



Large Majority of Prescription Drug Corporation CEOs Will Not Commit to Limiting Price Increases

A Survey of the Top Pharmaceutical Company CEOs Showed Lack of Interest in Lowering Prices

Acknowledgments

This report was written by Justin Mendoza, based on a survey conducted by Rania Kanj and Peter Maybarduk.

About Public Citizen

Public Citizen is a national non-profit organization with more than 400,000 members and supporters. We represent consumer interests through lobbying, litigation, administrative advocacy, research, and public education on a broad range of issues including consumer rights in the marketplace, product safety, financial regulation, worker safety, safe and affordable health care, campaign finance reform and government ethics, fair trade, climate change, and corporate and government accountability.



Public Citizen
1600 20th St. NW
Washington, D.C. 20009
P: 202-588-1000
<http://www.citizen.org>

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Key findings from Public Citizen's survey of pharmaceutical executives

On September 6, 2016, Brent Saunders, the CEO of pharmaceutical manufacturer Allergan PLC, released a blog post committing to restrict annual price increases of their pharmaceutical products to single digits.¹ Novo Nordisk and AbbVie's executives released similar policies.

Public Citizen asked the world's top 29 pharmaceutical companies (by revenue)² if they would take the same pledge as Allergan and commit to limiting any drug price increase to no more than a single-digit percentage annually.³

Table 1: Summary of Key Findings

<i>Corporation</i>	<i>No Response</i>	<i>Pledged</i>	<i>Did not Pledge</i>	<i>Public Statement</i>	<i>Reply Below</i>
<i>AbbVie</i>	X	X		X	
<i>Allergan*</i>		X		X	
<i>Amgen</i>	X				
<i>Astellas Pharma</i>	X				
<i>AstraZeneca</i>			X		X
<i>Bayer</i>	X				
<i>Biogen</i>	X				
<i>Boehringer Ingelheim</i>	X				
<i>Bristol-Myers Squibb</i>	X				
<i>Celgene</i>			X		X
<i>CSL Behring</i>	X				
<i>Daiichi Sankyo</i>	X				
<i>Eli Lilly</i>			X		X
<i>Gilead Sciences</i>	X				
<i>GlaxoSmithKline</i>			X		X
<i>Johnson&Johnson</i>			X		X
<i>Merck</i>	X		X	X	
<i>Merck KGaA</i>			X		X
<i>Mylan</i>	X		X	X	
<i>Novartis</i>			X		X
<i>Novo Nordisk</i>	X	X		X	
<i>Otsuka</i>			X		X
<i>Pfizer</i>	X		X	X	
<i>Roche/Genentech</i>	X				
<i>Sanofi</i>			X	X	X
<i>Shire/Baxalta</i>			X		X
<i>Takeda</i>			X		X
<i>Teva</i>			X		X
<i>Valeant**</i>		X			

¹Saunders, Brent. (Sep. 6, 2016). "Our Social Contract with Patients." *Allergan CEO Blog*. <https://www.allergan.com/news/ceo-blog/september-2016/our-social-contract-with-patients>

² Top 50 Pharmaceutical corporations by revenue, as reported by Pharma Executive: <http://www.pharmexec.com/2016-pharm-exec-50>

³ Public Citizen's outreach is described in full in Appendix .

*Allergan was not contacted; its pledge was the basis of this survey. **Valeant Pharmaceuticals requested a conversation with Public Citizen over the phone to discuss their policies, as reported below.

Our survey and review of public records found that, at the time of this report's release, only three out of the other top 28 companies, or 11 percent, would agree to match Allergan's pledge. Including Allergan in the calculation, 25 out of 29 companies, or 86 percent, would not agree to limit annual price increases to single digits.

Pharmaceutical corporations' price increases are commonplace

Every year, prescription drug corporations increase the prices of many medicines, as a standard practice. In January 2017, median prices for prescription drugs increased 8.9 percent on average. This average increase is roughly four times higher than the overall inflation rate (around two percent⁴) and more than double medical inflation, or total change in medical costs on a per-capita basis, which averaged 3.8 percent for 2016.⁵ *The Wall Street Journal* found that drug corporations increased the wholesale prices for the 30 top-selling drugs by an average of 76 percent from 2010 through 2014 – more than eight times the level of general inflation.⁶

A number of startling industry price hikes for prescription drugs and devices earned deserved notoriety in the past year:

- In the midst of the opioid epidemic, Kaleo raised the price of its Evzio anti-overdose auto-injector from \$575 to \$4,500 per prescription over three years.⁷ While Kaleo's version of the gadget itself is new, the drug it administers – naloxone – is an old and inexpensive chemical that works immediately to reverse the effects of opioid overdoses.⁸
- Mylan raised the price of the EpiPen, a life-saving injection device containing a century-old drug for people with severe allergies, from \$103.50 in 2009 to \$608.61 in 2016 per two-pack carton.⁹
- Turing Pharmaceutical raised the price of Darapim, a 60-plus-year-old treatment for toxoplasmosis, by 5,455 percent in 2015. The company increased the price of the life-saving treatment from \$13.50 to \$750 per pill, bringing the annual price into the

⁴ Rockoff JD & Loftus P, (Feb. 26, 2017). "Facing Criticism, Drug Makers Keep Lid On Price Increases." *The Wall Street Journal*. <http://on.wsj.com/2mKguzh>

⁵ See: Bureau of Labor Statistics. Consumer Price Index - All Urban Consumers: Summary of Data for medical care. Available at: https://data.bls.gov/timeseries/CUUR0000SAM?output_view=pct_12mths

⁶ Walker J, (Oct. 5, 2015). "For Prescription Drug Makers, Price Increases Drive Revenue." *The Wall Street Journal*. <http://on.wsj.com/2n1CSF6>

⁷ Dreyfuss E, (Feb. 15, 2017). "How Does a \$575 Life-Saving Drug Jump to \$4,500? Blame a Perverse System." *Wired*. <https://www.wired.com/2017/02/575-life-saving-drug-jump-4500-blame-perverse-system/>

⁸ *Ibid.*

⁹ Parker-Pope T & Peachman RR, (Aug. 22, 2016). "EpiPen Price Rise Sparks Concern for Allergy Sufferers." *The New York Times*, <http://nyti.ms/2mT2K5t>

hundreds-of-thousands for some patients.¹⁰

High prescription drug prices affect overall health care spending in serious ways. In 2015, U.S. prescription drug spending grew to \$457 billion, and represented 14.2 percent of overall health spending.^{11,12} The Peterson Health Center and Kaiser Family Foundation found that 18 percent of employer-based insurance premium costs in 2013 came from prescription drug spending, excluding inpatient purchases.¹³

Allergan's blog post stated, "we will take price increases no more than once per year and, when we do, they will be limited to single-digit percentage increases."¹⁴ Afterward, pharmaceutical corporations started to debate the merit of these price increase limits.¹⁵

Committing to this Allergan standard still would allow corporations to raise prices every year well ahead of the rate of inflation and medical inflation. It is a modest check on the extent of industry price abuse.

In order to determine whether the pharmaceutical industry would commit to Allergan's modest "self-regulatory" standard against steep price increases in the next year, Public Citizen asked the world's top 28 pharmaceutical companies (by revenue) if they would take the same pledge as Allergan and commit to limiting any drug price increase to no more than a single-digit percentage annually.¹⁶

Survey Results

Thirteen of the 29 drug companies Public Citizen surveyed replied to our query. Our survey, taken together with recent public statements from a few of the surveyed companies, indicate that, of the top companies, only Allergan, AbbVie, Valeant and Novo Nordisk have been willing to commit to keeping price increases in the single-digits for the foreseeable future. In conclusion, only 14 percent of the 29 most profitable pharmaceutical companies would agree to this modest limit on price increases.¹⁷

Specifically:

- Valeant Pharmaceuticals requested a phone call to reply to our query. Over the phone,

¹⁰ Lorenzetti L, (Sep. 21, 2015). "This 62-year-old drug just got 5,000% more expensive." *Fortune* <http://for.tn/2ngmpgB>

¹¹ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (Mar. 2016). *ASPE Issue Brief: Observations on Trends in Prescription Drug Spending*. <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>

¹² Martin AB, Hartman M, Washington B, & Catlin A, (Dec. 2016), "National Health Spending: Faster Growth In 2015 As Coverage Expands And Utilization Increases," *Health Affairs*. DOI: 10.1377/hlthaff.2016.1330

¹³Peterson-Kaiser Health System Tracker: <http://www.healthsystemtracker.org/chart-collection/what-are-the-recent-and-forecasted-trends-in-prescription-drug-spending/?slide=1>

¹⁴Saunders. *Allergan CEO Blog*. Sep 2016.

¹⁵Beasley, Deena. "Pharma company executives debate drug pricing increases." *Reuters Business News*. Jan. 2017: <http://reut.rs/2isk0fk>

¹⁶ See footnote 2

¹⁷ A full summary of responses is available in Appendix II of this report.

Joe Papa, CEO of Valeant since May 2016, described Valeant's new pricing policy following the company's 2015 pricing controversies and congressional inquiry. Valeant's patient access and pricing committee created a policy limiting price increases to single-digits and, further, to remaining within the five-year weighted average of price increases within the branded biopharmaceutical industry.

- Otsuka Holdings responded, “[f]or calendar year 2017, total percentage price increases for each Otsuka America Pharmaceutical, Inc. branded pharmaceutical product marketed in the U.S. will not exceed single-digits.” Although this statement comes in the same spirit as the Allergan pledge, it notably is time-bound to a single year.
- GlaxoSmithKline, Teva Pharmaceuticals, Johnson & Johnson¹⁸ and Takeda cited current and previous practices intended to reflect modest rates of price increases. Teva noted that its current practice “is to limit price increases to single digits in a calendar year.” These companies did not commit to a forward looking pledge, so are counted as a no, despite past records on price increases.
- Nine companies replied to our query expressing either opposition to or a lack of support for the pledge or any similar language. Novartis, Eli Lilly and Sanofi USA cited costs across the U.S. healthcare system as concerns, rather than prescription costs alone. Sanofi, GSK, Teva, Eli Lilly, Celgene and Shire/Baxalta cited the value of therapy, or value-based pricing as a key factor in their pricing practices.
- In all, 15 companies did not respond to any of Public Citizen's three requests for comment. Two of these companies, Novo Nordisk and AbbVie, released public statements to join Allergan's pledge on December 5, 2016 and January 11, 2017, respectively.¹⁹

Publicly Available Corporate Statements

In all, 15 companies did not respond directly to our survey. Where this was the case, we turned to public records to assess the stance of the company.

Merck Inc. released a Pricing Action Transparency Report 2016, with data on their pricing practices from 2010 to 2016. The company stated “our average annual net price increases (after taking sales deductions such as rebates, discounts and returns into account) across our portfolio have been in the low to mid-single digits since 2010.” As with Janssen Pharmaceutical Companies (a subsidiary of Johnson & Johnson) and Eli Lilly & Company's

¹⁸ Johnson & Johnson's pharmaceutical arm, Janssen, also released a “Transparency Report” showing annual price increases below 10% since 2012. Available here: <http://www.janssen.com/us/us-pharmaceutical-transparency-report>

¹⁹ See, e.g.: Nisen, Max. Novo's pricing pledge is a sign of more to come. *Bloomberg Gladfly*. Dec. 2016: <http://bloom.bg/2mTctsq>; Berkrot, Bill. AbbVie vows to keep drug price increases below 10 percent. *Reuters Health News*. Jan. 2017: <http://reut.rs/2nmC374>. Notably, Novo Nordisk's pledge permits price increases of up to 10 percent, which is particularly controversial given the company's role in the rising global prices of insulin.

transparency reports,²⁰ this data shows averages for list prices across their product portfolio.²¹ The company's data does not reflect the range of price increases used to determine the averages reported, or a variety of factors including therapeutic effects, market share of products and patent terms remaining on products with increased prices. Merck's disclosure greatly limits the ability to assess the impact of their price increases.

Biogen, which did not answer our query, has had a history of price increases exceeding the single-digit percentage limit proposed by Allergan. Over the past decade, Biogen has increased the price of their multiple sclerosis drug, Avonex, 21 times, at 16 percent per year.²²

Mylan PLC, did not reply to our survey, but the corporation's CEO, Heather Bresch, commented at the J.P. Morgan healthcare summit in January of 2017 that price increase caps at ten percent were "not the right solution." She noted that even increases at nine percent add more than \$30 billion to the annual prescription drug budget.²³ Pfizer did not answer our query. However, its prior practice includes two price increases annually across its portfolio, each time averaging between seven and nine percent.²⁴ Pfizer's history of price gouging has been noted by regulatory authorities as well. The United Kingdom's Competition and Market Authority fined Pfizer (and Flynn Pharma Ltd) \$160 million in 2016 for raising the price of an anti-epilepsy medicine by 2,600 percent in 2012.²⁵

Sanofi U.S. answered our query and published its statement on its website. Sanofi's response was, "Our objective is to ensure patients have access to our products, balancing clinical value and affordability while making continued investments in innovation. Any focus on accessibility of medicines in the U.S. should involve all relevant stakeholders who contribute to cost and value across the healthcare system – from the time a product is discovered to when it ultimately reaches the patient."²⁶ The reply did not answer the question posed about a single-digit price increase limit.

²⁰ See e.g. Janssen Pharmaceutical Companies of Johnson & Johnson 2016 Transparency Report: <http://www.janssen.com/us/us-pharmaceutical-transparency-report>; Lilly Pad. Finding Solutions for Patients. <https://lillypad.lilly.com/entry.php?e=10395>

²¹ Merck & Co., Inc. "Pricing Action Transparency Report 2016." Available: <http://www.msdrresponsibility.com/wp-content/uploads/2017/01/Report-on-Pricing-Practices-in-the-US-2010-2016.pdf>

²² Walker, Joseph. For prescription drug makers, price increases drive revenue. *Wall Street Journal*. Oct. 2015: <http://on.wsj.com/2mjSWNY>

²³ See Beasley, Deena. "Pharma company executives debate drug pricing increases." *Reuters Business News*. Jan. 2017: <http://reut.rs/2isk0fk>

²⁴ Keown, Alex. Pfizer drug prices rise by 8.8% average. *Pharmalive*. June 2016: <http://www.pharmalive.com/pfizer-quietly-raised-drug-prices-by-an-average-of-8-8-last-week/>

²⁵ Gower, Patrick. (Dec. 7, 2016) Pfizer, Flynn get record fine on 2,600% drug price increase. *Bloomberg Markets*. <http://bloom.bg/2nmEPsV>

²⁶ See Sanofi response to Public Citizen. (Oct 2016). Available: <http://www.news.sanofi.us/SANOFI-RESPONSE-TO-PUBLIC-CITIZEN>

Conclusion: Pharmaceutical Industry Unlikely to Self-Regulate

The Wall Street Journal reported in 2015 that drug price increases are a significant factor in pharmaceutical company revenues.²⁷

Prescription drug corporations continue to raise medicine prices on an annual basis several times the U.S. inflation rate.²⁸ Very few of the leading prescription drug corporations have committed to limiting price spikes. All signs suggest that preventing significant price increases, and the resultant treatment rationing and higher healthcare costs over time, will depend on government action and regulation.

²⁷Walker, Joseph. "For Prescription Drug Makers, Price Increases Drive Revenue." *Wall Street Journal*. Oct. 2015: <http://on.wsj.com/2mjSWNY>

²⁸Rockoff, Jonathan D. and Loftus, Peter. "Facing Criticism, Drug Makers Keep Lid On Price Increases." *Wall Street Journal*. Feb. 2017: <http://on.wsj.com/2mD2TrC>

Appendix: Survey Materials

I. Methods of Outreach

Public Citizen compiled a list of top global pharmaceutical companies, based on 2016 revenues and collected contact information for executives through company home pages. Each company was sent an initial e-mail and hard copy of the letter below, and responses were recorded. Any company that did not respond received two more email probes about matching Allergan's commitment.

Copy of Letter

I write on behalf of Public Citizen in Washington, DC. Public Citizen is a consumer advocacy organization with more than 400,000 members and supporters that works on a range of issues, including clean energy, money in politics and pharmaceutical and medical device safety and efficacy. Our access to medicines division works to expand access to affordable, lifesaving medicines in the United States and in low- and middle-income countries throughout the world.

Allergan recently announced a pledge to limit any price increases for its pharmaceutical products to no more than a single-digit percentage, and no more than once annually. The Allergan pledge, dated September 6, 2016 and titled "Our Social Contract with Patients," can be found at: <http://www.allergan.com/NEWS/CEO-Blog/September-2016/Our-Social-Contract-with-Patients>.

In the release, Allergan CEO Brent Saunders stated that "the health care industry has had a long-standing unwritten social contract with patients, physicians, policy makers and the public at large. [...] Those who have taken aggressive or predatory price increases have violated this social contract".

Will you make the same pledge and commit your company to limiting any drug price increase to no more than a single-digit percentage annually?

II. Annex of Replies

The following companies did not reply to inquiries:

Pfizer	Merck	Roche Holding/Genentech
Gilead	Abbvie	Amgen
Novo Nordisk	Bayer	Bristol-Myers Squibb
Boehringer Ingelheim	Astellas Pharma	Mylan
Biogen	Daiichi Sankyo	

Recorded Responses

Novartis:

Sent: Thursday, October 27, 2016 7:18 AM

Subject: Sent on behalf of J. Jimenez

Dear Mr. Maybarduk,

Please find attached Mr. Jimenez response to the email on your behalf of Public Citizen on October 13th.

Best regards,

Joia Buser



Joseph Jimenez
Chief Executive Officer
Novartis AG
Fabrikstrasse 18
4002 Basel
Switzerland

Telephone +41 61 324 0700

27 October 2016

Dear Mr Maybarduk,

Many thanks for your email dated October 13, 2016, on behalf of Public Citizen.

Novartis shares the concerns about cost of healthcare and the affordability of medicines in light of recent examples of aggressive price increases. We need a new approach to managing these costs. We believe in our mission to discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. Our business model is to create value based on innovation.

As an industry, we must shift to a model that focuses on value and outcomes delivered, both to patients and to healthcare systems. At Novartis, we're pioneering this change. We want prices to better align with four pillars of value that we see our drugs delivering: 1) Clinical value: the medical outcomes these drugs achieve, 2) Patient value, such as quality of life benefits, 3) Health System value, such as avoiding other costs, and 4) Societal value, such as improved productivity of the patient.

However, despite efforts from payers and policymakers today's healthcare system has many inefficiencies that create significant waste. Research suggests that this waste accounts for over 25% of total US healthcare spending. We need to look at the totality of healthcare costs and understand which interventions deliver the most value. We believe a value-based approach to healthcare spending best aligns the interests of all stakeholders and focuses everyone on doing the right thing: making the patient better. It offers more transparency, allowing patients, payers and governments to verify and track the value they obtain, and is cheaper for health systems in the long-term as resources are allocated to interventions that work.

This approach requires partnering with patients, healthcare providers, and payers to create real transformation. Novartis is a leader in developing outcomes-based agreements: we want to be rewarded for the tangible health outcomes our products provide patients. There are a number of examples where we've partnered on such agreements for recently launched innovative medicines.

To fully realize the promise of science and ensure patients benefit, we believe the entire system urgently needs to develop a new understanding of value that is centered on better utilization of medicines and resources to improve outcomes.

Best regards,

A handwritten signature in black ink, appearing to read "Joe Jimenez", is written over a printed name "Joe Jimenez". The signature is stylized and somewhat abstract.

Joe Jimenez

Sanofi:

Sent: Friday, October 28, 2016 1:34 PM

Subject: Sanofi Response to Public Citizen

Peter:

Please see below for Sanofi's response to your letter dated Oct. 13 re: the accessibility and affordability of drugs in the US.

<http://www.news.sanofi.us/SANOFI-RESPONSE-TO-PUBLIC-CITIZEN>

Sanofi Response to Public Citizen

Oct 28, 2016

Sanofi is committed to the development of innovative medicines and vaccines to prevent and treat important medical conditions around the world. Our objective is to ensure patients have access to our products, balancing clinical value and affordability while making continued investments in innovation. Any focus on accessibility of medicines in the US should involve all relevant stakeholders who contribute to cost and value across the healthcare system – from the time a product is discovered to when it ultimately reaches the patient.

Johnson & Johnson:

Sent: Friday, November 18, 2016 1:07 PM

Subject: Johnson & Johnson Response

Please see the attached response to your recent communication. A hard copy will follow in the mail.

Candace Houston
Executive Assistant
Johnson & Johnson
Government Affairs & Policy



WORLDWIDE GOVERNMENT AFFAIRS & POLICY

November 18, 2016

Peter Maybarduk
Access to Medicines Director
Public Citizen
1600 20th St. NW
Washington, D.C. 20009

Dear Mr. Maybarduk,

I wanted to share the following information in response to your recent communication.

As the world's largest and most broadly-based health care company, we acutely understand the challenges around access to medicines. At Johnson & Johnson, our first priority is the well-being of the people we serve, and therefore we have maintained a responsible approach to pricing our medicines. We consider a medicine's value to patients and society, access and affordability, and the need to continue to fund development of new breakthroughs. And we consider external input from physicians, patients, health economists and payers in developing our price.

Pharmaceutical advances have dramatically extended and improved human life over the past few decades. Medicines continue to bring tremendous value to patients and the healthcare system, accounting for over 70 percent of society's recent gains in life expectancy.ⁱ Yet, medicines in the U.S. represent about 14 percent of total healthcare spending and that share is projected to remain stable for at least the next decadeⁱⁱ. While nearly 9 out of 10 prescriptions are for lower-cost generic medicines, we recognize that some medicines are expensive, particularly those that treat challenging conditions.ⁱⁱⁱ

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we partner with payers and healthcare systems to support availability of our products, and we offer a variety of programs and services to assist with access to and appropriate use of new treatment options. For example, to help make sure high out-of-pocket costs don't prevent patients from getting the medicines they need, we offer assistance through our Janssen CarePath program.

We are committed to making our medicines available to patients who need them and to continuing to develop treatments and cures for tomorrow's patients. Achieving these goals will require changes in how our healthcare system covers and pays for healthcare, including medicines. That's why we're working with others in the system to move to a more value-based system that rewards the quality of treatment -- which has potential to improve patient health outcomes, increase access to medicine, and limit costs.

We're very proud of our legacy of delivering healthcare solutions and innovative therapies that make a meaningful difference in improving the lives of patients. We look forward to continued dialogue with all stakeholders to support continued patient access to our medicines.

Should you have further questions, please do not hesitate to reach out to me directly via phone or email at 202-589-1000 or

Thank you.

Sincerely,

Donald Bohn
Vice President, Global Government Affairs

ⁱ Lichtenberg, F. (2012, July). Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009. doi:10.3386/w18235.

ⁱⁱ Altarum Institute, "A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail," August 2015.

ⁱⁱⁱ Generic Pharmaceutical Association. (2016). Generic Drug Savings in the U.S. Seventh Annual Edition: 2015. Retrieved from http://www.gphaonline.org/media/5935694/PDF/GPhA_Savings_Report_2015.pdf.

GlaxoSmithKline:

Sent: Tuesday, October 25, 2016 9:49 AM

Subject: Letter dated 16 Oct 2016

Dear Mr. Maybarduk,

Thank you for contacting GlaxoSmithKline. We appreciate the concerns addressed in your letter dated October 16, 2016; please find our response attached.

Sincerely,

James Millar
Senior Vice President, Managed Markets & Government Affairs
GlaxoSmithKline
5 Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Maybarduk,

Thank you for contacting GlaxoSmithKline. We appreciate the concerns addressed in your letter dated October 16, 2016 and share your belief that medicines should be priced in a way that ensures that the 6.5 billion people around the world have access to the medicines and treatments that are right for them, no matter where they live.

When establishing prices in the US, GSK aims to strike a fair and appropriate balance between reward for innovation and market value while maintaining the broadest patient access possible.

To this end, during early stage drug development, our pricing decision process considers the perspective of payers, physicians, and patients on the value of a therapy. When our new medicines launch, we use a value-based pricing approach that seeks to quantify the clinical, economic and humanistic value of a therapy. These approaches have resulted in our six most recently launched new medicines being priced similarly or less than the competition.

In terms of annualized price increases, net prices are a better reflection of prices in a market based environment. From 2010-2015, our net prices across the portfolio have increased less than 2% (Compound Annual Growth Rate)

We are committed to working in the best interest of both patients and our shareholders; the price of our medicines reflects this in practice.

GSK recognizes that there is frustration around the price of pharmaceuticals in the US. Coming up with solutions will require making real changes, and no single part of the healthcare system or individual company can do it alone. That's why we are actively working with payers, policymakers, physicians, and others on solutions to address concerns about the cost of healthcare. Realizing and maximizing value – for patients, for providers, and for innovative companies – is critical to successfully addressing this important issue for everyone.

Thank you for contacting us.

Sincerely,

James Millar

AstraZeneca:

To: Rania Kanj

Sent on: October 18, 2016

To Public Citizen:

AstraZeneca is committed to patient access and improving patient outcomes, including developing and maintaining access and affordability programs for our medicines. We have one of the longest standing patient assistance programs in the industry, AZ&ME, which provides eligible patients with AstraZeneca medicines at no cost. In 2015, AstraZeneca provided more than \$617 million in savings to nearly 286,000 patients in the US through its patient assistance programs.

AstraZeneca makes decisions on price revisions based on market conditions, a common practice across the industry. When making any pricing decision, we price responsibly and in line with current treatment costs where treatment options exist, taking into account patient out-of-pocket costs and budget impact to payers to ensure our treatments reach the patients who need them. These decisions are designed to help us continue to invest in bringing new medicines to market to address unmet patient needs and continue to improve the lives of patients. In 2015, AstraZeneca invested \$6 billion in research and development.

We know AstraZeneca medicines can improve lives only if they are accessible and affordable for patients, and taken as prescribed. We are mindful of rising healthcare costs and are working to explore innovative solutions within the US Healthcare system to deliver new medicines with continued consideration of cost and value.

Regards,

Ruud Dobber
President US & EVP North America
AstraZeneca US

Teva:

Sent: Friday, October 28, 2016 9:24 AM

Subject: In Response to your Letter to Teva

Dear Mr. Peter Maybarduk,

We are in receipt of your letter and happy to share with you the following.

I'd like to start by sharing with you that last year, Teva was directly responsible for an estimated \$900+ million in direct drug acquisition cost savings to the U.S. healthcare system, inclusive of any price increases, across our entire portfolio (brand and generic) in 2015. We are proud that our unique business model enables us to provide overall savings to patients and payers alike.

While we do not usually comment on forward pricing actions for our brand products, Teva's current practice on our brand portfolio is to limit price increases to single digits in a calendar year. In addition, Teva has robust patient assistance programs for our brand products, which support our pledge to make quality healthcare accessible.

Creating a one-size-fits-all policy for generic medicine pricing is complicated given the dynamics and nature of the generic marketplace. We continue to review pricing across our generic portfolio to achieve the dual goals of bringing our products to market in a timely way and maintaining affordability for the patient and sustainability for the system. The value derived from our broad generic portfolio is represented most profoundly in the estimated \$214 billion in healthcare savings attributable to Teva over the last decade. Robust generic competition is the key to a system that seeks to encourage innovative new treatments and provide access. As the largest producer of generic medicines in the U.S., we welcome the opportunity to work with you and other stakeholders on policy solutions that continue to do both.

In fact, in 2015, the TevaCares Foundation's Patient Assistance programs provided medicines at no cost to approximately 20,000 patients in the U.S. who struggle to afford their medicines. In 2015, we also launched a new U.S. product donation program that provides generic medicine to patients in need at more than 1,000 clinics across the U.S.

We support the effort to work with companies to increase affordable access to medicines to patients in the U.S. If you'd like to speak with us to brainstorm ways to help create meaningful and sustainable policy around drug pricing, please contact Debra Barrett, our Head of Government Affair and Public Policy at [email address redacted]. You can also reach out to me if you have any other questions.

Best regards,

Denise Bradley
SVP Corporate Reputation
Teva Pharmaceutical Industries Ltd.

Eli Lilly:

Sent: Monday, October 31, 2016 10:18 AM

Subject: Response to your Oct. 12 inquiry

Dear Mr. Maybarduk -

Thank you for your letter—your inquiry is timely.

We do not plan to implement a pricing pledge, but we remain deeply committed to helping patients gain access to the Lilly medicines they need.

Dr. Lechleiter has articulated an agenda focused on reducing out-of-pocket costs to patients, elevating value as the preeminent criteria in pricing medicines, and increasing competition among medicines as a means for providing better access. This view was shared in a Forbes column in June, setting up a series for later in the year, “Ways to More Affordable Medicines.”

That series posted last week with additional ideas and perspective for moving us closer to a world in which all patients have access to a wide range of affordable, highly effective medicines. Those ideas have three common denominators:

- They put the needs of patients first, including access and affordability and better health outcomes.
- They reflect the real-world experience of patients, insurers, employers, and drug manufacturers navigating the virtually unfathomable complexities of drug development and of America’s health-care system.
- They focus on removing obstacles to a well-functioning marketplace for medicines rather than adding more obstacles.

Here are the links to the installments:

<http://www.forbes.com/sites/johnlechleiter/2016/10/26/introduction/#2dcd735e3fc4>
<http://www.forbes.com/sites/johnlechleiter/2016/10/26/cutting-out-of-pocket-costs/>
<http://www.forbes.com/sites/johnlechleiter/2016/10/27/elevating-value/>
<http://www.forbes.com/sites/johnlechleiter/2016/10/28/ways-to-more-affordable-medicines-speeding-up-development/>

We are engaged and committed to finding systematic solutions to address this issue.

Thank you for the opportunity to respond.

Best regards,

Barton R. Peterson
Senior Vice President, Corporate Affairs and Communications
Eli Lilly and Company

Takeda:

Sent: Sunday, January 22, 2017 8:26 PM

To: Peter Maybarduk; Rania Kanj

Subject: FW: Will Takeda match Allergan pledge to curb price spikes?

See attached.

Best,

Christophe



Better Health, Brighter Future

October 28, 2016

Mr. Peter Maybarduk
Access to Medicines Director
Public Citizen
1600 20th St. NW
Washington, D.C. 20009

Dear Mr. Maybarduk:

Thank you for your inquiry regarding our approach to pricing our medicines.

Takeda understands the challenges some patients face in affording their medications. We know there is concern focused on specialty medicines. Our price increases for specialty medicines in the U.S. have been limited to the single digits over the last ten years. Even with the significant clinical innovation our latest oncology product delivers coupled with our ongoing investment in its development, we elected to price it in line with our existing oncology product in the U.S., and lower than other newly approved products.

Although we've not made any public announcement on our pricing approach, since the beginning of the year the net price increases for our portfolio in the U.S. have been in the low- to mid-single digits. We plan to continue be thoughtful about our price increases, taking into account patient access and affordability.

We also understand that some patients who need our medicines lack insurance coverage and cannot afford their medications. Earlier this year, we expanded our U.S. patient assistance program, which is available for any of our non-oncology products where a generic version is not already available. We have a separate program for our oncology products which also seeks to ensure those in financial need have access to our products.

Going forward, we will continue to regularly evaluate our pricing, rebating, co-pay support and patient-assistance programs, in support of patients who need our medicines.

We appreciate the opportunity to share our views.

Respectfully,

A handwritten signature in blue ink, appearing to read "Christophe Weber".

Christophe Weber

Chief Executive Officer
Takeda Pharmaceutical Company, Inc.

Takeda Pharmaceutical Company Limited
12-10, Nihonbashi 2-chome, Chuo-ku
Tokyo 103-8668, Japan

Celgene:

Sent: Thursday, November 17, 2016 5:02 PM

Subject: Your Question About Drug Pricing

Dear Mr. Maybarduk:

Thank you for your question.

At Celgene, we are guided by our mission to fundamentally change the course of human health through bold pursuits in science and a promise to always put patients first. We believe that as a contributing member of the healthcare ecosystem, we owe a responsibility to all patients – the patients of today and the patients of the future – to continually invest in the discovery and development of innovative therapies to help treat and potentially cure devastating diseases afflicting our society.

The pricing of innovative medicines is complex and based on many factors. We follow a principled approach to pricing our medicines. This approach is grounded on the benefits and value that our therapies deliver to patients, healthcare systems and society and recognizes that pricing should provide incentives for the continued investment in the discovery and development of innovative medicines. We are committed to working collaboratively with governments, health systems, payers, patient advocates and all other stakeholders to find constructive solutions to health care cost and access issues.

We are transparent in our approach to pricing, and our principles can be found at <https://www.celgene.com/responsibility/patients-communities/principles-for-pricing-of-innovative-medicines/>.

We believe that our principled approach to pricing is the best way to ensure that the virtuous cycle of medical innovation continues and to advance our mission of discovering, developing and delivering transformational therapies to serve patients in need.

Thank you,

Mark J. Alles
Chief Executive Officer
Celgene Corporation

Merck KGaA:

Sent: Thursday, November 17, 2016 3:33 PM

Subject: FW: Will Merck KGaA match Allergan pledge to curb price spikes?

Mr. Peter Maybarduk

Access to Medicines Director

Public Citizen

Dear Mr. Maybarduk,

Thank you for your messages of October 15, 2016 and November 10, 2016 to Stefan Oschmann, Belen Garijo, and Mr. Gary Zieziula. I am responding for the company on their behalf.

At EMD Serono, we believe it is critical to strike a balance between advancing innovation and ensuring access to medicines. We are committed to ensuring that cost is not a barrier to our treatments, particularly as we are engaged in the discovery, research, and development of medicines for patients with difficult-to-treat diseases.

In regard to your request, we will continue to be part of a solutions-oriented and substantive dialogue about our healthcare system and the role of prescription medicines. This requires

consideration of all the factors contributing to the cost of care, and must have as its primary goal ensuring that patients have access to current and future innovations in medical treatment that offer the potential for longer and healthier lives.

Thank you for the opportunity to provide our views. Please direct any future correspondence on this matter to me.

Sincerely,

Michael J. Ruggiero
Vice President
US Government Affairs and Policy
EMD Serono
A business of Merck KGaA, Darmstadt, Germany

Valeant:

Sent: Tuesday, January 17, 2017 4:05 PM

Subject: Request for information

Peter,

Thank you for your email. Please call my office phone (908 541-3420) at your convenience and we can schedule a time to provide additional information on your question and the Valeant Patient access / Pricing committee.

Regards, Joe Papa

Editors note: This was followed up with a phone call, as recorded in the report.

Otsuka Holdings:

Subject: Otsuka America Pharmaceutical, Inc.

October 28, 2016

Peter Maybarduk
Access to Medicines Director
Public Citizen
1600 20th St. NW
Washington, DC 20009

Dear Mr. Maybarduk:

Thank you for your recent email inquiring whether Otsuka America Pharmaceutical, Inc. (OAPI), would commit to limiting any drug price increase to no more than a single-digit percentage annually.

OAPI takes a rational approach to its pricing decisions and considers many factors, including ensuring that patients who need an Otsuka America Pharmaceutical, Inc., product have access to it. We will continue to provide cost relief in the form of both patient assistance product support and co-pay program availability where appropriate.

For calendar year 2017, total percentage price increases for each Otsuka America Pharmaceutical, Inc. branded pharmaceutical product marketed in the US will not exceed single-digits.

Best regards,

Bob Oliver
President and CEO
Otsuka America Pharmaceutical, Inc.

Shire/Baxalta:

Sent: Friday, November 11, 2016 11:17 AM

To: Rania Kanj; Peter Maybarduk

Subject: Request for Shire's Response

Dear Mr. Maybarduk and Ms. Kania – Attached is Shire's response to your inquiry.

Regards,

Gwen
Gwendolyn E. Fisher
Head, U.S. Commercial Communications

Peter Maybarduk, Access to Medicines Director
Public Citizen

1600 20th St. NW
Washington, D.C. 20009
24 October 2016

Dear Mr. Maybarduk,

Thank you for your email.

Shire is committed to responsibly pricing its products to reflect their value and help support patient access while also ensuring we are able to continue to invest in developing innovative therapies for patients living with rare conditions. We believe that a central part of the ongoing industry discussion around pricing should focus on the value medicines bring to patients, caregivers, physicians, society and healthcare systems around the world. Many orphan drugs, such as those developed by Shire, can significantly help improve the lives of thousands of patients with rare diseases, and often provide a treatment option where only palliative care existed before.

An important part of our commitment to delivering innovative treatments to our patients is ensuring understanding around the factors that affect the cost of our products and our approach to pricing. These factors include development risk, patient population size and the return on investment needed to ensure continued innovation.

Every year at Shire we invest significantly- currently \$1 billion per year-- into the research and development of innovative therapies where there is an unmet need, the vast majority of which is focused on rare diseases. This ensures that we continue our work to find solutions for patients living with these rare conditions. We also dedicate extensive resources to patient assistance programs, which provide financial support to qualifying patients to help them access the Shire medicines that their physicians have prescribed.

Shire is dedicated to serving those around the world living with rare diseases and other highly specialized conditions. It is our hope that our sustained investment in world-class science for rare diseases may also help advance broad discoveries in other fields of medicine and for the greater benefit of all patients.

Yours sincerely,

CEO
Incorporated and registered in Jersey No. 99654