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The Honorable Claire McCaskill
Ranking Member
United States Senate
Committee on Homeland Security and Governmental Affairs
Washington, D.C. 20510-6250

Dear Senator McCaskill:

As you know, this firm represents Teva Pharmaceuticals USA, Inc. ("Teva"). We write in response to your letter dated July 26, 2017, to Dr. Yitzhak Peterburg, Interim President and Chief Executive Officer of Teva Pharmaceutical Industries Ltd. (a corporate affiliate of Teva). We appreciate the opportunity to continue our discussion about Teva's longstanding and aggressive efforts to prevent the diversion of controlled substances, including opioid medications. Teva has already engaged in discussions with your staff about the company's robust anti-diversion measures. Teva is committed to working with public officials like yourself (as well as law enforcement, including the U.S. Drug Enforcement Administration ("DEA") and various State Boards of Pharmacy), wholesalers and distributors of drug products, pharmacies, and physicians to prevent the diversion of opioid products to individuals who seek to obtain or use them for anything other than legitimate medical purposes.

All of the opioid products Teva manufactures and distributes are approved by the U.S. Food and Drug Administration (FDA) as safe and effective for the indications listed on their respective labels. When prescribed, and used appropriately, and dispensed as written, opioid products are an important and medically appropriate tool to help treat pain safely and effectively. Because opioid products are subject to abuse, however, they are listed as controlled substances and subject to stringent regulation by several governmental agencies. These regulations have created a closed system of distribution which imposes obligations on various health care entities, including health care providers, pharmacies, wholesalers, and distributors in addition to manufacturers. This "closed system" is a creation of federal legislation and regulation. One significant benefit of this federal system is the creation of a uniform set of laws and regulations governing the conduct of all participants in the distribution system throughout the country and across individual state borders. State legislation and judicial action that purport to create different standards threaten these important benefits and Teva therefore encourages the Committee to take proactive measures to establish and maintain uniform national standards applicable to the manufacture and distribution of opioid products.

Notably, opioid products are *prescription* drug products. They may not be dispensed lawfully to individuals who do not obtain a valid prescription written by a licensed and registered physician or other health care provider. Health care providers have an obligation to ensure that any prescription they

write must be for a legitimate medical purpose and they must exercise their medical judgment when selecting any course of treatment for their patients. In particular, health care providers are obligated to write opioid prescriptions only for those patients they believe, upon personal examination and evaluation, will benefit from opioid treatment. Inherent in this decision making is the consideration of the risks and benefits associated with a particular opioid product, in relation to the characteristics of a particular patient's condition. Likewise, because opioid products are *prescription* medications, patients may only legally obtain them from a licensed and registered pharmacist. Pharmacists in turn are required to ensure that any opioid prescription they fill is dispensed only to individuals for whom an appropriate prescription has been written and who are not obvious drug seekers. Providers and pharmacists are the only individuals in the closed distribution system that interact first hand with the patients and know to whom they are prescribing and dispensing these products.

Like health care providers and pharmacies, manufacturing companies like Teva and distributors and wholesalers also have specific obligations within the closed system of distribution. In particular, manufacturers and distributors must establish safeguards against theft and diversion of controlled substances while those substances are within their physical control. Both must also develop and implement systems to identify "suspicious orders," and any orders identified as potentially suspicious must be reported to DEA.

To meet its obligations, Teva maintains robust anti-diversion systems and procedures. First, the Company has extensive systems and procedures in place at its manufacturing facilities and distribution centers to prevent theft and diversion while these products are in the Company's physical possession. As discussed in previous communications, these systems are state-of-the art and comply with all applicable regulations. In addition, Teva delivers opioids (and other controlled substances) only to those wholesalers, distributors, hospitals and institutional pharmacies that are appropriately licensed and registered with the DEA.

Second, as previously discussed in prior communications, in addition to taking all appropriate steps to prevent theft and diversion of controlled substances, including opioids, while they are in the Company's physical possession, Teva maintains a robust system for identifying, monitoring, preventing and reporting "suspicious orders" of opioid products, as that term is understood in the industry and described by DEA. This system has several components. To begin, Teva thoroughly investigates any new customer that seeks to purchase opioids from the Company. Any such customer is investigated by Teva before Teva agrees to sell opioid products to that customer. Second, with respect to approved opioid customers, Teva has a sophisticated system and procedure for identifying, reviewing, investigating and reporting "suspicious orders" that includes computer analysis of all orders combined with a manual procedure for investigating all orders identified as potentially "suspicious." No order identified as an "order of interest" is filled until Teva's manual review is completed and the order has been "cleared." If after investigating an identified "order of interest" Teva determines that the order is in fact "suspicious," Teva cancels the order, reports any such order to DEA, and takes appropriate corrective action relative

to the buyer based on the results of Teva's review and investigation, including cutting off any further supply of any controlled substances, including opioid products.

Teva remains fully committed to being a collaborative partner in addressing any opioid misuse and thus we hope that the information provided herein, as well as information provided in our previous discussions, assists you and the Committee in understanding the role of manufacturers and distributors in overseeing opioid shipments and preventing diversion. While we consider our previous discussions and this letter to be a full response to your inquiry, we are happy to clarify any outstanding questions or concerns.

Very truly yours,

James Matthews