



Statement of  
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before the  
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United States Senate

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Chairman Collins, Senator McCaskill, and Members of the Committee, thank you for the opportunity to appear before you today and to address your questions about Valeant. I have had the privilege of serving as Valeant's CEO since 2008. As was recently announced, the Valeant Board of Directors has selected Joseph Papa, formerly the CEO of Perrigo Company plc, as Valeant's next CEO. I will be leaving the company as soon as he takes over, likely within the next few weeks.

During my service as CEO, Valeant has grown quickly and substantially – from a company with 3,000 employees and about \$650 million in revenue, to a leading global pharmaceutical and consumer products company with about 22,000 employees and approximately \$12 billion in revenue. This rapid growth was driven both by our acquisition of numerous highly respected companies, like Bausch+Lomb, Salix Pharmaceuticals, and Dow Pharmaceutical Sciences, and by internal growth that relied upon bringing new products to market more quickly and efficiently than our competitors.

Along the way, we made many decisions of which I am proud, such as launching new drugs, investing in U.S.-based R&D and manufacturing operations, and pioneering new ways to improve patients' access to medicines. But we have also made mistakes, including those that bring me here today. In particular, the company was too aggressive – and I, as its leader, was too aggressive – in pursuing price increases on certain drugs. Let me state plainly that it was a mistake to pursue, and in hindsight I regret pursuing, transactions where a central premise was a planned increase in the prices of the medicines, such as our acquisition of Nitropress and Isuprel from Marathon Pharmaceuticals.

Today, Valeant is a collection of world-class franchises. In the United States, we are a leading dermatology, gastrointestinal, ophthalmology, and consumer healthcare company. Valeant makes and markets approximately 1,800 products, including more than 200 prescription drug products in the United States. Price increases in a small segment of our company have overshadowed our activities in these broader areas, and I recognize that we therefore need to work to regain the confidence of Congress, the public, doctors, and patients.

We understand Congress's and the public's concerns about drug prices, and we have sought to respond. We have created a volume-based price rebate program for Nitropress and Isuprel, the two hospital drugs that prompted the Committee's inquiry. The program provides hospitals with tiered volume rebates up to 30% for the hospitals that are the most frequent users

of the drugs. These rebates have been implemented through two leading hospital group purchasing organizations, making the discounts widely available to hospitals – large and small – across the United States.

For prescription products purchased by consumers at retail pharmacies, we launched a 20-year program with Walgreens that will provide substantial savings for patients. In conjunction with that program, we will provide an average 10% list price 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. This innovative program recognizes that changes in the pharmaceutical sector have significantly altered the distribution of prescription drugs in the United States. With large national pharmacies like Walgreens serving most Americans, we can significantly reduce drug costs to patients by working directly with the pharmacies and avoiding distribution inefficiencies. For example, by selling drugs on consignment, Valeant has reduced the cost of inventory for the pharmacy, and those savings can be passed on to the consumer. Finally, as part of the company's reassessment of its approach to price increases, we limited recent price increases to those specifically addressed in our contracts with the large pharmacy benefit managers.

We have other longstanding programs that provide patient assistance, such as capped copays for commercially insured patients and up to zero copays for patients meeting certain income thresholds. These programs are designed to ensure that out-of-pocket expenses do not prevent eligible patients from receiving the medicines that their doctors have prescribed. Valeant offers patient assistance programs for more than 55 products, and we expect to spend more than \$1 billion on patient assistance in 2016. We are very proud of this ongoing effort to ensure affordable patient access to our prescription drug products.

## **Research and Development**

Like most large pharmaceutical companies, Valeant makes significant investments in research and development. Valeant's U.S. pharmaceutical R&D spending was about 8% of our U.S. branded pharmaceutical revenue last year, and we estimate that total U.S. R&D spending will be about \$400 million in 2016. We have 43 R&D facilities and approximately 1,000 R&D employees worldwide.

Unlike others in the industry, we have taken a different strategic approach to our R&D spending by avoiding open-ended research and focusing instead on R&D results. Our results speak for themselves. Over the past five years, our productivity (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 last three years, the FDA has approved 6 new drug applications and issued 13 device approvals to Valeant. Among these are drugs that Valeant took all the way from the pre-clinical stage to final FDA approval, such as Jublia and Onexton. 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.

Valeant currently has more than 20 active Phase II/III studies spanning ophthalmology, dermatology, and gastroenterology and many more early stage preclinical projects. We expect that these projects will provide new treatments for Crohn's Disease, acne, actinic keratosis, ocular inflammation, psoriasis, glaucoma, atopic dermatitis, and liver cirrhosis, and new options for cataract patients. Additionally, Valeant is developing a new trifocal lens, which would be the first of its kind in the United States and would give surgeons and patients a new option to help treat the growing elderly population worldwide. Our late-stage programs include brodalumab and IDP-118 (treatment of moderate to severe plaque psoriasis), Latanoprost Bimod (topical treatment of glaucoma), and a new state-of-the-art Lasik laser that is more effective and reduces post-operative scarring for patients requiring laser eye treatment. These innovations directly contradict the narrative advanced by those who have sought to minimize our commitment to R&D.

We have also tried to learn from the trends that have invigorated the technology sector by supplementing our internal R&D with acquisitions, licensing agreements, and partnerships with innovative startups and academic research institutions. Some of the most exciting innovations and developments in the healthcare sector are occurring in these settings, rather than in the large, bureaucratic research laboratories of big pharmaceutical companies. The Deloitte Center for Health Solutions recently looked at this trend and concluded that “smaller companies are delivering higher R&D returns” than 12 of the largest research-based life science companies. The smaller companies had both lower costs (25% lower, on average) and higher internal rates of return (340% higher) on their R&D spending. Deloitte’s findings very much track the philosophy that has shaped Valeant’s successful approach to R&D.

By acquiring innovative products developed in these smaller settings, and then investing significantly to bring the new products to market, Valeant has brought new products to market faster and more efficiently. As just one example, Valeant acquired the rights to our antifungal drug Jublia through our purchase of Dow Pharmaceutical Sciences in 2008. At that point, Jublia had a long way to go before it could be approved by FDA and made available to patients. We invested in Jublia through Phase I/II/III clinical trials and then achieved FDA approval in 2014. Jublia is not an anomaly – it was the fourth drug from the Dow acquisition for which Valeant received FDA approval.

We also invest in R&D following our larger acquisitions. For example, after Valeant acquired Bausch+Lomb, the FDA approved the company’s Ultra contact lenses, which use breakthrough technology to make contacts more comfortable. To support the production of the highly popular Ultra lenses, along with other lenses, Valeant expects to invest almost \$500 million and add approximately 630 jobs in Rochester, N.Y., including many highly skilled engineering and manufacturing jobs, over the next five years.

### **Cuprimine, Nitropress, and Isuprel**

The Committee’s investigation has focused on Valeant’s pricing of Cuprimine, Nitropress, and Isuprel – three of our 1,800 products. Each of these drugs was acquired by Valeant through commercial transactions: Cuprimine in 2010 through our purchase of Aton Pharma, Inc. in 2010, and Nitropress and Isuprel were acquired from Marathon Pharmaceuticals in 2015.

Early in my tenure as CEO, Valeant identified the ophthalmology sector as a strategic target for the company. The long-term implementation of this strategy began with our acquisition of Aton and culminated in our acquisition of Bausch+Lomb in 2013. Aton was attractive to Valeant because its glaucoma treatments provided Valeant with entry into the ophthalmology sector.

As part of the Aton transaction, Valeant also acquired Cuprimine and Syprine, two drugs for orphan diseases that are used primarily to treat a genetic disorder called Wilson's Disease. An orphan drug is generally a specialized drug that treats a rare disease. Valeant estimates that Cuprimine is taken, for example, by about 600 to 700 patients in the United States, an exceedingly small patient population even by orphan drug standards. For comparison, the FDA's official orphan drug designation includes drugs treating diseases affecting 200,000 or fewer patients in the United States.

Because these are critical and life-saving therapies for this extremely small patient population, Valeant maintains a robust patient assistance program for both Cuprimine and Syprine. The patient assistance program for Cuprimine and Syprine, called Valeant Coverage Plus, is one of our largest assistance programs. 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 (including \$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 is supported, in part, by a Valeant grant and it independently determines a patient's eligibility, pursuant to its own criteria. Finally, Valeant routinely provides hardship exceptions for patients who do not otherwise meet these criteria, when we are permitted to do so by law.

Nitropress and Isuprel were acquired by Valeant in a very different context and, in retrospect, I believe that our acquisition of these products was a mistake. Valeant was approached about the acquisition of Nitropress and Isuprel (along with some smaller products) from Marathon. It is my understanding that Marathon told us it was looking to divest these products as part of its own strategic restructuring and focus on raising capital to develop its rare disease pipeline.

From the beginning, a key selling point advanced by Marathon was data that it had accumulated showing that Nitropress and Isuprel were mispriced relative to their value to hospitals and the hospital reimbursement rates for the procedures in which these drugs are used. When, during our due diligence, we found that generics for both drugs were likely on the near-term horizon, we elected to implement the significant price increases immediately upon purchasing the drugs.

In retrospect, we relied too heavily on the industry practice of increasing the price of brand name drugs in the months before generic entry. Instead, in my view, we should have abandoned the transaction with Marathon when it became clear that the expected arrival of generic competition made the economics of the deal dependent on significant price increases. Howard Schiller's testimony before the House Oversight and Government Reform Committee in February has extensive additional details regarding the drugs, the pricing consultants' analyses,

and the bundled reimbursement rates paid to hospitals for the procedures in which these drugs are used. I refer the Committee to that testimony for these additional details.

Most hospitals use only very small amounts of Nitropress and Isuprel. Last fall, when it became clear to us that the price increases implemented as part of the Marathon transaction were having a significant and disproportionate impact on some hospitals that are the heaviest users of one or both of these drugs, we sought to implement a volume based rebate program to address these concerns. Over the last few months, we have contracted with two large group purchasing organizations – Premier and MedAssets, organizations that purchase pharmaceuticals on behalf of hospitals – to provide tiered volume-based rebates. Premier represents about 3,600 hospitals and MedAssets represents about 4,500.

There are about 5,600 registered hospitals in the United States, and we believe that these two overlapping GPOs provide access to the volume rebate to nearly all U.S. hospitals. I encourage any hospital that is not able to access these GPOs to contact the company directly. For example, we established a separate agreement with Kaiser Permanente to provide a discount to their 38 hospitals, and we recently agreed to a discount program for the Veterans Affairs Department's Federal Supply Schedule, which serves the VA hospitals and clinics, and other federal medical centers such as the Indian Health Service. Our intent is to ensure that the volume discounts are available to any hospitals that make use of Nitropress or Isuprel.

Our agreements with Premier and MedAssets provide the first tier of the discount to any hospital that purchases 10 or more units of Isuprel or 100 or more units of Nitropress in any calendar quarter. Our information shows that the volume rebate is working. Our sales volume of Nitropress and Isuprel in February, March, and April of this year have been greater than we predicted.

I regret that the narrow focus on Cuprimine, Nitropress, and Isuprel has given Congress and the public a misimpression that our strategic focus revolved around acquiring older, off-patent drugs, which in fact was not the case. The context of the Aton and Marathon acquisitions belies this misimpression.

The Aton acquisition occurred in the midst of Valeant's merger with Biovail, a \$3 billion transaction that doubled the size of the company, far surpassing the scope and corporate significance of the \$318 million acquisition of Aton. Likewise, the Marathon acquisition occurred between our attempted acquisition of Allergan in 2014 for approximately \$50 billion and our acquisition of Salix Pharmaceuticals in March 2015 for \$11 billion (\$16 billion, including debt and equity). Again, these transactions were far more significant for Valeant and its strategic focus than the \$350 million transaction with Marathon.

When considering Valeant's strategic focus and the allocation of our capital and management resources, these larger, more significant transactions were far more representative of our strategy, the Board's and my managerial focus, and the company's overall direction, than either the Aton or Marathon transactions.

Finally, Madam Chairman, I want to address one of my own personal regrets. In the course of addressing the recent criticisms of Valeant, I have come to realize that because many

of my public statements have occurred in the context of talking with shareholders – and those remarks naturally focused on shareholders’ interests – my cumulative public comments have left the misimpression that shareholder interests were my only focus as CEO of Valeant. That is absolutely not the case. It is not fair to the 22,000 Valeant employees who work every day to develop and make available important medicines for patients, nor to the doctors and patients that we serve. I am grateful for this opportunity to seek to correct this misimpression before my tenure as Valeant’s CEO comes to an end in the near future.

Valeant has obligations to many stakeholders, including patients, doctors, shareholders, and others. We have always sought to balance these obligations in an appropriate manner. When we have raised prices, we have done so knowing that there are many ways in which we work to ensure affordable patient access to our drugs. I believe that Valeant employees at every level always took seriously our mission to ensure patients’ access to the drugs that their doctors prescribed for them. And we still do. In the retail context, our patient assistance programs have been a critical means of ensuring patient access. In the hospital setting, where we have far less experience, we worked with expert consultants to assure ourselves that price increases would not impair patient access, in the context of high, CMS-approved reimbursement rates for hospital procedures. I regret that my public focus on shareholders left the seriously inaccurate impression that Valeant did not consider the impact of our decisions on patients. We absolutely did, and we still do.

In that regard, Valeant is intently focused on rethinking our approach to drug pricing going forward. I expect that under my successor, the company will no longer be seeking to acquire mispriced drugs. We expect our pricing actions to track industry norms. As I will be leaving the company soon, decisions regarding our process for setting drug prices will be made by others. But the new process is likely to involve greater formality, and certainly it will reflect the painful lessons we have learned over the last year.

Thank you again for the opportunity to testify today. I would be happy to answer your questions.