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Serializing your Global Supply Chain:

Forging a Path to Compliance Using Risk Management Strategies

Webinar

Dec. 15, 2015

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Speaker: Evren Ozkaya, Founder and CEO, Supply Chain Wizard, LLC

Operator: Hello and welcome to "Serializing Your Global Supply Chain: Forging a Path to Compliance Using Risk Management Strategies." This webinar is being presented by FDAnews.

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As a reminder, this call is being recorded and will be available as an audio CD and transcript package by calling FDAnews at 888-838-5578 or visiting our website, fdanews.com. I would now like to introduce our speaker.

Evren Ozkaya, Ph.D., an operations and strategy executive and entrepreneur with 11 years of deep experience in research, design and implementation of supply chain strategies and transformation initiatives across seven industries, primarily focusing on the pharmaceutical industry, with a track record of high impact projects, while building and coaching talented teams for sustainable results. Prior to founding Supply Chain Wizard, LLC, he worked with Sandoz as Director of their global track-and-trace program and did strategic planning for their North American supply chain. Other past employers include the United Nations World Food Program, Coca-Cola and Intel. His specialties include track and trace, serialization, strategic planning, project management, sales and operations planning, operational risk management, inventory optimization, forecasting and demand management, production planning and distribution strategies and procurement of transportation services. I'll now turn over the floor to Mr. Ozkaya.

Ozkaya: Thank you very much, very happy to be here. I should admit, this is the most thorough introduction I ever received in the last two years. I have given probably at least 20 different seminars, conferences, talks around the world and I'm very happy to be here for this audience. Like the introduction mentioned, please feel free to highlight questions for me any time. I might adapt to the questions and if you want to go into any specifics throughout the presentation, please let me know.

To get started, let me introduce a little bit about myself. As you see on page two here, I'm the founder and CEO of Supply Chain Wizard. We are a specialty consulting company focusing on track and trace

Ozkaya (cont.): serialization and implementation within the pharmaceutical industry and prior to Supply Chain Wizard, I was at Sandoz, the generic division of Novartis and prior to that, I was at McKinsey & Company as a supply chain management consultant.

A little bit about Supply Chain Wizard so everyone is familiar. We have three core competencies. No. 1 is the serialization and track and trace and we focus on this project globally, not only for U.S., but also for Europe, Turkey, China, Argentina, wherever there's legislation, we're following very closely and helping clients implement it for compliance reasons.

No. 2 is pharmaceutical supply chain management. Some of our management team are former executives from the pharma industry in the supply chain and operations field and finally, project management office and strategic planning.

To give you an idea of our expertise and understanding in the serialization track and trace topic, here are some example client projects that I show here the top five generic manufacturer in the U.S. For example, we have implemented initial strategic planning projects, as well as a track and trace IT vendor selection, helping them get to the first milestone of the U.S. serialization legislation, which is lot level traceability, helping them with the pilot line and then, the full rollout of their packaging line upgrades.

On the right-hand side, the top three global generic manufacturers, we are focusing on the supplier side of serialization, which is the contract manufacturing organizations, CMOs, helping them understand what the CMO readiness looks like from serialization perspective and helping with the IT connectivity of this client if there's CMOs, as well as to achieve the final compliance.

Besides the pharmaceutical industry, we're also focused on another industry, specifically non-profit sector for—a client example in here is the United Nations. Last year, for about three months, we spent with United Nations, helping them reorganize their supply chain organization in their largest entity, called World Food Program, so, our company also has a passion in helping the world from a non-profit perspective, especially in the food and non-profit sectors.

On the third slide, I'm going to show about our company is just to focus on the tools and software aspects of it, just to let know the attendees here, so we can trace a very complex project and also, is resource-intensive, so once we know the way that we took to help our clients is to establish some software tools and automation built into these tools so we can make significant progress in a short period of time, using some automated surveys that clients use to stand up their suppliers and understand where they are with their serialization compliance.

We have another tool called Serialization Wizard, that helps companies, let's say you're a pharmaceutical company. You haven't yet started, or just in the early stages. With this tool, we can create a strategy for your serialization program, meaning your budget, your resource plan, your timeline and your compliance risk within a couple of days, versus a typical long-term, three-four month project. So, this is to show you how differently we approach serialization problem.

Enough with the introduction about myself and the company. Here's the agenda. First of all, I would like to start by introducing the concept of track and trace. It's a risk or opportunity. I'm sure some of you might be here because of a perceived risk to the business. Some of you might be here because maybe it's an opportunity or somewhere in-between. Then, to offer you to a high-level strategic perspective, taking a manufacturer as an example, what does the journey looks like and how to start and finish the full compliance journey.

Ozkaya (cont.): I will have a deep dive in the CMO and supplier risk management aspect, managing your suppliers' compliance and per the title of the talk, some myths and misconceptions about track and trace, some interesting facts about how this project should be run and then, finally, ending with how to turn certain risks, market risks, into opportunities. I hope you will benefit from some of these specific points. I'll try to give examples from client situations as much as possible, or some case studies from other implementation. Feel free to also highlight questions if you want more specifics.

This is a typical question I open up with in my talks, just to understand the audience reactions, so whether you see this as a risk or an opportunity. The answer might be changing from two extremes, like significant risk with very little opportunity to very little risk and significant opportunity. I wonder. You can use your Q&A section on the right-hand side. I wonder if some of you would like to share their perspective, so feel free to write in there and then, let me know if you see it's a risk, as a more risky project, or as an opportunistic project.

As you type in, I want to move onto the next page and the next question. I ask if you think this is a risk, what do you see the largest risk for your organization. I here list some of the leading risk factors. No. 1 is the timely compliance for your internal site. If you are manufacturer with a packaging site, you need to make sure that those packaging sites and IT systems are compliant with the regulation for the markets you're serving and the timely compliance typically becomes the No. 1 risk.

Then the second highest risk might be your external supply or contract manufacturing organizations' compliance because you have little control over them. Many companies are worried about the cost impact, whether it's the CapEx, capital investments or OpEx to the business. Some companies are worried about the IT connectivity, how to connect all these suppliers into our network in an inter-operable section and then, there's a risk factor out there that is mostly about efficiency.

Just recently, I was able to attend, this week, on Monday when I was presenting an analysis result to one of our clients, one thing we found in their distribution center processes, for example, is after serialization is implemented, they are going to see up to 50 percent loss in efficiency because of the process changes required in the warehouse to be able to capture each and every serial number before they ship it to their customers. So, the operational efficiency, whether it's the warehouse or packaging line efficiency, is a significant concern and should be taken care of by the project team.

The next page, on page 10, is some of the largest opportunities for your organization. When I ask the question in conferences and say, "Who sees this as the biggest opportunity?" I see few hands and I ask like what kind of a company you're from and often, I hear that they are from a supplier organization. So, if you're a supplier, meaning you're a supplier of a technology, IT vendor or packaging equipment vendor or a consulting company, because this is one of the biggest opportunities right now for the service industry for the pharmaceutical.

But besides that, manufacturers also have a lot of opportunities out of track and trace. For example, more supply chain visibility and transparency with the ability to track each and every unit in the supply chain. Also, returns and recalls and inventory management, with more visibility, you can make improvements on those processes. If you're an early adopter, getting there and being compliant early, is a potential more market share for you to capture. I'm going to touch into that in a little bit.

The big data, the hot topic of many industries, the big data, I think for the pharmaceutical industry, this is what the big data is because if you imagine managing your supply chain with the lot number right now, consider that an average lot contains about 10,000, so 100,000 units, so now instead of one line of record, you're going to have 10,000 or 100,000 in a record. Across all your products, that number can easily

Ozkaya (cont.): reach to millions, hundreds of millions or billions for a specific market, so that's the big data and that's the standard data and there's a lot of opportunities to leverage this data from a market perspective.

On page 11, what I show here is the two-by-two—very typical of the management consultant—a two-by-two analysis of your—the true landscape of your company and risk management, how to handle the risks. First of all, the companies, specifically the internal site network, as well as the external network, the ones that you have and you have the control over versus your suppliers. There are two approaches to risk management. One is the protecting the down-side risk, protecting the business and then, the second half of that, it should not be forgotten, is the capturing the upside opportunity.

When faced with a serialization compliance issue, companies start with the first quadrant, right? They first initiate their internal track and trace program. Then, they need to look into their processes and data standard, because a lot of change is coming into the supply chain and then, if you're a contract manufacturer serving the industry, then you need to consider your customers' track and trace requirements. These are the set of initial initiatives or projects that you start with if you want to protect your business, protect from the risks, focusing on your internal network.

But then, many companies are using third-party suppliers, your contract manufacturers, to get the product and serve the market. In that case, you have to deal with an external track and trace program, making sure your CMOs are going to be compliant. Then, the second point on that is the cost containment because when your supplier is serving you and doing another project on top of what they are already doing for you, they might need to pass on some of the costs, whether it's a one-time capital investment request coming from the supplier, or an on-going, operational unit cost increase. Both of these are quite dangerous for the client organization and should be contained.

Then, finally, the third topic within that box is IT connectivity. Given that every company has different IT systems, and in some cases, no systems, the connectivity with these suppliers becomes a major issue. There are now projects happening in the industry just to focus on IT connectivity with CMOs. One of our clients, at least, it has more than 500-600 CMOs, contract manufacturers, so the scope of this project is enormous because they have to connect with all their suppliers.

When we go to the right-hand side and capturing the opportunities, once you secure your business, then you look for where I can find the opportunities. Most of the opportunities in the internal site network is around visibility, inter-company visibility and generating data-driven supply chain insights. Then, once you are after that set, the last quadrant here is focusing externally, some opportunities like external supply chain visibility, supplier collaboration or end-to-end supply chain optimization. These are different initiatives, most important initiatives, that a company should take. Of course, starting with No. 1, but depending on the company's strategy, you can move from one to two, three and four.

Here's a view on the industry, on where we think the industry is right now. If you're only focusing on No. 1, the quadrant No. 1, the segment, we call it, or the strategy that you're after, is minimum compliance. Let's comply with whatever is in the law and that's it. That's the minimum compliance. We believe about 85-90 percent of the industry players are in this bucket. Many of the late starters, many of the small companies, are only going to choose for a minimum compliance.

But then, some leading companies, or large contract manufacturers, will also go after the full compliance, meaning they will also initiate an external track and trace program to help their CMOs and contract manufacturers. That's about another 5-10 percent. When you secure the one and two, then the next segment is called the value beyond compliance. Some leading pharma manufacturers or wholesalers will be going after this and some examples already exist in how to turn their data into opportunities. Some

Ozkaya (cont.): companies are looking into this already, whether it's generating insights or using the data or using in other projects to improve the efficiency and we believe there's about 5 percent of the industry is in this bucket.

The final bucket, which we call the track and trace market leadership, is focusing on all of the quadrants, protecting the risk, but also capturing all of the opportunities, collaborating with the suppliers and we believe less than 1 percent of the industry in this bucket. If you look at this picture from a risk adverse perspective, you can say that, "Oh, there's a lot of risk. We need to make sure we do the minimum compliance and go for the minimum compliance," and maybe relax a little bit because the majority of the industry is in that bucket.

But if you look at this picture from a leader's perspective, you can say that, "Oh, my gosh. There's a lot of opportunity here because if nobody, or at least very few, companies are going after that leadership, then if we invest a little bit more than compliance, with serialization projects, then maybe there's a chance we can capture the market leadership, or get some value out of our investments," because let me tell you, the investment that companies make in this project is in the order of millions. We have seen projects that exceed $200 million in capital spending. They're not talking about additional operational cost increases. We have seen companies that are a few million dollars. If you have at least one packaging line, you can easily estimate that the project will cost you more than a million or two in full upgrade. This is an important picture to analyze.

In terms of the strategic perspective, the context that we are in right now is, right now, the majority of the world's GDP—is 82 percent of the world's GDP already is covered under some sort of serialization legislation. From a company perspective, 20-40 percent of business typically comes from the contract manufacturer and this business is at-risk if you're not managing it. The biggest issue is that this is a massive scale project which requires a lot of standardization, a lot of resources, and a high amount of budget with, of course, competing objectives with other initiatives, like possibly investing in new products, investing in a new SAP or ERP system, so this is a major risk for the industry.

The solution, of course, is to have a robust project management, a strong project management team, monitoring and risk assessment of the current risk and using some of the tools and services so that you can help your site, internal site and external suppliers, on the road to compliance and achieving the compliance in, like I explained a moment ago, is the bare minimum that you can do and generating the value beyond that is something that every example should be considering.

Let's say you are from a pharmaceutical manufacturing company or a company who's interested in implementing serialization. You have not been to many conferences yet. Let's say this is your first webinar where you've been hearing about it and possibly what you might be feeling is that this is a big, black box. I can assure you that you're not alone in the industry. When we do our research and we do surveys on behalf of our clients, we reach to hundreds of different contract manufacturers and I can tell you that the majority of them, more than 60 percent, does not yet have sufficient resources to implement it. More than 50 percent does not have enough budget yet secured to implement serialization, so if you're feeling like this is a big, black box, no worries.

There are a lot of companies in this bucket, but our job is to highlight to you, or uncover, what is under that black box, right? What we show here is three different categories, three different areas of focus. Most important one is in the middle in the pyramid. I don't know what happened to the lines there, but there are five layers of different technology and process changes a company should make. From the component level, which means the new printers, the camera, to the packaging line level systems, new equipment, print-and-check, print-and-slide systems, vision systems, the site-level systems, whether it's the

Ozkaya (cont.): packaging side or a warehouse and then, level four is the enterprise level serialization system and level five is the ePedigree, or data exchange with your trading partners.

This is the core of what serialization program looks like, five different layers. In order to engage on this project, the first step should be—and I emphasize this all the time—is to have a strategy. The left bucket over there is a strategy, meaning budgeting and financial planning, creating the rollout of strategic plan, creating an organization and a team, doing the vendor selection and then, having a plan aligned with the leadership to go into the execution model.

No. 1 mistake that companies make is ignore the strategy, jump right into the execution, call a vendor or two, get a quote and start the project. That often results in extra costs and timeline losses because this whole project needs to be coordinated cross-functionally and a solution should be created upfront before the execution step.

Let's go into the whole track and trace journey for pharmaceutical manufacturers. First step is why you are doing this, right? If you are listening right now and thinking that you need to sell this project internally to your leadership, you need to first answer their question of, "But, why are we doing this and why it matters now? Why can't I start on this next year? I don't have a budget this year."

Let's start with that. Then, once you go over that, you ask the question of, "How are we going to do it?" Once you achieve the compliance, the third question is, "What now? What are we getting out of this, any benefits, anything more valuable?" Then, throughout this journey, of course, there are strategic decisions to be made and that's what I'm going to cover with you today.

Why are we doing this? First and foremost, this is for patient safety. There's a counterfeit problem in the pharmaceutical industry around the world. According to the World Health Organization, an estimated 10 percent of the world's drugs are counterfeit. What does this mean? One out of ten pills, or drugs, that people are taking are not real. They are lucky if it's a placebo, meaning no effect, no active ingredients, but in some cases, they have the wrong active ingredient, or the wrong dose, too much or too little, of an active ingredient, and according to Interpol, about one million people die every year due to counterfeit drugs. Of course, hard to verify this number, but this is a serious problem threatening the public safety.

The track and trace legislations are designed to minimize, if not eliminate, the counterfeit drugs from the legal supply chain. This doesn't mean that you can't go online and buy a counterfeit drug. That happens all the time and according to the FBI, once they do the research, they found that more than 60 percent of the drugs purchased online, where the online pharmacy does not have a proper address listed, turns out to be a counterfeit drug. So, we cannot prevent people from going and buying counterfeit online, but we can prevent that happening in the real, legal supply chain, like once you walk into a pharmacy, you need to know that this is the real product.

Here's some pictures that I provide, or collected around the web, on publically-available resources. The problem of counterfeit drugs, when you see behind the scene, or behind the curtain, in what environment they are being produced, this is really, really eye-opening for some people when they're seeing it for the first time and the problem is not only these countries, just to highlight that. It happens everywhere, including the United States.

When this legislation for the U.S. started, it was led by the state of California and the executive director of the Board of Pharmacies of state of California was presenting different pictures that they have collected, or taken, from their visits, or unannounced visits or raids from pharmacies in California, like very similar pictures, if not back room operations trying to package pills into used bottles, things like that. This is a real safety concern.

Ozkaya (cont.): The question, then, becomes, once we understand why are we doing this, it's because of the patient safety, why this matters now? The first answer to that question that you should be using is that because we have little time. You see a selected number of countries here that are having their legislation and only Turkey, as you see, has started and completely finished its legislation implementation in 2012, so that's still the only country that has full serialization and track and trace in the last three years. All the other countries that are coming up with their deadlines, like India export products, South Korea, Saudi Arabia, they all have postponed the deadline multiple times and the final legislation for Korea, for example, is coming end of this year. China, the same way, end of this year, meaning in 15 days, all of their products are required to be serialized.

Brazil is up there. It has been passed end of 2013 for a deadline in 2016. The Brazilian legislation is currently on hold for the first milestone, but long legislation that is going very strong with no changes expected is the U.S. legislation. From the manufacturers' perspective, it is happening in two phases. The first phase, which is due end of '17, is the serialization at the unit level and then, the second phase, end of 2023, is the full visibility or tracking of the serialized units in the supply chain.

Every country that has come out with the legislation, at most require two-to-three years of time to be compliant and if you think that there is a single packaging line implementation takes at least six-to-twelve months, you can understand that there's really little time for the industry.

Then, what is at stake here? Let's say you or your clients have not yet started. I will tell you, your entire business might be at stake, your service levels, your margins, sales, shares, growth, everything's at stake. Currently, some of our clients are doing the analysis of their external supplier organizations and based on their readiness levels, they are actually making decisions to discontinue a supplier because they believe that they're not going to be ready and compliant on-time, so as a contract manufacturer, you might be on the hook to make sure your customers perceive that you are working on it right away and not yet started is not an acceptable answer nowadays, given that we have little time remaining.

We mentioned about the large scope. Right now, more than 40 countries have a legislation, serialization legislation. Another 150-plus countries in the world are expected to come on-board soon after, in the next few years, and even this picture, we have a data base of all the regulations we provide as a service to our clients. Even we are keeping—having a hard time keeping up-to-date with the changing regulatory landscape. In the last few months alone, Pakistan, Russia, Iran, they announced their draft legislation.

I just heard, I think last week or two weeks ago, the GCC countries, the Gulf Coast Countries, in Middle East are coming out with their legislation. This is an environment that's constantly changing and knowing what to do, what is required, is of critical concern to everybody.

This is kind of an eye chart. It's very difficult to read, I know, but I'm sure you have received the PDF version of this slide. So, based on our research, these are the countries that have final or draft legislation with specific deadlines for serialization, aggregation, tamper evidence, packaging and it shows you the scope. If I'm not mistaken, one of the participants here today was from an animal health product company, so for example, animal health may or may not be in the scope for different legislation.

In Turkey, it was in scope because it was for all pharmaceutical products, but if you're only serving United States, it's only for the human-use products, so animal health products, for example, are out-of-scope for the U.S. legislation. This doesn't mean that it will stay that way. It may or may not, but as of now, the legislation does not require animal health products or OTC, over-the-counter products, to be serialized and aggregated. You can take a look at this on your spare time and if you have specific questions, I'm happy to answer afterwards.

Ozkaya (cont.): Going into the U.S. legislation, I want to explain this a little bit more because this is where I live and most of the—the biggest market in the world in some of the pharmaceutical products and it's going at full speed. The first milestone for manufacturers was lot level traceability. It was due Jan. 1, 2015. A few days before the deadline, FDA released a guideline saying that they're not going to start enforcing it until May 1, giving kind of a four-month relief and after May 1, it went into effect, right? What was the requirement? It was about tracing the product at the lot level, creating a single document that has certain set of master data information and passing it onto your trading partners.

What it means, what it meant for the company is a new IT system, which did not exist before, some updates to the master data, new standard operating procedures in IT and commercial and sales operations. Many companies struggled to meet this deadline, but most of them did and it was the simplest milestone for the U.S. regulation.

For the second milestone, which is coming up around the corner in two years, less than two years, is called the unit level serialization. The deadline is Nov. 27, 2017, and the requirement is to serialize with a unique serial number, every single saleable unit, whether it's a folding box, or a bottle, it needs to have a 2D bar code that has the serialization information in it, together with the product ID, which is now going to be GTIN, Global Trade Identification Number. This requires the most significant investment which is the packaging line upgrade, new cameras, new printers. If the packaging lines are not yet automated, there may be some level of automation needed to meet the requirement in an efficient way.

So, there's a lot of changes coming in and we are in the middle of helping a number of clients implement their serialization at the packaging line level, as well as the IT level, like serial number management, like where will you get these serial numbers from. Are you randomizing it? Are you sequentially generating the serial numbers? How are you going to make sure that the same serial number is not printed twice? How do you ensure the uniqueness of the product? How do you handle the product in the warehouse?

The third milestone, which is the unit level traceability, goes into the IT side of the thing a little bit more, once the serialization is in there. Then, it requires the traceability of the product in the supply chain from trading partner to trading partner and that probably the most difficult part, which is left until the end, ensuring the data is matching the physical product at all times at the unit level, serial number level.

This is quite a challenging task because if there's any mismatch between serial number and a package, then there's a chance that the product is put on current time, under current time, or being recalled or returned by the customer. So, even if less than 1 percent of the products are this way, that means a tremendous cost to the industry. Doing it right is very important.

What is the large scope? We understand the large scope from the regulation perspective, but then, it also touches everywhere, from IT to packaging lines, supply chain, warehousing, customer service, and there are a number of issues that have been experienced already based on the previous country implementation. For example, how do I manage if I have multiple IT systems? How do I interface between them? I don't have enough resources in my company. Where do I get those resources? How do I find people who have done this before, or I implemented my first line. There's a 30 percent efficiency loss. What do I do now? The cost of the product jumped by 30 percent, so how do I contain that cost?

And your leadership is not believing in what I say. They think that the serialization is like many years ahead and we can do it later when it comes. How do I convince my senior leadership? I'm serving two markets, U.S. and Europe, but I only have one asset, one line. How do I meet both countries' regulations in a single asset? I find a vendor, but the vendor is quoting me six-month lead time. I don't have that

Ozkaya (cont.): much left. How can I find another vendor who can give me the product or the packaging material equipment sooner?

There are a lot of issues and challenges being experienced and each mistake can be quite costly, in time and in money. Leveraging experience is very important and finally, why it is so difficult? Because it requires a lot of capital and it requires a lot of people, but as all of us know, capital is always limited and there are budget cuts for various reasons and then, people is always limited and there are headcount reductions, or hiring freezes, that you have limited resources to work on them.

I wouldn't be surprised if the participants here today are the one-and-only person in their company either assigned to this project by the leadership or taken the initiative by themselves to learn about it so you can go back to your organization and do something about it. I wouldn't be surprised because there are a lot of companies now.

Let's move onto some of the solutions' aspect of it. How are we going to do this? Gaining the time is the simplest and smartest strategy. Why? Because if you start early, even in the worst case scenario, you can meet the deadline, but if you start late, there's a likelihood that in the worst case scenario, you cannot meet the deadline. I'll tell you right now, when I was presenting something similar last year, I said start early, but now that it's this year and end of this year, I can tell you, if your company has not started yet, I can easily say that you cannot be starting early at all. Any start after this point will be either right on-time, because your company is relatively small, or already too late.

Another strategy is to reduce the scope. When you think about serialization, it covers 100 percent of your scope, from all your CMO network and all inter-company network and all your customer network. How do reduce the scope with your CMOs is what companies are doing right now, which is consolidating the CMOs. If they have 100 CMOs, they might shoot for having 50 CMOs serving them in two-to-four years from now, transfer the products or you can use a 3PL to do some of the serialization on behalf of your CMOs. There are various ways to reduce the scope.

Inter-company, you might be familiar with the industry news, that there are always site closures in various parts of the world and consolidating the sites, consolidating the line, consolidating the DCs, these are all important things that if done right, might have a double win, meaning you might be implementing a company strategy and reducing the cost of your serialization project. Some customers I know are going through their products-by-product and saying, "I'm going to invest so much money in serialization, maybe that investment will make this product non-profitable. Maybe I don't need to serve this product after this date." These are some strategies, or work, that needs to be done to right-size your scope and if you're serving the customer, in let's say, wholesaler pharmacies, maybe you ignore the small orders from your small customers and try to consolidate to a bigger wholesaler and work with them and integrate them in your network instead of trying to deal with a lot of mom-and-pop or specialty pharmacies that may have limited resources and connecting to them with serialization may be difficult.

This last important advice that I can give you is to planning it right and based on a proper methodology, how to plan strategically for this project and we provide here a six-step process of how to create a strategic plan and then another six steps for the actual execution, piloting and execution of the project.

There are some important access factors including senior leadership support, that's always No. 1. If your leaders are not supporting you in this project, then you will have a lot of trouble down the line in terms of access to resources or capital. Access to the talent is important and your company may or may not have enough resources or talent to handle this. The budgeting, using the benchmarks so that you don't overpay or over-invest. Having the right vendors because the vendors are limited, very few companies with helping the industry, so it's important to pick the right one based on your needs and constant

Ozkaya (cont.): communication and alignment because it's very easy to over-engineer the solution based on the packaging needs, but then ignore the warehousing needs, either engineer for the warehousing and ignore the overall company or customer needs. So, there are a lot of trade-offs to be considered when you're designing your program and during the execution, speed is utmost critical. Standardization, create a solution and roll it out as fast as you can and then, collaborate with your customer and CMOs, collaborate with your vendors for some of the important access factors.

Then, now that we have figured out how to do this project, what are we going to get out of it, or what are some of the benefits? No. 1 benefit is the visibility. Now that you have a serial number on every unit, you have the ability to trace it in your inter-company site or function and if your customers and your CMOs collaborate, then you can also have some visibility into your extended supply chain.

Collaboration can become a reality because for the first time in the industry, that there will be some IT connectivity, all on the same standard, so you can exchange data that is beyond serial numbers with your customers or your CMOs and do some collaborative planning, collaborative forecasting, reduce the lead time and variability. There's all sorts of things that—it's a supply chain manager's dream that may come true with the availability of these systems.

Then, the last point I want to make is the data insights. There are some initiatives already around the world. For example, the cell phone or smart phone authentication, so if you are selling a specialty product, it is quite valuable, you might want to engage with your patients or consumers. If they scan the bar code and it comes to you and you verify that this is a real, authenticated product, they will be happy to know that and in return, they might be willing to give you some data, whether their location or why they take this product and it gives you a sense of where your patients or customers are and there are some marketing initiatives happening right now that for scanning of the bar code, the manufacturing company can give some coupons or something for the patient. Patients have value out of this anyway because they authenticate the product. This is an application that is designed by Turkish government, for example, for free, for the patients or the whole people can use it.

Another aspect of data insights might be on cost-to-serve. Right now in the industry, I work personally with a lot of finance people. They might look at a product profitability from an average sales price, an average cost and the margin, right? There are cases where every sales price, let's say, is $10 and your average cost is, let's say, $5. That's a 50 percent margin product. What does this mean? It's a very good product to keep, right? But if you have visibility into your granular data that you're going to get, and you capture that granular data, you might actually find that, let's say, your shipments from Monday-through-Thursday is, on average, actually $4 for those products, so the cost-to-serve, but because on Fridays, you end up expediting that product, that specific set of SKUs go up to $12 in costs, which makes this product unprofitable for that portion of the shipment.

If you have this data, if you have this visibility, you might initiate some simple policy changes, like this product is not suitable for expedite, therefore, do not expedite. All of a sudden, your overall costs go down to $4, so instead of a 50 percent margin for that, you have a 60 percent margin for that, that you are increasing your profitability and bottom line. Think of these type of possibilities where inventory is sitting in a warehouse more than it should and you have the data to find out why it sits and how long and even within the same batch, you have different patterns of operational realities that you can highlight and so which is the biggest opportunity for the inventory.

To sum up, the opportunity or ROI, first of all, the counterfeit market is about $75 billion globally in a given year. That means that any prevention of the counterfeit in the legal supply chain will return as higher sales for the original drug manufacturers. Based on a study we did with GS1 standards organization, they identified up to $14 billion of cost reduction and $94 billion of inventory reduction

Ozkaya (cont.): once these standards or bar code standard, communication standards are implemented. So, will your company be one of those companies to go and capture these opportunities? It's totally up to you or your company.

A lot of recalls by FDA posted and every one of these recalls are extremely costly for the companies who are involved. There are opportunities that you can do a better management of the recall to improve the patient safety. There was a case of a product recall where FDA found, even after one year of the recall, there were still some products in the shelves that were not recalled properly. So, with the traceability in the supply chain, FDA knows, or countries know, exactly which product, which unique ID is sitting in what pharmacy or what shelf that they can go and identify and reconcile so that immediately ends the issue to public safety and in some cases, manufacturers will benefit from the recall because they may end up isolating an issue with specific portion of the batch; that they might need to recall only that portion and not the whole thing, right? There are a lot of opportunities.

In countries like Turkey, for example, everything is centrally managed. There is a chance that a recall will happen. The Turkish government just turns off the product ID in the system. No pharmacy in the country can sell it at that moment. It doesn't even have a lead time anymore for the recall to be in effect. It's instantaneous, so think of the health benefit of this in the market.

That's an eye-level journey of it. I hope it made some good sense in terms of what the companies are going through, or will be going through soon. I want to go deeper into one topic, which is the supplier, or CMO risk management. Back to our two-by-two framework. What I'm specifically talking about is the external track and trace program from your suppliers.

Is there a methodology to assess the risk of your suppliers, so when we look at the risk—and we have built an algorithm to be able to assess all the suppliers for a given client organization. We ask certain questions on the timeline, on the scope of their project, on available resources, and identify whether their likelihood of noncompliance is high or low and business impact, of course, of noncompliance means it can be devastating because it's a lot of—millions of dollars being sourced from the supplier, or bare minimum.

We put that into a scale of one-to-five, as well as likelihood of noncompliance, one-to-five. When you're high on both dimensions, you are in that red zone, which is the high risk for the business. Some suppliers fall under the green zone, which is the low risk and that's how we prioritize, or that's how companies should be prioritizing their overall risk so they can react accordingly. In this example, the CMO No. 1 and 2 fall in the red zone and should be taken care of first versus CMO four might be left alone for awhile because probably they're on the right track.

In this picture, it's an output from a disguised client example where they did a survey of their suppliers. They asked where they stand in terms of their serialization effort, which program state they're at, it's not started yet, initial stages, strategic planning, when their selection pilot and full rollout. They get a good understanding of what the distribution is. They ask the questions of what are the challenges that you're experiencing and identified important challenges that maybe the client organization can help support their CMO community. Foremost, they identified their revenue at-risk, so how much of our revenue is high risk? How much is low risk? How much we don't know about? That's an important way to analyze.

Like I mentioned, what we do besides consulting is developing these software solutions or tools, that this tool is right now in use in multiple clients, right? They are looking at their suppliers on a real-time basis. As they update their survey on a regular basis, they see how the assessment is updated and they can be able to identify their biggest risk or threat that they can address directly.

Ozkaya (cont.): If you're a company that has a number of CMOs you're getting products from and you don't have a CMO program, you don't have any option in your risk management strategy but to accept the risk. There are five different risk responses a company can utilize and only one of that is available to you, which is accepting whatever risk you have.

But on the other hand, if you have a proper CMO program, CMO serialization support program, where you're identifying, measuring the risk, planning for it and even mitigating and reporting on this, on a regular basis, then you can pretty much utilize all of the available risk response types, like avoiding surprises or risk, transferring risk from a high risk CMO to a low risk CMO, reducing the impact of the risk, doing something with that CMO, maybe helping them out or doing something internally so your impact of that risk, when it's realized or materializes, is minimum. If accepting the risk is a better strategy in the case where the cost of mitigating it is too much versus the value of that risk is little, then in those cases, you can just sit and accept the risk and in the fifth scenario, you can plan for the Plan B, or contingency and in less time and effort in building your Plan B.

This is a proven methodology of risk management applied in every aspect of the business, but for this specific case, having the risk management program, or a CMO program, is highly valuable. To give you an idea on a case example on transferring the risk, right, this is a case of a new product launch. A company comes up with a new product. They know what they're going to produce, but there are only a number of CMOs available with the available technology to help them with it. Would you, if you're this company, took your product in a CMO that is on-track for serialization compliance? Or would you put it in a company that is not yet even started? This is a case where—and a real case—in generic industry, there are hundreds, if not thousands, of product launches every year, so the vendor selection, CMO selection, is a critical topic and we have real-life examples with our clients that the serialization now becomes a line item in their evaluation criteria.

Reducing the risk. Let's say a CMO came back to your company and said that, "I need a cost increase, a price increase, because I invested in all this equipment in my serialization project and now, the unit cost of my product would be 10 percent higher." What can you do in this case? Well, if you have a program, you might already collaborate with the CMO and identify the validity of the request. You do a bottoms-up analysis and say, "You know, 5 percent, or 10 percent, seems too much, but based on our analysis, maybe it should be around 4-5 percent increase," reasonable. Or maybe you find out that the unit cost increase is not even justifiable because there has been recent increases, way more than necessary, that is already should be covering the cost increase. So there are all sorts of scenarios.

One of our clients is approached by their CMO and exactly with a number of 10 percent increase and our initial reaction to this is, "Don't even accept it immediately. You need to analyze the situation and deal with it on a one-on-one basis," as mostly likely outcome is that there may be a few percentage increase, or not even a percentage increase. Maybe a few cents per unit increase, depending on the situation.

The last case example is the contingency, right? In the case where, let's say, one of the CMO, or a few of your CMOs, say that, "I cannot be on-time. I'm doing everything I can, but I cannot be on-time," so what are you going to do? In some of the countries that implemented serialization, the contingency plan was to hire a third-party service provider, or 3PL, and route all the products through that 3PL, which has the ability to open the box, put a serial number on, aggregate it, transfer it to the IT system and transfer back to the company, or even distribute to the market so that it's kind of an all-in-one kind of a service and this is successfully working in multiple markets. This might be a Plan B. If you're in a situation, either with your own compliance, or your suppliers' compliance, you can always find a partner, but finding that partner at the last minute, again, is a difficulty and a challenge, so doing the planning upfront is something of critical nature.

Ozkaya (cont.): Here's a product or a tool we developed. If you have a good number of CMOs, or if you're a CMO or a small pharmaceutical company who needs help in getting started, typically it takes three-four months of the project work to design your serialization program and strategy. We kind of automated a majority of the processes and inputs and the steps to create that program. With this tool, we have called Serialization Wizard, we can actually do that in a couple of days with a workshop where we can provide the budget, the timeline, the overall risk and resource plan of a serialization project, given the client's current situation. The help is available. Help is out there. It's just that companies need to realize what they need to do and where they need the help.

That's the conclusion of the CMO deep dive. What I would like to go in right now is some of the myths and misconceptions, as the title called for it, or some of the things to do or not to do in serialization. What to do. If you want to be a successful CMO with your track and trace, before your program starts, you need to communicate with your customers proactively. Select the right people, experienced project managers or team to lead the program and then, leverage some of the industry learnings and benchmarks so you know you're doing the right thing.

During the track and trace program, investing time upfront to do strategic planning is critical. Picking the right vendors is critical because if you pick the wrong vendor, the time and cost to replace it is going to be exponentially more than starting with the right vendor. Then, standardize the implementation on almost everything. Standardize equipment. Standardize the IT system. Standardize the project management approach, so everything happens relatively standard, so the timeline is getting shorter to implement a standard solution.

After the track and trace program, understand your losses in efficiency and understand your operational impact, how much extra IT, maintenance and licensing costs you're paying, how much extra people or engineers you're keeping on-staff to operate these systems? What's your loss in efficiency and then, you can realistically reflect that in your costs to your clients, or if you're the client, you can expect your CMOs to do the right thing based on your expectations. Then, finally, create some collaboration opportunities or ROI initiatives with your customers if you're a CMO so that you can get the most out of this track and trace system. If you do all this, then you remain as a long-term strategic trading partner for your client and you capture more market share.

Here's what not to do. Before the track and trace program, exact same key word, communication. There are some CMOs, in our experience, they're ignoring the customer surveys and not responding to them. They're assigning this project as a stretch assignment to a project manager, saying that, "You know what? On top of your 15 other projects, here's the 16th one. You can handle it. Good luck." They're using some benchmarks, or rumors, they found on conferences or on the web that say, "You know what? This such-and-such company has done this for $200,000 a line. Well, why do I need to pay $1 million?" Using the wrong benchmarks is the wrong thing to do.

Jumping right into the execution, skipping the strategic plan. Picking the vendor just because your customer uses the same vendor is the wrong thing to do. Skipping a pilot or an opportunity to standardize is the wrong thing to do and not planning properly for the budget and not accounting for the operational cost increases is a detrimental mistake that companies do make and unfortunately, find themselves in a situation to pass a lot of costs to their clients and then, not using this as a way to collaborate with your suppliers, but see them as a supplier, a transactional partner instead of a partner is the wrong approach. If you do all these what not-to-do items, then it's almost guaranteed that you'll be eliminated from your partner network and you'll lose market share.

I can tell you—I think this is the third time I'm telling—that companies right now, going through their supplier list and they're already making decisions on which suppliers to keep in their network and which

Ozkaya (cont.): suppliers to exit from the business. This is a very critical time and as the new year hits for the U.S. markets, you'll have less than two years to the deadline and the competition to find the right resources would be higher. It will be more and more difficult to do the right thing.

Another topic, another question. Are we late already? Well, that answer is highly dependent on what type of a company you are. If you are a small company, it may take one-to-two years to implement everything, so you might not be late yet, but if you don't start soon, you might be late for the U.S. market. If you are a medium-size company, which let's say number of sites around the world or the country and a good number of lines, then there's a chance that you are already late for the U.S. deadline, not so much for the European deadline, which is going to be end of '18 or early '19. If you're a large CMO, I would say at least three-four packaging sites, at least 20-25 packaging lines, then this would easily take you more than three years and if you haven't started yet, I can easily tell you that you are late.

This is illustrative. Please don't take this as a template for your own company and say, "Oh, my god. I'm late. Oh, my god, I'm OK." Every company is different. It highly depends on the size, the scope and the resources you have and many different factors. Finally, do I need a dedicated team or do I need a lot of resources? Here's a chart that I put here in front of you, a disguised client example. It's a resource plan for 2015-to-'17. The green bars represent internal resource needs that are absorbable, meaning from both existing in the company can take on this much work, but then, there's an increase, or surge, in work force or needs, that extra resources should be provided by the external sources such as consulting companies or vendors, which means that in this situation—this is a real-life example.

It's a company that is more than three sites and about 20-25 packaging lines. They need at least as much resources externally as they can spare internally. It's hard to find the resources right now because there's a lot of competition for the resources.

That's a couple of important myths and misconceptions and important facts about track and trace. I might have touched into the opportunity side and the risk side and know that they are related. How to turn the risk into opportunity, or how you look at this picture is up to you. If you look at that as a demand and supply, 40-plus countries, hundreds of manufacturers and distributors, thousands of pharmacies, 3PLs, packaging lines, is the demand.

The supplier side is only limited level five vendors, including SAP's latest product that they come up with. Less than 15 level three and four vendors. This is the IT system, serialization IT system, serial number management providers and less than 20 or so level one and two packaging equipment vendors that are out there right now helping the pharmaceutical industry globally, limited number of consultants and limited internal resources. That's a big mismatch of demand and supply.

How to turn this risk into opportunity from a demand side? If you're in the demand side, you might have been familiar with what's going on in the market already, that there are a lot of mergers and acquisitions; reducing the scope, consolidating the lines and the sites; starting early, which we discussed may or may not be an option for you now; standardizing, streamlining and automating the implementation.

If you are on the supply side of the equation, adding equipment capacity. Some of the companies that I know—and we know most of the companies in this field—have doubled or tripled their manufacturing capacity for the equipment. They're constantly hiring. One of the serialization IT vendors that I know is the leading one in the market, they were only 80-person company in the U.S. Now, they're in multiple different markets and they're more than 180, so within less than 10-11 months, they almost doubled their human resources.

Ozkaya (cont.): Some companies are investing in cycle time improvement, lead time improvement, so that they can reduce this increasing equipment lead time and many of the companies are going for partnerships to provide an end-to-end solution. When they're only providing part of the solution, they try to partner up to provide the full solution. These are some of the strategies to turn the risk into opportunity.

If you recap all the key messages and I know there's some limited time remaining at the end for questions, but what we discussed upfront in terms of risks, the compliance for internal and external supply is a risk item. The standardization of processes and data is critical and the minimum compliance is the mainstream strategy for the industry. The opportunity side, when you look at it, is as high as the risk and generating value or creating market leadership position out of the compliance initiative is a great way to get ahead of the market during the track and trace journey. We understand why we are doing it, because we have limited time, very large scope and highly limited resources and the value beyond compliance is about supply chain visibility, collaboration and data insights.

Within the deep dive of the CMO risk management, the key message is that the CMOs are lagging behind, according to the research we have done with our clients. A significant portion of the CMOs have problems, whether it's budgeting or resources. Establishing a robust CMO track and trace program is a winning strategy in order to prioritize value with CMOs you need to focus on. We discussed about five types of risk response types, like avoiding, transferring, reducing the risk, accepting the risk or planning for contingencies.

To turn the market risk into opportunity on the demand side, we can consolidate sites, lines and vendors. We can start early, get there early and leverage the expertise, the tools and benchmarks that's available in other markets and in other companies. On the supply side, adding more capacity, equipment and resources is a good strategy and improving service levels and lead times is another good strategy.

I would like to leave you with a final word from John F. Kennedy. "There are risks and costs to action. But, they are far less than the long range risks of comfortable inaction." Whether you are protecting the downside risk, or trying to capture for the upside opportunities, my strong recommendation would be to take an action. Thank you for your time and participation today.

I will do a little promotion here on the next event that we are organizing as a company, with our partners. If you have organizations in Europe, we are organizing this in Frankfurt in February, '16, and here's the link to the registration. This is an event, a round table event, to educate companies, especially CMOs on serialization and best practices and how to leverage learnings from others. I'm happy to take any and all your questions, either now or after the presentation. Thank you for your attendance. Thank you for the organizers.

Operator: Thank you, ladies and gentlemen. Now is your opportunity to have your questions answered by our presenter. Please remember this portion of the conference is also being recorded, and please limit yourself to one question at a time.

[Operator gives instructions for calling in or submitting questions.]

Operator: Our first question will come from Kyle Asay from FDAnews. You may go ahead, Kyle.

Asay: Hi. I was noticing when you had the chart with the timetables for the various countries, it seems like the final deadline for the U.S., the Phase II that's way out in 2023 is a lot further out than a lot of the other countries. Is that a function of the U.S.'s requirements being more comprehensive, or just that the other countries are doing the same stuff, but on a much more compressed timetable?

Ozkaya: Very good question. It's an excellent question. It is a function of many things, including the fact that U.S. requirements are kind of the most stringent out there. It is a full traceability in the entire market and it's a little complex to implement the traceability between the trading partners. Some other countries who implemented this in a quicker timeline have instituted a central government data base where a player, a manufacturer or a wholesaler or a pharmacy needs to communicate with, with that standard data base and that's the only communication that you do.

However, in the U.S., nobody actually in the manufacturing or wholesaler community wanted to have a government data base. Therefore, the resolution was that every trading partner will communicate with one another. That creates a huge challenge of data communication, integration and interoperability. That's the last milestone, which is to start in 2023 and that 2023 is actually a little misleading because that's for the entire supply chain, from manufacturer all the way to the pharmacy. In order for this to work at the pharmacy level, the wholesalers, who are a couple of years earlier than that, should be ready and manufacturers should be ready even before that.

There are certain language in the legislation that requires wholesalers to report the saleable returns by their serial numbers, which means that manufacturers should provide that serial number data to the wholesaler by 2019. What this means is instead of 2023, as it is in the law, some manufacturers might be forced by the wholesalers to provide that information many, many years earlier.

The companies that we serve, some of them realizes this fact and they target the entire compliance by 2017 or '18, or latest, by '19. Some companies are taking more like a wait-and-see approach and then, they're going to wait for the industry to come up with some kind of a guidance. There's an FDA pilot project planned, required by the legislation, that FDA is supposed to run some industry pilot and provide more guidance on how the rest of the milestones should be met. But until that time, one thing is clear, which is 2017, the deadline that everyone is shooting for, which is the serialization one.

Did that answer your question?

Asay: Yes, it does. Thank you.

[Operator repeats question instructions.]

Operator: There are no further questions. Do you have any closing comments before we wrap up?

Ozkaya: This is a great opportunity. Thank you for the FDAnews to invite me to this, so I'm very happy to be presenting here. This is one of the hottest topics in the pharmaceutical industry and it's a major concern because it requires a lot of capital and human resources investment. I'll be happy to be a resource for the participants here, even after this call and for any or all of your questions. Thank you for the opportunity.

Operator: Thank you very much. On behalf of FDAnews, I would like to thank our speaker and you. Just as a reminder, if you would like a recording of this session, you can order the CD and transcript package from FDAnews by visiting us on our website or contacting customer service. This now concludes today's webinar. To end this call, simply hang up your phone and close out your browser. Thank you.