TENCOUNT CONSULTING

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March 3, 2020
Dockets Management Staff (HFA–305)
Food and Drug Administration, 5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Attention: CMS-5528-ANPRM
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Sir or Madam:

Ten Count Consulting, LLC appreciates the opportunity to provide comments to the Proposed Rulemaking with Comment entitled "Importation of Prescription Drugs," 84 Fed. Reg. 70796 (December 23, 2019). We share the FDA's concern on making medicines affordable while ensuring they are safe.

As supply chain system consultants who have been working on implementing serialization laws like the Drug Supply Chain Security act for the past 7 years, we have helped stakeholders across the supply chain consider, design, implement and stabilize systems and processes to meet the requirements of the law and help further secure the US Drug Supply Chain. We know well the benefits of the law in closing loopholes on registrations and clearly requiring all sectors to take mandated actions where needed. These include the ability to scan, capture, share and store all ownership change events at a serialized saleable unit level which can clearly show the path of prescription drug products in the event of any questions on legitimacy. This system will eventually allow dispenser pharmacies to clearly differentiate between an authorized product and one that is potentially suspicious. We believe that the DSCSA helps to powerfully prevent and aid investigators in dangerous events that continue to happen such as those mentioned in this article from the Miami Herald in October of 2019. In such scenarios, DSCSA allows investigators to readily gain historical ownership changes of products that can quickly lead to any source of potential suspicious products.

https://www.miamiherald.com/news/health-care/article236411603.html

While we appreciate and support efforts to reduce drug prices for patients, we feel the proposed approach takes unnecessary risks, bypasses critical requirements of the new law and ultimately does not clearly address how this will in fact reduce drug prices without addressing the underlying challenges with today's US drug pricing systems. The Canadian government and drug distributors have already indicated they do not support this plan and do not plan to participate, which means there will be demand created without proven channels of supply. It is our belief that the only means of properly securing these sources, is to require that they all pass FDA site inspections and fully comply with DSCSA law to ensure that illegitimate sources do not have a source to bypass steps that legitimate sources take to comply with the law which is aimed at ensuring patience safety. We suggest the US government and agencies work more closely with the Canadian government to look for avenues to bring their markets into alignment on the requirements of US DSCSA, specifically in the areas of import/exports between the countries.

Once this alignment is achieved, it will more clearly open the path for legitimate sources and create a similar assurance of continued supply chain security.

We at Ten Count Consulting have spent over 50 years collectively in other industries and feel there is significant opportunity for a more logical approach of reducing cost through improving transparency by utilizing the saleable unit serialization in the supply chain. The US Drug Supply Chain and pricing system is overly complex with dollars flowing in many directions and this complexity limits the ability for anyone to understand what components are truly involved in the cost of a unit of any drug.

We recognize the tough position that state led efforts have put federal agencies and we are hopeful that this raised awareness will be directed towards meaningful calls to action for the industry as a whole rather than complicated solutions that introduce risk without clearly benefiting cost reductions such as the current proposal. As we stated in a recent trade article:

"How did we get to a place where re-importing and added supply chain complexity, including cross-border shipments, is actually less expensive for the consumer? We must focus on replicating and advancing what has succeeded in other industries for years through greater connectivity, visibility, transparency, collaboration, elimination of redundancy, and new supply chain best practices."
https://www.pharmaceuticalonline.com/doc/barriers-to-blockchain-adoption-in-the-rx-supply-chain-and-how-to-overcome-them-0001

We further support the comments submitted by industry groups such as The Partnership for Safe Medicine as well as those closest to patients at pharmacy trade groups such as: APA, ASHS, NABP, and NACDS. We thank the FDA for taking the time to documenting this proposal and we welcome any questions or feedback we can provide as industry professionals helping companies meet the requirements of DSCSA.

Thanks

Mark Karhoff
President/Founder
Ten Count Consulting, LLC