9% | 5.9% | 70.2% |
| | Norvir | 0% | 0% | 477% |
| **BMS** | Reyataz | 7.9% | 7.9% | 108.4% |
| | Evotaz | 7.9% | Launch | 7.9% |
| | Sustiva | 7.9% | 9.7% | 188.5% |
| **Gilead** | Atripla | 8.0% | 7.1% | 106.6% |
| | Truvada | 6.9% | 6.9% | 125.3% |
| | Complera | 6.9% | 6.9% | 38.1% |
| | Stribild | 4.9% | 4.9% | 15.4% |
| **Janssen** | Intelence | 7.9% | 7.9% | 66.7% |
| | Prezista | 7.9% | 7.9% | 81% |
| | Prezcobix | 7.9% | Launch | 7.9% |
| **Merck** | Isentress | 6.9% | 4.9% | 58.9% |
| **ViiV** | Epzicom | Pending | 6.9% | +89.9% |
| | Selzentry | Pending | 6.9% | +39.4% |
| | Tivicay | Pending | 6.9% | +12.1% |
| | Triumeq | Pending | 3.9% | +3.9% |

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January 25, 2016

The Honorable Elijah E. Cummings
United States House of Representatives
Ranking Member, House Committee on Oversight and Government Reform
Washington, DC

**Re: Massive Recent Price Increase in CaEDTA, a Drug Used to Treat Life-Threatening Lead Poisoning, after Its Acquisition by Valeant Pharmaceuticals**

**Specific Request:** Prompt action that will either result in a marked lowering of the cost of Valeant brand Calcium Disodium Edetate (also known as CaEDTA or Calcium EDTA), or that will enable United States hospitals to acquire CaEDTA from other international manufacturers who make their drug available at a far lower price.

Dear Representative Cummings:

We are writing to communicate our public health concern regarding the recent massive increase in the price of a generic drug, CaEDTA, that is used for the emergency treatment of severe and life-threatening lead poisoning in children and adults. The sole source for CaEDTA in the United States is a generic brand manufactured by Valeant Pharmaceuticals.

CaEDTA entered the US pharmacopoeia in the 1950s as a chelating agent that accelerates the removal of lead from the body. When used by medical toxicologists, it is administered by parenteral (i.e. intravenous or intramuscular) injection in a hospital setting to patients with extremely high blood lead concentrations, usually in excess of 100 µg/dl, who are suffering from severe or life-threatening complications of lead intoxication, such as encephalopathy or colic. Because the incidence of severe lead poisoning in the United States is limited (probably no more than one hundred or so cases per year) and because CaEDTA has few other indications, use of the drug by any one hospital is limited. Nevertheless, because severe lead poisoning such as lead encephalopathy requires prompt emergency treatment with CaEDTA, the California Poison Control System recommends that hospitals that treat medical emergencies maintain a minimum stock of CaEDTA ampules for injection on hand.

Until the past few years, it had been common for many major emergency hospitals in the United States to stock CaEDTA in their pharmacies. In the mid 2000s through 2011, the drug was manufactured by Graceway Pharmacueticals. After Graceway was purchased by Medicis Pharmaceutical in late 2011, production temporarily stopped. In 2012, Valeant Pharmaceuticals acquired Medicis. By 2013 or 2014, Valeant had resumed the manufacture and sale of CaEDTA. However, as shown in the table below, the price of CaEDTA produced by Valeant increased progressively by an enormous amount – 7150 % from the Graceway product wholesale price in 2008 to the Valeant product wholesale price at the end of 2014. This huge price increase resulted in some hospital's inability to stock the drug in their emergency department pharmacy. Indeed, we became aware of this problem when Children's Hospital in Oakland, CA informed the California Poison Control System that it could not afford the wholesale price of approximately $25,000 it was quoted in 2015 by a distributor, AmerisourceBergen, to purchase one box of 5 ampules of CaEDTA. One box of 5 ampules would typically be the amount needed to treat one young child with lead encephalopathy with a 5 day course of chelation (1 ampule per day).

**Table: Wholesale Prices for Calcium Disodium Edetate (Calcium EDTA) – 5 ml ampules (200mg/ml)** [Source: Red Book Online Database – Micromedex Solutions® accessed 1/23/2016]

| Manufacturer | Package Size (# of ampules) | Effective Date | Wholesale Acquisition Cost - Package | Average Wholesale Price – Package | Average Wholesale Price per ml | Percent Increase per ml |
|---|---|---|---|---|---|---|
| Graceway Pharmaceuticals | 6 | 10/02/2008 | $464.24 | $557.09 | $18.57 | |
| Valeant Pharmaceuticals North America | 5 | 12/22/2014 | $26,927.33 | $33,659.16 | $1346.37 | 7,150 % |

Additional Red Book data accessed on 1/23/2016 indicates that in 2014 alone, the unit wholesale price of the Valeant brand of CaEDTA increased by 278 percent, from $355.81 per ml on 01/06/2014 to $1346.37 on 12/22/2014. The massive nature of this ongoing increase in the Valeant drug was qualitatively confirmed by information we received from several hospital pharmacies. UCSF pharmacy paid a wholesale price of $179.36 for two 2.5 ml ampules (5 ml) a few years ago. However, they are now quoted a price of $4995.02 for a 5 ml ampule, a unit price increase of 2685%. San Francisco General Hospital paid $2904.81 for five 5 ml ampules in 2013. They are currently quoted a wholesale price of $26,927.33, an 822% increase in two years.

Valeant Pharmaceuticals is the only source of CaEDTA ampules available to hospitals in the United States. This week we conducted an investigation to determine whether the drug was for sale to hospitals in Canada and Mexico by other drug manufacturers at lower wholesale cost. Canadian colleagues at the IWK Regional Poison Centre in Halifax, Nova Scotia informed us that they obtain CaEDTA through Canada's Special Access Program from SERB Laboratories, France. They have recently purchased a box of ten 10 ml ampules (50 mg CaEDTA/ml) for $45 CND, or approximately $36 USD (at 2015 currency rates). This equates to a price of $7.20 per one gram dose of CaEDTA,

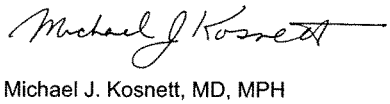
(an amount typically needed to treat a severely lead poisoned child for 1 day). In Mexico, CaEDTA is sold by Laboratorios Zafiro (Jalisco, MX) under the brand name Kedato. The sales department at Laboratorios Zafiro informed us last week that they sell CaEDTA in boxes of 50 ampules containing 1.5 g per 10 ml for the equivalent of $180 USD to hospitals and pharmacies in Mexico and South America. This equates to $2.40 per gram of CaEDTA. If the price of the French and Mexican drug are compared to the current price of the Valeant drug as quoted to San Francisco General Hospital ($26,927.33 ÷ 5 = $5385.47 for 1 gram CaEDTA), it can be seen that Valeant brand CaEDTA costs 748 times as much as the SERB Laboratories brand CaEDTA, and 2244 times as much as Laboratorios Zafiro brand CaEDTA.

It should be noted that CaEDTA is an off-patent generic drug that was developed in the 1950s and initially introduced by other pharmaceutical companies. Research and development costs for the drug were expended long before the drug was produced by Valeant. The cost of producing or purchasing CaEDTA as a commodity chemical is low. One kilogram (1000 grams) of sodium calcium edetate is currently advertised for sale in the Sigma Aldrich chemical company internet catalog for $333.00, or the equivalent of $0.33 per gram.

We consider the extremely high price of pharmaceutical CaEDTA ampules sold exclusively in the United States as a product manufactured by Valeant Pharmaceuticals to be an obstacle to the availability of a potentially life-saving medicine to patients who may require it for severe lead poisoning. Prior to Valeant's recent acquisition and manufacture of the drug, CaEDTA was available in the United States for decades from a succession of other pharmaceutical companies at far lower cost. Hospitals in Canada and Mexico continue to be able to acquire CaEDTA ampules for treatment of their severely lead-poisoned patients at a small fraction of the cost of the Valeant brand drug sold in the United States.

In the interest of public health, we encourage prompt action that will either result in a marked lowering of the cost of Valeant brand CaEDTA, or that will enable United States hospitals to acquire CaEDTA from other international manufacturers who make their drug available at a far lower price.

Sincerely,



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January 25, 2016

The Honorable Jason Chaffetz
Chairman, Committee on Oversight and Government Reform
U.S. House of Representatives
Washington D.C. 20515

The Honorable Elijah Cummings
Ranking Member, Committee on Oversight and Government Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Chaffetz and Ranking Member Cummings,

On behalf of the Human Rights Campaign's (HRC) more than 1.5 million members and supporters nationwide, I write to share our views in advance of the hearing scheduled for Tuesday, January 26, "Developments in the Prescription Drug Market: Oversight." As the nation's largest civil rights organization working to achieve lesbian, gay, bisexual and transgender (LGBT) equality, we have been extremely troubled by the recent, dramatic price increases in prescription drugs that have proven to be lifesaving. Over the past three decades investments in research and scientific advances by pharmaceutical companies have saved and dramatically improved the lives of many in our community. While we recognize the significant investment that must be made by companies engaging in research and development, we are deeply concerned that medications developed to treat or even cure chronic health conditions like HIV, Hepatitis C, or multiple sclerosis have been arbitrarily priced out of reach of many Americans.

This unconscionable price gouging undermines the care of patients most at risk. This past summer, Turing Pharmaceuticals purchased the exclusive right to market Daraprim, a 62 year-old drug to treat the deadly condition toxoplasmosis, a parasitic infection impacting patients with compromised immune systems. Overnight the price per pill was raised from $13.50 to $750. A 5000 percent increase in cost not only shocks the conscience, it reveals a company preying upon the most the vulnerable individuals in our society and those least able to shoulder the additional cost burden.

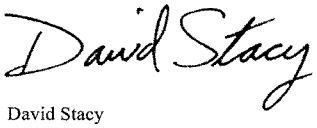
Turing Pharmaceuticals actions underscore a systemic, disturbing trend that impacts vulnerable populations nationwide. Health officials and the media have documented shocking price spikes in lifesaving medication including drugs to treat opioid overdoses and cardiac arrest. These price spikes for decades-old drugs increase the burden on hospitals, emergency responders, and state and local health

agencies. For example, in response to the worsening heroine epidemic, the city of Baltimore has increased training for dispensing an anti-overdose drug, Naloxone. This lifesaving medication blocks the effects of opioids on the body and reverses respiratory depression occurring during an overdose. Getting this drug into the hands of drug users and their family and friends is a critical step towards ending deaths from opioid overdose. According to the Harm Reduction Coalition, an advocacy group working to prevent overdoses, a dose of injectable naloxone costs $30 today – 1,000 percent more than the price 15 years ago. National Public Radio has reported that as of July 2015 the city of Baltimore paid $40 per intranasal dose – up from $20 per dose just six months earlier.

Pharmaceutical companies, including the maker of Naloxone, have stated that these sudden price increases are a result of multiple factors – including an increase in demand. At a time when the budgets of state and local health departments are already stretched, these drastic price increases mean that some will be forced to remove these lifesaving drugs from the shelves. Unfortunately, patients are already experiencing the impacts of these decisions. In response to Turing Pharmaceuticals price spike and closed distribution system for Daraprim, many local pharmacies have been unable to stock the drug. As a result, doctors treating a child with toxoplasmosis in North Carolina could not access the drug and were forced to treat the child with an alternative medication that had not yet been tested in children. The University of Utah Health System has also reported that it will no longer stock a life-saving heart drug for cardiac arrest patients citing drastic price spikes.

These corporate actions have real human costs. We greatly appreciate the work of the House Oversight and Government Reform Committee in monitoring the price and access to drugs like Daraprim and Naloxone and look forward to working with you to develop reasonable solutions to ensure these and other lifesaving medications are readily affordable and available.

Sincerely,



David Stacy
Director of Government Affairs

National
Multiple Sclerosis
Society

January 26, 2016

U.S. House of Representatives
Committee on Oversight and Government Reform
2157 Rayburn House Office Building
Washington, D.C. 20515

Re: Developments in the Prescription Drug Market January 26, 2016 Hearing – Comments for the Record

Chairman Chaffetz and Ranking Member Cummings:

The National Multiple Sclerosis Society appreciates the Committee's interest in the prescription drug market and the opportunity to provide insight on how it is impacting people living with multiple sclerosis (MS) and their families. **The National MS Society believes that both innovation and affordable access are critical to ensure people receive the medication and treatments they need.**

MS is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Symptoms range from numbness and tingling to blindness and paralysis. The progress, severity and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are leading to better understanding and moving us closer to a world free of MS. Most people with MS are diagnosed between the ages of 20 and 50, with at least two to three times more women than men being diagnosed with the disease. MS affects more than 2.3 million worldwide.

While each individual with MS is impacted differently by the disease, a growing body of evidence indicates that early and ongoing treatment with a disease modifying therapy is the best way to modify the course of the disease, prevent the accumulation of disability, and protect the brain. There are currently 13 disease modifying therapies (DMTs) available to people with relapsing remitting MS and ongoing access to these medications is essential for people with MS to be able to live their best lives.

Issues related to the affordable access of needed medications are complex, must be looked at holistically and must take into strong consideration the impact on people and families. All stakeholders—patients, healthcare providers, insurers, pharmaceutical manufacturers and others—must work together and share responsibility to ensure that people have affordable access to the therapies they need to live their best lives. In that vein, the full-range of FDA approved MS therapies should be covered and price and price increases should not be barriers for people with MS accessing the optimal MS treatment(s) for individual needs—as stated in the Society's Access to High Quality MS Healthcare Principles.

Yet, we have seen that increasing prices of the DMTs and restrictive insurance coverage are impacting the ability of people with MS to get the medications they need. A 2015 *Neurology*

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article[1] analyzed the pricing trajectories of MS DMTs from 1993 (when the first MS DMT came on market) to 2003 and found that the DMTs that originally cost $8,000-$11,000 annually grew in price to average $60,000/year. Costs for these DMTs have increased annually at rates 5 to 7 times higher than prescription drug inflation and newer DMTs commonly entered the market with a cost 25%–60% higher than existing DMTs. When examining these price escalations and prices, it is important to remember that MS is a chronic disease, generally requiring people to remain on their DMTs and bear their cost for a long period of time.

Updated information from the authors of the *Neurology* article indicate that prices have continued to increase, with all 13 now available disease-modifying therapies, including one generic, priced between approximately $60,000 to more than $75,000 per year. (see attachment)

While DMT prices have escalated, insurers are employing more utilization management strategies and formulary restrictions to the MS medications. For example, according to Avalere Health's PlanScape®, an increasing number of health plans put all available MS medications on the highest cost sharing tier with coinsurance as high as 40%.

While rebates are often used to bring down the costs of the medications for health plans, there is little to no transparency about these transactions. It is even unclear as to if and when rebate costs are passed along to patients. For example, when a person with MS has a 40% coinsurance—is that 40% of the average wholesale price, 40% of the negotiated price between the health plan and the pharmaceutical manufacturer, or 40% of another number?

Unfortunately, many people with MS are experiencing great difficulty accessing needed medications. In October 2015, the Society disseminated an electronic survey regarding the cost of MS medications to 1.3 million people—to which 11,194 people responded including 8,778 living with MS. 38.9% of people with MS said that it is very or somewhat difficult to afford their MS medications—compared to 24% of the general population as captured by the Kaiser Family Foundation.

People with MS often suffer "hidden" consequences of drug pricing that must be part of this conversation. In order to afford their prescription medications, in the past year, 21% of respondents said they spent less on entertainment and dining out, 16.4% used a credit care more often, 13.8% postponed paying other bills, 4.7% postponed retirement and 4% said s/he or a family member had to take on an additional job. These are choices that people shouldn't have to make simply because they live with a chronic disease.

Here are a few specific examples of the price and access issues that people with MS have experienced and the impact it has on their lives:

- "I have lived with MS for 20 years and have used a disease-modifying drug for 15 years. I have seen the price of my medication rise from approximately $800 per month in 2000

[1] Hartung, D.M., Bourdette, D.N., Ahmed, S.M., & Whitham, R.H. (2015). The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: Too big to fail? *Neurology, 84(21)*, 2185-2192. doi: http://dx.doi.org/10.1212/WNL.0000000000001608.

National
Multiple Sclerosis
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to $5,593.23 per month today ($9,600 to $67,118.76 per year respectively). In 2015, the price increased twice for an additional $541.40 per month."

- "I had to wait seven weeks for my medication because it was so expensive. My insurance did not want to cover it. During that time I suffered a relapse because I was not on medication and the stress from calling my insurance company 35 times, yes, 35, to try and get it approved. Now, instead of complete vision, I am partially blind in my right eye and have missed work, and time with my family. Because, I couldn't afford my medication. It's $16,000 for an 88 day supply."
- "I'm a single mother of 3. My MS is advancing everyday more and more and I have to choose between taking MS medication or feeding, clothing and keeping a roof over my family's head. Sadly I know and my kids know that I'm getting worse with each passing day. I get more stiff and my memory is going quickly. I keep asking for help but nobody can hear me."
- "I am a middle-class man that has worked hard all of my life. Now I can't. But I'm still "middle-class" but just 1 prescription drug for 1 month was more than my house and car payment together. Guess what I had to give up? My MS med."

The National MS Society thanks the Committee for highlighting this complex, but highly important issue that is impacting people and families every day in our country. We look forward to continuing to work with the Committee, Congress and all stakeholders to ensure that all of place a high priority on both innovation and affordable access. People with MS and others living with conditions, diseases and disabilities must be able to have affordable access to the medications they need to live their best lives. Should you have any questions, please contact Senior Director of Federal Government Relations Laura Weidner at laura.weidner@nmss.org or 202-408-1500.

Sincerely,

Bari Talente

Bari Talente, Esq.
Executive Vice President, Advocacy

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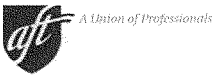


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January 29, 2016

The Honorable Jason Chaffetz, Chairman
Committee on Oversight and Government Reform
2157 Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Elijah Cummings, Ranking Member
Committee on Oversight and Government Reform
2471 Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Chaffetz and Ranking Member Cummings:

On behalf of the 1.6 million members of the American Federation of Teachers, including 120,000 physicians, nurses and other health professionals, I thank Chairman Chaffetz and Ranking Member Cummings for organizing the upcoming hearing on the rising cost of pharmaceuticals.

This hearing is critical given the deleterious effects the increase in pharmaceutical costs is having on our patients, our communities and our healthcare system; the hearing should serve as the first step in investigating the questionable behavior of some pharmaceutical companies.

Current conditions in the pharmaceutical industry present unprecedented challenges for ensuring that patients have access to high-quality, affordable drugs. I frequently hear stories from our members about patients who are skipping needed medications because they are forced to choose between their health needs, paying their mortgages, and buying food. It is devastating to hear from retired educators and nurses, who have spent their lives helping people, about the struggles they face in taking care of their own health needs. These choices and the all-too-often resulting tragedies are unnecessary.

As a union, we have worked hard to ensure that our members have access to high-quality, affordable healthcare, which is why we have fought for the Affordable Care Act and to repeal the excise tax on certain plans. It is clear, however, that more must be done to directly address the rising costs of certain pharmaceuticals. Indeed, drastic, unsustainable price increases can be alleviated through adequate checks on large monopolies, patent review that increases competition, and transparency in pricing. I encourage you to seek more information about each during your hearing.

The **American Federation of Teachers** is a union of professionals that champions fairness, democracy, economic opportunity, and high-quality public education, healthcare and public services for our students, their families and our communities. We are committed to advancing these principles through community engagement, organizing, collective bargaining and political activism, and especially through the work our members do.

**Patent monopolies stifle innovation and market competition.**
Proponents of generous patent protections argue that patents incentivize innovation by offering a measure of economic protection through exclusivity to developers of a pharmaceutical product. But the reality is that these incentives result in stifled competition, which means powerful monopolies emerge.

**Larger monopolies result in price gouging, even with generics.**
The recent increase in merger activity in the pharmaceutical industry is resulting in even larger monopolies. Unfortunately, the 5,000 percent increase in the cost of Daraprim is not an isolated example. According to pharmaceutical company Valeant's website, branded generics are an attractive business for the company because they enjoy low research and development costs and sustainable sales.[i] Valeant increased the cost of one of its heart drugs, Isuprel, by 525 percent shortly following its acquisition of the drug from Marathon Pharmaceuticals.[ii]

**Current price increases are unsustainable.**
Cost savings from an increased focus on preventive care and chronic disease management are being undermined by cost increases in pharmaceuticals. As Connecticut State Comptroller Kevin Lembo recently reported, the dramatic rise in drug costs, both traditional and generic, resulted in a 16.9 percent increase for non-specialty drugs—an increase he describes as "unsustainable."[iii]

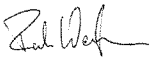
Generics are increasingly integral to patient care. In 2014, generics accounted for 8.6 out of 10 filled days, up from seven in 10 days in 2010. Among those with job-based insurance, "generic prescriptions" is the only medical service category for which utilization increased in 2014.[iv] It is unacceptable to see such high increases at a time when the change in utilization is concentrated in the generic prescription category.

**Lack of transparency obscures drug prices and effectiveness.**
Drug prices in the U.S. are obscured by proprietary rebates as well as several degrees of separation between the manufacturer and the patient. Further, patients have very little access to information on the comparative effectiveness of different drugs. Many countries use a combination of public sector purchasing power and pricing strategies based on clinical value to drive a hard bargain to the benefit of consumers and patients.[v]

As you approach this hearing, I strongly urge you to consider stronger anti-trust laws to limit consolidation in the pharmaceutical industry. We believe such action will ensure that adequate competition remains to drive competitive pricing in all drug classes. Additionally, I urge you to review the patent system. We believe that, when paired with stronger anti-trust laws, commonsense limits on evergreen patents will prevent indefinite monopolies by eliminating undue delay in the introduction of generic drugs.

Thank you again for your important leadership on this issue. Your work is crucial to protecting the viability of our healthcare system and ensuring that patients have access to lifesaving drugs at an affordable price.

Sincerely,



Randi Weingarten
President

RW:emc opeiu#2 afl-cio

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[i] Valeant Pharmaceuticals International Inc. website: http://www.valeant.com/branded-generics

[ii] Andrew Pollack, *New York Times,* Sept. 20, 2015. "Drug Goes from $13.50 a Tablet to $750, Overnight." http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0

[iii] Written testimony, Kevin Lembo, Democratic Steering and Policy Committee Hearing "Ensuring Access and Affordability of Prescription Drugs, While Spurring Innovation." Dec. 2, 2015.

[iv] Health Care Cost Institute. 2014 Health Care Cost and Utilization Report. October 2015.

[v] Whalen, Jeanne. "Why the U.S. Pays More than Other Countries for Drugs." *Wall Street Journal.* Dec. 12, 2015.

**AMERICAN ASSOCIATION OF POISON CONTROL CENTERS**

February 2, 2016

The Honorable Elijah E. Cummings
United States House of Representatives
Ranking Member, House Committee on Oversight and Government Reform
Washington, DC

Re: Price Increase in CaEDTA and other Valeant Pharmaceuticals Products

Dear Congressman Cummings,

On behalf of the physicians, pharmacists, and nurses who provide emergency care through our nation's fifty-five poison control centers, the American Association of Poison Control Centers (AAPCC) would like to voice our significant public health concern brought on by the actions of Valeant Pharmaceuticals.

As you already know, Valeant Pharmaceuticals has recently been under scrutiny for its astronomical pharmaceutical product cost increases. The company's strategy of purchasing the rights to existing pharmaceuticals, only to aggressively raise their cost prices, has left patients with the inability to afford continued therapy, with higher co-payments, and with the inability for health care practitioners and hospitals to afford to stock these drugs.

We are greatly concerned as potentially life-saving antidotes and other medications used to stabilize and treat poisonings have become inaccessible due to their extreme costs to hospital pharmacies, propagated by the business model used by Valeant Pharmaceuticals. Calcium Disodium Edetate (also known as CaEDTA or Calcium EDTA), phytonadione (Mephyton), and penicillamine (Cuprimine) are included on the World Health Organization's 19th Model List of Essential Medications. Though rarely utilized, it is crucial for hospitals that offer emergency services to stock these antidotes in case of a poisoning emergency.

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Since Valeant Pharmaceuticals has acquired manufacturing rights, many hospital pharmacies can no longer afford to keep these essential medications on the shelves and patients on long-term therapy cannot afford to continue their treatment.

For example, the Wholesale Acquisition Cost of CaEDTA, an antidote used for severe lead poisoning, rose from $464.24 per package (manufactured by Graceway Pharmaceuticals) in 2008 to $26,927.33 (manufactured by Valeant Pharmaceuticals) in 2015. Valeant Pharmaceuticals owns the sole manufacturing rights to CaEDTA, leaving hospitals without an alternative product to consider.

Another example is the price of one phytonadione tablet, used to reverse the effects of 'blood thinners' like warfarin, which rose from $9.37 to $58.76 in 2014.

A third example is Penicillamine, an antidote for severe copper, lead, and mercury poisoning, which now costs about $260 per tablet when manufactured by Valeant Pharmaceuticals, but is sold for $1 per tablet by various foreign manufacturers.

In the interest of public health, we encourage significant discussion of, and investigation into, the practices of Valeant Pharmaceuticals to ensure essential and potentially life-saving medications are available for use in our patients.

Sincerely,

Jay L. Schauben, PharmD, DABAT, FAACT

Director, Florida/USVI Poison Information Center – Jacksonville

Professor, Department of Emergency Medicine, College of Medicine University of Florida Health Science Center - Jacksonville

Board President, American Association of Poison Control Centers

Stephen T. Kaminski, JD

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February 3, 2016

Congressman Jason E. Chaffetz
Chairman
House Committee on Oversight
and Government Reform
2157 Rayburn House Office Building
Washington, DC 20515

Congressman Elijah E. Cummings
Ranking Member
House Committee on Oversight
and Government Reform
2471 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Chaffetz and Ranking Member Cummings,

As you convene the Government Reform Committee hearing on "Developments in the Prescription Drug Market: Oversight" on February 4, 2016, we write to urge that when exploring tools to ensure that patients have access to affordable drugs, you also recognize the importance of ensuring the safety and effectiveness of those medications. Proposals to rely on compounded drugs to address pricing concerns dangerously circumvent the Food and Drug Administration approval process, which is essential to ensuring that the benefits of medications outweigh their risks.

The Pew Charitable Trusts is a national nonprofit dedicated to advancing research and policy in the interest of the public. We have longstanding areas of work in the areas of drug quality, safety, and access.

Polls show that the affordability of prescription drugs is a top concern for the public.[1] Last year, Americans spent nearly $374 billion on prescription drugs, a 13.1 percent increase over 2013.[2] Specialty drugs, including those used to treat conditions such as cancer and hepatitis C, represent a significant portion of this spending. However, some off-patent drugs have also been increasing in price – some markedly – even when there have been no changes made to the drugs themselves to confer additional benefit to the patient. These cases raise significant concerns for the patients who rely on these important medications and the doctors who prescribe them.

Payers and policymakers must evaluate a variety of tools to manage drug costs, including improved utilization management, mechanisms to increase competition, faster market access for generic and biosimilar drugs, outcomes- and value-based frameworks and other options. Any such analysis should take into account the public benefit of Food and Drug Administration (FDA) approval, which includes review of safety and efficacy data for new products, bioequivalence data for generic products, and manufacturing quality standards for all products.

We are concerned about proposed solutions that could significantly compromise patient safety, specifically: relying on pharmacy compounding to produce alternate supplies of Food and Drug Administration (FDA) approved drugs. Compounding drugs solely for the purpose of creating a low-

[1] http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/
[2] IMS Institute for Healthcare Informatics, "Medicines Use and Spending Shifts: A Review of the Use of Medicines in the US in 2014." April 2015. Available at: http://www.theimsinstitute.org/en/thought-leadership/ims-institute/reports/medicines-use-in-the-us-2014

cost alternative to FDA approved products may expose patients to unknown risks, and threatens to undermine the critical protections built into the drug-approval system.

The Food, Drug and Cosmetic Act allows pharmacies to make customized medications for individual patients when commercially offered products are not available. But compounded drugs are not equivalent to approved drugs. They do not meet the same approval standards outlined above and, as such, compounding cannot become an alternative to the protections of FDA-approved manufacturing.

After well publicized safety problems in 2012 that injured hundreds and led to scores of deaths, the FDA increased its oversight of compounding facilities conducting over 200 inspections and issuing approximately 60 warning letters.[3] Indeed, while FDA visits to drug production plants far exceed compounding inspections,[4] warning letters to the latter facilities exceed those to the former in FY 2014 (25 versus 20).[5]

Quality is not the only issue. Allowing compounded drugs — even if made at a regulated facility — to be a market alternative to FDA-approved products creates a disincentive to take products through the approval process. The approval process is essential to ensuring that drugs have been tested so that patients know that they drugs they are taking are safe and effective.

As you consider mechanisms to ensure that patients have access to essential medicines at sustainable prices, we urge you to consider the importance of bioequivalence testing and manufacturing quality in protecting patient safety and drug efficacy, and to recognize the long-term importance of ensuring that manufacturers continue to take their products through the FDA approval process. Patients with legitimate clinical needs for compounded drugs should receive those products. However, we should not rely on compounding as a solution to the challenges of managing high drug costs.

Sincerely,

Allan Coukell
The Pew Charitable Trusts

CC: Members of the House Committee on Oversight and Government Reform

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[3] U.S. Food and Drug Administration, "Compounding: Inspections, Recalls, and other Actions." http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm
[4] U.S. Food and Drug Administration, FY 2016 Budget Justification, Field Human Drugs Program Activity. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM388309.pdf
[5] Joanne S. Eglovitch, The Gold Sheet, "FDA's Blizzard of Enforcement at Compounding Pharmacies Evident in GMP Warning Letters for FY 2014" February 26, 2015

hivma
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Pediatric Infectious Diseases Society Liaison
**Michelle Collins-Ogle, MD**
Warren-Vance Community Health Center Inc.
Pediatric Infectious Diseases

Executive Director
**Andrea Weddle, MSW**

February 3, 2016

Congressman Jason Chaffetz
Chair, Committee on Oversight
and Government Reform
U.S. House of Representatives
2236 Rayburn Office Bldg
Washington, DC 20515

Congressman Elijah Cummings
Ranking Member, Committee
on Oversight and Government Reform
U.S. House of Representatives
2230 Rayburn Office Bldg
Washington, DC 20515

Re: Developments in the Prescription Drug Market-Oversight

Dear Chairman Chaffetz and Ranking Member Cummings:

The HIV Medicine Association (HIVMA) commends you for your leadership in holding a bi-partisan hearing on recent price increases for older, off-patent medications and their impact on patient care. HIVMA is housed within the Infectious Diseases Society of America (IDSA) and represents more than 5,000 physicians, scientists and other health care professionals working on the frontlines of the HIV epidemic across the U.S.

Our members are facing new and significant challenges treating toxoplasmosis and other infections predominantly affecting patients with compromised immune systems due to sudden and dramatic price increases for medications that have long been the mainstay for treating these conditions. The result of these unjustified price hikes has been serious disruptions in care, higher medical costs and greater demands on the provider's time.

We greatly appreciate the Committee's ongoing efforts to address this critical issue. The memos released prior to the hearing documented not only the pure profit motive behind the price increases of the companies under investigation but even more concerning a disregard for their impact on patient care, and a faulty notion that medical providers and their institutions would not be sensitive to the price increases. In regards to these assumptions, we draw your attention to the attachment included with these comments that highlights the numerous reports that we received directly from providers across the country regarding the serious challenges that they and their patients have faced due to Turing Pharmaceutical's sudden price increase for pyrimethamine in August 2015. More detailed comments outlining our concerns and actions on this issue follow.

**Price Hikes for Older Medications Critical to Treating Serious Infections**

HIVMA is particularly concerned by the trend of companies leveraging the lack of competition for older (off-patent) medications critical to treating serious infections affecting small patient populations. Two recent examples of price increases hindering treatment of infections are pyrimethamine (marketed as Daraprim® and used for toxoplasmosis) and flucytosine (used for Cryptococcal meningitis) – approved by the FDA in 1953 and 1971 respectively.

Flucytosine is a key component of the preferred treatment for Cryptococcal meningitis – a serious infection of the brain and spinal cord that typically affects patients with compromised immune systems. Since Valeant Pharmaceuticals raised the price of flucytosine from $10 per tablet to $110 per tablet, providers have been forced to deviate from the preferred treatment for this condition as recommended by the *Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents.*[1]

The remainder of our statement focuses on pyrimethamine, a medication critical to treating toxoplasmosis, a parasitic infection that can lead to brain and organ damage, blindness and death in immunocompromised patients who are not effectively treated. While our comments focus on the drug's price, competition for pyrimethamine has been further stifled because of the drug's controlled distribution system implemented in the summer of 2015 that blocks potential manufacturers from obtaining samples of the medication necessary to develop and test a generic alternative.

**The Case of Pyrimethamine**

The 5000% price increase for pyrimethamine in mid-August generated immediate concerns within the infectious diseases community. In early September, after learning that the price increase occurred following the acquisition of pyrimethamine by Turing Pharmaceuticals, HIVMA and IDSA wrote to the company urging them to revise their pricing strategy. Turing responded promptly to HIVMA and IDSA indicating they were determined to develop new treatments for toxoplasmosis by conducting research and would ensure patients who needed the medication had access to it. Following the HIVMA and IDSA exchange with Turing, the issue generated intense media attention that subsided after Turing announced on September 22th that they intended to lower the price of pyrimethamine. The company's failure to take swift action led to more than 150 organizations sending an open appeal to Turing in mid-October urging them to return the price to the level prior to the August price increase in addition to enacting other programs to address serious access issues.

Turing announced in late November that they did not intend to lower the price of pyrimethamine but would begin offering discounts of up to 50% to some hospitals.[2] At the discounted price, the cost would still be 25 times higher than pyrimethamine's price prior to Turing's acquisition of the drug even if the maximum discount is secured. The new pricing strategy also failed to address patients with toxoplasmosis who rely on access to this medication for up to 12 months and a majority of that time as an outpatient. To illustrate the impact that

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[1] Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association and the Infectious Diseases Society of America. Online at https://aidsinfo.nih.gov/contentfiles/lvguidelines/Adult_OI.pdf.

[2] Turing announced on November 24, 2015 that they did not intend to lower the price but would offer discounts of up to 50% to hospitals. Accessed 12/8/2015.

this price increase has or could have, at my own institution, Emory Healthcare, in FY2015 we purchased 14 bottles of Daraprim® for $18,000. In FY2016, this same volume will cost the health system $1.05 million at the drug's list price or $525,000 if we secure the maximum discount of 50% that Turing indicated it would offer some hospitals.

On December 22nd, HIVMA, the Infectious Diseases Society of America and the Pediatric Infectious Diseases Society wrote to the Turing Interim CEO Ron Tilles to urge him to place patient interests and lives ahead of short-term profits by returning the price of pyrimethamine to $13.50. The company has not responded to the request.

We must not underestimate the cost burden of high prices for off-patent medications and the impact of these pricing strategies on patient access and healthcare expenditures in this country. While a bottle of 30 tablets of Daraprim manufactured by GlaxoSmithKline in Mexico is available for $211.66 Mexican pesos[3] (or $12.52 U.S. dollars), the same bottle purchased from Turing would cost $22,500 in the U.S.

**Impact on Patients with Toxoplasmosis**

In October, HIVMA and IDSA in partnership with other organizations developed a web-based blog for providers to report challenges regarding obtaining pyrimethamine. Through the blog and via email, we have collected case reports from providers across the country caring for HIV-infected patients, infants and pregnant women, young children, and transplant patients with toxoplasmosis. Providers have reported being unable to access pyrimethamine for patients and the lack of access resulting in extended hospital stays, prescribing of alternative therapies (including through compounding pharmacies) and treatment delays. One infectious diseases physician noted: "As congenital toxoplasmosis is relatively common in our state, I have treated many infants and children and adolescents with Daraprim [pyrimethamine] over the past 40 years. This is the first time I have had to prescribe alternative therapy because the drug was out of reach."

The lives of patients with toxoplasmosis and other life-threatening infections cannot hang in the balance of acquisitions and mergers. The increased drug prices and the increased demands and pressure that they place on patients, health systems and providers threaten our nation's public health and are simply unsustainable. As evidenced by the price of pyrimethamine in other industrialized countries, the U.S. healthcare market is unique in allowing this to occur. [4 5 6]

HIVMA welcomes the opportunity to work with members of the Committee on Oversight and Government Reform and other policymakers to develop solutions that ensure patient access to lifesaving treatments like pyrimethamine and fluctyosine, while supporting our nation's role as a leader in drug development and innovation. Please do not hesitate to contact me through the HIV Medicine Association (HIVMA) executive

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[3] See farmatodo website at https://www.farmatodo.com.mx/producto/DARAPRIM-25-MG-C30-COMP-561/. Accessed 12/8/2015.
[4] See BBCNews. What's a Fair Price for a Drug? September 22, 2015 Online at: http://www.bbc.com/news/health-34322720. Accessed 12/8/2015.
[5] See also Canada-Pharmacy.Com. Online at: http://www.canada-pharmacy.com/drug-prices/pyrimethamine.html. Accessed 12/8/2015.
[6] See also ndrugs.com. Online at http://www.ndrugs.com/?s=daraprime. Accessed 12/8/2015.

director Andrea Weddle at aweddle@hivma.org or (703) 299-0915 to discuss these issues further.

Sincerely,

Carlos del Rio, MD
Chair, HIVMA Board of Directors

**Daraprim (pyrimethamine) Access Issues**
**Case Reports**

The following patient case reports were reported through the Daraprim Access blog or via email to HIVMA from October to December 2015. Any possible patient-identifying information has been removed, including their state. Cases were reported from the following states: Alabama, Arizona, California, Colorado, Connecticut, Florida, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Minnesota, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Texas, and Wisconsin.

1) Yes, we have had a major issue getting pyrimethamine initially for a pregnant woman, and then for her baby following delivery.
2) I am an HIV provider with a Ryan White funded HIV clinic. I have not been able to access Daraprim for a patient of mine. After a lapse in care this patient's CD4 count dropped, and he needed Daraprim for dual prophylaxis against toxoplasmosis and PJP. He had previously been treated with Daraprim as part of his prophylaxis regimen because of a Bactrim allergy. When he came to clinic, I ordered Daraprim for him. Our pharmacy (340B) could not get it for him for multiple reasons: cost prohibitive even with 340B pricing and it also required paperwork which would delay access. After multiple phone calls we ended up having to switch him to atovaquone. This resulted in a delay in him receiving any prophylaxis at all (as atovaquone liquid was not in stock), and we have been unable to secure Daraprim for him since. He is very high risk and his current prophylaxis regimen in not optimal due to lack of access to Daraprim.
3) We do not have any Daraprim in our pharmacy. We haven't had need to order it recently, but if we need it, we anticipate trouble getting it.
4) It took us over a week to obtain any pyrimethamine for an inpatient.
5) Had a patient with ocular toxoplasmosis who was able to get daraprim for a 3 month course, but only after much wrangling with her insurance and after she had disease progression on bactrim (prescribed by another provider). Had to come from specialty pharmacy. This was last summer, and the first time I got pushback from insurance co on this med.
6) In addition to the issues that this outrageous profiteering may have create for older immunocompromised patients, I am concerned about the availability of pyrimethamine for congenital toxoplasmosis. We have encountered several children at our center in recent years with congenital toxoplasmosis, for which treatment of up to a year is required. Treatment mitigates many of the devastating consequences of congenital toxo.

7) I have had difficulty in accessing Daraprim. We are unable to get the medication through our inpatient pharmacies and are going to alternative agents.
8) I switched from daraprim pills to oral suspension. This was a lot less expensive and can be made through compounding pharmacies. Patient could not pay copay and state AIDS drug assistance program will not pay for compounded meds. I tried to use a much cheaper alternative but ran into roadblocks doing this. There may have been a lapse in therapy. We tried to get Ryan White funds to pay for this medication.
9) We had a case of toxoplasmosis just last week and had to use alternative medication as we only had 2 doses left of pyrimethamine. We have also had patients not able to afford it as outpatient.
10) Currently we have two inpatients on pyrimethamine for cerebral toxoplasmosis. We have two days left of pyrimethamine. A single bottle of 100 pills is the smallest the hospital can buy and will thus cost $75,000. Both patient will have to be switched to TMP/SMX.
11) I had a patient, 7 years old with active ocular toxoplasmosis. I was unable to oder Darprim from a local pharmacy becasue of cost and patient's inability to pay the insurance co-pay. We treated him with an alternative regimen to which he responded. I never had such issues in the past. As congenital toxoplasmosis is relatively common in [our state] - I have treated many infants and children and adolescents with Daraprim over the past 40 years. This is the first time I have had to prescribe alternative therapy because the drug was out of reach.
12) I have a patient who was unable to refill Daraprim for cns toxo since the pharmacy could no longer obtain. I had to switch to alternative clinda tmp/sfx to continue suppressive treatment awaiting immune reconstitution in this hiv infected patient.
13) Two patients:
    a. toxo retinitis - patient was quoted $26,000.00; upon calling us we tried to change his medications; sulfa allergy and he was desensitized and is on Bactrim now.
    b. cerebral toxo - could not get meds refilled (Medicaid) and he is on mepron; renal insufficiency and can't do sulfa agents.
    c. Neither therapy ideal and not first line. In the meantime, the pharmaceutical representative contacted us to introduce himself but requested a meeting first to guide us thru the process.
14) I had a significant delay in obtaining pyrimethamine for my patient. She is a renal transplant patient and had toxo in 2011 and also has a sulfa allergy and had been on pyrimethamine+clinda since 2011. One day she stopped getting it from her mail order pharmacy. She is not completely literate and it took her a little while to figure it out and see her output transplant ID doc. The transplant ID doc called Turing during her appt and was told to prescribe the med to the outpt pharmacy of the hospital. Of course, that did not work - so crazy that a Turing person would give wrong information out. So she went to pharmacy and they didn't have it. She didn't let her ID doc know. Then her mental status worsened and she was brought into the hospital. This is where I met her.

    a. Our hospital had a few days supply of pyrimethamine and with receipt of this, her mental status started to improve dramatically. Then 2 days in we were told that our hospital was running out. This was a Saturday. I was the ID consult fellow. So on Saturday, and then on

Sunday too, I called every number on Turing's website. Unfortunately I didn't see the blog with Martin Shkreli's number on it till much later otherwise I definitely would have called him. You'd think he'd put his cell phone number on the Turing website which is where physicians are looking for it rather than hidden away on a blog that is difficult to find unless you get a direct email about this issue from IDSA. All numbers stated their open hours which are M-F and left NO way to leave a voicemail. I emailed them. No reply.

b. By Monday we had run completely out and allergy was consulted to desensitize her to bactrim. FINALLY monday morning I reached a human being and faxed in the form to get the process started to get my patient her med. I labeled it STAT and circled it many times. I called Walgreens specialty pharmacy (the sole distributor to patients) 6 times per day on Monday and Tuesday. They first promised me a 24 hour turnaround bc this was a patient with toxo encephalitis who is allergic to the alternative. They said all my info checked out and they would call the patient to verify. I provided her hospital room number and her cell and explained that she was not able to talk fluently bc she was infected. By Monday night, they had not gotten through the insurance verification process. Really? Pharmacies do this in like 5-10 minutes while you wait! And I am a physician and was saying this was STAT, and it took 24 hours???

c. Then Tuesday I called again in the morning and early afternoon - insurance hadn't yet been processed. I asked to speak to a supervisor, who said this would be done and the patient would be called within the hour and we would have the med by 6am on Wed AM. Tuesday at 7pm after rounds I called to check in on Walgreens - they hadn't called the patient despite telling me at 1pm they'd do it 'within the hour.' I had already gone to my office, but walked back with them on the line back to my patient's hospital room to make sure that they were able to talk to my patient and not lie to me and just not call her. So they finally connected because I made sure it happened. They said they'd fedex us her med, but then wouldn't tell us when it would arrive.

d. It finally arrived Wed afternoon. I started the process Sat morning. This is an URGENT need for a patient with encephalitis with unknown sulfa allergy (she was unable to talk w/us - not in record) - I did literally everything anyone could to get her her med as soon as possible, and it took 4.5 days. REALLY? We pay 750 per pill for this, you'd think Walgreens specialty could afford to stay open on the weekend when they are the ONLY distributor of this critical medicine.

e. The price is outrageous, but the ACCESS is worse! Can you imagine if levophed wasn't available on the weekends? Utter insanity. Pyrimethamine needs to stop being accessed only through one distributor that is closed on the weekends.

15) I have had to change prophylactic therapy for an AIDS patient with prior ocular toxoplasmosis and likely past toxoplasma encephalitis because of an inability to obtain pyrimethamine.

16) What about the ~$2000 cost per day of flucytosine (5FC) by Valaent, Inc. whereby a 2 week treatment course is ~$30,000 for cryptococcal meningitis?

17) I have a patient with newly diagnosed AIDS who has CNS toxoplasmosis (brain abscess diagnosed presumptively by positive toxo serology and characteristic appearance on MRI), and had just completed

induction therapy with sulfadiazine and pyrimethamine at the time of the price increase. He is doing well now, although the price change of pyrimethamine had occurred between his initial prescription and when I ordered the drug at the maintenance dose. I was surprised to hear that now he could not afford the medication, and I was told by his insurance company that they would not pay for pyrimethamine at this new price. I was referred to the patient assistance program for which he did not qualify as he has insurance. I have not tried the state AIDS drug assistance program, as he lives out of state just across the state border. He is currently receiving sulfadiazine and atovaquone. Another patient of mine was diagnosed with cryptococcal meningitis (HIV-negative), and he paid out of pocket for flucytosine after the price increase for this med while undergoing treatment induction with concomitant liposomal amphotericin.

18) I currently have a patient I am treating for CNS toxoplasmosis and last week our hospital pharmacy was still not able to obtain daraprim. My patient is currently on high dose Bactrim, with ongoing concerns about toxicity from this drug.
19) We asked our pharmacy to try to "get" daraprim for a patient. The pharmacy was quoted $75,000 for a bottle of 100 pills.
20) The Inpatient Pharmacy doesn't have to go through the Turing website. But we do have to go through a wholesaler (Amerisource Bergen) to get the drug. AB subsequently gets it from Turing. We still have only 42 tablets in stock in Inpatient Pharmacy. We haven't had any inpatient requests for the drug, so have not ordered any more. My suspicion is that such a request would probably be escalated to [XXXX], given the cost impact to the hospital for what could be an extended course of therapy. The outpatient procedure, unfortunately, is still the cumbersome process of an MD filling out the Turing website form and getting up front approval from Turing/patient's insurance for the drug. As of Wed, when our buyer met with the rep, she was told that we could now purchase from Turing 100 -25 mg tabs for $75,000 (dropped from [initial price quote] $90,000). As you can imagine, we were less than impressed with the drop in price. It's still too expensive for any one patient.
21) YES! We have a patient with cerebral toxoplasmosis who has done well on pyrimethamine, and is not ready to have toxo therapy stopped, but for whom we can no longer obtain the drug (because of cost). We are now forced to use an alternative therapy.
22) Yes I do – a patient with CNS Toxoplasmosis, Medicaid, who has been unable to obtain it due to shortage as well as insurance reasons. Her state Medicaid doesn't yet have a contract with Walgreen's and so wouldn't cover it. So many man/woman hours lost working to get our patient emergent meds. Had another pt with CNS Toxo admitted to the hospital. Inpatient supply used up so no drugs available. She ended up getting her own from home.
23) I had one HIV+ patient miss doses of pyramethamine when she was being treated outpatient for CNS toxoplasmosis Yes, within the last month I was seeing a child recently diagnosed with toxoplasmosis and was unable to obtain pyrimethamine as all contacted pharmacies had it listed as discontinued by their distributors. I had to change to TMP/SMX despite the fact that data on that therapy in pediatrics is thin. We are using Septra (TMP-SMX) instead of pyramethamine and sulfadiazine.
24) I am replying to your query of problems accessing the drug. Major! I am caring for an infant, well-enough to be out-patient, who we confirmed congenital toxoplasmosis a month ago. I ordered the

drug(s) for treatment though our out-patient pharmacy. They have always used the tablets to make the formulation for infants. The insurance company would not approve payment initially (this is another problem, the "rules" were the patient had to be HIV+, they did not recognize congenital toxoplasmosis as a problem). The price using Daraprim tablets was $27,689 for one month supply, course for congenital toxoplasmosis is 12 months, so hundreds of thousands of dollars to complete the course. Parents obviously could not afford this. I started Bactrim while we tried to deal with this. Our great pharmacy staff located a company producing the powder, obtained this and compounded it here – after a couple weeks of significant efforts, we eventually got it to parents for a price of $48 dollars per month! So we are now trying to bypass the company whenever possible. Criminal in my mind.

25) If beneficial to discuss this case with the media or others, I would be happy to assist. I am also the Peds HIV physician at XX, and I do not look forward to trying to acquire the drug if needed for some of my older HIV+ patients.
26) I have "suggested" that patients look at Canadian online Pharmacies. I'm told that Daraprim is $145 for 90 25 mg tabs. Other patients tell me that they can get drugs no longer available in USA (e.g. Tetracycline HCL) very reasonably.
27) For an inpatient with strong suspicion of CNS Toxoplasmosis, in the week after Turing took exclusive control of pyrimethamine, the XXX was unable to access supply of Daraprim due to "not having an account with Turing" and Turing refused to supply any medication without this established relationship in place, resulting in inability to get the drug and the use of a less acceptable alternative regimen. This was an unacceptable situation for both the patient and the institution.
28) We only had one AIDS patient with toxoplasma encephalitis since the price increase of Daraprim in June this year. We used Bactrim successfully as a treatment alternative.
29) Yes. one patient who was wealthy was able to pay for it but we had to search to find a pharmacy.
30) A middle aged man was admitted with a new diagnosis of cerebral toxoplasmosis at our facility. He was ill enough to require discharge to a skilled nursing facility, but we could find no facility that would accept him due to the cost of pyrimethamine and sulfa regimen, thus we were forced to choose an alternate regimen to allow discharge from the hospital.
31) I had a patient on active toxo therapy- I had to first go through his managed Medicaid in XXX for prior authorization. That entailed sending hospital records, lab work and ambulatory medical records. After that approval, I had to submit the request and additional documentation to the central Walgreen's pharmacy who is distributing the meds. The only reason the patient did not run out of meds was that he had a repeat hospitalization early in therapy and had some "spares" of Daraprim. Otherwise, he would have gone 4 days without. Of course, had there not been this pricing issue, I could have just refilled his medication with his local pharmacy and no delay.
32) This group has 5 individuals on the caseload that have experienced issues with receiving Daraprim. In one case, the pharmacy was not able to get the medication requiring alternative treatment to be ordered.
33) Second occurrence with Daraprim in the past month. A women in X state correctional facility needed Daraprim for toxoplasmosis therapy. Ultimately, the DOC had to purchase the

leukovorin/pyrimethamine from the compounding pharmacy to prevent a disruption in therapy. Needless to say this process entailed hours of physician and pharmacy time.

34) We have had one or two occasions when the cost was prohibitive, and there were few or no options.
35) I am treating a patient with AIDS and CNS toxoplasmosis. As 10 days after diagnosis, we have been unable to obtain pyrimethamine for this patient following hospital discharge.
36) Last month we were treating an AIDS patient for suspected toxo at our facility. Patient was/is noncompliant and was off ARV for some time prior to admission. The patient's hospital course involved a trip to the ICU, intubation for several days, experiencing some delirium post extubation, and plenty of other unpleasant symptoms possibly related to the toxo and an extended hospital/ICU stay. Our inpatient pharmacy was able to acquire pyrimethamine from the local academic medical center in our area - the cost of acquiring the drug was not exorbitant from my recollection (thankfully).

    a. We treated the patient for several days with pyrimethamine and other supportive cares prior to discharge. Our case coordinators worked with the patient's community pharmacy to ensure they had pyrimethamine stocked and ready to be dispensed for the duration of the treatment course. Ample stock was confirmed two days prior to discharge.

    b. The patient was discharged, went to the pharmacy we had been working with, and then suddenly they didn't have stock of the drug. The pharmacist claimed they didn't have appropriate credentials to access the drugs. Bactrim was substituted, which ultimately wasn't tolerated, and another admission was required to treat the patient appropriately.

    c. We are currently investigating what slipped through the cracks at the initial discharge. But there are definitely more issues with accessing and acquiring the drug in recent months, based on our own experience, and based on accounts from colleagues.

37) I just learned that my patient's insurance was billed $54,000 for a one month supply of drug.
38) I had similar problem with flucytosine for crypto meningitis/endophthalmitis. Initial insurance refusal with $27,000 charge for 10 days ,causing readmission.
39) I was able to obtain Daraprim last week for a BCBS member, but only after completing a prior auth for a "high dollar exception." I also had to use Community Walgreens Specialty Pharmacy, which had to order it from their central office. I'm not sure what the actual cost was to the payer.
40) Shortly after the price increase I had to call the pharmacy to switch out pyrimethamine to Bactrim for a patient with ocular toxo. He was Canadian and I suggested that he return to his country to receive proper treatment, but he declined. Since then, I have had difficulty with cycloserine, praziquantel and albendazole with regards to cost.

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NATIONAL ALLIANCE OF STATE & TERRITORIAL AIDS DIRECTORS

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February 3, 2016

Representative Jason Chaffetz
Chairman
United States House of Representatives
Committee on Oversight and
Government Reform
2157 Rayburn House Office Building
Washington, D.C. 20515

Representative Elijah Cummings
Ranking Member
United States House of Representatives
Committee on Oversight and
Government Reform
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Chaffetz and Ranking Member Cummings:

The National Alliance of State and Territorial AIDS Directors (NASTAD), which represents public health officials who administer state and territorial HIV and hepatitis prevention and care programs nationwide, has been actively responding since September 2015 to the recent price increase for Daraprim (pyrimethamine), an antiparasitic agent used to treat toxoplasmosis in patients with HIV. Following the August 2015 transfer of ownership of Daraprim to Turing Pharmaceuticals and Turing's unconscionable increase in Daraprim's price, several state AIDS Drug Assistance Programs (ADAPs), which provide medications to people living with HIV, have experienced difficulty in acquiring Daraprim at the discounted price to which ADAPs are legally entitled under the 340B Drug Discount Program, depriving some patients of access to a critical medicine. NASTAD is concerned that the staggeringly high market price of Daraprim, now 5,000% higher than it was prior to the transfer of ownership, prevents ADAPs from being able to purchase the medication. In May 2015, 43 ADAPs indicated that they had direct access to Daraprim at the 340B price; by November 2015, Turing asserted that only four ADAPs had been able to access Daraprim at the 340B price following the price increase.[1] This massive decrease in access is directly attributable to Turing's decision to hike the price of Daraprim while limiting distribution - problems that NASTAD brought to Turing's attention in early September 2015 when we learned of them.

NASTAD has consistently notified Turing of access problems and attempted to work with Turing on solutions since September 2015, to little avail. In the Appendix to this letter, NASTAD has prepared a timeline of all our communications with Turing since September 2015, including both private conversations about access for specific states as well as public demands that Turing reduce the price and ensure access. This timeline shows that, contrary to Turing's assertion, Turing has not been proactive about ensuring access. Just as Turing walked back its promise to lower the price of Daraprim, Turing has not

been fully forthcoming in its communications with NASTAD, as the following highlights from the timeline demonstrate:

- In October 2015, Turing assured the Health Resources and Services Administration's Office of Pharmacy Affairs that the 340B price was available through Walgreens; NASTAD continues to hear from state health departments that they cannot access this price through Walgreens.
- On November 3, 2015, Turing pledged to the HIV community that it would soon provide full details about its patient assistance and co-pay programs; after repeated requests for the information, Turing finally provided this information to NASTAD on January 11, 2016 but indicated Turing would not make it public (NASTAD subsequently did).
- On January 4 and January 27, 2016, Turing asserted that a workaround to its limited distribution system had been tested with a state health department and was fully operational; on February 2, 2016, the state health department that Turing said had tested the workaround informed NASTAD that the system had still not been tested and that it still could not purchase Daraprim at the 340B price.
- On January 4, 2016, Turing declined NASTAD's offer to host a national conference call for state health departments to learn how they could access Daraprim.

As this timeline shows, NASTAD has repeatedly attempted to engage Turing in solutions to access issues, all the while still maintaining public pressure on Turing to reduce the price of Daraprim. While we remain hopeful that Turing will provide increased Daraprim access to ADAPs at the 340B price as required by law, the existing price hike and limited distribution mechanism have combined to severely hamper access.

Similar to Medicaid programs, ADAPs are able to purchase drugs at discounted prices via a rebate mechanism. The astronomical price of Daraprim, combined with Turing's obfuscation on the operation of the rebate mechanism, has left ADAPs unwilling to outlay the initial funds to purchase Daraprim in anticipation of an eventual rebate. For patients over 60 kg (132 lbs), federal guidelines recommend three pills of Daraprim per day for an initial treatment course lasting six weeks, and then two pills per day for maintenance therapy, lasting at least six months.[2] At $750 per pill, an ADAP would be forced to pay $94,500 for initial treatment and at least $270,000 for maintenance therapy, for a total of $365,500 in upfront costs. While the ADAP would be eligible to receive a rebate, ADAPs may not have sufficient funds on hand to front the cost and then seek rebates to mitigate the high price. Further, with no experience in receiving these rebates from Turing, ADAPs are unwilling to assume the risk that Turing will provide prompt and accurate rebates – even though it is required to do so.

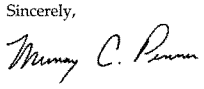
Due to Daraprim's high price, insurers are subjecting patients in need of Daraprim to prior authorization and other utilization management techniques. Moreover, expensive drugs such as Daraprim are often subject to burdensome cost-sharing and co-insurance requirements that require patients to pay a percentage of the drug's cost, sometimes up to 50% of the cost of the drug. ADAPs are allowed to purchase insurance for many clients; with Daraprim's exorbitant price, ADAPs are subject to both restrictive access and higher co-insurance policies, impairing the timely treatment of ADAP clients and substantially raising costs to ADAPs that pay the co-insurance payments on behalf of clients. Prior to Turing's price increase, insurers had not limited patient access to Daraprim; restrictions now in place result solely from the price increase.

NASTAD believes that Turing's distribution arrangements have been and may still be in violation of the 340B Drug Discount Program's non-discrimination provisions. NASTAD understands that, for outpatient prescriptions, Turing has a sole distribution agreement with Walgreens Specialty Pharmacy. However, it appears that Turing has not made the 340B price available to eligible 340B covered entities through Walgreens, instead only allowing purchases at the 340B price through a separate, drop-ship mechanism available through ASD Healthcare.

The Health Resources and Services Administration's regulations prohibit manufacturers from "singl[ing] out covered entities from their other customers for restrictive conditions that would undermine the statutory objective" of the 340B program and from "plac[ing] limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." (59 Fed. Reg. 25110 (May 13, 1994)) This prohibition, known as the non-discrimination provision, requires manufacturers to make 340B prices available to covered entities through the same distribution channels available to other purchasers. Without this protection, manufacturers could attempt to limit participation in the 340B program by placing additional barriers in the way of covered entities, ultimately harming patients. With the above accounts, it appears that Turing has done just that.

We appreciate your investigation of this matter. Please contact me if you have questions or need additional information.

Sincerely,



Murray C. Penner
Executive Director

[1] http://www.turingpharma.com/media/press-release?headline=texas-hiv-medication-advisory-committee-unanimously-votes-to-recommend-daraprim%25c2%25ae-be-added-to-its-formulary
[2] https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/322/toxo

## Appendix – Timeline of NASTAD-Turing Communications

- September 15, 2015 – NASTAD staff met with Turing representatives to discuss access issues created by the price increase and limited distribution mechanism. NASTAD staff attending were Murray Penner, Executive Director, and Sean Dickson, Manager, Healthcare Access; Turing representatives were Tom Evegan, Head of Managed Markets, and Kevin Bernier, National Director, Alliance Development and Public Affairs.
- September 22, 2015 – NASTAD submitted a letter to the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA) outlining Turing's violations of the 340B Drug Pricing Program and explaining how the price increase and limited distribution forced Georgia to remove Daraprim from its AIDS Drug Assistance Program, limiting patient access. (Exhibit A)
- September 22, 2015 – Turing publicly announced that it will lower the price of Daraprim.
- October 21, 2015 – NASTAD, in conjunction with 151 other organizations, submitted an open appeal to Turing highlighting access issues caused by the price increase and limited distribution. (Exhibit B)
- October 23, 2015 – NASTAD received a response from OPA regarding NASTAD's September 22, 2015 letter. In this response, OPA stated that Turing had assured OPA that Daraprim was available at the 340B price from Walgreens following a September 17, 2015 meeting between Turing and Walgreens. NASTAD continues to hear from state health departments that they cannot access the 340B price through Walgreens. (Exhibit C)
- November 3, 2015 – In response to the open appeal, Turing scheduled a meeting at NASTAD, including representatives from other HIV organizations (HIV Medicine Association (HIVMA), Infectious Disease Society of America (IDSA), Pediatric Infectious Diseases Society, Treatment Action Group (TAG), and Ryan White Medical Providers Coalition). At this meeting, Turing delivered a written response to the open appeal, including a pledge to "provide you with complete information regarding eligibility and documentation requirements for the patient assistance and co-pay assistance programs as quickly as possible." (Exhibit D) Turing's written response also included a pledge to "explor[e] potential distribution solutions and package sizes to better assist patients in an inpatient setting." During the meeting, Turing orally told attendees that it was still evaluating a lower price and would announce a lower price by the end of the year.
- November 4, 2015 – The HIV community attendees of the November 3 meeting, including NASTAD, released a joint statement after the meeting. The statement explicitly noted Turing's oral statement that it would lower prices by the end of the year and called on Turing to release details of its patient assistance programs, as pledged in Turing's response to the open appeal. (Exhibit E)
- November 9, 2015 – The HIV community attendees of the November 3 meeting, including NASTAD, sent a letter to Turing calling for details of the patient assistance program, as pledged in Turing's response to the open appeal, and calling for a return to the pre-Turing price for Daraprim. (Exhibit F)
- November 18, 2015 – Following reports that Turing had been attempting to meet with select state health departments to discuss Daraprim access, NASTAD sent a memorandum to all states requesting that states encourage Turing to work with NASTAD to develop access solutions for all states. NASTAD noted that Turing had not provided NASTAD with any information on where state health departments should submit rebate invoices for Daraprim purchases, as required by the 340B Drug Pricing Program. (Exhibit G)

- November 24, 2015 – Turing announced that it will not lower the list price for Daraprim and will only offer limited discounts for hospital inpatient use.
- December 1, 2015 – Turing provided information to the Texas AIDS Drug Assistance Program on how state health departments should submit rebate invoices under the 340B Drug Pricing Program. NASTAD shared this information with all state health departments. (Exhibit H)
- December 3, 2015 – NASTAD met with OPA to discuss continued Daraprim access issues for state health departments, indicating that state health departments were still unable to access Daraprim at the 340B price and had dropped coverage of Daraprim because they could not afford Daraprim at the increased list price.
- December 4, 2015 – NASTAD requested a national conference call with Turing to discuss how state health departments could access Daraprim at the prices required under the 340B Drug Pricing Program and other issues, including a review of the limited distribution mechanism, the rebate invoice process for state health departments, updates on the documentation of patient assistance and co-pay assistance programs pledged in Turing's November 3 response to the open appeal, and ongoing contracting issues with state health departments. NASTAD also requested a pre-call between NASTAD and Turing to discuss these issues and to plan for the national conference call.
- December 9, 2015 – Turing agreed to a call with NASTAD to discuss issues and to discuss participating in a national conference call.
- December 11, 2015 – NASTAD submitted comments to the Senate Special Committee on Aging hearing titled "Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines." These comments outlined continued access challenges for state health departments due to Turing's increased price and limited distribution for Daraprim. (Exhibit I)
- December 16, 2015 – NASTAD e-mails Turing to further conversation on a national conference call to address state health department access; NASTAD also provides examples of the comprehensive patient assistance program information released by other drug manufacturers.
- December 22, 2015 – Following the resignation of Martin Shkreli as CEO, the Fair Pricing Coalition, a network of drug pricing advocates in which NASTAD participates, sent a public letter to Turing requesting that Turing reduce the price of Daraprim to reduce access challenges. (Exhibit J)
- January 4, 2016 – NASTAD and Turing had a call to discuss access issues and a national conference call during which Turing would speak with state health departments about how they can access Daraprim. Turing declined to participate in a national conference call. NASTAD re-iterated that Turing had not provided the comprehensive patient assistance program information pledged in Turing's November 3, 2015 response to the open appeal; Turing stated that it is not industry practice to release such information. Turing asserted that a workaround to the limited distribution system had been successfully tested by a state health department; NASTAD later learned from the state health department that the mechanism had not been tested and that the health department was still unable to access Daraprim at the price required by the 340B Drug Pricing Program.
- January 5, 2016 – NASTAD sent an e-mail to Turing, quoting Turing's November 3, 2015 pledge to provide comprehensive patient assistance program information.
- January 11, 2016 – Turing sent NASTAD written information on the patient assistance program. NASTAD responded to Turing with requests for additional clarification on aspects of the patient assistance program. Turing responded by phone with clarification, and did not provide additional written clarification of the program.

- January 12, 2016 – NASTAD distributed information on Turing's patient assistance program to state health departments and the HIV community. This was the first public disclosure of the patient assistance program information pledged in Turing's November 3, 2015 response to the open appeal. (Exhibit K)
- January 13, 2016 – NASTAD was informed by a state health department that the rebate invoice contact provided by Turing on December 1, 2015 was no longer working at Turing. NASTAD requested updated information from Turing on the rebate invoice process; Turing provided NASTAD with a contact for "access issues."
- January 15, 2016 – Turing and NASTAD had a call to discuss access issues and rebate invoice processes; Turing provided NASTAD with an updated contact for rebate invoice submission.
- January 25, 2016 – NASTAD received a draft memorandum from Turing on how state health departments could access Daraprim at the price required by the 340B Drug Pricing Program. The memorandum stated that Turing was being "proactive" in resolving state health department access issues, which NASTAD asked Turing to remove. NASTAD provided comments on the memorandum, including providing Turing with additional education on the mechanisms by which state health departments purchase medications.
- January 27, 2016 – NASTAD notified Turing that a state health department had been refused in an attempt to purchase Daraprim through ASD Healthcare, Turing's limited distribution arrangement for the 340B Drug Pricing Program. NASTAD requested that Turing address the situation; Turing instead provided NASTAD with contact information for another pharmacy vendor.
- January 27, 2016 – NASTAD received an updated copy of the memorandum on Daraprim access for state health departments, which stated that the limited distribution workaround discussed on January 4, 2016 was operational and had been tested by a state health department.
- February 2, 2016 – NASTAD learned from the state health department referenced in Turing's January 27, 2016 communication that the limited distribution workaround still had not been tested and was not operational.
- February 3, 2016 – Turing asked NASTAD if NASTAD supported the release of the access memorandum if it did not reference the limited distribution workaround; NASTAD replied that it did not support the release and asked that NASTAD contact information be removed from the memorandum.

Exhibit A

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Executive Director
Murray C. Penner

September 22, 2015

Captain Krista Pedley
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W05A
Rockville, MD 20857

Dear Captain Pedley:

The National Alliance of State and Territorial AIDS Directors (NASTAD) has been actively monitoring recent price increases for Daraprim (pyrimethamine), an antiparasitic agent used to treat toxoplasmosis in patients with HIV, including AIDS Drug Assistance Program (ADAP) clients. Following a recent transfer of ownership to Turing Pharmaceuticals, several ADAPs have experienced difficulty in acquiring Daraprim at the 340B price.

NASTAD is concerned that Turing's distribution arrangements are in violation of the 340B Drug Discount Program's non-discrimination provisions. NASTAD understands that, for outpatient prescriptions, Turing has a sole distribution agreement with Walgreens Specialty Pharmacy. However, it appears that Turing has not made the 340B price available to eligible 340B covered entities through Walgreens, instead only allowing purchases at the 340B price through a separate, drop-ship mechanism available through ICS Connect.

On September 22, 2015, Turing's website for Daraprim, DaraprimDirect.com, directed prescribers to order through Walgreens Specialty Pharmacy; the website contains a separate drop-down box titled "For Hospital Pharmacists (Including: Institutions and 340B Facilities)" that provides separate ordering information through ICS Connect for 340B pricing. Previously, Turing's website made the separate distribution channels more explicit, as seen in the attached website capture. On September 12, 2015, Turing's website labeled the distribution channels as "Walgreens Specialty Pharmacy" for all "Outpatient/Retail" orders and "Integrated Commercial Services (ICS)" for all "Inpatient Pharmacies, Government Customers, and 340B/PHS Customers."

The Health Resources and Services Administration's (HRSA) regulations prohibit manufacturers from "sing![ing] out covered entities from their other customers for restrictive conditions that would undermine the statutory objective" of the 340B program and from "plac[ing] limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." (59 Fed. Reg. 25110 (May 13, 1994)) This prohibition, known as the non-discrimination provision, requires manufacturers to make 340B prices available to covered entities through the same distribution channels available to other purchasers. Without this protection, manufacturers could attempt to limit participation in the 340B program by placing additional barriers in the way of covered entities, ultimately harming patients.

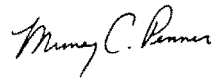
Indeed, Turing's restrictive purchasing program for 340B covered entities has harmed patients. Georgia has removed Daraprim from its ADAP formulary because it was unable to purchase Daraprim at the 340B price. Georgia, like many states, is only able to purchase drugs through vendors that have gone through state approval processes and is unable to make one-off drug

purchases through ICS Connect. Because the 340B price was not available through Walgreens Specialty Pharmacy and thus not available through any of the Georgia ADAP's standard purchasing channels, Georgia was forced to remove Daraprim from the formulary because of the excessive price. ADAP clients in Georgia who need Daraprim must access it through charity care or a patient assistance program, which can lead to delays in care that impact patient health. NASTAD is aware of ADAPs that have been able to establish accounts with ICS Connect after receiving special approval from their state purchasing authorities; however, this extra administrative process to receive 340B pricing is precisely the type of discriminatory barrier prohibited in the 340B program.

It is apparent that Turing has violated HRSA's non-discrimination requirements for the 340B program, and NASTAD believes that this discriminatory restriction on purchasing at the 340B price is ongoing. NASTAD requests that HRSA investigates Turing's violations of the non-discrimination requirement and imposes appropriate penalties.

We appreciate your investigation of this matter. Please contact me if you have questions or need additional information.

Sincerely,



Murray C. Penner
Executive Director, NASTAD

CC: Sen. Bernie Sanders, U.S. Senate
Rep. Elijah Cummings, U.S. House of Representatives
Michelle Herzog, Deputy Director, Office of Pharmacy Affairs
Heather Hauck, Director, Division of State HIV/AIDS Programs
Michael Goldrosen, Deputy Director, Division of State HIV/AIDS Programs
Glenn Clark, ADAP Advisor, Division of State HIV/AIDS Programs
Ann Lefert, Senior Director, Prevention/Care Program and Policy, NASTAD
Sean Dickson, Manager, Health Care Access, NASTAD

Attachment (1)

Exhibit A

You have reached the cached page for **http://www.daraprimdirect.com/how-to-prescribe (http://www.daraprimdirect.com/how-to-prescribe)**

Below is a snapshot of the Web page as it appeared on **9/12/2015** (the last time our crawler visited it). This is the version of the page that was used for ranking your search results. The page may have changed since we last cached it. To see what might have changed (without the highlights), go to the current page (http://www.daraprimdirect.com/how-to-prescribe).

You searched for: **daraprimdirect 340b** We have highlighted matching words that appear in the page below.

Bing is not responsible for the content of this page.

# How to Prescribe

**Now available exclusively through Walgreen's Specialty Pharmacy**

Click here to download Prescription and Enrollment form

(/forms/Daraprim-Prescription-Form.pdf)

## Outpatient/Retail

**Phone Walgreens Specialty Pharmacy**

Walgreens Specialty Pharmacy can be promptly reached by dialing 1-844-463-2727

**Download Prescription and Enrollment Form**

Download Prescription and Enrollment Form by clicking here (/Daraprim-Prescription-Form.pdf), have your physician complete and fax to 1-844-325-653

## Inpatient/Pharmacy

**Inpatient Pharmacies, Government Customers, and 340B/PHS Customers**

Order through Integrated Commercial Services Inc (ICS) by calling ICS at 800-554-6919. ICS can also be contacted by email daraprimdirectCS@icsconnect.com (mailto:daraprimdirectCS@icsconnect.com)

Prescribing Information Privacy Policy Turing Pharmaceuticals

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Exhibit A

## Important Safety Information

Expand

**INDICATIONS**

DARAPRIM (pyrimethamine) is indicated for the:

- Treatment of toxoplasmosis when used conjointly with a sulfonamide.
- Treatment of acute malaria only in patients infected in areas where susceptible plasmodia exist and when used conjointly with a sulfonamide (e.g., sulfadoxine) to initiate transmission control and suppression of susceptible strains of plasmodia. It should NOT be used alone to treat acute malaria. Fast-acting schizonticides such as chloroquine or quinine are indicated and preferable for the treatment of acute malaria.
- Chemoprophylaxis of malaria due to susceptible strains of plasmodia. It is not suitable as a prophylactic agent for travelers to most areas since resistance to pyrimethamine is prevalent worldwide.

**IMPORTANT SAFETY INFORMATION**

- DARAPRIM is **contraindicated** in patients with known hypersensitivity to pyrimethamine or to any component of the formulation and in patients with documented megaloblastic anemia due to folate deficiency.
- Potential for **folate deficiency**: Dosage required for toxoplasmosis treatment approaches the toxic level. If signs of folate deficiency develop, reduce the dosage or discontinue the drug according to patient response. Administer folinic acid (leucovorin) at 5-15 mg per day until normal hematopoiesis is restored.
- **Carcinogenic potential:** Data indicates that pryimethamine may be carcinogenic.

**Adverse reactions:**

- **Hypersensitivity reactions,** occasionally severe (such as Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, and anaphylaxis), **and hyperphenylalaninemia,** can occur particularly when pyrimethamine is administered concomitantly with a sulfonamide. Consult the full prescribing information for relevant sulfonamide-associated adverse events.
- **Megaloblastic anemia, leukopenia, thrombocytopenia, pancytopenia, atrophic glossitis, hematuria, cardiac rhythm disorders, anorexia and vomiting** may occur with doses used for toxoplasmosis treatment. Hematologic effects may also occur at low doses in certain individuals.
- **Pulmonary eosinophilia** has been reported rarely.

**Pregnancy Category C:**

- There are no adequate and well-controlled studies in pregnant women. DARAPRIM should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Women of childbearing potential should be warned against becoming pregnant during treatment with Daraprim.
- Pyrimethamine is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from pyrimethamine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
- **Keep out of the reach of infants and children:** Deaths in pediatric patients have been reported after accidental ingestion.

**Drug Interactions:**

- The concomitant use of pyrimethamine with other antifolic drugs or agents associated with myelosuppression including sulfonamides or trimethoprim-sulfamethoxazole combination, proguanil , zidovudine, or cytostatic agents (e.g., methotrexate), may increase the risk of bone marrow suppression. If signs of folate deficiency develop, pyrimethamine should be discontinued and folinic acid should be given until hematopoiesis is restored (see above).
- Use Daraprim with caution in patients receiving therapy, such as phenytoin, that affect folate levels.
- Mild hepatotoxicity can occur when lorazepam and pyrimethamine are administered concomitantly.

Exhibit A

**Dosing Information:**

- For specific dosing instructions see the Full Prescribing Information.
- Do not exceed the recommended dosage.
- Start with a small dose for toxoplamosis in patients with convulsive disorders to avoid the potential nervous system toxicity of pyrimethamine (see Overdosage).
- Use with caution in patients with impaired renal or hepatic function; in patients with possible folate deficiency such as individuals with malabsorption syndrome, alcoholism, or who are pregnant; and in the elderly due to the potential for decreased hepatic, renal, or cardiac function, and concomitant disease or other drug therapy in this population.
- Concurrent administration of folinic acid is strongly recommended when used for the treatment of toxoplasmosis in **ALL** patients.
- In patients receiving a high dosage, as for the treatment of toxoplasmosis, semiweekly blood counts, including platelet counts should be performed.
- Taking Daraprim with meals may minimize associated anorexia and vomiting.

**Overdosage**

- Following the ingestion of 300 mg or more of pyrimethamine, gastrointestinal and/or central nervous system signs may be present, including convulsions and death.
- There is no specific antidote to acute pyrimethamine poisoning. Symptomatic and supportive measures should be employed. Gastric lavage is recommended and is effective if carried out very soon after drug ingestion. Parenteral diazepam may be used to control convulsions. Folinic acid should be administered within 2 hours of drug ingestion to be most effective in counteracting the effects on the hematopoietic system. Daily monitoring of peripheral blood counts is recommended for up to several weeks until normal hematologic values are restored.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch (http://www.fda.gov/medwatch) or call 1-800-FDA-1088. To report SUSPECTED ADVERSE REACTIONS contact Turing Pharmaceuticals AG 1-877-258-2033 .**

**Please See Full Prescribing Information**

DARAPRIM is a licensed trademark of Turing Pharmaceuticals AG.

Exhibit B

Released: October 22, 2015

# An Open Appeal to Turing Pharmaceuticals:

We, the under-signed organizations, are concerned that despite a commitment by Turing Pharmaceuticals to lower the price of Daraprim (pyrimethamine) more than a month ago, the price has not been reduced nor have distribution issues been sufficiently addressed.

The controlled distribution system requiring purchase of Daraprim (pyrimethamine) through Walgreen's Specialty Pharmacy and its classification as a "specialty drug" also continues to create high and unreasonable hurdles for a medication that previously was widely available through local pharmacies to providers and their patients.

As a result, many individuals with toxoplasmosis in the United States are left without access to the preferred treatment for a condition that if not effectively treated can cause blindness, brain and organ damage or death. Patients already affected by the failure of Turing Pharmaceuticals to act on its commitment include pregnant women, children, infants, people with HIV and others with compromised immune systems across the country, for example:

> ***Within the last month I was seeing a child recently diagnosed with toxoplasmosis and was unable to obtain pyrimethamine as all contacted pharmacies had it listed as discontinued by their distributors. I had to change to trimethoprim/sulfamethoxazole despite the fact that data on that therapy in pediatrics is thin. – Reported by a physician***
>
> ***A patient with toxoplasmosis retinitis was quoted a price of $26,000 so we had to change his medication to Bactrim. A second patient had cerebral toxoplasmosis and was unable to get medications refilled by Medicaid. The patient was switched to a second line therapy. Neither therapy is ideal. – Reported by a physician***
>
> ***Currently, we have two inpatients on pyrimethamine for cerebral toxoplasmosis. We have two days left of pyrimethamine. A single bottle of 100 pills is the smallest the hospital can buy and will thus cost $75,000. Both patients will have to be switched to trimethoprim/ sulfamethoxazole.[1] [2] – Reported by a physician***
>
> ***Yes, we have had a major issue getting pyrimethamine initially for a pregnant woman, and then for her baby following delivery. – Reported by a physician***

We call on Turing Pharmaceuticals to take the following immediate actions regarding Daraprim (pyrimethamine):

1. Lower the price to a level comparable to the price prior to the August 5000% increase.
2. Provide parity on pricing for inpatient and outpatient settings.

[1] The Department of Health and Human Services guidelines on the Prevention and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents were updated on October 19th to offer guidance on the use of alternative therapies due to limited access to pyrimethamine.
[2] The Department of Health and Human Services guidelines on the Prevention and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents recommend a course of acute therapy for a minimum of six weeks followed by maintenance therapy for at least six months. Following their treatment recommendations, a minimum of 486 pyrimethamine tablets are required to effectively treat immunocompromised patients. Available online at: https://aidsinfo.nih.gov/contentfiles/lvguidelines/Adult_OI.pdf.

*For more information, contact Andrea Weddle with the HIV Medicine Association at aweddle@hivma.org.*

3. Offer support under the patient assistance program to patients with incomes at the level of at least 500 percent of the federal poverty level.[3]
4. Provide complete transparency regarding eligibility and documentation requirements for the patient assistance and co-pay assistance programs.
5. Cover the maximum out-of-pocket costs ($6,600 for an individual plan and $13,200 for a family plan in 2015) on co-insurance and copayments allowable under the Affordable Care Act. The co-pay assistance program should be front-loaded to ensure that coinsurance amounts, which can be between 25 and 50 percent of the retail drug cost, are fully covered until the out-of-pocket limit is reached.[4]
6. Ensure same day and direct access to the drug in the communities where patients live.

The unjustifiable actions taken to leverage the value of an effective 70-year old medication are jeopardizing the health of individuals with a serious, life-threatening condition. These individuals do not have the luxury of time to wait for promised new treatments – which also will likely be priced out of reach.

Endorsed by the 152 organizations listed below representing 29 states, the District of Columbia and Puerto Rico:

**Alabama**
AIDS Alabama
AIDS Alabama South
Blue Faery: The Adrienne Wilson Liver Cancer Association
Health Services Center
University of Alabama at Birmingham, 1917 Outpatient HIV/AIDS Clinic
Selma AIR
West Alabama AIDS Outreach
**Arizona**
El Rio Special Immunology Associates
HIV/AIDS Law Project
**California**
AIDS Healthcare Foundation
AIDS Project Los Angeles
Berkeley Free Clinic
Correlia Biosystems, Inc.
Cure for AIDS Coalition
Infectious Diseases Associates Medical Group, Inc.
Natural Wholistic Health & Wellness Research Center
Pangaea Global AIDS
Positive Life Series Palm Springs
Positive Women's Network - USA
Project Inform
San Francisco AIDS Foundation
San Francisco Hepatitis C Task Force
SumOfUs.org
The Ihangane Project
Tom Waddell Urban Health Center
WEB.PsyD
**Colorado**
Colorado AIDS Project
THRIVE!: The Persons Living With HIV/AIDS Initiative of
**Colorado**
Treatment Educat1on Network
**Connecticut**
Liberty Community Services, Inc.
**District of Columbia**
340B Health
ADAP Advocacy Association (aaa+)
AIDS United
Alliance for Retired Americans
American Academy of HIV Medicine
American Federation of State, County and Municipal Employees
Community Access National Network (CANN)
DC Fights Back
Fair Pricing Coalition
GLMA: Health Professionals Advancing LGBT Equality
HealthHIV
Human Rights Campaign
National Alliance of State and Territorial AIDS Directors
National Black Justice Coalition (NBJC)
National Center for Lesbian Rights
National Center for Transgender Equality
National Coalition for LGBT Health
National Latina Institute for Reproductive Health
National Latino AIDS Action Network (NLAAN)
NMAC
Pozitively Healthy
The AIDS Institute
Woodhull Freedom Foundation
**Florida**
Dab the AIDS Bear Project
Okaloosa AIDS Support & Informational Services, Inc. (OASIS)

[3] This is in line with the policies of manufacturers of other HIV-related medications. See National Alliance of State and Territorial AIDS Directors. Pharmaceutical Company Patient Assistance Programs and Cost-sharing Assistance Programs. Online at: https://www.nastad.org/sites/default/files/HIV-PAPs-CAPs-Resource-Document.pdf.
[4] IBID.

Exhibit B

3

**Georgia**
AIDS Research Consortium of Atlanta
Emory University
Georgia AIDS Coalition
Georgia Equality
HIV Dental Alliance
HOPE CARE FOUNDATION
**Hawaii**
The CHOW Project
**Illinois**
AIDS Foundation of Chicago
HIV Prevention Justice Alliance
Howard Brown Health Center
Recovery 2000, Inc.
TACTS-The Association of Clinical Trial Services
Test Positive Aware Network
The Legal Council for Health Justice
University of Chicago Infectious Disease
**Indiana**
Mohammad Sharief, MD
**Louisiana**
Aspirations
**Massachusetts**
Boston Healthcare for the Homeless Program
Community Research Initiative
David Morris Nutritionist
Fenway Health
Search For A Cure
Treatment Access Expansion Project
**Maryland**
AIDS Action Baltimore
LIGHT Health & Wellness Comprehensive Services, Inc.
PeterCares House
Racial and Ethnic Health Disparities Coalition
The Veterans Health Council of Vietnam Veterans of America
**Misouri**
Hep C Alliance
**Minnesota**
Positive Care Center, Hennepin County Medical Center
**New Jersey**
Buddies of NJ, Inc
New Jersey Association on Correction
Sandra Palleja, MD
**New Mexico**
Albuquerque Pride
H.O.P.E. Alliance
New Mexico Hepatitis C Coalition
Southwest CARE Center
**Nevada**
Amy Keller and Associates Consulting
**New York**
ACRIA
AIDS Treatment Activists Coalition (ATAC)
Albany Damien Center
American Association for the Treatment of Opioid Dependence
AVAC
COPE
Division of Infectious Diseases, New York University School of Medicine
Doctors of the World USA Inc.
End AIDS Now
GHAP
GMHC
Marriage Equality USA
National Queer Asian Pacific Islander Alliance (NQAPIA)
The Center for HIV Law and Policy
The Hepatitis C Mentor and Support Group
Treatment Action Group
Unity Fellowship of Christ Church NYC
VOCAL-NY
**North Carolina**
Division of Infectious Diseases, Department of Pediatrics, Duke University Medical Center
Southern HIV/AIDS Strategy Initiative
Warren-Vance Community Health Center, Inc.
**Ohio**
Association of Nurses in AIDS Care
Cincinnati Exchange Project
Nightsweats & T-cells, Co
**Oregon**
Caring Ambassadors Program
Cascade AIDS Project
Health Education Network
**Pennsylvania**
ACT UP Philadelphia
AIDS Resource Alliance
ALPHA Pittsburgh, Inc.
Prison Health News
Reading Health System
**Puerto Rico**
Pacientes de SIDA pro Política Sana
**Rhode Island**
American Academy of Addiction Psychiatry
The Center for Prisoner Health and Human Rights
The Miriam Hospital Immunology Center
**Tennessee**
National Health Care for the Homeless Council
Vanderbilt Comprehensive Care Center
**Texas**
Gordon Crofoot, MD PA
Migrant Clinicians Network
**Virginia**
American Medical Student Association
HIV Medicine Association
Infectious Diseases Society of America
Pediatric Infectious Diseases Society
Ryan White Medical Providers Coalition
**Washington**
defeatHIV Community Advisory Board
Fred Hutch- defeatHIV CAB
Hepatitis Education Project
Point Defiance Aids Projects
Young Activists Against AIDS
**Wisconsin**
AIDS Resource Center of Wisconsin
Steven Schwimmer, DO, SC
**No State Affiliation**
Engender Rights Centre for Justice (ERCJ)
FAM-CRU, Stellenbosch University
JAPETI
Public Union Against AIDS
Southern AIDS Coalition
Stop Tuberculose Bouaké

DEPARTMENT OF HEALTH & HUMAN SERVICES Health Resources and Services Administration
Healthcare Systems Bureau Rockville, Maryland 20857

Exhibit C

OCT 2 3 2015

Mr. Murray C. Penner
Executive Director
National Alliance of State & Territorial AIDS Directors
444 North Capitol Street, NW, Suite 339
Washington, DC 20001

Dear Mr. Penner:

Thank you for contacting the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA) regarding potential violations of the 340B Program's non-discrimination policy by Turing Pharmaceuticals in its sale of the drug, Daraprim. In your letter, you state that several state AIDS Drug Assistance Programs (ADAPs) have experienced difficulty in acquiring Daraprim since the transfer of ownership of the drug from Impax Specialty Pharmaceuticals to Turing Pharmaceuticals.

Specifically, you raise concerns that Turing is not making Daraprim available at the 340B price to eligible 340B covered entities through Walgreens, but instead requires these covered entities to purchase the drug through a drop-ship mechanism available through ICS Connect (also known as Daraprim Direct). You also state that Georgia removed Daraprim from its ADAP formulary because of its inability to purchase the drug at the 340B price through ICS Connect, because ICS Connect is not an approved State vendor for purposes of 340B pricing.

I understand that on September 15, 2015, your organization met with Turing to discuss Daraprim. At this meeting, Turing indicated that it planned to provide 340B pricing to all eligible covered entities and that it would follow-up to ensure that 340B pricing is available to covered entities through Walgreens. Turing further confirmed with OPA that, after meeting with Walgreens on September 17, 2015, that Daraprim is available for purchase at the 340B price through Walgreens.

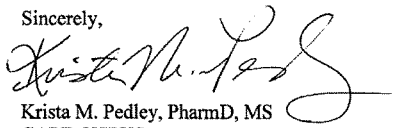
Exhibit C



Please be assured that OPA takes all allegations of potential 340B Program violations seriously and reviews every allegation of non-compliance. If NASTAD becomes aware of other ADAPs that are experiencing difficulty acquiring drugs at the 340B price, please alert our office as soon as possible.

Thank you again for your continued interest and attention to 340B Program compliance.

Sincerely,



Krista M. Pedley, PharmD, MS
CAPT, USPHS
Director, Office of Pharmacy Affairs

Exhibit D

**TURING**
PHARMACEUTICALS

1177 Avenue of the Americas, 39th Floor
New York, NY 10036

November 3, 2015

Ms. Andrea Weddle
Executive Director
Infectious Diseases Society of America
1300 Wilson Blvd
Suite 300
Arlington, VA 22209

Dear Ms. Weddle,

Thank you for sharing the "Open Appeal to Turing Pharmaceuticals" on behalf of 152 organizations recently. Turing appreciates our ongoing communication as we believe it is a critical path forward for outreach to the patient communities that we both serve.

As background, on March 10, 2015, Impax Laboratories, Inc. acquired Tower Holdings, Inc. (including operating subsidiaries CorePharma LLC and Amedra Pharmaceuticals LLC) (collectively, "Impax"). At the time, Amedra Pharmaceuticals LLC owned the rights to Daraprim®. On June 15th, Impax appointed a single specialty distributor for inpatient hospital pharmacies, government customers, and customers eligible for 340B pricing. A single specialty dispense pharmacy was also added to the distribution network to handle all non-340B outpatient prescriptions.

On August 7, 2015, Turing acquired the rights to market and distribute Daraprim® (pyrimethamine) in the United States from Impax. As part of that transaction, Turing was assigned the distribution contracts previously entered into by Impax.

Since acquiring Daraprim three months ago, our top priority has been to ensure that patients who need Daraprim have ready, affordable access to it. As a company, we have learned that there were distribution gaps even before we acquired the drug - gaps that we are working to fill - and by helping us to identify gaps in access, you provide a tremendous service to pharmaceutical companies and to patients across the country.

We hope that this letter addresses your concerns, as well as provides additional evidence to our commitment to ensure ready access to Daraprim for all patients

Most important to us, if there are ever any physicians who you learn are having difficulty accessing Daraprim, please send their information directly to me so that we can immediately get them the medicine they need.

Exhibit D

With respect to the specific issues you raised in your letter:

1. Since acquiring Daraprim, we have been focused on ensuring patients who need Daraprim have ready access to it, while minimizing their out of pocket costs. Turing is proud of our comprehensive patient assistance program that ensures affordable access to patients. As with any drug therapy, it's important to differentiate the wholesale acquisition cost (WAC) with the actual cost to patients. To our knowledge, no patient has paid the WAC for Daraprim.

   The current cost of Daraprim depends upon the specific population being served. For certain patient populations that qualify for charitable coverage, the cost of Daraprim is nothing. For government programs like Medicaid and Public Health Service (PHS)/340 B program, the cost of Daraprim is $0.01 per tablet - or "penny pricing". Nearly two thirds of our current patients receive the medication under these programs. For those patients served by Commercial insurance, Turing's Copay Support Program aids patients' cost-sharing obligations by mitigating their copayments to $10 per prescription.

2. Many safety net hospitals and other clinics participate in the 340B program, pursuant to which they may obtain the product at "penny pricing" as described above. We are currently exploring potential distribution solutions and package sizes to better assist patients in an inpatient setting.

3. As part of the Asset Purchase Agreement with Impax for the rights to Daraprim, Impax Laboratories currently manages the Patient Assistance Program ("PAP"). Impax maintains the business rules for this program and has not disclosed the proprietary rules of the program to Turing. Turing will take ownership of the PAP program on November 11th and has begun examining the process to provide a robust patient assistance program. Upon taking ownership of the PAP program, it is Turing's intent to offer Daraprim free of charge to qualified patients with demonstrated income at or below 500% of the federal poverty level, standard among the HIV community.

   Additionally, Turing's Bridge Program provides patients with product until their benefits investigation is completed. The program also serves patients who have been denied through their Commercial insurance provider while an appeal is being presented on the patients' behalf to the insurer.

4. Turing Pharmaceuticals will provide you with complete information regarding eligibility and documentation requirements for the patient assistance and co-pay assistance programs as quickly as possible. Currently, however, for uninsured patients who meet financial need criteria, Turing provides Daraprim at no out-of-pocket cost under the existing product patient assistance program. More details on the program can be found at www.DaraprimDirect.com. In addition, Turing contributes to Patient Services, Inc. (PSI), a longstanding independent charity that provides

support for financially needy patients' cost-sharing obligations for any toxoplasmosis therapies, consistent with PSI's advisory opinion from the HHS Office of Inspector General.

5. We will ensure that the co-pay assistance program is front-loaded so that coinsurance amounts are fully covered. Additionally, our Bridge Program ensures patients are able to receive the product until their benefits investigation has been completed. The program also serves patients who have been denied through their Commercial insurance provider while an appeal is being presented on the patients' behalf to that insurer.

6. Ensuring patient access to Daraprim is critically important to us. Turing continues to expand distribution relationships to broaden and facilitate patient access that will make it available on a same day basis in the communities where patients live. However, if there is ever a case where a gap in distribution is causing any hardship, patients or physicians can go to www.DaraprimDirect.com or contact me directly.

In conclusion, I want to assure you that we are absolutely committed to strengthening our ongoing relationships with community groups across the country. My colleague, Kevin Bernier, leads a national team of individuals whose primary responsibility is to communicate with community groups so that Turing Pharmaceuticals is hearing from impacted patients in real time. In the coming weeks, Kevin, or a member of his team, will be in touch with the organizations who co-signed this letter so that Turing can build the trusted relationship we all want.

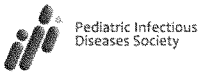
Thank you again Andrea for alerting Turing to the "Open Appeal" and I hope that we can stay in close contact moving forward.

Best regards,

Nancy Retzlaff

Chief Commercial Officer

Exhibit E

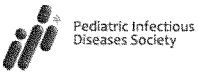


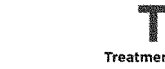
Released: 11/4/2015

A month and a half after Turing Pharmaceuticals' announcement that the company would return the price for pyrimethamine, the toxoplasmosis drug marketed as Daraprim to an affordable level, we met with Turing executives yesterday in the hope of learning when the drug will once again become fully accessible to the patients who need it. We have learned that the company, which raised the price of the drug from $13.50 per tablet to $750 per tablet shortly after acquiring it, has still not arrived at a revised price but plans an announcement before the end of year. We were encouraged that they are in the process of implementing programs to address the serious disruptions in access to treatment that have occurred over the last several months. While complete details of these programs have yet to be made public, we need full transparency on eligibility and information on how to access these programs for providers and patients as soon as possible. Meanwhile, we remain seriously concerned about the exorbitant price hike and its impact on patient care and the health care system.

More than 160 organizations from around the country have now joined with us by endorsing an open appeal calling on Turing Pharmaceuticals to take six actions to improve access to Daraprim.

Exhibit F





November 9, 2015

Martin Shkreli
Chief Executive Officer and Founder
Kevin Bernier
National Director, Alliance Development and Public Affairs
Turing Pharmaceuticals
1177 Avenue of the Americas, 39th Floor
New York, NY 10036

Dear Mr. Shkreli and Mr. Bernier:

Thank you for meeting with us last week in response to the open appeal sent by more than 150 organizations on October 22nd.

The assistance programs that Turing plans to implement to address the documented barriers to accessing Daraprim are urgently needed. We expect fully transparent details of these programs to become publicly available later this week. However, the four-pronged mitigation strategy outlined at the meeting would not be necessary if the exorbitant price and controlled distribution system were not put into place this summer. As discussed during the meeting, access to immediate treatment for a debilitating, potentially fatal condition cannot depend on clinicians and institutions calling a hotline on a case-by-case basis.

The disruptions in treatment and increased costs will continue if the price is not returned to its initial level across health care systems, including hospitals and other inpatient facilities regardless of their size. The significant burden of Turing Pharmaceuticals' exorbitant price increase, particularly for a decades-old drug that has not undergone any research or development to improve its utility for toxoplasmosis, will continue to be born by patients, health care providers, health insurers and taxpayers if corrective actions are not taken beyond the implementation of a complex network of assistance programs.

Sincerely,

Jenny Collier, Convener, Ryan White Medical Providers Coalition
Sean Dickson, Manager, Health Care Access, National Alliance of State and Territorial AIDS Directors
Tim Horn, HIV Project Director, Treatment Action Group
Amanda Jezek, Vice President, Public Policy & Government Relations, Infectious Diseases Society of America
Murray Penner, Executive Director, NASTAD
Christy Phillips, Executive Director, Pediatric Infectious Diseases Society
Andrea Weddle, Executive Director, HIV Medicine Association
David Wohl, MD, Attending as an IDSA/HIVMA Member

Cc: Nancy Retzlaff, Chief Commercial Officer
Tom Evegan, Head of Managed Markets

Exhibit G

**Sean Dickson**

| | |
|---|---|
| **From:** | Murray Penner |
| **Sent:** | Wednesday, November 18, 2015 5:21 PM |
| **To:** | Murray Penner |
| **Cc:** | Sean Dickson |
| **Subject:** | Update: Turing Pharmaceuticals' (Daraprim) Communication with ADAPs |

November 18, 2015

TO: NASTAD Members and ADAP Coordinators

FR: Murray Penner and Sean Dickson

RE: Turing Pharmaceuticals' (Daraprim) Communication with ADAPs

Recently, NASTAD has learned that Turing Pharmaceuticals, the company that increased the price of Daraprim by 5,000%, has been requesting meetings with ADAPs to discuss the product. NASTAD has been attempting to work with Turing to reduce the price of Daraprim and to expand distribution to allow ADAPs to more easily purchase at the 340B price, without effect. If you are having problems accessing Daraprim, please contact Sean Dickson to discuss some of the possible work-arounds to acquire Daraprim.

At this point, NASTAD encourages ADAPs and all 340B covered entities to decline requests to meet with Turing, stating that you would only consider meeting with Turing after Turing has returned the price of Daraprim to its previous price. We understand that a meeting with Turing may allow your ADAP to develop a work-around to access Daraprim, but we encourage ADAPs to first work with NASTAD to develop an access strategy rather than working with Turing. Previous community efforts to rebuff meetings over price increases have had some effect and we hope to continue the pressure on Turing to reduce the price.

Turing has not yet provided NASTAD with any information on how ADAPs should submit rebate invoices or any assurances that Turing will provide full and timely rebates, as required by the 340B program. If you decide to meet with Turing, we encourage you to ask for information on the rebate process and to share that information with NASTAD so that we can disseminate to other ADAPs.

If you have any questions, please contact Sean Dickson.

**Murray C. Penner, Executive Director**
National Alliance of State & Territorial AIDS Directors (NASTAD)

Exhibit H

**Sean Dickson**

**From:** Murray Penner
**Sent:** Tuesday, December 01, 2015 4:40 PM
**To:** Murray Penner
**Cc:** Sean Dickson
**Subject:** Update: Daraprim Rebate Procedures

December 1, 2015

TO: AIDS Directors and Part B Coordinators

FR: Murray Penner and Sean Dickson

RE: Daraprim (Pyrimethamine) Rebate Procedures

Turing Pharmaceuticals, the manufacturer of Daraprim (pyrimethamine), has recently shared procedures for ADAPs to submit rebate invoices for purchases of Daraprim. As many states continue to be unable to access Daraprim at the 340B price, this rebate procedure will allow ADAPs to purchase Daraprim at the list price ($75,000) and submit rebate invoices in order to obtain the 340B price ($1, as publically stated by Turing). ADAPs should also use this rebate process to submit rebate invoices for insured ADAP clients.

ADAPs should submit rebate invoices to:

Tom Evegan
Head Of Managed Markets, Turing Pharmaceuticals
1177 Avenue of the Americas
39th Floor
New York, NY 10036
917-636-0775

NASTAD recognizes that the initial cost of Daraprim continues to present a barrier to access, even with the availability of the above rebate process. If you have any issues accessing Daraprim, or any further questions, please contact Sean Dickson.

**Murray C. Penner, Executive Director**
National Alliance of State & Territorial AIDS Directors (NASTAD)
444 North Capitol Street NW, Suite 339
Washington, DC 20001
Phone: (202) 434.8099 Fax: (202) 434.8092
mpenner@NASTAD.org www.NASTAD.org

Exhibit I

444 North Capitol Street NW | Suite 339 | Washington, DC 20001-1512
Tel. (202) 434.8090 | Fax (202) 434.8092

www.NASTAD.org

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Hawaii

Randy Mayer
Iowa

Dawn Fukuda
Massachusetts

Dan O'Connell
New York

Jacquelyn Clymore
North Carolina

Jan Fox
Oklahoma

Paul Loberti
Rhode Island

Janet Tapp
South Carolina

Shelley Lucas
Texas

Diana Jordan
Virginia

Jim Vergeront
Wisconsin

Ex-Officio
NASTAD Past Chair
Maria Courogen
Washington

Executive Director
Murray C. Penner

December 11, 2015

Senator Susan Collins
Chairman
United States Senate
Special Committee on Aging
G31 Dirksen Senate Office Building
Washington, D.C. 20510-6050

Senator Claire McCaskill
Ranking Member
United States Senate
Special Committee on Aging
G31 Dirksen Senate Office Building
Washington, D.C. 20510-6050

Dear Chairman Collins and Ranking Member McCaskill:

The National Alliance of State and Territorial AIDS Directors (NASTAD), which represents public health officials who administer state and territorial HIV and hepatitis prevention and care programs nationwide, has been actively monitoring the recent price increase for Daraprim (pyrimethamine), an antiparasitic agent used to treat toxoplasmosis in patients with HIV. Following a recent transfer of ownership of Daraprim to Turing Pharmaceuticals, several state AIDS Drug Assistance Programs (ADAPs), which provide medications to people living with HIV, have experienced difficulty in acquiring Daraprim at the 340B Program discounted price to which ADAPs are legally entitled and therefore depriving some patients access to a necessary medicine. NASTAD is concerned that the staggeringly high market price of Daraprim, now 5000% higher than it was prior to the transfer of ownership, prevents ADAPs from being able to purchase the medication. Indeed, in May 2015, 43 ADAPs indicated that they had direct access to Daraprim at the 340B price. According to Turing, only four ADAPs have been able to access Daraprim at the 340B price following the price increase.[1] In addition, the limited distribution model for Daraprim has created access issues for ADAPs.

Similar to Medicaid programs, ADAPs are able to purchase drugs at discounted prices via a rebate mechanism. The astronomical price of Daraprim, however, combined with Turing's obfuscation on the operation of the rebate mechanism, has left ADAPs unwilling to outlay the initial funds to purchase Daraprim in anticipation of an eventual rebate. For patients over 60 kg (132 lbs), federal guidelines recommend three pills of Daraprim per day for initial treatment with the course of treatment lasting six weeks, and then two pills per day for maintenance therapy, lasting at least six months.[2] At $750 per pill, an ADAP would be forced to pay $94,500 for initial treatment and at least $270,000 for maintenance therapy, for a total of $365,500 in upfront costs. While the ADAP would be eligible to receive a rebate, ADAPs may not have sufficient funds on hand to front the cost and then seek rebates to mitigate the high price. Further, with no experience in receiving these rebates from Turing, ADAPs are unwilling to assume the risk that Turing will provide prompt and accurate rebates - even though it is required to do so.

Due to its high price, insurers are subjecting patients in need of Daraprim to prior authorization and other utilization management techniques. Moreover, expensive drugs such as Daraprim are often subject to burdensome cost-sharing and co-insurance requirements that require patients to pay a percentage of the drug's cost, sometimes up to 50% of the cost of the drug. ADAPs are allowed to purchase insurance for many clients and with this exorbitant price are thus subject to both new restrictive access and higher co-

insurance policies, impairing the timely treatment of ADAP clients and substantially raising costs to ADAPs that make the co-insurance payments.

Prior to the recent price increase, insurers had not limited patient access to Daraprim; restrictions now in place result solely from the price increase. The unconscionable price of Daraprim, combined with discriminatory purchasing restrictions that limit ADAPs' ability to purchase at the legally-required price, leave some ADAPs unable to obtain access to necessary drugs for some of its most vulnerable patients.

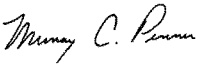
NASTAD believes that Turing's distribution arrangements are in violation of the 340B Drug Discount Program's non-discrimination provisions. NASTAD understands that, for outpatient prescriptions, Turing has a sole distribution agreement with Walgreens Specialty Pharmacy. However, it appears that Turing has not made the 340B price available to eligible 340B covered entities through Walgreens, instead only allowing purchases at the 340B price through a separate, drop-ship mechanism available through ASD Healthcare.

The Health Resources and Services Administration's (HRSA) regulations prohibit manufacturers from "singl[ing] out covered entities from their other customers for restrictive conditions that would undermine the statutory objective" of the 340B program and from "plac[ing] limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." (59 Fed. Reg. 25110 (May 13, 1994)) This prohibition, known as the non-discrimination provision, requires manufacturers to make 340B prices available to covered entities through the same distribution channels available to other purchasers. Without this protection, manufacturers could attempt to limit participation in the 340B program by placing additional barriers in the way of covered entities, ultimately harming patients.

Indeed, Turing's restrictive purchasing program for 340B covered entities has harmed patients. Georgia removed Daraprim from its ADAP formulary because it was unable to purchase Daraprim at the 340B price. Georgia, like many states, is only able to purchase drugs through vendors that have gone through state approval processes and therefore is unable to make drug purchases through ASD Healthcare. Because the 340B price was not available through Walgreens Specialty Pharmacy and thus not available through any of the Georgia ADAP's standard purchasing channels, Georgia was forced to remove Daraprim from the formulary because of its excessive price. ADAP clients in Georgia who need Daraprim must access it through charity care or a patient assistance program, which can lead to delays in care that impact patient health. NASTAD is aware that some ADAPs have been able to establish accounts with ASD Healthcare after receiving special approval from their state purchasing authorities; however, this extra administrative process to receive 340B pricing is precisely the type of discriminatory barrier prohibited in the 340B program.

We appreciate your investigation of this matter. Please contact me if you have questions or need additional information.

Sincerely,



Murray C. Penner
Executive Director, NASTAD

[1] http://www.turingpharma.com/media/press-release?headline=texas-hiv-medication-advisory-committee-unanimously-votes-to-recommend-daraprim%25c2%25ae-be-added-to-its-formulary
[2] https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/322/toxo

Exhibit J

December 22, 2015

Ron Tilles
Interim CEO
Chairman of the Board of Directors
Turing Pharmaceuticals LLC
1177 Avenue of the Americas, 39th Floor
New York, NY 10036

Dear Mr. Tilles:

Following Martin Shkreli's resignation as CEO, the Fair Pricing Coalition (FPC) urges you as interim chief executive and Chairman of the Board of Directors to end Turing Pharmaceuticals' egregious drug pricing practices and to reposition your company as an innovative and conscientious partner in the fight against rare, neglected, and life-threatening diseases.

As a show of good faith, we hope that Turing will promptly reduce its wholesale acquisition cost (WAC) price for Daraprim (pyrimethamine) to no more than $13.50 per 25 mg tablet. This is required to ensure affordability across U.S. payer systems and, importantly, to remedy the considerable provider and patient access challenges that have been documented. While we acknowledge that your company has implemented a patchwork of mitigation programs to minimize prohibitive out-of-pocket expenses, we contend that these would not be necessary if it were not for the exorbitant WAC price for Daraprim.

The FPC and its individual members take pride in establishing mutually beneficial relationships with biotechnology and pharmaceutical companies as partnered stakeholders in the fight against HIV, hepatitis C, and their sequelae. Turing's business practices thus far, notably an implausible and unjustified price increase for a drug that has not undergone any research to improve its formulation or safety, are unparalleled in their intractability and avarice. Our hope is that Mr. Shrkrelli's departure will signal a new beginning for Turing Pharmaceuticals and its relationship with domestic and global communities of providers, advocates, and people living with neglected diseases.

Very truly yours,

Tim Horn
Member, Fair Pricing Coalition

Cc: Nancy Retzlaff, Chief Commercial Officer
Eliseo O. Salinas, MD, MSc, Chief Medical Officer
Julio Casoy, MD, Senior Vice President, Medical Affairs
Kevin Bernier, National Director, Alliance Development and Public Affairs
Lynda Dee and Murray Penner, Co-chairs, Fair Pricing Coalition

Exhibit K

# PAP for Daraprim

Please see the following eligibility criteria for the Daraprim (Turing Pharmaceuticals) patient assistance program (PAP):

1. A valid and on-label prescription is required.
2. Eligibility income level is set at 500% of the Federal Poverty Level (as determined annually by the Department of Health and Human Services), based on the number of people in the household. Patients will be required to submit financial documentation. Total income before deductions is the amount utilized to determine eligibility.
3. There are no asset limitations for the program.
4. Patient must be a legal U.S. resident to be eligible. Patient is not required to be a U.S. citizen. A Social Security Number is not required.
5. Patients who have prescription drug coverage will be denied for the patient assistance program (PAP). This includes Medicaid, Medicare Part D, state-funded assistance programs, government or private subsidies, spend downs and non-formulary coverage.
6. Patients may appeal a denial to the PAP.

To apply for the Daraprim PAP, please visit www.daraprimdirect.com or call 1-800-222-4991.

**ConsumersUnion**

POLICY & ACTION FROM CONSUMER REPORTS

The Honorable Jason Chaffetz
Chairman, House Committee on
Oversight & Government Reform

The Honorable Elijah Cummings
Ranking Member, House Committee on
Oversight & Government Reform

February 4, 2016

Dear Chairman Chaffetz and Ranking Member Cummings:

Consumers Union, the policy and advocacy arm of Consumer Reports[1], appreciates this opportunity to provide our views on rising drug prices, the impact of high drug costs on consumers, and policy ideas to address the burden of drug costs on consumers. We applaud the Committee for addressing this important issue that affects the health and financial security of millions of Americans.

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. In 2004, we launched *Consumer Reports Best Buy Drugs* to help consumers find the best value when purchasing prescription 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.[2] We combine this information with reliable cost information, enabling consumers to truly identify the "best buy" for many drugs.

Spikes in drug prices, as well as prices that are simply too high, have been widely reported in the news and confirmed by Consumer Reports' own, nationally representative survey. Our recent poll found that thirty percent of people who regularly take at least one prescription drug

[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 8 million subscribers to its magazine, website, and other publications. Its policy and advocacy division, 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. This division 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] http://www.consumerreports.org/health/best-buy-drugs/index.htm. Note: We do 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).

experienced unexpected spikes in their out-of-pocket drug costs in the past 12 months—anywhere from just a few dollars to more than $100 per prescription.[3] High and rising drug prices are rightfully a major concern for the nearly 60% of adults who regularly take a prescription drug.[4]

A common reason for high out-of-pocket costs is that some drugs consumers take regularly have been placed in a higher cost-sharing tier by their insurance plan- thus they are personally paying a greater share of the cost.[5] But the underlying price of many drugs paid by health plans, state Medicaid programs, and other payers is also spiking. Researchers suggest factors such as long periods of market "exclusivity," insufficient competition, and materials shortages are contributing to higher prices.

In the short term, immediate relief to consumers can and should be provided by limiting monthly out-of-pocket costs and addressing concerns about discriminatory formulary designs.[6] Another key step is to increase transparency. Pharmacy Benefit Managers (PBMs) should be required to reveal the negotiated cost of medications to employers and Medicare Part D plans should be prohibited from using gag clauses that prevent pharmacists from offering drugs at a lower price, if one exists. Consumers and employers would benefit from published benchmark prices that signal a fair or reasonable price for the drug. To that end, the prices the Veterans Administration and other countries pay for drugs should be published.

These, however, are short-term solutions that do not get at the underlying cost drivers. To truly help consumers, we must address the root cause of high drug prices and take more aggressive steps to combat excess price gouging.

Measures that more directly address the underlying causes of high prices worthy of consideration include:

- Patent Reform -- Patent terms must be reasonable and granted only for real advances to, rather than minor tweaks or reformulations of, existing drugs. Limiting the monopoly period would speed up the entrance of competition that could drive prices down.

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[3] Consumer Reports National Research Center poll of 1,037 adults. *Are you paying more for your Rx meds? A Consumer Reports' poll shows one-third of Americans hit by high drug prices*: August 13, 2015.

[4] 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*

[5] In some instances, this activity is being investigated to see if these changes are in violation of the anti-discriminatory benefit design protections in the Affordable Care Act.

[6] 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.

- Strengthen FDA approval standards -- go beyond merely ensuring that the new drug is better than a placebo, by requiring it to be safer and/or more effective than existing drugs.
- Exclusivity Reform --The FDA should reexamine the criteria for granting periods of exclusivity that allow manufacturers to price drugs according to "what the market will bear".[7] Shortening these exclusivity periods may also lead to more competition which may lower prices.
- Increased Comparative Effectiveness Research -- New, expensive drugs may provide significant consumer benefits, but it is often difficult for payers to know if the benefits outweigh the costs when a cheaper, slightly different alternative is available. Increase funding for comparative effectiveness research, especially targeting expensive new drugs and drugs targeting a large patient population.
- Medicare Negotiation -- Allow Medicare to negotiate prices directly if the prices paid by Part D beneficiaries exceed the weighted average of what other developed countries pay.
- Drug Re-importation -- Study solutions that would legalize re-importation from Canada in a way that is overseen by FDA and ensures consumer safety.

Our own survey, as well as the research of others, shows that when people are unable to afford their medications, they frequently cut corners in ways that could be harmful to their health.[8] They might skip filling a prescription or they might take less of a medication than prescribed, which can lead to poor health outcomes and higher healthcare costs in the long run. The consequences of high drug prices are painful and real, both financially and it terms of the health of Americans, and must be addressed by Congress.

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 attention to this issue of profound importance to our health care system and to consumers.

Respectfully submitted,

Victoria L. Burack

Cc: House Oversight and Government Reform Committee

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[7] "How Pfizer Set the Cost of Its New Drug at $9,850 a Month" By Jonathan D. Rockoff | *The Wall Street Journal* | Dec. 9, 2015

[8] For example, sixteen percent of diabetes patients in Medicare fail to fill at least one prescription a year because of the cost, according to Williams J, Steers WN, Ettner SL, Mangione CM, Duru OK. 2013. "Cost-related Nonadherence by Medication Type among Medicare Part D Beneficiaries with Diabetes". Medical Care. 2013; 51(2):193-198

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