Congress of the United States

Washington, DC 20515

August 1, 2023

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

We write to you today to ensure that the Food and Drug Administration (FDA) is prepared to take action to minimize the potential for disruptions to supply and patient care as FDA approaches the final implementation of the Drug Supply Chain Security Act (DSCSA).

In 2013, Congress mandated that all U.S. manufacturers, distributors, and dispensers meet the DSCSA's final requirements no later than November 27, 2023. By that date, manufacturers, distributors, and dispensers must begin electronically capturing and sharing interoperable data at the individual package level. Currently, prescription drugs can only be traced at the lot level. This law has been phased in over the course of the last 10 years and ultimately will allow tracking of a product's chain of ownership at the unit level from the manufacturer to the pharmacy.

The FDA's efforts to protect patients have been enhanced by the systems and processes implemented across the supply chain over the past decade. Further efforts required by the DSCSA will ultimately improve the ability to trace pharmaceutical products and remove potentially dangerous products from the pharmaceutical supply chain.

However, it is our understanding that some supply chain participants are facing difficulties meeting DSCSA's full implementation requirements.[1,2] Based on what we are hearing from healthcare supply chain stakeholders about readiness for the November 27th deadline, absent government intervention, there will likely be disruptions that could lead to patient access problems and further drug shortages. As you are aware, Congress is examining the issue of drug shortages and we are concerned about how these interruptions will affect our constituents, many of whom are already experiencing the consequences of various drug shortages. It is likely that FDA will need to take action to avert significant disruptions in patient care and access to medications.

Effective November 27, 2023, products that are not DSCSA compliant cannot be sold, distributed, nor can they be dispensed to patients. Those non-compliant products will include legitimate prescription drugs whose products do not have corresponding serialized electronic data records.

---

[1] https://www.nacds.org/news/pharmacy-and-pharmacist-groups-urge-fda-to-adopt-phased-approach-to-implementation-of-enhanced-drug-distribution-security-requirements-of-drug-supply-chain-security-act-in-order-to-prevent-interruptio/

[2] https://www.hda.org/getmedia/c1deccbd-3dfd-4765-bbe6-126deaccafaa/HDACommentsonFDAMeetingFollowUp262023.pdf

We are committed to helping FDA ensure that the lack of readiness by some in the supply chain as well as failures in data exchange do not pose serious risks to patients. Please respond to the following questions by September 15, 2023, and inform us of the steps FDA is taking to address the issue of potential disruptions to patients as a result of DSCSA noncompliance.

1. How is FDA assessing the readiness of trading partners to meet the enhanced distribution requirements under the DSCSA by November 27, 2023? How is FDA currently utilizing its internal data provided for under FDCA to assess this readiness?
2. DSCSA noncompliance could cause more drug shortages and interruptions to patient care. If trading partners are not ready to comply, how will that affect the pharmaceutical supply chain? What actions is the FDA taking to prevent these concerns? What support does the FDA need to address these concerns?
3. There are reports that some trading partners are not connected yet with other trading partners to enable electronic, interoperable data exchange.[3] It is our understanding that testing technology and interoperability can take months. If some trading partners are not compliant with the November 27th deadline, will FDA consider a phased-in approach to implementation to provide flexibility while allowing product to still move through the supply chain, as has been done previously with DSCSA implementation?
4. The Department of Defense (DoD) also gets their medications from pharmaceutical manufacturers and distributors. If DSCSA is not implemented properly, it could cause a shortage of battlefield medications, putting our national security at risk. What is the FDA doing to ensure that the DoD gets its medication in a timely manner if there are implementation challenges with DSCSA?
5. Although Congress intended for this law to be fully implemented this year, if the supply chain is unable to fully implement the DSCSA by November 27, will FDA issue guidance within the next 30 days on enforcement policies for certain DSCSA requirements?

Given the timing of implementation, we urge the FDA to move quickly to address these questions and concerns to avoid potentially significant disruptions to patient access.

Sincerely,

Troy Balderson
Member of Congress

Ann McLane Kuster
Member of Congress

[3] https://www.hda.org/newsroom/2023/hda-survey-results-indicate-more-preparation-necessary-for-connecting-epcis-enabled-systems-before-d/

Mariannette Miller-Meeks, M.D.
Member of Congress

Earl L. "Buddy" Carter
Member of Congress

Angie Craig
Member of Congress

Dan Crenshaw
Member of Congress

Donald G. Davis
Member of Congress

Lori Trahan
Member of Congress

Brian Fitzpatrick
Member of Congress

Carol D. Miller
Member of Congress

Mike Carey
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Doug Lamborn
Member of Congress

Patrick Ryan
Member of Congress

Bill Johnson
Member of Congress

Kim Schrier, M.D.
Member of Congress

Bradley Scott Schneider
Member of Congress

Michael C. Burgess, M.D.
Member of Congress

Gus M. Bilirakis
Member of Congress

Claudia Tenney
Member of Congress

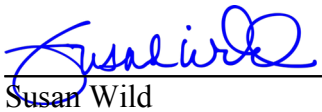
David Kustoff
Member of Congress

Diana Harshbarger, Pharm.D.
Member of Congress

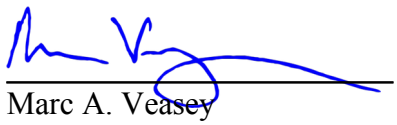
Debbie Dingell
Member of Congress

John Joyce, M.D.
Member of Congress

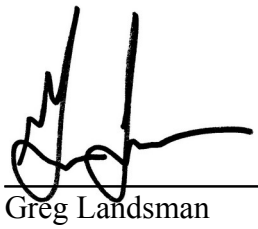
Robert E. Latta
Member of Congress



Susan Wild
Member of Congress



Marc A. Veasey
Member of Congress



Greg Landsman
Member of Congress