Public Meeting on the Drug Supply Chain Security Act (DSCSA) Pilot Project Program and Enhanced Drug Distribution Security- Adobe Connect Closed Captioning Transcript, December 9, 2020

This transcript reflects the closed captioning from the live meeting. It has been edited from its original format to include speaker names and exclude dialogue regarding technical difficulties.

Tia Harper-Velasquez:
Good morning everyone. It is 9:00 so we will go ahead and get started for today. I am Tia Harper Velasquez, Branch Chief of the Supply Chain Strategy and Policy Branch in the Office of Compliance. This morning it is my honor to introduce Mr. Don Ashley . Don is the director of CDERs Office of Compliance at the FDA and he will give his opening remarks. I will turn it over to you.

Donald Ashley:
Thank you Tia, and Good morning everyone and welcome to day two of our DSCSA public meeting. We're very pleased to have you join us today to discuss the importance of protecting the integrity of the nation's drug supply. Securing the drug supply chain is a top priority for FDA. This is especially important during this ongoing pandemic in order to help ensure access to critical drugs needed to treat COVID-19 patients and also to protect the American public from potentially dangerous medication. With today's global environment, this is truly a worldwide effort as you all know a large percentage of FDA approved drugs are actually manufactured outside of the United States. To help ensure ready access, critical drugs needed during the pandemic we issued a guidance, in April this year , highlighting the public health and emergency exemption as well as the exclusion under DSCSA for trading partners responding to the COVID-19 public health emergency. These flexibilities are built into the DSCSA and they aim to balance the need for effective distribution of products under emergency conditions and the need to protect the public from exposure to products that may be counterfeit or stolen otherwise harmful. I would also like to take a moment to echo Dr. Cavazzoni's points from yesterday on the importance of implementing DSCSA. Doing so will enable us to prevent harmful drugs from entering the supply chain, to detects and identify harmful drugs, if they do enter the supply chain and to respond rapidly whenever harmful drugs are found. The interoperable electronic system we are developing will enable secure product tracing and verification at the package level, enable prompt response when suspects or illegitimate products are found and will also improve the efficiency of our recalls. Our future vision for enhanced drug distribution security involves knowing one, what drugs are still the supply chain, and two, who was involved in the manufacture, distribution and dispensing or administration of those products. As well as maintaining product quality and supply integrity. Today's discussion will specifically focus on a couple of items. Starting off with system needs for security, appropriate access, and functionality for enhanced product tracing and verification at the package level. Processes operationalized, the electronic data exchange, investigations and response when suspect or illegitimate drugs are found in the supply chain and also data analytics or supply chain risk. Our discussion will focus on certain requirements outlined in the statute and regulations. Now, your input is absolutely critical. We really want to hear from you today on these topics. Our goal is to learn from your perspective in order to help inform DSCSA implementation.
I am confident that we will all benefit from this discussion today and together we will continue to combat supply-chain problems as they arrive. And also increase confidence in the

integrity of the lifesaving prescription drugs that all Americans rely on. Thank you very much. Thank you for the introduction Tia and thank you all for attending today. We look for to some very productive discussions.

Tia Harper-Velasquez:
Thank you Don. These are the goals of the meeting that are shown on your screen right now. Today we will focus on our goal to further inform FDA's development of the enhanced drug distribution security provisions of the DSCSA. We heard a lot of interesting pilot project results yesterday and today we hope to discuss how the strategies and issues to enhance product tracing and verification.
Like yesterday our main meeting with all meeting attendees will continue in Adobe. You are in listen only mode. We made some adjustments and we will conduct breakout sessions after a short FDA presentation. If you received an invitation for a breakout session, we will be providing new links today for those breakout sessions. Please do not use the links that were e-mailed to you previously. Breakout session A will occur first followed by breakout session B. with a different set of attendees and covering the same topic. FDA will capture the discussions and aggregate the summation and not associates specific individual company. While FDA will be reviewing certain concepts before each breakout session, I am reminding you that there is a concept and terminology sheet posted on our public meeting webpage that may be useful to you. So here's the agenda for today. Everyone should be able to see that or printed out if you need it. I will now turn it over to Abha. Abha is going to review the enhanced drug distribution security requirements and needs. I will also advance the slide for you.

Abha Kundi:
Thank you Tia. Good morning everyone. I informally introduce myself yesterday for a bit. But I think many of you know me from public meetings past. What you see projected on the screen here is unlike in public meetings past, we are focusing more on primers rather than giving you an overview of the law and regulatory activities by the FDA up to this point. We are assuming that our audience has more familiarity with the law and with FDA efforts for implementation. But if you don't or you want a refresher, we have our FDA DSCSA website and the public meeting website as Tia mentioned, has supporting documents for this meeting as well. Here you will see, this is the primer before we get into the breakout session discussion which we really hope today will go more smoothly and we hope to have some robust conversation. What you see here is enhanced drug distribution security requirements and needs. That needs refers to items that are not in the law but based on what we have heard over the years. They are things that folks have identified as being needed for enhanced drug distribution security to be effective. As you will see for enhanced drug distribution, there is expectation and requirements and be fully electronic and interoperable, it must secure data and systems against falsification, malicious attacks, and breaches. Ensures protection of confidential commercial information and trade secrets. Enable authorized trading partners to exchange and store data accurately and efficiently for each transaction. Enable authorized trading partners to promptly respond to a request for product tracing information. Enable prompt gathering of the information necessary to produce the transaction information for each transaction going back to the manufacturer when appropriately requested. Enables authorized trading partners to verify product identifiers accurately and efficiently to facilitate investigations of suspect or illegitimate product, recalls, and salable returns. Alerts that a

product has been determined to be a legitimate has also come up as an enhanced drug security distribution item. Enables scalability for integration by any business size, so small or large, it is workable for everyone in the supply chain. Ensure appropriate users have access to the data and systems.
We will quickly go into what we have covered in other meetings up to this point. I know there was some talk about different types of structures, or system architecture but here as you see on the slide, we quickly summarized the centralized system which is trading partners provide data to a central suppository. Product tracing and verification is performed by querying the central repository. In a decentralized system, trading partners maintain the data in their own local database or data storage provider database. Product tracing and verification is performed by querying the multiple databases. A communications hub, active or passive, connects different databases. Then we have featured on the bottom of the slide semi-centralized which is trading partners maintain data into the same centralized databases or storage providers databases. Product tracing or verification is performed by querying each of those databases and a communication hub connects different databases. You have a spectrum of solutions here and our sense from dialogue with the industry and other stakeholders up to this point, is there seems to be some gravitation towards a semi-centralized model but based on conversations we heard a little bit about yesterday, I know folks were [Indiscernible] around different types of database options.
Again this is just a primer and this is a very brief summary of the changes that we are going to see with enhanced requirements . In 2023 the electronic transaction information or TI, must include the product identifier at the package level for each package included in the transaction. What this means is the TI will include more information than what it is required today. With that that I think that we can start setting up discussing the first breakout session. As you can see these are the questions that we would like to tackle. First, with the A group, which means the B group will be on break or waiting until its their turn. I'm going to [Indiscernible]. I think Kristle just provided the link to the Concepts and Terminology document which is going to be helpful during the breakout sessions too. We will refer to that while we talk . These are the questions that we will tackle and the first breakout session. Which is how can we ensure appropriate access to the electronic, interoperable system in 2023? We know that access is a big question out there for that. What steps are you or your sector taking to incorporate product identifier and product tracing information, transaction information as required in 2023? And how can product tracing be done in 2023 accurately and effciently? How does inference affect product tracing for the seller? For the buyer? How will trading partners reconcile TI data and product sold or purchased? Some pretty meaty question but I think we have a really good and we can tackle these questions and we will come back together. Kristle has set up a link here so find your link and I will meet my breakout group in WebEx. Thank you everyone.

Connie Jung:
This is Connie. Looking at the participant chat if you are assigned to group A we will be assigning breakout sessions now and transition over to the break out session A. If you were originally and group A one and two please use the first link. If you in group A, three and four please use the second link . That includes Candace's link. If you are in group A, five and six please use the WebEx link in the chat that has Joseph's name in it. We will then transition into breakout sessions Be in about 35 minutes. We will adjust the time slightly . Breakout session Awill start now at 9:14 and to make it easy I could say that breakout sessions will go

30 minutes to 9:45 with a five-minute transition so , therefore, breakout session B will be at , 9:50. We will put that information in the chat. Thank you. >> We will try to manage the questions also in the chat box in the main room. Thank you .

[The event is on a recess. The session will reconvene at 9:45 Eastern. Captioner on stand by.] >> >>

Abha Kundi:
I think folks are returning and want to make sure that we have enough time for the breakout sessions. We never do. And I will set up my WebCam. I hope you had a good break. Let us get into something that I know came up yesterday. Which is another enhanced requirement that presents procedural , operational, technical challenges. Current state. we are working with three pieces of transaction documentation , TI, TS , transaction statement and transaction history. In the enhanced world, the transaction history is no longer a third distinct piece of documentation that accompanies transactions. Instead, we need to have the ability to facilitate the gathering and it is essentially what we put up here on the slide. Which is in the instance of recalls or suspect or illegitimate product investigation, trading partners must have the systems and processes necessary to promptly respond with the transaction information and transaction statement, and to promptly facilitate the gathering of information necessary to produce the product the transaction information for each transaction going back to the manufacturer upon request by a regulator or authorized trading partner.
With that again we are really doing these more as primers and really want to get into the discussion. So, with that definition in mind, we are going to get back into our next round of breakout sessions and we're going tackle these questions which is how can technologies and functions of the 2023 system be used to accurately and efficiently facilitate the gathering of transaction information? More specifically, what does a request for product tracing information look like? What is the minimum data or information needed in such a request? Is this different for each trading partner or regulator such as the FDA? What would an information response look like? What is the minimum data and information needed in such a response and consider how inference would impact response? Is the response different for each trading partner? And then how long should it take for trading partner to respond to all product tracing information request? I think we were talking about yesterday about timing. With that Kristle has posted the links for the groups, I apologize for the background noise. I will ask that group letter a breakout session participants get into the WebEx soon and breakout session B will join in just over 30 minutes from now. I am checking the agenda to make sure. Okay. With that I will see everybody in my group A in the WebEx breakout room. Thank you.

>> [The event is on a recess. The session will reconvene at (not provided). Captioner on stand by.]
>> [Captioners transitioning]

>> [Captioner Standing By]

[The event is on a lunch break. This session will reconvene at 1:20 pm. Captioner on stand by.] >>

[Captioners transitioning]

Abha Kundi:
We have one more breakout session after this, and then we'll do a recap and closing remarks. So again, just going to do a primer before we get into the discussion, and it will proceed the same way, which is group A, and then after that, group B will go to the WebEx breakout room and there will be a facilitator or two, and scribes as well. So enhanced verification. The definition of verifier verification is determined whether the product identifier sticks to or imprinted upon a package or homogenous case, corresponds to the SNI or lot number and expiration date assigned to the product by the manufacturer or repackager as applicable. Why is this important? You can check the authenticity of the product that you have. It indicates whether the product should be in the supply chain, and identifies the product identifier associated with an illegitimate product. So the breakout session, you know the questions might look -- are kind of in parallel to the previous question, but obviously related to verification. So how can verifications be done in 2023 to verify product identifiers accurately and efficiently, and here we want you to consider what you have learned from preparation for the verification requirements or saleable returns. What do the verification request look like? What is the minimum data or information needed in a verification request? Is it different for each training partner and FDA? And what would a verification response look like. What was the minimum verification needed and with that, consider how inference will impact a response. And is it different depending on the trading partner? How long should it take a training partner to respond to a verification request? With that we'll once again go to the same format we've been using. If you're in breakout session A, please go to your designated WebEx room, and if you're in session B, you've got a 35 minute break and then you will go to the WebEx room for your session. Thank you, everyone.

[Captioner standing by]
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Connie Jung:
Thank you. We did run a little late. I was a facilitator and we were trying to provide a summary of both dates. Sorry about that. What you see now is our recap slide. So thank you for coming to our recap session. These are not perfect and not final. But we just wanted to be able to give you of little bit of a taste or flavor of what we heard yesterday and today. Again, this won't have everything that we discussed but we tried to highlight a few things here. In terms of day one, we focused on pilot projects and pilot activities. We know there's probably a lot more to do but just based on some of the many questions that we received and the participant chat, but also in the breakout sessions that we were able to occur in our larger session, we wanted to highlight a few things that we thought were important. In terms of what technology messaging systems could enable and enhance verification. The credentialing for determining authorized trading partners seems to be a very interesting topic for folks and the pilot that were , that was presented yesterday. And other discussions that are happening in other groups. This is an very important issue for not just to follow the requirements of the law

but for you, as a member of the supply chain, for you to know where you dealing with. The other thing that we heard yesterday, a lot of discussion was related to the two dimensional barcode and the quality around that. That also led to discussions around the data and data quality as well. So it does sound like because the barcode is where the data is, the barcode will be utilized for capturing data and enabling data exchange. In addition there was a lot of discussions and questions around RFI. tags as another data carrier. That could enhance some product tracing and possibly verification. Now we just want to know that the DSCSA does not require the use of RFID tags, that currently the law requires two dimensional data matrix barcode. The pilot that we heard about yesterday and part of our program did point out some functionalities that may be of interest to folks.

The other thing that we heard about yesterday and even today, centered around the types of systems or databases and in terms of what we saw and some of the pilots is whether they, the data was more centralized versus decentralized. And that is something that still warrants further discussion. Also the verification router services and that model is, it can be used for obviously verification steps but it not necessarily all trading partners adopting that model or method right now. So some additional opportunities here to think about. Additional testing or piloting that is our recap of day one.

For today it was jammed full of a lot of various discussions. What we try to do here is also highlight some of the key things that we heard in our breakout sessions related to enhanced product tracing. So we kind of broke these up. The first bullet was related to ensuring appropriate access to the electronic, interoperable systems in 2023. Focusing on the fact that it is, the expectation is everything moves to electronic and what efficiencies would we see in 2023. The confirming authorized trading partner status was , talked about a lot. And there were even some comments about whether that information should be from one source or one body. To assure that entity, reported entity and access to the system. Also discusses here around centralized versus decentralized databases. And who maintains control of the data. And the efficiencies around, that occur when data may be in a centralized database versus a decentralized database or system. You will hear this several times but there seems to be a need for continuing to educate small entities, small training partner entities that while there are some folks that are very engaged in DSCSA implementation, there are so many entities that are not fully engaged are not fully aware of how complicated this may be to actually implement by 2023.

In terms of what steps that the entity may be taken to incorporate the product identifier and to the transaction information as required in 2023 this is the change to transaction information . It seems that there are many manufacturers have already begun incorporating this information into their transaction information by using a EPCIS. There are some training partners that are still using EDI via the advanced ship notice. There are some comments about in terms of this , that is still revolves around the data around the product and maybe even master data. While the product identifier is defined under the law to include the four data elements , NDC; serial number; lot number and expiration date, there seems to, industry seems to be relying on master data and if the master data is not there , completely missing or not accurate it will cause errors. And if the industry is using the NDC via the GTIN to look for that master data if there any issues with the NDC or even the GTIN in the barcode that could also result in errors in reads errors in look up and retrieval and those issues. Again the need for educate the small trading partners.

The other topic that we covered in the breakout was related to enhanced product tracing in terms of the affect of inference on product tracing whether you are the seller or the buyer and also how trading partners tend to reconcile the transaction information data with the actual physical product that is either sold or purchased. And what we heard is that for many trading partners specifically the manufacturer, the aggregation is essential operationally for putting together homogenous cases and shipping these cases and pallets. In addition we heard from many of the trading partners that the process of inference , which is inferring from the content of case or palette from a data file is also essential for operations. But that inference, the practice, would have to stop once the homogenous case or pallets are open or broken. This kind of came up of whether , it was something that seem to be of interest of whether there are technologies that could help training, what are the additional technologies that we should be thinking about to help trading partners be able to work in efficiencies and automation for data capture without having to individually scan each package, barcode or even case depending on what steps of the operations you're talking about. Also that in terms of reconciling the data , physical product which will likely involve actually scanning or reading of the barcode that the scanning of the two dimensional data matrix barcode is more likely to occur on the outbound or sell of the product when you are composing an order to be sold rather than on the receipt for the inbound or receipts of that product.

The last topic related to enhance tracing that we tackle today was related to facilitating the gathering or probably facility the gathering of the transaction information that will go into effect in 2023. We talked a lot about how this would essentially replaces the having to provide the transaction history but of course these type of different, request for this information would be in the event of either a recall or an investigation of suspect for illegitimate product. And we wanted to know what folks, what stakeholders thought about whether these requests for this gathering of the transaction information back to the manufacturer, what the request might look like, and what will be the minimal information and what would that response to such a request look like. Would it be different whether you are trading partner or an FDA. Some very high-level summary comments here is that the request for the product tracing information that would be the transaction information all the way back to the manufacturer would likely look different. That whether it would be for an individual product identifier or serial number or NDC or possibly with the request be related to a recall and in that case could be involved in a entire lot. Based on that, the response would also likely be different because of the request. And that currently if they are receiving these requests, which doesn't sound like it is a high-volume, that they are only providing the data that is requesting. They are not providing all TI data. It would be really focused on the request and what the request is asking. The response to such a request would also look different. And then in terms of how long should it take for trading partner to respond to a request for product tracing information in the scenarios, the response time , the comments from many of the group, it would depend on the volume of data needed for the response. And so we didn't necessarily , we will have to look in our comments if we actually have more detailed specifics about actual time, but this is just a general comment from many of our groups. In terms of recalls , the frequency of the types of requests may dictate the amount of data provided. And there is some uncertainty about the value here in terms from recalls for this type of requests. Those are very high-level, we may have missed a few items but we just want to give the folks a flavor of some of the comments that we received during the breakout session. So I appreciate folks contributing there. I think the last group or breakout topics was related to enhanced verification. How can the product identifiers

being used accurately and efficiency for enhanced verification in 2023? Similarly we wanted to understand whether a verification request was looking different if for trading partner or coming from FDA and what would be the information in that request. Also what with the response to a verification request look like and also what would be the response time. How long will it take for the trading report to respond to a verification request. Here are our nose including comments about , that is a typo, should say some may not rely on the VRS in 2023 and do what we say self-verify which is a direct verification request for example to the manufacturer as opposed to the VRS model. And manual verification may still be needed even in 2023. And that would be possibly either phone or email. It sounds like that some manufacturers meet choose to retain the basic backup in case the trading partner making a request is not able to do it in the enhanced system. And the VRS, VRS model, is being used for verification of saleable returns and can also be for verification and 2023. But one thing that was very important is that the communication related to the verification request and even the response need to be standardized across the supply chain. This communication that also may be applicable to the enhanced product tracing as well. In terms of the response, I think we heard in multiple groups that there needs to be a balance with giving a trading partner in a reasonable time to respond to the request but also for the trading partner that made the request that it may be time sensitive. For them to be able to carry on and carry through with their investigation of a suspect or a legitimate product, that they obviously want those responses as soon as they possibly can.

That is our quick recap. We will , we intend to provide a summary of the public meeting after the public meeting so this will likely be cleaned up a little bit. And so we will be able to share it with you and you can check our website for the information. With that I do appreciate and want to say thanks to everybody that participated in both days or one day. It was really great to see folks through this virtual setting and I think I'm going to turn it over to Leigh, Dr. Leigh Verbois our Office Director to do our closing remarks. Thank you.

Leigh Verbois:
Thank you Connie. I really appreciate it. Thank you to everyone for staying with FDA for the virtual meeting on DSCSA requirements. Thank you to our speakers and for all of those that attended the meeting. It is never easy to send spend two days in meetings but it is important to discuss the topical please continue to checking out our webpage for updates as noted in the chat, please contact CDERODSIR public meetings if you're interested in the slides. We will be willing to share them with you through that venue. I am so glad that there was an active discussion today that builds on yesterdays material. Today session focused on the 2023 requirements and the need for security appropriate access, and functionality for enhanced product tracing and verification at the product level. We heard about processes, standards and systems to operationalize the electronic data exchange. Investigations of suspect and in a illegitimate product including how to respond and the case illegitimate products are found. The recent compliance policy published in October, regarding certain wholesale distributors and dispense verification requirements provide time to comply with these requirements by 2023. We believe this allows trading partners to focus resources and efforts on requirements for enhanced drug distribution security requirements by 2023. There is no doubt in our minds

this is compressed and likely will need alignment on a few things. This includes business processes, architecture, data, and communication on messaging. FDA, trading partners and other stakeholders will need to continue to work together on the 2023 enhanced drug distribution security requirements. Throughout the meeting you have heard FDA commitment to protecting the supply chain. And I continue to reinforce that commitment. Implementation of the DSCSA enables more effective prevention, detection and response for supply-chain events. Only together can we ensure reliable patient access and safe and effective medicine and ensure the authenticity of those products. I want to remind you to submit any comments or feedback to any of the topics raised at today's public meeting and yesterday to our public docket. The instructions are in the Federal Register notice which you can find on our public meeting webpage. Your comments are extremely important to us and we review all comments. The public comments are currently due by December 28th. With that I will close out our meeting. Thank you tremendously for your participation in this meeting and I thank you in advance for your commitment to 2023. >> Thank you everyone and have a great evening. >>

[Event Concluded]