

Congress of the United States
Washington, DC 20515

October 2, 2014

Joseph Renner
Chief Executive Officer
Zydus Pharmaceuticals USA Inc.
73 Route 31 North
Pennington, NJ 08534

Dear Mr. Renner:

We are conducting an investigation into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to life-threatening illnesses. As part of this investigation, we are working with a network of hospitals, group purchasing organizations (GPOs), consumer organizations, and government representatives to determine the factors contributing to these price increases and to identify measures to help reduce costs for patients, healthcare providers, and hospitals across the country.

We are writing to your company to request information about the escalating prices it has been charging for two drugs: Divalproex Sodium ER, which is used to prevent migraines and treat certain types of seizures, and Pravastatin Sodium, which is used to treat high cholesterol. According to data by the Healthcare Supply Chain Association (HSCA), the average price charged for these drugs have increased by as much as 736 percent for Divalproex Sodium and 573 percent for Pravastatin Sodium from October 2013 to April 2014. Over that time period, the average market price went up by as much as \$735 for Divalproex Sodium and \$426 for Pravastatin Sodium.¹

Drug	SKU	Average Market Price October 2013	Average Market Price April 2014	Cost Increase	Average Percentage Increase
Divalproex Sodium ER	bottle of 100, 250mg tablets ER 24H	\$30	\$179	\$150	566%
Divalproex Sodium ER	bottle of 100, 500mg tablets ER 24H	\$43	\$351	\$308	667%
Divalproex Sodium ER	bottle of 300, 500mg tablets ER 24H	\$145	\$880	\$735	570%
Divalproex Sodium ER	bottle of 80, 500mg tablets ER 24H	\$31	\$235	\$204	736%

¹ Healthcare Supply Chain Association, *Survey of Group Purchasing Organizations* (Oct. 2013 to Apr. 2014) (HSCA surveyed the average costs paid by four GPOs from October 2013 to April 2014. One GPO provided percentage increases rather than price increases, so the average reflects additional price data not captured by the average market price increase. One GPO provided price information for January 2013 to April 2014.).

Drug	SKU	Average Market Price, October 2013	Average Market Price, April 2014	Cost Increase	Percentage Increase
Pravastatin Sodium	bottle of 1000, 20mg tablets	\$77	\$368	\$291	447%
Pravastatin Sodium	bottle of 1000, 40mg tablets	\$114	\$540	\$426	528%
Pravastatin Sodium	bottle of 500, 10mg tablets	\$27	\$196	\$169	573%
Pravastatin Sodium	bottle of 500, 80mg tablets	\$59	\$299	\$240	365%
Pravastatin Sodium	bottle of 90, 10mg tablets	\$6	\$34	\$28	420%
Pravastatin Sodium	bottle of 90, 20mg tablets	\$7	\$35	\$28	446%
Pravastatin Sodium	bottle of 90, 40mg tablets	\$9	\$51	\$42	473%
Pravastatin Sodium	bottle of 90, 80mg tablets	\$14	\$52	\$39	334%

This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country “have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate,” and “77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug’s acquisition price.” These price increases have a direct impact on patients’ ability to purchase their needed medications. The NCPA survey found that “pharmacists reported patients declining their medication due to increased co-pays,” and “84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a ‘very significant’ impact on their ability to remain in business to continue serving patients.”²

As strong supporters of access to generic pharmaceuticals, we know from the Congressional Budget Office and the Government Accountability Office that generic drugs provide tremendous cost savings to our health care system and to the federal government.³ Generics now account for 29 percent of pharmaceutical spending and 86 percent of drugs dispensed in the United States.⁴ However, higher generic drug prices increase the costs to American taxpayers.

In order to evaluate the underlying causes of recent increases in the price of your company’s drugs, we request that you provide the following documents and information for the time period covering January 1, 2012, to the present:

² Letter from B. Douglas Hoey, Chief Executive Officer, National Community Pharmacists Association, to Chairman Tom Harkin, Senate Committee on Health, Education, Labor, and Pensions, Ranking Member Lamar Alexander, Senate Committee on Health, Education, Labor, and Pensions, Chairman Fred Upton, House Committee on Energy and Commerce, and Ranking Member Henry Waxman, House Committee on Energy and Commerce (Jan. 8, 2014) (online at <https://www.ncpanet.org/pdf/leg/jan14/letter-generic-spikes.pdf>).

³ Congressional Budget Office, *Competition and the Cost of Medicare’s Prescription Drug Program* (July 2014); Government Accountability Office, *Drug Pricing: Research on Savings from Generic Drug Use* (Jan. 31, 2012) (GAO-12-371R).

⁴ IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare* (Apr. 2014).

Mr. Joseph Renner

Page 3


- (1) total gross revenues from the company's sales of these drugs;
- (2) the dates, quantities, purchasers, and prices paid for all sales of these drugs;
- (3) total expenses relating to the sales of these drugs, as well as the specific amounts for manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;
- (4) sales contracts or purchase agreements for active pharmaceutical ingredients for these drugs, including any agreements relating to exclusivity, if applicable;
- (5) a description and valuation of the specific financial and non-financial factors that contributed to your company's decisions to increase the prices of these drugs;
- (6) any cost estimates, profit projections, or other analyses relating to the company's current and future sales of these drugs;
- (7) price of these drugs in all foreign countries or markets, including price information for the countries paying the highest and lowest price; and
- (8) the identity of company official(s) responsible for setting the prices of these drugs over the above time period.

Please provide the requested documents and information by Thursday, October 23, 2014 to 2471 Rayburn House Office Building, Washington, D.C. 20515. If you have any questions, please contact Una Lee of Ranking Member Cummings' staff at (202) 225-5051 or Sophie Kasimow of Chairman Sanders' staff at (202) 224-5141.

Sincerely,



Representative Elijah E. Cummings
Ranking Member
Committee on Oversight and Government Reform
United States House of Representatives



Senator Bernard Sanders
Chairman
Subcommittee on Primary Health and Aging
Committee on Health, Education, Labor, and
Pensions
United States Senate

cc: The Honorable Darrell E. Issa
Chairman, House Committee on Oversight and Government Reform

The Honorable Tom Harkin
Chairman, Senate Health, Education, Labor, and Pensions Committee

The Honorable Lamar Alexander
Ranking Member, Senate Health, Education, Labor, and Pensions Committee

The Honorable Richard Burr
Ranking Member, Senate Subcommittee on Primary Health and Aging