HDMA Qs and As on the Drug Supply Chain Security Act (DSCSA)

Version 2.0 - March 2015

This document, the HDMA Qs and As on the Drug Supply Chain Security Act (DSCSA), has been prepared by the Healthcare Distribution Management Association (HDMA) in consultation with its Traceability Implementation Work Group (Work Group). This document discusses how the DSCSA applies to several areas of wholesale distributor operations.

These Qs and As should be used in conjunction with other documents provided by HDMA such as the transaction scenarios, ASN business examples, ASN exceptions guidelines, returns transaction scenarios, and other documents, including the DSCSA, for a full picture of the related requirements.

These materials are not legal advice and are based on evolving requirements. As such, they may change as the Food and Drug Administration (FDA) issues guidance and regulations implementing the DSCSA. Each company must make its own business decisions about DSCSA implementation. Please consult your operations, regulatory and information technology staff, consultants and legal counsel as well as your trading partners for further implementation guidance.

901 North Glebe Road • Suite 1000 • Arlington, VA 22203
(703) 787-0000 • (703) 812-5282 (Fax) • www.HealthcareDistribution.org

NOTE 1: On December 24th, 2014, FDA issued a guidance document entitled, "DSCSA Implementation: Product Tracing Requirements – Compliance Policy" ("compliance policy guidance").[1] In the compliance policy guidance, FDA announced that it would exercise enforcement discretion with respect to the DSCSA's product tracing requirements until May 1, 2015. Specifically, the agency stated, "FDA does not intend to take action against trading partners (manufacturers, wholesale distributors, and repackagers) who do not, prior to May 1, 2015, provide or capture the transaction information, transaction history, and transaction statement required by section 582 of the FD&C Act (product tracing information) …" FDA continued by describing the limited scope of this enforcement discretion: "This compliance policy is limited to the requirements that trading partners provide and capture product tracing information; it does not extend to other requirements in section 582 of the FD&C Act, such as verification related to suspect and illegitimate product (including quarantine, investigation, notification and recordkeeping) and requirements related to engaging in transactions only with authorized trading partners."

Accordingly, although some of the responses below identify a statutory implementation date of January 1, 2015, we recognize that FDA has stated that it intends to exercise "enforcement discretion" and does not intend to begin enforcing the product tracing requirements of the DSCSA until May 1, 2015. We have added an asterisk (*) to those Qs and As below related to product tracing requirement, that though effective on January 1, 2015, are subject to FDA's exercise of enforcement discretion until May 1, 2015. However, the May 1, 2015 enforcement discretion extension does not apply to all sections of DSCSA, therefore January 1, 2015 remains the implementation date for some sections.

NOTE 2: We have revised this document based on our evolving understanding of the DSCSA and the emerging questions we have received as wholesale distributors continue to implement the statutory requirements. Version 2.0 does not change the intent or interpretation of either the questions or answers from that of the prior versions. Rather, Version 2.0 is an update primarily to reflect the effect of FDA's Compliance Policy Guidance described above on compliance and business practices as, to answer additional questions the FDA Policy raises. It also contains a limited number of modifications to certain questions for clarity.

[1] 79 C.F.R. 78874 "The Drug Supply Chain Security Act Implementation: Product Tracing Requirements – Compliance Policy; Guidance for Industry; Availability" December 31, 2014.

Index of Questions

I. DEC 31, 2014 COMPLIANCE POLICY GUIDANCE

1. Does the compliance policy guidance released by FDA on December 31, 2014 extend the deadline to implement DSCSA?

No, it does not. FDA has granted enforcement discretion for one part of the DSCSA, which means that the law is still in effect and should be implemented. However, FDA is intending to exercise enforcement discretion for trading partners that meet the description in the policy guidance. For additional information, see Note 1 above in cover page.

2. Does the compliance policy guidance grant enforcement discretion for implementation of the entire DSCSA until May 1, 2015?

No, the compliance policy guidance only affects the data transmission portion (TI/TH/TS) of the DSCSA. It does not change or modify the implementation dates or deadlines of any other DSCSA requirements including but not limited to submitting licensure registration, suspect and illegitimate product, etc. For additional information, see Note 1 above in cover page.

3. Who does the compliance policy guidance released by FDA on December 31, 2014 apply to?

The compliance policy guidance only applies to manufacturers, wholesale distributors and repackagers. For additional information, see Note 1 above in cover page.

II. GENERAL

4. Will wholesale distributors be required to provide lot number (in TI and TH) to downstream trading partners starting January 1, 2015*?

Under DSCSA, a "direct purchase wholesale distributor" [i.e., one that acquired the product directly from the manufacturer, exclusive distributor or repackager (in the case of a repackager, only if the repackager purchased directly from the manufacturer)] is NOT required to pass lot number. If a wholesale distributor is not a "direct purchase wholesale distributor," it must pass lot number as part of TI and TH when transferring ownership of the product. For additional information see the separate HDMA ASN Business Examples Document.

5. What transaction data (TI/TH/TS) needs to be passed in the following scenario: Affiliate Manufacturer to Affiliate Repackager to Wholesale Distributor? In this scenario, one affiliate manufactures the finished product and sells to the other affiliate, who is the repackager. The repackager packs into NEW finished product packaging and sells to wholesale distributors.

First, because the manufacturer and repackager are affiliates, the manufacturer's transfer of product to the repackager qualifies for an exemption from the definition of "transaction." Thus, the manufacturer would not have to pass TI/TH/TS to the repackager. Second, the repackager would have to pass TI/TH/TS to the wholesale distributor, with TH starting with the repackager. Finally, DSCSA § 582(c)(1)(A)(ii) [21 U.S.C. 360eee-1(c)(1)(A)(ii)] creates the "direct purchase option" under which purchases made directly from (i) the manufacturer, (ii) the exclusive distributor, or (iii) a repackager that purchased direct from the manufacturer, qualify for abbreviated TI and TH. Under this transaction scenario, because the wholesale distributor is purchasing from a direct-purchase repackager, the wholesale distributor would not have to include the lot number in TI or TH, and would not have to include the transaction date or shipment date (associated with its acquisition of product from the repackager) in TH.

6. How should wholesale distributors address the gap between the requirement for wholesale distributors to provide TI/TH/TS on January 1, 2015*, and the requirement for dispensers to receive it on July 1, 2015?

Trading partners will need to decide how they wish to address this gap as a business matter.

7. Does shipment date need to be included in TI and TH for compliance with DSCSA?

Shipment date is only required to be included in TI/TH when the shipment date is more than 24 hours after the transaction date.

8. For a given transaction, when does ownership transfer take place?

Supply agreements may specify different points for actual transfer of title of goods, *e.g.*, title may pass when goods leave the shipper's dock, when the goods are delivered to the buyer's dock, or when the buyer opens the truck, inspects the delivery and accepts it. "Transaction" is defined in DSCSA as "the transfer of product between persons in which a change of ownership occurs." § 581(24)(A); 21 U.S.C. § 360eee(24)(A). HDMA has recommended that FDA permit trading partners to use any commercially reasonable and supportable transaction date.

9. Can you provide clarification on transaction date and shipment date as it relates to the ASN and packing list?

For the purposes of the DSCSA, transaction date is the date of ownership transfer as recognized by the trading partners. The DSCSA does not define specifically how a company is to determine transaction date. HDMA has recommended that FDA permit trading partners to use any commercially reasonable and supportable transaction date in whatever document is sent, whether the ASN or a packing slip. In the ASN, the segment containing the transaction date is the Beginning Segment Date or "BSN".

10. When a seller prepares a packing list, the shipment date is unknown. It might ship the same day or within the next couple of days. Which date should be printed on the packing list? After the ASN is sent, the seller has an actual ship date. Does the ship date in the ASN need to match the date on the packing list? If so, how can this be achieved?

The transaction date must be included on whichever document/documents that the seller designates to satisfy the DSCSA requirement to pass TI/TH/TS (whether packing slip, ASN or other). DSCSA does not require that the dates used on the packing slips and ASNs match, nor does HDMA offer any guidance on this.

11. FDA recognizes 10-digit NDC numbers, yet certain customers require 11 digit or 12 digit NDC numbers for a variety of business reasons. What NDC number should be included in the TI/TH in order to comply with the DSCSA requirements?

Trading partners should use the same NDC number (whether 10 or 11 digits) when placing orders and sending ASN's.

III. SALEABLE RETURNS

12. What is a "return" under the Drug Supply Chain Security Act (DSCSA)?

"Return" as used under the DSCSA means providing product to the authorized immediate trading partner from whom such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product. §581(17). Sending product to a trading partner from whom the product was not purchased is a new transaction and not a return. As discussed in Question 13 below, the DSCSA provides streamlined procedures for certain product movements that meet the definition of a "return."

13. How does DSCSA address saleable returns to a wholesale distributor?

Beginning January 1, 2015*, until November 27, 2019, a wholesale distributor may accept a return from a dispenser or repackager pursuant to the terms and conditions of an agreement between the parties. The parties may agree that the dispenser or repackager does not need to provide TI, TH and/or TS with the returns it makes to its wholesale distributor supplier. The wholesale distributor may resell the returned product without providing TH that reflects the prior sales. For any subsequent resale of the returned product, the TH begins with the wholesale distributor that accepted the return. §582(c)(1)(B)(i)(I).

After November 27, 2019, a wholesale distributor may accept returned product from a dispenser or repackager only if it can associate the returned product with the TI and TS associated with the original sale of that product to the dispenser/repackager. For all transactions after that date, the TH shall begin with the wholesale distributor that accepted and verified the returned product. However, the TH need not include transaction dates if it is not reasonably practicable to obtain those dates. §582(c)(1)(B)(i)(II).

14. Are TI/TH/TS required if a "secondary distributor" is returning a drug product to a direct purchase distributor? Can the direct purchase distributor resell these returned products?

This transaction is a return under the DSCSA, but because it is from a wholesale distributor rather than from a dispenser or repackager, the return is not eligible for streamlined treatment under the DSCSA. Therefore, the return from the "secondary distributor" to the direct purchase distributor constitutes an independent transaction that requires full transaction data. The "secondary distributor" must provide TI/TH/TS to the direct purchase distributor. And yes, while the direct purchase distributor may resell the product, the DSCSA is unclear as to whether the TH for the subsequent sale may begin with the direct purchase distributor or whether the direct purchase distributor must show the previous sale to and return from the "secondary distributor," as well as all prior TH back to the original manufacturer.

15. Are TI/TH/TS required if a direct purchase distributor is returning drug product to an exclusive distributor? Can the exclusive distributor resell the drug product? If so, what TI/TH/TS does the exclusive distributor have to provide with a subsequent resale of the product?

This transaction is a return under the DSCSA, because it is from a wholesale distributor to the party (the exclusive distributor) from whom it acquired the product. However, the return is not eligible for streamlined treatment under the DSCSA applicable to returns accepted by wholesale distributors from a dispenser or repackager. Therefore, the return from the wholesale distributor to the exclusive distributor constitutes an independent transaction that requires full transaction data. The wholesale distributor must provide TI/TH/TS to the exclusive distributor.

And as in Question 14 above, while the exclusive distributor can resell the product, the DSCSA is unclear as to whether the TH for the subsequent sale begins anew with the exclusive distributor or whether it must show the previous sale to and return by the wholesale distributor, as well as all prior TH back to the original manufacturer.

16. When a dispenser changes wholesale distributor suppliers, can the new wholesale distributor (Distributor Y) accept as a return product that was originally sold to the dispenser by its initial distributor (Distributor X)?

Distributor Y can accept product from the dispenser, but the product would not be treated as a "return" under the DSCSA and thus would not be entitled to the streamlined treatment described in Question 13. The sale from the dispenser to Distributor Y would represent a new transaction for which the dispenser would have to pass TI/TH/TS (and, technically, be licensed as a wholesale distributor because it is engaging in wholesale distribution). Further, if Distributor Y makes a subsequent sale of that product, the TH it passes would need to include the transaction with the dispenser, as well as all other prior transactions. If a return is nonsaleable, TI/TH/TS would not need to be passed.

17. Does the DSCSA define what a returns processor is? Can a returns processor handle both saleable and nonsaleable products?

Yes. The DSCSA defines returns processors (or "reverse logistics provider") as "a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsalable product received from an authorized trading partner such that the product may be processed for credit … or disposed of for no further distribution." §581(17). Thus, the returns processor is allowed to handle both saleable product and nonsaleable product under the DSCSA. However, there is no provision that permits a returns processor to sell the returned product. As a result, if the returns processor sells the returned goods, it would be acting as a wholesale distributor and would have to comply with the traceability and licensure requirements applicable to a wholesale

distributor (including receiving and passing full TI/TH/TS and including TH for the product's prior transactions).

18. What TH must a wholesale distributor provide when it resells returned product that it originally sold prior to January 1, 2015*, but seeks to resell after that date?

The answer to this question is not affected by when the product was initially sold by the wholesale distributor. A wholesale distributor may accept returns from a dispenser or repackager to whom it sold the product pursuant to the terms and conditions of an agreement between the parties. Starting January 1, 2015*, the TH the wholesale distributor provides for any subsequent sale of that product does not have to reflect the prior transactions. For any resale, the TH begins with the wholesale distributor that accepted the return.

19. Can a wholesale distributor accept returns from a repackager, and if so, what TI/TH/TS must be passed by the repackager on the return transaction, and what TI/TH/TS must be passed by the wholesale distributor if and when it resells the product?

See Question 13 above regarding the streamlined procedure under the DSCSA that permits a wholesale distributor to accept returns from a repackager (or dispenser) to whom it sold the product pursuant to the terms and conditions of an agreement between the parties. The TH the wholesale distributor provides for any subsequent sale of that product does not have to reflect the prior sale to or return by the repackager. For any resale transactions, the TH would begin with the wholesale distributor that accepted the return.

However, if the repackager has repackaged the product (*e.g.*, with new labeling, new lot number and new NDC number), this would appear to be a new product, which, we believe, would not qualify as a "return" under DSCSA; rather, the repackager's shipment back to the wholesale distributor would constitute a new transaction involving a new product. Moreover, if the wholesale distributor sought to sell the indirectly sourced repackaged product, it would have to pass full TI/TH/TS tracing back to the original sale by the manufacturer (which would present a significant challenge).

20. What if a wholesale distributor ships a product to a licensed practitioner and the licensed practitioner returns the product? What TI/TH/TS would the wholesale distributor need to provide on a subsequent resale of the returned product?

The DSCSA includes licensed practitioners within the definition of "dispenser," but provides that licensed practitioners are exempt from complying with the traceability requirements generally applicable to dispensers. Although the statute is far from clear, we believe returns by licensed practitioners would be treated in the same manner as returns from any other dispenser. That is, a licensed practitioner could return product to the wholesale distributor from whom he/she purchased the product (pursuant to an agreement between the parties) without having to provide

TI/TH/TS, and the wholesale distributor could then resell the product by providing TH that started with the wholesale distributor's resale.

21. Does DSCSA affect the return of product from wholesaler distributors back to the manufacturer? Or 3rd party processors? If so, what information has to be passed?

DSCSA provides that a wholesale distributor may return non-salable product to the manufacturer from whom it acquired the product without having to pass TI/TH/TS. Such return can be made directly to the manufacturer or through a 3rd party returns processor.

DSCSA does not specifically address returns of salable product from a wholesale distributor to the manufacturer. Accordingly, at least arguably, such return transactions would not be exempt from the traceability requirements and the wholesale distributor would have to pass TI/TH/TS to the manufacturer (whether directly or through a 3rd party returns processor). The content of the TH would depend on the prior transactions associated with the product. [NOTE: If the product is sent back to the manufacturer prior to the wholesale distributor formally taking ownership of the product, then the movement of goods would not constitute a transaction and thus the wholesale distributor would not need to pass TI/TH/TS when shipping the goods back to the manufacturer.]

IV. NONSALEABLE RETURNS

22. What requirements apply to nonsaleable returns to or from a wholesale distributor?

Under the DSCSA, a wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, such as a returns processor, without providing TI/TH/TS.

Further, the DSCSA does not require a dispenser to provide TI/TH/TS when it returns nonsaleable product to the wholesale distributor from whom it acquired the product. Implicitly, this means that the wholesale distributor is relieved of any requirement to receive TI/TH/TS when accepting the nonsaleable returned goods from the dispenser. Further, we believe this transfer may be outside the scope of the DSCSA because when a drug is nonsaleable, it is not for "administration to a patient." If a drug is not for administration to a patient, it does not meet the definition of "product" under the DSCSA in §581(13).

V. SUSPECT AND ILLEGITIMATE PRODUCT

23. The DSCSA does not require wholesale distributors to report suspect product. However, DSCSA does require wholesale distributors to report to FDA if a suspect product is determined NOT to be illegitimate (thus, implicitly notifying the FDA that the wholesale distributor had considered the product suspect in the first place). How should wholesale distributors address this apparent inconsistency in the law?

The DSCSA states that the wholesale distributor shall, upon clearing suspect product, provide notice to "the Secretary, if applicable." §582(c)(4)(A)(ii). A wholesale distributor can make an independent determination that a product is suspect, or it can find out about suspect product through a request for verification from the Secretary.[2] Thus, the phrase "if applicable" in the statute should be read to mean that a wholesale distributor must notify the Secretary that suspect product is cleared (*i.e.*, is NOT illegitimate) only when the investigation was initiated in response to a request for verification from the Secretary.

VI. DATA TRANSMISSION AND ASN-RELATED QUESTIONS

24. How should wholesale distributors handle shipping a discrepancy? Shortage, Damage, Overage?

FDA has not addressed discrepancies or the need for changes to correct information in TI/TH/TS. Certainly the DSCSA requires that accurate TI/TH/TS be passed, received and stored, so if errors are discovered, they need to be corrected. In the HDMA ASN Exceptions Guidelines for the Drug Supply Chain Security Act ("ASN Exceptions Guidelines"), HDMA describes various scenarios in which there is a discrepancy or error in TI/TH/TS, and proposed responses/corrective actions.

25. If a wholesale distributor receives more product than it receives data for (*e.g.,* it orders 150 units but only receives TI/TH/TS for 100 units), how does the wholesale distributor handle the 50 units for which it does not have data? How should the manufacturer correct the missing data?

The DSCSA provides that a wholesale distributor may not accept ownership of a product (that is, accept product into inventory) unless, prior to or at the time of product receipt, it has also received sufficient transaction data (TI/TH/TS). So, in the above example, the wholesale distributor could accept ownership of 100 units because it received transaction data for 100 units. Before the wholesale distributor could accept ownership of the final 50 units, the manufacturer

[2] §582 (c)(4)(A)(i) "*Upon making a determination that a product in the possession or control of a wholesale distributor is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a wholesale distributor is a suspect product…"*

would need to send the transaction data for those 50 units to the wholesale distributor. The ASN Exceptions Guidelines addresses this and other discrepancy issues in more detail.

26. If a wholesale distributor receives less product than it receives data for (*e.g.,* it orders 300 and receives TI/TH/TS for 300 units but only 200 units are shipped), how should the wholesale distributor handle the discrepancy? How should the manufacturer correct the missing units ordered?

As noted in the response to Question 25, the DSCSA prohibits a wholesale distributor from accepting ownership of a product unless it has received sufficient transaction data. In the present example, the wholesale distributor received transaction data for the 200 units shipped, so the wholesale distributor may accept ownership of the 200 units. For the quantity not shipped, the parties would use standard business practices to resolve the shortage. The ASN Exceptions Guidelines addresses this and other discrepancy issues in more detail.

27. For a particular transaction, Company Y is the seller and the "ship from" within the TI, and Company X is the buyer and the "ship to". In the ASN, does Company Y need to send the information in four different segments or can Company Y just send it in two segments?

Company Y should send all four segments, even if the information is the same. In the ASN Guidelines, HDMA intentionally created this structure to make clear (i) the buyer and seller information for DSCSA compliance, and (ii) the logistical movement of product. Even though the buyer and "ship to" are the same in this scenario, the buyer is not the same entity as the "ship to" in all transactions.

28. Has FDA approved of the transaction statement language used in HDMA's ASN Guidelines?

HDMA's legal interpretation is that the example language in the ASN Guidelines is sufficient. The transaction statement can be sent or exchanged in one Yes/No Question ("YNQ") segment per the guidelines. [3]

29. Can you use more than one YNQ segment in the ASN to provide the transaction statement?

HDMA recommends that trading partners use one YNQ segment for the TS. [4]

30. Has FDA approved of the direct purchase statement language in HDMA's ASN Guidelines?

HDMA's legal interpretation is that the language in the ASN Guidelines is sufficient. [5]

[3] Please contact HDMA's Industry Relations team for more technical detail on ASN segments at 703-787-0000.
[4] Ibid.
[5] Ibid.

31. My shipment contains exempted products or other products not covered by the DSCSA, can I use the same ASN?

Yes you can, however, you only need to send TI/TH/TS for products covered by DSCSA.

32. My shipment contains items that are exempt from DSCSA. Can I use the same ASN?

Yes you can; however, you only need to send TI/TH/TS for products covered by DSCSA. Distributors typically 'flag' exempt items in their internal systems based on information from the manufacturer for each product. (For example, manufacturers will be prompted when completing the HDMA Standard Product Information Form for Pharmaceutical Products [the 'HDMA New Item Form'] to indicate if that particular product is exempt from DSCSA requirements.)

33. Where in the ASN is the transaction date identified?

In the ASN, there is a spot at the Beginning Segment for Ship Notice (BSN) segment for transaction date. The date the trading partners choose as the ownership transfer date should be inserted there by the seller.

34. Would an ASN from a manufacturer include more than one product/different lots, etc.? If there are different products/different lots, do they provide the TS at the item/line level?

Yes, an ASN can still accommodate multiple products and different lots. There is line item detail which can provide a TS, including direct purchase statements and other detailed information (name, NDC#, lot #, container size, number of containers, etc.) about the product. The TS at the shipment level directs the receiver to line level for detailed direct purchase statements.

35. Does TH require only an additional N1 loop or a new ASN attached to the previous one in the chain?

HDMA believes that all of the required information can be sent in the one ASN between the two trading partners. Furthermore, the ASN does <u>not</u> have the capability to "follow" a single product or single lot through the supply chain. Each shipment generates a new ASN. For example, the manufacturer generates an ASN for a case of drug product; the ASN and the product are then provided to the purchasing wholesale distributor. Once the case is received, the wholesale distributor typically removes the individual units from the case and warehouses them. For its customers, the wholesale distributor then creates a new ASN, from the wholesale distributor to the dispenser, to accompany the shipment that identifies all of the different drugs, from all of the different suppliers, and other relevant shipment information.

36. What will the receiving party do if an ASN is not received at the time the shipment arrives at the receiving party's dock? Hold-off on formal receipt?

The law states that "A wholesale distributor shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history, transaction information, and a transaction statement for the product, as applicable under this subparagraph." § 582(c)(1)(A)(i). This means that the wholesale distributor must have TI/TH/TS at the time of or before the change of ownership. Trading partners will need to determine how the seller will provide TI/TH/TS to the receiving party (whether by paper, ASN or other form) so that the receiving party may accept ownership of the product.

Because the time at which an ownership change occurs varies based upon commercial agreements between the parties, if product were to arrive at a buyer's warehouse without TI/TH/TS, holding off on the physical receipt of product would be a business decision of the individual trading partners. Certainly if the buyer physically receives the product prior to receiving TI/TH/TS, the goods would need to remain quarantined until receipt of TI/TH/TS so that ownership could lawfully be accepted. See HDMA's ASN Exceptions Guidelines for more details.

VII. EXCEPTIONS TO TRANSACTION DATA REQUIREMENTS

37. Are free-of-charge items subject to TI/TH/TS requirements? There is change of ownership but no exchange of money.

There are a variety of scenarios under which products change ownership, but do not trigger the requirement for passing TI/TH/TS. Specifically, if the transfer of goods is exempt from the statutory definition of "transaction" (§581(24)), then the change in ownership does not trigger the TI/TH/TS requirement (similarly, if the distribution of product is excluded from the statutory definition of "wholesale distribution" (new FDCA § 503(e)(4)), TI/TH/TS would not be required to be passed/received). For example, the distribution of product samples by a manufacturer or licensed wholesale distributor is exempt from the definition of "transaction" (§ 581(24)(B)(v)) and, therefore, the transfer of samples would not need to be accompanied with TI/TH/TS.

38. Are donated items subject to TI/TH/TS requirements? There is change of ownership but no exchange of money.

As noted in the response to the previous question, if the distribution of product is excluded from the statutory definition of "transaction" or "wholesale distribution", TI/TH/TS would not be required to be passed/received. For example:

- Charitable Organizations: The distribution of product by a 501(c)(3) charitable organization to a non-profit affiliate is exempt from the definition of "transaction" (§

581(24)(B)(viii)). [Please note that the transfer of ownership from a manufacturer (or wholesale distributor) to a charitable organization – even if the product is donated – would constitute a "transaction" and, therefore, the transfer would require the transmission of TI/TH/TS.]

- Specific Types of Products and Specific Parties: The definition of "transaction" excludes the distribution of a number of types of products (e.g., convenience kits that contain certain specified drugs), regardless of the parties involved in the transfer, as well as distributions to specific parties (e.g., transfers among affiliates, or transfers to or from a facility licensed by the Nuclear Regulatory Commission), regardless of the product involved. Please see §581(24)(B) for details.

39. Are products designated for destruction subject to TI/TH/TS requirements? There is a change of ownership but no exchange of money.

Products designated for destruction are covered by the DSCSA's "non-saleable returns" provisions. Under DSCSA, the transfer of product by a manufacturer, wholesale distributor, or dispenser (with or without the use of a returns processor) for destruction is exempt from the requirements to pass TI/TH/TS.

40. Are items distributed for emergency medical reasons subject to TI/TH/TS requirements?

The distribution of product for emergency medical reasons (which does not include a drug shortage) is exempt from the definition of "transaction" (§ 581(24)(B)(iii)), and thus exempt from the requirements to pass TI/TH/TS.

VIII. GRANDFATHERED PRODUCT

41. What are a wholesale distributor's obligations with respect to passing TI/TH/TS for product that was received prior to January 1, 2015*, but sold after January 1, 2015*?

[***NOTE 2***: *FDA's guidance mentioned in Note 1 above does not specifically address how, if at all, the "grandfathering" provision of the DSCSA (discussed further below) would be affected, but the only logical assumption is that the provision would be affected because it addresses product tracing requirements.*

Accordingly, while the response below includes the statutory implementation date of January 1, 2015, FDA should agree that the "cut-off date" for grandfathered product is now May 1, 2015. For consistency, HDMA has continued to use the statutory deadline of January 1, 2015 (with an asterisk) which can be read as May 1, 2015 if the guidance applies to grandfathering.]

Starting January 1, 2015*, the DSCSA requires a seller to pass transaction data (TI/TH/TS) when it transfers ownership of its drug products. The DSCSA includes a provision (entitled, "Grandfathering Product") that describes the TI/TH/TS requirements for products entering the supply chain before January 1, 2015*. [See section 582(a)(5)(B)] With respect to transaction data requirements, this provision provides as follows:

For a product that entered the pharmaceutical distribution supply chain prior to January 1, 2015*—

> (i) authorized trading partners shall be exempt from providing transaction information as required under subsections (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii) [these are citations to the transaction data requirements for manufacturers, direct purchase wholesale distributors, dispensers, and repackagers, respectively];
>
> (ii) transaction history required under this section shall begin with the owner of such product on such date; and
>
> (iii) the owners of such product on such date shall be exempt from asserting receipt of transaction information and transaction statement from the prior owner as required under this section.

This section of the DSCSA is not particularly clear, and in the absence of any FDA guidance, we interpret this provision to mean:

Prior to January 1, 2015*:

- When engaging in wholesale distribution of a drug, a company must comply with the requirements of the Prescription Drug Marketing Act (PDMA) and pass a pedigree when appropriate.

Starting January 1, 2015*, for any drug that entered the supply chain prior to January 1, 2015*:

- The entity that owns the product on January 1, 2015* is not required to pass, receive or store any transaction data that it was not required to receive.

When engaging in a new transaction after January 1, 2015*:

- It is not clear from the statutory provision set forth above whether the seller is required to pass TI. Because TI can be generated by the seller in a new transaction and is not dependent on the information that the seller received prior to January 1, 2015* for the product, FDA likely would interpret the statutory provision as requiring the seller to pass TI.

- The seller must pass TH, but the TH can start with the entity that owns the product on January 1, 2015*.

- The entity that owns the product on January 1, 2015* must pass TS when it sells the drug, but is not required to assert that it received TI and TS from the prior owner (two of the elements of a full TS). All subsequent owners must pass full TS.