

October 14, 2015

The Honorable Claire McCaskill
Permanent Subcommittee on Investigations
Committee on Homeland Security and Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Senator McCaskill:

Thank you for your letter to me of September 23, 2015. I appreciate the opportunity to address your questions concerning Valeant Pharmaceuticals International, Inc. ("Valeant") and recent increases in the list prices of our products Nitropress and Isuprel.

As noted in your letter, our board member and former chief financial officer, Howard Schiller, testified before the Subcommittee in July concerning international tax issues that are the subject of the Subcommittee's formal investigation. As you know, Valeant cooperated fully in that investigation and provided extensive information to the Subcommittee in advance of the hearing. We understand that your questions on the topic of drug pricing, which are unrelated to the Subcommittee's investigation, are posed on your own behalf, in follow up to your discussion with Mr. Schiller about your concerns.

Valeant's Investment in the United States

Valeant is a global specialty pharmaceutical and medical device company, with operations in the United States, Canada, Europe, the Middle East, Latin America, Russia, Africa and Asia Pacific. Our products primarily address dermatology, eye health, gastrointestinal health, and neurology. Valeant employs approximately 20,000 people worldwide, with more than 6,000 employees in the United States. We are investing substantially in the United States, particularly in manufacturing. Valeant has 12 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. As noted in Mr. Schiller's testimony, many of these investments are a direct result of Valeant's acquisitions.

For example, before its acquisition by Valeant, Bausch + Lomb intended to move its manufacturing facilities from Rochester to Ireland, with the associated job loss and adverse economic impact on an already vulnerable Rochester community. Valeant took a different approach. We decided not only to retain our contact lens facility in Rochester but also to expand. Since that decision, in Rochester, we have invested more than \$250 million in capital and expanded our manufacturing work force by 191. To provide additional support for four new product lines for Bausch + Lomb Ultra contact lenses and other contact lens projects, over the

next five years we expect to invest approximately \$484 million more and add approximately 630 jobs in Rochester, including many highly skilled engineering and manufacturing jobs.

Yesterday, our Greenville plant celebrated the production of its four billionth bottle of eye care solutions. 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 largely the result of our growing sales within and outside of the United States. In St. Louis, since acquiring Bausch + Lomb, we have made more than \$3.5 million in capital investments and created 41 jobs. In addition, we expect to develop the next generation of our cataract and retina surgery equipment in St. Louis, at a cost of over \$10 million, which would create an additional 30 jobs. From the United States, we export to more than 100 countries, including to countries like China that are traditionally viewed as lower-cost manufacturing centers. 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 retaining skilled manufacturing jobs in the United States.

As detailed in Mr. Schiller's testimony, a portion of Valeant's growth in recent years has come through strategic acquisitions that are designed to bring innovative drug products to patients and hospitals more quickly and efficiently. Last year, Valeant launched 20 products in the United States, many of which grew out of Valeant's investments in developmental drugs following an acquisition. For example, last year Valeant announced FDA approval of Jublia topical solution, an innovative topical antifungal product that treats a condition that afflicts an estimated 35 million people in the United States. After we acquired Dow Pharmaceutical Sciences in 2008, Valeant decided to invest in Dow's pre-clinical compound, then known as IDP-108, which after years of investment, development, and clinical trials by Valeant, eventually became Jublia.

Nitropress and Isuprel History

Your letter addresses Nitropress and Isuprel, two of the approximately 209 prescription products sold by Valeant in the United States. Broad conclusions about Valeant cannot be drawn from the pricing or history of any one drug or set of drugs. Because your letter addressed Nitropress and Isuprel, this letter focuses on the price and history of those products.

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. Although there are many other drugs that can be used to lower blood pressure, Nitropress is considered the standard of care and is recognized for its unique ability to act quickly. Sodium nitroprusside, the active ingredient in Nitropress, was first introduced during the nineteenth century.

Isuprel is indicated for mild or transient episodes of heart block that do not require shock or pacemaker therapy and for serious episodes of heart block and Adams-Stokes attacks (except when caused by ventricular tachycardia or fibrillation), 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. They typically are not sold to patients at a traditional consumer pharmacy. Moreover, Nitropress and Isuprel are commonly used as part of a larger hospital procedure or protocol. They normally are not administered as stand-alone treatments.

Valeant acquired Nitropress and Isuprel from Marathon Pharmaceuticals in February of this year. Prior to that acquisition, Marathon had engaged an outside consultant to study the market for these two drugs. We understand that the consultant examined the uses of the products, interviewed health care professionals, determined the current pricing of hospital protocols 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 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.

Nitropress and Isuprel Pricing and Hospital Reimbursement

In the U.S. health care system, the list price of a drug is not the same as the amount that a drug manufacturer receives from selling a product. 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 group of hospitals). Following a procedure, the hospital typically will seek reimbursement from the patient's health insurance provider, such as a commercial payer or a federal health 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. Federal programs are likewise subject to a variety of limitations that restrain the price that a pharmaceutical company can charge for a drug.

In the specific case of Nitropress and Isuprel, we understand that the drugs are used by hospitals and other care providers as part of protocols that are subject to their own overall pricing caps. The specific price that a hospital is reimbursed for these procedures will vary depending on the details of the procedure and the payer. Importantly, however, the amount that a hospital is reimbursed for a procedure that includes Nitropress or Isuprel 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 Classifications" for outpatient services and "Diagnosis-Related Group" rates for inpatient treatments. Even then, however, the reimbursement rates may 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 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. In the case of Nitropress and Isuprel, which face near-term competition from generic versions of both drugs, it is far from clear that the increase in the price of the branded versions of those drugs ultimately would increase reimbursement rates for the overall protocols in which they are used.

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

Valeant's increases in the list prices of Nitropress and Isuprel have had limited impact on the average hospital's costs. Since our price increases, the average spend per hospital was about \$281,000 for Isuprel and \$44,000 for Nitropress, compared to the average hospital's overall expenses of approximately \$150 million per year. A few institutions use a disproportionate share of the overall volume. For those institutions where the impact was significantly greater, we are beginning to reach out to hospitals to determine an appropriate pricing strategy. In addition, Nitropress volumes have fallen 24% year-over-year (based on the first nine months of 2015), reflecting the market's response to the increase in price and competition from alternative products.

Valeant Revenues

Your letter inquired about Valeant's revenues that are attributable to the U.S. Department of Veterans Affairs. Valeant's sales under the Veterans Affairs Federal Supply Schedule ("FSS") actually illustrate quite well the challenges of the existing pharmaceutical pricing system. As of September 30, 2015, Valeant's gross sales of Isuprel this year under the FSS were \$10,887,353. Notably, however, those sales were subject to discounts of \$9,882,951, pursuant to the requirements of federal health care programs such as the FSS federal ceiling price. After accounting for the cost of goods sold and distribution costs, Valeant's total net revenue on those sales was only \$317,588. The increase in Valeant's total net revenue on those sales to federal

health care programs under the Public Health System (“PHS”) was \$3.2 million for Nitropress. Our records do not show any sales of Nitropress under the FSS in 2015. Due to PHS’ reimbursement methodology, Valeant received no additional net revenue from the price increase in Isuprel. Any future increase in the FSS will be statutorily limited to increases of no more than the previous year’s FSS price plus Consumer Price Index for All Urban Areas.

Valeant manages a large portfolio of products. Overall, Valeant reported 2015 revenues of \$4,923 million through the second quarter. In the same time period, Valeant reported revenues from Nitropress of \$126 million and revenues from Isuprel of \$121 million. Accordingly, revenues from Nitropress and Isuprel represent a relatively small portion of our overall revenue and profitability.

Nitropress and Isuprel Following Valeant’s Acquisition

During the acquisition of Nitropress and Isuprel from Marathon, Valeant commissioned an update of the 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 pricing procedures. 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 protocols in which Nitropress and Isuprel are used, there was considerable room to increase the price of both drugs without unduly depleting the funds available to the hospitals from payers. In other words, the consultant found that hospitals were receiving from federal payers, and likely commercial payers, payment amounts for the typical protocols in question that were significantly higher than the cost of the drugs used. Because these drugs are hospital-administered, and generally are not purchased by patients directly, increasing the cost of the drugs to hospitals should not reduce patient access. Valeant’s current list price is \$880.88/vial for Nitropress, \$1,472.25/vial for Isuprel in a 1mL package, and \$1,709.11/vial for Isuprel in a 5mL package.

Economic and Social Benefits of Rational Pricing

As discussed above, Valeant implemented these increases in list prices to ensure that the prices reflected the value of the drugs to the hospitals and patients. Beyond those considerations, however, there are economic benefits that extend more widely to our healthcare system when older drugs that are dramatically underpriced relative to their clinical value are priced to reflect their true market value.

Older drugs sometimes languish for long periods at prices that do not reflect their actual clinical value to doctors and patients. There may be many reasons for this, including inefficiencies in the healthcare system and regulatory impediments. In the case of hospital-administered drugs like Nitropress and Isuprel, which typically are not purchased directly by patients, the systematic underpricing of these drugs meant that hospitals recouped a larger (perhaps much larger) share of the fixed reimbursements that they received from government and commercial payers for the procedures in which these drugs are used. When drugs like Nitropress and Isuprel are priced to reflect more closely their true clinical value, the more accurate price signals will tend to incentivize needed competition and innovation.

The prices for both of these important drugs have been rising significantly over the last decade, since before Valeant purchased them. Not surprisingly, this price trajectory, which highlighted for the market the value of both drugs, has stimulated not just one but several other companies to file applications with the FDA to market generic alternatives. One or more generics could be approved within the next 12 to 24 months. These generic products will inevitably be lower priced alternatives, and their imminent arrival in the market will tend, in the near-term, to put downward pressure on the cost of procedures in which Nitropress and Isuprel are currently used.

There is a misperception in the media that Valeant's revenue growth for existing products has been driven primarily by price. The average selling price of products that we owned a year ago was \$280.82 for the third quarter of 2014 and \$316.86 for the third quarter of 2015, representing a 13% increase. But our prescription volume for these products over this same timeframe increased by approximately 20%, showing that volume growth contributes significantly more than price for our U.S. branded pharmaceutical business.

Valeant's Patient Assistance Programs

Although it is not directly relevant to Nitropress and Isuprel, which are hospital administered, it is important to note that Valeant devotes a significant portion of its revenue to patient assistance programs that are designed to make important medicines more affordable to the patients who need them. In 2014, Valeant spent \$544,000,000 on patient assistance programs. As of September 2015, the company has spent \$476,000,000 in 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 Vesneo (latanoprostene bunod), we expect to spend more than \$1 billion on patient assistance in 2016 in the United States alone.

Valeant offers patient assistance programs for more than 55 different products in the United States.¹ 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 insurance, subsidized prescriptions for patients without insurance or with low incomes, 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.

Additional Questions

You asked for specific additional information concerning the manufacturing and sale of Nitropress and Isuprel. Both drugs continue to be manufactured by Hospira, Inc. under contracts that existed at the time they were acquired by Valeant. Valeant has not implemented material changes to Nitropress or Isuprel since the products were acquired from Marathon. As noted above, both products have been on the market and off-patent for many decades.

Valeant's Approach to Research and Development

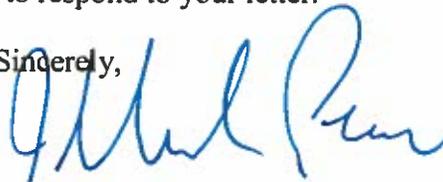
Finally, while your letter focused on just two drugs in Valeant's growing portfolio of hundreds of prescription drug products in the United States, let me address Valeant's overall approach to developing and marketing pharmaceutical products. We have consciously avoided building a large, fixed-cost research infrastructure, which often proves inefficient and is not necessarily indicative of productivity. We believe innovation should not be judged by how much you spend, but by the new products that a company is able to bring to market, and our goal has been to bring multiple, high-quality, innovative products to the market year after year.

We have harnessed the considerable investment capital at our disposal to identify and acquire innovative companies that have developed, or are on their way to developing, valuable pharmaceutical products. In so doing, we help allocate capital to developmental stage products in a more nimble fashion. We recognize that this is not the R&D model that has governed the pharmaceutical industry in past decades. It is, however, a model that is used to great effect in the technology industry, for example, where innovative companies acquire new technologies developed by myriad incubators, and we expect it will be a defining attribute of the industry in the years ahead, alongside traditional in-house research programs.

¹ A complete list is available at <http://www.valeant.com/about/us-assistance-programs/patient-assistance>.

Thank you for the opportunity to respond to your letter.

Sincerely,



J. Michael Pearson
Chairman of the Board and Chief Executive Officer

cc: The Honorable Rob Portman, Chairman, Permanent Subcommittee on Investigations