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MEMORANDUM

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Re: **FDA Releases Blueprint for the New Era of Smarter Food Safety**

The U.S. Food and Drug Administration (FDA) recently released its "Blueprint for the Future" (Blueprint) as part of the New Era of Smarter Food Safety initiative. Launched in April 2019, this effort seeks to build upon FDA's work implementing the FDA Food Safety Modernization Act (FSMA) by establishing a new approach to food safety that leverages technology and other tools to create a safer and more traceable food system. 1/ The Blueprint "envision[s] a framework that will enable food to be traced to its source in seconds and will utilize new data analytical techniques to strengthen prevention of foodborne illnesses, alerting consumers in real time before contaminated or misbranded foods are consumed." In many respects, the Blueprint is a strategic plan that will guide FDA's food safety priorities in the coming years. As such, there are no specific timelines or action steps set out in the document.

FDA was poised to release the Blueprint in March 2020, but was delayed when the agency pivoted to focus its efforts on its response to the COVID-19 pandemic. In his comments announcing the release of the Blueprint, Dr. Stephen M. Hahn, the Commissioner of Food and Drugs, explained how events and trends that arose following the outbreak of COVID-19, such as supply-chain imbalances and increased reliance on food delivery services, have underscored the importance of the initiative. 2/

The Blueprint outlines goals for FDA over the next decade to enhance traceability, improve predictive analytics, respond more rapidly to outbreaks, address new business models, reduce contamination of food, and foster the development of a food safety culture. It is organized around the four core elements, explained below, which the agency initially identified in the "Food for

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1/   New Era of Smarter Food Safety: FDA's Blueprint for the Future (July 2020), available at https://www.fda.gov/media/139868/download.

2/   Remarks by Dr. Hahn on the release of a Blueprint for the New Era of Smarter Food Safety (July 13, 2020), available at https://www.fda.gov/news-events/speeches-fda-officials/remarks-dr-hahn-release-blueprint-new-era-food-safety-07132020.

Thought" outline of ideas the agency released in October 2019. 3/   FDA also has identified the senior leaders who will lead FDA's efforts in achieving the goals in each of the four core elements. 4/

This memorandum highlights some of the goals within in each of the four core elements. More details are provided in the Blueprint itself.

Core Element 1: Tech-Enabled Traceability

FDA seeks to advance traceability to protect consumers from contaminated products by performing rapid tracebacks, identifying the sources of contamination, and removing products from the marketplace as quickly as possible. The agency's ultimate goal is to have end-to-end traceability throughout the food safety system. FDA states its first step in this area will be completing its rulemaking under Section 204 of FSMA "to harmonize key data elements and critical tracking events needed for enhanced traceability." 5/   FDA will seek to enable compliance with its forthcoming traceability regulation through existing consensus standards, where possible.

Within this element there are three primary goals:

1. Develop Foundational Components: This involves entities throughout the food system using the same "traceability language" by standardizing critical tracking events and key data elements, as well as ensuring systems are designed with interoperability as a foundational component. The agency aims to expand FDA's capacity to process data quickly for all food commodities by encouraging the expansion of traceability to cover the broadest range of commodities on a voluntary basis.

2. Encourage and Incentivize Industry Adoption of New Technologies: FDA seeks to promote industry adoption of new technologies by promoting the benefits of traceability in outreach with the food industry and more non-traditional stakeholders such as the financial industry and technology firms. The agency hopes to explore ways to recognize adoption of strong traceability systems in how it approaches food safety oversight activities, such as its risk-based planning for inspections.

3. Leveraging the Digital Transformation: The agency intends to review its current outbreak and recall protocols, including how the agency makes traceback requests of firms and receives information in digital form, and work with state and local partners to establish methods of conducting accelerated tracebacks and trace forwards. The agency's goals include conducting a pilot on concepts needed to further scale traceability. Commodities that have been the subject of recent outbreaks, including leafy greens in particular, would be given a high priority. Implementing an internal digital technology system, such as blockchain, to receive critical tracking events and data from industry also is a goal for the

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3/   Food for Thought: Ideas on How to Begin a New Era of Smarter Food Safety (Oct. 2019), available at https://www.fda.gov/media/131682/download.

4/   New Era of Smarter Food Safety Management Team, available at https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-management-team.

5/   As part of a consent decree, FDA has committed to designating a list of high-risk foods and issuing a proposed rule that would establish recordkeeping requirements for these foods by September 8, 2020, and then issuing the final rule by November 7, 2022. *See* HL Memo - Settlement Reached in Lawsuit to Compel FDA to Implement FSMA Traceability Provisions (June 12, 2019), available at https://www.hlfoodlaw.com/2019/06/settlement-reached-in-lawsuit-to-compel-fda-to-implement-fsma-traceability-provisions/.

agency, as is harmonizing its work for foods with traceability efforts for other FDA-regulated products.

Core Element 2: Smarter Tools and Approaches for Prevention and Outbreak Response

This element focuses on enhancing and strengthening root cause analyses and predictive analytics. It includes six key goals and focus areas:

1. Invigorate Root Cause Analyses: This objective includes strengthening and standardizing root cause analysis procedures and reporting formats and enhancing communication tools. FDA also wants to incorporate root cause analysis data into the agency's risk ranking and predictive analytical systems to increase the likelihood of predicting and mitigating future contamination events.

2. Strengthen Predictive Analytics Capabilities: This goal involves expanding the use of artificial intelligence (AI) and learning tools, including expanding the proof of concept completed by FDA on using AI for screening imported foods. FDA also is exploring methods to create public-private "data trusts," or large volumes of data generated by industry that can be accessed for analytical work to strengthen preventive approaches. FDA wants to begin by working to create a "leafy greens data trust." FDA also aims to work with stakeholders to develop a process to analyze big data and non-traditional data sources of information (e.g., rain, temperature) that could be used to strengthen foodborne predictive capabilities and make more informed risk management decisions.

3. Domestic Mutual Reliance: FDA explains that "domestic mutual reliance" is an initiative to partner with the states to leverage each other's data and analytics to ensure optimal use of resources and maximize their food safety reach. The agency wants to work in partnership with state and local entities on issues such as establishing an integrated approach to risk prioritization/categorization on topics such as inspection frequency mandates and sample collection. This goal also includes advancing an integrated approach to emergency and incident response coordination by expanding federal-state rapid response teams. Additionally, FDA wants to harmonize food testing methodologies used by state and federal laboratories.

4. Inspection, Training, and Compliance Tools: FDA seeks to evaluate the feasibility of using remote, virtual, and/or component inspections of foreign and domestic firms with a demonstrated history of compliance for agency prioritization purposes, as well as to modernize the agency's inspectional and reporting process by leveraging mobile inspection technology and digital reporting tools. FDA also aims to support and evaluate the use of sensor technology by industry to strengthen monitoring of critical and preventive control points. Additionally, the agency would like to increase the use of "reliable" third-party audits, including exploring the use of such audit data in risk-prioritization for FDA regulatory activities such as inspections.

5. Outbreak Response: FDA wants to explore barriers and mechanisms to better leverage industry food testing results to identify possible outbreaks. FDA also hopes to explore options for accelerating the submission of reports of foodborne illnesses from state agencies to federal authorities. FDA's goals also include expanding the use and capacity of existing tools such as GenomeTrakr and PulseNet, as well as using AI to mine nontraditional sources of information (e.g., customer online reviews) to detect outbreaks.

6. Recall Modernization: FDA's goals for recall modernization focus largely on data communication, including harmonizing how FDA and USDA communicate recall information

to consumers, developing best practices on consumer notification of recalls, and exploring different technologies to enhance external communications and the effectiveness of recalls (e.g., establishing a government app for alerting consumers about recalls). FDA also aims to enhance the connectivity of data from the Reportable Food Registry submissions and food recalls.

Core Element 3: New Business Models and Retail Modernization

FDA's third core element focuses on protecting foods from contamination as new business models emerge. It is aimed at issues such as the growth of e-commerce, new food delivery models, and innovations in novel ingredients, foods, and production systems. FDA also is exploring how to modernize and ensure the safety of foods sold at restaurants and other retail establishments. This core element includes two primary goals:

1. <u>Ensure the Safety of Food Produced or Delivered Using New Business Models</u>: FDA wants to work with regulatory partners to address new business models that my not currently be regulated by FSMA in order to address the entity that "owns" the food in the last mile. It also hopes to partner with food delivery companies to provide education on the importance of food handling, including outreach to delivery services such as UPS, Uber, DoorDash, etc. FDA also aims to encourage the use of technology that monitors product risk factors such as time and temperature. FDA would like to hold a new food business model summit to identify future courses of action to address potential food safety vulnerabilities. This goal also includes facilitating the safe development of new food ingredients and production technology.

2. <u>Modernize Traditional Retail Food Safety Approaches</u>: FDA is considering a host of measures to modernize retail food safety, such as encouraging the development of commercial smart kitchen equipment capable of monitoring time and temperature processes, encouraging the use of new digital tools that prompt desired behaviors (e.g., handwashing), and identifying intervention strategies known to be effective at reducing foodborne illness risk factors. FDA also wants to work with the Conference for Food Protection to increase uniform adoption of the FDA Food Coe and more fully incorporate into the Food Code a food safety management approach for retail establishments. The agency also hopes to increase use of a risk-based inspectional approach consistent with Annex 5 of the Food Code.

Core Element 4: Food Safety Culture

The fourth core element focuses on fostering food safety culture on farms, in food facilities, and in homes. This element includes three primary goals:

1. <u>Promote Food Safety Culture Throughout the Food System</u>: This goal includes developing a food safety culture social marketing plan, encouraging influencers to model desired safe-food behaviors, and providing training, education, and inspectional tools that incorporate established behavioral science principles that foster a food safety culture. FDA also wants to ensure behavioral science principles are incorporated as a critical component of the food safety work performed with federal, state, and other regulatory partners.

2. <u>Further Promote Food Safety Culture Throughout the Agency</u>: FDA's work in this area would include considering how a company's strong food safety culture can factor into reduced inspection frequencies and educating investigators on the characteristics that indicate a company has a strong food safety culture.

3. <u>Develop and Promote a Smarter Food Safety Consumer Education Campaign</u>: As part of the consumer education campaign, FDA wants to engage new partners in a coalition to

promote food safety and use new, tech-enabled popular mediums and tools to reach consumers with food safety messages. FDA also intends to develop strategies to help consumers access new technologies relevant to food safety and facilitate their adoption of new food safety tools such as apps.

Next Steps

In his statements announcing the Blueprint, Commissioner Hahn described the Blueprint as a "work in progress," and he encouraged stakeholders to continue providing feedback on the agency's initiatives. FDA's FAQs for the Blueprint similarly describe it as "a living document that is intended to keep pace with new food technologies, methods of food production and delivery, and new tools for oversight." 6/ Although FDA does not have any specific action items or timelines set out in the Blueprint, the release of the document presents an opportunity to engage with the agency to provide input and assistance on its efforts to pursue these initiatives.

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We will continue to monitor FDA's progress in implementing the New Era of Smarter Food Safety. Should you have any questions, please do not hesitate to contact us.

6/ New Era of Smarter Food Safety: Frequently Asked Questions, available at https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-frequently-asked-questions.