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CDR Krista Pedley
Director
Office of Pharmacy Affairs ("OPA")
Health Resources and Services Administration ("HRSA")
Department of Health and Human Services ("HHS")
5600 Fishers Lane, Parklawn Building, Mail Stop 10C-03
Rockville, Maryland 20857

**Letter to HRSA's Office of Pharmacy Affairs
Regarding the Zyprexa® Limited Distribution System**

Dear CDR Krista Pedley:

Eli Lilly and Company ("Lilly") distributes Zyprexa®, a neuroscience product used to treat schizophrenia¹ in the United States. Effective on April 1, 2012, the 340B ceiling price for Zyprexa® will be \$0.01 per capsule pursuant to the 340B Program "penny pricing" policy. We anticipate that we may be unable to meet demand for Zyprexa® because of increased ordering activity anticipated as a consequence of the "penny price".

Therefore, in an effort to ensure that all patients have an equal opportunity to obtain Zyprexa®, we are instituting a limited distribution system for Zyprexa® beginning on the first day of the second quarter of 2012. This system will apply to all orders for Zyprexa® received on, or after, April 1, 2012 and will limit the amount of Zyprexa® any customer (340B and non-340B) may purchase to that customer's historical average ordering volume on a percentage basis applied to the then current quarter's available supply. We anticipate that the limited distribution system will remain in place at least through the end of the second quarter of 2012.

This system will affect all customers, including 340B covered entities, in a fair and consistent fashion. This letter is in follow-up to our previous correspondence, in which Lilly requested guidance from OPA that the limited distribution system described in this

¹ For more product information, including safety information, please see www.Zyprexa.com.

letter complies with the relevant 340B program guidance. Please feel free to share this information with 340B covered entities and other interested parties as you think appropriate. For further information on maximum allotment quantities, entities may contact The Lilly Answers Center at 1-800-LillyRX (1-800-545-5979).

Limited Distribution System

Under Lilly's limited distribution system, Lilly will limit the number of Zyprexa® packages each United States customer may purchase beginning with the second quarter of 2012. An average quarterly purchase volume for each customer will be calculated based on purchases made between October 1, 2010 and September 30, 2011 (the "Measurement Period"). A percentage will be calculated for each customer representing their portion of the overall purchases of Zyprexa® by NDC during the Measurement Period. That percentage will then be applied to the then current quarter's available supply² to determine a customer's maximum allotment.

This percentage-based allocation will provide Lilly the necessary means to adjust customers' maximum allotment in response to changes in product availability, as they may occur, while maintaining equity among all customers. Wholesalers will be instructed to fill all orders for all customers on a first-in, first-out ("FIFO") basis until a customer reaches its determined allotment for the quarter. Neither a customer's 340B participation status, nor the price it pays for Zyprexa® will affect its quarterly allotment of Zyprexa®. Lilly will not require minimum purchase amounts per transaction.

Lilly has calculated the average quarterly Zyprexa® purchasing volume for its customers who purchased the product during the Measurement Period. For customers with no purchases of Zyprexa® during the Measurement Period, Lilly will establish a maximum order quantity based on the overall average quarterly purchase volume of customers in that new purchaser's class of trade. Lilly will advise wholesalers of the purchasing limits and will ask wholesalers to accordingly limit Zyprexa® sales to all of their customers. Wholesalers will be requested to accept orders from customers on a FIFO basis. Lilly notified existing direct customers of the distribution system beginning on March 16, 2012.

In the event that, as of the fifteenth (15) day before the end of any quarter in which the managed distribution system is effective, supply still exists, all customers will be permitted to make purchases, on a first come, first served basis, up to twice their allotment, adjusted for their purchases as of the applicable date of their order. Lilly will continue to monitor its inventory during the period of penny pricing.

Conclusion

Lilly is committed to making our products available through the 340B program at appropriately discounted prices. However, Lilly anticipates being faced with a

² Allocation of supply will be adjusted to package quantities to facilitate ordering and shipping of product.

distribution problem, which threatens the ability of patients to obtain Zyprexa® from their customary health care provider. Without equitable and non-discriminatory restrictions on Zyprexa® purchasing beginning with the second quarter of 2012, 340B covered entities, as well as the Medicaid program, the Department of Veteran Affairs and Federal Supply Schedule entities, could be precluded from being able to purchase Zyprexa®. We are implementing this limited distribution system in order to best ensure that all patients of all providers have equal access to Zyprexa® during the time period in which the 340B penny price policy is in effect.

Lilly appreciates your office's cooperation during this period.

Very truly yours,

Heather Dixon
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Lilly USA, LLC
Eli Lilly and Company