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MEMORANDUM

February 2, 2016

To: Democratic Members of the Committee

Fr: Democratic Staff

Re: Documents Obtained by Committee from Valeant Pharmaceuticals

As part of its investigation into the skyrocketing prices of certain prescription drugs, the Committee has obtained more than 75,000 pages of documents from Valeant Pharmaceuticals International, Inc. In February 2015, Valeant purchased Isuprel and Nitropress, which treat abnormal heart rhythms, congestive heart failure, and hypertensive episodes, for $350 million, and increased their prices by 525% and 212% overnight. The documents obtained by the Committee include emails to and from Valeant executives, including CEO Michael Pearson, internal and external company projections and analyses on revenues and profits, and various public relations strategy documents.

The documents indicate that Mr. Pearson purchased Isuprel and Nitropress in order to dramatically increase their prices and drive up his company's revenues and profits. Valeant's actions followed nearly identical actions by its predecessor, Marathon Pharmaceuticals, which bought the same two drugs in 2013, and increased the prices by 384% and 486%. Marathon's actions resulted in significant public criticism and congressional attention, including at a hearing before the Senate Subcommittee on Primary Health on November 20, 2014, directly before Valeant purchased the drugs.

The documents obtained by the Committee demonstrate that Valeant identified goals for revenues first, and then set drug prices to reach those goals. Valeant employed this strategy for both Isuprel and Nitropress, generating gross revenues of more than $547 million and profits of approximately $351 million in 2015 alone. In contrast, Valeant's research and development expenses for Isuprel and Nitropress were "nominal."

The documents also demonstrate that Valeant employed a public relations strategy used by other drug companies to distract public attention away from its price increases to focus instead on patient assistance programs, particularly with respect to several Valeant drugs that treat small patient populations. In fact, the documents indicate that Valeant used its patient

assistance programs to justify raising prices and to generate increased revenues by driving patients into closed distribution systems.

Although Valeant officials anticipated that both drugs would eventually face competition from generic manufacturers, the documents obtained by the Committee show that they sought to exploit this temporary monopoly by increasing prices dramatically to extremely high levels very quickly.

Information obtained by the Committee shows that Mr. Pearson utilized this strategy with many more drugs than Isuprel and Nitropress. From 2014 to 2015, Valeant increased the prices of more than 20 additional "U.S. Prescription Products" by more than 200%. Valeant raised the prices of several of these products multiple times from 2014 to 2015, in some cases by as much as 800%.

This memorandum provides excerpts from the documents obtained by the Committee in order to help Members prepare for Thursday's hearing on this topic.

I. PURCHASE OF ISUPREL AND NITROPRESS AND MASSIVE PRICE INCREASES

The documents obtained by the Committee demonstrate that Mr. Pearson purchased Isuprel and Nitropress with the purpose of increasing their prices in order to generate massive revenues for his company. The documents indicate that Valeant believed it could repeatedly increase prices without negative repercussions since these drugs are administered by hospitals, which are less sensitive to price increases than individual consumers. The documents also show that Valeant developed a strategy of raising prices to meet revenue goals that it applied across a wide range of pharmaceutical products.

- On December 3, 2014, Andrew Davis, Valeant's Senior Vice President for Business Development, emailed Laizer Kornwasser, a former Valeant Executive Vice President, and others at Valeant about purchasing Isuprel and Nitropress from Marathon. He wrote: "FYI, potential 'Other' opportunity company is marathon, value is largely derived from 2 hospital products they bought from Hospira which have no IP [intellectual property protections]." Steven Sembler, the General Manager of Neurology, responded: "In looking at the information, we would have to do this for the two products that make up VAST majority of revenue. … This would also have to be a price play (if we determine there is upside to take price) as we don't have a sales team calling on hospitals (ie no direct promotion)."[1]

- On December 29, 2014, an analyst with an outside consulting firm sent an email to Mr. Pearson with a presentation on Isuprel and Nitropress. He wrote: "In a nutshell, most of the products reviewed (Marathon, Covis, and VRX) are not on the radar and have material pricing potential." The attachment stated: "Smaller/older products (e.g. Isuprel and Nitropress) are not reviewed on formulary … Products have been in the system for so long that reviews are practically rubber stamped." It added: "However, some P&T [pharmaceutical and therapeutic] committee members have noticed a spike in older

product pricing (and supply issues). … Select manufacturers have pick [sic] up these types of old products and raised prices dramatically … Manufacturers have used product shortages to drastically increase price post-resolution … P&T committee starting to look into use of drugs that exceed certain pricing threshold (e.g., increase of 2x, price/dose $200, total cost >$20k)."[2]

- A presentation dated January 16, 2015, from an outside consulting firm entitled "Nitropress and Isuprel Pricing Flexibility Review" stated, with respect to Nitropress: "With roughly 1 year of data showing essentially static volume performance after a substantial price increase (350%), MME [Medical Marketing Economics] believes pricing flexibility may still exist for the product up to the perceptual price point of $1,000 per vial." The presentation concluded: "With current WAC [Wholesale Acquisition Cost] pricing at $214 per vial, Nitropress is likely to still have flexibility by multiple orders of magnitude." Regarding Isuprel, the presentation stated: "Similar to Nitropress, one year of market data does not indicate negative consequence, following a substantial price increase (350%). … MME believes the price for one vial of Isuprel may be adjusted to $700."[3]

- On March 24, 2015, after Valeant purchased the drugs, an outside consultant sent an email to Andrew Davis, Valeant's Senior Vice President for Business Development, writing: "Are you ok with the above assumptions? They are leading to high gross margins (more than 99%)." Mr. Davis replied: "Standard costs looks right, and I'm not surprised they are extremely profitable."[4]

- On May 21, 2015, then-Chief Financial Officer Howard Schiller sent an email to Mr. Pearson with the subject "price volume." He wrote: "Last night, one of the investors asked about price vs volume for Q1. Excluding marathon, price represented about 60% of our growth. If you include marathon, price represents about 80%."[5]

- On July 21, 2015, an investment banking advisory firm analyst emailed Laurie Little, the Senior Vice President for Investor Relations, writing: "I've tried to break down Valeant's upcoming quarterly earnings into key drivers." Describing Isuprel and Nitropress, he wrote: "These products have become a meaningful part of EBIDTA [Earnings Before Interest, Taxation, Depreciation, and Amortization] … in 1Q15, Marathon products were top 2 products for Valeant!" He continued: "Recall, Valeant took 500% price increase on Isuprel in Feb 2015 … and yet another 15% price increase in July 2015." Ms. Little forwarded this email to Mr. Pearson the same day, writing: "Heading into earnings.…"[6]

- An undated presentation summarizing Valeant's neurology business unit showed the "Top 10 brands responsible for 63% of revenue." Isuprel, the first drug listed, had a "FY 2015 Plan Revenue" of "$279.30" million and a "Revenue Contribution" of "14.52%." Nitropress, the third drug listed, had a "FY 2015 Plan Revenue" of "$245.52" million and a "Revenue Contribution" of "12.76%." According to the presentation, 2014 revenues for Isuprel and Nitropress were only $54.5 million and $98.7 million. The presentation

explained these dramatic increases in revenues: "Aggressive Pricing through consultant recommendation."[7]

- On July 20, 2015, Mr. Pearson sent an email to a number of Valeant executives asking for "updated neuro, dental, and generics forecasts." The next day, Brian Stolz, a Senior Vice President for Neurology & Other, Dentistry and Generics replied, writing: "Overall, the numbers are down as Xenezine looks like it is at risk. … Here is what we are planning: Take a price increase this week assuming we get agreement. … Take additional price increase on Isuprel and WBXL."[8]

II. PUBLIC RELATIONS STRATEGY TO DISTRACT FROM PRICE INCREASES AND FOCUS ON PATIENT ASSISTANCE PROGRAMS

The documents obtained by the Committee suggest that Valeant focused on developing a public relations strategy to try to divert attention away from its price increases to its patient assistance programs (PAPs), particularly for the drugs it sought to categorize as "Orphan Drugs," which treat small patient populations. The documents also indicate that Valeant believed PAPs could actually generate increased revenues by closing distribution channels and allowing Valeant to continue increasing prices.

- An undated internal Valeant presentation outlined the proposed launch of a new patient assistance program called the "Valeant Coverage Plus Program." The presentation described this program as an "Opportunity to expand patient access and utilization while maximizing value for niche brands." According to the presentation, the program "Involves a combination of alternative/restricted distribution model, advocacy support and patient assistance programs" and includes "planned pricing actions expected to maximize overall returns." It stated: "Utilizing self-funding model with program costs offset through enhanced cash flow generation … Progressive pricing actions to bring in line with comparable Orphan products (6-7X current levels)." It also outlined Valeant's intention to "Expand use of program to other niche assets" and "Acquire additional assets and utilize infrastructure and support mechanisms."

- The presentation also identified "Critical Risks" to the program, including "PR Mitigation." Two "Objectives" to mitigate this risk were to "Privately address concerns from patients, insurance companies or managed care providers to prevent public displays of negative sentiment" and "Minimize media coverage of the pricing increase." The presentation also identified "Payor Risk … At What Price (Per Patient Per Year) Does an Orphan Drug 'Hit Your Radar Screen'?"[9]

- The presentation also contained a "PR Draft Communications Plan: Orphan Drug Rate Increases," dated June 4, 2013, which provided an explanation for the rise of orphan drugs: "This shift has been caused by rising R&D costs and the ability of orphan disease drugs—which often command a substantial premium in the market—to offer pharmaceutical companies a greater return on investment." The plan stated: "While the high cost of orphan drugs has been largely tolerated by the medical community because the overall impact of these pharmaceuticals on health budgets has been relatively small,

there has recently been a renewed focus on the cost of these drugs as the market continues to grow. … The press has also picked up on these trends … Valeant's upcoming price increase on three drugs … has the potential to insert Valeant into the ongoing dialogue about orphan drugs, and therefore needs to be managed carefully.[10]

- An undated internal Valeant analysis outlined the company's "Orphan Drug Model" for three drugs used to treat diseases affecting small patient populations—Syprine, Cuprimine, and Demser. The analysis stated: "Assumptions: Maintain current sales/patients … Take initial 25% price increase to drive patients into the restricted distribution model … High deductible copay requires increased foundation support." The analysis stated: "Assume target price increases of 100% for Demser and Cuprimine ($8,924 & $1,970.4) … Assume target price increases of 500% for Syprine ($9288.90)."[11]

- On September 20, 2013, Valeant executives reviewed a draft response to a customer complaint regarding Syprine. The draft response, prepared for Cheryl Volker, the Senior Manager of Customer Service, stated: "We're sorry that you are upset by the recent price increases for Syprine. We remain keenly focused on providing all patients with the highest quality pharmaceuticals for the treatment of Wilson's disease and are committed to ensuring that everyone who needs our specialty therapies is able to access them." Valeant marketing executive Jeff Strauss commented on the draft, writing: "At the end of the day the story is 'many people were denied access to the Syprine and Cuprimine as they were either under insured or had copay deductibles that were just too high. Valeant undertook an initiative to ensure all patients would have access to these lifesaving medication whereby we provide the drug at minimal or no cost to the patient (no more than $25/30 day supply). These patients are not profitable for Valeant therefore the price increases offset the costs associated with supporting this initiative.'… Kind of hard to paint us as greedy if we have removed financial barriers for patients."[12]

III. INCREASE IN PRICES BEFORE NEW GENERICS ENTERED MARKET

The documents obtained by the Committee show that Valeant believed Isuprel and Nitropress would face generic competition within a few years, which would lead to a sharp decline in Valeant's sales volumes for both drugs, an assessment that Valeant took advantage of in its acquisition and pricing strategies.

- On December 26, 2014, Steven Sembler, Valeant's General Manager of Neurology, sent an email to Andrew Davis, the Senior Vice President for Business Development, and others, writing: "Andrew—please see attached foe [sic] external competitive intelligence report on two Marathon hospital products and potential generic entries. From this research it looks like there could be more than one generic entry in 2016/2017 timeframe. I believe this event would occur sooner than business model assumptions. We should take this potential risk into consideration with our offer."[13]

- A December 26, 2014 outside consultant presentation entitled "Isuprel & Nitropress: Generic Threats in the U.S." stated: "Valeant should assume there will be two (2)

generic sources for ISUPREL and our (4) for NITROPRESS in the U.S. by mid-2017, with more to follow."[14]

- A similar presentation provided by the same outside consultant almost a year later, on November 3, 2015, stated: "Valeant should prepare for several generic nitroprusside [Nitropress] approvals and at least one generic isoproterenol [Isuprel] approval towards the end of 2016 and expect at least four generic players for nitroprusside and two for isoproterenol by year end 2017. With the increased staff and efficiencies finally bearing fruit at the FDA, an approval *could* occur earlier in 2016."[15]

- A December 23, 2014, presentation entitled "Marathon Pharmaceuticals" outlined pricing "assumptions" relating to Valeant's purchase of Isuprel and Nitropress, including: "30% price increase day 1 … 10% price increase year 2+." The presentation also identified assumptions relating to future sales of Isuprel and Nitropress: "10% volume decrease each year … generic entry on Nitropress and Isuprel in 2018 … 80% decline on generic entry … Terminal growth: 0%." The presentation also contained a line graph entitled "Revenues," showing an eventual decline in projected revenues from about $200 million in mid-2017 to $50 million in mid-2018.[16]

- A December 30, 2014, presentation entitled "Marathon Valuation Update" stated: "Changed generic ent[r]y to 2017 (lose 80% of value in that year implying late 2016 or 2017 entry)." The presentation also outlined a "Potential Structured Deal" with Marathon: "Upfront: ~$280M … Milestones: $30M each no generic entry by end of 2016, 2017, 2018 … If they are correct on generics, get more, $370M, if we are correct they get $310M."[17]

ENDNOTES

[1] VRX_OGR_00024136.

[2] VRX_OGR_00031745- VRX_OGR_00031775.

[3] VRX_OGR_00056666- VRX_OGR_00056717.

[4] VRX_OGR_00017413.

[5] VRX_OGR_00077149.

[6] VRX_OGR_00077058.

[7] VRX_OGR_00023906- VRX_OGR_00023932.

[8] VRX_OGR_00077073.

[9] VRX_OGR_00031839- VRX_OGR_0031870.

[10] VRX_OGR_00031871- VRX_OGR_00031880.

[11] VRX_OGR_00023619.

[12] VRX_OGR_00076270- VRX_OGR_00076272.

[13] VRX_OGR_00024128.

[14] VRX_OGR_00001286- VRX_OGR_00001302.

[15] VRX_OGR_00068408- VRX_OGR_00068438.

[16] VRX_OGR_00000331- VRX_OGR_00000337.

[17] VRX_OGR_00001109- VRX_OGR_0001113.