Dispenser Guide to Achieving

Drug Supply Chain Security Act Compliance

NABP
National Association of Boards of Pharmacy

1600 Feehanville Dr
Mount Prospect, IL 60056

1.847.391.4406
help@nabp.pharmacy

Table of Contents

Dispenser Guide to Achieving
Drug Supply Chain Security Act Compliance

Introduction

This guide was developed by the National Association of Boards of Pharmacy® (NABP®) to assist dispensers[1] in establishing processes to comply with the Drug Supply Chain Security Act (DSCSA) law enacted November 27, 2013. NABP has identified four operational imperatives recognized by industry and regulator collaborators, if implemented, result in DSCSA compliance, and minimize threats to patients. To protect patients most effectively, the processes and due diligence described in the guide are the same as, and additional to, what the law states.

Four Operational Imperatives to Achieve DSCSA Compliance and Minimize Threats to Patients

1. **Know your prescription drug suppliers (sources)**. They must be a *trading partner* that is *authorized* as defined in Section 581 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[2]
2. **Know where your product tracing, also known as transaction information (data), is being stored and how to access it**.
3. Know what suspect product is, how to **identify it,** how to **investigate it**, and **what to do if it is deemed illegitimate**.
4. **Develop, update, and adhere to robust prescription drug purchasing policies and procedures** (P&Ps) that accurately reflect your internal processes.

[1] All categories of pharmacies that dispense or administer prescription drugs defined in section 581 of the Drug Supply Chain Security Act (DSCSA).
[2] Also known as *authorized trading partner* (ATP).

Discussion

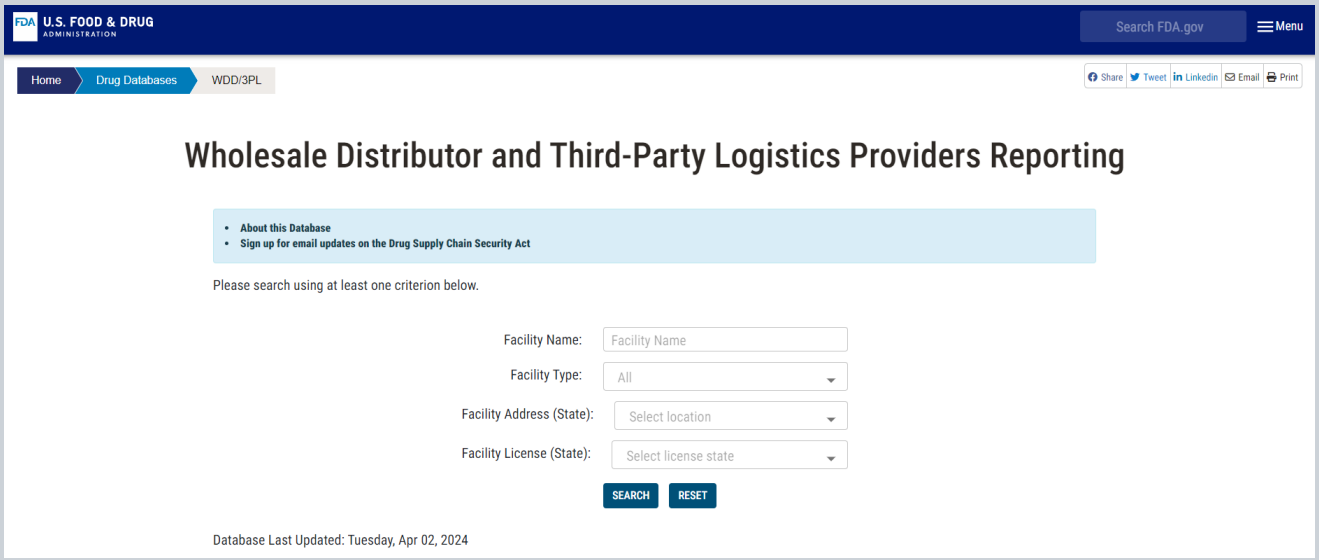
A. Only purchase and receive prescription drugs form authorized trading partners.

Manufacturers and Repackagers

- "Under section 510 of the FD&C Act, and part 207 (21 CFR part 207), with some limited exceptions, any person who owns or operates any establishment that manufactures, prepares, propagates, compounds, or processes drugs in the United States, or that are offered for import into the United States, must be registered with the FDA. Thus, under section 581(2)(A) of the FD&C Act, such manufacturer establishments must be registered in accordance with section 510 of the FD&C Act to be considered an authorized trading partner." Verify registration status by using the FDA Drug Establishment Current Registration database, *https://dps.fda.gov/decrs.*
- "An entity that falls within the definition of repackager in section 581(16)(A) of the FD&C Act 407 who repacks and relabels a product or package "for further sale" must comply with all 408 requirements under section 582(e) of the FD&C Act. Repackagers defined under section 409 581(16)(B) of the FD&C Act who repackage and relabel product "for distribution without a 410 further transaction" must comply with only section 582(e)(1)(B)(ii) and (e)(3) of the FD&C 411 Act.35." Verify registration status by using the FDA Drug Establishment Current Registration database, *https://dps.fda.gov/decrs.*
- Some states license manufacturers and repackagers that sell within and into their borders. Although this is not a DSCSA requirement, to comply with state regulations, dispensers must verify with states in which business is conducted if a manufacturer or repackager license is required for their trading partner.

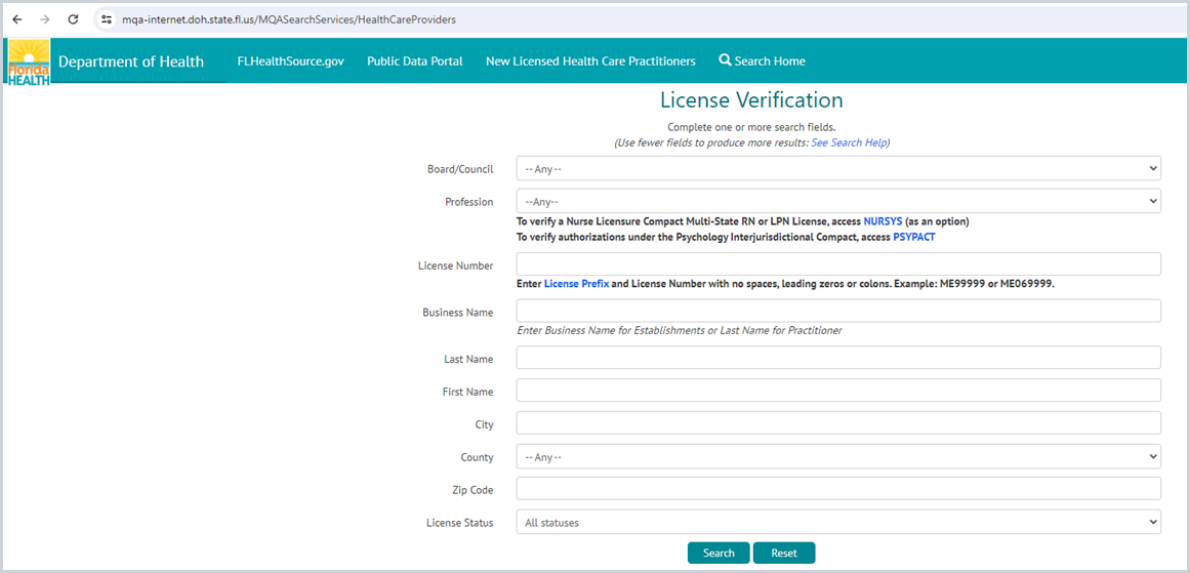
Wholesale Distributors and Third-Party Logistics Providers

- DSCSA requires wholesale distributors (WDs) and third-party logistics providers (3PLs) to report annually. Verify registration status by using the FDA Wholesale Distributor and Third-Party Logistics Providers Reporting database, *https://dps.fda.gov/wdd3plreporting*



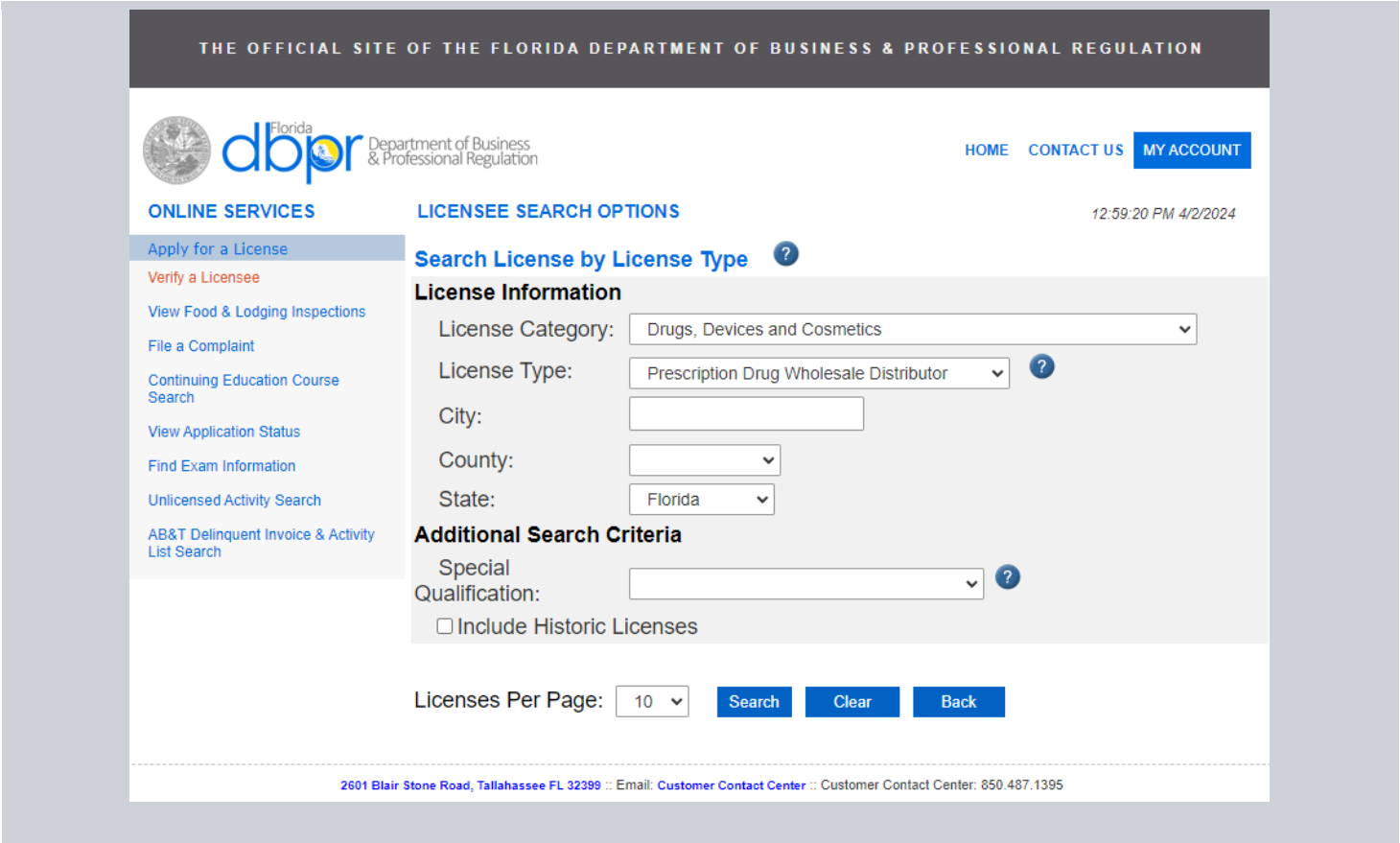
- DSCSA requires WDs and 3PLs to be licensed by their resident state and states into which they are distributing (both as applicable) or licensed as described in Section 583 and 584 of the FD&C Act.[3] Every state licenses WDs; approximately 40 states license them through their Board of Pharmacy (BoP) with other state agencies license the remainder.

  For example, the Florida Department of Health's BoP no longer licenses drug wholesalers, *https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders*



  The Florida Department of Business and Professional Regulation currently licenses WDs and 3PLs *https://www.myfloridalicense.com/wl11.asp?mode=2&search=LicTyp&SID=&brd=&typ=.*

[3] February 2, 2022, FDA published its proposed rule for the national standards for the licensing of prescription drug wholesale distributors and third-party logistics providers as required by sections 583 and 584 of the FD&C. When implemented the proposed rule will establish standards for all state and federal wholesale distributor licenses issued.



B. Conduct as many due diligence checks as necessary to protect your patients. Different suppliers may represent different levels of risk. This could be because of your relationship with them (eg, how frequently you buy from them) or their business model (eg, who they purchase from). For example, if your primary supplier purchases exclusively from manufacturers, your risk level is lower than average and fewer checks may be appropriate.

Example Possible Due Diligence Checks (non-exhaustive list)

- Check whether the suppliers' licenses have been disciplined by any state.
- Subscribe to US Department of Justice news and press releases, *https://public.govdelivery.com/accounts/USDOJ/subscriber/new*
- Subscribe to FDA press releases, *https://www.fda.gov/news-events/fda-newsroom/press-announcements*
- Request or require that suppliers only source their drugs exclusively and directly from the manufacturer or, alternatively, from a wholesale distributor that purchased exclusively and directly from the manufacturer. Fewer changes of ownership reduce the risks in the supply chain; consequently, the shortest distance from the manufacturer to the patient is the safest.
- Consider price or unique availability as warning signs for safety. Question prices that are not consistent with standard published rates. "If the price is too good to be true, it is [too good to be true]!" Alternatively, drugs in short supply are sometimes sold at extremely inflated prices. When purchasing a short supply drug, regardless of the price, ask the supplier how they were able to obtain the drug when other suppliers cannot.
- Request and examine the invoice of sale to the supplier for two pieces of information: some states require the state license of the purchaser (pharmacy, practitioner, wholesaler, etc) to be included, and some sellers require a Drug Enforcement Agency (DEA) registration number for purchasers. If either is included, this is an opportunity to verify the license and/or the DEA number of the purchaser, and to ensure the supplier is selling drugs that were purchased

using a wholesale distributor license and not another type of license held at their address (such as a pharmacy license).

- Require that drugs purchased from the seller were not previously sold under the following conditions:
  - A short-supply drug sold to you by a WD that purchased the drug from a pharmacy on an allocation by the wholesaler; and/or
  - Special limited-distribution or contract-priced drugs sold to a pharmacy and not for wholesale distribution (ie, long term care pharmacy pricing, hospital pricing, specialty pharmacy pricing).

Imperative 2: Know where your product tracing, also known as transaction information (data), is being stored and how to access it.

- Product tracing/transaction records must be maintained for at least six years. The dispenser's records may be maintained by a third party (like a WD) under a written agreement with the dispenser. Some drug WDs maintain transaction data for dispenser customers, but only for drugs they have sold to the dispenser. When entering into these agreements know that using a third party to maintain records does not excuse a dispenser from complying with the law.[4] Dispensers must still know if information is being accurately received, where it is stored, and how to access it in the event of a product trace request from state or federal agencies or investigating trading partners.
- Dispensers are not to accept ownership of a product, unless the previous owner prior to, or at the time of the transaction provides transaction history, transaction statement, and transaction information.[5] It is acknowledged that this information is not always received; however, it is a dispenser's responsibility to work with its trading partners to ensure the safe movement of product through the supply chain.

Imperative 3: Know what suspect product is, how to identify it, how to investigate it, and what to do if it is deemed illegitimate.

A. Know the definitions.

Definitions – Section 581 FD&C Act (DSCSA)
"(21) SUSPECT PRODUCT.—The term 'suspect product' means a product for which there is **reason to believe** [emphasis added] that such product— (A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans."
"(8) ILLEGITIMATE PRODUCT—The term 'illegitimate product' means a product for which **credible evidence** [emphasis added] shows that the product— (A) is counterfeit, diverted, or stolen; (B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is the subject of a fraudulent transaction; or"

[4] See section 582 (d)(1)(B) regarding agreements with third parties.

[5] As of November 27, 2023, transaction histories are not required. However, FDA recommends that trading partners continue to utilize them until they are successfully receiving electronic transaction information for each transaction and no later than the Stabilization Period.

(D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

B. Know the red flags.

Excerpt From the US FDA Guidance, Drug Supply "Chain Security Act Implementation: Identification of Suspect Product and Notification, Guidance for Industry, June 2021, including FDA's Suggestions for Identifying Suspect Products.

"A. Specific Scenarios That Could Significantly Increase the Risk of a Suspect Product Entering the Pharmaceutical Distribution Supply Chain

There may be situations involving trading partners where heightened vigilance would be appropriate. In addition, there could be identifiable characteristics of products that might increase the likelihood that they are suspect products. The following are examples of some specific scenarios that could significantly increase the risk of a suspect product entering the drug supply chain. Thus, trading partners should be particularly diligent when engaging in transactions that involve[6]:

Trading Partners and Product Sourcing

☐ Purchasing from a source new to the trading partner.

☐ Receiving an unsolicited sales offer from an unknown source. Trading partners might receive unsolicited offers or advertisements through an email, a fax, a telephone call, or an in-person sales call from a person or entity with whom they do not have an established business relationship.

☐ Purchasing on the Internet from an unknown source. Trading partners might be searching for a better price on the Internet or for a product that they cannot obtain from their usual source, and might be tempted to turn to a person or entity with whom they do not have an established business relationship.

☐ Purchasing from a source that a trading partner knows or has reason to believe has engaged in questionable business practices that could increase the risk of suspect product entering the supply chain, such as:

☐ A trading partner that has been involved in business transactions where they sold or delivered illegitimate product.

☐ A trading partner that has a history of problematic or potentially false transaction histories, such as those that contain misspelled words or incomplete information.

☐ A trading partner that is reluctant to provide a transaction history associated with the product being purchased, or does not do so in a timely manner. [Added*, the guidance document references "transaction history", however, some trading partners may be sharing EPCIS transaction data.*]

☐ A trading partner that provides transaction information, a transaction statement, and/or transaction history that appears to be incomplete or questionable.

Supply, Demand, History, and Value of the Product

☐ Product that is generally in high demand in the U.S. market.

☐ Product that is in higher demand because of its potential or perceived relationship to a public health or other emergency (e.g., antiviral drugs).

☐ Product that has a high sales volume or price in the United States.

☐ Product offered at a price that is "too good to be true."

☐ Product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs).

☐ Product that has been previously or is currently the subject of a drug shortage (see a list of current drugs in shortage at *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages*,

[6] See section 582(b)(4)(A)(i), (c)(4)(A)(i), (d)(4)(A)(i), and (e)(4)(A)(i) of the FD&C Act.

https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm, https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages).

☐ Product that has been or is the subject a public alert or announcement related to drug quality issued by a trading partner or FDA.

☐ Product that has been or is the subject of an FDA counterfeit or cargo theft alert (See *https://www.fda.gov/drugs/buying-using-medicine-safely/counterfeit-medicine* and *https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/cargo-thefts* for more information).

Appearance of the Product

☐ Appearance of a package or a container used for transport (e.g., case or tote) that seems questionable (e.g., it has a label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise).

☐ Package that exhibits unusual or excessive adhesive residue.

☐ Package that contains foreign identification features (such as a different drug identification number where a National Drug Code (NDC) number would be expected).

☐ Package that is missing information, such as the lot number or other lot identification, or the expiration date.

☐ Package that is missing security or anti-counterfeiting technologies normally featured on the FDA-approved product that are easily visible to the eye, such as holograms, color shifting inks, neckbands, or watermarks.

☐ Finished dosage form that seems questionable (e.g., it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints)."

"B. Recommendations on How Trading Partners Might Identify Suspect Product and Determine Whether the Product Is a Suspect Product as Soon as Practicable

The following are recommendations for trading partners, as applicable, on ways that they can expeditiously identify suspect product and determine whether the product is suspect (and, after investigation, whether it is illegitimate). In general, trading partners should exercise due diligence and shall only conduct business with authorized trading partners. Trading partners should discuss with each other any observations, questions, or concerns they have related to the status of a drug as a suspect product to aid them in determining whether the drug should be considered a suspect product. Because a product's manufacturer is usually the best able to assess the authenticity and quality of a product, a trading partner should consult with the manufacturer when conducting any investigation of suspect product. Trading partners should also contact regulatory authorities, law enforcement, or other available resources to aid in that determination when additional expertise is called for to make an accurate assessment of the status of a drug as asuspect product. If a trading partner receives a product in a secured transport container or sealed homogenous case, trading partners should examine the appearance of that container as recommended below. If trading partners observe anything questionable, they should take steps to ascertain whether the product inside the transport container is suspect. Strategies to identify suspect product include, but are not limited to, the following recommendations:[7]

☐ Be alert for offers of product for sale at a very low price or one that is "too good to be true."

☐ Closely examine the package and the transport container (such as the case or tote):

☐ To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or otherwise altered). If a trading partner receives a product in a secured transport container or sealed homogenous case, trading partners should examine the appearance of that container to see if anything about that appearance seems questionable, such as shrink wrap that has unexpected markings, or a seal that is broken, torn, or repaired. Such examinations may include:

☐ Seeing if the package or the transport container has changed since the last shipment of the same product type was received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received).

[7] See section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act.

☐ Seeing if product inserts are missing, do not correspond to the product, or are questionable in some way.
☐ For shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source.
☐ Closely examine the label on the package, and the label on the individual retail unit, if applicable, for:
☐ Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug.
☐ Any altered product information, such as smudged print or print that is very difficult to read.
☐ Misspelled words.
☐ Bubbling in the surface of a label.
☐ Lack of an "Rx only" symbol.
☐ Foreign language with little or no English provided.
☐ Foreign language that is used to describe the lot number.
☐ A product name that differs from the name that appears on the FDA-approved drug label or labeling.
☐ A product name that is the product name for a foreign version of the drug.
☐ A product that is transported in a case or tote, when not expected under the circumstances.
☐ Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container."

Real-World Cases That Demonstrate Opportunities for Identifying Suspect Products and the Impact to Patients When Left Unchecked.

Case Study 1: Counterfeit Gilead HIV Medication Being Distributed in the US

Background
In August 2021, Gilead Sciences, Inc, warned that tampered and counterfeit versions of its once-daily, single tablet HIV treatment regimen Biktarvy® (bictegravir 50 mg, emtricitabine 200 mg, and tenofovir alafenamide 25 mg tablets) and its HIV treatment and prevention medication Descovy® (emtricitabine 200 mg and tenofovir alafenamide 25 mg tablets) were in circulation within US drug distribution networks. Distributors not authorized by Gilead to sell Gilead-branded medicine sold the counterfeits to pharmacies where genuine Gilead bottles were tampered with by using a counterfeit foil induction seal or label and containing incorrect tablets. Working in communication with US FDA, Gilead alerted potentially impacted pharmacies to investigate the potential for counterfeit or tampered with Gilead medication sold by distributors not authorized by Gilead that may have been/or were currently within their recent supply and to remain vigilant to the potential for this to occur in the future. Gilead further cautioned that the authenticity and safety of Gilead-branded medicines are secure only when obtained directly through Gilead's authorized distributors.

Gilead later started its investigation into how the counterfeits entered the legitimate drug supply chain in September 2022 and identified two individuals selling the drugs through suppliers created solely to transact the counterfeit sales. These individuals sold the drugs to licensed distributors who then sold the drugs to pharmacies. In addition, individuals illegally purchased bottles of HIV medication from patients to create more counterfeits.

Sources
https://www.gilead.com/news-and-press/company-statements/gilead-warns-of-counterfeit-hiv-medication-being-distributed-in-the-united-states

https://www.gilead.com/news-and-press/company-statements/gilead-continues-efforts-to-halt-the-distribution-of-counterfeit-hiv-medications-and-protect-patient-safety

Discussion
It stunned the prescription drug industry that only two years before the November 27, 2023, DSCSA implementation date, counterfeiters were able to sell and introduce into wholesale distribution more than $250 million of counterfeit

HIV medication; Descovy and Biktarvy. The drugs were found at seventeen locations in 9 states, largely due to a willingness by purchasers to source products with questionable origins from trading partners who lacked authorization.

The authentic Descovy and Bitarvy were removed and replaced with counterfeits; therefore, the bottles displayed valid standardized numerical identifiers[8]. Gilead would have confirmed to anyone contacting them that they [Gilead] did issue the serial numbers. Dispensers must consider that verification processes and systems would not have detected the counterfeits because the identifiers were legitimate Gilead serial numbers. These dispensers therefore needed to follow their due diligence processes to detect the red flags prompting them to conduct product traces.

Most HIV medications are paid for by third parties including Medicaid, state health departments, and 340B programs[9] and are known to be diverted from patients back into the supply chain (WDs and pharmacies) which often makes them the subject of criminal cases. The investigation uncovered unauthorized drug wholesale distributors selling the drugs to pharmacies.

[8] A unique set of numbers comprised of a serial number and National Drug code number (NDC)

[9] Manufacturers participating in Medicaid agree to provide outpatient drugs to covered entities at significantly reduced prices. https://www.hrsa.gov/opa#:~:text=The%20340B%20Program%20enables%20covered,entities%20at%20significantly%20reduced%20prices.

Pedigree that Safe Chain sent to pharmacy

SAFE CHAIN SOLUTIONS, LLC

Drug Supply Chain Security Act Document Doc# 00000019202

(TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size:
BIKTARVY 30CT,
50/200/25 MG
NDC: 61958-2501-01

Reference Number: 01I40811
Document Type: Invoice
Reference Date: 01/08/21

Lot Number	Quantity	Unique Serial #
6400505A	3	
CDGXBA	1	
CCZCFA	1	

(TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES
Manufacturer's information:

SOLD TO:	SHIPPED TO:
Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Purchased & Ref :	Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref :
Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 01/07/21 PO#01211389	Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref : 01/08/21 RC#016349
Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Purchased & Ref : 01/08/21 01S36758001	Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Received & Ref : 01/08/21 01S36758001
Name: Address: Date Purchased & Ref :	Name: Address: Date Received & Ref :
Name: Address: Date Purchased & Ref :	Name: Address: Date Received & Ref :

Pedigree that Safe Chain sent to Gilead

SAFE CHAIN SOLUTIONS, LLC

Drug Supply Chain Security Act Document Doc# 00000019202

(TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size:
BIKTARVY 30CT,
50/200/25 MG
NDC: 61958-2501-01

Reference Number: 01I40811
Document Type: Invoice
Reference Date: 01/08/21

Lot Number	Quantity	Unique Serial #
6400505A	3	
CDGXBA	1	
CCZCFA	1	

(TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC
Manufacturer's information: 1800 WHEELER AVENUE LA VERNE,CA 91750

SOLD TO:	SHIPPED TO:
Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725 Date Purchased & Ref : 10/05/20 85160	Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725 Date Received & Ref : 10/05/20 85160
Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Purchased & Ref : 10/06/20 2719	Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref : 10/06/20 2719
Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 01/07/21 PO#01211389	Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref : 01/08/21 RC#016349
Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Purchased & Ref : 01/08/21 01S36758001	Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Received & Ref : 01/08/21 01S36758001
Name: Address: Date Purchased & Ref :	Name: Address: Date Received & Ref :

Authorized Distributors of Gilead products
https://www.gilead.com/purpose/medication-access/authorized-distributors

Atripla®, Biktarvy®, Complera®, Descovy®, Emtriva®, Genvoya®, Hepsera®, Odefsey®, Ranexa®, Stribild®, Truvada®, Tybost®, Vemlidy®, and Viread®

AmerisourceBergen Corporation d/b/a Cencora	Capital Wholesale Drug Co.	Cardinal Health
Dakota Drug	Dixon Shane LLC d/b/a R&S Northeast LLC	DMS Pharmaceutical Group
Drogueria Betances	J.M. Blanco, Inc., an AmerisourceBergen company	Louisiana Wholesale Drug Co.
McKesson Corporation	Morris & Dickson Co., LLC	N.C. Mutual Wholesale Drug Co.
Smith Drug Company	Value Drug Company	

Case Study 2: FDA warns consumers not to use counterfeit Ozempic (semaglutide) found in U.S. drug supply chain

Background

In December 2023, the US FDA informed the public it was investigating counterfeit Ozempic® (semaglutide) injection 1 milligram (mg) in the legitimate supply chain and that it had seized thousands of units of the product. It advised wholesale distributors, retail pharmacies, and health care practitioners and patients to check the product they received and to not distribute, use or sell products labeled with lot numbers NAR0074 and serial number 430834149057. Immediate testing of the seized products identified the use of counterfeit needles; therefore, making it impossible to determine their sterility. Five incidents of non-serious patient illness were reported after injecting counterfeit Ozempic.

Sources

https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-use-counterfeit-ozempic-semaglutide-found-us-drug-supply-chain

https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-use-counterfeit-ozempic-semaglutide-found-us-drug-supply-chain

https://nabp.pharmacy/news/blog/regulatory_news/counterfeit-ozempic-found-in-us-retail-pharmacy/

Discussion

The facts of this case spotlight a multitude of suspect product red flags identified by FDA in its June 2021 guidance, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry. While this list has been developed by FDA based on the current landscape, it is important to consider that new red flags regularly emerge.

☐ Purchasing from a source new to the trading partner.

☒ Receiving an unsolicited sales offer from an unknown source. Trading partners might receive unsolicited offers or advertisements through an email, a fax, a telephone call, or an in-person sales call from a person or entity with whom they do not have an established business relationship.

☒ A trading partner that provides transaction information, a transaction statement, and/or transaction history that appears to be incomplete or questionable.

☒ Product that is generally in high demand in the U.S. market.

☒ Product that has a high sales volume or price in the United States.

☒ Product that has been previously or is currently the subject of a drug shortage (see a list of current drugs in shortage at *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-shortages-and-discontinuations* and *https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm* for more information).

☒ Appearance of a package or a container used for transport (e.g., case or tote) that seems questionable (e.g., it has a label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise).

☒ Package that exhibits unusual or excessive adhesive residue.

☒ Finished dosage form that seems questionable (e.g., it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints).

☒ Be alert for offers of product for sale at a very low price or one that is “too good to be true.”

☐ Closely examine the package and the transport container (such as the case or tote):

☒ To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or otherwise altered). If a trading partner receives a product in a secured transport container or sealed homogenous case, trading partners should examine the appearance of that container to see if anything about that appearance seems questionable, such as shrink wrap that has unexpected markings, or a seal that is broken, torn, or repaired. Such examinations may include:

☒ Seeing if the package or the transport container has changed since the last shipment of the same product type was received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received).
☒ Seeing if product inserts are missing, do not correspond to the product, or are questionable in some way.

Exhibits

NABP National Association of Boards of Pharmacy

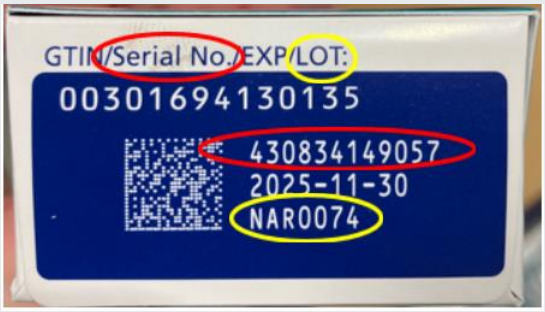
Programs Members Initiatives Meetings News & Resources About

Counterfeit Ozempic Found in US Retail Pharmacy

August 7, 2023
Categories: Recalls and Warnings

Novo Nordisk, the manufacturer of Ozempic® (semaglutide injection), is alerting consumers that a counterfeit version of Ozempic, which reportedly contained insulin glargine instead of semaglutide, was purchased in a retail pharmacy in the United States. Ozempic is a diabetes treatment that has gained widespread popularity as a weight loss drug, spurring a black market for the medication. In June 2023, United Kingdom reporters found Ozempic for sale on Facebook, and Nigerian authorities found fake Ozempic pens containing insulin in nine countries. Novo Nordisk advises retail pharmacies to always purchase semaglutide medications "through authorized distributors of Novo Nordisk and reliable sources" and shared a list of tips to help health care providers and patients recognize signs that a medication may be counterfeit when purchasing Ozempic or other semaglutide injection products.

https://www.novonordisk-us.com/media/news-archive/news-details.html?id=166119



Authentic Ozempic® Needle	Counterfeit Needle
	

Authentic Ozempic® Needle	Counterfeit Needle
	
What to look for in a genuine needle: • The paper tab on the needle is imprinted with the needle lot number (ME61216 in this case) • The blue area on the paper tab only contains the lot number, no other text • The inner needle cover is transparent • The paper tab states 'NovoFine® Plus'	**What to look for in a counterfeit needle:** • The paper tab on the needle is imprinted with the Ozempic® product carton lot number NAR0074 • The inner needle cover has a blue transparent color • The paper tab states 'NovoFine®'

Authentic Ozempic® Pens	Counterfeit Product
With Cap 	With Cap 
Without Cap 	Without Cap 

Authentic Ozempic® Carton	Counterfeit Carton
	

WHAT TO LOOK FOR: OZEMPIC® PEN AND CARTON

Genuine

- Genuine Novo Nordisk Ozempic® pens do not extend or increase in length when setting the dose.
- The dose dial window only shows intended doses:
    - On the pen intended to deliver 0.25/0.5 mg doses, it only shows -0-, 0.25 and 0.5 once dialed up to the intended doses
    - On the pen intended to deliver 1 mg dose, it only shows -0- and 1 mg once dialed up to the intended dose
    - On the pen intended to deliver 2 mg dose, it only shows -0- and 2 mg once dialed up to the intended dose

- Authentic Ozempic® pens are currently available in the following configurations:
  - 0.25/0.5 mg pen
  - 1 mg pen
  - 2 mg pen
- The box containing authentic Ozempic® will include 4 needles which attach directly onto the pen, except the Ozempic® 0.25/0.5 mg dose carton which has 6 needles.

Counterfeit

- A counterfeit pen may be identified based on scale extending out from the pen when setting the dose.
- The label on a counterfeit pen could be of poor quality and may not adhere well to the pen.
- A counterfeit carton may have spelling mistakes on the front of the box (i.e., 1pen and 4 doses without space between '1' and 'pen') as seen in photo above.
- A counterfeit carton may not include the tamper resistant/perforation.
- The batch number printed on a counterfeit box may not correspond to the product strength stated on the same box and pen.

Case Study 3: [redacted] Wholesale [redacted], Inc, [redacted], [redacted]

Background

A WD purchased a high-value drug that, per the transaction history, had been sold and purchased four times in one day prior to their ownership. The same transaction history included pharmacies also licensed as WDs that used their pharmacy licenses to obtain special purchase pricing and after significantly marking up the price, sold it using their wholesale distributor license. The WD did not regularly verify the identity, legitimacy, proper operation, and [authorized] trading partner status of the entities from where they purchased drugs or to whom they sold them. This included not determining from where their vendors sourced the drugs sold to the WD and not obtaining assurances that they were receiving prescription drugs obtained from lawful sources.

Discussion

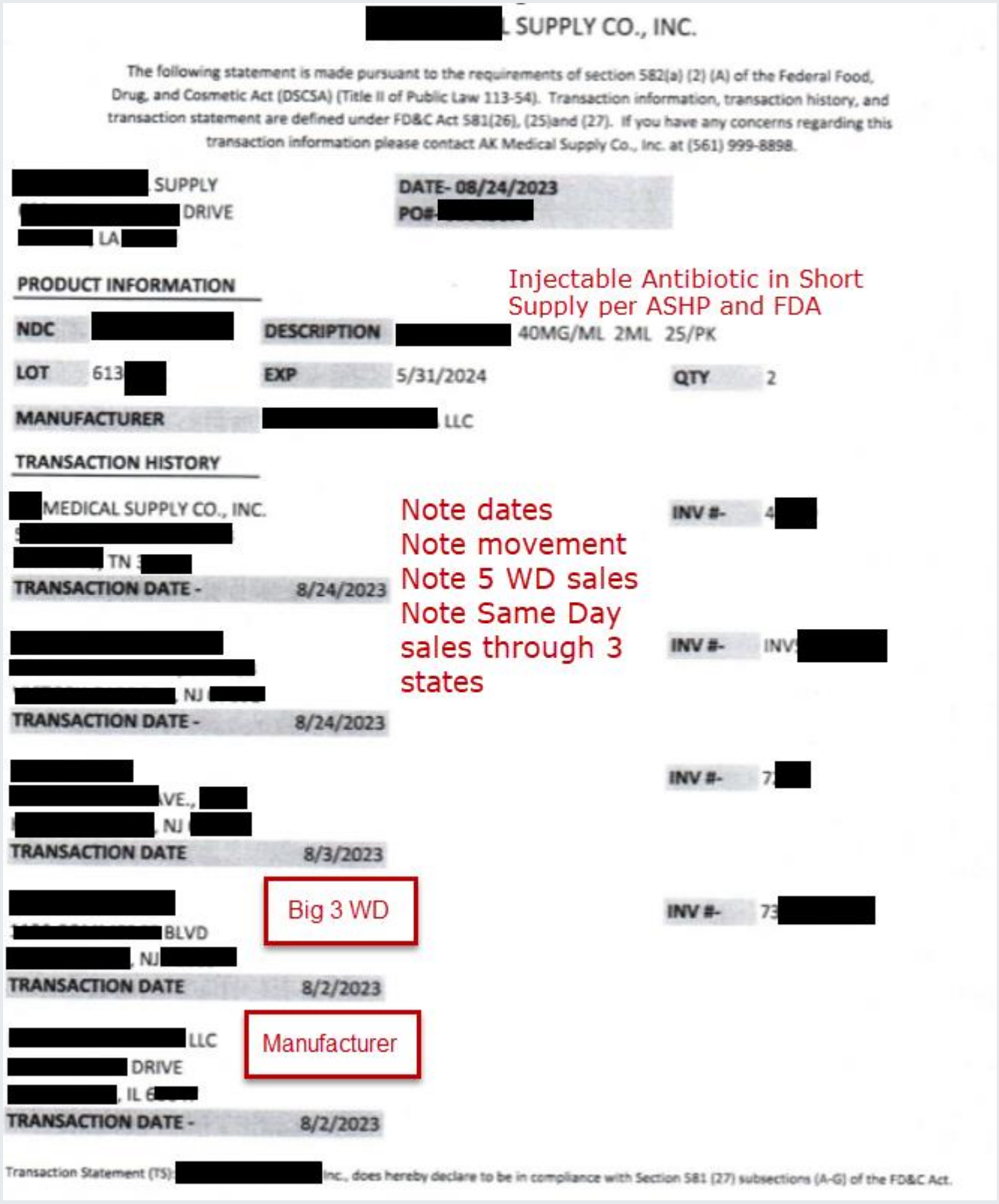
The drug involved was sold by five WDs; thus, necessitating additional due diligence by the dispenser due to the high number of transactions to occur following the initial sale by the manufacturer to the first WD. The transaction history also shows the drug's expiration date as May 31, 2024, nine months beyond the initial transaction.

A dispenser that purchases product in this scenario has additional due diligence to **consider** or do, some of which is stated below.

1. How much additional shelf-life does the drug have?
2. If it is a short-supply drug, how were the supplier(s) able to acquire it?
3. Will the supplier provide their invoice of purchase?
4. Check references for suppliers of concern.
5. Conduct an investigation in coordination with upstream trading partners.
6. Conduct a trace of the drug back to the manufacturer.
7. Examine the number of times and how quickly the drug(s) was sold.
8. Verify whether all sellers were licensed as wholesale distributors?
9. Use state license databases to determine if sellers have both pharmacy and wholesale distributor licenses at the same address under the same name. If yes, ask for verification the drugs were purchased with a wholesale distributor license.
10. Check the manufacturer's website to see if it lists authorized distributors for the drug to be purchased.

Exhibits

[Referenced] Transaction History



[redacted] SUPPLY CO., INC.

The following statement is made pursuant to the requirements of section 582(a) (2) (A) of the Federal Food, Drug, and Cosmetic Act (DSCSA) (Title II of Public Law 113-54). Transaction information, transaction history, and transaction statement are defined under FD&C Act 581(26), (25)and (27). If you have any concerns regarding this transaction information please contact AK Medical Supply Co., Inc. at (561) 999-8898.

[redacted] SUPPLY
[redacted] DRIVE
[redacted] LA [redacted]

DATE- 08/24/2023
PO#-[redacted]

PRODUCT INFORMATION

Injectable Antibiotic in Short Supply per ASHP and FDA

NDC [redacted] DESCRIPTION [redacted] 40MG/ML 2ML 25/PK

LOT 613[redacted] EXP 5/31/2024 QTY 2

MANUFACTURER [redacted] LLC

TRANSACTION HISTORY

[redacted] MEDICAL SUPPLY CO., INC.
[redacted]
[redacted] TN [redacted]
TRANSACTION DATE - 8/24/2023 INV #- 4[redacted]

Note dates
Note movement
Note 5 WD sales
Note Same Day sales through 3 states

[redacted]
[redacted]
[redacted] NJ [redacted]
TRANSACTION DATE - 8/24/2023 INV #- INV[redacted]

[redacted]
[redacted] AVE., [redacted]
[redacted] NJ [redacted]
TRANSACTION DATE 8/3/2023 INV #- 7[redacted]

[redacted]
[redacted] BLVD
[redacted] NJ [redacted]
TRANSACTION DATE 8/2/2023 INV #- 73[redacted]

Big 3 WD

[redacted] LLC
[redacted] DRIVE
[redacted] IL [redacted]
TRANSACTION DATE - 8/2/2023

Manufacturer

Transaction Statement (TS): [redacted] Inc., does hereby declare to be in compliance with Section 581 (27) subsections (A-G) of the FD&C Act.

Similar Scenarios
Drugs purchased under GPO contract pricing, stolen drugs, diverted long term care contract priced drugs

Lead Defendant in Health Care Fraud and Rogue Internet Pharmacy Scheme Sentenced to 12 Years in Federal Prison and Ordered to Pay $68 Million in Restitution

Case Involved More Than $200 Million in Fraudulently Obtained Pharmaceuticals

U.S. Attorney's Office — **Northern District of Texas**
December 11, 2009 — (214) 659-8600

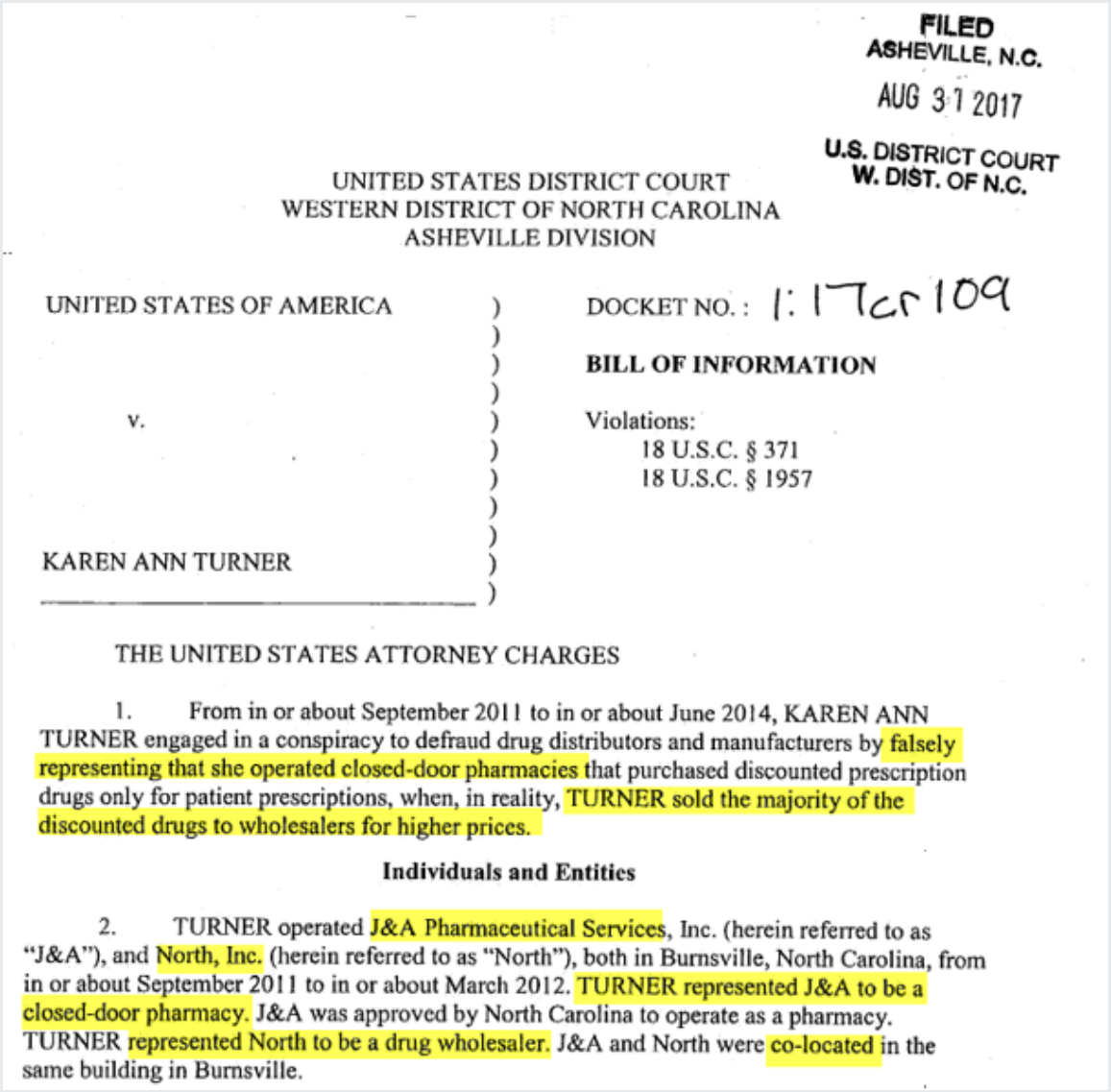
- Rakesh Jyoti Saran operated 23 Texas-incorporated pharmacies.
- Saran purchased expensive pharmaceuticals at significant discounts from pharmaceutical wholesale suppliers, including AmerisourceBergen/Anda, Inc/Cardinal Health/H.D. Smith/Morris & Dickson Co, LLC.
- To receive the discounts, Saran obtained fraudulent memberships in Group Purchasing Organizations (GPOs).

In 2013, Miami-Dade police officers conducted a search of a Kendall house and left with a batch of pharmaceuticals, which over the next six years blew up into a $78 million prescription drug and money-laundering scheme.

14 individuals have been indicted in Miami federal court, and one suspect, Angel Caminero Alvarez, remains a fugitive.

They're accused of operating a network that dealt in illegally purchased or stolen prescription drugs, mostly to treat HIV, cancer and psychiatric illnesses. Labeled by prosecutors as a "pharmaceutical diversion" operation involved businesses in Florida, Arizona, Delaware, Washington and Puerto Rico.

Sources
https://archives.fbi.gov/archives/dallas/press-releases/2009/dl121109.htm
https://www.justice.gov/archive/usao/txn/PressRel09/saran_sen_pr.html



FILED
ASHEVILLE, N.C.
AUG 31 2017
U.S. DISTRICT COURT
W. DIST. OF N.C.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION

UNITED STATES OF AMERICA)
)
v.)
)
KAREN ANN TURNER)

DOCKET NO.: 1:17cr109

BILL OF INFORMATION

Violations:
18 U.S.C. § 371
18 U.S.C. § 1957

THE UNITED STATES ATTORNEY CHARGES

1. From in or about September 2011 to in or about June 2014, KAREN ANN TURNER engaged in a conspiracy to defraud drug distributors and manufacturers by falsely representing that she operated closed-door pharmacies that purchased discounted prescription drugs only for patient prescriptions, when, in reality, TURNER sold the majority of the discounted drugs to wholesalers for higher prices.

Individuals and Entities

2. TURNER operated J&A Pharmaceutical Services, Inc. (herein referred to as "J&A"), and North, Inc. (herein referred to as "North"), both in Burnsville, North Carolina, from in or about September 2011 to in or about March 2012. TURNER represented J&A to be a closed-door pharmacy. J&A was approved by North Carolina to operate as a pharmacy. TURNER represented North to be a drug wholesaler. J&A and North were co-located in the same building in Burnsville.

Imperative 3B: [Know] What to do with illegitimate product.

Excerpted from the US FDA guidance, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry, June 2021

"Again, under section 582 of the FD&C Act, trading partners must have systems in place that enable them, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from FDA that has made a determination that a product within the possession or control of the trading partner is a suspect product, to quarantine suspect product and promptly conduct an investigation, in coordination with the manufacturer and other trading partners, as applicable, to determine whether a suspect product is illegitimate. In addition, trading partners must, as applicable, make the notifications described in section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B) of the FD&C Act related to illegitimate product determinations and, for manufacturers, the notification of a high risk of illegitimacy described in section 582(b)(4)(B)(ii)(II)."

Notify FDA and trading partners of illegitimate product.

- Notify FDA and all appropriate immediate trading partners within 24 hours after determining a product is illegitimate. The product(s) should already be quarantined.
- Notify FDA of illegitimate products at this link: *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/notify-fda-illegitimate-products*
- Link to FDA form 3911 for reporting Illegitimate products: *https://www.fda.gov/media/99185/download?attachment*

Imperative 4: Develop, update, and adhere to robust prescription drug purchasing policies and procedures (P&Ps) that accurately reflect your internal processes.

A 2023 survey conducted by NABP and responded to by its member regulators indicated the DSCSA topic of greatest interest to them is P&P adherence amongst its licensees, followed by their licensees' ability to demonstrate adherence to a process for verifying suspect and illegitimate products in their inventory and responding to regulator and trading partner verification requests. The regulators' interest in P&Ps is indicative of their importance to the operational consistency necessary for securing the drug supply chain. To be effective, P&Ps designed to ensure the identity, strength, quality, and purity of drug products must adequately demonstrate how business is conducted and be written to facilitate the sequential execution of operations. They must be drafted, reviewed, and approved by the appropriate organizational units and employees must be continually trained on the P&Ps applicable to the function(s) they perform.

Key Takeaways

1. Establish, update, and adhere to robust prescription drug purchasing policies and procedures (P&Ps) that accurately reflect your business location's processes.

2. Know how to determine if suppliers are authorized trading partners (ATPs).
   - Manufacturers and Repackagers register with Food and Drug Administration (FDA).
   - Wholesale distributors WDs and third-party logistics providers (3PLs) report to FDA and are licensed by the state where they are located or selling into (as applicable per state).

3. Know the level of risk associated with how your drugs are sourced; beware of a [potential] trading partner's business model and how they source prescription drugs; know whether they are appropriately licensed and whether they have discipline involving their drug supply.

4. Establish a thorough and consistent process to know your prescription drug suppliers.

5. "If it is too good to be true, it *is* [too good to be true]"; check references for suppliers of concern.

6. Know the suspect product red flags; develop procedures to identify them and to conduct the necessary verifications; train all applicable personnel on how to adhere to them.

7. Develop procedures for responding to product tracing requests from authorities and trading partners; train all applicable personnel on how to adhere to them.

8. Know where your product tracing information is stored and how to easily access it for the legally required time frame (usually a minimum of six years).