HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

August 19, 2024

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Docket No. FDA-2023-N-4806[1]

Re: Immediate Action Needed to Forestall Disruptions to the Drug Supply Chain and Patient Care in November

Dear Dr. Throckmorton, Dr. Verbois, and Ms. Kundi,

The Healthcare Distribution Alliance[2] (HDA) appreciates the long-standing joint public/private efforts to reach stability in implementing the Drug Supply Chain Security Act (DSCSA). HDA and its wholesale distributor members have long supported the DSCSA and have invested years of work and millions of dollars to reach the DSCSA's final requirements.[3]

Unfortunately, despite a concerted effort, some in the supply chain appear to remain short of reaching our joint goal of complete implementation. HDA is writing this letter to urge the Food and Drug Administration (FDA) to take immediate action to forestall potential disruptions to the drug supply chain and patient care that could stem from incomplete implementation of the enhanced drug distribution security (EDDS) requirements set to go into effect on November 27th of this year.

Specifically, we write to support and amplify the concerns stated in the National Association of Chain Drug Stores' (NACDS) letter[4] submitted to FDA on July 29, 2024, which requests that FDA adopt a phased, stepwise approach to implementation of the EDDS requirements. In alignment with NACDS' letter, **HDA and its members are concerned that incomplete implementation of the EDDS requirements could potentially lead to disruptions in the supply chain, including, but not limited to, stopping the movement of drugs in the supply chain, which could exacerbate existing drug shortages and delay patient care**.

As you are aware, HDA has continued to advocate for phased milestones for industry to allow adequate time for stabilization of the complex processes necessary for compliance with EDDS

[1] HDA previously submitted comments to this docket in February and again in July of this year. HDA, https://www.hda.org/getmedia/985a0319-ff04-4469-8775-b902545e0f89/HDA-Comments-FDA-DSCSA-RFI.pdf (Feb. 20, 2024) & https://www.hda.org/getmedia/ef4574fe-e46a-4064-b6d9-6e1550138fd4/HDA-Comments-FDA-DSCSA-RFI-7-16-24.pdf (July 16, 2024).
[2] HDA represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently.
[3] HDA, Pharmaceutical Traceability (DSCSA), *available at* https://www.hda.org/pharmaceutical-traceability/.
[4] NACDS, July 30, 2024, *available at* https://www.regulations.gov/comment/FDA-2023-N-4806-0021.

requirements.[5] The crux of this approach is simple; it is premised on the realities that electronic serialized data, as required to move product under EDDS requirements, flows from upstream trading partners. Without DSCSA-compliant data exchange for products, **distributors cannot lawfully purchase products from upstream trading partners and then in turn, cannot provide complete serialized data to sell products to customers downstream**. To that end, our members have told us that data exchange continues to be unstable and that the above scenario could become a distinct reality in November.[6]

Given the feedback from key supply chain stakeholders in both the distribution and pharmacy sectors, as well as growing public and policymaker concerns related to supply chain disruption, HDA strongly encourages FDA to take the following immediate actions:

1. **FDA should establish narrow guardrails that provide a phased approach to allow more time for the supply chain to stabilize data exchange between trading partners.**

HDA continues to urge FDA to adopt a phased, stepwise approach to compliance that would provide additional time to stabilize trading partner data exchange, which is consistent with what the NACDS letter is seeking.[7] In adopting such an approach, FDA would in fact be implementing DSCSA's EDDS requirements for the top of the supply chain, while also minimizing potential disruptions for the flow of drugs in the supply chain that could occur at the distributor and dispenser levels.

FDA stated just last year that, in providing one year of enforcement discretion, FDA is committed to the successful implementation of interoperable systems. Specifically, Dr. Verbois, director of Center for Drug Evaluation and Research's (CDER's) Office of Drug Security, Integrity and Response, said "[w]e have heard concerns about supply chain readiness, and we believe that some flexibility will support successful implementation and lead to a stronger and safer drug supply chain."

FDA has mechanisms to provide more time and narrow guardrails. The approach that FDA provides more time for implementation should be applicable at the federal and state levels, ensuring consistent compliance and enforcement expectations for trading partners in the drug supply chain. For instance, per DSCSA, FDA could *initiate* under the "Waivers, Exceptions, and Exemptions" (WEE) process its own exemption for trading partners or even sectors,

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[5] HDA, *available at* https://www.hda.org/getmedia/ef250538-55dc-4074-80b7-3f100b463603/HDA-Recommended-Phased-Approach-Letter-6-2-23.pdf (June 2, 2023); https://www.hda.org/getmedia/099ec708-dd7e-425b-b829-bfbb12ff3bd8/Letter-to-FDA-on-Recommendations-to-DSCSA-Stabilization-Policy.pdf (Oct. 17, 2023); https://www.hda.org/getmedia/985a0319-ff04-4469-8775-b902545e0f89/HDA-Comments-FDA-DSCSA-RFI.pdf (Feb. 20, 2024).

[6] HDA is currently surveying members to collect the most recent data on the state of data exchange. HDA hopes to share this data with FDA is the near future. Further, HDA's publishes a survey of manufacturers and distributors to benchmark quarterly data exchange for the purposes of DSCSA systems stabilization and compliance. This Q4 2023 summary is the second survey in the series: https://www.hda.org/publications/data-exchange-benchmarking-survey-q4-2023/.

[7] DSCSA compliance policies establish 1-year stabilization period for implementing electronic systems, Aug. 30, 2023, *available at* https://www.fda.gov/drugs/drug-safety-and-availability/dscsa-compliance-policies-establish-1-year-stabilization-period-implementing-electronic-systems.

which could be designed in a manner that would enable a stepwise, phased approach recognized by state and federal regulators.[8] FDA could add conditions or guardrails that would have the effect of doing more than just "kicking the can down the road."[9] Leading up to November, now is the time for FDA to engage with distributors to help ensure that product can continue to move downstream and minimize any unnecessary supply disruption.

2. **FDA should swiftly approve WEEs requested by trading partners that could mitigate the potential for supply chain disruption.**

FDA has stated that trading partners can request a WEE if they do not think they can comply with EDDS requirements by November and recommended that such WEE requests be submitted by August 1st. Thus, as of the date of this letter, FDA should have a sense of volume on how many products and/or transactions may need to be subject to a WEE. We ask that FDA make known publicly the volume of these applications, the number of applications per sector, and the types of categories of challenges and gaps that stakeholders are identifying in the WEE requests. We also ask FDA to provide a status update on the approval process for the requests. This information can help distributors prepare for potential disruptions with trading partners. FDA should consider publishing these updates on one of its public dashboards.[10]

Further, as you are aware, some distributors have submitted WEE requests due in part to the lack of readiness of upstream trading partners. HDA supports FDA consideration of such requests that demonstrate through data that the granting of such requests could mitigate potential for supply chain disruption. We also reiterate our recommendations in HDA's letter submitted to this docket in July, which outlines other factors FDA could consider relative to WEE requests.[11]

3. **FDA should initiate weekly "rapid response" calls with industry stakeholders leading up to, and in the immediate aftermath of, the implementation of EDDS requirements on November 27, 2024.**

More frequent communication and engagement with stakeholders is essential as we move closer to November, especially as the threat of potential disruption to the drug supply chain and patient care is real. To that end, among other collaborative measures, it would be prudent for FDA to establish a weekly call cadence with representatives from authorized trading partners leading up to the November compliance date and continue into the immediate future. These calls could help both FDA and the supply chain share information, including compliance challenges, related supply disruptions, and potential solutions given the inevitable

[8] Section 582(a)(3)(A) of the Food Drug & Cosmetics Act; *see also* FDA, The Drug Supply Chain Security Act [] Waivers, Exceptions, and Exemptions, *available at* https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-waivers-exceptions-and-exemptions.
[9] Regulatory Focus, Cavazzoni: No more 'kicking the can' down the road for DSCSA compliance, May 16, 2024, *available at* https://www.raps.org/news-and-articles/news-articles/2024/5/cavazzoni-no-more-%E2%80%98kicking-the-can-down-the-road-f.
[10] FDA Data Dashboard, *available at* FDA Dashboards - Home; FDA-TRACK: Center for Drug Evaluation and Research Dashboards, *available at* FDA-TRACK: Center for Drug Evaluation and Research Dashboards | FDA.
[11] HDA, WEE Clarifications, July 16, 2024, *available at* https://www.hda.org/getmedia/ef4574fe-e46a-4064-b6d9-6e1550138fd4/HDA-Comments-FDA-DSCSA-RFI-7-16-24.pdf.

complications that could arise during this transitional period. FDA could consider the approach used by various Health and Human Services (HHS) and Administration emergency preparedness teams through weekly calls with industry during the COVID-19 pandemic. For instance, separately, the Centers for Disease Control (CDC), Administration for Strategic Preparedness and Response (ASPR), and the HHS Office of the Secretary had frequent, routine calls with numerous supply chain entities leading up to, and throughout, the rollout of the distribution of the COVID-19 vaccine under the Federal Retail Pharmacy Program.[12]

Conclusion

As the trade association representing the key stakeholders that interact with upstream and downstream trading partners, HDA has unique insights and information that can help FDA in its outreach, education, and policy considerations. **We, therefore, request a meeting at your earliest convenience to discuss the above points**.

We look forward to continuing to work with FDA and our supply chain trading partners, both upstream and downstream, to move forward with DSCSA implementation in a manner that will mitigate the potential for disruptions.

Sincerely,

Chester Davis Jr.

CC:
Dr. Corrigan-Curay
Dr. Cavazzoni

[12] CDC, Federal Retail Pharmacy Program Highlights, *available at* https://archive.cdc.gov/www_cdc_gov/vaccines/covid-19/retail-pharmacy-program/index.html.