

Mary Dwight: Good afternoon, everyone and welcome. Thank you so much for joining the Alliance for a Stronger FDA for what I hope will be an excellent presentation this afternoon. We are delighted to welcome Alliance members, the media, and our guests to this webinar with FDA principal deputy commissioner Dr. Janet Woodcock.

My name is Mary Dwight. I am the president of the Alliance for a Stronger FDA, and I am the senior vice-president and chief policy and advocacy officer for the Cystic Fibrosis (CF) Foundation.

I'm particularly pleased to introduce our guest today, Dr. Woodcock, as I think everyone knows, she's devoted her career to making FDA an active supporter of innovation. We in the CF community have been a beneficiary of her actions and her commitment to innovation. FDA has reviewed numerous transformative therapies that have greatly improved the lives of people with CF. So, it's been great to partner with her through the years.

I'm also joined today by our Alliance executive director Steven Grossman who is an acknowledged expert on FDA budget, programs, and organization.

First, a quick word about the Alliance for a Stronger FDA. We're a multi-stakeholder coalition that advocates for increased appropriated resources for the agency and have been an important force in the doubling of the FDA's budget authority from \$1.6 billion to more than \$3.3 billion dollars. Those monies have been critical for the needs of everything the FDA touches. The other mission of the Alliance is to educate policy makers, the American people, and the media about the FDA's growing mission and responsibilities. We are the only advocacy organization focused on resources for both food safety and medical products, as well as other components of the FDA mission. Our members include consumer groups, patient groups, research advocates, health professional societies, trade groups, and industry. We have about 150 members, and we welcome new members to further strengthen our advocacy and education efforts.

For this webinar, Dr. Woodcock has agreed to respond to questions from our moderators and you, the audience, and you may submit questions in the Q&A box via the platform on the bottom of your screen. Just a note, not the chat box, the Q and A box. Now, before introducing Dr. Woodcock, I would like to thank Jacque Thomas

of Dr. Woodcock's staff, who has a close collaborator with us in preparing this webinar.

It's now my privilege to introduce our esteemed speaker for today's webinar, Dr. Janet Woodcock. Dr. Woodcock is the FDA's principal deputy commissioner. In this role, she collaborates closely with the commissioner of the FDA to develop and implement key public health initiatives and help oversee the agency's day to day functions.

She's also served, as I think we all know, as acting commissioner for the FDA from January 2021 to February 2022 - quite a busy time to serve in that role. Dr. Woodcock has had a long career involved in numerous senior leadership positions and really there's very little with the agency that she has not touched. She holds a Bachelor of Science from Bucknell, a Doctor of Medicine from the Feinberg School of Medicine at Northwestern, completed further training in fellowship in rheumatology. Really, there's nothing Dr. Woodcock has not done.

Today's topic, modernization of the FDA's infrastructure-information infrastructure, is of critical importance to any FDA stakeholder. It's one of her important themes that knowledge management is not just about efficiency, but it is profoundly important to the FDA's ability to make better and more complete regulatory decisions in an increasingly complex world. Dr. Woodcock, thank you very much for joining us today. We're delighted to have you and excited to hear from you. Let me turn over the stage to you.

Janet Woodcock: Thanks very much, Mary. And it's great to talk to all of you. And people, I hope you're interested in this. I'm spending a lot of time on this effort, something I've long wanted to work on and now I have the opportunity. So, I'm really bearing down on this.

We're talking about modernization in a different kind of way. We're talking about modernization of process and the infrastructure that the FDA runs on. I'm going to give you a little bit background first so that you understand, more or less, the situation we find ourselves in, and what problem am I working on that I've wanted to work on for so long.

Well, as most of you know, FDA is in the business of information. Data and information are really our lifeblood. We intake

information of different kinds, we process that information, then we put out decisions and other information. And so, the whole process, although there are physical parts like lab testing and inspections, it's the information we gather from those, as well as other data, that we make into our decisions. But historically, we've taken a program or organization-based approach to our business process development - in other words, Centers, product areas, but also to our IT investments.

Thus, unlike many large organizations you might see where they have both centralized and decentralized, we have mainly decentralized IT development and process development. And this has resulted in a very fragmented business and data environment that's not interoperable. The majority of these systems additionally were developed in-house. They're customized. Most are not interoperable even within the Center or the organizational unit with other systems in that unit. And so, we have to write programs and write code and so forth or do other maneuvers to gather information from the various systems. There was a real absence of data standards and change control and much of the information and data has to be manually searched.

I call these our "archeological expeditions" that we have to go on because the data are not in a condition to be accessed automatically and generate analyses. And worse, underlying this, much of this supporting software, because of our chronic budget problems, is old. These programs are old. They are end-of-life or end-of-support. Our central IT organization has to keep these within cybersecurity limits because none of you would be very happy if your data were hacked, nor would we. And also have to maintain resuscitation, maintain these on life-support where the manufacturer is not currently supporting them.

If we look at our administrative systems, which are more common functions in other organizations, nevertheless, these are also custom, standalone, not integrated with the program, the distributed program areas. So, for example, our HR, or whatever, we have a central system that runs hiring, but it doesn't extend out to the Centers. Same with many of the other administrative processes. And so, each center, ORA, and the Office of Operations have developed their own software to run their own processes.

And the central IT organization has to continue to support all these different approaches. Because of this fragmented development, and

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also, of course, because information transfer and this includes all kind of IT like telephones and everything, we spend about a billion dollars annually on information processing. However, information needs are not really being met. We have to do a lot of manual processing and we also eventually rely upon informal networks to exchange important information because we don't have systems to do that.

We don't have, for example, a single workflow management system for regulatory activities that need cross-agency processes. For example, inspections. We don't have standard ways to collect and share structured data across different commodities, for example, firms, companies, or establishments. We don't have a single source dataset for things like firms and establishments, which is really a problem because, of course, we have to regulate across imports, a flood of imports. But we don't have a single source of truth for many of these data points that are so essential to regulation.

I've already alluded to the consequences of this a little bit, but I think they're more than just "we're spending too much money." They're way more. First of all, there's waste of our personnel time. They spend inordinate amount of time on manual searches to find information from various sources where the information, the report should be automated.

We have very poor knowledge management. And this I think is what Mary was alluding to. We continue to get external complaints about inconsistency in our regulatory decisions. But if we can't keep those in a place where they're accessible, staff may not even be aware of the prior decision and how it was made and what the consequences were. And so, they would have to go on one of these archeological expeditions to try and find that.

We're not able to analyze unstructured or unstandardized texts. Of course, you can do full text searching and everything, but doing things like trend analysis and so forth doesn't really work very well, especially if you haven't standardized the terms.

And then the actual effectiveness of our regulatory programs is impacted because the right staff at the right time may not have access to the data that would be critical to making the correct decision. And this of course is a thing that concerns me very greatly about our current situation.

For example, our import screening may rely on incomplete data sources. We also have very fragmented process management so for inspections. Those processes are not connected across the product programs and field. There are manual handoffs of an inspection request and then inspection results back. Same with hiring. As I said, there's no single source of truth about certain agency regulatory activities that we have to monitor and try to report on and be transparent to the public. And it's often stated that we're not very transparent but, for example, the resiliency report that we did on the inspections we did during Covid, that's something you'd think we would have at our fingertips. It took quite a long time for data reconciliation before we can get that report out on the number of inspections that were done against each commodity during the pandemic period.

The cost I've already alluded to. System maintenance of these somewhat outdated systems is very high, while return on investment is low. And then inefficiency, we're resource constrained as it is, and lack of automation and information inaccessibility creates a huge workload for us. I will go through a few worked examples because what I said, although it sounds rather grim, it's actually very high level and didn't have real examples.

So, the Center request for inspections and the Center workflows for providing a prioritized list of who should be inspected and so forth are not integrated with ORA. There's no workflow management system. So, they have to use emails or SharePoint in order to do that. And then investigators may need to interact with multiple databases during the inspection process and they may not have good access to some of the information they need. The data elements in the inspections and inspection reports and Center activities are not standardized, so it's difficult to reconcile various inputs, particularly the inspection reports themselves. Inspection results are not smoothly integrated between ORA and the Center. So, when it comes back it's not well integrated and it isn't well integrated with data on the establishment itself, the firm and the product. So, finding all that information in the same place, which is what we want and what is ideal, is not the case right now. Other kinds of data that may relate to a product, like product quality or safety complaints or other findings, lab results, other issues with the firm from other Centers or products, are not integrated in a way

that we can see the complete picture. And trend analysis is difficult and may require manual data assembly.

Another example, and these are multiplied by dozens so I'm simply giving you a few examples: there are at least four different IT platforms currently used to accomplish Freedom of Information work in the different Centers. And there are additional and multiple different applications that are used for eDiscovery work. Some Centers can't afford to have a platform at all. There are variable backlogs across the agency, some of which are very concerning to various stakeholders and some FOI requests, of course, cut across programs and so they have to be done in different ways. Everyone agrees that a standardized agency solution to this would be highly desirable and that's one of the things Enterprise Transformation Group is working on, which is why can give this rather detailed example.

In addition to the business challenges, there are underlying technology challenges and that's why we put out our other plans. Moving from paper to digital is a conceptual matter. Our legacy systems work basically like electronic PDF, right? And so, they were built and developed in a paper-oriented way. And, of course, everybody's working remotely now or virtually, and the environment is digital as well as the data, and the legacy systems are not designed to work that way. From a data point of view, strictly from our data scientists, the legacy systems were built in a manner that results in this fragmented environment and impedes the ability to share data and interoperability.

Now, I learned a new term: "legacy burden." Apparently, we're not the only people who have this problem, but there's a big cost of this legacy burden. This technical debt that has accrued because the legacy systems have been surpassed by several generations of technology and they're the kind of systems, many of them, that even minor changes to them - adding a new field or something - is very costly. And right now, the majority of existing funds are consumed by operation and maintenance of these legacy platforms with little left over to fund modernization activities. So, it's as if the patient is getting a whole lot of bandages all over, but nobody is really looking at why are they bleeding.

And we must keep these systems going because that's what we use right now. Parallel conversion is another technology challenge that our tech people have identified because, although the legacy

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systems have to be completely overhauled given how old they are, they will require we maintain parallel systems while this work is underway because we have to use the data. We have to maintain information. This will temporarily somewhat double our cost but lead to long term returns. But of course, we're not a well-resourced group and so any additional costs are hard to fund. And I think this is how we've come to the situation we find ourselves in.

The Enterprise Transformation Framework is really how we plan to solve our problems. We issued an action plan on this in the spring and really, we are trying to identify which processes are what we call "enterprise." And by that we mean they go across the organization where they can be supported centrally, and then other parts of the organization can utilize them. The product specific processes in the Centers and so forth are not part of the enterprise effort although we are trying to make sure that we have a common really vetted set of applications and platforms that are to be run instead of a free-for-all.

This enterprise transformation is going to be an agency-wide enterprise business process data and IT management approach that will really allow us to collect data in a standardized way, to save, and to leverage all the data as the foundation of our work. And we recognize this will require a multiyear effort and more investments. First we published the Technology Modernization Action Plan (TMAP) in September of 2019. This was fundamental. This had to do with the technology infrastructure, the technological infrastructure underlying our systems, and this really would move to the Cloud and so on and so forth. All these types of things that we must do to modernize our system.

Then, in 2021 in the spring, we released the Data Modernization Action Plan (DMAP), and we are recruiting data scientists. We are identifying data projects that will be the most bang for the buck in developing really good data practices. And of course, because we're mainly an information agency and we have so much data, this is not a short-term effort, but we are starting with some of the fundamental identifiers: the data points that we use such as regulated firms, the names of those firms, their locations, their establishments, the products they make in the case of highly regulated products, and all sorts of other identifying information that pertains to that.

In the Commissioner's Office, currently reporting to me, we have the Enterprise Transformation Operation, and that is a small group of people who are supported by funding from multiple Centers that are working to standardize business processes that are enterprise and develop a common enterprise approach. We have proposed to codify this group as an Office and we have put forth a reorganization request to do that. Currently what we're doing is we are doing inspection process optimization because ordering up and executing and then evaluating the results of an inspection are some of the core activities that we do at enterprise level.

And we're doing a pilot on inspections that includes CFSAN and CDER. The pilot will use inspection protocols that will have standardized data elements. We will then have data from the inspection rather than a text report and will be able to perform analysis on that. The pilot will be going on for quite a number of months because it also uses a single workflow management platform to move the inspection request from a Center and everything that surrounds it there, out to ORA, conduct the inspection using the platform in the standardized protocol, then back through ORA, and back to the Center. All on the same platform. So, everyone can see the steps, they can see where things are, and they can see all the results.

We are hoping that will be a successful pilot. We're also beginning to work on master data management. To start, it will be a firm inventory: who the firms are and where they are, what they make, and where are their establishments and so forth. And to have a single source of this information that we can rely upon. And then FOI process optimization. It's something that's common across all different parts of the program including the Commissioner's Office, and can we get to a single way of doing this, single platform and so forth.

So, we hope to have funds to sustain this in any FY23 budget that is passed, and then we would hope in FY24 to be able to stand up an Office of Enterprise Transformation. Of course, we would have to go through a number of processes to get that done. In the meantime, in the data and technology world, they're making a lot of progress because these efforts were started earlier. When I was Acting, I elevated the Office of Digital Transformation up to report to the Commissioner and made sure they had stronger oversight over new application development and so forth.



So, they have been building what you might call a modern information technology organization. They have developed an infrastructure library. They're working on a next generation data center and so forth, and they're trying to get rid of the end of service and end of life part of our infrastructure. Although it's difficult, since some of it we must continue to use, they are trying to move things to the Cloud as we get these applications capable and move them up. And of course, I think our cybersecurity program is very strong, but we need to keep working on that because we continue to have many, many, many attempts at breaching our firewalls.

So, we are seeking funding as part of our FY23 President's Budget to improve the enterprise IT by accelerating the TMAP and DMAP programs, increasing our cybersecurity, tightening that up. And then we will also then be trying to develop very advanced data management using techniques such as machine learning or artificial intelligence for our supply chain issues, some of our product review issues, imports management and so forth. We really need to get this up to a higher level and so, we have asked for additional funding there.

In summary, FDA has a huge legacy burden with outdated software and fairly fragmented business processes. Our enterprise transformation effort seeks to modernize this, to standardize the data and create modern platforms that are common and shared across the agency where those processes are common or shared. We formed an Enterprise Transformation Group and we're doing pilots and we will continue to seek additional funding to accomplish these changes. So, thanks very much for listening to this, and I'm really happy to take questions and have a discussion.

Mary Dwight:

That was great. I certainly learned a lot. Thank you so much, Dr. Woodcock. I know we have a lot of questions and I welcome Steve to join me for the Q&A session.

So, really, you painted a clear picture of the need and I have a feeling that many on the call will really resonate with a lot of what you said: understanding complex systems, multiple systems, and particularly the challenge of legacy systems. So clearly opportunities to improve that will really benefit everyone. And you also did a great job of presenting a high-level overview of where we're going.

Can we dive in a little more to the workplan, if you will? So, you outlined a significant scope of work and some of your key priorities, those high value driver projects.

So, I have a multi-part question here. Can you speak a little more to the cadence of the work? Why do you think certain projects are really important to come first? Can you speak to how you're approaching change management? It's such a vast project across a vast agency. And then I think, perhaps particularly interesting for people on the call is: how might an FDA users experience be different during this product modernization effort and then once its complete?

Janet Woodcock: Wow. All right. Well, to start with the cadence, of course, we had to start small. We're in the middle of a pandemic. We have several other crises going on. Management attention has to be in many different directions, and we didn't have a lot of extra money that we could stand up in office. As I said, this current office, the ETO operation is funded by donations from ORA and CDER, and Commissioner's Office of course. So, it's a very small group.

What they are doing right now is, first of all they are scoping out these major processes that are across agency: the inspection process and the master data project. The pilot is ongoing now and it will go for a while. Probably five months or something and then we will look at the results of the pilot.

What we desire, should we get additional funding in FY23, we would desire to expand that group, the operation, and we would want to expand the scope of the project, but keep them on what we're doing. In other words, can we really develop an inspection workflow platform that everybody can use? That would be a tremendous benefit. And that should be obvious to everyone.

We hope we can get classifications done quicker. We can understand what the trends in different citations that are found during inspection. We can really look at trends in the firms and so forth and save a lot of time because this is manual work back and forth between ORA and the different Centers.

At the same time, we'd also be working on this master data management, putting in things like a change control board, a thesaurus or whatever so that we would have standardized terms that we would use that we'd all have to agree on. And we would

expand that and make it faster so that we could move toward having a master data source and just build on that over time. The IT organization already has the kind of data base that they'd like to use, but, really, it will require a lot of work as you point out.

And that gets to change management. I think my experience from CDER is it's very hard. I was the person who forced everybody to go from paper to electronic back in the '90s. From today's vantage point, that looks like a no-brainer, but it was a big deal then. I told them, "You'll really like this because instead of going into the document room which has hundreds of miles of shelves and trying to find your records of your meeting last year. You'll have an electronic dossier of what happened." They weren't totally convinced, but then I also said, "Well, you can't approve any drugs or not approve any drugs unless you do this because you'll have to do an electronic signature from now on. Period." And so, it came to pass. Now of course people wouldn't part with their electronic systems - that's precious to them. That's the lifeblood of having this electronic storage, electronic library that saves all the letters, all the transactions, all the submissions. They're all in there. But now we need to modernize that again.

Now, there's a great deal of concern about that change. So, I think people recognize the need for change because what they have isn't working, but they're very reluctant because it's a pain to learn new technology. And we all get used to our old technology, we're happy with it even though it's really a pain because we don't want to expend that energy of activation a few days or however long it's going to take to get used to the new technology. So, it's going to be hard, and the plan is that we're going to have to convince people in order to make this happen more quickly.

Mary Dwight: So, I will ask my next question and then I'll turn it over to Steve. As you have said today, the FDA is primarily an information agency, and your many stakeholders may define it in a variety of different ways: consumer protection, product approval, standard setting, or enforcement. How do you see in the big picture how information ties all those roles together?

Janet Woodcock: Clearly, we are a standard setting, science-based, law enforcement, consumer protection agency. And the way we do all that, everything from standards to consumer protection, is through having information. If we want to do enforcement and we want to take a court case, we have to have the data. We have to have the

information and the briefs and the whatevers to make our case. If we want to set a standard, we have to gather the scientific information. Everything we do is controversial and so it's those data, that information, whether it's science, whether it's information about a criminal act, whatever it is an import that shouldn't be coming across the border so we can protect people -- the more information we have the more effective we are at carrying out that mission and the more of the mission we can actually carry out. So, gathering the information and assembling it shouldn't be the burden that it is right now for our people.

Steven Grossman: Thank you Mary. I'll pick up here with the next two questions. Dr. Woodcock, thank you for joining us. I think just by the attendance and the number of media outlets that have chosen to join us, there's a lot of interest in what seems like an arcane subject that is nonetheless fundamental to everything the FDA does.

My first question is: companies and most non-profits have an operating cost budget, and they have a capital cost budget. How did the FDA working capital fund come into being? How large is it? To provide more monies for it, does Congress have to specifically direct the money to the fund?

Janet Woodcock: No. The working capital fund was established a number of years ago, but fairly recently, like within the last five years. And it puts money into shared services, basically, and allows that money to be used over time as a capital fund rather than operating dollars. Where the money came from originally was--they took the money used for those programs and they simply transferred it to the working capital fund. But to do that they had to give it to the Centers first. I don't understand government finance very well, but you had to give it to the Centers and then the Centers had to provide it to the working capital fund.

So, that's what happened and then there are two ways a working capital fund can get more money: Congress can appropriate more money to it, or the Centers could give it more money out of their operating dollars, which they're of course very reluctant to do because their operating dollars are very scant. And the allocation in the working capital fund needs to be proportional to the type of money that was given, so foods money should be proportional to foods support, and so forth.

Steven Grossman: So, the most direct pathway is for Congress to supply an amount of money and say it should go to the working capital fund.

Janet Woodcock: That's right. For additional dollars. Yes.

Steven Grossman: We're going to be working on that.

So, changing the focus a bit, can you provide us an example of when FDA made a decision based on the best available information where more information existed, but was either inaccessible or incapable of being sorted and analyzed?

Janet Woodcock: Well, I think there are examples like that. I hate to get in the litigation world, and I hate to talk about them.

Steven Grossman: We can give you a pass on that if you want.

Janet Woodcock: Well, let it stand that yes, there are definitely instances, including recent instances, where we probably could have made better decisions, or more timely decisions, or different decisions had we had more information that theoretically could have been made available to us.

Steven Grossman: Okay. Mary?

Mary Dwight: Can I go back to money? And sort of a big picture and hot topic now which is for the first time in recent memory Congress has failed to pass the User Fee authorization before August recess, which is upon us. As you well know that could leave a big gaping \$2 billion dollar hole in your budget. So, what are the consequences for your agency operations and the impact on the medical product reviews and review staff?

Janet Woodcock: Yes. We're very concerned that reauthorization be timely for the following reasons. At some point, if it appears we're not going to have a reauthorization in a timely manner, we do have to honor obligations to our staff, our employment obligations, and notify them of that fact and that they might be facing being laid-off or terminated even. But even should we not do that, they read the papers and people know about this.

We have about over 600 people in the pipeline that we're hoping to recruit as we're recruiting ahead of this next user fee program because, as you know, there are a couple large areas where we

need more staff -- for example, cell and gene therapy. And our experience in the past where there's been delay in authorization is not only do we get a lot of attrition, but people decide to take other offers and not come join the agency.

Now, the shortest runway we have for the carry over balance is the Prescription Drug User Fee Program. That has a very short amount of carry over balance. And so, if it doesn't get authorized in September, we're just running a pretty short clock. We can't say exactly how long because it depends on our payroll burn and so forth. But we're running a short clock before we run out of money in that program. So that if we get to that point, I think we will have more people panicking.

So, if we don't accomplish this hiring ahead, and if we run over the deadline and it's not reauthorized – in '97 when that happened, it took us 18 months to get back to our previous state. We lost so many people. And then it's a very competitive environment right now for hiring people and we are very concerned that, especially these innovative programs in the real cutting edge areas, that we just won't have the staff to do it. We are very hopeful. We think there's every intent to reauthorize these programs. That's not what this has been about. It's been about, let's delay it and just sort of run out the clock. But that's not going to work for us.

Mary Dwight: Sobering, but helpful for you to walk through that. Thank you.

On another significant topic, can you talk about information security? And how you're thinking about that and integrating data management security into all this broad work that you're speaking about with us today?

Janet Woodcock: Sure. Well, it's going to be easier. I'm not an IT expert obviously. According to our security expert, it will be easier to secure when we have the modern platforms in place and we're in the Cloud and so forth. So, they are very eager to get this migration done. We have very robust protections and we have been very good, but we get, like everybody else, we get the phishing attempts and the this and the that all the time. And we do get serious assaults against our protections. So, people are interested in the data that we have, and that's another compelling reason for us to modernize our systems.

Steven Grossman: Dr. Woodcock, I want to ask a little bit about the congressional viewpoint on this. Have you had opportunity to present the

modernization plan to Congress? How is it received? Do you need any legislative authority to implement the modernization program?

Janet Woodcock: Yes, we really haven't talked to Congress directly about this. I've testified at the budget hearings and put in the written testimony about the modernization and Dr. Califf did the same this year. Many of the people in this audience are in companies or in large programs -- you understand these IT challenges, right? But people in Congress might not necessarily understand these problems even though they're ubiquitous. And also, I really appreciate everyone's attention because you have to admit they're kind of eye glazing, right? They aren't really sexy problems. They're terrible problems, but they aren't that sexy. And so, no. I think there isn't complete understanding on Hill.

I think the budgets have been put out both by the House and by the Senate Committee do recognize this for FY23 and do provide some funding that will be extremely helpful. Because right now, as I said, we're running on hand-outs from the Centers and the Commissioner's Office to put this program together. So, we're very grateful for what Congress has provided and hopefully will provide in FY23. It's hard to describe all this and I probably didn't do the greatest job. I'm doing the best I can.

Steven Grossman: Okay. Thank you. Taking you back a few years to when Obamacare had an open season and it crashed with all the people who wanted to register.

Janet Woodcock: Yes, it did.

Steven Grossman: At the time, Representative Eshoo asked why CMS didn't call 1-800-Flowers and learn more about their approach to surge management. And I guess I'm sort of asking you a similar question. Do you talk to companies like Amazon, Google, Walmart, and Microsoft that have overseen these kinds of systems problems and how to scale them? Which is obviously an additional concern.

Janet Woodcock: Yes. Indeed, we do. I'm very happy with our current IT staff. We have people who are experts. People who have good lines of communication with those gigantic information technology programs and companies. And yes, I think we aren't lacking access to really good minds and understanding how to do these things. But Amazon can't tell us how to standardize the name of an

inspection or something like that. Our staff has to decide how to do that. Right now, even what inspections are called can differ: we have “for cause”, and we have “surveillance”, and we have this, and everybody calls them something different.

And so that kind of work, that’s why we have the Enterprise Transformation Operation because, really, program is more of the problem than technology. The technology is so advanced it can do a lot of these things, but you have to know what you want it to do and then train the people, as Mary was saying. We’re going to have to train the people during change management and how to interact with the new systems. So, it is more of a people in a business process problem than it is a technology problem at this point.

Steven Grossman: Okay. Good. Thank you.

Janet Woodcock: Yes.

Steven Grossman: Mary, I’m going to go search some of the Q&As.

Mary Dwight: I actually have a good one.

Steven Grossman: Perfect. Let’s start it.

Mary Dwight: I’m going to jump back into the PDUFA relations which is the user fees that are proposed do include funds and work to improve IT infrastructure and processes in the drug review processes in CDER and CBER.

Janet Woodcock: Right.

Mary Dwight: So, how would you describe the relationship between those efforts within the user fees and the broader one workwise that you just described? Are there interdependencies? Can they succeed independently? Are there synergies?

Janet Woodcock: Yes, we’re hoping to create synergies. We work very closely with those programs and, as I said, if you think of the model - corporate level and then subsidiaries - that’s how the FDA works. So CBER and CDER are subsidiaries and they’re going to improve their review management process with IT, right? But there need to be links, say to the inspection part of a review, so we check with CDER and the other Centers to make sure their software can integrate with the software we’re using for the inspection pilot. So



eventually, hopefully this could be seamless.

And so, when you're reviewing an application, then the need for a pre-approval inspection is entered in and seamlessly goes into the queue rather than having to be thrown over the wall. So we assure, for example, that those systems are compatible, and that we'll be able to do this. Of course, the Centers want to develop applications to support their own work, and that's fine. The key is that we use compatible platforms and that our data are interoperable because we are using standardized data.

Steven Grossman: So, all the modernization efforts need both budget authority and user fees to succeed. Is that correct?

Janet Woodcock: Yes. We probably need a little bit more budget authority on the enterprise transformation side because we're doing foods and we're going all the way across the agency and we must have a fair contribution, a prorated contribution, from each type of money that we get. And we have used user fee dollars and industry knows that to upgrade our distributed IT platforms. For example, generics had a total overhaul back in the day when we did GDUFA.

Steven Grossman: So, the emphasis is still on appropriated dollars rather than user fee dollars to drive this process?

Janet Woodcock: Yes, for the enterprise side. Although we can use some user fee dollars.

Steven Grossman: Some -

Janet Woodcock: – it has to be proportional. We can't use an excessive amount of user fee dollars.

Steve Grossman: Yeah. Maybe I should- can do the follow-up to that question, which is: Where does that leave food safety, which doesn't have user fees? How are they impacted or served?

Janet Woodcock: We have received money for food safety and as I've said, ORA, which has most of the foods program, is supporting the Enterprise Transformation Office significantly. One of the pilots we're doing on inspection is the food inspection pilot. That is post-market surveillance, of course, because they don't have a pre-market approval program. So, that is a post-market surveillance inspection program for food that we're piloting.

Mary Dwight: Great. I'm watching the clock and I know we're just about out of time, so I think we'll let that be our last question. This has been fascinating and clearly so, so important. Let me give you one last shot at the apple. Is there anything we haven't asked that you really wanted to convey or just sort of, what is your elevator pitch at the end that you want our listeners to take away?

Janet Woodcock: Well, I think we should all step back and think what is at stake here, Mary. When you were talking at the very beginning of this, I remembered the approval of drugs so long ago for cystic fibrosis. Look where we've come since then, what that innovation has meant to patients. And look at all the food safety issues and how important they are. We need an effective agency, both to deal with innovation on the medical product side and on the food side - because there's going to be innovation in the food side as well that's going to be pretty spectacular - as well as supporting safety and quality and consumer protection overall. It's such a broad remit. The agency's always, always short of resources to do it all. And so, it is critically important in my mind that we have an efficient infrastructure that enables our experts, our scientists and doctors and so forth, to do their jobs with a minimum amount of paperwork and archaeological expeditions and everything because it matters so much to the people of this country that they are able to do their job right and as effectively as possible. So, this, I would say, would be an investment well made if we are able to pull this off. Because here I am. I'm still here, right? Because it's worth doing. Because it will really make a difference.

Mary Dwight: Great. Well, thank you. The Alliance stands ready to help in any way we can. It's been really insightful to hear you unpack this and to see all the myriad ways this will make a real impact in efficiency and better decision making. So, thank you so much for your time and for the detailed overview. We really appreciate it.

Janet Woodcock: Thanks.

Mary Dwight: And thanks to everyone for listening today to the webinar. I think Steve put it in the Q&A section early on, but the slides and a summary will be in tomorrow's Friday Update from the Alliance. If you got an email to tell you about this webinar and you want more information about how you can get that Friday Update because you don't yet receive it, that is your secret ticket to find out more about the Alliance. Thank you all so much for joining us

and a particularly huge thanks to you, Dr. Woodcock, for your leadership and for all your insights today.

Janet Woodcock: Thank you. Take care.

**[End of Audio]**