PDG-FDA Joint Public Meeting

DSCSA Stabilization Period Midway Checkpoint

June 17-18, 2024
Washington, D.C.

pdg Partnership for DSCSA Governance

FDA

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We are an independent, sector-neutral governance body, and an FDA public-private partnership dedicated to developing, advancing, and sustaining an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S.

www.DSCSAgovernance.org

In-Person Office Logistics

Restrooms

- Women's: Walk out of the door nearest to the conference room and it is directly past the stairs to the left.
- Men's: Walk past the Elevator bank and to the left towards the hallway with the Men's room.

Phone Booths

- If you need to take a call or hold a meeting during the event, please ask one of our staff to direct you to one of our many private phone booths.

Drinks

- Soft drinks and bottled water are available in small refrigerators in the conference room. Feel free to take anything you would like.

Front Desk Support

- Please speak with our administrative assistants if you have any questions or need support.

Virtual Attendee Logistics

- *Thank you!*
- We aim to make the virtual experience as similar as possible to the in-person experience.
  - We will be intentional about creating opportunities to engage, but please also be proactive in joining the conversation.
- You are automatically muted, but if you would like to speak, use the raise your hand function, we will unmute you and invite you to join by video.

- **The Day One and Day Two Zoom Links are *different*, please join the link provided for each specific day.**

- **If you experience any technical difficulties, please email admin@members.dscsagovernance.org**

Joint Public Meeting Steering Committee

Jacqueline Corrigan-Curay, FDA
Jennifer Clements, FDA
Lysette Deshields, FDA
Tia Harper-Velazquez, FDA
Sara Keller, FDA
Abha Kundi, FDA
Leigh Verbois, FDA
Menglu Yuan, FDA

Ameer Ali, Cencora
Melva Chavoya, Walgreens
Scott Mooney, Mckesson
Arthi Nagaraj, Sanofi
Max Peoples, RxScan
Christian Tadrus, Sam's Health Mart

Public Meeting Agenda

Day 1

12:30-12:50 - Welcome and Introductory Remarks

12:50-1:15 - Key Takeaways from FDA's RFI on Implementation of Enhanced Drug Distribution Security Requirements

1:15-1:40 - PDG Perspective on Stabilization Status

1:40-2:30 - Manufacturer Perspectives on Stabilization

2:30-3:00 - Break

3:00-3:45 - Wholesale Distributor Perspectives on Stabilization

3:45-4:45 - Panel: Stabilization of Manufacturer to Wholesaler Data Exchange

4:45-5:30 - Reactions and Takeaways

Day 2

10:00-10:10 - Highlights and Conclusions from Day 1

10:10-11:10 - Dispenser Perspectives on Stabilization

11:10-12:15 - Panel: Stabilization of Wholesaler-to-Dispenser Data Exchange

12:15-1:15 - Lunch

1:15-2:00 - Panel: Stabilization Progress from the Perspective of Supporting Organizations

2:00-2:30 - Discussion: State Perspectives on Stabilization

2:30-3:15 - Stakeholder Comments

3:15-4:00 - Actions for Success

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What is the DSCSA?

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Which of the following activities has the stabilization period allowed your organization to focus on? (Select all that apply)

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Which of the following do you believe is the greatest barrier to stabilization? (select all that apply)

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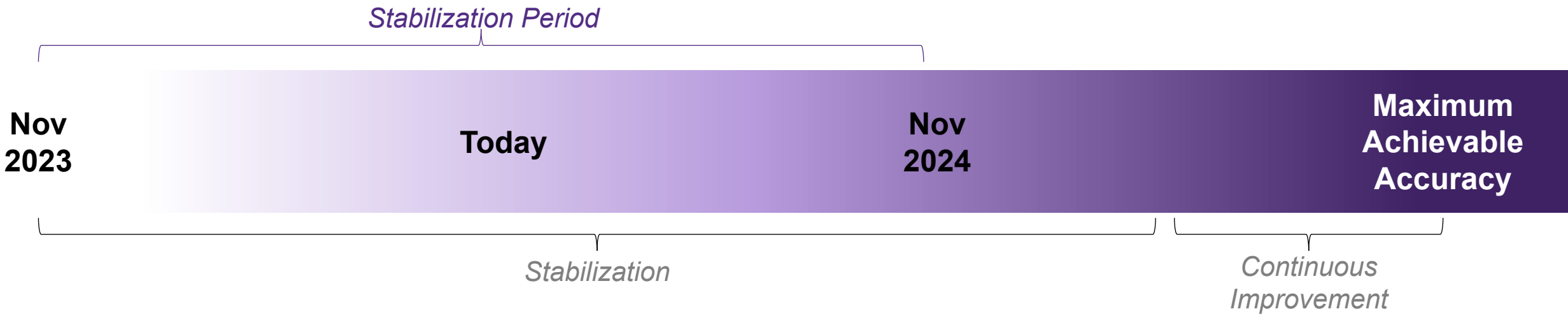
Welcome and Introductory Remarks

- Jacqueline Corrigan-Curay, Principal Deputy Center Director, FDA, CDER
- Eric Marshall, Executive Director, PDG



- Systems and Data Flow
- Data Quality and Exceptions
- Product Access
- Process
- Resource

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Key Takeaways from FDA's RFI on Implementation of Enhanced Drug Distribution Security Requirements

- Abha Kundi, JD, MPH. Team Lead, DSCI, ODSIR, CDER, OC

Key Takeaways from FDA's RFI on Implementation of Enhanced Drug Distribution Security Requirements
&
DSCSA Updates

PDG/FDA Joint Public Meeting: DSCSA Stabilization Period Midway Checkpoint
June 17, 2024

Disclaimer

This presentation is intended only to provide a general overview. It is not intended to be comprehensive, nor does it constitute legal advice. Please refer to appropriate guidelines, regulations, or law for specific information.

Please go to www.FDA.gov for more information on topics covered in this presentation

Request for Information (RFI)

- Topic: Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act
- Opened November 20, 2023
- Received 17 comments
- In consideration of joint public meeting, RFI is reopened until September 12, 2024

Request for Information (RFI)

1. How are you using the stabilization period to:
    a. Troubleshoot and mature secure, electronic, interoperable systems and processes for enhanced drug distribution security with upstream trading partners?
    b. Troubleshoot and mature secure, electronic, interoperable systems and processes for enhanced drug distribution security with downstream trading partners?

2. What are the most significant challenges you have overcome? What strategies did you employ to overcome those challenges?

3. What aspects of your systems and processes have you successfully operationalized?

4. What are the next steps in your strategy to ensure successful implementation of the enhanced drug distribution security requirements by November 27, 2024?

Request for Information (RFI) | Themes

Theme 1: Technical Implementation and Readiness Concerns

Technical Implementation

- Troubleshooting Data Exchange & Quality
  - Trading partners working through data quality issues (incomplete or inaccurate data)
  - Need for best practices re: data aggregation and standardizing data
  - Trading partner connections, communications and interdependency

Readiness Concerns

- Lack of understanding and/or processes to be DSCSA compliant
- Costs and resources needs to be compliant

Future Concern

- How will new NDC format disrupt data exchange and how will it impact trading partners?

Request for Information (RFI) | Themes

Theme 2: Requests for FDA to Provide Additional Information or Clarity

- More clarity on the **WEERs process** before the end of the stabilization period
- More stakeholder outreach, education, and collaboration both generally and with a focus on "**how to become compliant with DSCSA requirements**"
- Additional guidance on how **to confirm the identity and status** of an authorized trading partner

Update: Small Dispenser Exemption

- FDA issued exemptions from certain requirements of section 582 of the FD&C Act (enhanced drug distribution security and certain verification requirements) to small dispensers and where applicable their trading partners, until November 27, 2026.

- This provides small dispensers additional time to stabilize their operations to fully implement the enhanced drug distribution security requirements of the Drug Supply Chain Security Act (DSCSA).

- A dispenser is considered a small dispenser, for the purposes of these exemptions, if, as of November 27, 2024, the corporate entity that owns the dispenser has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians.

Update: Waiver and Exemption Requests

- Trading partners that do not qualify for the small dispenser exemptions and are unable to meet the enhanced drug distribution security requirements of section 582 of the FD&C Act by November 27, 2024, may request a waiver or exemption from those requirements.

- Although requests can be submitted at any time, FDA recommends trading partners submit a waiver or an exemption request by August 1, 2024. The agency cannot guarantee it will grant or deny the waiver or exemption by November 27, 2024, but will make every effort to do so.

- A trading partner's obligation to comply with enhanced drug distribution security requirements by November 27, 2024, will not be paused or extended upon submission of a request or while FDA's response is pending. The agency expects the trading partner to continue their efforts to meet the requirements until FDA has approved or denied the request.

FDA Resources

- DSCSA main webpage:

  https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

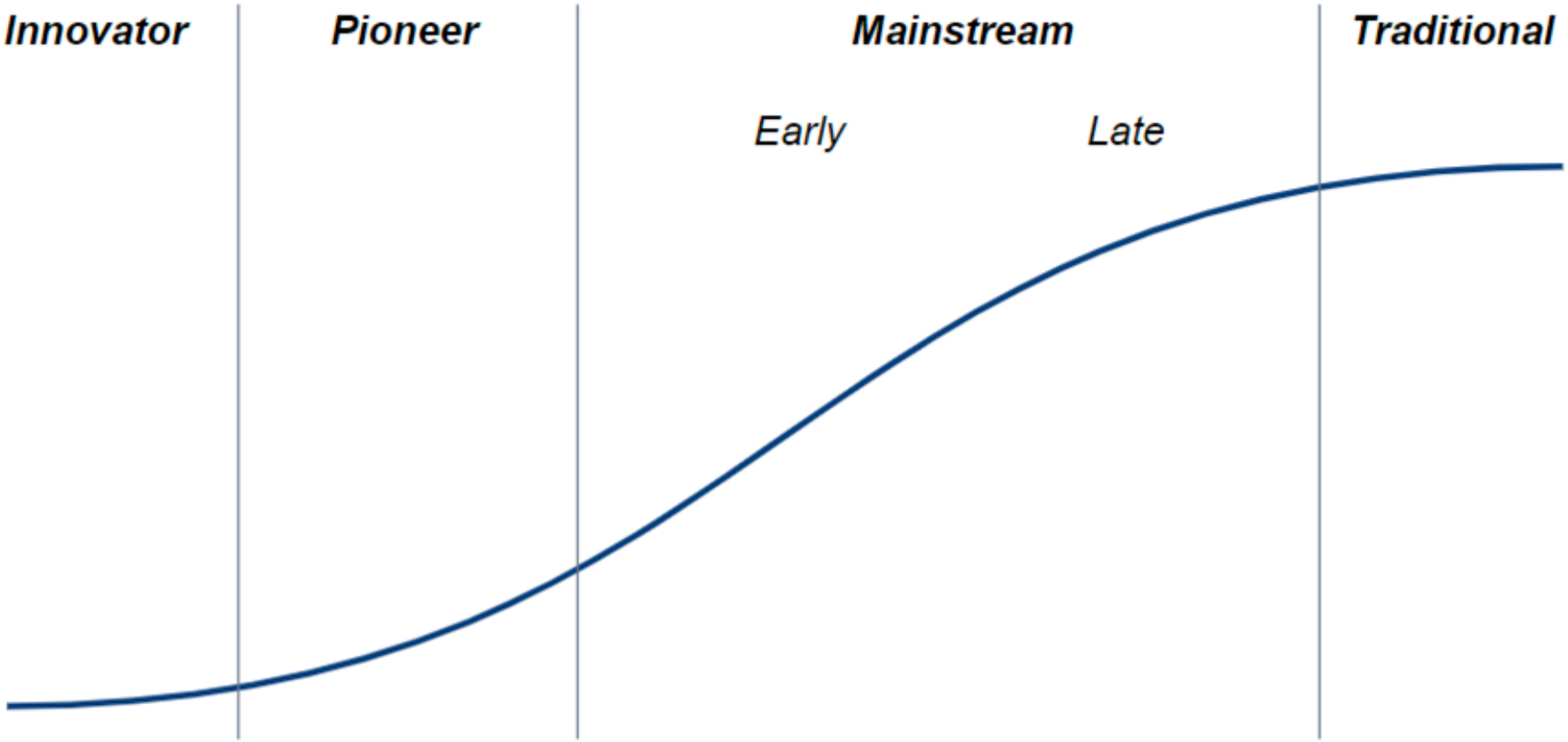
- DSCSA regulatory documents (i.e., regulations, guidances, federal register notices, RFIs):

  https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm

PDG Perspective on Stabilization Status

- Matt Price, Board Chair, PDG

DSCSA Adoption Curve



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Implementation Progress

- The following response summaries are from a limited number of members of the pharmaceutical supply chain and are not meant to represent the entire industry.
- Only PDG members participated in these discussions, so the takeaways only represent the views of some individuals, all of whom are members of PDG.
- PDG has asked different individuals to share each month, so these response summaries do not represent the same individuals speaking at every meeting.
- Figures reported are intended to demonstrate qualitative progressions on the adoption curve, not quantitative representations of the entire industry.

Implementation Progress – Then and Now

PDG Manufacturers

- Start of Stabilization Period
  - Connections with 80–90% of downstream distributor trading partners
- Most Recent Updates
  - Generally reporting connections with close to 100% of downstream distributor trading partners
  - Manufacturers shipping directly to dispenser trading partners reported work continues to onboard and connect to dispensers able to receive EPCIS files

Implementation Progress – Then and Now

PDG Wholesalers

- Start of Stabilization Period
  - Connections with 75–90% of upstream trading partners
  - Not receiving live EPCIS data from all connected upstream trading partners or for all transactions
- Most Recent Updates
  - Seeing increases in data quantity, though more work is needed
  - Estimates reported of receiving some type of data for 70% of purchase orders and 65% of product; seeing increases in these numbers each month

Implementation Progress – Then and Now

PDG Dispensers

- Start of Stabilization Period
  - Not seeing much live EPCIS data yet
  - Starting to work with EPCIS but mixed bag regarding how complete the data was
  - Reported great commitment from major distributors, but still waiting for kick off
- Most Recent Updates
  - Concern voiced that some struggling to focus on DSCSA due to limited bandwidth / competing priorities
  - Improvements in onboarding processes (establishing connections) and increases in data received from upstream trading partners
  - Issues with master data and data inconsistency
  - Lack of implementation progress among some, especially smaller, dispensers

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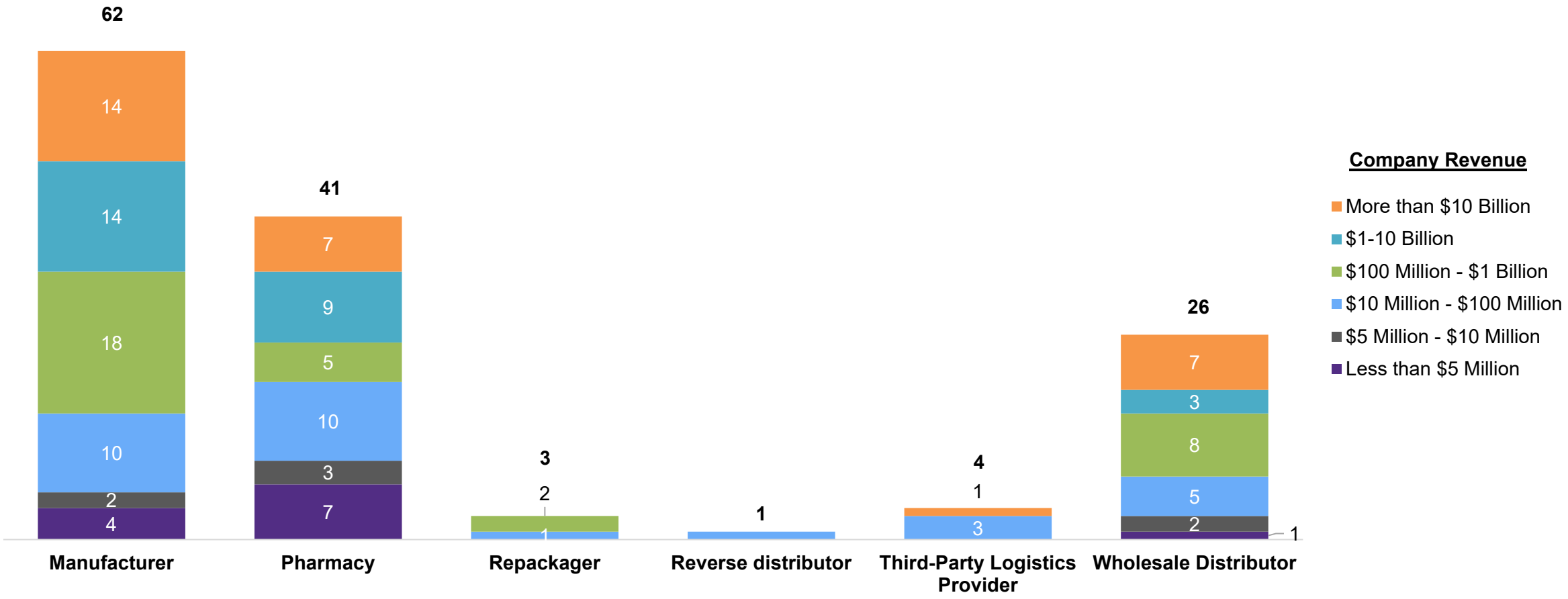
Implementation Progress – Then and Now

PDG Solution Providers

- Most Recent Updates
  - Increase in number of companies exchanging data, representing good progress in DSCSA implementation
  - Overall quality of data = Poor
  - Exception handling/management top-of mind for stakeholders
  - Some reports of slower rate of supplier and dispenser on-boarding and go-lives based on perceived decrease in urgency during the stabilization period
  - Onboarding generally goes well when adhere to PDG Blueprint; notably more difficult and time-consuming when do not

136 Survey Respondents



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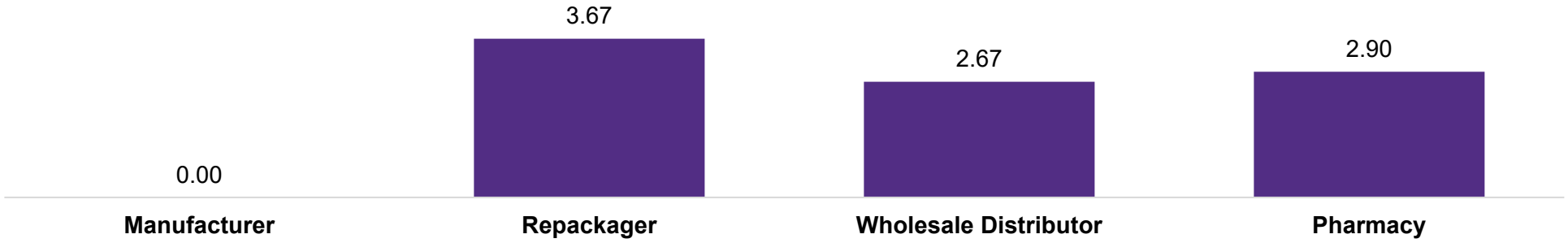
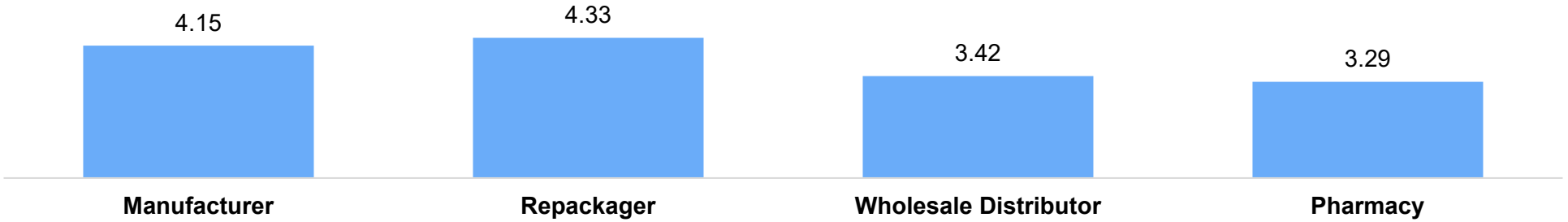
On a scale of 1 to 5, how Confident are you…

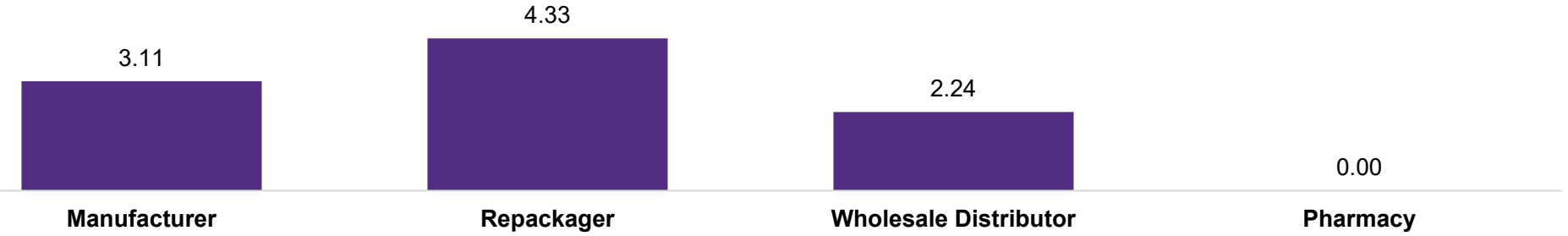
that the unit-level tracing systems and process of trading partners **you purchase product from** will be stabilized by November 27, 2024?



that **your organization's** unit-level tracing systems and processes will be stabilized by November 27, 2024?



that the unit-level tracing systems and process of trading partners **you sell product to** will be stabilized by November 27, 2024?



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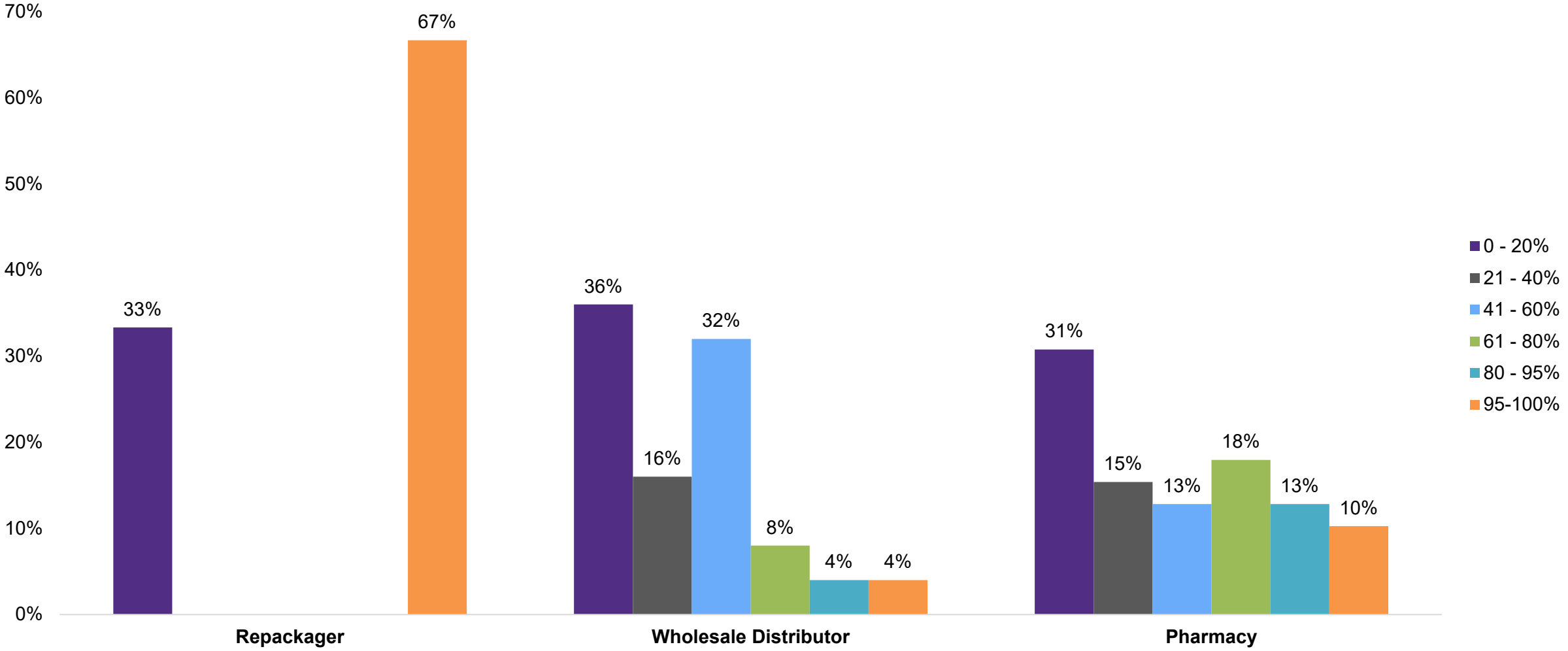
When Purchasing Product: From approximately what percent of your suppliers are you routinely receiving complete serialized data (i.e., transaction information)?



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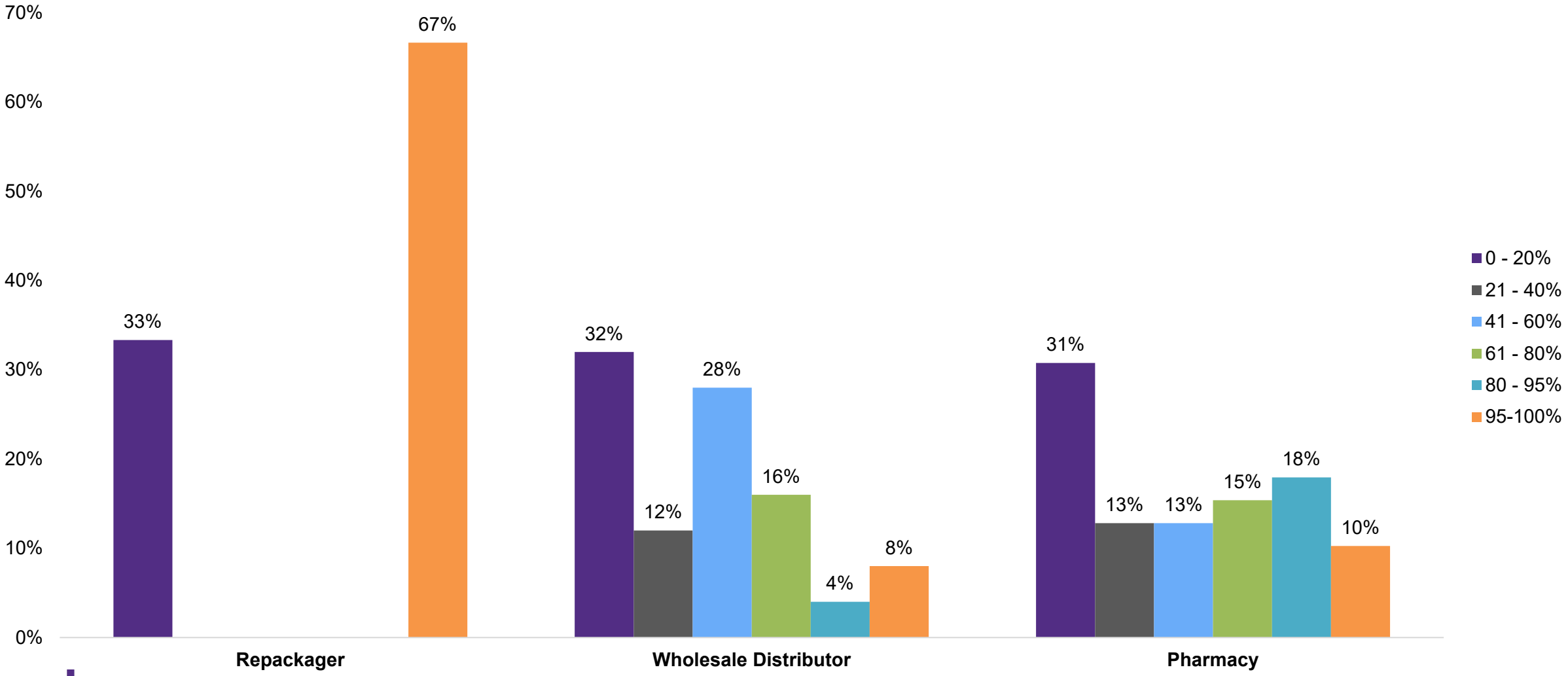
When Purchasing Product: For approximately what percent of product you purchase are you routinely receiving complete serialized data (i.e., transaction information)?



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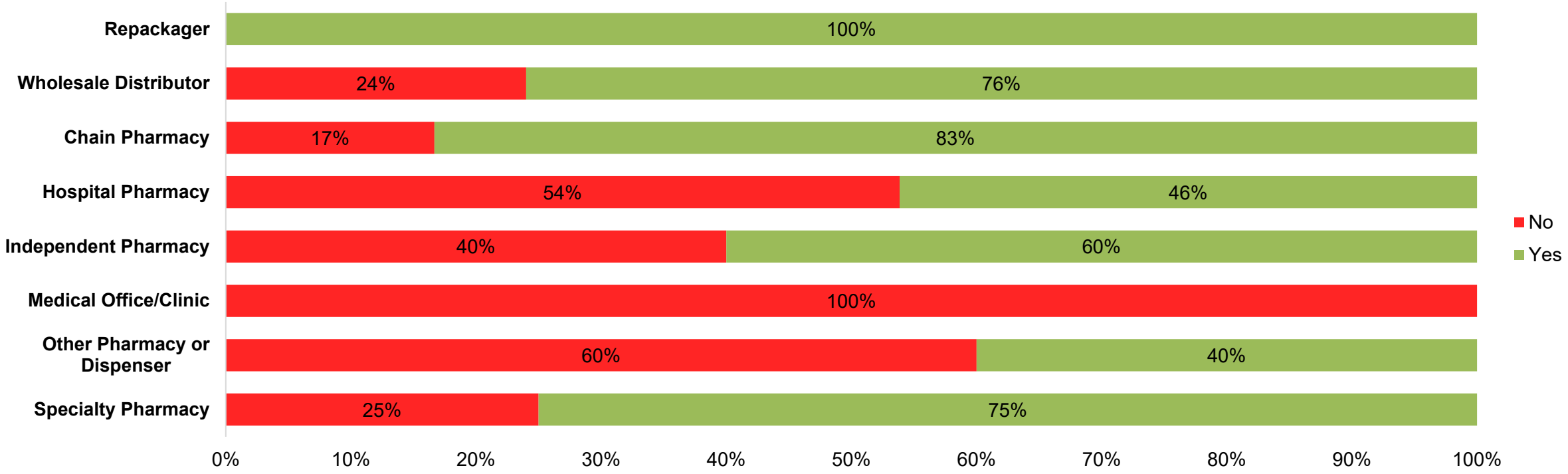
Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you receive?



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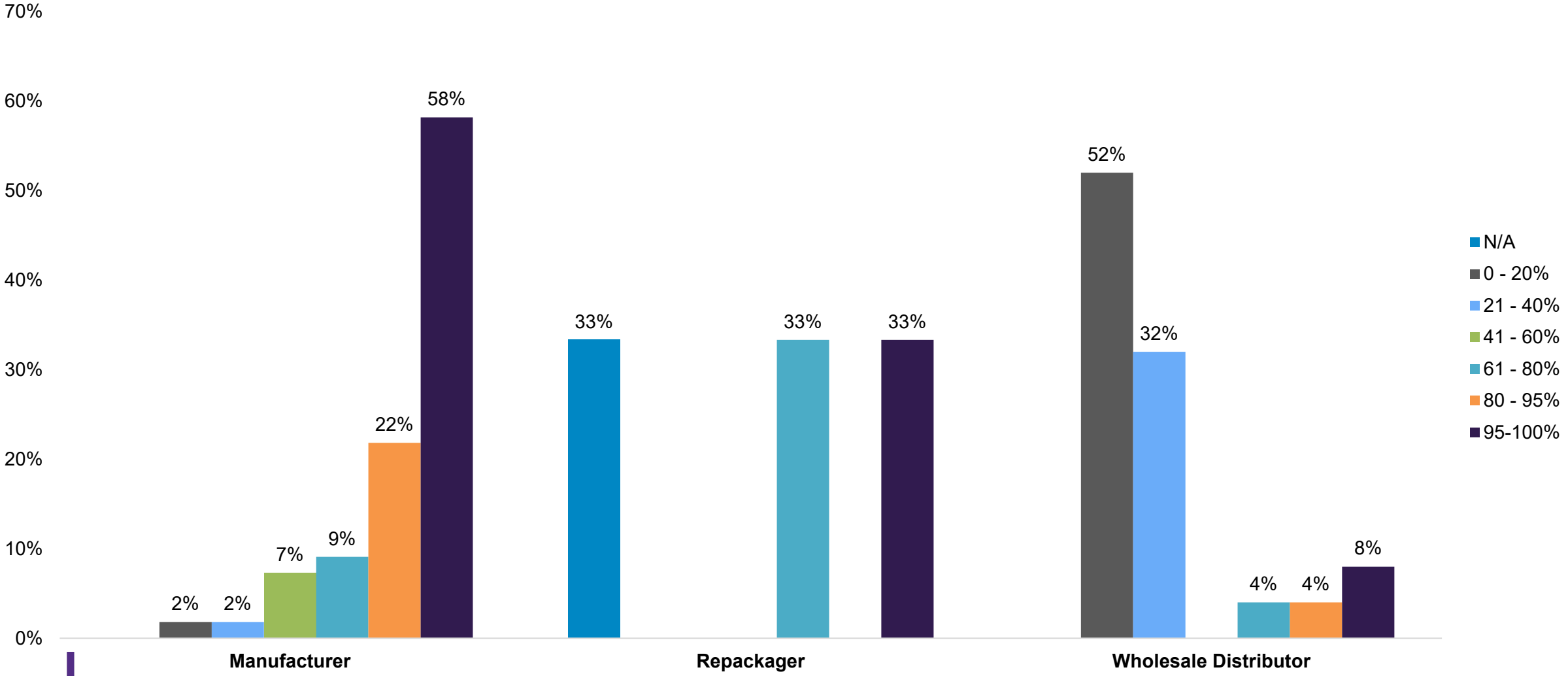
To approximately what percent of your customers are you routinely providing complete serialized data (i.e., transaction information)?



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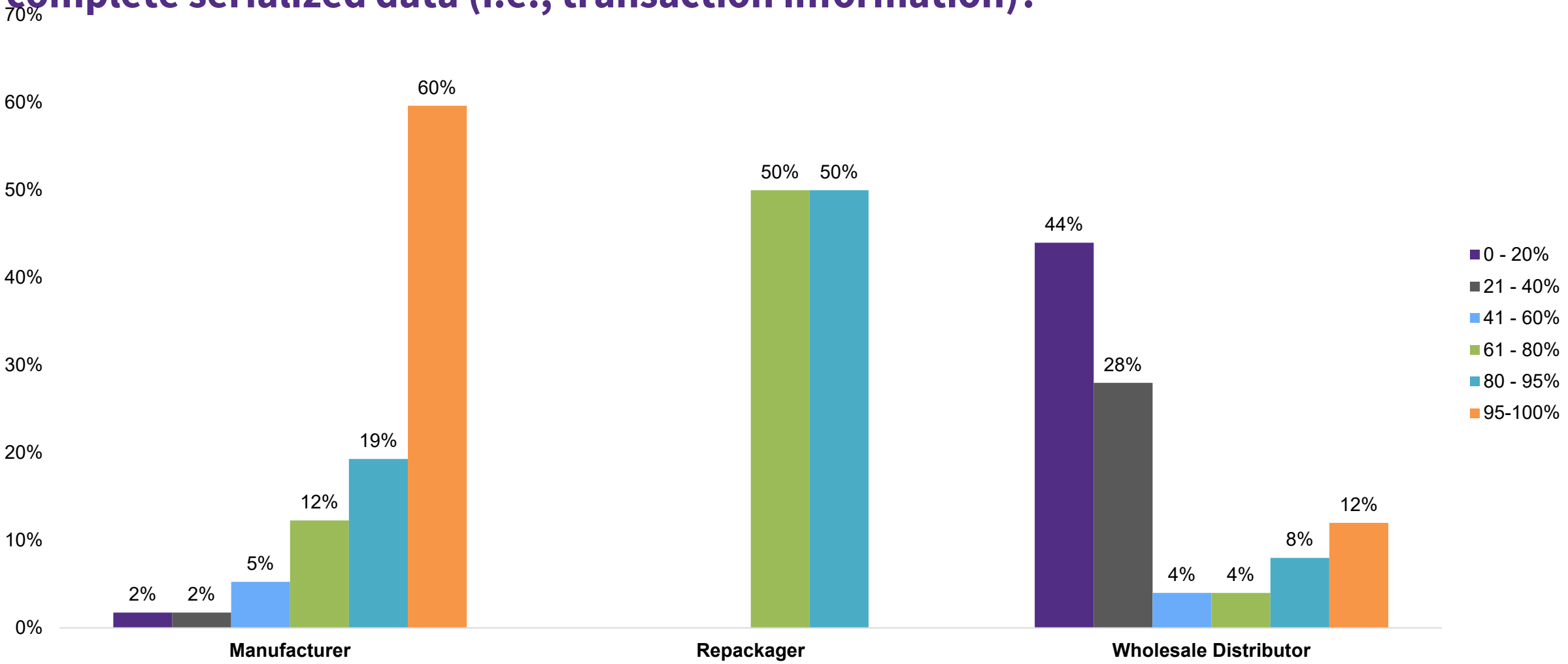
For approximately what percent of product you sell are you routinely providing complete serialized data (i.e., transaction information)?



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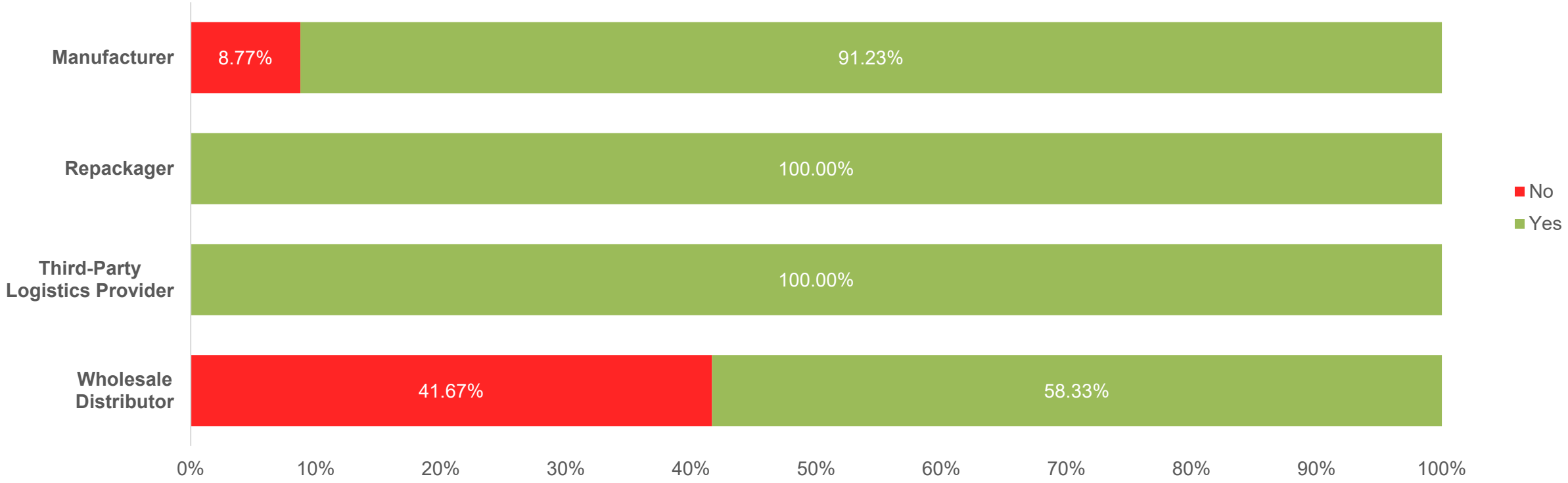
Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you send?



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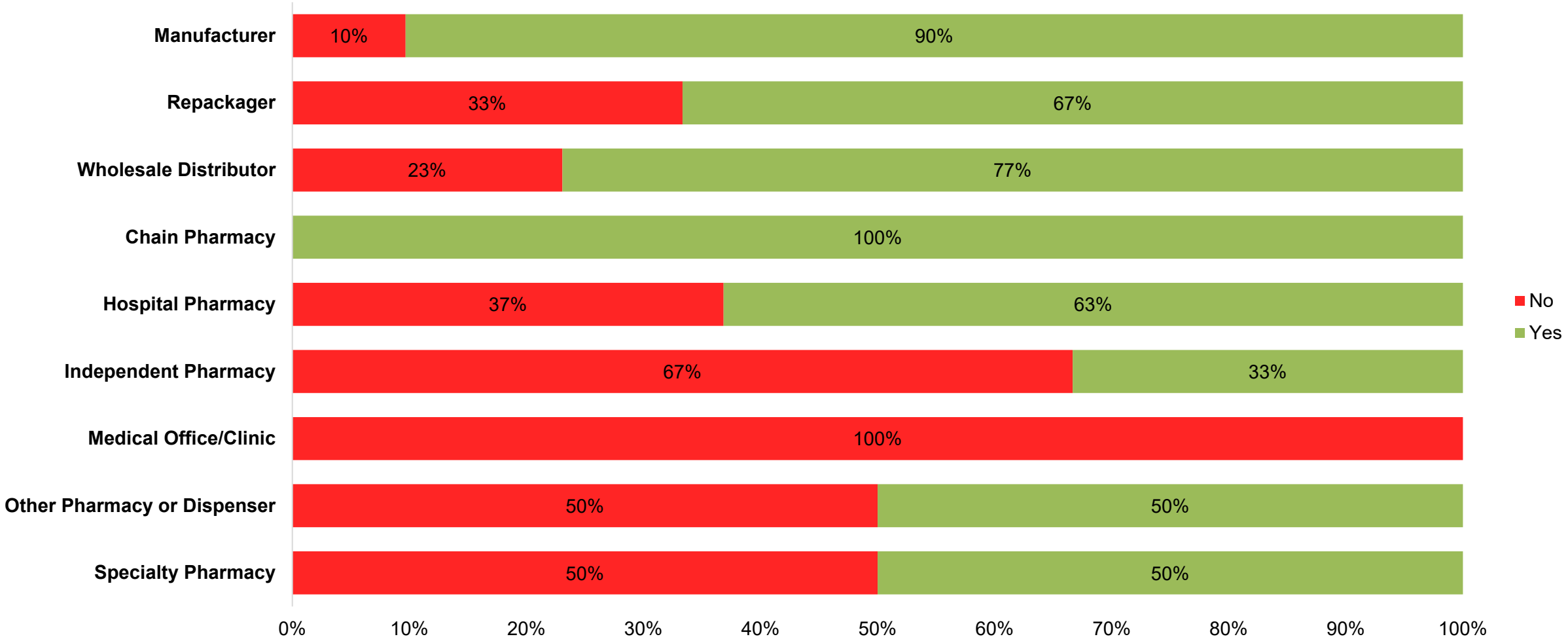
Do you have interoperable electronic systems and processes to verify product identifiers?



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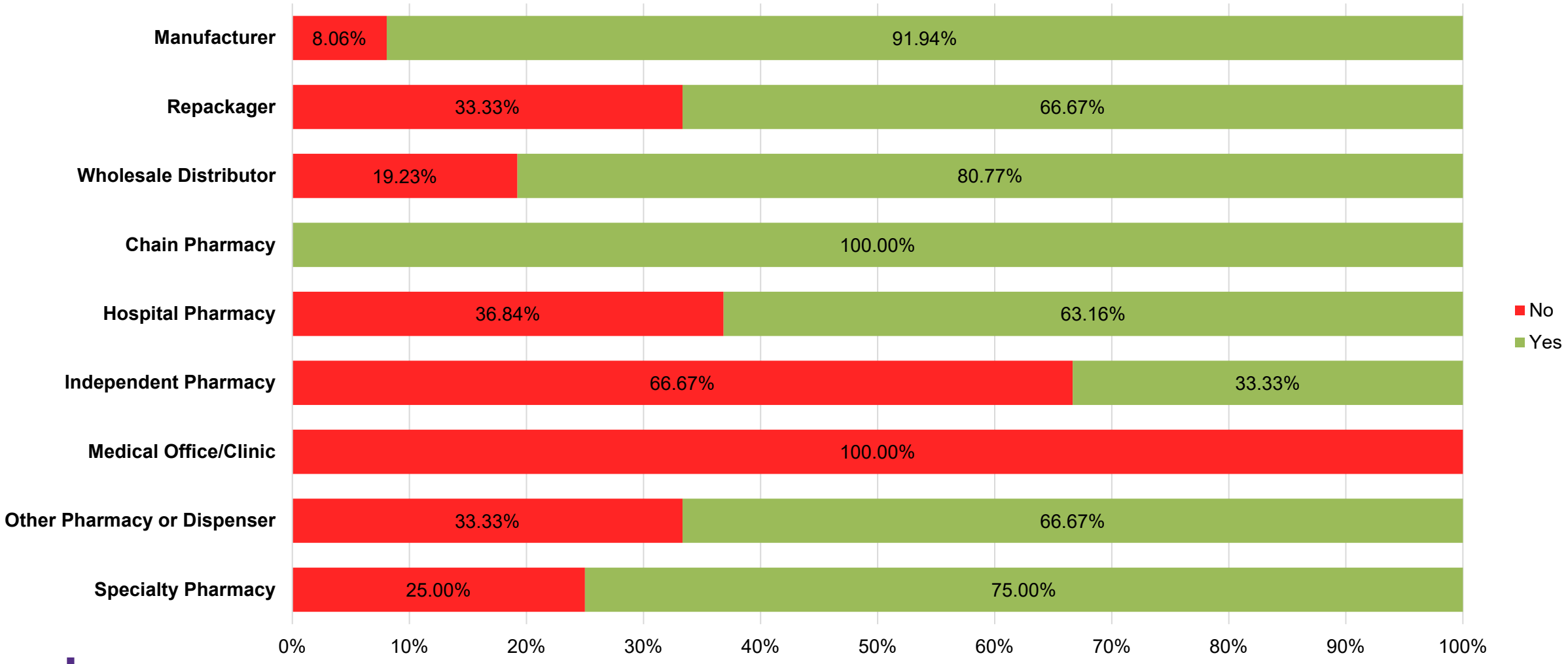
Do you have interoperable electronic systems and processes to facilitate gathering the information necessary to produce the TI for each transaction back to the manufacturer (i.e., trace)?



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What do you believe is the biggest risk to your organization's ability to stabilize its systems and processes for unit-level tracing?

Manufacturers

- Predominant concerns are **lack of feedback** on data quality from downstream trading partners and management of **exceptions**.
- Many concerned with availability of **resources** and staffing.
- Many also indicated they don't foresee risks.

Wholesalers

- Overwhelmingly predominant concern is readiness/amount of **data flowing from manufacturers**, though several noted that it is limited to a small number of manufacturers.

Dispensers

- Predominant concern among **chains and hospitals** is **upstream readiness** of their suppliers, with some also concerned about data quality.
- **Independent** pharmacies much more focused on **competing business priorities**.

What do you believe is the biggest risk to the industry's ability to stabilize its systems and processes for unit-level tracing?

- **Uncertainty of requirements—regulatory clarity and trading partner understanding**
- **Trading partner readiness**
- **Data quality and exceptions**
- Master data
- Variability of approaches and methods for data exchange
- Risk to patient access
- Time and resources

What is the most important/beneficial action the industry needs to take to stabilize systems and processes for unit-level tracing?

- **Increase standardization of data exchange practices**
- **Increase downstream feedback on data quality**
- **Test and improve data quality**
- Agree on ways to manage exceptions
- Get more data flowing
- Communicate
- Don’t slow down
- Improve master data sharing
- Phase the implementation by sector

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What is the most important/beneficial action regulators need to take to stabilize systems and processes for unit-level tracing?

- **Start enforcing/auditing; no more delays**
- **Extend the stabilization period**
- **More/clearer guidance and willingness answer questions**
- Communicate to/educate dispensers
- Clarify dispensing expectations when exceptions occur
- Phase requirements in by sector
- Pursue global interoperability

Manufacturer Perspectives on Stabilization

Moderator

- Lysette Deshields, PharmD, JD, Regulatory Counsel, DSCI, ODSIR, CDER, OC

Panelists

- Gillian Buckley, Pharmaceutical Research and Manufacturers of America (PhRMA)
- E'lissa Flores, Biotechnology innovation Organization (BIO)
- Scott Kuzner, Association for Accessible Medicines (AAM)
- Gil Roth, Pharma & Biopharma Outsourcing Association (PBOA)

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PhRMA
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Feedback on the Implementation of DSCSA

Updates and Suggestions for the Midway Stabilization Checkpoint

PhRMA

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $1.2 trillion in the search for new treatments and cures, including $100.8 billion in 2022 alone.

Background

Uneven preparedness to meet DSCSA requirements

- Interoperability depends on collaboration, communication, and alignment among trading partners
- PhRMA members have used the first half of the stabilization period to work with trading partners to:
  - identify and correct problems with EPICS data sharing
  - support trading partners to jointly implement DSCSA.
- While PhRMA members have systems and processes to meet the DSCSA requirements, we understand that some trading partners may not have the same level of readiness – for example, members have reported that not all trading partners are:
  - Providing feedback on the completeness of data exchange
  - Aware of how to manage data discrepancies
  - In a position to accept serialized data at the package level

Promote readiness

PhRMA encourages FDA to promote readiness

- FDA should urge all trading partners, during the stabilization period, to:
  - Enhance supply chain collaboration to enable seamless data exchange
    - Implement systems and processes for interoperable serialized data exchange
    - Provide feedback on the completeness of the data exchanged
    - Establish a process to reconcile the product to electronic EPICS data
    - Promptly notify manufacturers of data gaps and collaborate in their correction
    - Ensure all downstream trading partners adopt these measures to achieve stable process, systems, and data quality at scale
  - Exchange serialized data at the package level – and relatedly to
    - Highlight data aggregation and EPICS as the recommended means of DSCSA data exchange

Support for monitoring and risk-based enforcement

PhRMA encourages FDA to:

- Continue to monitor implementation of DSCSA systems and processes for the remaining stabilization period
- Publicly reinforce a risk-based approach to enforcement
- Provide further clarity on waivers, exceptions, and exemptions (WEEs)
  - Appreciate new guidance and clarity around enforcement discretion
  - FDA could be inundated with requests for WEEs, and may need a process where trading partners can rely on a submitted request and continue transactions while a request is pending with FDA

Further education and outreach

Support for:

- DSCSA portal in the CDER NextGen portal
  - PhRMA supports the portal and its goal of facilitating communication among FDA and trading partners when there is a recall or suspicion of illegitimate product
    - Portal Guidance and FAQ was useful
    - Acknowledge FDA's intent to publish a step-by-step tutorial on using the portal
    - PhRMA encourages FDA to issue this tutorial in an effort to build competency across all supply chain partners
- Authorizing trading partner status
  - PhRMA encourages FDA to provide guidance on how sponsors can verify the identity of authorized trading partners
    - especially for indirect trading partners or in responding to FDA or government requesters under 582(g)(1)(D) and (E) of the FDCA

Association for Accessible Medicines (AAM)

FDA/PDG DSCSA Public Meeting

June 17-18, 2024

aam
Association for Accessible Medicines

Your Generics & Biosimilars Industry

Association for Accessible Medicines (AAM)

- AAM represents generic and biosimilar medicines in the U.S.
- Generic and Biosimilar products account for over 90% of annual US unit volume – but only 17.5% of expenditures.
- AAM members investment in DSCSA has been considerable.
- Our members have complex ecosystems.
- This level of unit volume portends a similar share of data exchange, enhanced verification and tracing activity, etc. after November 27th, 2024.

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1. Meeting the DSCSA requirements for November 2024:
Enforcement Discretion / Data Stabilization Period

"***Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies***", was released August 25, 2023.

As of today – The Enforcement Discretion / Data Stabilization Period has been in effect for 297 days – and has 163 days to go to Nov 27th, 2024.

1. Meeting the DSCSA requirements for November 2024: Data Stabilization

- **What does it mean to AAM members for DSCSA systems and processes to be stabilized**?
  - Perspective of AAM manufacturers.
  - "*To be stabilized would mean that we have reliable systems and processes to confidently exchange data with all Trade Partners and have Trade Partners receive it – with a clear process for the resolution of data discrepancies*."
  - Integrate DSCSA data into everyday systems and processes.
  - Achieve high integrity and accuracy of the DSCSA data.
  - Some AAM members said that the "go-live" will tell us how stabilized we actually are in terms of data quality.

1. Meeting the DSCSA requirements for November 2024: Tracking stabilization process

- Percent of On-boarded Trade Partners for Data Exchange.
- Percent of total transaction volume where unit-level data is sent in Transaction Information (TI).
- Quality and Accuracy of the transaction data being exchanged.
  - What is the data error rate today?
  - What will the data error rate be on Nov 28th?
    - Putting this in context for 4.5B units/ year – a 2% error rate means 90 million data discrepancies/ year. A 5% error rate means 225,000,000 / year.
- The quality and accuracy of the data, once known, may require our members to pivot quickly to adjust resources and staff differently depending on the number of reported discrepancies and resulting investigations.
- What will happen to otherwise-good product with incorrect TI unit-level data after November 27th?
- AAM members perspective on how Stabilization is progressing generally.

1. Meeting the DSCSA requirements for November 2024:
Data Discrepancies – Discovery, Notification, Resolution

- Are these discovered before the first change of ownership (within our ecosystem) – by us?
- Our members ecosystems may include Contract Manufacturers and 3PL's to make the data association between the units in a transaction and that shipment.
- Are these discovered after the first change of ownership – by another trade partner?
  - Reporting of Discrepancies between trade partners should contain standardized data elements included in prompt communications to allow faster and more efficient investigations.

2. Trend:
Demographics of direct trade partners not yet on-boarded for data exchange

- AAM members did not cite any sector.
- Lack of contact tends to occur more in smaller companies.
- Members have been surprised that scorecarding results are as different from company to company as they have been thus far given that the systems and processes to generate and send data are the same.
- Members stated that one trade partner does not reflect another in a similar business – companies are performing differently in stabilization from one another.

3. AAM Recommendations:
What should FDA do between now and November 27th?

1. AAM supports PDSA's recommendation that FDA provide written communication to all trade partners within each sector of the US supply chain.
    - AAM recommends that this communication should list the "2023" DSCSA unit-level requirements that sector must achieve.
    - It should also list the penalties for trade partners who do not comply.
2. We believe that FDA should prepare for a possible increase of Waiver, Exceptions, Exemption (WEE) requests, that would need to be answered by Nov 27th. Industry should file any WEE requests involving go-live to FDA - as early as possible.
3. (Industry) Some AAM members are considering having a final date to on-board trade partners, after which their data would be placed in a data portal to be made available to them until they can be on-boarded using EPCIS. The date would be determined by the individual company and its trade partners.

Wholesale Distributor Perspectives on Stabilization

Moderator

- Sara Keller, MD, MPH, Regulatory Counsel, DSCI, ODSIR, CDER, OC

Panelists

- Elizabeth Gallenagh, Healthcare Distribution Alliance (HDA)
- Christina Lavoie, Health Industry Distributors Association (HIDA)

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Stabilization of Manufacturer-to-Wholesaler Data Exchange

Moderator

- Elizabeth Gallenagh, Healthcare Distribution Alliance (HDA)

Panelists

- Pam Clements, Smith Drug
- Kristen Mattioni, Teva
- Arthi Nagaraj, Sanofi
- Maryann Nelson, Cardinal Health

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Reactions and Takeaways

- Leigh Verbois, PhD., Director ODSIR, OC, FDA
- Eric Marshall, Executive Director, PDG

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PDG-FDA Joint Public Meeting

DSCSA Stabilization Period Midway Checkpoint

June 17-18, 2024
Washington, D.C.

pdg Partnership for DSCSA Governance

FDA

Wi-Fi Network: Leavitt Guest

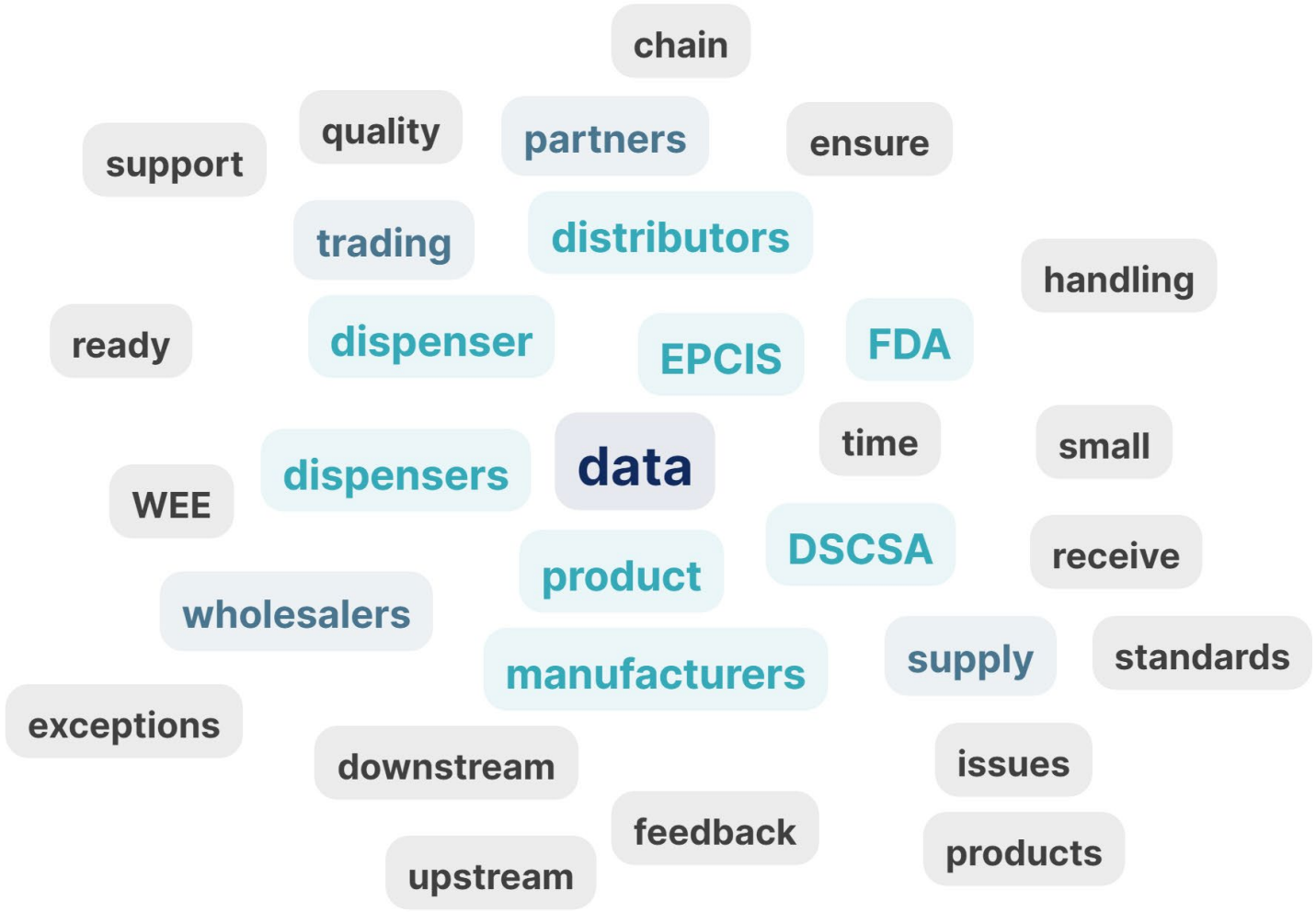
Wi-Fi Password: Connect!

Highlights and Conclusions from Day 1

- Leigh Verbois, PhD., Director ODSIR, OC, FDA
- Eric Marshall, Executive Director, PDG

Highlights and Conclusions from Day 1

Q&A word cloud



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Dispenser Perspectives on Stabilization

Moderator

- Tia Harper-Velazquez, JD, Division Director, DSCI, ODSIR, OC, CDER, FDA

Panelists

- Dr. Ilisa Bernstein, Member of the American Pharmacists Association (APhA)
- Lisa Schwartz, National Community Pharmacists Association (NCPA)
- Jillanne Schulte Wall, American Society of Health-System Pharmacists (ASHP)

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Stabilization of Wholesaler-to-Dispenser Data Exchange

Moderator

- Dr. Ilisa Bernstein

Panelists

- Julie Malone, Value Drug Company
- Marian Daum, VA Medical Center
- Scott Mooney, McKesson
- Denise Rodriguez, Rite Aid
- Christian Tadrus, Sam's Health Mart

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Lunch (12:15-1:15 PM EST)

For In-Person Participants: Find a Leavitt Partners Administrative Assistant near the elevator bank and they will show you up to the roof deck if you would like to eat lunch there.

Stabilization Progress from the Perspective of Supporting Organizations

Moderator

- Matt Price, Board Chair, PDG

Panelists

- Wyn Gary, ConsortiEX
- Tracy Nasarenko, GS1 US
- Anil Suresh, SAP
- Mark Tate, Infinitrak

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State Perspectives on Stabilization

Moderator

- Josh Bolin, National Association of Boards of Pharmacy (NABP)

Panelists

- ***Todd Dear, Mississippi Board of Pharmacy***
- ***Alexandra Blasi, Kansas Board of Pharmacy***
- ***Jenni Wai, Ohio Board of Pharmacy***

Stakeholder Comments

Virtual

- Nivrutti Patil, Ajanta Pharma Ltd
- Shereen Awad and Bala Bhaskar, Aurobindo Pharma Ltd
- Subramanya Gumma, Working with Bio and PhRMA
- Himani Singh Mengi, Ecolab Inc.
- Anurag Saxena, Icon Indices
- Dave Mason, Novartis
- Janne Rokossa, Regulator
- Stephanie Byrne, SL Byrne Consulting

In-Person

- Herb Wong, Antares Vision
- Gary Lerner, Gateway Checker
- Scott Hatakeyama, Kaiser Permanente
- Andre Darville, LumiRx
- Mark Hendrickson, PDSA
- Michael Rowe, Two Labs

DSCSA EDDS Readiness for Virtual Pharma Manufacturers

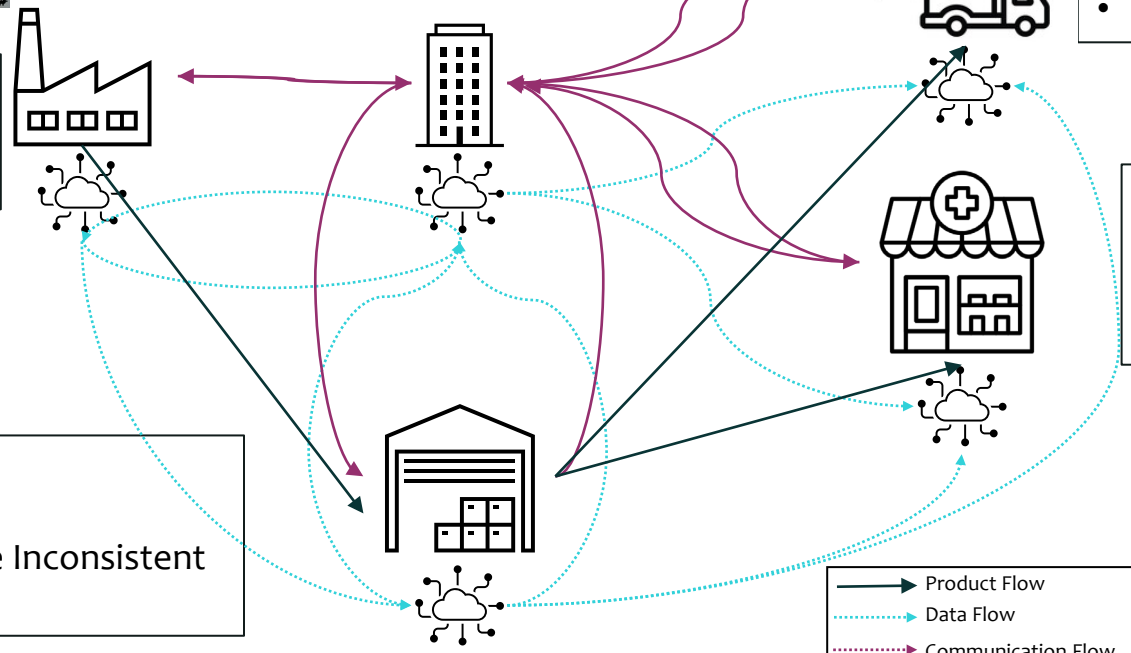
< 50% - 100%
Success Rate in Sending EPCIS

>90%
Of Exceptions Are Due To Data Issues

> 2 weeks
Average Time to Correct Data Issues

Manufacturers:
- Need Enhanced Tracking & Coordination
- Need to Refine Alignment/RACI

CMOs/CPOs:
- Still some challenges in adhering to standards



Wholesale Distributors:
- Not Yet at Full Scale
- Notifications and Reporting are Inconsistent
- Inadequate Support

Dispensers:
- Not Yet at Full Scale
- Lack of Knowledge in Dispenser Community

3PLs:
- Not Yet at Full Scale
- Notifications and Reporting are Inconsistent
- Inadequate Support

Solution Providers:
- Underlying Weaknesses are Being Exposed
- Lack of Functional Corrections
- Inadequate Support

Stephanie L. Byrne, DSCSA Consultant
slbyrne.consulting@gmail.com

Enhanced Drug Distribution Security

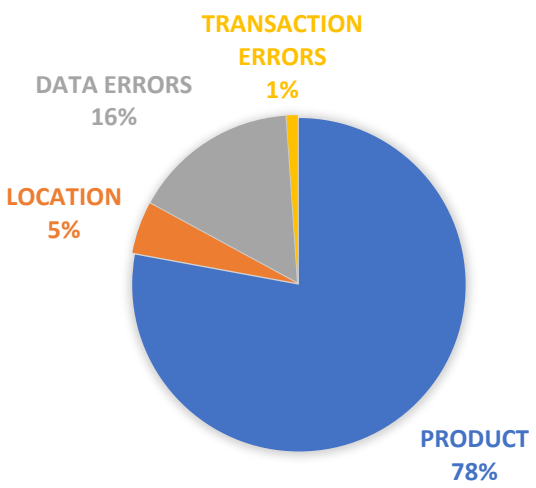
Status Update During the Stabilization Period

Enabling supply integrity and trade partner information interoperability

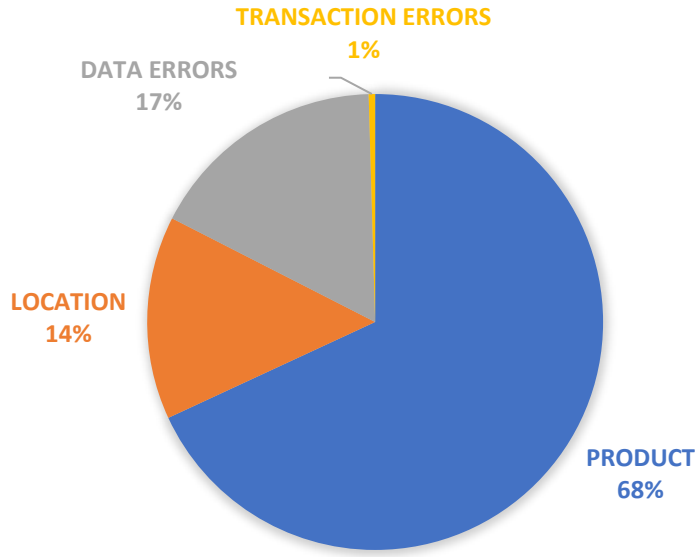
GATEWAYCHECKER™

Gateway Checker Corporation ♦ Lexington, MA 02420 ♦ 781-861-9760

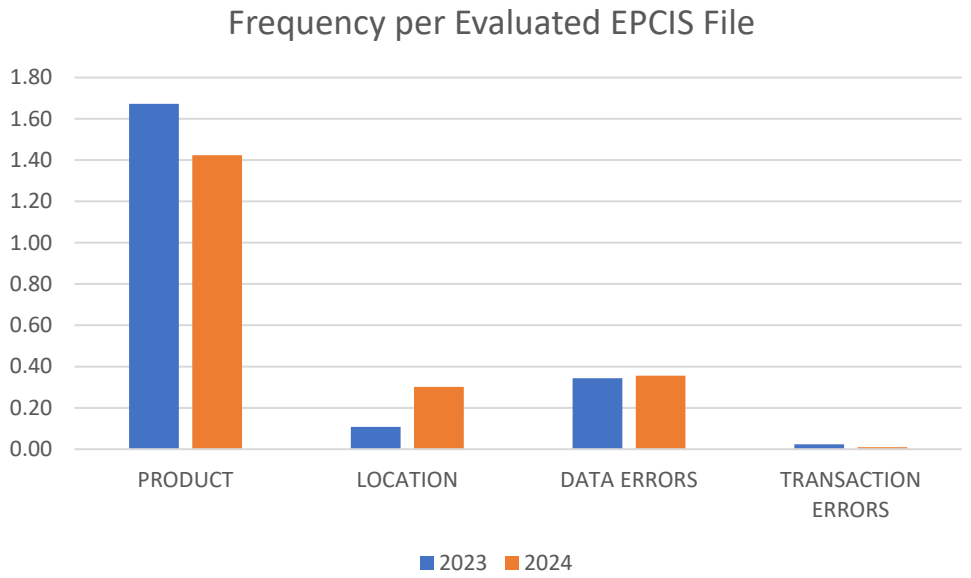
EPCIS Evaluation Findings – 2023 vs 2024 YTD



2023



2024 (250% more Files Evaluated)



PRODUCT		LOCATION		DATA ERRORS		TRANSACTION ERRORS	
Dosage Form Type	117%	Street Address issues	25%	SN with Leading 0	20%	Readpoint not well-formed SGLN	1%
CMS NDC 11	36%	Zip Code issues	2%	Event Time sequence	9%	Missing Transaction Statement	0.5%
Master Data missing	1%			Child count inconsistent	1%	PO value blank/null	0.5%
				Commission items not shipped	0.5%	Multiple POs not assigned to SN	0.5%
				SGLNs not well-formed	0.5%		

EPCIS TRIVIA - TRUE OR FALSE ?

- The FDA recommends Electronic Product Code Information Services (EPCIS) as the only widely recognized international standard that allows supply chain partners to share data that complies with the Drug Supply Chain Security Act (DSCSA).
- EPCIS is an open standard which cannot be unambiguous assessed for DSCSA compliance because all guidelines are voluntary and were authored by a voluntary healthcare user group
- A GS1 US Trustmark is issued on behalf of a GS1 company prefix holder (manufacturer or wholesaler) for each role-based pharmaceutical traceability scenario successfully executed.
- There is a GS1 Certified Conformance Testing Service that has tested thousands of DSCSA EPCIS 1.2 files for pharmaceutical manufacturers, 3PLs, and wholesale distributors since 2019.
- The Drug Product master data, as mandated by DSCSA regulations, is accessible programmatically from the published FDA National Drug Code Database.
- The Drug Dosage Form Type should exactly match one of the standard FDA drug forms

Are these Dosage Form Types one of the standard FDA drug forms?

- FILM COATED TABLETS
- SOLUBLETABLET
- LIQUID FILLED CAPSULES
- SOLUBLE FILM
- INJECTION, SUSPENSION, EXTENDED RELEASE
- TABLET, MULTILAYER, EXTENDED RELEASE

Which of the following is the correct representation of the CMS 11-digit NDC derivative within the EPCIS 1.2 Application Standard?

- **65862-927-30**
- **65862-0927-30**
- **65862-927-030**
- **6586292730**
- **65862092730**

Actions for Success

- Leigh Verbois, PhD., Director ODSIR, OC, FDA
- Eric Marshall, Executive Director, PDG

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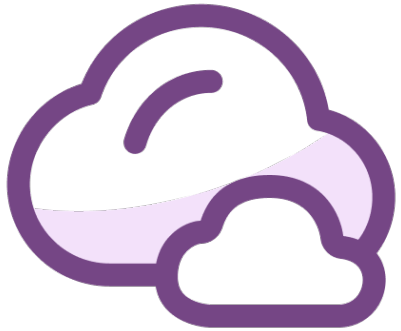

What action do you believe is most needed over the next 5 months in order to stabilize interoperable systems and processes?

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What actions should be taken to improve trading partner engagement in the stabilization process?

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