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Dear Ms. Kirk and Ms. Velez:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide public comments to the Food and Drug Administration (FDA) regarding the Agency’s review of existing regulations as noted in the September 8 Federal Register [82 Fed. Reg. 42499 and 42506, respectively (Sept. 8, 2017)].

HDA represents primary pharmaceutical distributors – the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national pharmaceutical supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient and highly regulated.
HDA commends the Agency for its response to Executive Orders (EOs) 13771 and 13777, including issuing these notices requesting public input, as a strong step in the right direction to support its effort to evaluate regulations that may be appropriate for “repeal, replacement, or modification.”

HDA’s detailed comments are included in the attachment to this letter. As part of our comments, we frequently reference statements HDA has made to FDA in earlier written comments or in other public statements. We incorporate by reference all such public statements, cited in the attachment, into the dockets for these notices.

For ease of review, the attachment is divided into two sections. These sections and the accompanying recommendations can be summarized as follows:

**Section I – Recommendations pertaining to FDA’s guidances, regulations and other efforts related to implementation of the Drug Supply Chain Security Act (DSCSA) by wholesale drug distributors and their trading partners.**

1. HDA urges FDA to issue as soon as possible the DSCSA-mandated regulations defining state licensure standards for wholesale distributors and third-party logistics providers (3PLs).

2. HDA urges FDA to focus on the DSCSA’s requirements effective currently and through 2023 before setting new and more expansive goals.

3. FDA should revise its Draft Guidance on product identifiers – which provides one year of enforcement discretion from the serialization requirements – by eliminating any additional recordkeeping requirements applicable to other members of the supply chain. FDA also should revise the Draft Guidance so it does not accelerate the date by which distributors and dispensers may no longer transact in unserialized products.

4. HDA urges FDA to state, in guidance or another appropriate document, that data errors should not automatically be considered an indication that a product is a “suspect product.”

**Section II – Recommendations pertaining to guidances, regulations and interpretations of all other (non-DSCSA) elements of the Food, Drug and Cosmetic Act (FD&C Act) affecting wholesale drug distributors and their trading partners.**

5. HDA urges FDA to continue to recognize the challenges and costs that would be presented by the commercial importation of non-FDA-approved products.

6. HDA urges FDA to clarify the applicability of DSCSA requirements when allowing drugs to be imported under an Emergency Use Authorization or in other emergency shortage situations.

7. HDA supports FDA enforcement actions against illegal imports of unapproved drugs.
A key concern we urge the Agency officials charged with implementing these EOs to address pertains to a DSCSA requirement for FDA to issue a regulation defining federal licensure standards for wholesale distributors and third-party logistics providers (3PLs)\(^1\) by November 27, 2015. Unfortunately, two years after the statutory deadline, FDA has yet to issue this regulation and its absence is exacting a toll on resources.

Compliance with the DSCSA requirements would be challenging enough with clear direction from FDA. However, the lack of this regulation has resulted in additional unnecessary burdens as supply chain members seek appropriate licenses and work to comply with other statutory responsibilities without the much-needed clarifications this regulation is intended to address. States, which share certain implementation responsibilities, would also greatly benefit from further FDA clarification.

Despite the absence of these critical regulations, the Agency appears to be contemplating numerous additional functionalities, well beyond the DSCSA’s scope, that would add compliance and resource expenditures onto supply chain members and likely consume additional Agency and state resources. As we explain thoroughly in the attachment, we believe these suggested additional functionalities would add greatly to the supply chain’s burdens without a clear indication of the need for, or their ability to achieve, a substantial public health benefit. We believe this situation could be readily ameliorated with two fundamental policy approaches. Specifically, we urge that,

1. FDA ensure that the regulations defining DSCSA-required federal licensure standards receive top Agency priority, and
2. The Agency focus its implementation efforts on the DSCSA’s mandates and avoid attempting to address potential measures that are not part of the DSCSA’s requirements.

HDA thanks FDA for this opportunity to provide comments and suggestions on FDA’s Federal Register notices requesting input on its review of existing regulations.

If you have questions regarding Section I, please contact Anita Ducca at 703-885-0240 or aducca@hda.org. For questions regarding Section II, please contact Ruth Miller at 703-885-0266 or rmiller@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs

Attachment

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\(^1\) “Third Party Logistics Provider,” is defined in the FDC Act § 581(22); also, see FDC Act § 583 NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS and § 584 NATIONAL STANDARDS FOR THIRD PARTY LOGISTICS PROVIDERS
Comments by the Healthcare Distribution Alliance on the Review of Existing Center for Drug Evaluation and Research Regulatory and Information Collection Requirements; and Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration [82 Fed. Reg. 42499 and 42506, respectively (Sept. 8, 2017) and 82 Fed. Reg. 57560 (December 6, 2017)]
February 5, 2017

INTRODUCTION

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to respond to FDA’s request for public input as the Agency moves forward with implementation of Executive Order 13771, “Reducing Regulation and Controlling Regulatory Costs,” and Executive Order 13777, “Enforcing the Regulatory Reform Agenda.” HDA is pleased to provide recommendations to help identify existing regulations and related paperwork requirements that “could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing [FDA] us to achieve [its] public health mission and fulfill statutory obligations.”

Although the Federal Register notices requested information regarding existing regulations, we have included a recommendation regarding a regulation that has not yet been issued even in proposed form. This regulation is highly relevant to the regulatory review process now underway, as it would aid, clarify or simplify potential and existing regulatory burdens, assist with compliance, and reduce or avoid additional costs. As explained further below, HDA strongly and specifically supports the issuance of the regulation. We would not wish to see the regulation delayed further based on a perception that, merely because it is new, it might impose a greater burden on wholesale distributors, when its absence is, in fact, imposing its own burdens and costs.

HDA has divided its comments into two sections as follows:

Section I – Recommendations pertaining to FDA’s guidances, regulations and other aspects related to Drug Supply Chain Security Act (DSCSA) implementation.

Section II – Recommendations pertaining to guidances, regulations and interpretations of other elements of the Federal Food, Drug, and Cosmetic Act (FDC Act).

Where there is overlap between items listed in Section I and Section II, we will explain such overlap as appropriate.
Section I – Recommendations pertaining to FDA’s guidances, regulations and other information related to Drug Supply Chain Security Act (DSCSA) implementation.

Background

Upon enactment in 2013, the DSCSA amended the FDC Act\(^1\) to replace a 50-state patchwork of pedigree requirements with one federal solution to trace prescription medications through the supply chain. The DSCSA established a 10-year implementation timetable, with a series of requirements applicable to the various members of the supply chain, including manufacturers, wholesale distributors and dispensers.

The DSCSA requirements are phased in, at appropriately staggered intervals, to allow each new requirement to build upon the preceding ones, culminating in a comprehensive system to

- strengthen distributor licensure standards across the United States,
- increase the efficiency and safety of the supply chain, and
- establish new processes for identifying suspect and illegitimate products.

In support of these requirements and to facilitate supply chain member compliance, the DSCSA established a series of milestones for FDA, as well. The milestones applicable to FDA involve:

- issuing clarifying regulations and guidances,
- obtaining input from the public, including by conducting public meetings, and
- undertaking certain studies to help identify potential compliance methodologies and challenges.

Taken together, the milestones are intended to support the DSCSA’s ultimate goal of an “Enhanced Drug Distribution Security”\(^2\) system by November 27, 2023.

HDA has noted and appreciates the Agency’s efforts to engage with stakeholders, to issue certain draft guidances, and, in general, to attempt to identify the concerns of the supply chain members subject to the DSCSA. Thus, we offer these comments in the spirit of supporting the DSCSA’s important mandates with the least amount of disruption to the supply chain, and with as little additional cost to all stakeholders, including the patients that we serve, as possible.

However, we note that FDA has not yet met certain of its statutory obligations and has not yet answered numerous important questions regarding appropriate interpretations of the DSCSA’s current requirements. Concurrently, the Agency appears to be contemplating additional measures that would: impose burdens upon supply chain members that go far above and beyond the DSCSA’s scope; be extremely costly to implement; and/or would be impossible to accomplish within the DSCSA’s 10-year implementation timeline. Possible adoption of the Agency’s desired “add-ons to DSCSA requirements” might only be achieved after the processes and measures the DSCSA actually requires are developed, tested, revised and determined to be operationally feasible and accurate. Moreover, many of the Agency’s apparent aspirational goals

\(^1\) The DSCSA is Title II of Public Law 113-54 and amends the FDC Act, 21 U.S.C. § 301 et. seq.

\(^2\) FDC Act § 582(g).
have been discussed without a clear indication of the need for, or of their ability to achieve, a substantial public health benefit.

As we explain below, wholesale distributors and others in the pharmaceutical supply chain urgently need FDA to issue and/or finalize DSCSA-mandated guidances and regulations, all of which are intended to clarify requirements, reduce business uncertainty, and support compliance with obligations under the DSCSA.

Our comments also touch on other DCSA-related recommendations that are consistent with the administration’s goals of simplifying regulatory requirements without jeopardizing public health or safety.

**Recommendation 1: HDA urges FDA to issue as soon as possible the DSCSA-mandated regulations defining state licensure standards for wholesale distributors and third party logistics providers (3PLs).**

Type of product or FDA Center regulating the product.

- All prescription drugs covered by the DSCSA
- Center for Drug Evaluation and Research

Citation to Code of Federal Regulations and statutory citation (as applicable).

- FDC Act, §§ 581(18), (22), and (29), 583, 584, 585; *Identifying Trading Partners Under the Drug Supply Chain Security Act; Draft Guidance for Industry; Availability*, 82 Fed. Reg. 40159 (Aug. 24, 2017); 21 C.F.R. §§ 203.3 and 205

Approved information collection and OMB Control Number (as applicable).

- N/A

**Brief Description of Concern.**

The DSCSA directs FDA to issue regulations defining new federal licensure standards for wholesale distributors and third-party logistics providers (3PLs) by November 27, 2015. Once FDA standards are finalized, states have two years to adopt these standards.

A driving force behind the DSCSA’s enactment was the recognition that establishment of wholesale distributor licensure standards on a state-by-state basis was no longer sufficiently protective of the pharmaceutical supply chain. During the DSCSA’s development, Congress and many stakeholders recognized this deficiency and agreed that a single, national licensure standard was not only desirable, but essential. This approach to licensure standards is intended to create greater uniformity across

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3 “Third Party Logistics Provider,” is defined in the FDC Act § 581(22); also, see FDC Act § 583 NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS and § 584 NATIONAL STANDARDS FOR THIRD PARTY LOGISTICS PROVIDERS.
states and clarify federal authority, while enabling states to maintain their authority to issue licenses and partner with FDA in enforcement efforts.

Despite these important considerations, the Agency has yet to even propose the required regulations — more than two years after the statutory deadline.

Available Data on Cost or Economic Impact.

The federal approach mandated by the DSCSA will moderate the burdens imposed upon wholesale distributors to obtain licenses related to the differing state-by-state requirements. In the absence of the DSCSA-mandated regulations establishing a single, uniform federal standard for licensure, wholesale distributors and 3PLs remain challenged by 50 different sets of state licensure standards, which serve only to confuse them and their trading partners, and results in higher costs and compliance burdens that are both unnecessary and counterproductive to supply chain security.

On numerous occasions over the last two years, HDA has reminded the Agency of the pressing need to issue the required regulations defining these federal licensure standards, and has also explained the difficulties wholesale distributors are facing in the absence of the FDA standards. For example, in our comments4 responding to the Agency’s inquiries regarding the status of compliance with the DSCSA’s 10-year implementation time horizon:

We… emphasize that Congress unequivocally intended, and so specifically stated in the DSCSA, that wholesale distributor and 3PL licensure standards were to be uniform, national, and established by FDA, and were to preempt State requirements.5 The absence of federal licensure standards, however, is raising additional concerns:

- Resource-constrained State pharmacy boards that chose to implement the DSCSA without the benefit of the federal standards will likely have to go back and redo their codes once FDA releases the federal standards;
- Believing that their own laws and regulations persist, some States are continuing to permit activities that the DSCSA was intended to stop, such as dispensers acting as wholesalers without obtaining appropriate licenses or complying with the DSCSA’s data and other requirements in § 582;
- Some States are imposing requirements that are contrary to and more burdensome than what the DSCSA requires; and
- For wholesale distributors and their advisors and consultants, there are only a limited number of people who possess the necessary expertise to guide the industry into the 2019 and 2023 requirements. The same people that are wrestling with State licensure inconsistencies are also deeply involved with

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5 See FDC Act § 585(b)(1) which provides for the preemption of any state requirements “with respect to” wholesale distributor licensure that are “inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under §503(e).” In turn, FDC Act §503(e) mandates the establishment of federal requirements that states may then adopt; each such federally and state-issued license “shall meet the standards, terms, and conditions established by the Secretary under section 583.”
every other part of their companies’ implementation of the DSCSA. Dealing with State licensure requirements that are inconsistent with each other and with the DSCSA should not be the distraction that it has become…

In prior communications with FDA, HDA has also provided specific examples of state-related actions which would result in burdens the DSCSA, through preemption and establishment of uniform national standards, were supposed to eliminate:

- The different requirements regarding 3PL licensure have created irreconcilable conflicts between the DSCSA and State law. One State has established a 3PL license and requires a non-resident 3PL to prove it is licensed by its own home State as a 3PL. However, many States are either still licensing 3PLs as wholesaler distributors or not licensing 3PLs at all. As a result, these entities are unable to obtain an out-of-state license from the State they are shipping into.7

- A State effectively requires manufacturers that distribute their own drugs to be licensed as a wholesale distributor in the State, which is in conflict with the DSCSA…8

- Recently, one State Board of Pharmacy (BOP) sent a letter to licensees describing its initial plans for DSCSA implementation activities. The preliminary terms and definitions the BOP put forth did not match the DSCSA and would require entities to hold registrations that FDA simply does not issue or recognize. The proposals would also allow for sales the DSCSA was intended to stop, such as the so-called “5 percent rule” which permits up to 5 percent of a pharmacy’s sales to be to other pharmacies without it being classified as a wholesale distributor.

The delay in issuance of uniform federal standards, in contravention of the DSCSA’s clear mandate, severely impacts the pharmaceutical supply chain in another profound way. The DSCSA expressly preempts the authority of states to impose upon wholesale distributors and 3PLs licensure requirements that are inconsistent with these yet-to-be-issued uniform federal standards. In this critical sense, these missing licensure regulations would meet – and even exceed – the goals of EOs 13771 and 13777. Given that the DSCSA expressly preempts 50 varying and inconsistent sets of state requirements,9 a regulation establishing uniform federal standards would represent a “50 for one” replacement, and not the mere “two for one” replacement regulation the EOs contemplate.

HDA addressed its views on the importance of national uniformity in licensure standards and preemption of state requirements in comments to FDA DSCSA dockets in November 2016,

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6 Examples are found in comments by HDA on “Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act; Public Meeting; Request for Comments,” 81 Fed. Reg. 64175 (Sept. 19, 2016), Dkt. No. FDA-2016-N-2673, filed November 14, 2016.

7 § 585(b)(2) and § 503(e)(5) prohibit a state from regulating a 3PL as a wholesale distributor.

8 § 503(e)(4)(H).

9 The DSCSA preserves states’ traditional authority to charge for and issue licenses and may partner with FDA in enforcement actions.
December 2014 and at other times. Section 585 of the FDC Act, as amended by the DSCSA, is entitled “National Uniform Policy” and provides for the preemption of any state requirements “with respect to” wholesale distributor and 3PL licensure that are “inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under” FDC Act § 503(e) and § 584. In turn, § 503(e) and § 584 mandate the establishment of federal licensure standards for wholesale distributors and 3PLs, respectively.

Apart from the fact that Congress specifically mandated preemption of state licensure laws in favor of a uniform national authority that FDA has not yet asserted, the absence of federal licensure standards has, as quoted extensively above, created significant burdens and concerns. Confused state regulators are implementing (or continuing) requirements that are inconsistent with the DSCSA or with each other, thereby prolonging the 50-state compliance burden (for wholesale distributors and 3PLs) the DSCSA was supposed to eliminate. Legitimate businesses are unable to obtain appropriate state licenses. Meanwhile, the absence of federal licensure standards is enabling some businesses to continue to engage in conduct that the DSCSA was intended to prohibit. The continuing need by the pharmaceutical supply chain to deal with 50 different state requirements when there was only supposed to be one set of requirements also strains scarce resources, particularly human capital.

Proposed Solution.

While HDA noted that the most recent Regulatory Agenda indicated the Agency plans to issue the proposed regulation in June of this year, given the concerns expressed above we urge the Agency to issue these regulations as soon as possible.

**Recommendation 2: HDA urges FDA to focus on the DSCSA’s requirements effective currently and through 2023 before setting new and more expansive goals.**

Type of product or FDA Center regulating the product.

- All prescription drugs covered by the DSCSA
- Center for Drug Evaluation and Research

Citation to Code of Federal Regulations and statutory citation (as applicable).

- FDC Act § 582(g)

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11 HDA’s analysis of the DSCSA’s state preemption provisions is available here: https://www.regulations.gov/document?D=FDA-2014-D-1411-0010

12 The Regulatory Agenda’s intended publication date may be viewed here: https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=0910-AH11

13 Whether as part of the licensure rulemaking or as an independent rulemaking effort, we also urge FDA to amend its existing regulations at 21 C.F.R. Part 203 so that they are consistent with the DSCSA. For example, the definitions of “manufacturer,” “wholesale distribution,” and “wholesale distributor” in 21 C.F.R. § 203.3 should be replaced with the DSCSA definitions of those terms.
Approved information collection and OMB Control Number (as applicable).

- N/A

Brief Description of Concern.

FDA has described a vision for DSCSA implementation in 2023 and beyond that we believe is inconsistent with the law itself, Congress’s intent, and EOs 13771 and 13777. It was at the first of the three Agency-sponsored public meetings (to discuss the “Enhanced Drug Distribution Security”14 that the DSCSA builds over its 10-year implementation time frame) that FDA first explained its expansive vision. Similar themes were covered during the second public meeting.15

While FDA is concerned with compliance in 2023, many of the functionalities FDA described during these meetings may best be described as aspirational and were not within the mandates that Congress set forth in the DSCSA. Moreover,

- Many of the aspirational functionalities could only be achieved by placing added and significant burdens on the supply chain – financial and otherwise.

- Developing and implementing many of the aspirational functionalities could only be achieved by effectively reprioritizing Congress’s intent. We say this because resources, particularly individuals with expertise in the DSCSA’s complexities who are guiding compliance for their companies, would likely have to be diverted from efforts to comply with deadlines effective well before 2023, to build the new system(s) FDA’s vision would require.

- In some instances, the value of these functionalities would be extremely limited unless all supply chain members were to participate fully. However, full participation in a function not mandated by the DSCSA is highly unlikely unless FDA were to issue a mandate to do so. Yet, the DSCSA contains specific prohibitions to certain mandates, such as § 582(g)(4)(A)(i), which does not permit promulgation of regulations “requiring the adoption of specific business systems for the maintenance and transmission of data.” If participation is solely voluntary, the system or functionality would likely not contain the data (or could experience delays in receipt of the data) for which it was designed. Supply chain members could spend considerable time and resources attempting to develop a system or functionality that is significantly lacking in an ability to reliably provide complete and timely data that would be needed to meet the functionality’s intended security and safety objectives.

- Many of these aspirational functionalities may pose greater (not fewer) security risks.

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14 FDC Act § 582(g)(1).
15 The meetings were announced in July of 2017. The first two meetings were held on August 23 and December 5 and 6, 2017 respectively. The third will be held on February 28. The meetings announcement can be found here: https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-15204.pdf.
Some, if not most, could not be accomplished without many additional years of technological development well beyond 2023.

At the same time, much of the critical information and many of the clarifications that supply chain members need from FDA to enable them to meet the DSCSA’s established deadlines, up to and including the final stage of implementation in 2023, have not been provided by the Agency. As HDA described in written comments\(^\text{16}\) after the August meeting:

> On November 27, 2023, in order to comply with [FDC Act] § 582(g)(1)(A), for each transaction (i.e., change of product ownership), the “selling” authorized trading partner must send transaction information (TI), including product identifiers, and a transaction statement (TS) (but not transaction history (TH)), to the “purchasing” authorized trading partner in a secure, interoperable, electronic and standardized manner. To be able to meet this deadline, FDA and stakeholders must align on the basic elements for DSCSA compliance – what interoperable means, how to make a system interoperable, who sends data, who receives data, what data must be sent and in what format, and what international standards apply to this exchange. Establishing this interoperable system is also a prerequisite to being able to meet other requirements of § 582(g)(1), such as being able to respond to appropriate requests for TI and TS in a recall or suspect product investigation.

During the August 23 public meeting, much of the discussion seemed centered around the things an interoperable electronic system for tracking pharmaceuticals theoretically might do, without sufficient explanation of what an interoperable system is and what it must do by November 27, 2023. HDA recognizes the appeal of aspirational features of this system and fully supports trading partners voluntarily exploring additional functionality.

However, with 2023 requirements still to be met and transaction data that must be exchanged seamlessly between trading partners throughout all sectors of the supply chain, we believe focus upon potential, future capabilities is distracting from the considerable work that must be done, particularly item-level serialization, verification, serialized data exchange, and providing certain transaction data upon request by an appropriate entity. Wholesale distributors look forward to exploring with their trading partners the potential additional opportunities interoperability provides, though not at the risk of sacrificing compliance with the DSCSA’s requirements by 2023.

HDA further noted in its comments that the supply chain is already far more secure than it was prior to the DSCSA’s enactment. Moreover, supply chain security will be strengthened further with the implementation of the DSCSA’s additional milestones and security measures leading up to and including those effective in 2023. In FDA’s press to identify new add-on functionalities beyond those mandated by the DSCSA, the additional security features that have already been put in place, as well as those that are still to be accomplished between now and 2023, seem to be forgotten or given little consideration. Nor, to our knowledge, is there any specific security issue that would justify the burden and distraction of these new “add-ons.” If the Agency is aware of a

security threat that may justify the need for additional functionalities, FDA should explain that threat and describe for the supply chain why the DSCSA’s existing requirements will not adequately meet it.

Available Data on Cost or Economic Impact.

The supply chain would need to invest significant resources to develop and implement the non-statutory functionalities seemingly desired by FDA. The costs would far exceed those anticipated at the time of the DSCSA’s enactment. Further, the supply chain’s current priority is to achieve compliance with Congress’s express mandates in the DSCSA. Siphoning off resources and expertise to also meet FDA’s expansive vision (which far exceeds the DSCSA’s requirements) would present added operational and resource challenges for supply chain stakeholders.

Some companies are voluntarily considering potential additional functionalities for supply chain security systems that differ from the DSCSA’s mandates. However, industry’s focus is primarily concentrated upon the necessity of achieving compliance with requirements effective now and those upcoming over the next few years through 2023. Most wholesale distributors, particularly regional wholesale distributors, have limited capacity to accomplish both what must be done for DSCSA compliance and the additional functionalities FDA believes would be “nice to have.”

We also believe capacity for handling their own responsibilities for such aspirational functionalities may be limited among multiple government entities. Promulgating new requirements absent a statutory mandate to do so would be a monumental task for the entities charged with overseeing DSCSA compliance i.e., FDA and/or the states. They would need to invest additional resources to take on the administrative responsibilities these aspirational goals would demand, e.g., for rulemaking and guidance development, economic and small business impact analyses, sponsoring additional public meetings, providing opportunities for public comment, and responding to such comments. The resource challenges they would likely face are of particular concern when the Agency has not been able to meet all of the guidance and regulation deadlines mandated in the DSCSA.

Thus, in addition to supply chain members, FDA’s extra-statutory aspirations would also burden the regulators seeking them.

Proposed Solution.

- Research on, and possible pursuit of, such non-DSCSA-mandated goals should be undertaken by trading partners on their own, without FDA intervention, and on a voluntary basis.

- Congress selected the DSCSA’s existing requirements based on their ability to enhance safety without compromising the efficient provision of needed medications to patients. Thus, the Agency’s focus is better placed on helping the supply chain to meet the DSCSA’s mandates before considering any other system functionalities.
- At the very least, we urge the Agency to conduct an in-depth analysis of whether and what type of safety risks would remain after implementation of the DSCSA’s mandates before proposing new, additional functionalities. We suspect that a cost–benefit analysis of any additional functionalities would strongly tilt toward costs.

- We urge greater consideration of the impact on supply chain stakeholders before the Agency pursues further non-mandated functionalities. Much of the DSCSA is built around requirements that each trading partner provide and receive data when a product changes ownership: manufacturers, distributors, and repackagers provide product data to their purchasing customers who must be able to receive, maintain, and, under certain circumstances, retrieve their own data. (Dispensers are not required to provide data when they dispense or administer products to patients.) The data flow forward, from seller to buyer, in one direction.

FDA’s vision, however, would seem to involve active surveillance where information would always be available and visible about a single product’s “status” in the supply chain, e.g., if the product was sold/purchased, where it is located in inventory (such as with a distributor or with a dispenser), if it was dispensed to a patient, returned, destroyed, etc.

If downstream customers were to also affirmatively communicate product “status” back up the supply chain, trading partners would have to create this status data about each product they buy and sell and post it to a data repository or repositories. It is our understanding that some forms of status data may be included in pharmaceutical transaction systems used in other countries around the world. However, such a requirement is not applicable to the US system, and there is nothing comparable currently planned for inclusion in the US law.

Thus, bringing this concept to fruition would likely mean having to voluntarily build an extraordinarily complex system that functions across all manufacturers, wholesale distributors, repackagers and dispensers that can surveil the millions of pharmaceuticals that move in the supply chain every day. To accomplish this would involve redesign of the system that is used to transmit transaction data in forward sales to one that also communicates information going back in the opposite direction through the supply chain -- a major, and exceedingly complicated, modification. If a redesign of the same system were not possible, the likely alternative would be to create an entirely new, and separate, system, also a considerable time and resource intensive effort.

Moreover, once designed, day-to-day implementation likely would involve substantial -- and disruptive -- modifications to workflow and operational processes to assure capturing such data on an individual transaction basis, and potentially, on a product-by-product or even a patient-by-patient basis.

We do not believe this type of bi-directional communication could be accomplished by 2023, and would not be possible without the other foundational work that must occur first. If it were to be developed after 2023, it would still likely mean building an extraordinarily complex, time and resource intensive system.
We cannot urge the Agency enough to conduct a thorough analysis of the impacts, benefits, and costs of such a bi-directional information flow, before it is given further consideration.

- The DSCSA does not require trading partners to report their product purchases and sales; nor are dispensers required to report when they administer or dispense products. Any electronically interoperable system for 2023 DSCSA compliance should not, in our view, rely upon trading partners voluntarily submitting data to it, because there would likely be significant information gaps in such a system. Moreover, we do not believe FDA has the statutory authority to mandate universal participation and we believe such a system would be of very limited effectiveness and usefulness unless all or most supply chain entities participate in it. Thus, if FDA disagrees and wishes to proceed, before doing so, we believe the Agency should
  - explain the legal basis for creation of such a complex system,
  - if there is no legal basis for its creation or participation, estimate the likely voluntary participation rates, and,
  - conduct a thorough analysis of its impacts, benefits and costs.

- Determining and assuring appropriate data access, ownership and security would pose significant hurdles because transaction and product identifier data residing in a centralized database (or databases) would be a temptingly lucrative target for counterfeiters and hackers. A significant advantage of a distributed model over a centralized one is that each party retains its own data and a “hacker” would need to breach security in multiple secure systems to obtain equivalent information. Thus, we urge an assessment of the potential security risks likely to be experienced while attempting to fulfill many, if not all, of FDA’s aspirational goals.

In sum, HDA believes, and, as we understand it, many other supply chain members would agree, that once the above recommendations are fully considered, the most appropriate action for the Agency would be to discontinue pressing supply chain members to adopt the non-DSCSA-mandated system functionalities discussed at FDA’s recent public meetings.

**Recommendation 3:** FDA should revise its Draft Guidance on product identifiers – which provides one year of enforcement discretion from the serialization requirements – by eliminating any additional recordkeeping requirements applicable to other members of the supply chain. FDA also should revise the Draft Guidance so it does not accelerate the date by which distributors and dispensers may no longer transact in unserialized products.

Type of product or FDA Center regulating the product.

- All prescription drugs covered by the DSCSA

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17 See, for example, comments and testimony filed under Docket No. FDA-2017-N-3857 regarding “Enhanced Drug Distribution Security under the Drug Supply Chain Security Act; Public Meetings; Request for Comments.”
In July of 2017, FDA issued a Draft Guidance for comment entitled; “Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy; Draft Guidance for Industry; Availability”\(^\text{18}\) (Draft Guidance). The intent of this Draft Guidance was to grant manufacturers of pharmaceutical products subject to the DSCSA a one-year period of enforcement discretion to meet their serialization requirements (that otherwise went into effect as of November 27, 2017).

While HDA supports temporarily easing the serialization burden by providing this one-year reprieve for manufacturers, FDA’s Draft Guidance imposed two new, substantial burdens upon the other segments of the supply chain:

- A requirement that wholesale distributors and dispensers document when the manufacturer introduced a product in a transaction into commerce,\(^\text{19}\) and
- “Beginning November 27, 2018, wholesale distributors and dispensers who purchase product from a repackager should ensure that they bear product identifiers.”\(^\text{20}\)

Unfortunately, these new requirements are contrary both to the DSCSA and to the goals of the EOs.

In HDA’s previously submitted comments to FDA, we set out the technical and legal reasons for eliminating the documentation requirement described above.\(^\text{21}\) To very briefly summarize our chief objections:

- The documentation provision unfairly shifts the burdens of compliance from manufacturers to wholesale distributors and other downstream trading partners,
- Without item-level serialization and the provision of product identifiers, it is not possible for downstream trading partners to know or document when a single package entered the supply chain, and

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\(^\text{19}\) Draft Guidance at lines 250-270.
\(^\text{20}\) Draft Guidance at lines 205-207.
The DSCSA specifically exempts the manufacturer’s initial trading partner from providing the manufacturer’s initial transaction date in Transaction Information (TI) or Transaction History (TH) between trading partners in subsequent transactions.

As noted above, the Draft Guidance also improperly accelerates the date by which distributors and dispensers can no longer transact in unserialized products. As further explained in our comments:

HDA believes this provision is contrary to the DSCSA and should be stricken. As the Draft Guidance correctly points out elsewhere, wholesale distributors and dispensers may engage in transactions with unserialized product before November 27, 2019 and 2020, respectively. See Draft Guidance at lines 196-198 (wholesale distributors); 199-201 (dispensers).

In specifying that wholesale distributors and dispensers “should,” beginning November 27, 2018, confirm product identifiers on product from repackagers, the Draft Guidance flatly contradicts § 582(c)(2) and § 582(d)(2). These provisions of the DSCSA do not mandate transacting only with serialized product until 2019 (wholesale distributors) and 2020 (dispensers).

In sum, if the Final Guidance contains the same provisions found in the draft version, wholesale distributors will be significantly challenged by what is supposed to be merely a short-term policy on enforcement discretion.

Available Data on Cost or Economic Impact.

HDA has not attempted to determine a cost estimate of what is not possible to execute or of requirements that we do not believe the Agency has statutory authority to mandate. However, in our earlier comments, we qualitatively explained the resource intensive efforts that wholesale distributors and others in the supply chain would likely have to undertake if they were to attempt to implement the additional documentation requirement.

Even assuming that a package’s initial transaction date was “knowable” at this time, [which, as we explain in our comments, is not possible]… Adding the initial transaction date means developing and updating a guideline, publishing the guideline, and modifying the existing 856 maps. It also involves intensive efforts by stakeholders to provide and accept the data, and each selling entity must test it across hundreds if not thousands of trading partners. Validation may also be involved, as well as additional changes based on the test results. If trading partners are using portal systems to provide and maintain transaction data, these would also have to be modified. Trying to change existing practices and develop new standards to cover a year-long accommodation would divert important attention and resources from other looming DSCSA deadlines, such as 2019 verification of saleable returns and development of a “vision” for 2023 – a vision that, when realized, will achieve what the Draft Guidance seeks – traceability through item-level serialization supported by product identifier data in TI.

22 Id.
To explain further, this lack of feasibility and the statutory restrictions on adding these provisions to a guidance, we refer to the comments HDA submitted to this Draft Guidance’s docket. They are also incorporated by reference to this docket.

Proposed Solution.

We reiterate the recommendation that we included in our comments to the Draft Guidance:

HDA requests that the following immediately be stricken from the Draft Guidance:

- Section III.B.4, lines 250-270; and
- The sentence beginning on line 205, “Consequently, beginning November 27, 2018, wholesale distributors and dispensers who purchase products from a repackager should ensure that they bear identifiers.”

HDA believes that the Agency’s subsequently released Draft Guidance Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier (Draft Grandfathering Guidance) appears to have attempted to rectify this concern. However, we note that neither the Draft Guidance on product identifiers nor the Draft Grandfathering Guidance have been finalized. Thus, we encourage the Agency to finalize both guidances, consistent with the above recommendations and aligned with each other, as soon as possible.

Recommendation 4: HDA urges FDA to state, in guidance or another appropriate document, that data errors should not automatically be considered an indication that a product is a “suspect product”.

Type of product or FDA Center regulating the product.

- All prescription drugs covered by the DSCSA
- Center for Drug Evaluation and Research

Citation to Code of Federal Regulations and statutory citation (as applicable).

- FDC Act § 582(c)(1)(A); § 582(c)(1)(B); § 582(g)(1)

Approved information collection and OMB Control Number (as applicable).

- N/A

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23 Id.
Brief Description of Concern.

On several occasions HDA has pointed out to the Agency that with the tremendous volume of products and data being transferred to meet the DSCSA’s requirements, errors in the data will occur. Such data errors, however, will not necessarily indicate that there is a concern with the product’s safety and suitability for patient care. As HDA has recently stated.25

> The data elements of transaction information (TI), transaction history (TH) and the transaction statement (TS) are complex... there will be good faith mistakes due to simple confusion and data entry and typographical errors. We do not believe that a product is more likely to be suspect or illegitimate because of errors or omissions in TI, TH or TS, absent other indicia that the product may be suspect.

If the flow of product is to continue without undue disruption, it is imperative for the Agency to recognize publicly that

- Inevitably, on occasion, transaction data containing errors will be transmitted,
- A data error does not automatically indicate that a product is “suspect,”
- While the trading partner who identifies such an error bears a responsibility to further review the product and/or the data, automatically initiating an extensive suspect product investigation may not be necessary, and,
- Other actions, such as quarantining a product, are not automatically warranted.

Available Data on Cost or Economic Impact.

A number of DSCSA requirements could give rise to the type of data error that we reference.

Even a very small error rate, (e.g., less than 1 percent) would likely result in tens of thousands of errors per year, translating into a tremendous burden to address concerns with products that are “suspect” only because of a typo, a data entry or other paper error, not because the product itself potentially has a problem. Moreover, if these data errors trigger a suspect product investigation, meeting such DSCSA requirements as quarantining the product, recordkeeping, and other measures, would become a tremendous burden not only for the wholesale distributor who identifies the error, but also for its suppliers who provided the product and data.

Perhaps more importantly, it may also affect dispensers who may not receive the product they ordered in a timely manner. Thus, the impact is not only financial, but also a likely, and unnecessary, obstruction to patient access. We emphasize that these are errors (such as missing or incorrect TI) that might occur in routine product transactions between regular authorized trading partners such as might be seen in daily or weekly shipments a distributor receives directly from its regular pharmaceutical manufacturer supplier. There is no reason to believe that the product is irregular in any way. Rather, it is expected that in the millions of regular, routine purchases and sales every day between authorized trading partners, occasionally, the data and the product will not match as they should.

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The potential exists for these types of data errors to increase over the next few years as trading partners work to meet the upcoming DSCSA requirements to apply product identifiers at the individual unit level and, by 2023, include the product identifiers in TI. We are hopeful that as trading partners adapt to the new requirements, and systems for exchanging data undergo continuous improvements, the error rates will eventually decline. However, these improvements will take years to evolve and, again, due to volume, are unlikely to ever be eliminated entirely.

**Proposed Solution.**

HDA urges the staff performing the regulatory review process to support and encourage clarification, in an appropriate guidance, regulation or Agency statement, that errors associated with transmitting DSCSA-required data for DSCSA-covered products do not, in and of themselves, indicate that a product is a “suspect product.”

We further urge that FDA recognize that before a product is designated as “suspect” it should be acceptable to perform further data review, such as those steps recommended by HDA’s Exceptions Handling Guideline,26 rather than immediately meeting a “suspect product” designation. Appropriate business processes for handling data errors may include the distributor contacting its manufacturer supplier for clarification, the manufacturer generating a new transaction, or the distributor returning the product to the manufacturer.

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Section II – Recommendations pertaining to guidances, regulations and interpretations of other elements of the FDC Act.

Recommendation 5: HDA urges FDA to continue to recognize the challenges and costs that would be presented by the commercial importation of non-FDA-approved products.

Type of product or FDA Center regulating the product.

- Drugs and biologics

Citation to Code of Federal Regulations and statutory citation (as applicable).

- 21 U.S.C. § 384

Approved information collection and OMB Control Number (as applicable).

- N/A

Brief Description of Concern.

HDA urges FDA to continue to recognize the challenges and costs that would be presented by any plan to allow for commercial importation of non-FDA-approved pharmaceutical products.

To date, no Secretary of the U. S. Department of Health and Human Services (HHS) has been able to certify that importation will both pose no additional risk to public health and safety, and generate cost-savings that are passed on to American consumers. While language added by the Medicare Modernization Act of 2003 contemplates the possibility of commercial importation of non-FDA-approved drugs from Canada, such a plan would first require the Secretary to make such a certification.27 HDA believes that the Secretaries have been correct to conclude that the facts do not support this certification.

As former FDA Commissioners Robert Califf, Margaret Hamburg, Mark McClellan and Andrew Von Eschenbach noted in a letter to members of Congress, importation is “complex and risky.”28 They further affirmed that, in the U.S., “the ‘closed’ distribution system undertaken by the FDA under the direction of broadly supported drug safety legislation, provides assurance that good manufacturing practices are used and that the increasingly complex supply chain, including shipment and storage, is carefully monitored to ensure the quality and security of approved medications.”29 Thanks to FDA’s comprehensive drug approval and oversight, medicines on the U.S. market are widely regarded as the safest in the world.

The U.S. pharmaceutical supply chain is a sophisticated, efficient and highly secure system, and in 2013, Congress made a firm commitment to further strengthening it by passing the DSCSA. Yet recent importation proposals would not fully incorporate critical protections established by the DSCSA. The DSCSA, for instance, requires the standardized application of unique product identifiers

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29 Id.
by manufacturers, a streamlined regulatory framework with stringent wholesaler licensure requirements, and a provision that all business be conducted between “Authorized Trading Partners.” In addition, the law requires the exchange of transaction data that will enable tracing of prescription drug products through the supply chain, including enhanced capabilities designed to identify and investigate instances of suspect and illegitimate product. Non-FDA-approved products that arrive under an expanded importation scheme could lack these mandatory safety protections, essentially becoming untraceable.

Moreover, foreign governments are not in the position to monitor medicines that are intended for the U.S. market. The Canadian government is on record saying that while it regulates medicines manufactured for its citizens, it cannot be expected to ensure the safety of medicines that are shipped through Canada for export to the U.S. or other countries. Moreover, since the drugs will effectively lack oversight by any health authority, they also are more likely to be mishandled, in that proper temperature control may not be maintained, for instance, before they reach the U.S.

Thus, expanded commercial importation of prescription medicines could expose the domestic supply chain to unnecessary risk. Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products could more easily infiltrate the U.S. pharmaceutical supply chain, with potentially life-threatening consequences. Counterfeiters are increasingly technologically sophisticated and can easily make bottles and packages look genuine even when they are filled with laced, adulterated or fake pills that are dangerous to patients.

Available Data on Cost or Economic Impact.

The importation of prescription drugs from foreign markets often has emerged as a quick-fix proposal, purported to enhance affordability and patient access. While action on certain drug pricing issues may be appropriate, the risks of importation far outweigh any potential benefits. Importation would threaten and destabilize the significant industry-government collaboration already in place to help ensure the safety and security of the domestic pharmaceutical supply chain, and would undermine the work supply chain stakeholders and regulators have undertaken since the passage of the Prescription Drug Marketing Act in 1987, the Prescription Drug Amendments of 1992, and the DSCSA four years ago.

Permitting commercial importation of non-FDA-approved drugs would involve significant oversight costs. As the HHS Task Force on Drug Importation concluded in 2004:

> Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities. The public rightly expects that, under any legal importation program, the imported drugs will be safe and effective. To accomplish this, additional safety protections would need to be

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32 Pub. L. No. 100-293.
33 Pub. L. No. 102-353.
added that would increase the costs of the program in an additive way as more safety measures are put in place. Substantial resources would also be needed to ensure adequate inspection of imported drug products. In addition to other factors that are likely to reduce potential consumer savings, these increased regulatory and program costs will also impact potential savings to consumers. Furthermore, intermediaries will likely capture at least half of any savings between the U.S. and price-controlled countries and potential quantity constraints imposed by foreign governments and manufacturers will likely further limit the supply of these drugs to U.S. consumers.\textsuperscript{34}

That Task Force also concluded that “total savings to drug buyers from legalized commercial importation would be one to two percent of total drug spending.”\textsuperscript{35} The Congressional Budget Office in 2005 reached a similar conclusion.\textsuperscript{36}

Thus, the concerns and risks posed by importation far outweigh any potential benefit to the supply chain, public health or patients. We, and ultimately the patients we serve, simply cannot afford to risk the entrance of substandard, unsafe medicines into one of the safest and strongest supply chains in the world.

Proposed Solution.

HDA opposes permitting the commercial importation of non-FDA-approved pharmaceuticals into the United States. Importation significantly increases the likelihood of counterfeit or adulterated prescription medicines entering the U.S. marketplace and places U.S. patients at risk. Limiting commercial importation to a specific country or countries will not diminish the likelihood of counterfeit or adulterated drugs entering the U.S. Further, permitting such importation will not ensure significant reductions in the costs of prescription drugs. HDA, of course, supports FDA’s use of its importation authority under Emergency Use Authorization procedures, which we discuss in greater detail in the following section.\textsuperscript{37}

\textbf{Recommendation 6:} HDA urges FDA to clarify the applicability of DSCSA requirements when allowing drugs to be imported under an Emergency Use Authorization or in other emergency shortage situations.

Type of product or FDA Center regulating the product.

Drugs and biologics

\textsuperscript{35} Id. at 65.
Citation to Code of Federal Regulations and statutory citation (as applicable).

- 21 U.S.C. § 360bbb-3

Approved information collection and OMB Control Number (as applicable).

- N/A

Brief Description of Concern.

In two circumstances, products may be lawfully imported into the U.S. market without meeting all of FDA’s statutory and regulatory requirements. First, FDA may grant an Emergency Use Authorization (EUA) under 21 U.S.C. § 360bbb-3. Second, FDA may allow importation of specific products in the event of natural disaster or other shortage-causing situation, as FDA did in 2017 in response to certain slow-downs in manufacturing in Puerto Rico following Hurricane Maria. For instance, FDA has recently allowed Baxter to temporarily import intravenous drug products from Australia, Canada, and Ireland. See https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM579561.pdf.

In these circumstances, the imported product itself, as well as subsequent transactions involving the product, may not comply fully with DSCSA requirements. For instance, FDA might temporarily allow a product to be distributed in the U.S. even though the product does not bear the product identifier required under § 582 of the FDC Act. Subsequently, a wholesale distributor may need, in an emergency, to distribute the products to entities such as first responders who do not meet the DSCSA criteria for “Authorized Trading Partner.” Moreover, the DSCSA-defined transaction data, required in most prescription drug product transactions, may not be available.

Thus, while FDA’s importation authorization may ease DSCSA compliance concerns for the importer, it may not equally provide assurances for supply chain entities beyond the importer. A company that buys or distributes pharmaceuticals in the situations just described could be viewed as violating the FDC Act if FDA does not likewise make accommodations for their DSCSA compliance obligations. Additionally, individual state regulatory authorities, who will serve as enforcement partners in FDA’s DSCSA implementation efforts and may be involved in emergency response efforts, may not be fully aware of the DSCSA’s complex requirements and how the EUA may impact them.

It is not entirely clear what steps wholesale distributors should take in handling these products. FDA’s Draft Guidance for Industry and Public Health Stakeholders – Emergency Use Authorization of Medical Products and Related Authorities (“Draft Guidance”) does not reference the DSCSA. In announcing imports to respond to the recent shortages, manufacturers have informed wholesale downstream customers that the barcodes on the products may not scan properly, but neither FDA nor manufacturers have addressed the DCSCA compliance issues.

38 For instance, FDA has recently allowed Baxter to temporarily import intravenous drug products from Australia, Canada, and Ireland. See https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM579561.pdf.
In recognition that emergencies may justify exemptions from its requirements, the DSCSA definitions of “transaction” and “wholesale distribution” exempt the distribution of a product for “emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act.”

Moreover, FDC Act section 582(a)(3)(A)(i) provides that FDA shall provide for a process by which an authorized manufacturer, repackager, wholesale distributor or dispenser may request a waiver from any of the requirement of §582 for emergency medical reasons. However, emergencies can take many forms beyond those specifically mentioned in the DSCSA and the need for very rapid delivery of medical products would not allow for even minimal delays potentially associated with applying for, and receiving approval of, an exemption request.

Proposed Solution.

To avoid confusion about the potential applicability of the DSCSA that could slow the distribution of products under an EUA or in an emergency shortage situation, HDA suggests that FDA revise its Draft Guidance and issue additional guidance regarding waivers from the requirements of FDC Act §582.

HDA suggests that FDA add the following to the Draft Guidance after line 796:

FDA will consider on a case-by-case basis the extent to which the Drug Supply Chain and Security Act (DSCSA) applies and, if appropriate, will exercise enforcement discretion and excuse entities and/or EUA products from the requirements of [FDC Act] §582 and any applicable implementing regulations or guidances.

FDA may also wish to ask applicants for EUAs to address in the application the extent to which an exemption from FDC Act §582 is necessary and how that exemption, if granted, will be communicated to downstream trading partners.

Because in an emergency shortage situation it may be difficult to process a waiver request, FDA also should ensure that any Agency notice regarding an EUA or authorization of any other importation:

- Separately and expressly references the DSCSA;
- Explicitly states whether the requirements of FDC Act §582 are applicable; and,
- If FDA deems that the requirements of FDC Act §582 are applicable, the extent of its enforcement discretion exempting the product and transactions of that product from §582 and any other DSCSA requirements.

Recommendation 7: HDA supports FDA enforcement actions against illegal imports of unapproved drugs.

Type of product or FDA Center regulating the product.

- All FDA-regulated products, but particularly drugs and biologics.

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40 See, e.g., FDA Act §581(24) (definition of “transaction”); §503(e)(4)(C) (definition of “wholesale distribution”).
Citation to Code of Federal Regulations and statutory citation (as applicable).

- Authorities granted under Title VII of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA).

Approved information collection and OMB Control Number (as applicable).

- N/A

Brief Description of Concern.

American patients can be placed in harm’s way due to the presence of substandard, spurious, falsely labelled, falsified and counterfeit medicines in other countries, in part through purchases made from illegal internet drug sellers, who often hide the true origin of products.

FDA’s activities in preventing this illicit importation, using longstanding authorities and those more recently provided in FDASIA, are critically important in preventing overdose deaths as well as other adverse health outcomes. As the President’s Commission on Combating Drug Addiction and the Opioid Crisis (President’s Commission) recently reported:

> [I]ndividuals can simply go online to one of many internet drug marketplaces and purchase illicit drugs for their own personal use or for further sale on a limited scale, creating a constellation of “micro-networks” across the country that are difficult to locate and nearly impossible to dismantle. The ability to easily purchase drugs like fentanyl online, which are subsequently shipped in a manner and at volumes that make them hard to detect, demonstrates a new pathway for these potent drugs to enter the domestic supply chain. This change carries enormous implications for the law enforcement and justice communities, and requires a framework of relationships, laws and regulations, and procedures to deal with an environment of drug trafficking and use the nation is just beginning to see.41

HDA applauds FDA’s recent successes. In June 2015, the FDA and Interpol announced the seizure of illegal medicines and medical devices from more than 1,050 websites, many of which claimed to be approved generic versions of branded drugs.42 A recent federal indictment charged a major Canadian online pharmacy and a number of related entities with conspiring to smuggle mislabeled and unapproved prescription medicines into the U.S.43 Even so, the President’s Commission recently suggested that “The Federal Government currently lacks a sustained, coordinated, and well-resourced effort to attack the illicit drug online purchase infrastructure to identify and target the network of actors involved. . . .”44 And the Partnership for Safe Medicines expressed that “without any electronic

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44 Final Report, supra note 41 at 62.
tracking information and with reduced resources, the ability for [a Customs and Border protection] inspector to effectively detect counterfeit pharmaceuticals becomes almost a random chance.”

**Proposed Solution.**

HDA supports FDA’s efforts to combat illegal imports of unapproved drugs, including its careful coordination with other federal authorities and its communication with the public about the dangers. To the extent that changes to federal law can improve the ability of other federal agencies to intercept such products before they cause harm to Americans, we are prepared to support such initiatives.

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HDA thanks FDA for this opportunity to provide our input on EOs 13771 and 13777. If you have questions regarding Section I above, please contact Anita Ducca at 703-885-0240 or at aducca@hda.org. For questions regarding Section II, please contact Ruth Miller at 703-885-0266 or rmiller@hda.org.

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