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1	UNITED STATES FOOD AND DRUG ADMINISTRATION
2	CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
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8	Virtual Public Meeting
9	Data and Technology in the New Era
10	of Smarter Food Safety
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14	DATE: April 24, 2024
15	TIME: 10:00 a.m.
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1	PROCEEDINGS
2	GREETING & HOUSEKEEPING/LOGISTICS
3	MS. FINNEGAN: Good morning. The U.S. Food
4	and Drug Administration is pleased to welcome you to
5	today's virtual public meeting on "Data and Technology
6	in the New Era of Smarter Food Safety." I'm Lauren
7	Finnegan, a health communications specialist with the
8	FDA's Center for Food Safety and Applied Nutrition,
9	and I will be your moderator today, along with my
10	colleague Michael Kawczynski.
11	The New Era of Smarter Food Safety
12	Initiative was launched in 2019 to signal a new
13	approach to food safety, leveraging technology and
14	other tools and approaches to create a safer and more
15	digital traceable food system. Today, during the
16	morning session, you will hear presentations on FDA's
17	current thinking on the potential for new, innovative
18	or different data and technology activities to create
19	a safer food system, while the afternoon session will
20	be reserved for public comment.
21	Here are a few notes before we get started.
22	The meeting agenda, speakers' biographies and a

1	document entitled "How to Comment" are posted on the
2	FDA's public meeting webpage for this event. This
3	meeting is being transcribed and recorded and will be
4	posted on the same webpage when it becomes available.
5	The recording should post within a week, and the
6	transcript will be posted within a few weeks.
7	It is now my pleasure to begin our meeting
8	by introducing Jim Jones, FDA's deputy commissioner
9	for human food, to provide opening remarks.
10	OPENING REMARKS
11	MR. JONES: Good morning. I am so glad that
12	you are joining us for today's public meeting on the
13	New Era of Smarter Food Safety. As you are likely
14	aware, we are in a transition period waiting for
15	Commissioner Califf's proposal for unified Human Foods
16	Program to go through the external review required for
17	all federal reorganizations. But our work has not
18	slowed, and our approach going forward is already
19	taking shape.
20	Now and in the future, we are focused on
21	making food about wellness through ensuring food

safety, enhancing food chemical safety and improving

22

1	nutrition, and technology and innovation are critical
2	to meeting these goals, as are you, our stakeholders.
3	Your input and engagement are essential to helping us
4	to identify and leverage those innovations that can
5	make us more efficient and effective in achieving our
6	mission to protect public health through a safer, more
7	nutritious and sustainable food supply.

From the early days of the New Era of 8 9 Smarter Food Safety through our most recent work, your 10 expertise and collaboration have been integral to the 11 tremendous amount of important work that has been 12 accomplished in the past five years, as you'll hear 13 throughout the course of the morning. We are here 14 today because there's an opportunity for us to refocus 15 New Era on those technologies and innovations that can 16 turbocharge the advancement of food safety.

We are looking to you to help us chart a path forward. Through our work together today, we hope that you will share your thoughts on what you see as the most important areas for us to leverage technology and data under New Era. This feedback, along with the comments received to the accompanying

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1	docket,	will	be	used	as	we	identify	the	areas	FDA	will
2	priorit	ize fo	or 1	Jew Ei	ca.						

3 I encourage you to think about food safety from all aspects, from foodborne outbreak prevention 4 5 and response, from the farm to the facility to the point of sale, from testing the laboratories and 6 7 fields, to our inspection and compliance actions. There is little in the modernized world where data and 8 9 technology do not make a difference. With our limited 10 resources, the question is where can we make the 11 biggest differences for the most people.

12 We know that advancements in predictive 13 analytics, the use of intuitive and effective data 14 sharing systems and artificial intelligence, along 15 with increased participation in GenomeTrakr and 16 virtual reality-assisted training, we can help prevent foodborne illness outbreaks. But we also know that in 17 18 a resource constrained environment, prioritization is key, that if we are spread too thin, we may miss an 19 20 opportunity to create largescale, long-term, positive 21 public health changes.

22

We also know that there is a lot at stake.

1	For every foodborne illness outbreak we prevent or
2	contain, we reduce the devastating toll experienced by
3	those impacted and their families, and we also avoid
4	the tremendous waste caused by recalls that cast nets
5	that are overly wide because we lack critical
6	information to target only the implicated products.
7	So today, as you consider the possibilities
8	we have thought of and those that we have not, I
9	encourage you to think what you do best. Think
10	strategically and big, share with us your experience
11	and insights, and work with us to reshape our future
12	into one where we are more efficient and effective in
13	meeting our public health missions, and where
14	foodborne illness outbreaks are a thing of the past.
15	Thank you, and I look forward to working with you
16	together.
17	MS. FINNEGAN: Thank you so much for those
18	remarks, Deputy Commissioner Jones. I'd now like to
19	introduce our next speaker, Adam Friedlander, one of
20	the co-leads for Core Element 1: Tech-Enabled

21 Traceability. Adam, I'll turn it over to you now.22 DATA AND TECHNOLOGY IN THE NEW ERA OF SMARTER FOOD

1 SAFETY

2 CORE ELEMENT 1: TECH-ENABLED TRACEABILITY

3 MR. FRIEDLANDER: Good morning, and thank you all for joining today's public meeting on the New 4 5 Era of Smarter Food Safety. My name is Adam Friedlander, and I'm a policy analyst in FDA's Office 6 7 of Coordinated Outbreak Response and Evaluation Network in the Center for Food Safety and Applied 8 9 Nutrition. I'm also the co-lead for our tech-enabled 10 traceability initiative, Core Element 1 here at FDA, 11 and I'm very excited to give some remarks today about 12 the background of our tech-enabled traceability 13 initiative, some of our key accomplishments, and 14 really, I'm looking forward to hearing from you today 15 about how you envision the future of this initiative. 16 So we know that tech-enabled traceability

17 has grown in awareness over the last several years, 18 and for far too long, we've relied on very manual 19 processes to investigate foodborne illness outbreaks 20 here in the United States. And this tech-enabled 21 traceability initiative, we believe, puts front and 22 center a focus on using technology and data to improve

Pac	re	12

public health outcomes around the country and the globe.

3 We know that better food traceability data can result in fewer foodborne illnesses and deaths. 4 5 In a world where traceability records were predominantly paper-based and very manual processes on 6 7 the industry side, the same was true at FDA, where we're relying on a variety of records such as purchase 8 9 orders, invoices to try to triangulate the eventual 10 source of the outbreak.

11 These traceback investigations at FDA could 12 take days or weeks, and some of these outbreaks led to 13 significant market withdrawals from the product, and 14 we weren't even able to find the root cause of the 15 illness. We know that we need faster identification 16 for that source of contamination and the rapid removal 17 from the market, and we believe that by harmonizing 18 the definitions for traceability data, we can more 19 rapidly and accurately link products and shipments 20 together and ultimately stop that source of the 21 outbreak.

22

So early on, when we first started this New

1	Era Initiative, we knew that we had to write a	
2	traceability rule under FSMA Section 204. And before	
3	we wrote the proposed rule, we leveraged this	
4	initiative, which is FSMA-based, people led, to try to	
5	understand where the industry was in their	
6	traceability journey. And we did many listening	
7	sessions and we learned from some of the leading	
8	experts in the food traceability space, and that did	
9	inform the proposed rule.	
10	But this New Era Initiative is not a	
11	regulation. And the eventual final rule of the	
12	traceability final rule was predominantly based on the	
13	public comments that we received to strengthen even	
14	the proposed rule. And we know that it's going to be	
15	a very long journey ahead to truly make food	
16	traceability at the speed of thought a reality. But	
17	we have already seen so much innovation within the	
18	food industry ever since we finalized the final rule	
19	in 2022.	
20	But this New Era Initiative is more than	
21	about a final regulation. It's about going above and	
22	beyond that foundational level of key data elements	

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1	and critical tracking events and truly leveraging that
2	data to not only think about how can we improve this
3	from a food safety perspective, but thinking about
4	some of the other benefits of food traceability as
5	well, such as better visibility within your supply
6	chain or having a better understanding of where the
7	greatest need for certain product may go in the supply
8	chain.
9	And we have also heard loud and clear from
10	the food industry that data interoperability is
11	incredibly important. So instead of relying on one
12	system to track the entire food supply chain, is there
13	a way for data systems to talk to each other so that
14	it doesn't require just one system? You can still
15	leverage many different IT systems, but you're still
16	ultimately seeing that same food traceability
17	language. And this is something that we're incredibly
18	excited to continue to see progress on and see the
19	innovation that's taking place every single day.
20	But we know that collaboration is going to
21	be a critical component of how we move forward in the

22

future. We need to bring multidisciplinary teams

	Page 15	
1	together. We need to bring the food safety folks, the	
2	IT folks, the legal folks, marketing and supply chain,	
3	a variety of teams need to come together and tackle	
4	this issue.	
5	So we know that the industry can voluntarily	
6	work together to improve upon some of the greatest	
7	operational, organizational and technological pain	
8	points that we're currently seeing. But we are very	
9	confident that through collaboration, we can make	
10	great progress in tech-enabled traceability.	
11	You know, I just want to highlight some of	
12	our key successes in our current activity that we have	
13	here at FDA and our tech-enabled traceability	
14	initiative. We have had over 70 listening sessions	
15	and tech demos with the industry since 2020, and we	
16	learned so much during each of these, and it's	
17	incredibly impressive to see. We have also hosted the	
18	tech-enabled traceability challenge, where we had over	
19	90 submissions from all over the world provide a	
20	snapshot into what they're doing to reduce the	
21	barriers of entry into leveraging traceability	
22	technology.	

1	And then IFT also produced an independent
2	report highlighting some of the key outcomes and
3	themes from this challenge. There is also a tech talk
4	that was centered around food traceability, where some
5	leading experts from the food traceability space
6	provided a lay of the land of the current situation in
7	tech-enabled traceability, and from an internal
8	perspective, we have taken in the last few years and
9	developed a prototype for our product tracing system,
10	and now we're in the process of developing this
11	product tracing system internally. And we're excited
12	to continue sharing resources with you all about this
13	PTS.
14	Currently we're producing a tech-enabled
15	traceability video series where we're highlighting
16	certain service providers who participated in the
17	traceability challenge. And we've already released
18	one of the episodes, but we have a few more on the
19	way. So we're very excited to showcase those videos
20	and roundtable discussions with you all.
21	From an international outreach and
22	engagement perspective, we know that this is a global

food supply chain, and it's going to require global harmonization and collaboration. So we're in the future looking to continue doing outreach with international governments and international industry groups as well to try to speak the same food traceability language.

7 And we're also developing different software tools that are going to support those traceability 8 9 efforts. We've already highlighted some of those 10 technological components on our website, talking about 11 our product tracing system. But we look forward to sharing more information about some of the tools that 12 13 we're leveraging, not so people can duplicate or 14 replicate what we're doing, but so that they can 15 consider the technologies that we're using in their 16 own digital transformation journeys.

And then lastly, we're participating in a group called SHOP. And that's organized by the Association of Food and Drug Officials. But it's really looking at the role of consumer purchase history data during outbreak investigations. And we know that with the food traceability rules that the

1 records really end at the point of receiving at 2 retail. But we know that during the first leg of an 3 investigation, we rely on what did that sick patient 4 or customer eat that made them sick.

5 So how do we tie in the records from the 6 consumer all the way back to that point of receiving 7 at retail? It's a gap, and we know that there are some industry groups already out there who are trying 8 9 to solve this, and that's an example of going above 10 and beyond the rule and leveraging traceability data. 11 And we're just very excited to see this level of 12 collaboration and ingenuity happen in our supply 13 chain.

14 So, today I'm most looking forward to 15 getting feedback from you all on what you believe the 16 next five years, ten years, 20 years look like for 17 tech-enabled traceability. On the screen you'll see 18 several questions. And we're going to put these 19 questions in the docket. And I hope also during the 20 oral comments today that we'll hear from you on some 21 of these ideas.

22

If you have any other ideas beyond just

1 these questions, we're very eager to learn and to
2 listen for you, but we're very interested to
3 understand how we can improve traceability, leveraging
4 technology, leveraging data to improve public health
5 outcomes. So we're very excited to hear from you all,
6 and just wanted to say thank you all for joining
7 today.

8 And I'll leave with this. We know that at 9 FDA we can only do so much to improve food 10 traceability across the industry. But we rely on 11 working with industry, government, academia partners, 12 and this is a global effort too. And together, we can 13 reduce that burden of foodborne diseases and truly 14 leverage the power of data to improve the public 15 health outcomes for our U.S. and global population. 16 So thank you all so much and I'm looking forward to 17 hearing from you.

MS. FINNEGAN: Thank you so much for your presentation, Adam. Next, I would like to turn it over to Mark Moorman and Vinetta Howard. They will be presenting on "Smarter Tools and Approaches for prevention and Outbreak Response."

1	CORE ELEMENT 2: SMARTER TOOLS AND APPROACHES FOR
2	PREVENTION AND OUTBREAK RESPONSE
3	DR. MOORMAN: Well, hello. My name is Mark
4	Moorman. I'm the director of the Office of Food

5 Safety at the Food and Drug Administration.

I'm thrilled today to talk about a topic 6 7 that our team cares deeply about, and it's the Core 8 Element 2: Smarter Tools and Approaches for Prevention 9 and Outbreak Response. I'll take you back to the Food 10 Safety Modernization Act to introduce this topic. You 11 know, that was an overhaul of our country's food 12 safety system, directing the FDA to develop a number 13 of regulations aimed at preventing foodborne illness.

But, you know, like many things in life, life happens. Along the way comes technology that is evolving so rapidly and the question that New Era asked us to struggle with is how can we deploy this technology in a way that assures and improves public health. FSMA didn't envision that. New Era does.

The Core Element 2 seeks to do a couple things: first, to advance the use of root cause analysis, and I'm not going to talk about that today.

1	That's a topic I would love to talk more about because
2	our team has been doing a lot of work on it. Our
3	objective here is to introduce or to advance the use
4	of root cause analysis by all stakeholders, including
5	the FDA, to create a culture of learning. You know,
6	in life, you can't solve a problem you don't
7	understand, and that's what root cause analysis is
8	there to do to help you to understand what happened.
9	What I will be spending more time on today
10	is the second area, and that is where we seek to
11	strengthen the safety of our food supply by looking
12	for novel approaches, and these novel approaches are
13	based on data and data sharing. I'll also be wrapping
14	up by talking about a tremendous tool that we have
15	called the GenomeTrakr.
16	You know, if you're in this webinar today,
17	you've benefited from the use of better data. I'm
18	guessing right next to you right now is a cell phone.
19	And with that cell phone, well, you've probably used
20	it. You've used data to help you get to the right
21	destination and perhaps even on time. You've used
22	that cell phone with that data to be able to order

something online and have it received at the right
 location and in fact probably got notified when it was
 delivered.

Well, a good friend of mine, a great colleague to those of us in food safety, Frank Yiannas, has said better food safety begins and ends with better data. And he is absolutely right. Our quest in this Core Element 2 is to better connect to that data and use it to make better decisions or better, even better predictions.

As you'll see here, our scope isn't just the FDA in the use of this data. What I hope you see is that we're looking to create platforms or tools that can be applied by all the stakeholders in the food safety arena.

Today specifically, I'm going to be talking about data, our use of that data, our use of that data with these tools called artificial intelligence and machine learning. I'll also be talking about data sharing in what we call data trusts. And then finally, as I mentioned, I'll be talking about this game changing tool called GenomeTrakr.

1	So, my first job out of school, I worked out	
2	in the Oakland area, and I would look out over these	
3	massive docks where all these containers would be	
4	launched. And I remember thinking, new in the food	
5	safety world, how do the import folks know what to	
6	Screen? How would you know what to sample to find out	
7	what could be unsafe or violative? Imagine you're	
8	that person.	
9	Well, as it turns out, the FDA has been at	
10	this for a while, and it has good systems. One that's	
11	called PREDICT, which is a risk-based tool to be able	
12	to know what to sample, which of those containers to	
13	sample. Well, in the universe of data predictive	
14	analytics, we're using these tools called artificial	
15	intelligence and machine learning to help us to make	
16	better predictions.	
17	Now we started with the application of	
18	machine learning with seafood. And you might say, why	
19	seafood? Well, because about 90 percent of the U.S.	
20	food seafood supply comes in from outside the United	
21	States. A huge amount is imported. And the team has	
22	worked through three phases. We're in the midst of	

1 phase three right now. Phase one was a proof of 2 concept. Could we apply machine learning? The second 3 was to integrate this machine learning into our existing PREDICT systems. And we're today at phase 4 5 We're using this tool, machine learning, to three. better determine what we could sample to find 6 7 violative compounds. Well, what could those be? Ιt 8 could be disease-causing organisms. It could be 9 seafood decomposition, the presence of unapproved 10 antibiotics or other hazards. 11 Now, we've also developed an AI-powered 12 emerging chemical hazard intelligence platform, which is known as horizon scanning. Very excited about that 13 14 tool. 15 So where are we today? Well, as you know, 16 like me, you go through the grocery store, there's 17 more than just seafood that's imported and so we're 18 looking to apply machine learning to other imported 19 foods coming to the United States. We're also looking to apply machine learning 20 21 to domestically produced foods. And then thirdly, and 22 very importantly, we're using this tool to try to

1 understand what are those drivers of contamination,
2 the drivers of those violative foods, what is causing
3 those foods to become a problem or risk to public
4 health.

5 So as I mentioned, we are using machine learning to make better predictions at import and 6 7 looking to apply it to domestic foods. The request that you've heard from Deputy Commissioner Jones is to 8 9 Well, give us the gift of feedback. help us. What 10 other food safety problems could be solved through the 11 use of artificial intelligence and machine learning?

12 We're also asking questions. Are you, is 13 your firm, is your area of food safety using machine 14 learning, predictive analytics? Thirdly, what 15 limitations exist? This is a great tool, but what 16 limits us from being able to apply this against our 17 food system? And then thirdly, what can FDA do to 18 provide or facilitate the application of machine 19 learning to the food safety system?

20 Please give us that gift of feedback for our 21 use of artificial intelligence and machine learning. 22 We're, as you can tell -- you can hear the excitement

in my voice. We're big on this. We think there's
 tremendous applications, but it's bigger than FDA.
 The applications are bigger than the FDA, and we want
 to be champions of this technology.

5 So I've talked about artificial intelligence and machine learning as part of this Core Element 2.2 6 7 on predictive analytics. I'll take you to a different 8 component of this, and it's on data sharing. And you 9 might ask why would anybody share with a regulatory 10 agency their data? Why would anybody do that? Well, I'll ask you, and we have a lot of discussions in the 11 12 agency about this, to think about it differently.

13 You see, many of the categories that all of 14 us worry about have known existing hazards that have 15 been in that category for quite a long time. It's We can either deal with it or not deal with 16 there. 17 If we're going to deal with it, we need to it. 18 visualize it. We need to come together and to compile the data that is out there to be able to better 19 20 visualize that data and for all of us to have to be 21 able to visualize it and make better decisions about 22 the data.

1	There are many categories that have existing
2	hazards, and we want to apply the seafood data sharing
3	platform that we've built to seafood, but as you'll
4	see, we want to apply it to other categories.

5 We have worked with our federal and state regulatory partners to be able to compile that data, 6 7 and we've had a lot of success. With this seafood 8 data sharing platform, we've worked with a platform 9 built by Creme Global that is enabling us to see these 10 toxic elements, to see PFAS. There's enormous amounts 11 of PFAS data that we've pulled into this, aquaculture 12 residues, seafood decomposition, marine biotoxin data 13 globally. It is profoundly exciting and the ability 14 to visualize the data, the levels, the regions, is 15 very exciting.

So where are we going with this? Well, we've built a heck of a tool, but like any tool in your toolbox, it's only going to be as good as your ability to use it and to apply it. And we're looking to take this tool and expand it to other categories of the grocery store. There's many.

22

So we would ask for feedback on what are

1 some of those application areas for this data sharing 2 platform. We want to work with partners that have 3 You know, on any given day, industry is doing a data. lot more testing than the regulatory agencies are. 4 But, having come from industry, I can tell you that 5 there's not nearly the amount of sharing across the 6 7 category, across an industry and there's often very 8 little sharing with the regulatory agencies.

9 We're trying to change that. Yes, we are a 10 regulatory agency, but we're putting our prevention 11 hat on and we're trying to build a tool that enables 12 or that addresses of the concerns that many would have 13 of providing that information to a regulatory agency. 14 Could it be blinded? Yeah, we can work with that. 15 Aggregated data? Yes, we can work with that. We know 16 that there's trade secrets that have to be protected, 17 but we know in our core that the way through this, 18 with these hazards and for better protecting health is by using these platforms, this platform to share data, 19 20 to bring partners in, to understand the data.

I will tell you that we're very excited to work with a leader known as Western Growers. These

1 are produce manufacturers, produce growers out West 2 that have been working with the FDA to be able to 3 share their data. We're working through the concerns 4 that exist with sharing data, but I believe we are 5 going to get there.

6 We have a very strong desire to be able to 7 conduct predictive analytics with all of you on this 8 information. We also want to encourage industry to 9 use the data and the technology. There's a lot of 10 exciting stuff out there in the area of sensor 11 technology, data digitalization. This is a very 12 exciting space.

13 So the feedback that we would request is 14 what food safety challenges are out there in your part 15 of the world that could be addressed through data 16 sharing. What are they? We're happy to talk with you 17 about that. Me and my team would be happy to talk 18 with you. We're partnering with our Office of 19 Compliance to be able to build these data sharing 20 agreements. What data would you share in this public-21 private trust?

22

And I'll finish up with this, the

1	GenomeTrakr 2.5. If you've never heard of this, I'll	
2	explain it. And it's an area that many of us have a	
3	lot of passion for in the agency. It is a tremendous	
4	public health tool. So what is it? Just like you and	
5	I have fingerprints, so do bacteria, so do parasites,	
6	so do viruses. These fingerprints are encoded through	
7	their nucleic acid sequences, just like you see there,	
8	the G and C and the A and T of DNA. Those are their	
9	fingerprints.	
10	Whole genome sequencing does just that. It	
11	determines the entire sequence of that genome, of that	
12	organism. What do we do with that information? It	
13	enables us to make associations. If there's clusters	
14	of illness, we're able to see that, well, there's more	
15	than just one person. In fact, as you dive into this,	
16	these people all appear to have consumed the same	
17	food. Oh, and by the way, we're able to find that	

18 that same organism was in that growing arena or that 19 manufacturing facility.

It enables us to connect dots. And that's the beauty of this GenomeTrakr tool. The FDA established the GenomeTrakr. It's a laboratory

1	network. We've got it in 28 states, and we're looking	
2	to get it in the remaining 50. It really is the case	
3	of as a kid when you would just add water to a sponge.	
4	This literally is adding water to the sponge. There	
5	are resources that are needed to be able to conduct	
6	the training and to bring forward the technology to	
7	these remaining 25 states to be able to use, to be	
8	able to determine these whole genome sequences and to	
9	be able to submit them for bioinformatics analysis.	
10	Just to illustrate how important this is,	
11	the FDA, there's about 150 FDA regulatory actions per	
12	year, per year that are informed by this GenomeTrakr.	
13	It's a tremendous tool.	
14	So what do we need? Yes, we are asking for	
15	feedback, but it's very clear here. There's no	
16	secret. We really do need funding to be able to	
17	expand this from the existing 27 to all 50 states. We	
18	would be able to build a continuous flow of	
19	pathogenomic data, genomic data from humans and	
20	animals gathered by the CDC and the USDA and FDA	
21	partners. We'd be able to detect the signals, and	
22	that's the beauty of this tool.	

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1	There is just so much work that's been done
2	in this data space, and we at FDA see tremendous
3	opportunities in this Core Element 2. We're very
4	excited to work with all of you and would welcome the
5	feedback on how else we can use these tools of
6	predictive analytics and data trusts and GenomeTrakr.
7	And with that, I thank you.
8	MS. HOWARD-KING: Good morning. I'm Vinetta
9	Howard-King, director of FDA's Office of Human and
10	Animal Food East in the Office of Regulatory Affairs.
11	I'm also the lead for several goals under
12	the Core Element 2 of the New Era of Smarter Food
13	Safety blueprint. Specifically, I lead goals under
14	2.3, domestic mutual reliance, 2.4, inspection,
15	training and compliance tools, and 2.6, recall
16	modernization.
17	As we build on the progress we've made in
18	implementing FSMA, the New Era of Smarter Food Safety
19	blueprint centered on three main principles: people-
20	focused and led, FSMA-based and technology-enabled.
21	Over the past three years, we've had many
22	successes and some challenges that we've had to

1 continue to work through, like funding and resources. But some examples of successes under 2.3, domestic 2 3 mutual reliance goals, include establishing domestic 4 mutual reliance partnership agreements with state 5 regulatory agencies that allow FDA and states to leverage inspectional coverage. This helps to reduce 6 7 redundancy and allows each organization to focus on 8 the highest priority work.

9 Harmonization of food testing methodologies 10 used by state and federal labs, including collection, 11 sample collection, analysis and reports. Last year, over 8,000 micro and over 6,000 chemical food samples 12 were analyzed by state laboratories, resulting in 21 13 14 human food recalls, two consumer advisories, eight 15 firms or countries being added to import alert, and 16 one FDA outbreak notice. We've also enhanced IT 17 platforms to allow better data sharing with state 18 partners to include system to system reporting, firm 19 search and history, produce safety farm inventory and 20 inventory reconciliation.

21 During the COVID-19 pandemic, FDA worked 22 with our industry partners to develop, pilot and

1 implement remote inspectional tools. In the domestic 2 arena, these remote regulatory assessments are a 3 voluntary process that allow industry to share pertinent information with FDA prior to us conducting 4 5 onsite visits. For example, for firms with a demonstrated compliance history with FDA, we've used 6 7 remote regulatory assessments, or RRAs, to verify corrective actions to previous inspectional 8 9 observations. This verification is done prior to an 10 onsite visit by FDA. It has led to focus and time 11 saving interactions between FDA and the firm doing the 12 future onsite inspection

13 In the foreign arena, FDA has been able to 14 utilize RRAs to both verify corrective actions and 15 assess compliance with FDA food safety laws and regulations with firms that are located in countries 16 17 and regions where there are State Department security 18 concerns that prevent onsite inspections. We have 19 found RRAs to be an excellent educational tool, as 20 many foreign firms are not as well versed in our food 21 safety regulations, so they are very appreciative of 22 this outreach opportunity. Again, industry

	rage 55
1	participation in RRAs is a voluntary process.
2	FDA continues to work to modernize our
3	recall process, which includes better recall
4	communications and the use of technology. For
5	example, in April 2021, FDA rolled out its enforcement
6	report subscription service that allows consumers and
7	industry to sign up for email notifications of new and
8	updated recalls that are posted to the FDA's
9	enforcement report.
10	Since the initiation of the subscription
11	service, there have been updates to the service that
12	allows for subscribers to subscribe based on keywords
13	such as specific allergens. As of February 2024,
14	there are over 11,000 active subscribers to the
15	enforcement report subscription service,
16	And FDA continues to be very interested in
17	your feedback, as we are always looking for ways to
18	make our service more useful. So please feel free to
19	use the link in my presentation to send your feedback
20	to FDA.
21	Other recall modernization activities
22	include the public meeting held last September 2023.

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1	As you know, FDA's recall process is enterprise-wide,
2	meaning our recall process covers the multitude of
3	commodities regulated by FDA; for example, human and
4	animal food, medical products, cosmetic and tobacco
5	products. As a result of the recall modernization
6	public meeting held last September, FDA received over
7	200 comments that were relevant to food recalls.
8	We're still reviewing the public comments and plan to
9	share the summary and outcomes in the near future.
10	Now let's talk about next steps. We plan to
11	continue our work on establishing and enhancing
12	domestic mutual reliance partnership agreements with
13	our state partners. They have proven to be invaluable
14	in our efforts to promote and enhance an integrated
15	food safety system. We're looking at ways to enhance
16	inspectional tools using artificial intelligence,
17	machine learning and GeoWeb mapping technology. We
18	want to explore different training modalities to
19	include virtual reality. We will increase our efforts
20	to effectively monitor and modernize the human food
21	supply chain oversight.

22

We want to work collaboratively with

1	external partners on food recall solutions to better
2	communicate recall information to the public. I look
3	forward to hearing your feedback and to working
4	together on common sense solutions. Thank you.
5	MS. FINNEGAN: Thank you for those
6	presentations, Vinetta and Mark. We will now take a
7	15-minute break, and when we return, we will hear from
8	the director of the Office of State Cooperative
9	Programs at the Office of Regulatory Affairs, Laurie
10	Farmer.
11	(Break)
12	MS. FINNEGAN: Welcome back everyone. Now
13	we have Laurie Farmer presenting on Core Element 3:
14	New Business Models and Retail Modernization.
15	CORE ELEMENT 3: NEW BUSINESS MODELS AND RETAIL
16	MODERNIZATION
17	MS. FARMER: Hello. I'm Laurie Farmer,
18	FDA's director of the Office of State Cooperative
19	Programs. I am the Core Element 3 co-lead with my
20	colleague Andreas Keller, and I'll be sharing the work
21	of the team with you today.
22	Core Element 3 is about ensuring the safety

of produced and delivered using new business models and modernizing traditional retail food safety approaches. When considering food safety and risk management, we have a global food supply. Consumers are more knowledgeable about safety and want immediate access to ready-to-eat goods. Innovation and technology, including data analytics, are tools to leverage.

8 The questions that we have been working to 9 answer and areas we want to hear feedback are how do 10 we support innovation yet still ensure food safety and 11 e-commerce? How can we use technology to monitor and 12 gather data on sales of food through e-commerce to 13 better understand the supply chain and identify 14 How do we modernize the retail food sources? 15 protection system in this country, and how can we work 16 with retail food safety stakeholders to encourage 17 innovation and technological development, digital 18 tools, data sharing and training methods to control foodborne illness risk factors? 19

This conversation is a request for feedback about where FDA should target our resources and leverage stakeholders and data and technology. What

1 are we doing well, what do we need to expand on and 2 where are the gaps and how can we improve?

3 The FDA retail food program has been dealing with the growth of food e-commerce, including evolving 4 5 delivery models. The challenges in new business models include issues stemming from delivery practices 6 7 of meal kits and groceries, such as key drop deliveries to unmanned retail establishments, also 8 9 known as micro markets, and even to robotics, where 10 machines do everything such as making pizza or cupcakes in a vending machine. FDA's retail food 11 12 safety team has been engaged and working 13 collaboratively with all our retail stakeholders, as 14 well as USDA FSIS in addressing these emerging issues 15 surrounding meal kits and food delivery practices 16 through guidance development and policy changes to the food code. 17

This includes working within the Conference for Food Protection on its e-commerce committee developing guidance for direct to consumer and thirdparty delivery services and guidance for mail order food companies. With FSIS, FDA developed a meal kit

1 video and infographics for consumers. Throughout this 2 process, we learned that the biggest challenges faced 3 by stakeholders are around regulatory scope. Stakeholders want to understand the regulatory 4 5 framework and their role in it, as well as liability issues and who has the ultimate responsibility for the 6 7 food delivered direct to consumers. 8 E-commerce of foods continues to grow and 9 evolve as domestic and foreign companies increasingly 10 use e-commerce sales platforms such as websites and 11 mobile applications to sell food products and arrange 12 delivery to consumers. We all felt the impact on the 13 industry during the coronavirus pandemic. Consumers 14 accelerated the utilization of e-commerce to make food 15 purchases amidst the coronavirus restrictions. Our 16 work has evolved and it is involved identifying and 17 learning more about the production and delivery of 18 human and animal food sold throughout e-commerce,

19 understanding the food safety vulnerabilities,

20 developing educational and outreach tools to combat 21 the vulnerabilities, working with the Conference for 22 Food Protection on its committee developing guidelines

1 for home delivery of food, and determining whether 2 they existing regulatory structure provides adequate 3 protection for consumers.

In reflecting on the foundational work already accomplished, we realized we need to focus efforts on emerging mechanisms and online platforms for food delivery and how to protect foods from contamination as e-commerce business models expand to meet the needs of modern consumers.

10 With our refreshed focus on technology and 11 data, we're seeking feedback on how to use technology 12 to monitor and gather data on food safety risks 13 related to food sales through e-commerce and to better 14 understand the supply chain and explore ways to 15 improve our understanding of retail food e-commerce trends with enhanced technology. Also, we're seeking 16 17 feedback regarding how to clearly define the 18 regulatory framework for e-commerce and gather data in 19 partnership with stakeholders to assess the extent to 20 which the existing domestic and international 21 frameworks operate to regulate food safety online. 22 We will also continue to work with the

Conference for Food Protection on identifying best practices and existing guidance that pertains to ecommerce shopping at retail. We will also work with them on developing a comprehensive guidance document for retail food establishments with best practices specific to e-commerce food shopping to ensure general food code recommendations are followed.

8 These recommendations would include; proper 9 handling during the shopping process to ensure 10 adequate time temperature control and prevent cross-11 contamination, construction and equipment requirements 12 for areas where shopped products are held, procedures 13 to address the items that were shopped but not picked 14 up by the consumer, and any other concerns that may 15 arise during the guidance development.

As we move from new business model to discussing retail food safety modernization, it's important to recognize that retail food protection is an integrated partnership program. FDA cannot modernize retail food safety alone. We rely on strong partnerships with stakeholders, including our state, local, tribal and territorial colleagues, the

1	Conference for Food Protection, the industry, academia
2	and professional associations. Equally important is
3	having good communication and strategic alignment.
4	FDA has established deliberate, targeted partnerships
5	in retail food protection. There are specific
6	objectives and alignment with retail food regulatory
7	associations and targeted efforts with CDC and
8	industry to put research into action to provide tools
9	for regulators and industry.
10	As part of Healthy People 2030, we're
11	working towards reducing the burden of norovirus, the
12	leading cause of foodborne illness in retail. One
13	important avenue FDA is working toward addressing
14	norovirus is through the AFDO norovirus workgroup.
15	We're currently focused on employee health.
16	My team created a National Food Code
17	adoption strategy that is completed by a toolkit
18	designed by the association collaborative for use by
19	state, local, tribal and territorial regulatory
20	agencies to realize food code adoption in their
21	jurisdictions. Retail associations have built on this
22	

1	build	on	the	work	I'm	sharing	today.
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2 FDA requests that the CFP establish a 3 conference for food protection food safety management systems committee to engage with stakeholders. 4 5 Industry really needs to lead this effort to take us to the next level in building tools for small 6 7 operators who have limited resources. They are beginning to build a toolkit, which will include 8 9 templates and examples on topics such as employee 10 health, and my hope is that these efforts will align 11 with the AFDO Healthy People norovirus group where 12 they are employee health-focused.

We have expanded our communication methods and sharing of information, including six podcasts and webinars ranging in topics from FDA food code adoption to the behavioral science of retail food safety hosted by groups such as Food Safety Magazine. All of these things can be easily found on the FDA New Era Smarter Food Safety website on the activity page.

In the area of expanding resources, the FDA retail food flexible funding model has dispersed over \$22 million in a three-year period to over 500

regulatory jurisdictions for development, capacity
building, mentorship and other special projects
supporting the retail program standards. We have also
awarded funding to regulatory associations to work
with federal partners to collaboratively advance
retail food initiatives to try to reduce foodborne
illness.

FDA and CDC developed five strategic action plans, or roadmaps, that address key areas to improve retail food safety. These objectives align with the FDA retail food program's strategic plan and the retail collaborative's objectives. Our goal is full and complete adoption of the latest code nationally.

14 This is the biggest complaint we get from 15 industry. Different code requirements depending on the version of the code the state has adopted. 16 The 17 roadmaps includes: developing a strategy to support 18 national food code adoption. This requires an environmental scan, defining states' current code and 19 20 anything unique in the state regulation, barriers for 21 adoption, tools and support to address the barriers 22 and then targeting states, including strategies to

1	move the needle.
2	Increasing the use of risk-based inspections
3	and intervention strategies. This start with
4	agreement on what risk-based inspections mean and what
5	it looks like, ensuring implementation and putting in
6	place interventions and measuring their effectiveness.
7	Increased use of FDA's voluntary national
8	retail food regulatory program standards. The
9	standards are a quality continuous improvement
10	framework for retail food safety regulatory programs.
11	These standards exist for manufactured program, feed
12	programs, eggs and they're being developed for
13	produce.
14	Improving foodborne outbreak investigation
15	methods. We're starting with environmental assessment
16	resources where we will centralize those, conduct a
17	gap analysis, do course assessments, make development
18	and the implementation of tools for the field.
19	We will increase the number of restaurants
20	and other retail food establishments with well-
21	developed food safety management systems that use
22	active managerial control. FDA will be supporting the

1 CFP committee.

2	These strategic action plans provide a
3	roadmap to align various projects, leveraging the
4	strengths of each agency and group, and avoiding
5	duplication of effort. Work in these areas includes
6	FDA's internal workgroup activities, the Retail
7	Regulatory Associations collaborative project, the CDC
8	and FDA MOU activities, DFP's initiatives and the New
9	Era for Smarter Food Safety work, and currently the
10	association collaborative is reviewing these roadmaps
11	and providing feedback.

12 The Retail Regulatory Association collaborative brings together representatives from 13 14 seven member organizations with a role of improving 15 retail food safety in the United States. FDA and CDC 16 are members of this group. We leverage our combined 17 strengths and resources to create and share tools and 18 resources for food safety programs so they can use 19 these to improve their food safety in their 20 jurisdictions.

21 The collaborative's six objectives are 22 poised to influence or benefit regulatory food

1 programs and the food safety culture within regulatory 2 jurisdictions and at restaurants and other retail 3 establishments.

Pictured here are many leaders within the collaborative. And this is a meeting where the FDA's deputy commissioner for food, Jim Jones, met with them. This was a 20-year vision of many to bring retail food safety regulatory associations together to target the reduction of foodborne illness risk factors in the industry.

The group has made a commitment to work together without funding. We have had the opportunity most recently to fund the work of our objective, and that has exponentially moved our collective work forward.

In addition to the association Collaborative, we are also actively working with these groups on the screen to advance retail food safety initiatives. The Conference for Food Protection committees, the CFP has multiple committees that are progressing the work of New Era. This includes the previously mentioned food safety management system and

1 the e-commerce committee, as well as committees on 2 food safety culture at retail. These groups include 3 stakeholders from industry, regulatory, academia, as 4 well as FDA and CDC.

5 I am very excited about a project the CFP is It's a research project focused on enhancing 6 leading. food safety and quality through digital systems and 7 advanced technologies. Industry collects a lot of 8 9 information in this arena. Some examples include 10 health department, their inspectional data, third-11 party audit data that could have significant value for 12 predictive modeling. This has real potential.

13 The CFP is conducting a literature review 14 examining the use of predictive modeling to enhance 15 food safety, including behaviors and practices in the food industry. Focus groups will be convened to 16 17 explore participants' experiences with data 18 digitization and digital transformation. They will also discuss and explore the utilization of various 19 20 technologies, artificial intelligence, augmented 21 reality and machine learning to evaluate food safety 22 and quality standards.

1	The AFDO Healthy People 2030 norovirus
2	Group. This workgroup focuses on putting research
3	into action in the prevention of norovirus
4	contamination of food and services in retail settings.
5	Activities will include identifying best practices,
6	vulnerabilities, mitigation and prevention strategies,
7	potential public health measures and identifying
8	barriers at retail food establishments that will
9	decrease the presence and spread of norovirus,
10	including tool to help prevent employees from coming
11	to work sick.
12	FDA and CDC signed an MOU to formalize the
13	partnership between the agencies for the purpose of
14	focusing on combined efforts on reducing foodborne
15	illness in retail and food service establishments.
16	The goal is to create practical, operational tools
17	that are demonstrated effective through research in
18	preventing foodborne illness.
19	In order to modernize retail food safety, it
20	would be beneficial to have a national benchmark. We
21	know some of the strengths that our national retail
22	food safety systems have, but do stakeholders believe

1	it would be helpful to have an independent body
2	conduct a review of the retail food safety system in
3	this country and how FDA supports it? Would you find
4	this data valuable, with the idea to ensure FDA is
5	targeting and prioritizing the support needed for our
6	primary customers who are state, local, tribes and
7	territory jurisdictions?
8	The FDA retail program standards provide a
9	framework on which retail food protection programs can
10	access how they stack up against nine standards. They
11	can identify gaps through this process and they can be
12	addressed and their accomplishments get national
13	recognition on our website. As you see on this map,
14	
	these pockets of coverage are fairly vast, with 969
15	these pockets of coverage are fairly vast, with 969 jurisdictions currently enrolled as of December 2023.
15 16	
	jurisdictions currently enrolled as of December 2023.
16	jurisdictions currently enrolled as of December 2023. While this seems like a large number, it's
16 17	jurisdictions currently enrolled as of December 2023. While this seems like a large number, it's still far from the 2,500-plus jurisdictions that
16 17 18	jurisdictions currently enrolled as of December 2023. While this seems like a large number, it's still far from the 2,500-plus jurisdictions that regulate retail food in this country. A national
16 17 18 19	jurisdictions currently enrolled as of December 2023. While this seems like a large number, it's still far from the 2,500-plus jurisdictions that regulate retail food in this country. A national study on retail food safety would help determine if

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1 target and prioritize work to improve retail food 2 safety.

Regarding retail food safety modernization, 3 as we look to the future, we would like to explore 4 5 with stakeholders how to leverage technological advances in food safety and data we collect in retail 6 7 food space to advance the food safety and to prevent 8 foodborne illness. Further advance the importance of 9 facility and equipment design as preventive controls 10 for retail food safety management, and particularly 11 encouraging the development and use of commercial 12 smart kitchen equipment capable of automatically 13 monitoring temperature and temperature processes.

14 Exploring and encouraging the use of new 15 training technologies to better reach the vast network 16 of retail food protection stakeholders. Encouraging 17 and exploring the use of new digital tools and 18 incentives that prompt desired behavior, such as 19 handwashing and managing manual temperature 20 monitoring. Evaluating and analyzing new and existing 21 retail food safety data sources, and encourage the 22 sharing between stakeholders.

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1	Retail food protection is a team sport and
2	all of us here today want to protect the food supply.
3	It is an all these areas that we look forward to
4	hearing your feedback from you today and in the
5	docket. Thank you.
6	MS. FINNEGAN: Thank you for that
7	informative presentation, Laurie. Our last presenter
8	before we move on to the public comment session is
9	Chris Waldrop, a co-lead for Core Element 4. Chris
10	will be presenting updates about food safety culture.
11	CORE ELEMENT 4: FOOD SAFETY CULTURE
12	MR. WALDROP: Hi. My name is Chris Waldrop.
13	I'm a senior health scientist in the Center for Food
13 14	I'm a senior health scientist in the Center for Food Safety and Applied Nutrition, and I'm also one of the
14	Safety and Applied Nutrition, and I'm also one of the
14 15	Safety and Applied Nutrition, and I'm also one of the co-leads for our work on food safety culture here at
14 15 16	Safety and Applied Nutrition, and I'm also one of the co-leads for our work on food safety culture here at FDA.
14 15 16 17	Safety and Applied Nutrition, and I'm also one of the co-leads for our work on food safety culture here at FDA. Today I'd like to talk briefly about the
14 15 16 17 18	Safety and Applied Nutrition, and I'm also one of the co-leads for our work on food safety culture here at FDA. Today I'd like to talk briefly about the work we've done regarding food safety culture here at
14 15 16 17 18 19	Safety and Applied Nutrition, and I'm also one of the co-leads for our work on food safety culture here at FDA. Today I'd like to talk briefly about the work we've done regarding food safety culture here at FDA. We included food safety culture as part of our
14 15 16 17 18 19 20	Safety and Applied Nutrition, and I'm also one of the co-leads for our work on food safety culture here at FDA. Today I'd like to talk briefly about the work we've done regarding food safety culture here at FDA. We included food safety culture as part of our New Era of Smarter Food Safety because we recognize

1 do more to influence what employees think about food 2 safety and how they show a commitment to this goal in 3 their everyday work.

Food safety is the result of individual and 4 5 collective behaviors, and behaviors stem from attitudes, perceptions, beliefs and values of both 6 7 individuals and organizations. We wanted to better understand how those attitudes, perceptions and 8 9 behaviors can be harnessed to improve food safety and 10 we wanted to support efforts to make food safety a 11 social norm across the food industry.

12 There are three key areas we have focused on 13 in our work for food safety culture. First is to 14 promote food safety culture throughout the food 15 system. We know that more and more companies are 16 working to develop and enhance a culture of food 17 safety throughout their companies and in their 18 facilities, and we want to support those efforts.

We also want to help promote best practices and examples of effective food safety cultures across the food supply, and we want to encourage other companies who may not yet have embarked on a food

1 safety culture journey to begin taking steps to do so. 2 Second, we wanted to promote food safety 3 cultures throughout FDA. We want to explore internally our own culture of food safety within the 4 agency, and we want to lead by example and learn from 5 our own journey so we can better support food safety 6 7 culture across the food supply. 8 Third, we wanted to develop and promote a 9 smarter food safety consumer education campaign. 10 While we often think about food safety culture in the 11 context of companies and people producing our food, we 12 also know that consumers have a role to play in food 13 safety as well. We wanted to look at how we could 14 better communicate with consumers about food safety 15 and to do so using new digital tools, and we wanted to 16 see if there were lessons from the work the food 17 industry is doing on food safety culture that we could 18 apply to our engagement with consumers to help influence their behavior when they're handling food in 19 20 their homes. 21 I want to mention three accomplishments that 22 we have done over the last few years. First, we

1	conducted a systematic literature review of the
2	scientific literature on food safety culture. This
3	helped ground us in the science of food safety culture
4	and the work that's already been done. We learned
5	that there's general consensus in the literature on
6	how to define food safety culture, and we also learned
7	that there is general agreement in the literature on
8	the determinants of a strong and effective food safety
9	culture. We posted our literature review on our
10	website so you can examine these findings more deeply
11	if you'd like.
12	We also learned there are a few gaps and
13	areas we might want to explore further. First, more
14	research is needed to assess the validity of
15	assessment tools across different organizational
16	settings, and we also learned that more research is
17	needed to quantitatively demonstrate the connection
18	between food safety culture and food safety outcomes,
19	and I'll talk a little bit more about that in just a
20	minute.
21	Second, we developed a training course for

22 our investigators and other FDA staff. This was an

1 introductory course really designed to expose FDA
2 staff to the concepts of food safety culture. The
3 course looked at a number of different issues,
4 including how you identify whether a firm has a good
5 food safety culture and how to know the
6 difference between a food safety program and a food
7 safety culture.

8 Now this wasn't designed as a course so our 9 investigators could begin inspecting a firm for a food 10 safety culture; rather, the course serves as a food 11 safety culture 101 so we could begin socializing the 12 idea within FDA. We trained over 1,200 FDA staff in 13 both our human and animal foods programs and the 14 course is now available to our federal, state, local, 15 tribal and territorial partners as well.

And third, we organized a webinar series with the Alliance to Stop Foodborne Illness. Hopefully many of you all were able to participate in at least some of the webinars we held over the past three years. This was really an opportunity for us to be able to collaborate with our stakeholders in both the food industry and the public interest community.

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1	We wanted to elevate best practices, learn from some
2	of the leaders in food safety culture and hear
3	directly from our audience about the questions they
4	had and the issues they were grappling with and wanted
5	to hear more. In total, we had nearly 23,000 people
6	register across the ten webinars we've conducted.
7	We explored a range of issues such as how to
8	build a coalition of food safety culture champions
9	across your organization. We talked about the
10	importance of measuring food safety culture and
11	provided some ways that you might be able to do it.
12	We talked about storytelling and the importance that
13	can play in shaping and reinforcing messages and
14	inspiring employees, and we talked about how food
15	safety culture and food safety management systems work
16	together to improve food safety. And because people
17	learn in different ways, we've also been posting white
18	papers after each webinar that summarizes the content
19	and highlights the key points of what was talked about
20	in that webinar. These are all downloadable from
21	FDA's website.

22

Our final webinar will be broadcast live

1 from the Food Safety Summit on May 9th, which will be
2 both a virtual and a live event. We'll be looking at
3 everything we've learned about food safety culture
4 over the course of our webinar series as well as
5 getting some fresh perspectives and new ideas. So we
6 hope you'll be able to join us for that last final
7 webinar.

8 In closing, I wanted to mention one area 9 where we think new data could really help inform our 10 work on food safety culture, and that is the linkage 11 between food safety culture and food safety 12 performance and to what extent a strong, mature food 13 safety culture is predictive of food safety outcomes.

We're pretty confident that a mature food 14 15 safety culture leads to positive food safety outcomes. 16 But what data can we rely on to demonstrate that in a 17 quantitative way? Are there ways we can look at data 18 from the food industry that's maybe anonymized or 19 disaggregated and use machine learning and AI to 20 explore that correlation between food safety and 21 culture maturity? With enough data, what insights can 22 we learn about the development of food safety

1	measures? How can we better understand the drivers
2	for food safety and food safety culture performance?
3	So that's an area we'd like to explore
4	further, and we would really welcome your thoughts on
5	that as well as other ways that data and technology
6	can support our work on food safety culture. We'd
7	also of course love your input on how best FDA can
8	continue to support and foster industry efforts in
9	this space.
10	So thank you for your engagement over the
11	past years on food safety culture. We've learned a
12	lot. We hope others have as well, and we look forward
13	to continuing our food safety culture journey
14	together. Thank you very much.
15	MS. FINNEGAN: Thank you, Chris. We will
16	now take a break for lunch and when we return, we will
17	begin our public comment session.
18	(Break)
19	MR. KAWCZYNSKI: All right. Good afternoon.
20	We'll get started here shortly. So I welcome everyone
21	to our "Data and Technology in the New Era of Smarter
22	Food Safety" webinar. Again, we're just going to come

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1	back	from	break	, and	we'll	get	started	roughly	in
2	about	ca m	inute	or so					

All right. Good afternoon, and welcome back from that break. I'm Mike Kawczynski, and this is the "Data and Technology in the New Era of Smarter Food Safety" webinar. At this time, I'd like to hand it off to my co-host, Lauren Finnegan. Lauren, if you're ready, take it away.

9 PANELIST INTRODUCTION

10 MS. FINNEGAN: Thank you, Michael. I hope 11 you all had a great break. Now we'll get into our 12 afternoon session, which will consist of comments from 13 members of the public, followed by responses by our 14 group of panelists. Before we hear from our public 15 commentators, I'd like to introduce our panel members. 16 From Core Element 1, we have Adam Friedlander. From 17 Core Element 2, we have Mark Moorman, Ruth Timme and 18 Vinetta Howard, and from Core Element 3, we have Laurie Farmer and Glenda Lewis. 19 20 And now we'll hear from our public

20 And now we if hear from our public 21 commentators. Just a quick reminder before we get 22 started, that the views expressed today don't

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1	necessarily	represent	the	views	of	FDA.	First	up	we
2	have Celina	To.							

MR. KAWCZYNSKI: Good afternoon, everybody.
First we'd like to please introduce each one of our
panel members. So let's go around with Core Element
Adam, would you please introduce yourself and tell
us what element you're managing?

8 Hi. Thanks, Mike. MR. FRIEDLANDER: And 9 thank you, Lauren, as well. My name is Adam 10 Friedlander. I'm a policy analyst in FDA's 11 coordinated outbreak response and evaluation network, I'm also the co-lead for New Era 12 also known as CORE. 13 of Smarter Food Safety Core Element 1, which is the 14 tech-enabled traceability initiative, and I co-lead 15 that core element we're Captain Kari Irvin, who is, 16 CORE's deputy director. And I'm very happy that you all are here today. And I'm looking forward to your 17 18 comments. Thank you.

MR. KAWCZYNSKI: I'm going to hand it back to Lauren, who can go around and introduce each one and allow them to give their opening remarks.

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Lauren, you want to take it away?

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1		MS. FI	NNEGAN:	Yeah.	So,	Mark,	would	you	
2	like to	introduc	e yoursei	lf?					

3 DR. MOORMAN: I'd be happy to. My name is I'm the director of the Office of Food 4 Mark Moorman. 5 Safety. I've been with the Food and Drug Administration for five years, prior to that in the 6 7 private sector. I have the privilege of leading the 8 Office of Food Safety, where our team spends a lot of 9 time thinking about when outbreaks happen, how do we 10 prevent them? What are those levers of prevention 11 that that we pull in that space of post response? 12 within that, we do a lot of work on policy, research 13 supporting our subject matter experts, support the 14 Office of Compliance. And very importantly for today, 15 I have the privilege of calling Core Element 2 with 16 Vinetta. So, thank you so much for taking the time to 17 be with us today. And look forward to hear from you. 18 MS. FINNEGAN: Thanks, Mark. Ruth, would 19 you like to begin? 20 DR. TIMME: Yeah, sure. I'm really happy to 21 be here today. My name is Ruth Timme. I'm a research

microbiologist at the FDA within the Office of

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1	Regulatory Science and I've been with the FDA going on
2	13 years now. And for most of that time, I've been
3	really actively involved in FDA's initiative to use
4	genomics for foodborne pathogen surveillance. We call
5	this the GenomeTrakr program. And I'm the lead for
6	that program. And within New Era, that program, the
7	GenomeTrakr contributes to Critical Element Number 2,
8	along with Mark Moorman. Thanks.
9	MS. FINNEGAN: Thanks, Ruth. Vinetta?
10	MS. HOWARD-KING: Hi, everyone. My name is
11	Vinetta Howard-King. I am the director of the Office
12	of Human and Animal Food East in FDA's Office of
13	Regulatory Affairs, where I have executive oversight
14	over inspections and investigations, sample
15	collections and, for a while longer, compliance and
16	enforcement activities, foreign and domestic. I'm
17	also, as Mark mentioned, the co-lead for New Era of
18	Smarter Food Safety Core Element 2. Specifically, I
19	lead Elements 2.3, domestic mutual reliance, 2.4,
20	inspection, training and compliance tools and 2.6,
21	recall modernization.
22	MS. FINNEGAN: Thanks, Vinetta. Laurie?

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1	MS. FARMER: Hi. So glad to be here. So
2	I'm Laurie Farmer. I'm the director of the Office of
3	State Cooperative Programs, and this team of subject
4	matter experts work in the field in the areas of
5	retail food protection, mollusk and shellfish,
6	sanitation and Grade A milk safety. And I'm just so
7	glad to be here. I co-chair the Core Element 3 with
8	Andreas Keller. And I work very closely with Glenda
9	Lewis, who is here today. So, looking forward to hearing
10	from you. Thank you.
11	MS. FINNEGAN: And Glenda?
12	MS. LEWIS: Good afternoon, everyone, or good
13	morning. So happy to be here today. I am the
14	director for the retail food protection staff in
15	CFSAN's Office of Food Safety, and I've been at FDA
16	since 1996 in the retail program and I currently have
17	responsibility for oversight of the retail policy
18	component at FDA, and I work with a fantastic group of
19	staff on a team developing national retail food policy
20	and interstate travel program policy.
21	I co-lead the New Era 3.1 core element on e-
22	commerce with Andreas Keller. So happy to hear from

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1 everyone today. Thank you.

2 PUBLIC COMMENT

MS. FINNEGAN: Great. Thanks, Glenda, and thank you all for being here today. Now we'll go switch over to our public commentators, and we have Celina To first.

7 MS. TO: Thank you. Good afternoon. Thank you for this opportunity to provide feedback 8 9 specifically, to align with the continued New Era work 10 and WGS and ways to monitor and gather data. Oxford 11 Nanopore Technologies has created greater access for 12 labs to bring genomics and health due to capital 13 free, scalable and real-time devices with end-to-end 14 workflows like No-MISS, nanopore-only microbial 15 isolate sequencing.

These simpler workflows can accelerate the implementation of GenomeTrakr across 50 states and internationally, similar to ongoing efforts with CDC PulseNet. Also, access to EPI2ME, a point and click solution with optional use of smaller robotics like TurBOT can potentially integrate Galaxy Tracker and FDA BAM pipelines, similar to our integration of 602

1	for salmonella serotyping. The intent is to
2	streamline training of technicians, especially during
3	a staff turnover.

4 This type of technology can become useful 5 when responding to emerging pathogens like Cyclospora. Similarly, if we were to face another Cronobacter 6 7 outbreak, we would be prepared with the ability of 8 this technology to further shorten root cause analysis 9 and response time. The real-time capability is 10 pivotal not just for the FDA, but for all stakeholders 11 in food safety.

12 I also hope the FDA will consider developing 13 and validating quasimetagenomics, metabarcoding or 14 targeted panel approach to update FDA BAM as a cost 15 and time saving strategy and screening and 16 confirmation. These tests can better align with 17 private sector and current operations and may allow 18 easier sharing of data anonymously by creating a safe 19 haven through similar setup like the Food Industry 20 Intelligence Network with Creme Global. Such a 21 collaborative environment would improve our ability to 22 predict an event day, build trust to encourage sharing

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1	of WGS data, and exchange effective corrective actions
2	ahead of FDA sampling assignment and before an
3	outbreak occurs.
4	Thank you for considering these initiatives.
5	I look forward to seeing the FDA lead in these
6	innovative areas, setting a global standard for food

7 safety and public health preparedness.

8 MS. FINNEGAN: Thank you, Celina. Now up 9 next, we have John Bailey.

10 MR. BAILEY: Thank you, everyone. My name I'm the executive director of Top 10 11 is John Bailey. Produce LLC located in Salinas, California. We have 12 13 growers in 25 states who utilize our low cost 14 traceability system currently. For the past 14 15 years, we've been assigning globally unique GS1 global 16 location numbers, commonly known as GLNs, to uniquely 17 identify each of our growers nationwide.

Our growers use their global location numbers, which we have assigned to them, as the traceability lot code source reference. It is our position that this current ongoing practice is in compliance with the Food Safety Modernization Act 204

1 final rule. There are currently just under 2 million 2 farms nationwide who are looking for clear and direct 3 answers related to FSMA, the Food Safety Modernization 4 Act.

5 So the most significant action the FDA could 6 undertake to enable our independent growers to enhance 7 traceability across the global supply chain would be 8 for the FDA to confirm that the use of these unique 9 GLNs as a traceability lot code source reference is in 10 compliance with the FSMA 204 final rule. Thank you.

MS. FINNEGAN: Thank you, John. We appreciate those remarks. Next up we have Alexander Kashef.

14 First, I would like to really MR. KASHEF: 15 thank FDA for this opportunity and also share my 16 excitement and passion from New Era. My name is 17 Alexander Kashef. I live in Los Angeles next to UCLA. 18 I'm the owner and the president of the Food Safety and 19 Geospatial Data Analysis Training Institute. It is 20 basically two institutes all together. Now, in terms 21 of my educational background, my degree is geology, 22 astrogeology, environmental science, microbial

1	ecology.
2	And I also want to share with you, the first
3	time I heard about HACCP was in the class of was
4	astrogeology. That changed my whole life. So this is
5	my beginnings in terms of getting involved in HACCP.
6	I'm also a GIS specialist. I generally believe that
7	if it is not mapped, it is not done. So, I'm
8	basically, involved in mapping and teaching mapping in
9	addition to being a (indiscernible) specialist.
10	I'm also lead instructor for 22 HACCP and
11	FSMA classes. I teach human food, PCQI for human
12	food, PCQI for animal food, for produce, imported food
13	and food defense. I also have established and written
14	for six different classes for the New Era. In
15	addition to six New Era HACCP class that I teach
16	already, and it's pretty much popular and also teach
17	FSMA classes, but also teach another 11 HACCP classes
18	that pretty much are regulated by FDA. Meat, poultry,
19	package, dietary supplement. So pretty much whatever
20	is regulated by FDA, my institute is teaching them.
21	So I would like to concentrate on the six
22	classes that I'm teaching and what basically I'm

1	learning	from	the	bus	sines	ss,	the	industry	and	the
2	academia	in t	erms	of	New	Era	l.			

Since New Era came, I pretty much spend most of my time developing class for New Era. I strongly believe that the New Era is a whole new paradigm that is going to change everything. But my focus is this, basically using DNA fingerprinting, spectral fingerprinting and geospatial data collaboratively bringing them all to handheld devices.

10 So the issues that I cover in all these 11 classes are artificial intelligence. I would love to 12 share with you the six classes that I teach related to 13 food safety era. The number one is how to write a 14 HACCP plan to this class for traceability. So I 15 really go in detail talking about Section 204 and how 16 to write them with the addition or how to map 17 everything. If is not mapped, it is not done. Ι 18 strongly believe that we have to introduce geospatial 19 data, when 70 percent of the data has a geospatial 20 component. Bring them to all aspects of food safety. 21 So I introduce that to traceability class.

22

Now I also have developed four courses for

1	Core Number 2, and these are the following four
2	courses. I'll just talk about number two. Number
3	one, two-day class for the application of artificial
4	intelligence into food safety. So basically upon
5	completion of this class, pretty much everybody knows
6	what is AI and how it is used in food safety, all the
7	way from farm to table.
8	The second course related to the second core
9	is basically called food safety omics. it's the only
10	course on Earth that basically bring the whole issue
11	of omics, genomics, proteomics and transcriptomics,
12	other genomics, and teach them how to apply them in
13	food safety to this class for basically using all
14	kinds of omics in terms of in food safety.
15	And the third class is basically it
16	started eight, nine years ago. In Europe, there's an
17	consortium called Food Smartphone, and the address is
18	www.foodsmartphone.eu. They give PhD in how to use a
19	smartphone in food safety and with food quality. I
20	have been following what they have been doing. But I
21	have my own approach using NASA information and USGS
22	and other a spectral databases. It's very crucial to

Page 73 1 really bring --2 MR. KAWCZYNSKI: Please wrap it up. 3 MR. KASHEF: -- signature in food safety. And the last one is basically food safety 4 5 modernization, food retail modernization. Do I have any more time? 6 7 MS. FINNEGAN: No. That's it. 8 MR. KAWCZYNSKI: No. 9 MS. FINNEGAN: Thank you, Alexander. We 10 appreciate it. 11 MR. KASHEF: Thank you so much. 12 Next up we have Jim White. MS. FINNEGAN: 13 MR. WHITE: Hello, everyone. My name is, 14 I'm president of ENSESO4Food. Jim White. The FDA's 15 FSMA 204 regulation requires traceability for specific 16 This means tracking them from farm to fork. foods. 17 ENSESO4Food is here to help companies comply by 18 creating a system of traceability lot codes. These 19 codes are essential for the FDA to quickly investigate 20 outbreaks. 21 Primary source data collection from farms 22 and fishing enterprises will be the first big

1	challenge. Cost effectively capturing source
2	traceability lot codes has become one of our passions.
3	We're experts in traceability. We won the FDA's low
4	cost food traceability challenge and have experience
5	managing billions of transactions globally.
6	ENSESO4Food recognizes the importance of a diverse
7	traceability ecosystem and is committed to working
8	with other solution providers.
9	Our Trakkey system is one such solution
10	proven to support complex traceability needs. Trakkey
11	already manages billions of transactions in Europe and
12	around the world for both tobacco and pharmaceutical
13	serialization. Collaboration is key to success.
14	ENSESO4Food is a strong supporter of standards like
15	GS1 for standardization and interoperability. But
16	true success requires collaboration beyond just
17	standards. That's why we invite other technology
18	vendors to call us to discuss how our systems can work
19	together to seamlessly share data across the supply
20	chain.
21	ENSESO4Food's solutions are designed for
22	ease of use. We offer smartphone apps with

1	multilingual capability, ensuring a familiar and
2	comfortable experience for everyone involved. But
3	user friendliness goes beyond the interface. Our
4	solutions can enforce and automate workflows,
5	minimizing errors in manual data entry. They also
6	integrate with existing systems like accounting
7	systems, warehouse management systems, ERPs and MRPs.
8	This eliminates the need for duplicate data entry and
9	streamlines existing operations.
10	ENSESO4Food understands the challenges of a
11	small farm. We are piloting a solution to get source
12	traceability lot codes into the system easily and cost
13	effectively. This pilot includes offering our device
14	as a service, or DaaS model, as an option. DaaS can
15	simplify adoption for farmers and fishing operations
16	that are still transitioning to digital tools. It
17	provides a bundled solution with hardware, software
18	and support at an affordable monthly cost.
19	FSMA 204 is a starting point. ENSESO4Food's
20	solutions go beyond just compliance. For example, we
21	offer IoT sensors to monitor the cold chain.
22	Traceability solutions also provide valuable data for

1 recordkeeping related to GAP or planting strategies.
2 These tools can empower small businesses to improve
3 their operational efficiency and productivity today.
4 While predictive analytics, machine learning and AI
5 hold exciting opportunities, the foundation for a
6 robust food safety system rests on high quality source
7 traceability data.

8 Accurate data allows for faster outbreak 9 identification and targeted interventions minimizing 10 risks and protecting consumers. ENSESO4Food is 11 committed to a safer, more efficient and transparent 12 food system. We believe that FSMA 204 is a catalyst 13 for positive change. We are here to help businesses 14 of all sizes thrive in this New Era of Food Safety. 15 Thank you for your time.

MS. FINNEGAN: Thank you, Jim. Next up, we have Dr. Marcia Lee Herzberg.

DR. LEE: Hello. First of all, I'd like to say thank you for allowing me to be here and speak, looking at this data and technology in the New Era. I find it to be very exciting. I am a former regulator myself, having worked in the retail food segment,

1 manufactured food segment and also having worked in 2 the public sector and working as an adjunct professor 3 for Northeastern University for their master's program 4 in regulatory affairs for food.

5 What I'd like to speak about is the data systems that have been spoken about previously. 6 And 7 I'd like to speak about it in regards and in relation to the retail food program. 8 I did a study, 9 "Inspection, Laws, Risk Factors and Foodborne 10 Illness," and an important question that I posed was 11 how the current regulatory system could uphold its 12 responsibility to the public, enforcing the law and 13 food safety without adequate funding, with an 14 increasing number of food establishments, insufficient 15 numbers of food inspectors, budget constraints for 16 regulatory agencies and a pandemic of foodborne 17 illness, particularly relating to the food segment, 18 often managed by small county or small town boards of 19 health responsible for the majority of foodborne 20 illness and the only segment of the food system not in 21 the Code of Federal Regulation, the CFR, whose 22 regulations are voluntarily adopted from the FDA,

1	Model Food Code, which changes every four years.
2	They are supported by the FDA's retail food
3	program, which provides tremendous tools and
4	tremendous resources. But somehow there's a gap and I
5	know that's one of the things that Laurie mentioned,
6	that they're looking to try to find a way and assess
7	how to best address that task that they have.
8	My data demonstrated frequency of
9	inspections, had a high negative correlation
10	relationship with foodborne illnesses, frequency of
11	inspection increases or decreases, foodborne illness
12	will travel in the opposite direction. Every year
13	that the frequency of inspection rose in subject
14	cities, the per capita foodborne illness rate
15	decreased, and in the years where the frequency of
16	inspection was stagnant, the foodborne illness rates
17	were relatively unchanged.
18	Frequency of inspection and high risk
19	factors had a high positive correlation relationship.
20	The more frequent the inspections, the higher the
21	incidence of high-risk factors was noted. Risk

22 factors are used to reduce foodborne illness. They

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1	are a preventive control.
2	By correcting these critical items, if
3	properly reported, an establishment can theoretically
4	prevent foodborne illness, and the high-risk factors
5	had a high negative correlation with foodborne illness
6	in the years that foodborne illness decreased,
7	demonstrating its functions as a preventative control,
8	the preventative control it is meant to be.
9	Risk factors were coded by assigned values
10	by state law and under a common numbering system. It
11	was designed to see if the food law changed the
12	assignment of the risk factors. The coded controlled
13	law and assigned law risk factors did demonstrate
14	a significant difference of means in each year of the
15	study, establishing that food law does influence risk
16	factor assignment, demonstrating the need for a
17	similar or the same standardized food code to be used
18	throughout the country.
19	One of the leading drivers to the success of
20	this study was the ability to access research material
21	through databases. It took a tremendous amount of
22	time and analysis. But from this study, I concluded

1	the retail food system would benefit from a study on a
2	viable national electronic inspection platform, an
3	information database system accessible across all
4	states by multiple agencies and all retail food
5	programs nationally.
6	The sharing of information in real time is
7	key to identifying factors that can mitigate risk of
8	foodborne illness effects, not only at the local
9	level, but nationally. And it's through data sharing
10	that we can create a dynamic food safety system that
11	can impact foodborne illness, necessary policy change,
12	and make the most of scarce resources in the public
13	health sector. If we can create
14	MR. KAWCZYNSKI: That's time.
15	DR. LEE: Okay. Well
16	MR. KAWCZYNSKI: Just go ahead and wrap
17	you have a few minutes. Wrap it up, and then stay on,
18	please.
19	DR. LEE: Okay. So, I just wanted to state
20	that good policy is always driven by good data and
21	that this aligns with the harmonization of
22	traceability again through data. And we can use the

1	same type of system to do tracebacks and trace
2	forwards and to align with what we find in the retail
3	food system. Thank you.

4 MS. FINNEGAN: Thank you, Doctor. Next up, 5 we have Sharmeen Khan.

MS. KHAN: Good afternoon. My name is 6 7 Sharmeen Khan, and I am the chief strategy officer of 8 OpsSmart Global. We are also one of the winners of 9 the tech-enabled traceability challenge that was 10 referenced earlier. We at OpsSmart belief that the FDA must stop looking at food safety through a topic-11 12 based vision and start looking at it from a broader 13 spectrum.

14 It will require us to combine tech-enabled 15 traceability, predictive analytics and data sharing, 16 ambient IoTs. As said earlier, we must think 17 strategically and big. What I mean by that is that 18 the most significant and overarching focus should be 19 on interoperability. Until we move away from silo-20 based data systems, we will never be fully able to 21 flex the muscle of data.

2.2

All companies, big or small, have some sort

of data in some sort of format. However, their
 inability to share that data within their own
 organizations and with their partners handicaps them,
 the FDA and the public.

5 My first recommendation is that as the FDA continues to harmonize the critical tracking events 6 7 and key data elements, the FDA also needs to harmonize how data is shared. If you look at the 8 9 seafood industry as an example, organizations such as 10 Global Dialog of Seafood Traceability, MSC, AFC, et 11 cetera, got together and devised one method of 12 electronic data exchange. They created a system to 13 authorize technology providers to implement that 14 methodology of electronic data exchange. The FDA must 15 investigate finding a similar path in order to create 16 a unified path forward so there are standardized tools 17 for gathering and sharing data from industry to 18 government and the public.

My second recommendation is that the first steps taken by the FDA in FSMA 204 have been a game changer, but they are not enough. Telling people or the industry that they need electronic sortable

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1	spreadsheets, then saying that they don't have to have
2	a digital method of collecting their data, it's
3	sending the industry a very confusing message that
4	will hurt them in the long run. I believe the FDA
5	needs to speak more clearly as to what is
6	technologically expected of food growers and
7	processors. We need the FDA to possibly find a method
8	of subsidizing access to simple data collecting
9	methodologies, such as Microsoft Word or Excel, Google
10	Sheets or Docs, something. Let's make it easier for
11	the food industry to meet FDA's requirements by
12	becoming digitized.
13	Lastly, to answer Adam's questions, all of
14	which were fabulous, is what other areas can tech-
15	enabled traceability create value? My answer is
16	sustainability. If we can trace products, how they're
17	grown, where they're grown, how they're grown, we can
18	also capture the amount of waste, how product is
19	reutilized, how soil and water is reused, what type of
20	packaging we're using. By collecting how much we
21	reuse, how much we waste, we improve a company's

22 sustainability posture, but we also improve our

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1	national carbon footprint.
2	In conclusion, it is important to remember
3	that we are a global food system and a product can
4	exchange multiple hands before it ends up on our
5	shelves. So adopting a data exchange-centric or
6	interoperability-centric approach to food safety
7	enhances visibility across the supply chain, which
8	translates to a safer food system. Thank you so much.
9	MS. FINNEGAN: Thank you, Sharmeen. So just
10	a general reminder to all of our public commentators,
11	please stay on the line so our panel, if they have any
12	questions for follow up, they can contact you again.
13	Next up, we have Tom Ragsdale.
14	MR. RAGSDALE: Hello everyone. I'm Tom
15	Ragsdale, I'm an app developer living here and in
16	Henderson, Nevada. Now, last year I worked for a
17	small company here in the Las Vegas area that sells
18	Vegas-themed candy to a number of stores, mostly in
19	casinos on the Strip. Their tracking paperwork was
20	entered into a ledger by hand, both incoming and
21	outgoing product.
22	And after I left the company, I happened to

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cross the FDA requirements that go into effect, I
guess, next January. And at first I started working
on an app customized for the candy company, but then
realized there are probably a lot of other mom and pop
shops, as well as larger companies that would benefit
from a more generic app that would meet the FDA law
tracking and reporting requirements.
The app's nearing completion. It's fully
menu driven and has four sections. I call it Lot
Number Tracker. The first section, it allows the user
to enter products, multiple ingredient products,
manufacturers and suppliers of those products and
customers that they send the product to. And then
there's a section to be able to edit all that in case
they make mistakes.
There's a section to input tracking data for
both incoming and outgoing products. And then,
there's a section allowing the printing of reports.
In the event of a recall of a particular product or an
ingredient in a product, with one click reports can be
generated, all incoming product and any products that

22 have been distributed to customers containing the

1 ingredient with the suspect lot number, one report for 2 each customer that has received any of the product in 3 question.

At this time, the reports are in a PDF 4 5 format and not Excel format, but Excel can import from PDF files. I've done it this way because text files 6 7 are more susceptible to accidental corruption. The app will be available on Apple products, Android 8 9 products and Windows products and could in the future 10 be available on servers.

Again, my name is Tom Ragsdale. I can be reached at tomragsdale@cox.net, and my mobile phone number is 702-704-9497. That's 702-704-9497 or tomragsdale@cox.net. Thank you for your time.

MS. FINNEGAN: Thank you, Tom. Next up, we have Mara Burr.

MS. BURR: Thank you very much. I appreciate the opportunity. My name is Mara Burr. I'm the vice president for clinical affairs at Consumer Brands Association, and I appreciate the FDA providing this opportunity to speak on the data and technology in the New Era of Smarter Food Safety.

1	The Consumer Brands Association champions
2	the industry whose products Americans depend on every
3	day, representing nearly 2,000 iconic brands, from
4	household and personal care products to food and
5	beverage products to consumer packaged goods
6	(indiscernible) industry plays a vital role in
7	powering the U.S. economy, contributing \$2 trillion to
8	the U.S. GDP and supporting more than 20 million
9	American jobs.
10	We appreciate the FDA's blueprint for the
11	future of a New Era of Smarter Food Safety, and the
12	opportunity to provide input on how data, innovation
13	and technology are utilized to produce better food
14	safety outcomes. Each of the core elements require a
15	strong, transparent and inclusive FDA that is
16	delivering on its mission as the lead food safety
17	regulatory agency in the United States.
18	Our members innovate on traceability,
19	safety, nutrition, sustainability and other
20	information to address consumer preferences. We
21	created the Facts up Front program in collaboration
22	with FDA, providing transparent information through

1	front of pack labeling so consumers can make informed
2	choices about the products they purchase. Although
3	this is not a technology, it is an innovation. And
4	with respect to technology and data specifically,
5	industry leaders from manufacturers and retailers came
6	together to create SmartLabel, a transparency tool
7	that has become the standard for sharing product
8	information beyond what is on the label.
9	SmartLabel currently has over 1,000 brands
10	and over 100,000 products, all participating
11	voluntarily. Consumers can gain access to ingredient
12	definitions, context run allergen statements,
13	nutrition resources, safe handling instructions and
14	more, all with just a simple QR code scan. More
15	recently, it was employed to facilitate recall
16	notifications to consumers at the tail end of 2023 and
17	into early 2024. Hundreds of thousands of consumers
18	benefited from SmartLabel.
19	The private sector will continue to innovate
20	to improve food safety and increase transparency, and
21	we would urge FDA to continue working with the
22	industry to encourage and incentivize innovation. FDA

1 should continue to incentivize the creation of 2 technological tools, including artificial intelligence 3 to address food safety issues, increase predictive tools and allow for recall communication technology 4 5 that is implementable for companies and is accessible 6 to consumers. 7 We all have a role to play in fostering, supporting and strengthening a food safety culture. 8 9 But at the center is a strong FDA playing a leading 10 role in enforcing its core mission of food safety. 11 State and local governments, private sector partners 12 and consumers are looking for leadership from the FDA 13 and for it to be a collaborative partner to develop 14 data and technological innovations to support the New 15 Era of Smarter Food Safety. Thank you very much. 16 MS. FINNEGAN: Thank you, Mara. Next up, we 17 18 MS. BARR: Thank you. 19 MS. FINNEGAN: -- Katy Jones. 20 MS. JONES: Yes, thank you so much. Thank 21 you for the opportunity to speak today. My name is 22 Katy Jones, and I am the CEO of Trustwell, a nutrition

1	analysis, food labeling, traceability and recall
2	software company. I speak before you today not just
3	as the CEO of a food technology company, but as a
4	mother whose child's life can be threatened by
5	something as simple as a snack.

6 My son's severe tree nut allergy not only 7 has reshaped our family's life, but has also 8 galvanized my dedication to ensuring the safety of 9 every item of food that reaches the consumer's hands. 10 At Trustwell, we recognize that technology and data standards are not just tools for business efficiency 11 12 or regulatory compliance. They are vital lifelines 13 that can protect consumers and enhance the integrity of our food supply chain. 14

15 As everyone here knows, each year millions are affected by foodborne illnesses and one of the key 16 17 areas preventing these incidents is traceability. 18 With precise tracking, we can swiftly identify and address the source of contamination or mislabeled 19 20 product, potentially saving lives. Technology plays a 21 key part in this process, ensuring that in the event 22 of a recall, we can quickly isolate the affected

1 products.

16

And as has been mentioned, it's also 2 critical that we think about traceability technology 3 beyond food safety as well. There are tremendous 4 5 opportunities to leverage this data in other areas of the business for sustainability, real-time inventory 6 7 management, supplier scorecarding, just to name a few. Data standards like GS1, the GTIN and the 8 9 (indiscernible) that have been mentioned are the 10 foundation that makes this possible. 11 Standardizing data across the industry 12 ensures that every stakeholder across the supply chain 13 speaks the same language, making the process of 14 tracing products not just possible, but seamless. 15 This uniformity also allows for the interoperability

17 today. We all want to work together to have better 18 traceability in the supply chain from those small 19 farmers to large retailers.

of systems. We've had many software providers here

The work we do at Trustwell, in partnership with our customers, is driven by the belief that technology can and should create a safer and more

1	transparent food industry. We are dedicated to
2	developing and implementing systems that ensure
3	traceability, compliance and quality across the supply
4	chain. And with that goal of turning this belief into
5	reality, our offerings across tech solutions,
6	training, training and services represent our mission
7	to change the food industry for the better.
8	Whether tracing and tracking with our
9	product, FoodLogiQ, or creating accurate and consumer-
10	focused nutrition labels with Genesis Foods, our
11	software gives companies the tools they need to adhere
12	to FDA regulations. We work with some of the best
13	food companies in the world who stand with us as
14	leaders and innovators, ready to go beyond compliance
15	to remain always ahead, tech-connected and focused on
16	safe food for all. In fact, we have tracked nearly
17	200 million critical tracking events, or CTEs, already
18	around the world to date.
19	In closing, I urge the FDA to continue its
20	commitment to advancing tech-enabled traceability
21	through the execution of FSMA 204 and emphasizing

22 recall technology as well in the food industry.

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1	Together, we have the power to protect our nation's
2	health and well-being, ensuring that no one has to
3	face the unthinkable because of what's unknowingly in
4	their food. Thank you again for the time, your
5	attention and your commitment to the safety of our
6	food.
7	MS. FINNEGAN: Thank you, Katy. Next in the
8	lineup, we have Neil Wieselman
9	MR. WIESELMAN: Hi. My name's Neil
10	Wieselman. I am the director of infection prevention
11	for Intercon Chemical in St. Louis. And everybody's
12	been having really great points and traceability and
13	education and new technology are all really important.
14	But the one thing that most people aren't talking
15	about is hand hygiene. And the fact that alcohol-
16	based hand sanitizers do not have norovirus efficacy.
17	Most people I talked to are unaware of the
18	fact that they don't have norovirus efficacy with
19	their hand hygiene programs. And if everybody is
20	aware, norovirus is the leading cause of foodborne
21	outbreaks. So we have a hand hygiene program that
22	doesn't kill the leading cause of foodborne outbreaks.

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1	And it's been this way for years.
2	My company manufactures alcohol-based hand
3	sanitizers, and we're going around trying to alert as
4	many people as possible about the lack of efficacy so
5	that they're aware of that at least. And until COVID,
6	it was a major concern. Of course, COVID put
7	everything into the backseat. So this actually made
8	things worse because during COVID, first of all,
9	norovirus is a non-enveloped virus where COVID, which
10	was caused by SARS-CoV-2 is an envelope virus.
11	And actually alcohol hand sanitizers do have
12	envelope viral efficacy like SARS. But they do not
13	kill non-envelope viral organisms like norovirus. So
14	during COVID, the CDC correctly was pushing alcohol
15	hand sanitizer use and their recommendation increased
16	the usage of alcohol hand sanitizers exponentially.
17	And it's caused the dependance on alcohol hand
18	sanitizers. And now that we're somewhat out of COVID
19	and we're somewhat normal, everybody's dependent on
20	alcohol hand sanitizers because for one, they're
21	convenient and, two, the CDC pushed them like
22	constantly, which was great for our business and they

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1	actually worked for that.
2	But now the only thing that the CDC is
3	saying right now, if you go and look at their
4	norovirus prevention page, it says hand sanitizer does
5	not work well against norovirus. It's not a
6	substitute for washing your hands with warm with
7	soap and water, which is great except for the fact
8	that it doesn't really come out and say hand sanitizer
9	does not kill norovirus, period.
10	I mean, except for the fact that I hate to
11	use someone's name, but he was quoted in an article,
12	Dr. Aron Hall, the former chief of viral
13	gastroenterology for the CDC, actually was quoted in
14	an article in Forbes last year saying alcohol gels
15	won't kill the virus. Even if you were to use so much
16	hand sanitizer on your hands that you felt like you
17	were wearing hand sanitizer mittens, the live virus
18	could still remain on your hands.
19	And that's the thing is, the CDC is not
20	doing their job in making sure that everybody is aware
21	of the problem, and the only thing they're telling
22	people to do is wash your hands, which is great. And

1 hand washing is a very important aspect of hand 2 hygiene. But hand washing doesn't kill norovirus. 3 You can remove it if you use the proper 4 technique, but that's according to the USDA that's 5 done less than 50 percent of the time. So if you'v 6 got a sick employee who has norovirus, or if you ha 7 contaminated food that comes in with the porovirus

done less than 50 percent of the time. So if you've got a sick employee who has norovirus, or if you have contaminated food that comes in with the norovirus or if you have a customer coming into your food service place with norovirus and they start touching things, anyone that were to touch anything they touched is going to start spreading around norovirus and their hand hygiene isn't going to kill it.

13 So we have a major problem here with hand 14 hygiene not killing norovirus is being the leading 15 cause of foodborne outbreaks. And on top of that, alcohol-based hand sanitizers also can dissolve the 16 17 lipid layer of your skin, which causes dermal damage, 18 which causes the lipid barrier of your skin to no 19 longer function properly, which allows --20 MR. KAWCZYNSKI: Time --

21 MR. WIESELMAN: -- organisms into -- okay,
 22 I'll finish up -- which allows organisms to --

1	actually like norovirus actually to contaminate you
2	easier. So something needs to be done. The UK and
3	Europe use hypochlorous acid for hand hygiene and for
4	surface hygiene. And so we need to follow what the UK
5	and Europe do and switch everything to hypochlorous
6	acid. But we need to make sure you use one that is
7	safe for your hands, because some of them are not.
8	There's a lot more to this, but apparently my time's
9	up. So I'd be more than happy to continue on if
10	anybody would like me to point out a few more things.
11	So thank you.
12	MS. FINNEGAN: Thank you, Neil. Next up, we
13	have Julie McGill.
14	MS. MCGILL: Thank you, and good afternoon.
15	My name is Julie McGill, and I'm the vice president of
16	supply chain strategy and insights at Trustwell. At
17	Trustwell, we provide food companies with a connected
18	platform managing food formulation, nutrition
19	labeling, supplier compliance, traceability and recall
20	management. And I thank you for the opportunity to
21	provide comments today.
22	
	So I'd like to address a few questions for

1 consideration that were included in today's event 2 material. First, what are the greatest challenges to 3 creating a more digital, traceable global food supply? 4 And how can the FDA and stakeholders work together to 5 approach this in a manner that creates shared value 6 for all participants?

7 So first I'd like to point out, change is hard, right? It just is. However, many companies 8 9 don't realize that they do collect most of the 10 information they need today for food safety and 11 traceability recordkeeping. It may be in multiple 12 systems that aren't connected. It might be on paper, 13 but that data is available and we look to the FDA to 14 continue organizing virtual meetings like this one, 15 but also to provide other educational opportunities to 16 engage all stakeholders.

Next, we need solutions for all. Industry partners are often surprised that solution providers do offer food safety solutions for companies of all sizes. To enable the industry, we must meet companies where they are but continue to educate on new tools and technologies. Today, many companies are using

1 tools such as RFID, IoT, API or might have a robust 2 (indiscernible) but others are using barcodes to scan, 3 maybe mobile apps or spreadsheet upload to share 4 information.

5 What we want to recognize is that when we level the playing field, all companies can benefit, 6 7 and value can be found in many areas, such as inventory management and freshness. And we've seen 8 9 this in action with companies' timesheets and lot data 10 information to their slotting systems. This allows 11 them to move from FEFO, first expired, first out for 12 their produce items, which provided better shelf life 13 to the distributor and fresher products for their 14 customers and consumers. But it also help reduce 15 waste for both parties.

And with the advent of new technologies such as ambient IoT, we can seamlessly capture information beyond traceability data such as temperature and humidity, which can adversely affect produce items and other products as they move across supply chain. Helping companies to achieve accurate and precise lot level traceability is a reality today, and with new

1 technologies, we will continue to see improvements in 2 read rate, data accuracy and enable connectivity with 3 more systems than ever before.

Looking ahead, we need to pilot these 4 5 solutions and much of the pilot work today has been focused on data capture, and we need the FDA's help to 6 7 conduct more pilots that are focused on data exchange. 8 GS1 US, IoT, GDSG, they also have helped traceability 9 pilots to demonstrate how using standards can help 10 achieve interoperability across diverse tracing 11 systems that leverages blockchain and cloud 12 technologies. More pilots such as these are needed 13 with various stakeholders solutions and product 14 scenarios. And with the FDA's direction and 15 partnership, we can get these pilots underway.

So I'll wrap up with technology, which is, as we know, outpacing industry, and the time is now to engage and demonstrate how we can enable digital food safety and traceability, adding value for all industry stakeholders. Thank you.

21 MS. FINNEGAN: Thank you, Julie. Stepping 22 up to the spotlight next is Erik Lieberman.

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1		MR.	LIEBERMAN:	Hello.	Can yo	u hear	me?
2		MS.	FINNEGAN:	Yes, we	can he	ar you.	. Go
3	ahead.						
4		MR.	LIEBERMAN:	Okay,	great.	Okay,	great

5 I'm Erik Lieberman, president of U.S. Food Imports. 6 I'd like to thank FDA today for the opportunity to 7 speak and hosting this meeting and just generally 8 thanking the agency for really fostering public 9 participation in all of these FSMA rulemaking. So 10 I've been involved with them since the beginning, you 11 know, over ten years ago.

12 So we are a company that provides food 13 regulatory compliance software and services. We have 14 a platform that's called FSMA Cloud, which is utilized 15 by supermarket chains, wholesalers, manufacturers and 16 trading companies for compliance with FSMA We built a module for compliance with 17 regulations. 18 Section 204 with the aim of automating compliance to the greatest extent possible and minimizing burdens on 19 20 food industry firms.

I'm going to address today some of the questions that the agency had posed to the public as

1	topics for consideration, starting with the tech-
2	enabled traceability, Number 2, how can FDA promote
3	collaboration and information sharing between tech
4	providers and food supply chain entities to support
5	low or no cost traceability?
6	I'd just caution the agency there's no such
7	thing as a no cost traceability solution. And many of
8	these costs get passed down the supply chain,
9	ultimately to consumers. Given the high cost of food,
10	minimizing compliance costs should be a top
11	consideration for FDA as it continues to work to
12	implement Section 204.
13	What are the greatest challenges in creating
14	a more digital and traceable food supply chain, and
15	where can FDA help? I would say FDA support of a
16	global standard and recognition of it is critical and
17	I envision this much the way that FDA did with certain
18	GFSI schemes, in the context of the produce safety
19	rule and the preventive controls for human food rule.
20	FDA recognized certain GFSI schemes as being aligned
21	with those, and that those regulations, and that
22	gives industry confidence that they can rely on those

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schemes for purposes of supporting compliance with FDA
 requirements.

3 And we want to invest as a -- you know, as a 4 provider of compliance solutions, we want to invest 5 and develop standards that support FDA's mission of strengthening food safety throughout the supply chain. 6 7 We want to create a system that helps FDA do its job. So I think, you know, making sure that the 8 9 expectations of the agency on what records need to be 10 kept and how they should be provided to the agency or 11 perhaps, you know, the agency's preferences and 12 getting that data, that should be absolutely made 13 clear so we can start working on that now as opposed 14 to reacting after, you know, this regulation starts 15 getting enforced.

Beyond food safety, where can tech-enabled traceability create value? Absolutely in prevention of food fraud. We've just seen the U.S. Department of Agriculture put into place the strengthening organic enforcement regulation, went into effect last month and it requires traceability. So industry efforts on traceability would support compliance with this rule

1	and efforts to combat food fraud. There was recently
2	a report that FDA released, I believe, about, sampling
3	imported honey and now 10 percent of imported honey
4	was found to be adulterated for economic purposes.
5	So, you know, traceability can go a long way in
6	combating those food fraud issues.
7	Now, obstacles on sharing data with the
8	agency, of course, ensuring confidentiality,
9	protecting data from FOIA requests. And what kind of
10	incentives can FDA give for sharing data? Fewer
11	inspections is a consideration for businesses that
12	share data voluntarily. Also, reduced penalties is
13	something the agency should consider if a firm is
14	found in violation. And also, a safe harbor for
15	sharing data in certain circumstances.
16	How should FDA share data with industry and
17	technology providers? I can tell you from a software
18	developers perspective, API is very helpful. And that
19	would be our preference. In terms of e-commerce,
20	obviously that's a that's a growing area. It's an
21	area that regulations are working to catch up with and

22

obviously FDA is contemplating that by posing these

1	questions to the public. One of the challenges with
2	e-commerce is that we have lots of from the import
3	side is we have a lot of small value shipments that
4	fall under the de minimis standards for importation.
5	It's section they're coming in under a Type 86
6	entry, Section 321. FDA doesn't get all the data that
7	they would for a shipment with larger value.
8	But, you know, these consolidated shipments
9	are very important for entrepreneurs that are using
10	the third-party fulfillment services. So, you know,
11	it would be requiring food to be sent in larger
12	quantities would certainly pose challenges for a
13	number of importers. But, you know, FDA could look at
14	requiring importers to keep more data that FDA could
15	audit at a later time. That would be, you know,
16	something that they could consider.
17	Ambiguity in e-commerce. What are the
18	responsibilities of third-party fulfillment providers?
19	That's something that the courts
20	MR. KAWCZYNSKI: Time.
21	MR. LIEBERMAN: Okay. Can I should I
22	finish this one thing?

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1	MR. KAWCZYNSKI: Yeah. Finish your thought.
2	MR. LIEBERMAN: So yeah, the courts, that's
3	one thing the courts are grappling with now. They
4	don't own, import or sell the product, but they are
5	providing a way for entrepreneurs to get the product
6	into, you know, the U.S. marketplace. And they're
7	very important for small businesses. So I would just
8	urge the agency to allow these platforms to continue
9	to innovate because it's very important for small
10	businesses in selling food products in the United
11	States. Thank you.
12	MS. FINNEGAN: Thank you, Eric. And
13	finally, our last public commentator of the day is
14	Steven Mandernach.
15	MR. MANDERNACH: Thank you to Deputy
16	Commissioner Jones and the FDA for holding this public
17	meeting. The Association of Food and Drug Official,
18	or AFDO, is a regulatory organization that connects
19	food and medical product safety stakeholders and
20	impacts the regulatory environment by shaping sound
21	science-based rules, laws and regulations, and sharing
22	best practices that protect public health. Founded in

1896, AFDO is an international professional
 organization consisting of state, federal and local
 regulatory officials as members. AFDO and its members
 were among the early advocates working with Dr. Harvey
 Wiley for the adoption of the nation's first food
 safety laws, including the Pure Food and Drug Act in
 1906.

8 Today we'll focus on four topics: data, 9 recall food safety, traceability and recalls, and 10 public-private partnerships. First, we at AFDO have 11 been very engaged in data work, which currently we 12 support over 25 state agencies and their regulatory 13 data systems. We have also been bringing together 14 larger data sets, including a retail inspections 15 database of about 900,000 inspections from nine 16 states.

We then use this data to look at improving inspection outcomes and improving inspections overall. We have partnered with another group of states to bring together a similar (indiscernible) in the manufactured food space. Lastly, we are currently building the system for agriculture, food, health, e-

1 inspections and registration, or SAFHER, a regulatory 2 data system for states and local governments with 3 financial support from FDA and states. We are 4 beginning to understand the data available and use it 5 to improve regulatory programs. We have far more we 6 can accomplish using this data.

7 In retail food safety, the second area, much of the work that is in retail food safety has been 8 9 funded and supported partially through the FDA Retail 10 Food Safety Regulatory Association Collaborative. 11 This first of its kind program partners FDA, CDC, 12 AFDO, ASTHO, CFP, NACCHO and NEHA to set programmatic 13 goals and develop action plan today, leveraging the 14 each group's strength and focusing all on the same 15 objectives: reducing foodborne illness, implementing 16 risk based inspections, assisting and promoting food 17 code adoption and implementing program standards. 18 This small amount of FDA funding is essential in 19 accelerating this work in retail food safety, the area 20 with the greatest opportunity to reduce foodborne 21 illness and bend the illness curve.

22

We also believe a comprehensive review of

1	the retail food safety program is needed. We believe
2	this review is fundamental for the retail food safety
3	(indiscernible) to be timely and to keep up with the
4	innovation of industry. This review must engage all
5	stakeholders and help ensure that we have an FDA
6	retail food safety program that meets the needs and
7	the current needs of industry, state and local
8	regulators and the American consumers.
9	With traceability and recalls, we strongly
10	support a traceability rule, but also recognize some
11	challenges of the rule and its implementation.
12	Currently, there is a lack of clear enforcement
13	strategy and implementation strategy with restaurants
14	and grocery stores, nearly all of which fall under
15	federal food safety regulation for the first time with
16	traceability. We urge the FDA to work more
17	proactively with these areas that will be new to
18	federal regulation and the state and local agencies
19	that typically regulate them.
20	We also urge FDA to be open and flexible
21	with the rule to these unique industry segment

22

challenges. No one is favorably impacted if the rule

1	goes into effect in portions cannot be successfully
2	implemented. Further, we hope FDA can move toward
3	using and coalescing around current industry best
4	practices such as the GS1 standard, which is widely
5	adopted and used with all products and barcodes.

6 We see enormous opportunity for FDA to modernize and embrace technology and improve 7 8 communication with recalls. In September 2023, FDA 9 had a public meeting on recalls, and it was clear 10 there was a desire to modernize food recalls through 11 both technology and improved communication to 12 consumers based on good risk communication practices. 13 We hope the FDA human food program continues to 14 prioritize this effort. We continue to observe 15 ineffective recalls resulting in unnecessary illnesses 16 and exposures, including in the most -- in the recent applesauce recall. 17

Lastly, we continue to work on publicprivate partnerships in bringing together all areas of the human food program. We see a game-changing opportunity to work with industry to jointly use shared data to improve regulatory outcomes and more

1 efficiently use regulatory resources. 2 Some very practical methods could be sharing regulatory inspections, third-party audit information, 3 and industry and regulatory samples for use by both 4 5 industry and regulatory agencies. We also see ways to improve access to regulatory information to consumers. 6 7 The technology exists. The challenge today relates to 8 trust and willingness to embrace change. 9 Together, we do believe FDA, state and local 10 governments and industry can use data to improve 11 regulatory and food safety outcomes. We would urge 12 FDA and state and local regulatory agencies to promote 13 and allow this safe space and to move forward to a New 14 Era of Food Safety that is focusing on preventing 15 foodborne illness and improving outcomes, and less on 16 building a case for compliance and enforcement. Thank 17 you for the opportunity to comment today on behalf of 18 the boots on the ground state and local regulatory 19 programs. 20 PANEL DISCUSSION 21 Thank you, Steve. And before MS. FINNEGAN: 22 we bring the panel back to respond to those, I just

1 wanted to thank all of our speakers today for offering 2 your thoughts and ideas. So now we will have our 3 panel respond to those comments. Adam, we'll start 4 off with you first.

5 MR. FRIEDLANDER: Hi. Well, I'm Adam Friedlander. I'm the co-lead for Core Element 1, 6 7 tech-enabled traceability. And I also just want to echo Lauren's comments and thank everyone for 8 9 providing their expertise, their feedback. And I 10 really enjoyed listening to everyone's comments today. 11 And I certainly encourage people to respond in writing 12 to the docket questions as well.

13 There were many common themes that I heard 14 around tech-enabled traceability. And I just want to 15 just go a little bit into some of the common themes 16 that I wrote down today. There is an incredible 17 amount of effort being put into complying with the 18 traceability rule. And although I cannot comment on 19 FDA's compliance efforts about the rule, we heard 20 themes about going above and beyond the rule's 21 requirements to improve traceability, and how there 22 were other themes that can improve food traceability

1	that extends beyond food safety, such as improving
2	sustainability efforts, reducing food waste,
3	preventing food fraud, and just to name a few. And I
4	really appreciated those insights.
5	There were also conversations about how FDA
6	can continue to support the harmonization of data
7	that's used for traceability and the importance of
8	interoperability, and I certainly agree that FDA can
9	continue to support those industry-led efforts and to
10	help everyone speak that same food traceability
11	language.
± ±	
12	We also heard about some of the challenges
12	We also heard about some of the challenges
12 13	We also heard about some of the challenges that are currently present in today's food
12 13 14	We also heard about some of the challenges that are currently present in today's food traceability system. And one comment mentioned that
12 13 14 15	We also heard about some of the challenges that are currently present in today's food traceability system. And one comment mentioned that there is data that is currently available to advance
12 13 14 15 16	We also heard about some of the challenges that are currently present in today's food traceability system. And one comment mentioned that there is data that is currently available to advance food traceability today, but it may be in separate IT
12 13 14 15 16 17	We also heard about some of the challenges that are currently present in today's food traceability system. And one comment mentioned that there is data that is currently available to advance food traceability today, but it may be in separate IT systems. And I found that fascinating.
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12 13 14 15 16 17 18 19 20	We also heard about some of the challenges that are currently present in today's food traceability system. And one comment mentioned that there is data that is currently available to advance food traceability today, but it may be in separate IT systems. And I found that fascinating. So although I can't comment on the rule, I just want to point people towards the FSMA technical assistance network on FDA's website if they have any

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	, s
1	people to ask those questions, so you can get an
2	official response. And I encourage people to be as
3	specific as you can in those questions so that way you
4	can get the best response that that you can get.
5	So with that, I just again wanted to thank
6	everyone for providing the comments today. And I'll
7	turn it to my colleagues over at Core Element 2.
8	Thank you.
9	MS. FINNEGAN: Thank you, Adam. Mark, would
10	you like to begin?
11	DR. MOORMAN: I am more than happy to. Yes.
12	I heard some interesting things that were brought up
13	that I'll comment on first. One of the speakers
14	mentioned WGS expansion and the I think you get a
15	flavor from the FDA, we're very interested in the
16	expansion of that technology. You know, we all have a
17	lot to learn about these strains and attribution and
18	very importantly, ecology of these strains. So a lot
19	of shared ground between what the first person on the
20	group spoke to and the FDA.
21	One of the other things that was said I

22 captured was, how the FDA can encourage, incentivize,

1	incentivize data sharing. And, you know, certainly we
2	can do sessions like we're doing today to encourage
3	it. But the word incentivize is a very interesting
4	word. And I think it's an important one. And I'll
5	talk this out, as we've spent a lot of time thinking
6	about this topic.

7 You know, if you if you read the Reagan-8 Udall report on the FDA, they acknowledged there's a 9 lot of work being done in the agency and we've all 10 determined that one of the things we have to do a better job of is identifying and discerning \$5 11 12 problems from five cent problems. My words, not the 13 FDA's. And it's true, if everything's a priority, 14 nothing's a priority. And one of the incentives to 15 think about in this space, I'll reflect on this, is 16 that if we can work with those that have data to 17 better understand hazards and to characterize those 18 hazards, the more that we can be informed as to what we think are the \$5 problems and what are not. 19

A good example of this is what is being done with our toxic elements group and close to zero. We've clearly signaled a desire to have groups provide

us with data so that we can better understand what
 levels can be achieved. So that's the second thing
 that that jumped out at me.

4 And then the third I think is a really 5 important question that we should all struggle with, 6 which is what are the greatest challenges to 7 digitization? And I'll reflect on that, that, you 8 know, when our group started thinking a lot about 9 data, data trusts and building those, of course we 10 spent a lot of time thinking about the first part of 11 But I've come around to realizing that a that, data. 12 very important point that we don't talk enough about 13 is trust.

14 There's a there's a great quote I heard a 15 long time ago that progress in life happens at the 16 speed of trust. And there is a reticence to share 17 And I think we've got to find a way to build data. trust and to talk about how we can do that better, 18 19 both across the stakeholders and even with the FDA. 20 So I would submit trust is an important one that we 21 have to spend time thinking about and what can be done 22 to build that trust.

1	And then number two, I think we need good
2	stories to tell, you know, where have we had some wins
3	in data sharing? I just think that that's a really
4	important one, if we can. You know, one of the things
5	I like a lot about the traceability challenges is it
6	showed some good examples of where traceability could
7	be done. And it doesn't have to cost \$30 million in
8	capital. There are some simple tools that are out
9	there. And I think of those as good stories to tell.
10	And I think in the data sharing, data trust,
11	predictive analytics space, we all need to do a better
12	job of telling stories and what works. So my
13	thoughts. Over to Ruth or Vinetta. Thank you.
14	MS. FINNEGAN: Thanks, Mark. Ruth, you're
15	up next.
16	
17	DR. TIMME: Yeah. Thanks for all the
18	comments. I really enjoyed listening to all the
19	different perspectives as well (indiscernible) food
20	safety. I wanted to first mention the commenter who
21	talked about pathogen and genomic surveillance, Celina
22	To, and just respond specifically to her inquiry on
23	the validation of new technologies such as Oxford

1 Nanopore.

2 And I just -- I want to asssure both Celina 3 and the general public that GenomeTrakr is committed to really thorough testing of all new technologies and 4 5 chemistries, including OIT and we really prioritize the accuracy and reliability in our methods. 6 We've 7 been fairly stable over the past decade. But as new technologies come up, we evaluate them intensively. 8 9 We work alongside our other U.S. agency partners to 10 ensure that new data types that are generated for 11 public health response are validated and can be 12 seamlessly integrated. They're all interoperable, 13 right, with our huge, large historical databases of 14 genomic data for testing. So, thank you for bringing 15 up that important topic (indiscernible). 16 There were a couple other questions that 17 were that were submitted asking -- surrounding 18 GenomeTrakr, and I thought I'd chat about the one

19 about how important it is to make data public, since 20 Mark talked about it so eloquently. One of the 21 biggest strengths of our GenomeTrakr program, and its 22 database, is that we make all the whole genome

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sequence data public immediately after the data are
collected. And this really benefits all the
stakeholders collaborating to create a safer food
system in the U.S., including industry, and this kind
of transparency allows industry to independently
monitor this public database, these pathogen genomes
coming in every day for signals. And they can respond
to those signals without any direct communication with
the FDA.
And so this strength of really standard
data, really current data being publicly being made
publicly available to stakeholders is really what I
think New Era is all about, and I think New Era can
even it's so important for GenomeTrakr in that our
missions really align perfectly (indiscernible) New
Era really has the capacity to potentially integrate
GenomeTrakr's genomic information with other digital
food system databases.
You've heard a lot of these today, including
the supply chain, tech-enable traceability. So as we
go into the future, you know, GenomeTrakr is well

22 integrated with these other efforts at the FDA for

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1	digital data and improving (indiscernible) technology.
2	So with that, I will close my remarks and thank
3	everyone again for all the comments. I really enjoyed
4	it. Thank you.
5	MS. FINNEGAN: Thank you so much for those
6	thoughts, Ruth. Next, we'll move on to Vinetta.
7	MS. HOWARD-KING: Hi. Yeah. So, you know,
8	first I want to thank all of the FDA and industry
9	stakeholders who took the opportunity to join us today
10	for this extremely important public meeting. A
11	special thanks to those who provided comments today on
12	how FDA can work with our stakeholders to leverage
13	data and technology.
14	I heard a few comments that sort of
15	resonated with me. The need to maybe look at some
16	handheld tools and other data innovation and
17	technology platforms to provide real-time recall
18	notifications to consumers. I would also be
19	interested in handheld tools for inspectional
20	purposes. So thank you for that. We definitely will
21	be looking into that more.
22	Like, Mark said, the need to incentivize has

1	really, you know, struck me, to incentivize data
2	sharing. Like, fewer inspections, I find this could
3	be a better way to manage everyone's very limited
4	resources, from the regulator side and industry side.
5	So it's really a topic that we need to look at
6	carefully.
7	And in order to really embrace data sharing,
8	I agree with Mark. I agree with Steve Mandernach.
9	There is a need for a trusted and safe place for all
10	involved. So that that's an area that we that we need
11	to work on, all of us, we need to work on. We can't
12	do this alone. No one can do this in a bottle.
13	I also wanted to take this opportunity to
14	address a few questions on data sharing that was
15	submitted prior to the public meeting. There was a
16	question regarding data connectivity with FDA's
17	reportable food registry. I want to mention that FDA
18	has been working on various projects to allow and
19	enhance connectivity with the RFR; for example,
20	activities to make RFR filings more user friendly. We
21	believe that enhanced data connectivity with FDA
22	databases would be in line with how we're looking at

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1	leveraging	existing	data	to	advance	food	safety
2	outcomes.	So that's	s one	are	ea.		

3 There was also a question on how FDA is going to work with -- I'm sorry, how FDA is going to 4 5 work with state level regulators to improve access to and acceptance of new technology. So, I want to first 6 acknowledge the very important partnership that FDA 7 8 has with our state and public health regulators, our 9 state regulators and our public health partners. This 10 this can't be understated. We can't do this without 11 them.

12 And so our ability to work with our partners 13 is extremely important. So, one example of this 14 partnership is the work FDA is doing with the 15 Association of Food and Drug Officials, or AFDO, under 16 a cooperative agreement with AFDO is working -there's work being done to update, as Steve mentioned, 17 18 the regulatory program management system for states 19 called SAFHER (System for Agriculture, Food, Health, E-Inspections, and Registration). 20 This effort actually would allow for a 21 system-to-system integrated data sharing with our FDA applications. So, I mean, these are just a few 22

1	examples of how FDA is actually working with our
2	stakeholders to leverage data and technology.
3	So again, thank you. I heard a lot of great
4	ideas. And we are actually taking this all in, and we
5	are also going to utilize this information with
6	information and comment that we got from the recall
7	public recall modernization public meeting. And so
8	you'll be hearing from us soon. Thank you.
9	MS. FINNEGAN: Thank you, Vinetta. And now
10	to start off for Core Element 3, Glenda Lewis.
11	MS. LEWIS: Hi everyone. I just really
12	enjoyed hearing so much of the comments that have come
13	in and been made. I'm like Vinetta. We're taking it
14	in. I heard about just, you know, that we want other
15	engagement opportunities and the virtual meetings and
16	great. And, and we actually had a question that came
17	in with registration around how are we going to
18	interact with industry stakeholders and continue to
19	modernize and prepare for food delivery. And I'm here
20	speaking on behalf of three, Core Element 3, industry
21	(indiscernible) space related to that e-commerce. And
22	in that area, we do plan further engagement together.

1	We've been working with regulatory partners,
2	industry partners, consumers and we just want to
3	continue that outreach. We really want to continue
4	the (indiscernible) protection on their guidance
5	document. And we just know the regulatory landscape
6	is of interest to that group, and it can be daunting.
7	And so lots of stakeholders have questions. What is
8	it like in my lane? What's your lane look like? How
9	do we drive this this car together?
10	So, as we further explore challenges and
11	barriers faced by regulatory partners, we want to
12	bring folks together. We want to bring them to the
13	table. We want to have a dialog, hear concerns, gain
14	ideas and really work together to address barriers as
15	we proceed. As we continue to do this, we know
16	(indiscernible) and education, and that's really going
17	to be the focus. We have to work together, as many of
18	my colleagues have already said, so that we can avoid
19	foodborne illnesses happening.
20	So we do anticipate and envision stakeholder
21	meetings, webinars for these dialogs and engaging in
22	different sessions with that. We have already

1	addressed some issues with consumers by providing
2	educational materials. We have fact sheets. We have
3	a video out and infographics around that and our focus
4	is going to be on that regulatory framework and
5	(indiscernible) and what data speaks (indiscernible)
6	as we close out, about what data pieces may be, could
7	be involved in that was the question.
8	But I also heard many comments around we
9	need to meet companies where they are, and that's what
10	we want to do in the 3.1 New Era space and to have
11	that level playing field. So, as we look at the
12	regulatory scope of e-commerce, we'll keep that in
13	mind. And I like the idea of raising the challenge to
14	the company so that we can move forward into the
15	future.
16	And I really found interesting the comment
17	by Marcia, Dr. Lee Herzberg. I'd like to hear more of
18	your study that you're doing. So we may reach back to
19	you on to learn more about your study.
20	And lastly, I guess I wanted to compliment
21	AFDO and its work with state partners and the work
22	that that we have been doing and the interest there

1 that they're capturing in terms of the data and 2 looking at the reporting, you said over 25 state 3 agencies (indiscernible).

I think all of that can help us strengthen 4 5 what the technological system will look like going into the future in this New Era of Food Safety, the 6 7 idea of having someone else, having uniformity in the system is what we need (indiscernible) and I think 8 9 that's key. And that will be key across all of the 10 core elements. So, I really appreciate the comments 11 today and looking forward to hearing more. And I'll 12 turn it over to Laurie. She's going to talk a little 13 bit more about the broader scope of retail food and 14 retail food (indiscernible). Laurie?

15 MS. FARMER: Great. Thanks, Glenda. Ι 16 appreciate that. So, I'm Laurie Farmer. Glad to see 17 all of you today. Thank you for taking the time to be 18 I know this is a long webinar and just so happy here. 19 that you're here. Happy for the engagement and want 20 to thank you for the comments.

You know, I heard an overall desire forcollaboration and a desire for a transparent food

1	system. And I especially appreciate Katy Jones
2	putting a face on food safety issues to really bring
3	it. You know, I wrote in the chat, oh, I got a chill.
4	This kind of storytelling, a way to communicate the
5	need for an organization's food safety culture is
6	critical for all of us. I just really appreciated
7	that.

And I really want to also thank the speaker 8 9 recognizing the leading cause of foodborne illness in 10 the retail industry is norovirus, and how we need to take approaches to reduce foodborne illness in the 11 12 I am co-leading with the CDC the AFDO industry. 13 Healthy People Norovirus workgroup, and we are working 14 with regulators and industry to develop an employee 15 health toolkit to get employees not to come to work 16 sick.

I mean, this includes an employee health assessment tool that is being piloted that can be used by both regulators and industry. And we also look at the use of sanitation and disinfectants on surfaces to reduce the norovirus load, and we're doing that with the lead of NoroCORE, Lee-Ann Jaykus, who is on this

1 team. So all of us who are familiar with foodborne 2 illness risk factors, we also know the great benefits 3 of handwashing, and other things that I've heard that 4 relate to the retail food safety sector for the Core 5 Element 3, which is, you know, one is retail is a team 6 sport.

7 This is something that we're going to have to do together, we're going to do together and we 8 9 continue to do together with states, locals, tribes, 10 territories, industries and academia. Glenda talked 11 about the conference for food protection and that is 12 one place where we all come together. The recognition 13 for the heavy lift that state and local regulators 14 have in conducting retail food inspections and the 15 need to focus on risk factors and the relationships with food laws and standardization. 16

And the point about policy is driven by good data, so I really appreciated that from Dr. Marcia Lee Herzberg. So thank you for that. And there is already happening, and Vinetta pointed to this, the electronic gathering of regulatory inspection findings. This information can be used for

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1	improvement of inspections and public health outcomes.
2	So, one of the questions that we received you were
3	able to, in your registration submit questions and
4	you'll also be able to ask questions in the docket
5	and provide additional information. So, I encourage
6	you to do that.
7	But one of the questions that came in was,
8	how can we address the diversity of data systems and
9	low data literacy across local food inspection
10	agencies? And wanted to make sure that you heard the
11	talking point that I actually also heard Steve
12	Mandernach talk about from AFDO, and he talked about a
13	pilot that FDA is funding around regulatory data
14	sharing, and it is the SAFHER system, S-A-F-H-E-R (System for Agriculture, Food, Health, E-Inspections, and Registration), and
15	this is an example of how data can be shared across
16	systems. And it's starting with a relatively small
17	number of jurisdictions. But it also includes not
18	only manufactured foods, but retail food safety. The
19	goal is to have all regulatory jurisdictions on a
20	interoperable platform where inspectional data is
21	transparent to regulators and holistic
22	interoperability of data systems was something that a

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speaker touched on today from a broad perspective, and that's a need.

The vision here is all regulatory 3 4 jurisdictions have access to the data. There is 5 reciprocal data from states and FDA. We are going to be able to trend analysis. What could be done to 6 7 inform interventions such as training? You heard Mark talking about trend analysis and how that's so 8 9 important with our learning for the future. FDA wants 10 to encourage progress on data sharing and improving 11 data literacy and technology use, while still meeting 12 jurisdictions wherever they currently are so nobody 13 gets left behind.

14 Other things that I've heard also are I 15 heard the ask for the agency to keep an item that was 16 in the original New Era blueprint, which is prioritizing the comprehensive review of the national 17 18 retail food safety system in this country and how FDA supports it. I heard the importance of, and the need 19 20 for the agency to continue to prioritize and support 21 the FDA retail food regulatory association, that it's 22 really a force. It's a force of four regulatory

1	associations,	FDA and	CDC	working	together	towards
2	targeted obje	ctives ir	n the	retail	sector.	

And again in the retail and restaurant food sector, FDA does not have regulatory authority but provides support to states and local jurisdictions. I heard the concern for implementing the traceability rule as it relates to any enforcement strategy and the implementation with restaurants and grocery stores, and I heard that Adam recognizes that as well.

10 So, I want to thank you for the time today, 11 for you coming, and I really am looking forward to 12 more engagement. This is the beginning of a lot of 13 conversation that is already been talked about today. 14 So I will, at this point, pass it back to Lauren. 15 CLOSING REMARKS

MS. FINNEGAN: Thank you, Laurie, for those remarks. Now I'd like to open the floor to all of the panelists for closing remarks. Adam, we'll start with you.

20 MR. FRIEDLANDER: Thank you, Lauren. And I 21 just wanted to reiterate my huge thanks to everyone 22 today for joining this conversation. As Laurie

1 mentioned, this is just one of many conversations that 2 we're looking forward to having in the future. I want 3 to thank the commenters today. I want to thank you in 4 advance for submitting your questions or your written 5 comments into the docket.

And while this panel is up here, you know, 6 7 we're just a small subset of many people behind the scenes who are working on this New Era Initiative, and 8 9 it is incredibly important for us to always look 10 toward the future. How can we make progress in our 11 food safety system? How can we better protect 12 How do we leverage data and technology at consumers? the intersection of all of our core elements with 13 14 traceability, whole genome sequencing, recall 15 modernization, e-commerce modernization, and retail 16 modernization as well, as well as safety culture. We 17 all intersect with one another, and we all have a role 18 to play along with you, the public, the industry, 19 consumer groups, other regulatory agencies, academia, 20 solution providers. We're all part of the same team. 21 And I'm just excited to continue these efforts with 22 each of you. And I strongly encourage people to

1	submit their thoughts, ideas into the docket and
2	always feel free to reach out to because we want to
3	help. So thank you.
4	MS. FINNEGAN: All right. Now let's move on
5	to Mark.
6	DR. MOORMAN: Yeah. I will join my fellow
7	panelists in saying a big thanks for the questions,
8	the comments that we received today. There were some
9	that came in that I thought I would briefly touch on
10	in the limited time that I have.
11	One of them spoke to can artificial
12	intelligence help us in navigating the potential
13	problem based on past history and product risk
14	Assessment. I think it's a really important question,
15	the way that it was phrased in navigating, because,
16	well, indeed, we do have to navigate these challenges.
17	You know, the way that I think about problems in food
18	safety is sometimes it's based upon something the firm
19	or individual did. And sometimes these hazards in the
20	food supply are just there. Mother Nature put them
21	there or it's an artifact of human behavior from a
22	long, long time ago.

1	Artificial intelligence and machine learning
2	gives us an opportunity to step back and to look at
3	all of the data that might be out there that can help
4	us color the drivers of those hazards and, you know,
5	things like the production region, the size of the
6	firms, the history of the firms, seasonality, climatic
7	drivers, all of those factors can help us, to give an
8	example, an understanding, as I said in the opening
9	comments, what containers do we sample when they come
10	to the United States. Artificial intelligence and
11	applying that to machine learning gives us the ability
12	to tap into all of that information and better
13	understand what can be the best signals, the best,
14	drivers so that we know what to do.
15	There was another question that I thought
16	was really important and it is will FDA consider
17	research in data collection and sharing platform
18	technologies funded by public-private collaborations
19	to inform future policies. And the answer that is a
20	big fat yes, flat out. We are very interested in
21	understanding what information is out there. If I can
22	just reflect on this, you know, one of the things that

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1	I have learned in life is you can't solve a problem
2	you don't understand. And, you know, we're in a
3	discipline, particularly in the food microbiology
4	that's about 300 years old. There's so much that we
5	don't understand about these microorganisms. So, we
6	look at genomics now and we've gone from detection to
7	sequencing. We look at massive data sources. These
8	are two things that fundamentally change the way we go
9	about doing food safety.
10	We're interested in canvasing to get what

information is out there. Now one of the things that I think has to be called out is why would a firm or why would anybody share information with the Food and Drug Administration. And I want to just tell you that I think it's a really important one to speak to and it does involve trust.

The FDA wears many different hats. We do have -- you know, Congress has given us the regulatory hat that we have to wear, the compliance hat, if you will, that we have to wear. But as I talked about earlier, there are many of us that spend all of our time thinking about prevention, and when we talk about

1	data sharing, I have my prevention hat on. I have my
2	hat on to say how do we work together to build data
3	sets so that we can all make better decisions. I
4	don't have that compliance hat on. I understand many
5	people will question then how does how does that
6	happen, and I will tell you that we've got some people
7	that have given a lot of thought. I'll call out Dr.
8	Stacy Wig and Dr. Nate Anderson from our team that has
9	spent a lot of time thinking about how information can
10	be provided to us and be protected so that it doesn't
11	impact the firms.
12	We're getting really good at this. You're
12 13	We're getting really good at this. You're all going to hear about longitudinal studies that are
13	all going to hear about longitudinal studies that are
13 14	all going to hear about longitudinal studies that are coming out from the Yuma, Arizona region, later next
13 14 15	all going to hear about longitudinal studies that are coming out from the Yuma, Arizona region, later next month. Those studies were conducted because we got
13 14 15 16	all going to hear about longitudinal studies that are coming out from the Yuma, Arizona region, later next month. Those studies were conducted because we got really good at understanding how do we collect data
13 14 15 16 17	all going to hear about longitudinal studies that are coming out from the Yuma, Arizona region, later next month. Those studies were conducted because we got really good at understanding how do we collect data and not put firms at risk. And so I want to say that,
13 14 15 16 17 18	all going to hear about longitudinal studies that are coming out from the Yuma, Arizona region, later next month. Those studies were conducted because we got really good at understanding how do we collect data and not put firms at risk. And so I want to say that, yes, the FDA would very much like to have a seat at
13 14 15 16 17 18 19	all going to hear about longitudinal studies that are coming out from the Yuma, Arizona region, later next month. Those studies were conducted because we got really good at understanding how do we collect data and not put firms at risk. And so I want to say that, yes, the FDA would very much like to have a seat at the table. But when we look at this New Era effort,

1	And then the final point that I'll make is a
2	question came in, gosh, I would like to work with
3	other companies and share data, but how do we do that?
4	And I want to point out that I think the data sharing
5	is actually topic two. Topic one is the question.
6	You know, I often get asked can we share coliform
7	data. Can we share fecal coliform play count data
8	with the FDA? And I think sure. But that's the easy
9	part. The question is what's the question. What's
10	the problem that we're trying to solve? And if you
11	really focus on that, it brings out creativity and
12	thinking of if we aggregated data, how could we answer
13	some problems. From a food manufacturing standpoint,
14	I always wonder how our plant environmental results
15	compared to other companies. That's a really good
16	question. I always wondered with pathogen detection
17	that we would find is it seasonal. I was wondering
18	about toxic elements and is it regional. Companies
19	have the opportunity, stakeholders have the
20	opportunity to compile that data and to answer those
21	really important questions. So how could you go about
22	sharing that information? I'll tell you these four

1	areas. Number one, we have firms, groups that work
2	directly with us. Number two, we have others that
3	work directly with platforms like Creme Global that
4	we've contracted with. We have they don't provide
5	data to us. They provide it to Creme Global and they
6	work to make sure that it's presented in a way that
7	protects all parties. I think the trade associations
8	are very central to answering category problems, and
9	they can serve to compile data. Number four, we have
10	law firms that work with us directly to provide that
11	information.
12	And then, one of the questions asked, well,
13	how do I do this? Well, if you want to learn more,
14	there's a simple email. And I'm sure it's out there
15	on our websites. It's
16	foodsafetydatasharingplatform@fda.gov. And we are
17	more than happy. We watch that. And we're very happy
18	to talk more with anybody about what information can
19	be shared. So with that, I thank you.
20	MS. FINNEGAN: Thanks, Mark. Appreciate it.
21	Ruth, would you like to go next?
22	DR. TIMME: Yeah. Sure. I just have a

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1	couple closing comments. Again, thank you all for
2	your comments. It's been a good discussion. I
3	thought I'd just dovetail on something that Mark
4	mentioned. And, you know, that is the recognition
5	that, you know, there's Mother Nature out there.
6	Foodborne pathogens kind of grow and exist and are
7	quite happy in kind of the food facility and
8	environmental spaces all across the country and across
9	the world. And one of our goals in GenomeTrakr is to
10	try to sample that space to get an idea about what are
11	these pathogens doing out there and how are they
12	intersecting with our food supply, And so this just
13	goes to address one of the questions that came in, in
14	the registration, about why, why we're monitoring, you
15	know, why we're sequencing pathogens for food in
16	environmental spaces.

You know, you don't usually think about this for other pathogens like COVID or avian flu. Those are -- you know, those pathogens transmit from animal to animal or human to human. But foodborne pathogens are quite different. You know, those contamination events come in from an environmental source and then

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1	spread out from there.
2	And so, yeah, so with that, I think I'll
3	just hit on that common theme that has come up about
4	data sharing. The GenomeTrakr program, you know, in
5	conjunction with New Era, is a really good example of
6	us sharing data as soon as it's generated. And I
7	think this really helps the entire collaborative
8	stakeholders that are trying to make food supply safer
9	in the U.S. And so with that, I will thank you and
10	turn it to the next person.
11	MS. FINNEGAN: Thanks, Ruth. Vinetta, go
12	ahead.
13	MS. HOWARD-KING: Hi. So in closing, I
14	again just want to thank all of the stakeholders and,
15	of course, my FDA colleagues for joining us today.
16	Another reminder that the docket is open. So please
17	don't hesitate to send in your comments and your
18	ideas. I want to say that we're always looking for
19	sensible and meaningful ways to leverage with our
20	stakeholders. We're never closed to that. And we
21	should never be closed to that. That's just a
22	necessity in order for us all to continue to develop
	necessity in order for us all to continue to develop

1 and grow.

2	One area that I heard was the
3	interoperability of IT systems to leverage data. I
4	can tell you now that FDA, we're actually working on
5	trying to do that our very self internally. And
6	that's not easy because anything dealing with IT, you
7	need funding and you need resources. And so we know
8	that that's limited for everyone. So how do we do
9	this with the resources that we have? But that that
10	is something that we're working on internally as well.
11	We hear the need to harmonize data that's
12	shared so that we have a unified data sharing tool.
13	That goes without saying. We're working with our
14	state and local public health regulators on that that
15	effort. And we want to be making sure we want to
16	make sure that we're working with industry partners as
17	well. We know that no one, no one entity, be it
18	federal, state, local, territorial, tribal, industry
19	or academia, none of us can do this alone. You know,
20	none of us can ensure food safety by ourselves. We
21	just can't.
22	And so, you know, it's going to take a

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1	collaborative, integrated partnership and a
2	relationship, a trusted relationship. And that's
3	going to come with a culture change as well, not only
4	internally with FDA, but with some of our stakeholders
5	and some of our partners. There is a culture change
6	that needs to happen across the board in order for us
7	to all be on the same playing field.
8	So, we're at the table. We're going to stay
9	at the table. We know you're at the table. And so,
10	you know, let's start talking. Let's look at what
11	each one can bring to the table and let's help
12	consumers. And so, you know, I just want you to
13	please continue to share your ideas, please. And
14	thank you again for talking with us today.
15	MS. FINNEGAN: Thanks, Vinetta. Glenda,
16	you're up next.
17	MS. LEWIS: I just all I can say is, wow,
18	this has been really great. I am so honored to sit
19	here with my FDA colleagues, with colleagues on the
20	phone, with the attendees to the meeting today and
21	just have this conversation and hear the ideas that
22	folks are bringing to the table and just taking notes

1 on, you know, so much is going on and so many ideas 2 that you've given to us to reach back and to engage 3 with you even further.

4 I think about it I guess in two ways, coming 5 from retail, everything ends up at retail. So all the food, all the food safety information and controls and 6 7 things that are in place, that my colleagues have mentioned, I'm happy to hear that, and Laurie and I 8 9 are committed to, at the retail level, you know, 10 making sure with our state and local partners, our 11 industry partners, that when it gets to the consumer 12 that it's safe and whether that's by e-commerce or 13 other ways. Probably some of us on this call today 14 are going to order lunch or order dinner to be 15 delivered this evening. And so we know that --16 talking about that e-commerce section of it, that it's 17 so entrenched in our environment now and in the way we 18 And so leveraging that data and technology for live. 19 a strong infrastructure, we want to continue 20 conversations around that and to any data usage. So again, for the docket as well, there were 21

22 several questions, three questions that were in there,

1	24, 25 and 26 where we talk about utilizing
2	technologies in ways that can help strengthen the
3	program. So I encourage you to review that. And when
4	you look at those questions, I did just want to say a
5	little bit sort of frame up of why we asked some of
6	those questions. Right? The first question was, and
7	these are ways to use technology to monitor and gather
8	data.
9	And we asked, how can FDA, industry and our
10	state, local, tribal and regulatory partners use
11	technology to monitor and gather data on sales of food
12	through e-commerce. So, we're interested there on
13	whether and how data on e-commerce products and sales
14	can inform the regulatory landscape. Remember when we'
15	looking at what lanes do we survey? How can we drive
16	food safety and what types of technologies and data
17	sources can help us to inform future implementations
18	and perhaps any enforcement efforts?
19	And then, we had a second question. We asked
20	what data and research can be collected in partnership
21	with stakeholders to help assess the existing
22	regulatory framework in place domestically and

1	internationally for the (indiscernible). Some things
2	that we are looking for there, you know, what policies
3	or rules are in place currently? What impact does it
4	have has it had or could it have or maybe that it
5	did not have, alternatives that could be modeled at a
6	national level, you know? Is that an approach we
7	should take? Why or why not? So that's something to
8	think about and just look at Question 25.
9	And I think Question 26, it asks we asked
10	are there current ambiguities related to sales of food
11	through e-commerce that could pose a risk to the
12	consumer. So, we know it's happening everywhere. It's
13	on the Internet. But the advent of cottage food
14	(indiscernible) in states, there are social media, we
15	have Facebook Marketplace and other similar platforms

So it's very convenient for the general public, but does it pose a risk or can it pose a risk to consumers that we may not be aware of. So we're mindful of that food safety (indiscernible).

that may not necessarily have regulatory oversight.

16

21 And we're thinking about too what actions 22 could FDA and partners take. So this one's kind of a

1	tough one. It could be perceived as an infringement
2	on rights to do business or to earn money, that type
3	of thing. But we're approaching it more in a
4	different context of being able to sell or serve safe
5	food. And we want to ensure that there's a level
6	playing field. I heard that in the comments. Make
7	sure we all have a level playing field that's there
8	for anyone who steps into that platform
9	(indiscernible).
10	And we do define the e-commerce space as a
11	retail space. And just encourage folks to take a look
12	at those. Thank you again for joining us today, and
13	we look forward to continued conversations around data
14	and technology in e-commerce. So with that, I'll turn
15	it back to Lauren, over to Laurie.
16	MS. FINNEGAN: Thanks, Glenda, and I'll turn
17	it over to Laurie.
18	MS. FARMER: All right. Well, again, I want
19	to thank you. I want to thank my fellow panelists and
20	all those that put this event together. It is a lot
21	to put one of these things together. So thank you.
22	And we're here representing a much larger workforce of

1 collaborators. And as we consider the future of the 2 FDA human foods program, please know that we want to 3 take food safety to the next level, and we want to do that with stakeholders. Please think about the ideas 4 5 posed today. What areas would you like to see FDA prioritize and invest in? Please be specific in your 6 7 feedback to the docket. Your input is essential for us to have an effective human foods program. 8

9

At the point of food safety as a system, 10 we're talking about connections in the system. Within 11 retail food protection, we're making transformational 12 changes that will impact our strategic goal of 13 reducing foodborne illness in the industry. FDA has a 14 variety of ways we currently support data and 15 technology with regulatory jurisdictions. Retail 16 regulatory food programs, our program standards, this 17 is where we lift regulatory programs up to performing, 18 top performing organizations. And one example of how 19 we support that is our food shield risk factor study 20 database. As an enrolled jurisdiction, you can request access to the same data collection and 21 22 analysis program that the FDA uses for our national

1	study. The risk factor study database provides cloud
2	storage for your data as well as customizable data
3	collection forms. The database is built and quality
4	assuranced has built-in quality assurance checks,
5	and it's really a saving time mechanism for you. And
6	it'll decrease errors. And the system provides
7	several reporting options, including some that do the
8	heavy lift for your analysis. So FDA is sharing the
9	same tool we utilized for our national risk factor
10	study.
11	FDA has made a large investment in retail
12	regulatory jurisdictions working towards conformance
13	with our program standards. Between 2022 and 2024
14	this year, we've been able to fund \$22.8 million to an
15	average of 237 jurisdictions each year, for a total of
16	1 107 metail program standards projects to date. Come
	1,487 retail program standards projects to date. Some
17	of these funds were used to support data and
17 18	
	of these funds were used to support data and
18	of these funds were used to support data and technology initiatives.

22

21

journey with stakeholders. We've identified areas to

work in partnership that will have significant impact

1	in the retail sector. They are food code adoption,
2	leveling the playing field across the country, risk-
3	based inspections and intervention strategies, having
4	a uniform assessment of risk and providing
5	interventions and measuring effects (indiscernible)
6	retail regulatory program standards, increased work
7	towards conformance of a quality improvement framework
8	for a regulatory program, outbreak investigations
9	improving the use of existing resources and
10	identifying areas for improvement, food safety
11	management systems.
12	Our goal is to increase active managerial
13	control in the retail restaurant setting. We need
14	your help in validating these existing partnerships
15	and identifying new ones, identifying groups that we
16	need to work closely with. Tell us what you want us
17	to prioritize in this space.
18	Some questions in the docket targeted to

retail food protection are the following. What can FDA do to have the biggest impact to meet our retail food program strategic goal and take it to the next level? What can FDA do, working in partnership with

1 regulatory, industry and academic partners to impact 2 the reduction of foodborne illness in retail food 3 safety environment?

Are there specific collaborations between 5 FDA and industry that will help to ensure the safety 6 of retail food? What benefits will be gained by 7 conducting an audit of the traditional retail food 8 safety systems' effectiveness and how FDA supports 9 that system?

10 And food safety culture is also a very 11 important aspect of food safety, so please feel free 12 to post additional feedback beyond the questions posed 13 in the docket. Other areas to consider are what food 14 safety challenges you're facing that could be 15 addressed by data sharing. Are there public-private 16 partnerships that could help move the needle on the 17 reduction of foodborne illness in the industry? We 18 look forward to seeing your comments and future 19 stakeholder engagement. Thank you all and I will pass 20 it back to Lauren.

21 MS. FINNEGAN: Thank you, Laurie, and thank 22 you for all the panelists today for all your thoughts

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1 and expertise. Now, before we adjourn today's meeting, I'd 2 like to encourage you all to submit comments to the 3 docket by June 24, 2024. The link to the docket can 4 5 be found if you scroll down to the "More Info" section underneath the stream, and you can also enter the 6 7 number up on the screen on regulations.gov. 8 A recording of the public meeting will be 9 posted on the FDA's public meetings webpage shortly. 10 The meeting transcript will also be posted within a few weeks, as well as a summary of themes shared 11 12 through the listening session. 13 Thank you for your time today, especially to 14 everybody watching at home, all of our public 15 commentators and, again, our panelists and everybody 16 who made this possible. We hope you have a great rest 17 of your day. Thank you. 18 (Whereupon, the proceeding was 19 concluded.) 20 21 22

1

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