Congress of the United States

Washington, DC 20515

October 7, 2024

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

Dear Commissioner:

As the Food and Drug Administration (FDA) approaches the end of the stabilization period for implementation of the Drug Supply Chain Security Act (DSCSA), we write to you today to ensure that the Agency is prepared to take additional action to minimize the potential for disruptions to drug supply and patient care.

In 2013, Congress mandated that all U.S. manufacturers, distributors, and dispensers meet the DSCSA's final enhanced drug distribution security requirements no later than November 27, 2023. This includes electronically capturing and sharing interoperable data in a secure manner at the individual package level. Given the complexities of implementing the DSCSA's requirements, the FDA issued guidance last August allowing for a "stabilization period" until November 27, 2024, for trading partners to further implement, troubleshoot and mature their systems and processes. The stabilization period has enabled trading partners to establish necessary technical connections for serialized data exchange, increase the volume of data being exchanged, improve the quality of data exchanged, and refine processes for managing data exceptions. We appreciate the FDA's commitment to ensuring the healthcare supply chain has the time needed to incorporate these changes.

It is our understanding that there are remaining challenges for some pharmaceutical supply chain participants to meet DSCSA's full implementation requirements by the November 27, 2024, deadline. At the FDA-PDG Joint Public Meeting: DSCSA Stabilization Period Midway Checkpoint, held in June, stakeholders shared that while tremendous progress has been made during the stabilization period, there are critical gaps particularly regarding data quality and accuracy. Although incremental progress has been made since June, significant challenges remain that will invariably create supply chain constraints and delays impacting product from continuing to move through the supply chain.

Absent government intervention, there will likely be disruptions that could lead to drug shortages and patients being unable to access critical medications. We were encouraged to see the FDA's recent announcement of exemptions from certain DSCSA requirements for many small dispensers and applicable trading partners until November 27, 2026. However, given the varying degrees of readiness among trading partners across the supply chain, we believe that the FDA needs to take additional steps beyond that exemption to prevent shortages or access constraints.

Based on the FDA's recommendation that a trading partner submit a request for a waiver or exemption if the trading partner does not believe it will be in full compliance by November 27, 2024, we understand that FDA has already received a large volume of Waivers, Exceptions, and Exemptions (WEE) requests.

We ask that the FDA work expeditiously to evaluate and respond to waiver or exemption requests on a case-by-case basis to ensure continuity across the supply chain. We also ask that FDA evaluate whether the volume and nature of WEE requests justifies that FDA on its own establish exemption(s) for specific products or transactions from certain requirements to provide trading partners more time to stabilize data exchange.

If the Agency reaches such a conclusion, we urge the Agency to consider a phased implementation consistent with the stepwise approach advocated by numerous groups representing pharmacies and pharmacists. Such an approach could be effectuated through various mechanisms available to FDA, but the premise of the approach could narrowly permit manufacturer-level trading partners to comply with the November 27, 2024, date, then wholesalers complying six to eight months later, and pharmacies complying by February 27, 2026. This approach has been broadly endorsed and advocated throughout the industry, as evidenced by prior written proposals from numerous trade associations and repeated stakeholder comments at the recent FDA-PDG Joint Public Meeting.

Please reply to this letter by October 25 with a status update to Congress including the following:

1) How many NDCs have been included in the WEE applications to date?
2) What is the timeline for reviewing and considering the WEE applications?
3) By the date of this letter, how many WEEs has FDA received? How many has FDA approved? How many have they rejected?
4) What communication strategies has FDA engaged in with industry to minimize supply chain disruption in November and support the implementation needs of trading partners? What communication strategies does FDA plan to initiate past the November compliance date?
5) How does FDA intend to enforce DSCSA post-November 27 and how are they instructing state regulatory agencies?
6) Does FDA intend to communicate each specific requested WEE; its scope and duration, and subsequent FDA determination to ensure supply chain partners are prepared and in compliance?
7) Is there a WEE submission threshold that would prompt the agency to issue an FDA-initiated WEE exemption for the supply chain industry?
8) How will FDA communicate and respond to any unintended supply chain disruptions as a result of DSCSA implementation?

Ensuring that patients across the country have continual access to their medications is the upmost priority. We ask that the FDA move quickly to address these concerns to avoid potentially significant disruptions to patient care.

Sincerely,

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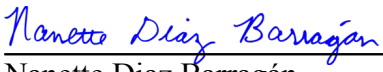

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