Partnership for DSCSA Governance (PDG) Suspect and Illegitimate Product Investigation Workshop Report

On February 27 and 28, 2024, the Partnership for DSCSA Governance (PDG), hosted a two-day workshop (the "Workshop") for industry participants and regulators to discuss challenges and opportunities in collaboration as part of suspect and illegitimate product investigations. This report summarizes the Workshop and captures conclusions for industry and regulators.

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PDG Overview

PDG is an independent, balanced, sector-neutral, nonprofit industry governance body that supports the secure, electronic, interoperable tracing, and verification of prescription drugs in the U.S. supply chain, as required by the *Drug Supply Chain Security Act* (DSCSA). Through our public-private partnership with FDA, we collaborate to develop, advance, and sustain an effective and efficient model for interoperability.

PDG membership includes leading authorized manufacturers, re-packagers, wholesalers, third-party logistics providers, and dispensers (hospitals and retail and independent pharmacies), as well as leading industry trade associations and technical experts. Together, these members are working to establish a comprehensive vision for industry's implementation of secure, electronic systems and processes for drug traceability in the United States.

For additional information, visit www.DSCSAgovernance.org.

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Background

The *Drug Supply Chain Security Act of 2013* (DSCSA)[1] is a comprehensive set of requirements to enhance the security of the legitimate pharmaceutical supply chain in the U.S. The DSCSA establishes traceability of prescription pharmaceuticals by requiring supply chain trading partners—manufacturers, repackagers, wholesale distributors, and dispensers—to implement interoperable systems and processes to exchange and maintain record of transaction information (TI) for each change in ownership of a prescription pharmaceutical covered by the DSCSA. Trading partners began exchanging lot-level TI in 2015, enhanced requirements took effect on November 27, 2023. In November 2023, FDA announced that trading partners would be given until November 27, 2024, to stabilize their systems and processes to account for these enhanced requirements.

In addition to data exchange and traceability, other critical pieces of the DSCSA require the implementation of systems and processes to identify, investigate, and respond to product that is, or is potentially, counterfeit, diverted, or stolen, adulterated, subject of a fraudulent transaction, or otherwise unfit for distribution such that the product would result in serious adverse health consequences (*i.e.*, suspect or illegitimate product). A suspect or illegitimate product may be identified by a trading partner or regulator, and when identified, a trading partner that may have possession or control of the product has multiple obligations, including systems and processes to:

- Quarantine the suspect or illegitimate product.
- Investigate—in coordination with other trading partners—the circumstances related to the product to determine whether the product is illegitimate and respond appropriately.
- Verify the product identifier of the product as part of the investigation.
- Conclude its investigation of a suspect product with a conclusion that the product is cleared or illegitimate.
- If the product is illegitimate, work with trading partners to disposition the product.
- If the product is illegitimate,[2] notify other trading partners that may have received the product.
- If the product is illegitimate,[3] notify FDA using FDA Form 3911.
- Retain documentation of the investigation and response for six years.

[1] The Drug Supply Chain Security Act of 2013, 21 U.S.C. § 582 (2013).
[2] Manufacturers must also make such notification if there is a high-risk of product illegitimacy.
[3] Manufacturers must also make such notification if there is a high-risk of product illegitimacy.

Goals of the Workshop

The Workshop focused specifically on the ATP-to-ATP and ATP-to-regulator interactions that occur as part of a suspect/illegitimate product investigation, including, where required, the illegitimate product notification and the 3911 filing processes. The goal of these discussions was not to delve into internal business processes or individual company compliance decisions about whether a product is suspect or how to conduct their investigation. Instead, discussions focused on the ATP-to-ATP and ATP-to-regulator collaboration that is necessary to support investigations and notifications.

Structure of the Workshop

The workshop was centered around four suspect/illegitimate product investigation and notification exercises that tried to simulate real-world situations. These exercises were not meant to constrict participant discussion to the facts at hand, but rather left general enough for each participant to make assumptions and think of different scenarios and how to best solve problems brought up.

At the start of the Workshop, participants were divided into small groups of six or seven people and assigned one of six supply chain or regulatory roles. Each exercise included at least one manufacturer, one wholesaler, one dispenser, and FDA/State Regulators. Participants rotated through these roles over the course of the Workshop to ensure every participant could look at scenarios from multiple perspectives.

Each scenario included a hypothetical fact scenario with accompanying DSCSA data for the groups to analyze and discuss. During these discussions, participants were asked to identify and discuss the business processes they would use to recognize the problem presented and how to resolve the suspect product investigation through collaboration among trading partners and regulators.

Once the small groups finished their discussion, the Workshop organizers expanded the discussion to encompass the entire Workshop. Other groups could hear how their peers approached the scenario from different perspectives and different industries.

Overall Takeaways

The following reflect participants' key high-level takeaways from the Workshop:

- No organization can do an investigation alone. Interaction with other trading partners is essential. Investigations are human-to-human engagements, and collaboration must be continuous throughout the investigation and, as necessary, notification process.
- Each organization must make its own business decision as to (i) whether a product is suspect, (ii) whether a suspect product is illegitimate, and (iii) how necessary notifications will be made. Generally speaking, each fact pattern will be unique but will escalate to a point where the suspect or illegitimate threshold is met (or not met). Standards and Processes ("SOPs") are

essential to this fact escalation. While unique to each organization's business, these SOPs provide the foundational principles and process that business uses to determine whether it will consider a product suspect/illegitimate and/or will notify FDA and trading partners.

- Trading partners and regulators will almost never have perfect or complete information as part of an investigation. Gaps will exist, and assumptions will have to be made based on individual business processes and decisions. This, again, makes investigation and notification SOPs essential.
- There is a tension between over-reporting and precise notifications. On the one hand, there is often a natural inclination for an organization to, when in doubt, cover its bases and err on the side of making illegitimate product notifications. On the other hand, every notification triggers a response from the recipient (including regulators), which consumes time and resources. Precise reporting promotes efficiency.
- In addition to collaborating with other trading partners, there is a complex array of internal stakeholders and other regulatory requirements/agencies beyond the DSCSA. Investigations involving larger organizations may involve product security, legal, compliance, quality, and operational functions, each of which add layers of collaboration, coordination, and time to the process. Similarly, many suspect/illegitimate product scenarios implicate legal and compliance obligations beyond the DSCSA, such as state requirements to report thefts or DEA requirements for controlled substances diversion. These additional requirements also add complexity and layers of coordination to the investigation and notification processes.
- Non-DSCSA business records are critical to DSCSA suspect/illegitimate product investigations. DSCSA data is only the change of ownership record and often do not answer all of the question necessary to successfully complete an investigation. Integration of these additional business processes and records also add complexity and layers of coordination to the investigation and notification processes.
- Patient safety requires more than just "checking the DSCSA boxes," even if those are business practices (*i.e.*, non-compliance requirements). The DSCSA represents *one tool* in the toolkit available to trading partners and regulators to protect patients. While each company must make their own business decisions as to the specific steps they will take to protect patients, it is important that they maintain a broader view than DSCSA.

Regulator Panel

At the conclusion of the Workshop, a panel of FDA and State Board of Pharmacy representatives provided their reactions and insights from the exercise. Their key insights are below.

- Collaboration is key. A regulator (state or FDA) is very limited in their ability to respond to a suspect or illegitimate product without significant collaboration with trading partners. Relationship and trust building, along with their maintenance, is key.
- Regulators can only act on things they know about, so often, the onus of reporting and initiating investigations is on the organizations within the supply chain.

- A wide range of expertise in the DSCSA space persists. Some have focused their careers around the DSCSA, while many pharmacies may only be vaguely aware of the law. This diversity of expertise means regulators need to calibrate their messages depending on how sophisticated their audience is in understanding DSCSA matters.
- The law has defined requirements, but it gives the supply chain a lot of latitude in individual business practices to meet those requirements. That latitude is important to maintain business efficiency, but it makes it difficult for a regulator to give clear and definitive expectations.
- Opportunities for regulators to speak face-to-face with industry and understand exactly what is happening behind the scenes of DSCSA implementation are limited. The Workshop was a valuable opportunity to have those types of discussions and begin to build the types of relationship necessary to support effective investigations. Moving forward, regulators have an opportunity to do a better job of reaching out to industry, and industry has an opportunity to do a better job reaching out to regulators.
- FDA and states continue to work to strengthen their relationships and improve their ability to coordinate effectively in response to a suspect or illegitimate product.

Exercises Summary and Report Outs

Each exercise is summarized below, along with the key takeaways and points of discussion from the exercises.

Exercise One: Find the Bad Actor

Exercise One Fact Pattern

This exercise began with a pharmacy that dispensed a three-month supply (3 bottles) of a medication to a patient. When the patient opened the third bottle, she noticed that the tablets looked different than the tablets from the other two bottles. The patient brought the bottles to the pharmacist who called the manufacturer's medical information number on the bottles. The pharmacist provided images of the bottle including the serialization information. A verification of the sGTIN indicated that the serial information was valid but identical to one reported in a previous complaint. Bottle 1 and 2 of the product were legitimate product properly distributed. Bottle 3 was a counterfeit, illegitimately acquired by a bad actor wholesaler and sold down the supply chain.

The counterfeit product entered the supply chain via the wholesaler who was buying counterfeits and selling them into the supply chain. A few months before the original product was dispensed, the wholesaler was approached by a business associate with an offer to buy the product at an 80 percent discount. The wholesaler was very suspicious but could not pass up the profit opportunity. Over the next few months, the wholesaler bought and distributed about 1,000 bottles of product. Each was accompanied by TI showing that they purchased the product directly from the proper manufacturer. The wholesaler was a small operation with only three people in corporate functions, so it was easy for all three of them to align around this opportunity and sweep things under the rug. The overall point of this

exercise was to both discover who the bad actor was and determine how to notify legitimate trading partners of the suspect product.

Exercise One Participant Report Out

- How hard was it to determine what happened?
    - It is important to recognize that investigations often begin from a point where very little information is known. Trading partners must collaborate to maximize information that is available and how they might proceed to uncover more information. For example, in this scenario, many participants were initially tripped up by the fact the TI was not sent correctly. With exercise participants at the same table, it was eventually easy to figure this out. In the real world, however, the communication that took seconds in the exercise might take days, weeks, or even months.
    - The absence of information is felt acutely by regulators, as they often have to rely on companies to learn the specific facts of any situation. In this exercise, the regulators sitting at each table gained valuable insight into how and when each company in the supply chain would notify a trading partner of a suspect product. One lesson learned from this exercise is trading partners should always keep the potential investigations of regulators in mind when conducting their own investigations.
    - The question of who should file 3911 forms is of particular note. Some regulators pointed out that too many 3911s for a single incident could create too many forms for the regulator to sift through, while others noted that a 3911 form should always be filed. This is a good example of where business practices and standards and processes play a major factor in how suspect and illegitimate product investigations are handled in the real world.

  Suspect product investigations take time. Every company will have their own standards and processes to guide their investigation procedure as the one business day requirement for notification to FDA does not kick in until a company has made a definitive determination the suspect product under investigation is illegitimate.
    - Suspect product investigation can be lengthy, so companies should balance the need to get all the information they can with the concern that bad actors (like the bad actor in the exercise) are still authorized to sell when these investigations occur.
- What worked well or didn't work well as a collective supply chain?
    - Communication among trading partners is always critical when conducting a suspect product investigation, but it is especially critical when there is a bad actor who may be actively hampering the communication process.
    - One area of continued confusion that participants discovered is how much information organizations are allowed to disclose. If communication is critical, then the content of the communication is what drives a suspect product investigation forward. If businesses are hesitant to share what actually happened during the course of a suspect product investigation, the entire supply chain will have issues determine what actually happened and keeping patients safe. .
    - In situations where a bad actor has been discovered to have been putting illegitimate product into the supply chain, a recall may often be one possible remedy. Depending on how widespread the illegitimate product is, a recall might even become advisable, even when accounting for logistical difficulties and temporary drug shortages.
- Takeaways and lessons learned from Exercise One.

- Interacting with other trading partners is a key ingredient to determining what actually happened. Be curious and stay engaged.
- It would likely be easier for bad actors to obscure their actions in the real world because they don't have to talk to everyone at once nor face to face.
- In a real-world situation, with these same facts, companies would likely spend a significant amount of time investigating a data failure, when the real issue was a bad actor.

Exercise Two: Who to Notify?

Exercise Two Fact Pattern

A manufacturer received a monthly report from its Returns Processer of all serial numbers returned and processed for credit/destruction. Over the last three months for which the participants were given data, the manufacturer has seen the same sGTIN appear multiple times in each monthly report from multiple pharmacies. A closer inspection of the product at the returns processor indicated that the label and product are counterfeit. The overall objective of this exercise was for participants to discuss how/who they would notify as they discovered the counterfeit drugs at various points in the exercise.

Exercise Two Participant Report Out

- What worked well? What didn't work well?
  - Most suspect product investigations begin with extremely limited information, and sometimes trading partners may never find out exactly what happened or how bad product got into the system. When dealing with such extremely opaque situations, trading partners must work together, and especially involve any pharmacies affected. While sometimes communication with smaller dispensers regarding suspect product investigations can be challenging, it is imperative that upstream trading partners and smaller pharmacies, like the ones involved in this exercise, work together to find out as much about the suspect product as possible.
  - Communication between trading partners for a suspect product investigation doesn’t have to follow the usual paths. In a real-world scenario, manufacturers would have likely reached out to the pharmacies earlier than is depicted in the scenario. This illustrates that every organization in the supply chain can play a role in the investigation process no matter how large or small, and that unusual collaborations can provide effective results. In addition to collaboration in the investigation, trading partners also can and should coordinate mass notifications if any recalls or public announcements are needed when trading partners deem product illegitimate.
  - . This exercise also illustrated how the various players would fill out a 3911 is up to each organization. They could fill them out with each suspect serial number listed, or they could fill out a separate 3911 for each individual suspect product serial number. In other words, how detailed a 3911 form should be, beyond a certain level of baseline information, is up to each individual organization.
  - Different organizations have different approaches, which is informed by the different personalities making decisions in these organizations. The suspect product investigation

process is run by humans, so trading partners should recognize they are not just communicating with a large manufacturer or a smaller wholesaler, but rather the individuals that make up those organizations. Understanding the very human nature of the investigation process will likely improve every organization's SOPs and the communications underpinning every investigation.

- General Lessons Learned and Key Takeaways
    - There are variably approaches among industry as to whether reverse logistics providers collect and share serial number information. Such activity is not required under the DSCSA, but some in industry recognize it as a valuable business practice that provides security benefit.
    - The notification issue is the main problem. Getting broad communication to all dispensers is a challenge.
    - In real life, it is unlikely a returns processor would have caught the serial number issue as quickly as this exercise implied.

Exercise Three: The Inside Job

Exercise Three Fact Pattern

A distributor called a manufacturer's customer service to report a data mismatch for a recent delivery. The distributor could not reconcile several of the physical products in their possession with the TI provided by their upstream trading partner. An inquiry with the manufacturer reveals that the serial numbers on the items were not generated by the manufacturer.

After further investigation from the wholesaler and law enforcement, the wholesaler discovered the data mismatch was caused by illegal activities (theft) conducted by an employee. After extensive interviews, law enforcement informed the wholesaler that the employee confessed to, over the last three months, stealing hundreds of cases of legitimate product as they were leaving the facility and replacing the stolen cases with cases of counterfeit product. The overall point of this exercise was to explore how to notify trading partners when bad product may have gotten in the system for an unknown, at first, reason.

Exercise Three Participant Report Out

- What did you do when you determined what happened?
    - Bad actors do not only show up in shadowy, unknown companies, but can appear as employees in upstanding companies with a strong commitment to DSCSA compliance and product safety. The supply chain is a human process and will only be as strong as the weakest link. In Exercise three, the weakest link broke the chain by stealing legitimate product and replacing it with counterfeit product. While even the best hiring processes will fail to catch every potential bad actor, this scenario is a good reminder that the suspect product investigation is not the only area of supply chain safety where organizations need to have strong SOPs in place. In many cases, the best way to prevent a suspect product investigation from becoming necessary is hiring the right people to manage the supply chain in the first place.

  - This Exercise also presented participants with another scenario where the root cause of the problem was unclear at the beginning. Going through proper procedures is critical to actually determine what happened and whether bad actors were involved, or just simple honest mistakes. Investigation thresholds, such as when to involve certain individuals in the investigation process, are critical for organizations to have in their standards and processes.
  - In the real world, some dispensers may not always report issues when patients alert a dispenser to a potential problem with their medications. Dispensers are in the business of providing medications to patients, so their first priority will likely be to ensure their patients get the correct medication. When patients do alert dispensers to potential issues with their medication, the dispenser's first instinct might not be to assume the product is illegitimate, but rather to assume a mix-up occurred somewhere higher up the supply chain. This is why all dispensers need to have robust SOPs when encountering potentially suspect product and ensure all of their employees who are making these determinations on the ground fully understand the importance and gravity of suspect products. While dispensers are unlikely to begin a suspect product investigation due to a single phone call from a patient, how to handle even seemly innocuous situations may need to be included in dispensers' SOPs.
  - With this in mind, however, not everyone along the supply chain has a large, sophisticated structure to conduct exhaustive suspect product investigations. For example, some small dispensers only have a few employees. This means what a proper SOP looks like can vary wildly from company to company and is ultimately a human process. However, regardless of the sophistication of an organization's SOPs, whenever an organization has determined suspect product is illegitimate, regulators made clear during this exercise that filing a 3911 is always an appropriate choice.
- General Lessons Learned and Key Takeaways
  - Upstream notification to trading partners in your supply chain is just as important as FDA notification. Upstream notification is currently inconsistent in the supply chain.
  - Inventory management is a critical component of the investigation process, though there is a wide variety of inventory management systems and processes.
  - At the dispenser level, they need to think through data management practices to ensure these issues are caught before they are sent to a patient.
  - Sometimes the only choice is to recall the product when it is being counterfeiting or adulterated. Manufacturers, however, generally only recall at the batch level, not the serial number.

Exercise Four: Stolen and Lost Product

Exercise Four Fact Pattern

Rather than focus on a single event and its consequences, this Exercise focused on numerous, unconnected events that resulted in lost or stolen product. In one instance, product was stolen in the parking lot of a dispenser shortly before it was delivered from the wholesaler. Another scenario asked participants how they would deal with product lost in transit, with no evidence of theft or foul play,

from a distribution center. Finally, participants had to grapple with a scenario where a dispenser's facility is robbed during closed hours and the dispenser struggles to determine which drug products were taken. The overall goal of this exercise was to get participants to think about how they would handle lost and stolen product situations where they are given varying amounts of information.

Exercise Four Participant Report Out

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    - While communication between trading partners may be the most important aspect of suspect product investigations, communication with law enforcement (when appropriate) is also critical. In situations where a bad actor may have disrupted the pharmaceutical supply chain, law enforcement will play as large, or larger of, a role as trading partners or FDA.
    - Lost and stolen product, while resulting in the same outcome, have vastly different implications. A situation resulting in lost product will likely have produced little information on which to base an investigation and will not automatically involve law enforcement. Stolen product will usually be surrounded by more information to conduct an investigation and will usually involve law enforcement directly or indirectly.
    - Every company should have a policy and procedure in place for reporting a lost product. Though all members of the supply chain agree and recognize implementing and following a SOP for lost product is often difficult due to the lack of information usually associated with lost product.
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General Lessons Learned and Key Takeaways

- The lost versus stolen product distinction is critical in any suspect product investigation.
- There is an open question surrounding how long to keep suspect product investigations, especially when product is lost or stolen and unlikely to be recovered. While there is no standard, trading partners should keep FDA informed throughout the investigation process, no matter how long it lasts. However, if product is found or new information comes to light, it is possible to open a new 3911 with the new information.
- In stolen product situations, collaboration and coordination with law enforcement is a key piece of any suspect product investigation.
- FDA has a standard process for following-up on open Form 3911s; such follow-ups should not necessarily be construed as an indication of new information and a recommendation to close the Form 3911.

Conclusion

Throughout the Workshop, industry participants demonstrated a commitment to working collaboratively to resolve suspect product investigation challenges. One key throughline during every Exercise and conversation was the human element of the suspect and illegitimate product investigation process. Organizations are made up of individuals and it is these individuals who handle all communication and decision-make during the investigation process. Understanding this human-centered process is the cornerstone of any investigation is critical to understanding how to successfully

build collaborative SOPs within every organization. This level of collaboration will be necessary once the DSCSA stabilization period deadline arrives on November 27, 2024. While the Workshop identified areas of continued work, the members of PDG, regulators, and industry participants across all sectors will continue to discuss, explore, and respond to the various challenges that occurring while preparing to successfully implement all requirements of the DSCSA.

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Appendix A: In-Person Participants

Government Representatives

Connie Jung, FDA
Abha Kundi, FDA
Sarah Venti, FDA
George Lovecchio, Louisiana Board of Drug & Device Distributors
Traci Collier, South Carolina Board of Pharmacy
Tyler Laetsch, State of South Dakota Board of Pharmacy
Beth O'Halloran, Virginia Board of Pharmacy
Josh Bolin, NABP

Manufacturers

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Mike Mazur, Pfizer
April Sese, Johnson & Johnson
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David Mason, Novartis
Kevin Duffy, Novartis
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Pam Clements, Smith Drug
Julie Malone, Value Drug Company
Maryann Nelson, Cardinal Health

Mignette Strife, Cardinal Health
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Max Peoples, Uptown Pharmacy
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Erin Parsons, Rite Aid
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Kevin Capatch, Geisinger