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October 5, 2017

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, we represent Teva Pharmaceuticals USA, Inc. ("Teva") (which is a corporate affiliate of Teva Pharmaceutical Industries Ltd.). We write in response to your letter dated September 28, 2017. At the outset, we wish to reiterate to you that Teva recognizes the pressing issue of prescription opioid abuse in the United States, and has long been committed to working with leaders in government, the healthcare community, and the non-profit sector to address this crucial public health concern, and remains committed to doing so. Teva also appreciates that in this same spirit, you are focused on learning more about the dynamics underpinning opioid abuse in the United States in order to seek public policy solutions that will benefit our fellow citizens. We remain prepared to work with you to make progress toward this goal. At the same time, Teva has a responsibility to undertake this cooperation in a way that will protect its most important stakeholders – its patients – as well as its employees, including those many who reside in your home state of Missouri.

Your letter is the latest in several communications between you or your staff and Teva on the topic of your effort to "understand the role of manufacturers and distributors in overseeing opioid shipments and preventing diversion." As you know from our previous discussions, Teva has a demonstrated track-record of establishing and implementing state-of-the-art systems for preventing diversion of opioid products. Teva has a strong track-record of being a collaborative and solutions-focused partner in working with federal, state and municipal officials in our common effort to address prescription drug abuse. We welcome the opportunity to continue our dialogue with you and any other public official seeking to address and resolve these difficult and pressing issues.

Beginning in late Spring of 2017, Teva has engaged in numerous communications with your staff about the issues addressed in your letter. These communications culminated in a 90-minute discussion with your staff on July 24, 2017. During that discussion, Teva described in detail the multifaceted systems Teva has developed and implemented for identifying potentially "suspicious" opioid orders. This discussion went into depth about channels of distribution and practices and methods for identifying, investigating and reporting potentially suspicious orders.

In addition, Teva described how it uses "chargeback" information to obtain information about sales made by its customers' customers and explained how this information is limited in its usefulness from the position of an isolated company. As Teva explained, because of these practical limitations, Teva invested in state-of-the-art analytic database solutions for tracking not only the sales it makes directly to its own customers, but also sales made by the customers of Teva's customers. We discussed in detail efforts made by Teva to require its customers to buy-in to these efforts to ensure that all parties had even more information about how opioid products in the chain of distribution are being dispensed at the pharmacy level. Finally, Teva described in detail the questions each of its affiliates uses with new customers and any existing customer that seeks to increase its purchases of opioid products together with the types of remedies imposed because of any such orders. We were told by your staff that the information Teva shared with them during our July 24 conversation was extremely helpful.

After receipt of your July 26, 2017 letter, we supplemented our earlier oral discussions with a written response referring to those discussions. We believe that between our written and oral communications to date, we have provided the Committee with the information that is most critical to assisting it to "understand the role of manufacturers and distributors in overseeing opioid shipments and preventing diversion." We hope and expect that the information we provided in these lengthy communications has assisted the Committee in these efforts.

Given the extensive communications between your staff and Teva representatives about these issues, we were dismayed by your recent disappointment with Teva's responses to your July 26, 2017 letter. In that letter, you requested five categories of information: (1) a detailed description of Teva's anti-diversion efforts, including the systems it has developed and implemented to identify and report orders that it determines may be "suspicious;" (2) copies of questionnaires provided to customers; (3) copies of correspondence between Teva and its customers relating to anti-diversion efforts; (4) the identification of any orders for opioid products originating from a customer located within Missouri for the period 2012-present together with the identity of the customer making the order and detailed information about the order; and (5) the identification of any instance in which Teva has conducted an "audit" of any customer whom Teva determined may have submitted a suspicious order for opioid products. We believe that our lengthy discussions with your staff fully and fairly covered virtually all of these topics at an appropriate level of detail.

While Teva has been willing to discuss at a general level the information responsive to your third, fourth and fifth requests, Teva has declined to produce the documents specifically requested. Each of these document requests seeks specific information about certain of Teva's customers or communications between Teva and its customers. We have declined to provide copies of these documents for several reasons. First, we do not believe that these specific documents will advance your stated goal: "to understand the role of manufacturers and distributors in overseeing opioid shipments and preventing diversion." Indeed, it seems likely that publicly disclosing specific and sensitive proprietary information about Teva's customers will chill the willingness of such customers

to share information with your Committee and participate in our collective efforts to address opioid abuse.

Second, and more importantly, much of this information, including specifically the reports of suspicious orders Teva has made to the United States Drug Enforcement Administration (DEA), is available to you as it is in the possession of the DEA. Teva believes DEA is in the best position to make decisions about the appropriateness of disclosing such sensitive information publicly, in accordance with its policies on protecting confidential and proprietary information collected in the course of carrying out its official duties. As we have discussed before, unlike Teva and other individual manufacturers, wholesalers and distributors, DEA has broad insight into the opioid sales made by all industry participants, not just those made by a single business, such as Teva. As a result, DEA has the ability to analyze all of the sales made by all participants in each individual market to determine whether it appears that a particular market may be "over served" and thus subject to diversion. In addition, DEA has a record of all "suspicious orders" reported by all industry participants for each particular market. As a result of its access to this information, we believe DEA is in the best position to determine whether ad hoc disclosure of suspicious orders identified by individual industry participants would be likely to lead to successfully identifying and addressing opioid diversion, or whether such disclosure might frustrate important regulatory objectives.

Third, Teva believes the records you have requested could, if publicly released, be potentially misused in pending litigation. As you are aware, many states and municipalities in the United States have responded to the opioid addiction issues by, among other steps, initiating litigation against pharmaceutical manufacturers. These suits are often brought by private plaintiffs' counsel on a contingency fee basis in which the attorneys themselves seek to recognize personal financial gain by bringing suits on behalf of state and local governments. Teva has publicly stated its position that these suits are without merit. More importantly, Teva has also stated its belief that these suits stand as an obstacle to constructive dialogue and collaborative efforts aimed at addressing opioid addiction, wasting time and money on litigation that could be better spent working together to find effective solutions. Nonetheless, these suits continue to be filed, creating risk for Teva's patients, employees and shareholders. In such an environment, Teva has a responsibility to be judicious in determining what documents and information to release publicly.

Simply put, Teva believes that to understand how manufacturers, wholesalers, and distributors can best develop and implement systems to prevent diversion of opioid products, the Committee needs information about how these products are distributed, how they can be tracked, what steps have been taken that have worked, and what new steps can be taken that might enhance existing anti-diversion programs and regulation. Teva has already provided this type of detailed information to you in response to your July 26, 2017 letter. We reaffirm our commitment to meet with you and discuss these issues in a collaborative effort to identify additional issues and potential solutions.

Thank you for the opportunity to assist you with this worthy undertaking. Please let us know if there are other ways we can be of further assistance to the Committee.

Very truly yours,

James W. Matthews

JWM:dc

cc: The Honorable Ron Johnson