

Congress of the United States
Washington, DC 20515

October 2, 2014

Brian Lortie
President, U.S. Branded Pharmaceuticals Business Unit
Endo International plc
Endo US Headquarters
1400 Atwater Drive
Malvern, PA 19355

Dear Mr. Lortie:

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 three drugs: Divalproex Sodium ER, Doxycycline Hyclate, and Glycopyrrolate, which are used to prevent migraines and treat certain types of seizures, to treat a variety of infections, and to prevent irregular heartbeats during surgery, respectively. According to data provided by the Healthcare Supply Chain Association (HSCA), the average prices charged for these drugs have increased by as much as 736 percent for Divalproex Sodium ER, 8,281 percent for Doxycycline Hyclate, and 2,728 percent for Glycopyrrolate from October 2013 to April 2014. Over that time period, the average market price went up by as much as \$735 for Divalproex Sodium ER, \$1,829 for Doxycycline Hyclate, and \$1,213 for Glycopyrrolate.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%
Doxycycline Hyclate	bottle of 50, 100mg capsules	\$4	\$191	\$187	5,025%
Doxycycline Hyclate	bottle of 50, 100mg tablets	\$3	\$191	\$187	4,986%
Doxycycline Hyclate	bottle of 50, 50mg capsules	\$3	\$70	\$67	2,191%

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.).

Doxycycline Hyclate	bottle of 500, 100mg capsules	\$27	\$1,849	\$1,822	7,105%
Doxycycline Hyclate	bottle of 500, 100mg tablets	\$20	\$1,849	\$1,829	8,281%
Glycopyrrolate	box of 10 0.2mg/mL, 20mL vials	\$65	\$1,277	\$1,213	2,728%
Glycopyrrolate	box of 25 0.2mg/mL, 1mL vials	\$19	\$225	\$206	1,153%
Glycopyrrolate	box of 25 0.2mg/mL, 2mL vials	\$31	\$402	\$371	1,444%
Glycopyrrolate	box of 25 0.2mg/mL, 5mL vials	\$58	\$865	\$807	1,650%

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 prices 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:

- (1) total gross revenues from the company’s sales of these drugs;

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).

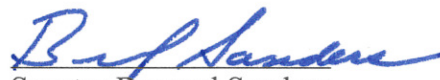
- (2) the dates, quantities, purchasers, and prices paid for all sales of these drugs;
- (3) total expenses relating to the sales of these drugs, as well as the specific amounts for manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;
- (4) sales 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 price 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) prices of these drug in all foreign countries or markets, including price information for the countries paying the highest and lowest prices; 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