



U.S. Department of Health and Human Services  
**Office of Inspector General**

# **Ownership—But Not Physical Movement—of Selected Drugs Can Be Traced Through the Supply Chain**

**OEI-05-17-00460**

February 2020

[oig.hhs.gov](http://oig.hhs.gov)

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## Ownership—But Not Physical Movement—of Selected Drugs Can Be Traced Through the Supply Chain

### What **OIG** Found

We found that the ownership of 37 of 44 selected drug products could be traced through the supply chain using drug product tracing information that the Drug Supply Chain Security Act (DSCSA) requires. Seven selected drug products could not be completely traced to manufacturers. Typically, this was because tracing documents exchanged between the wholesale distributor and manufacturer were missing or had mismatched tracing information. In one instance, a wholesale distributor refused to provide tracing documents. When tracing information is missing or mismatched, a complete tracing record for a drug product may not always be available to support investigations of suspect or illegitimate drug products in the supply chain, which could delay investigators. Indeed, staff at the Food and Drug Administration (FDA) reported that accurate tracing information is critical to identifying a drug product quickly in the event of a recall or when removing an illegitimate drug product from the supply chain.

Additionally, for 21 of 44 selected drug products, we found that—unlike with their ownership—we could not trace their physical movement through the supply chain using tracing information. We could not identify the shipping locations of trading partners (e.g., manufacturers, wholesale distributors, and dispensers) or third-party logistics providers that shipped or stored the drugs on behalf of the trading partners. Although the DSCSA does not require this information, should FDA not have access to this information in case of a drug safety emergency, FDA and other investigators would need to request additional documents, which could delay investigations and hamper FDA's ability to identify sources of potentially harmful drugs in a timely manner.

### What **OIG** Recommends

We recommend that FDA follow up with the wholesale distributor that did not provide tracing information. We also recommend that FDA offer educational outreach to trading partners about required drug product tracing information and data standardization guidelines. Lastly, we recommend that FDA seek legislative authority to require information about a drug product's complete physical path through the supply chain on tracing information. FDA concurred with all of our recommendations.

### Key Takeaway

Drug product tracing information can be used to trace the ownership, but not the physical movement, of selected drug products through the supply chain. Not being able to trace a drug's physical movement delays FDA and other investigators and makes it more difficult to ensure that potentially harmful drugs do not enter the supply chain.

### Why **OIG** Did This Review

Drug diversion, counterfeiting, and the importation of unapproved drugs may result in potentially dangerous drugs entering the drug supply chain, posing a threat to public health and safety. To enhance the security of this supply chain, the DSCSA requires trading partners in the drug supply chain to create a record of each drug product transaction. FDA can use these records to investigate and identify potentially harmful drug products, prevent further distribution, and facilitate efficient recalls.

This is the third Office of Inspector General study about drug supply chain security. The previous two studies found that overall, selected wholesale distributors and dispensers were moving toward full implementation of DSCSA requirements for drug product tracing, although we found that some tracing documents were missing required information.

### How **OIG** Did This Review

We used drug product tracing information to trace—backwards through the drug supply chain, from the dispenser to the manufacturer—44 high-risk drug products billed to Medicare Part D by high-risk dispensers. We reviewed trading partners' tracing documents to determine whether information necessary to trace drugs was present and accurate. We also surveyed wholesale distributors and manufacturers to obtain information about their documents and interviewed FDA to understand how our results impact its investigations and the safety of drugs in the supply chain.

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# BACKGROUND

## Objectives

To determine the extent to which:

1. Selected drugs' ownership can be traced through the drug supply chain—from dispenser to manufacturer—using drug product tracing information.
2. Drug product tracing information reflects the selected drug's physical movement through the supply chain.

Potentially dangerous or compromised drugs entering the drug supply chain and being dispensed to patients presents a serious threat to public health and safety. Drugs may also be bought and sold numerous times before reaching patients, which creates multiple opportunities for tampering or diversion by bad actors. When dispensers and wholesale distributors buy diverted drugs from those operating outside of the secured supply chain, patients may be exposed to substantial risk.<sup>1</sup> In one example from 2016, HIV medication was diverted from the supply chain and illegally resold to pharmacies in the New York area. The scheme exposed patients with a compromised immune system to substantial risk because the bad actors treated the diverted drugs with hazardous chemicals to conceal their wrongdoing.<sup>2</sup> Likewise, as drugs move through the supply chain, they may be mishandled or stored improperly, which can compromise the drugs' integrity and potentially harm patients. To protect public health and safety, FDA must be able to identify harmful drugs in the supply chain to prevent further distribution and facilitate efficient drug recalls.

To strengthen the drug supply chain and protect patients from harmful drugs, Congress passed the Drug Supply Chain Security Act (DSCSA) in November 2013.<sup>3</sup> Among other things, the DSCSA established drug product tracing requirements for certain prescription drugs (hereinafter referred to

<sup>1</sup> Senate Staff Report, *Shining Light on the Gray Market*, June 25, 2012. Accessed at <https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/migrated/uploads/7.25.12%20Staff%20Report%20Shining%20Light%20on%20the%20Gray%20Market.pdf> on February 26, 2018.

<sup>2</sup> FDA, *April 29, 2016: Manhattan U.S. Attorney Announces Arrest of Black Market Distributor of Diverted HIV Medications Worth Approximately \$4 Million*, April 29, 2016. Accessed at <https://www.fda.gov/ICECI/CriminalInvestigations/ucm498710.htm> on April 8, 2019.

<sup>3</sup> Drug Quality and Security Act, Title II, P.L. No 113-54 (enacted November 27, 2013), amending and adding sections 581 through 585 to the Federal Food, Drug, & Cosmetic Act (FD&C Act).

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as drug products).<sup>4, 5</sup> These requirements are being phased in through 2023, which is when the DSCSA requires the electronic interoperable exchange of drug product tracing information.<sup>6</sup> The DSCSA generally requires that trading partners in the drug supply chain—e.g., drug manufacturers, wholesale distributors, and dispensers (primarily pharmacies)—exchange information about each drug product every time a transfer of ownership occurs, creating a record of each trading partner’s ownership of the drug product. This record should help the Food and Drug Administration (FDA); other appropriate State and Federal agencies; and various stakeholders investigate and identify harmful drugs in the supply chain to prevent further distribution and facilitate efficient drug recalls.

This study is the third in a series of examinations by the Office of Inspector General (OIG) of drug supply chain security and the DSCSA. The previous OIG studies found that all selected wholesale distributors exchanged and most selected dispensers received drug product tracing information.<sup>7, 8</sup> However, our work raised concerns about missing information and a lack of awareness among dispensers of DSCSA requirements.

### **The Drug Supply Chain**

The distribution of drug products from manufacturers to patients involves a variety of trading partners that take ownership of a drug product, including manufacturers, repackagers, wholesale distributors, and dispensers.<sup>9</sup> Generally, a manufacturer holds a drug product’s FDA-approved application or license, or it manufactures the product. A repackager owns or operates an establishment that repacks and relabels a product or package for further sale or distribution.<sup>10</sup> A wholesale distributor engages in wholesale distribution, which is the distribution of a drug product to, or receipt of a drug product by, a person other than a consumer or patient. A dispenser, such as a retail pharmacy, dispenses or administers prescription drugs to a patient. (See Appendix A for complete definitions.) Generally, drug

<sup>4</sup> § 582 of the FD&C Act.

<sup>5</sup> The DSCSA defines a “product” as a “prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing.” § 581(13) of the FD&C Act. For the complete definition of “product,” please see Appendix A.

<sup>6</sup> § 582(g)(1) of the FD&C Act.

<sup>7</sup> OIG, *Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information*, OEI-05-14-00640, September 2017.

<sup>8</sup> OIG, *Drug Supply Chain Security: Dispensers Received Most Tracing Information*, OEI-05-16-00550, March 2018.

<sup>9</sup> The term “trading partner” includes a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product. § 581(23)(A) of the FD&C Act.

<sup>10</sup> § 581(16) of the FD&C Act.

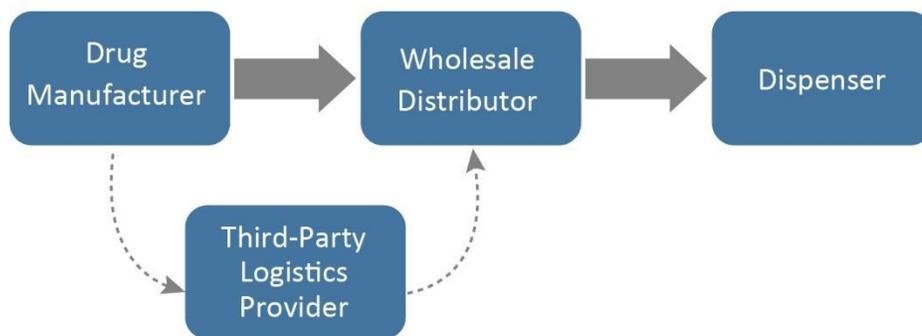
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products pass between trading partners through the supply chain until they reach the dispensing pharmacy and ultimately the patient.

Drug supply chains can involve a small number of trading partners or they can be more complex, involving multiple trading partners. In drug supply chains that involve a small number of trading partners, for example, a dispenser may purchase a drug product directly from a wholesale distributor, which may purchase directly from a manufacturer. In a more complex supply chain, drug products may pass between additional trading partners. For example, some supply chains may involve additional wholesale distributors that do not purchase the drug product directly from the drug manufacturer, but rather purchase the drug products from another wholesale distributor.

Also, as drug products pass through the supply chain, third-party logistics providers (3PLs) may physically possess drug products, but do not take ownership of the drug products. Third-party logistics providers provide or coordinate warehousing or other logistics services, such as shipping, for a drug product on behalf of a manufacturer, wholesale distributor, or dispenser.<sup>11</sup> For example, because manufacturers may not own warehouses, trucks, and other shipping equipment, they may hire 3PLs to ship their drug products to customers. See Exhibit 1 for an illustration of this example.

**Exhibit 1: Drug products may pass between manufacturers, wholesale distributors, dispensers, and third-party logistics providers.**



Source: OIG research, 2018.

### **DSCSA Requirements for Exchanging Drug Product Tracing Information**

The DSCSA requires trading partners to exchange drug product tracing information whenever there is a transaction that involves a change of ownership of a drug product.<sup>12</sup> Tracing information currently must be

<sup>11</sup> § 581(22) of the FD&C Act.

<sup>12</sup> The DSCSA defines a “transaction” generally as “the transfer of [a drug] product between persons in which a change of ownership occurs.” § 581(24)(A) of the FD&C Act.

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provided for all drugs at the lot level, which means multiple units of the same drug in a lot can be traced as a single group.<sup>13, 14</sup> By 2023, tracing information must be provided at the package level, which is the smallest saleable unit of a drug product.<sup>15</sup>

The DSCSA also requires manufacturers, wholesale distributors, dispensers, and repackagers that repack and relabel drug products for further sale to provide tracing information to FDA or other appropriate Federal or State agencies in the event of a recall or for the purpose of investigating a suspect drug product or illegitimate drug product. Wholesale distributors, manufacturers, and certain repackagers generally must provide the drug product tracing information within 1 business day of a request.<sup>16</sup> Dispensers generally must provide the drug product tracing information within 2 business days of a request.<sup>17</sup> FDA has authority to take appropriate action against any person who does not comply with drug product tracing requirements.<sup>18</sup>

Drug product tracing information includes three components: transaction information, transaction history, and a transaction statement. Transaction information is composed of 10 elements that describe the transaction, including drug product information, such as the dosage form and National Drug Code (NDC).<sup>19, 20</sup> Transaction history is a statement that shows the transaction information for each prior transaction, such as the name of each previous trading partner going back to the manufacturer.<sup>21</sup> The transaction statement is a set of assertions about compliance with the DSCSA that the trading partner that is transferring ownership provides to the subsequent purchaser.<sup>22</sup> See Appendix A for complete definitions.

Third-party logistics providers are not required by the DSCSA to exchange drug product tracing information because they do not take ownership of the drug product. By definition, a 3PL only physically possesses a drug product on behalf of a trading partner.<sup>23</sup>

<sup>13</sup> § 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act. 21 CFR § 210.3(b)(10).

<sup>14</sup> The DSCSA requires drug product tracing information at the package level (i.e., the smallest saleable unit of a drug product) by 2023. §§ 582(g) and 581(11) of the FD&C Act.

<sup>15</sup> § 582(b)(1), (c)(1), (d)(1), (e)(1), and (g)(1) of the FD&C Act.

<sup>16</sup> § 582(b)(1)(B), (c)(1)(C), and (e)(1)(C) of the FD&C Act.

<sup>17</sup> § 582(d)(1)(D) of the FD&C Act.

<sup>18</sup> §§ 301(t) and 303(a) of the FD&C Act.

<sup>19</sup> § 581(26) of the FD&C Act.

<sup>20</sup> Drugs are identified using NDCs—unique, three-segment numbers that serve as universal product identifiers for drugs. The segments identify (1) the firm that manufactures, distributes, or repackages the drug product (i.e., the “labeler”); (2) the specific strength, dosage form, and formulation of the product; and (3) the product’s package size. Definition available at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>.

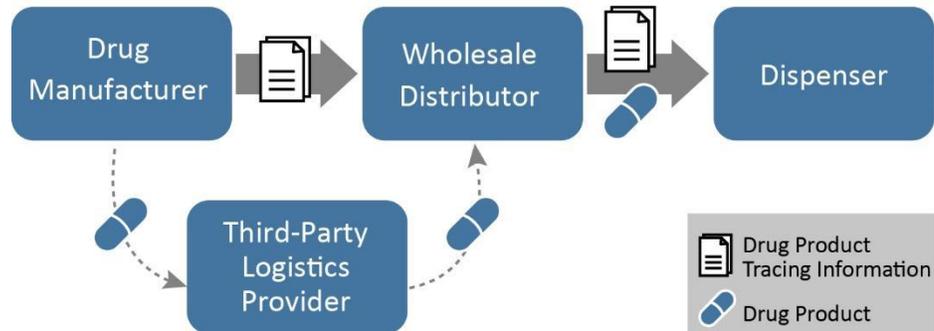
<sup>21</sup> § 581(25) of the FD&C Act.

<sup>22</sup> § 581(27) of the FD&C Act.

<sup>23</sup> § 581(22) of the FD&C Act.

As a result, drug product tracing information and associated drug products may move along different paths—tracing information is transmitted from trading partner to trading partner as they have ownership, while drug products physically move between trading partners and 3PLs that only take direct physical possession. Exhibit 2 illustrates the potential separate paths of drug product tracing information and drug products in the supply chain.

**Exhibit 2: Drug product tracing information and drug products may not always follow the same path through the supply chain.**



Source: OIG research, 2018.

### FDA Guidance

To facilitate implementation of drug product tracing requirements, the DSCSA required FDA to issue guidance to establish initial standards for the exchange of drug product tracing information.<sup>24</sup> FDA issued that guidance in November 2014.<sup>25</sup> This guidance outlines general parameters for the exchange of tracing information and gives trading partners latitude to report and exchange the required information in a variety of ways.<sup>26</sup>

FDA has released additional guidance related to the exchange of drug product tracing information. In March 2018, FDA issued guidance to assist trading partners in standardizing the data contained in tracing information.<sup>27</sup> In August 2017, FDA issued guidance to help stakeholders understand how the DSCSA requirements apply to various types of entities and to provide specific descriptions of entities that may be considered

<sup>24</sup> § 582(a)(2)(A) of the FD&C Act.

<sup>25</sup> FDA, *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information; Draft Guidance for Industry*, November 2014.

<sup>26</sup> *Ibid.*

<sup>27</sup> FDA, *Standardization of Data and Documentation Practices for Product Tracing; Draft Guidance for Industry*, March 2018.

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trading partners.<sup>28</sup> In December 2016, FDA issued guidance to help trading partners identify suspect drug products.<sup>29</sup>

## Methodology

We traced a purposive sample of 44 high-risk drug products billed to Medicare Part D by high-risk dispensers between January and May 2018. We purposively selected high-risk drug products and dispensers to test the drug product tracing information for drugs and dispensers at the greatest risk of counterfeiting and diversion. We traced these drug products backwards through the drug supply chain—from the dispenser back to the manufacturer—using lot-level drug product tracing information required by the DSCSA.

We considered high-risk drug products to be those at high risk of diversion, counterfeiting, or theft. We considered dispensers to be high-risk if they were independent dispensers that dispensed Medicare Part D drugs in combinations that could lead to severe drug-to-drug interactions in patients.

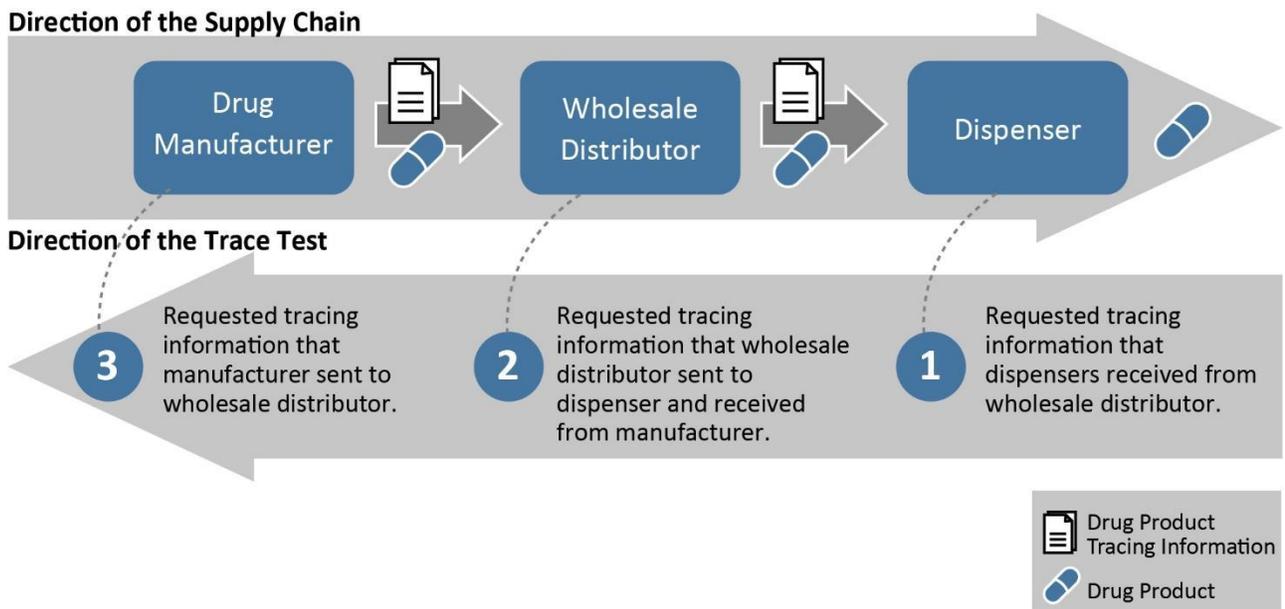
To select our purposive sample, we identified 10 high-risk drug products and then randomly selected Part D claims billed for those drugs by the high-risk dispensers. The 10 high-risk drug products included all NDCs affiliated with that drug product name, brand alternatives, and any FDA-approved generics. See the Detailed Methodology in Appendix B for a list of the 10 high-risk drug products. We sampled more than the number of claims needed to ensure that our final sample included at least 4 dispensers for each of the 10 high-risk drugs. Our final sample that we traced included 44 drug products.

For each drug product, we requested drug product tracing information from the dispensers and used it to identify the other trading partners in the supply chain. Next, from the identified wholesale distributors, we requested (1) tracing information they sent when they sold the drug and (2) tracing information they received when they purchased the drug. Lastly, from the identified manufacturers, we requested tracing information they sent when they sold the drug product. From each trading partner, we also requested supplemental business documents, including invoices and packing slips, that were associated with each transaction. Exhibit 3, on the next page, illustrates one example of how we requested tracing information to trace each selected drug product backwards through the supply chain.

<sup>28</sup> FDA, *Identifying Trading Partners Under the Drug Supply Chain Security Act; Draft Guidance for Industry*, August 2017.

<sup>29</sup> FDA, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification, Guidance for Industry*, December 2016.

**Exhibit 3: We traced each selected drug product backwards through the supply chain—from the dispenser to the manufacturer—using drug product tracing information.**



Source: OIG data collection methods, 2018.

We considered a drug product to be untraceable if a trading partner did not respond after three requests or if any data elements that we used to conduct tracing for the purpose of this study were missing or did not match between trading partners. We identified the data elements used to conduct tracing for this study’s purpose: the drug product name; the NDC, the lot number; the number of containers; the business name and address of the buyer; and the business name and address of the seller.<sup>30</sup> The drug product name, the NDC, the lot number, and the number of containers allowed us to confirm that we were tracing the correct drug product and transaction. The business name and address of the buyer and business name and address of the seller allowed us to confirm that we were tracing the correct trading partners. If any of these data elements were missing or mismatched, we identified where in the supply chain the transaction could not be confirmed. We also considered a drug product to be untraceable if a trading partner did not provide tracing information after three requests, because without documentation we were unable to confirm ownership and continue tracing the drug beyond that identified trading partner.

We also surveyed wholesale distributors and manufacturers to obtain additional information about their submitted documents and about their

<sup>30</sup> For the purpose of this study, we did not use the following elements to conduct tracing: the strength and dosage form; the container size; the transaction date; the shipment date; the direct purchase statement; and the receipt of direct purchase statement. OIG considered FDA’s comments on our categorization of these tracing-information elements.

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use of 3PLs. Finally, we interviewed FDA to understand how our missing or mismatched tracing information might impact its ability to oversee the drug supply chain.

For a detailed description of our methodology, see Appendix B.

## Limitations

Our findings represent only the trading partners in our sample and cannot be projected to the whole population of trading partners. Our findings also represent only the specific, selected drug products we traced for this study and cannot be projected to the whole population of these drugs. We based our findings on drug product tracing information that trading partners submitted and survey data that trading partners self-reported. We did not conduct onsite inspections to verify tracing information, and we did not independently verify survey responses.

## Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

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# FINDINGS

## **Ownership of 37 of 44 selected drug products could be traced through the supply chain using drug product tracing information**

Ownership for 37 of the 44 selected drug products could be traced through the supply chain using drug product tracing information. Using tracing information required by the DSCSA, we identified each trading partner that owned the drug products through the entire supply chain—starting with the dispensers, continuing to the wholesale distributors, and finally going back to the drug manufacturers. We were able to trace ownership because all the data elements of tracing information that we used to conduct tracing were available and matched between trading partners as expected.

*Untraceable drug products.* Seven drug products' ownership could not be completely traced through the supply chain using drug product tracing information. Six of these drug products could not be traced between the wholesale distributor and manufacturer because data elements used for tracing were missing or mismatched. Four drug products' ownership could not be traced back to the manufacturer because data elements were missing from the manufacturer's documents. Two other drug products' ownership could not be traced back to the manufacturer because a given data element—which *should* be the same on tracing information for both sides of the transaction—did not match. And in one instance, a drug product could not be traced because we could not confirm ownership of a drug product beyond the wholesale distributor we identified. The wholesale distributor refused to provide drug product tracing information, and without this information, we could not continue tracing the drug product beyond this wholesale distributor. Exhibit 4, on the next page, shows the seven selected drug products and the reasons their ownership could not be traced.

**Exhibit 4: Ownership of seven selected drug products could not be traced because data elements were missing or mismatched or because a trading partner did not respond.**

Count	Drug	Buyer Business Address				Number of Containers	Did Not Provide Tracing Information
		Street Address	City	State	ZIP Code		
1	Abilify						Wholesale Distributor
2	Humira	Missing					
3	Humira	Missing			Mismatched		
4	Humira	Missing	Mismatched		Mismatched		
5	Humira	Missing	Mismatched	Mismatched	Mismatched		
6	Spiriva					Mismatched	
7	Spiriva					Mismatched	
<b>Total</b>		<b>4</b>				<b>2</b>	<b>1</b>

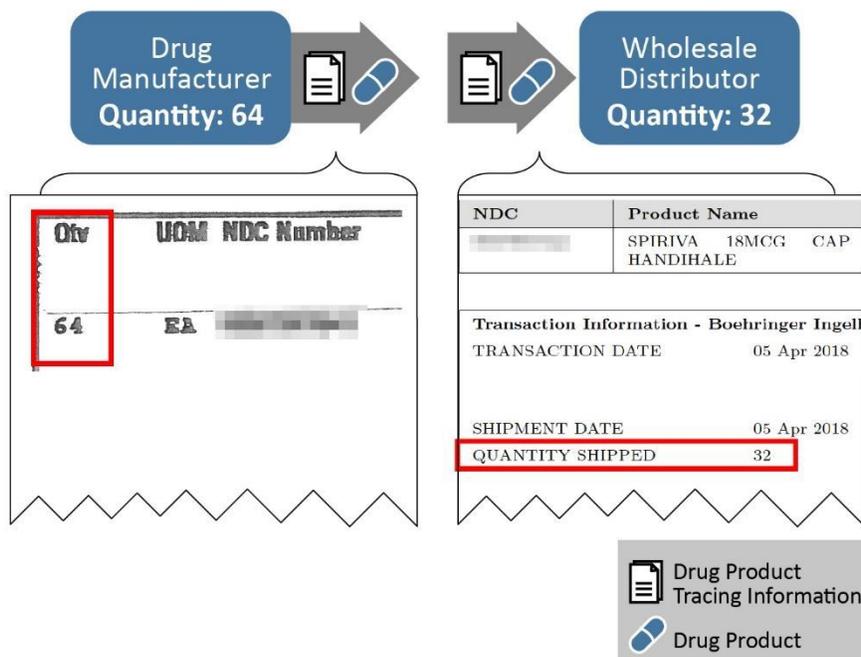
Source: OIG analysis of submitted drug product tracing information, 2019.

For the four Humira drug products that could not be traced because of missing information, the tracing documents that the manufacturer provided were missing the street addresses for the wholesale distributors. These four drug products came from one manufacturer and went to four different wholesale distributors. For each of these drug products, the manufacturer’s documents were missing the street address for the corresponding wholesale distributor. The street address is the most specific component of the DSCSA-required business address for a trading partner. Other necessary components of a business address include city, State, and ZIP Code. For three of the four drugs, one or more of these components on the manufacturer’s tracing information did not match the information that the wholesaler distributors provided for their business locations. Without having accurate information about the wholesale distributors’ business addresses on the manufacturer’s tracing documents, FDA or other investigators would not be able to immediately trace a drug’s path through the supply chain. To conduct their onsite investigations, they would first have to obtain additional information to determine where the wholesale distributors are located. This could cause delays in potentially time-sensitive investigations, such as investigating products that are suspected of being tampered with or having other quality issues.

Two Spiriva drug products could not be traced because of mismatched tracing information. In both instances, the number of containers listed on the tracing information provided by the manufacturer did not match the

number of containers listed on tracing information provided by the wholesale distributor. These two drug products came from one manufacturer and went to two different wholesale distributors. The number of containers that trading partners report should be the same on both sides of a transaction. But for both of these drug products, the manufacturer's documents reported a higher number of containers sold than the two wholesale distributors' documents reported that they each purchased. Exhibit 5 provides an example of one of the drug products for which the number of containers did not match on tracing information.

**Exhibit 5: The number of containers did not always match on drug product tracing information exchanged between trading partners.**



Source: OIG analysis of submitted drug product tracing information, 2019.

To better understand why these two mismatches may have occurred, we reviewed (when available) supplemental documents, including invoices and packing slips. For both drug products, we believe the mismatches were likely caused by the manufacturer and wholesale distributors defining and counting containers differently. For example, for one of the drug products, the manufacturer may have listed each *container* in a shipment (64), while the wholesale distributor may have listed the total number of *cases* holding the containers (32) in the shipment. In the event of an investigation or recall, such mismatches could delay investigators in accounting for and removing all illegitimate drug products in the supply chain. FDA staff reported that it is critical to identify all illegitimate drug products quickly to ensure that these harmful drugs are not dispensed.

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Finally, ownership of one drug product could not be traced because the wholesale distributor refused to submit drug product tracing information to OIG. This wholesale distributor, which purchased the drug directly from the manufacturer, stated that it would not supply drug product tracing information because complying with the DSCSA's requirements was too time-consuming. Without being able to review the wholesale distributor's tracing information or supplemental business documents, we could not continue tracing or make further conclusions about this drug product. We have referred this wholesale distributor to FDA for appropriate action.

Missing and mismatched drug product tracing information may signify a problem with a drug product—for example, that the drug might be suspect or illegitimate. If a drug product is suspect, trading partners must quarantine, investigate, and verify whether the drugs are legitimate.<sup>31</sup> Drugs are considered suspect if there is reason to believe that, among other things, the drug is potentially counterfeit, diverted, or stolen, or potentially the subject of a fraudulent transaction.<sup>32</sup> A drug is illegitimate if credible evidence shows that, among other things, the drug is counterfeit, diverted, stolen, or the subject of a fraudulent transaction.<sup>33</sup> Indeed, FDA guidance notes that missing tracing information for a drug product may indicate that the drug product is suspect or illegitimate.<sup>34</sup> Additionally, mismatched information, such as number of containers, may delay investigations or prompt a quarantine or recall.

Mismatched tracing information also may have implications in the future when the DSCSA requires the electronic interoperable exchange of drug product tracing information.<sup>35</sup> Specifically, for some data elements, like number of containers and the associated container size, mismatched information may lead trading partners to inappropriately identify a drug product as suspect. FDA released draft guidance intended to assist trading partners in standardizing the data contained in drug product tracing information.<sup>36</sup> In this guidance, FDA recommended that the number of containers should reflect the quantity of individual saleable units of a drug product with the same lot number included in a transaction and that the

<sup>31</sup> § 582(b)(4)(A)(i), (c)(4)(A)(i), (d)(4)(A)(i), and (e)(4)(A)(i) of the FD&C Act.

<sup>32</sup> § 581(21) of the FD&C Act.

<sup>33</sup> § 581(8) of the FD&C Act.

<sup>34</sup> FDA, *Drug Supply Chain Security Act Implementation: Identification of a Suspect Product and Notification Guidance for Industry*, December 2016, p. 5. Accessed at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf> on March 29, 2019.

<sup>35</sup> § 582(g)(1) of the FD&C Act.

<sup>36</sup> FDA, *Standardization of Data and Documentation Practices for Product Tracing; Draft Guidance for Industry*, March 2018. Accessed at <https://www.fda.gov/media/111451/download> on December 4, 2019.

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container size should reflect the packaging configuration of the individual saleable unit, and not larger shipping units such as a box, case, or tote.<sup>37</sup>

*Traceable drug products.* For the 37 selected drug products we successfully traced ownership of, we identified 23 drugs that were missing or had mismatched tracing information that is required by the DSCSA but not used to conduct tracing for our analysis. Fifteen of these selected drug products had missing or mismatched strength and/or dosage form. Previous OIG work also found strength and dosage form to be missing.<sup>38</sup> Trading partners included in these previous OIG studies noted that they felt this information was not needed on tracing documents because it was already represented in the NDC.<sup>39, 40</sup> See Appendix C for a summary of missing or mismatched data elements that we did not use to trace ownership of selected drug products.

Transaction date was also frequently mismatched or missing from tracing documents. Seven of the 37 traceable drug products had mismatched transaction dates, and 2 were missing transaction date. Most transaction date mismatches were different by only 1 day. FDA staff explained that trading partners may define “transaction date” differently—some may use shipping date, some the invoice-paid date, and some the date on which the payment was received.

Differences among strength and dosage form and transaction date on tracing documents may be a result of clerical errors, or they could indicate a more serious problem like an illegitimate drug product. According to two trade industry groups familiar with data exchange, clerical errors may occur because trading partners typically populate tracing documents with data from their internal systems rather than passing the exact data received from

<sup>37</sup> FDA, *Standardization of Data and Documentation Practices for Product Tracing; Draft Guidance for Industry*, March 2018, p. 8. Accessed at <https://www.fda.gov/media/111451/download> on December 4, 2019.

<sup>38</sup> OIG, *Drug Supply Chain Security: Wholesalers Exchanging Most Tracing Information*, OEI-05-14-00640, September 2017; OIG, *Drug Supply Chain Security: Dispensers Received Most Tracing Information*, OEI-05-16-00550, March 2018.

<sup>39</sup> Ibid.

<sup>40</sup> Drugs are identified using NDCs—unique, three-segment numbers that serve as universal product identifiers for drugs. The segments identify (1) the firm that manufactures, distributes, or repackages the drug product (i.e., the “labeler”); (2) the specific strength, dosage form, and formulation of the product; and (3) the product’s package size. Definition available at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>.

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**Unlike ownership, the physical movement of 21 of 44 selected drug products could not be traced through the supply chain using drug product tracing information**

the previous trading partner.<sup>41, 42</sup> In draft guidance, FDA recognizes that clerical errors may occur, but says that trading partners should resolve them as quickly as possible and that this resolution may include immediately contacting the trading partner that provided the tracing information.<sup>43</sup> If clerical errors cannot be resolved, it could be a sign of more serious problems with the drug product.

Unlike ownership, the physical movement of 21 of the 44 selected drug products through the supply chain could not be determined using drug product tracing information. To identify a drug's complete physical movement through the supply chain, information is needed about both the shipping location for the trading partners that own the drug and the companies that store or ship drugs on behalf of the owners, also known as third-party logistics providers (3PLs). However, the DSCSA does not require that trading partners include a shipping address on tracing information. And because the DSCSA is tied to ownership and not physical location, it does not require 3PLs to be listed on tracing information.

Knowing a drug's physical movement through the supply chain expedites investigations by FDA, State, and other investigators and helps them ensure that adulterated or mishandled drug products do not end up in the drug supply. Before the DSCSA was passed in 2013, FDA staff testified to Congress that if FDA does not know a drug's physical movement through the supply chain, it must reconstruct the chain by asking trading partners and their contracted 3PLs for the information when a potentially dangerous drug enters the supply chain. FDA staff testified that this request-and-reply process takes time, which delays these drugs from being removed from the supply chain.<sup>44</sup> FDA staff echoed this in a 2019 interview with OIG, stating that shipping location and 3PL information is critical in determining where in the supply chain an illegitimate product was introduced or where diversion occurred.

<sup>41</sup> Pharmaceutical Distribution Security Alliance (PDSA) public comment, *Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act; Public Meetings; Request for Comments*, Docket No. FDA-2017-N-357, May 1, 2018, pp. 3-4. Accessed at <https://www.regulations.gov/document?D=FDA-2018-D-0688-0008> on March 31, 2019.

<sup>42</sup> Healthcare Distribution Alliance public comment, *Comments to Standardization of Data and Documentation Practices for Product Tracing; Draft Guidance for Industry*, Docket No. FDA-2018-D-0688, April 30, 2018, p. 5. Accessed at <https://www.regulations.gov/document?D=FDA-2018-D-0688-0005> on March 31, 2019.

<sup>43</sup> FDA, *Standardization of Data and Documentation Practices for Product Tracing; Draft Guidance for Industry*, March 2018, p. 14. Accessed at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM598734.pdf> on April 19, 2019.

<sup>44</sup> *Securing our Nation's Prescription Drug Supply Chain: Hearing Before the Subcommittee on Health of the Committee on Energy and Commerce House of Representatives*. 113<sup>th</sup> Cong. (2014).

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## **Shipping location for trading partners was not available on drug product tracing information for nearly half of selected drug products**

Nineteen of 44 selected drug products did not always include the shipping address for each owner in the supply chain as part of the tracing information. Trading partners reported that the addresses on their tracing information reflected only business facilities (e.g., corporate, headquarters, or billing facilities), not shipping locations. In contrast, trading partners for the remaining 25 selected drug products reported listing addresses that reflected shipping locations, including storage facilities only or addresses that reflected both storage and business facilities.

The 19 drug products without a shipping address were associated with only a few trading partners. Thirteen of these drug products—owned by one wholesale distributor—did not have the wholesale distributor’s shipping address on documents supplied to buyers. Five drug products—four of which were owned by one manufacturer—did not have the manufacturer’s shipping address on documents supplied to buyers. One drug product lacked shipping addresses for both the manufacturer and the wholesale distributor. See Appendix D for additional information about tracing information not including trading partners’ shipping locations.

During an investigation, shipping addresses can be used by FDA or other appropriate Federal or State officials to identify where drug products were physically located. In draft guidance, FDA generally recommended that trading partners include their shipping addresses on tracing information.<sup>45</sup> When trading partners’ shipping addresses are not listed on tracing information, investigators need to request additional documents, like invoices and packing slips, to determine the location. This takes additional time and effort and can delay an investigation to locate suspect or illegitimate drug products and ensure that they are not dispensed to patients.

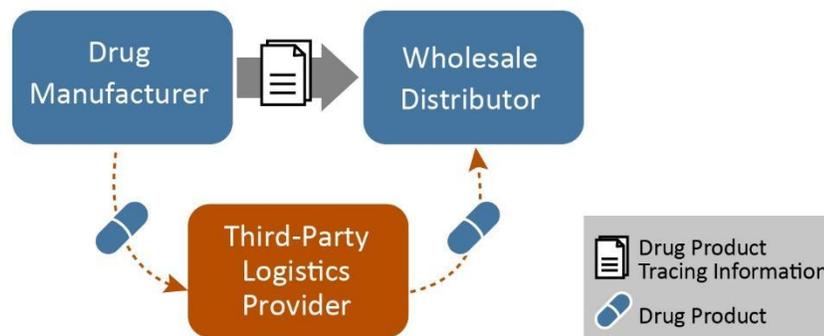
## **Drug product tracing information did not always include—nor is it required to include—a record of all third-party logistics providers that took possession of drugs**

Third-party logistics providers that handled—but did not own—selected drug products were not always listed on drug product tracing information. The DSCSA does not require 3PLs to be listed on tracing information because they do not own the drugs, nor does the DSCSA provide FDA with the authority to require that 3PLs be listed on tracing information. For 15 of the 44 selected drug products, trading partners reported that they

<sup>45</sup> FDA, *Standardization of Data and Documentation Practices for Product Tracing; Draft Guidance for Industry*, March 2018, pp. 9-10. Accessed at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM598734.pdf> on April 19, 2019.

contracted with a 3PL to store or ship the selected drug products. When 3PLs are present in the supply chain, tracing information and drug products move along different paths: tracing information moves from one trading partner to the next trading partner, whereas the drugs move between trading partners and 3PLs. When 3PLs are not listed on tracing information, a drug's complete physical path through the supply chain cannot be determined. See Exhibit 6 for an illustration of how the physical movement of drugs through 3PLs differs from the movement of drug product tracing information that moves from one trading partner to the next when the drug transfers ownership. Although the DSCSA does not require trading partners to include the 3PL on tracing information, 8 of these 15 drug products included a record of the 3PL on tracing information. See Appendix D for additional information about which drug products did not list 3PLs on the tracing information.

**Exhibit 6: Third-party logistics providers handle drug products but are not always listed—and are not required to be listed—on drug product tracing information.**



Source: OIG analysis of submitted drug product tracing information, 2019.

When the presence of a 3PL is not reflected on tracing information, there is a break in the record of the drug's physical path through the supply chain. In other words, a drug's complete physical movement through the supply chain cannot be determined using tracing information alone.<sup>46</sup> This could delay FDA's oversight efforts. FDA and other Federal and State investigators would need to request additional documents from trading partners, as well as from 3PLs, to (1) determine the 3PLs that handled the drug product and (2) reconstruct the drug's physical path through the supply chain. Moreover, FDA staff have stated that each time a drug product changes possession, it presents an opportunity for the drug to be mishandled or

<sup>46</sup> FDA must publish regulations establishing national standards for 3PL licensure. The regulations must require 3PLs to maintain written policies and procedures that address the storage, shipment, and distribution of drug products, among other things. § 584 of the FD&C Act.

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stored improperly, which can compromise the drug's safety and integrity. If this information were present on tracing information, it could help investigators more quickly identify where a drug product may have been compromised, determine where it is located, and then ensure it is removed from the supply chain.

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# CONCLUSION AND RECOMMENDATIONS

If potentially harmful drugs enter the drug supply chain, investigators from FDA, the State(s), and elsewhere will need complete information about the trading partners that bought and sold the drug products and about the drug's physical movement through the supply chain. Knowing which trading partner owns a drug, where it is in the supply chain, and where it has been can help investigators do the following: ensure the drug's removal from the supply chain; identify breaches; and protect patients from the effects of dangerous, ineffective, and illegitimate drugs.

The DSCSA established a system to trace drug product ownership through the supply chain to ensure the security of the drug supply. We found that on the whole, drug product tracing information for 44 high-risk drug products we reviewed could be used to trace ownership through the supply chain. However, we also found that tracing information could not be used to identify the physical movement of about half of selected drug products through the supply chain.

We offer FDA several recommendations as it continues to implement the DSCSA. FDA should:

## **Follow up with the wholesale distributor that did not provide tracing information to OIG**

One wholesale distributor did not provide drug product tracing information in response to our request. We provided FDA with the wholesaler distributor's name. This wholesale distributor might benefit from technical assistance. We recommend that FDA communicate with this trading partner to ensure that it understands the DSCSA requirements for wholesale distributors. If FDA finds that this wholesale distributor has not complied with the requirements of the DSCSA, FDA should take appropriate steps to ensure compliance.

## **Provide educational outreach to trading partners about required drug product tracing information and data standardization guidelines**

FDA should provide educational outreach to trading partners to make sure they are aware of: (1) their responsibilities to provide complete drug product tracing information to their subsequent trading partners and (2) FDA's guidance about data standardization among drug product tracing information. In addition to educating all trading partners, FDA should specifically educate manufacturers about the two tracing-information elements we found to be missing or mismatched: the trading partner's complete address and the number of containers of the drug product. FDA also should conduct outreach with trading partners about the

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recommendations it made in guidance for data elements to be standardized to enable interoperable exchange of tracing information. To do so, FDA could provide outreach by holding webinars, creating a Frequently Asked Questions document, or speaking at conferences targeted at specific types of trading partners.

**Seek legislative authority to include information about a drug product’s complete physical path through the supply chain on drug product tracing information**

Knowing the physical movement of a drug through the supply chain is important for ensuring that adulterated or mishandled products do not enter the supply chain. Because of this, FDA should seek legislative authority—whether through an amendment to the DSCSA or through rulemaking—to include information about a drug product’s physical movement through the supply chain on drug product tracing information. Information about a drug’s physical movement could include, but is not limited to, the shipping locations of trading partners and the identities and addresses of third-party logistics providers that ship or store drugs on behalf of trading partners.

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# AGENCY COMMENTS AND OIG RESPONSE

FDA concurred with all three of our recommendations and described steps to implement each.

In response to our first recommendation, FDA plans to communicate with the wholesale distributor that did not provide tracing information to OIG. FDA also plans to make resources available to help this trading partner better understand its obligations under the DSCSA.

FDA says that to address our second recommendation, it intends to conduct targeted outreach to small wholesale distributors. FDA reported that it has heard concerns—particularly among small trading partners—about lack of knowledge regarding traceability requirements. FDA’s planned outreach activities include presenting at stakeholder meetings and conducting educational webinars and public meetings. We continue to recommend that—in addition to outreach with small wholesale distributors—FDA conduct outreach with manufacturers to educate them about the two tracing-information elements that we found to be missing or mismatched on manufacturers’ tracing documents.

In response to our third recommendation, FDA agreed that information about the physical custody of a drug product is important for investigating suspect or illegitimate drug products and said that it welcomes the opportunity to provide input to Congress. We recommend specifically that—to better protect the drug supply—FDA seek legislative authority to require the inclusion of information about the complete physical path of drug products through the supply chain.

For the full text of FDA’s response, see Appendix E.

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# APPENDIX A: Definitions from the Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA) generally defines product, manufacturer, repackager, wholesale distributor, and dispenser as follows:

## **Product**

The term “product” means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B.<sup>47</sup>

## **Manufacturer**

The person who holds a product’s FDA-approved application or license or, if a product is unapproved, the person who manufactures the product. It also includes a co-licensed partner or an affiliate of the application holder.<sup>48</sup>

## **Repackager**

A person who owns or operates an establishment that repacks and relabels a product or package for further sale or for distribution without a further transaction.<sup>49</sup>

## **Wholesale distributor**

Generally a person who engages in wholesale distribution, which is the distribution of a drug product to, or receipt of a drug product by, a person other than a consumer or patient.<sup>50</sup>

<sup>47</sup> § 581(13) of the FD&C Act.

<sup>48</sup> § 581(10) of the FD&C Act.

<sup>49</sup> § 581(16) of the FD&C Act.

<sup>50</sup> §§ 581(29) and 503(e)(4) of the FD&C Act.

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## Dispenser

A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.<sup>51, 52</sup>

## Third-party logistics provider

An entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have the responsibility to direct the sale or disposition of the product.<sup>53</sup>

The DSCSA generally defines transaction information, transaction history, and transaction statement as follows:

## Transaction information

The term “transaction information” means –

- (a) the proprietary or established name or names of the product;
- (b) the strength and dosage form of the product;
- (c) the National Drug Code (NDC) number of the product;
- (d) the container size;
- (e) the number of containers;
- (f) the lot number of the product;
- (g) the date of the transaction;
- (h) the date of the shipment, if more than 24 hours after the date of the transaction;
- (i) the business name and address of the person from whom ownership is being transferred; and

<sup>51</sup> § 581(3) of the FD&C Act.

<sup>52</sup> Physicians and other licensed health care practitioners who dispense drug products in the usual course of professional practice are exempt from DSCSA drug product tracing requirements. § 582(d)(5) of the FD&C Act.

<sup>53</sup> § 581(22) of the FD&C Act.

- 
- (j) the business name and address of the person to whom ownership is being transferred.<sup>54</sup>

### **Transaction history**

The term “transaction history” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.<sup>55</sup>

### **Transaction statement**

The “transaction statement” is a statement, in paper or electronic form, that the entity transferring ownership in a transaction –

- (a) is authorized as required under DSCSA;
- (b) received the product from a person that is authorized under the DSCSA;
- (c) received transaction information and a transaction statement from the prior owner of the product;
- (d) did not knowingly ship a suspect or illegitimate product;
- (e) had systems and processes in place to comply with verification requirements;
- (f) did not knowingly provide false transaction information; and
- (g) did not knowingly alter the transaction history.<sup>56</sup>

<sup>54</sup> § 581(26) of the FD&C Act.

<sup>55</sup> § 581(25) of the FD&C Act.

<sup>56</sup> § 581(27) of the FD&C Act.

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## APPENDIX B: Detailed Methodology

For this study, we traced a purposive sample of 44 high-risk drug products billed to Medicare Part D by high-risk dispensers. We traced these drug products backwards through the drug supply chain—from the dispenser to the manufacturer—using drug product tracing information required by the DSCSA.

### Sample Selection

We purposively selected these 44 drug products from Part D claims for high-risk drugs billed by high-risk dispensers between January 1, 2018 and May 31, 2018. We defined high-risk drug products as those that are high cost, in high demand, or have prior evidence of diversion, counterfeiting, or theft. We identified the following high-risk drug products:<sup>57</sup>

- Abilify
- Advair
- Crestor
- Enbrel
- Harvoni
- Humira
- Isentress
- Lantus
- Spiriva
- Truvada

Next, we defined high-risk dispensers as independent dispensers that dispensed drugs in combinations that could lead to severe drug-to-drug interactions in patients.<sup>58</sup> We concluded that such dispensers may be more likely to engage in other questionable business practices. We assigned each dispenser a score based on the relative risk of its dispensing patterns.

To select the purposive sample, for each of the high-risk drug products, we identified high-risk dispensers that billed for the selected drug products. We sorted the dispensers from high to low risk score. We then randomly selected a Part D claim for the drug product from the dispensers with the top 20 risk scores for each drug product. Next, we contacted the dispensers

<sup>57</sup> When a dispenser billed for a generic version of the brand-name drug, we included the generic drug in our selection.

<sup>58</sup> We used the National Council of Prescription Drug Program's definition of "independent" pharmacies as dispensers that had one to three pharmacy locations.

with the four highest risk scores and requested tracing information for the drug on their respective Part D claims. If dispensers did not respond, we contacted the next dispenser on the list.<sup>59</sup> We oversampled to ensure that our final sample included about four dispensers associated with claims for each high-risk drug product. Our final sample included 44 drug products billed and dispensed by unique dispensers.<sup>60</sup> See Exhibit 7 for the number of drug products in our final sample.

**Exhibit 7: The final sample included 44 drug products billed for and dispensed by unique dispensers.**

Drug product name	Number of drug products
Abilify	5
Advair	4
Crestor	5
Enbrel	4
Harvoni	6
Humira	5
Isentress	3
Lantus	4
Spiriva	4
Truvada	4
<b>Total</b>	<b>44</b>

Source: OIG sampling Medicare Part D claims and analysis, 2018.

**Traceability Test**

To trace drug products backwards through the drug supply chain, from each of the 44 dispensers, we requested drug product tracing information associated with the Part D claim for the selected high-risk drug product. From this information, we determined the dispenser’s supplier (i.e., wholesale distributor). From the wholesale distributor we identified, we requested two sets of drug product tracing information: (1) documents that it sent for the sale of the drug product and (2) documents that it received

<sup>59</sup> Our final selection for each of the 10 high-risk drug products does not always include 4 claims associated with high-risk dispensers. For some drug products, dispensers responded to our request after we had already contacted the next dispenser on the ranked list.

<sup>60</sup> We contacted 55 dispensers; 9 did not provide tracing information and did not respond to followup inquiries.

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from the purchase of the drug product (e.g., from the manufacturer).<sup>61</sup> Lastly, from the manufacturer we identified, we requested the tracing documents that it sent for the sale of the drug product.

We used the submitted drug product tracing information to trace drug products until either (1) the drug supply chain successfully ended at the manufacturer or (2) the supply chain became untraceable. A supply chain became untraceable if data elements of the transaction information that we reviewed to determine traceability were missing or did not match between trading partners. If a trading partner did not submit tracing information after three requests, we could not confirm ownership of the selected drug in that supply chain and could not continue tracing that drug product. We were able to trace 43 of 44 selected drug products through the supply chain. Our traceability test included 73 trading partners—44 dispensers, 16 wholesale distributors, and 13 manufacturers. It did not include any repackagers.

We recorded all data elements from the drug product tracing information for comparison across trading partners. For the purpose of this study, we used the following data elements to conduct tracing: the drug product name; the NDC; the lot number; the number of containers; the business name and address of the buyer; and the business name and address of the seller. Data elements we did not use to conduct tracing for this study included: the strength and dosage form; the container size; the transaction date; the shipment date; the direct purchase statement; and the receipt of direct purchase statement. We used the drug product name, the NDC, and the lot number to confirm that we were tracing the correct drug product on each side of a transaction. Using the number of containers, we verified that all selected drug products were accounted for in the drug supply chain. We used the business name and address to confirm that we accurately had identified the trading partners on both sides of a transaction. For each transaction, we recorded all of the data elements from documents the seller sent and the buyer received. We then compared these elements to determine whether any were missing or did not match between trading partners.

We also requested invoices and packing slips associated with the sale and purchase of the drug product, if available. We collected these supplemental business documents to verify that we received the correct drug product tracing information for the selected drug product. We also reviewed these documents to identify any possible evidence of tampering, which can indicate fraud or diversion.

<sup>61</sup> The supply chains for only five drug products included more than one wholesale distributor. In these cases, we traced the drugs through all wholesale distributors in the supply chain back to the manufacturer.

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## Surveys and Structured Interview

To address our second objective, we surveyed wholesale distributors and manufacturers to gather additional information about addresses on their drug product tracing information and about their use of 3PLs. Specifically, we asked whether their addresses reflected business facilities (e.g., corporate, headquarters, or billing facilities) or product storage facilities (e.g., warehouse or receiving facilities), and whether those addresses represented the drug product's shipping location. We also asked whether and for what purposes they used a 3PL. We received responses from 15 wholesale distributors and 13 manufacturers, a 100-percent response rate.<sup>62</sup>

We also conducted a structured interview with FDA to determine how issues that OIG identified with drug product traceability and drug product tracing information affect FDA investigations of drug product recalls and illegitimate drug products.

<sup>62</sup> We did not survey the wholesale distributor that did not respond to our request for drug product tracing information.

# APPENDIX C: Missing or Mismatched Data Elements That Were Not Used To Trace Ownership

Drug product tracing information for 23 selected drug products had missing and/or mismatched tracing information that we did not use to trace ownership through the supply chain.

Count	Drug	Strength	Dosage Form	Container Size	Transaction Date	Shipment Date	Receipt of Direct Purchase Statement
1	Abilify						Missing
2	Abilify						Missing
3	Advair	Missing*	Missing				
4	Advair	Missing*	Missing				
5	Advair	Missing*	Missing				
6	Advair	Missing*	Missing				
7	Crestor		Missing				
8	Enbrel	Mismatched	Mismatched		Mismatched	Mismatched	
9	Enbrel	Mismatched	Mismatched		Mismatched		
10	Enbrel	Mismatched	Mismatched	Mismatched	Mismatched		
11	Enbrel	Mismatched	Mismatched				
12	Harvoni	Missing					
13	Harvoni	Missing					
14	Humira			Mismatched			
15	Isentress				Mismatched		
16	Isentress				Mismatched		
17	Isentress				Mismatched		
18	Lantus		Missing				
19	Lantus		Missing	Mismatched	Mismatched		
20	Lantus		Missing				
21	Spiriva				Missing	Missing	
22	Spiriva				Missing	Missing	
23	Truvada		Missing				
<b>Total</b>		<b>10</b>	<b>13</b>	<b>3</b>	<b>9</b>	<b>3</b>	<b>2</b>

\* Missing unit of measure, such as mg.<sup>63</sup>

Source: OIG analysis of drug product tracing information, 2019.

<sup>63</sup> Strength should include the amount of the active ingredient and the unit of measure. FDA, *Standardization of Data and Documentation Practices for Product Tracing; Draft Guidance for Industry*, March 2018, p. 7. Accessed at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM598734.pdf> on March 31, 2019.

# APPENDIX D: Shipping Locations and Third-Party Logistics Providers Not Included on Tracing Information

Drug product tracing information for 21 selected drug products did not include a trading partner’s shipping location, a record of the presence of a third-party logistics provider (3PL) in the supply chain, or both.

Count	Drug	Trading-Partner Shipping Location	Record of a 3PL
1	Abilify	Not included	Included
2	Abilify	Not included	Included
3	Advair	Not included	Not included
4	Advair	Not included	Not included
5	Enbrel	Included	Not included
6	Enbrel	Not included	No 3PL in supply chain
7	Harvoni	Not included	No 3PL in supply chain
8	Harvoni	Not included	No 3PL in supply chain
9	Humira	Not included	No 3PL in supply chain
10	Humira	Not included	Not included
11	Humira	Not included	No 3PL in supply chain
12	Humira	Not included	Not included
13	Humira	Not included	No 3PL in supply chain
14	Isentress	Not included	Included
15	Isentress	Not included	Not included
16	Isentress	Not included	Included
17	Lantus	Not included	No 3PL in supply chain
18	Lantus	Not included	No 3PL in supply chain
19	Lantus	Not included	No 3PL in supply chain
20	Truvada	Not included	No 3PL in supply chain
21	Spiriva	Included	Not included

Source: OIG analysis of survey responses, 2019.

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# APPENDIX E: Agency Comments



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

**DATE:** February 18, 2020

**TO:** Suzanne Murrin, Deputy Inspector General, Office of Evaluation and Inspections

**FROM:** Lisa Rovin, Director, Public Health Strategy and Analysis Staff  
FDA Office of Economics and Analysis *Lisa Rovin*

**SUBJECT:** Draft Report, OEI-05-17-00460

Attached are the Food and Drug Administration's general and technical comments to the Office of Inspector General's January 10, 2020 draft report entitled Ownership—But Not Physical Movement—of Selected Drugs Can Be Traced Through the Supply Chain. Thank you for the opportunity to provide feedback.

Attachments

**U.S. Food and Drug Administration**  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

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## FDA's General Comments

### **OIG Draft Report: Ownership – But Not Physical Movement – of Selected Drugs Can Be Traced Through the Supply Chain, OEI-05-17-00460**

FDA appreciates the opportunity to review and comment on OIG's draft report. We have the following comments regarding the draft recommendations from OIG.

#### **Follow up with the wholesale distributor that did not provide tracing information to OIG**

FDA concurs with this recommendation. After publication of this report, FDA will send a communication to this trading partner and make FDA resources available to help them better understand their obligations under the law.

#### **Provide educational outreach to trading partners about required drug product tracing information and data standardization guidelines**

FDA concurs with this recommendation. FDA has heard concerns from multiple stakeholders about the lack of awareness or understanding of DSCSA requirements by many trading partners, particularly those that may be small companies (i.e., small manufacturers, repackagers, wholesale distributors, and dispensers). FDA intends to conduct targeted outreach to small wholesale distributors, which would include the wholesale distributor in OIG's referral, to increase their understanding of DSCSA requirements. These efforts support FDA's broader stakeholder engagement that includes increased outreach and education to other small trading partners across the supply chain about DSCSA requirements. FDA activities include engagement of all trading partners, presenting at stakeholder meetings and conducting educational webinars and public meetings.

#### **Seek legislative authority to include information about a drug product's complete physical path through the supply chain on drug product tracing information**

FDA concurs with this recommendation. FDA agrees that knowledge of the physical custody of product as it is distributed in the U.S. is important when investigating suspect or illegitimate product and understands the product tracing requirements under the Drug Supply Chain Security Act are based only on change of ownership. FDA welcomes the opportunity to provide input to Congress on these potential legislative changes.

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# ACKNOWLEDGMENTS

Melissa Baker served as the team leader for this study, and Kayla Phelps served as lead analyst. Others in the Office of Evaluation and Inspections who conducted the study include Lauren Anderson. Office of Evaluation and Inspections central office staff who provided support include Clarence Arnold, Seta Hovagimian, Christine Moritz, and Mike Novello.

We also would like to acknowledge contributions of other Office of Inspector General staff, including Sara Bodnar, Robert Gibbons, and Peter Taschenberger.

This report was prepared under the direction of Thomas F. Komaniecki, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Laura Kordish and Kelly Waldhoff, Deputy Regional Inspectors General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at [Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).

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## **Office of Evaluation and Inspections**

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

## **Office of Investigations**

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## **Office of Counsel to the Inspector General**

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.