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MEMORANDUM

From: Joseph A. Levitt
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Re: **Trump Administration Announces Planned Nomination for FDA Commissioner and Takes Further Steps to Implement Regulatory Reform Agenda**

The White House recently announced that President Donald J. Trump plans to nominate Scott Gottlieb, M.D., to serve as FDA Commissioner. This appointment requires Senate confirmation.

Additionally, the past couple weeks have seen several actions by the Trump Administration to advance its regulatory reform agenda.

- First, the Department of Commerce issued a request for information (RFI) to assist in its development of a plan to streamline permitting and reduce regulatory burdens for domestic manufacturing. The RFI is an opportunity for food manufacturers to voice concerns about regulations affecting the industry.

- Second, the White House has issued a memorandum with instructions for agencies to implement Executive Order (EO) 13771 (i.e., the order establishing the "one in, two out" rule) in developing their Spring Unified Agenda submissions. It requests that agencies identify the costs of significant regulatory actions for fiscal year (FY) 2018, as well as the cost savings for the regulatory actions to be rescinded to offset those costs.

- Third, President Trump has issued a new EO requiring the Office of Management and Budget (OMB) to develop a plan for reorganizing executive branch operations, including the potential elimination of agencies, components of agencies, or agency programs. It is not clear at this stage how the EO will affect the U.S. Food and Drug Administration (FDA) or U.S. Department of Agriculture (USDA).

President Trump Announces Plan to Nominate Scott Gottlieb as FDA Commissioner

President Trump has announced his intent to nominate Scott Gottlieb, M.D. to serve as FDA Commissioner, a position requiring Senate confirmation. A physician, Dr. Gottlieb previously served at FDA during the George W. Bush administration as Deputy Commissioner for Medical and Scientific Affairs. More recently, he has served as a resident fellow at the think tank American Enterprise Institute (AEI) and a clinical assistant professor at New York University School of Medicine. If confirmed, Dr. Gottlieb would bring the rare quality of becoming FDA Commissioner

with direct, prior FDA experience. 1/ His nomination has drawn praise from the Grocery Manufacturers Association (GMA). 2/ The Senate has not yet scheduled his confirmation hearing. In the meantime, Stephen Ostroff, M.D., continues to serve as Acting Commissioner.

Department of Commerce Request for Information

The Department of Commerce (Commerce) has issued an RFI on the impact of federal permitting requirements on the construction and expansion of domestic manufacturing facilities and of regulations that adversely affect domestic manufacturers. Commerce has issued the request as directed by the White House memorandum, "Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing," issued January 24, 2017. 3/ The memorandum directed Commerce to work with other agencies to conduct stakeholder outreach on the effect of federal regulations on domestic manufacturing, including soliciting public comments for up to 60 days. Commerce will use the information obtained during its stakeholder outreach to prepare a report to the White House, including a plan to streamline federal permitting and reduce the regulatory burdens affecting domestic manufacturers.

In its RFI, Commerce asks that domestic manufacturers (defined to include food manufacturers) explain "how the construction, operation, and expansion of domestic manufacturing facilities are affected by (1) the process of acquiring Federal permits required for the construction, expansion, or operation of such facilities and (2) the burdens of complying with Federal regulations for manufacturing facility construction, expansion, or operation." Manufacturers also are asked to provide suggestions for simplifying regulatory compliance within their particular industry or sectors, as well as recommendations for reducing unnecessary federal regulation.

With respect to the general category of regulatory burdens, the notice asks stakeholders to respond to three questions:

1. List the top four regulations you believe are the most burdensome for your manufacturing business.
2. How could regulatory compliance be simplified within your industry or sector?
3. Provide any other specific recommendations that you believe would help reduce unnecessary regulation of your business.

The RFI is an opportunity for food manufacturers to voice their concerns related to regulations governing the industry. Comments must be submitted by 5 p.m. (EST) on March 31, 2017.

White House Memorandum on Creating Spring Unified Agendas

On March 6, the Trump Administration issued a memorandum providing agencies with guidelines and procedures for preparing the 2017 Spring Unified Agenda. 4/ The memorandum asks that as agencies prepare their submissions, they give careful attention to the requirements in EO 13771,

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1/ Most FDA Commissioners have come to the agency with no prior FDA experience, necessitating a steep learning curve. The only exceptions were Jane Henney, M.D. and Robert Califf, M.D., both of whom had also served as deputy commissioners.

2/ GMA issued the following statement: "Scott Gottlieb is an excellent choice to lead FDA. His experience as FDA deputy commissioner and in other key FDA positions will enable him to quickly step into this important role after his confirmation. His appointment will be good for American consumers, the safety of their food and the role of continuous innovation…."

3/ *See* HL Memo, "Trump Administration Issues Executive Order on Reducing Regulation and Controlling Regulatory Costs," (February 2, 2017).

4/ The Unified Agenda is published twice a year and lists all planned rulemaking activities for each agency.

which established the requirement that the cost of each new regulation must be offset by the savings of rescinding two existing regulations, among other EOs. The memorandum anticipates that agencies likely will include in their submissions the regulatory actions they plan to issue in FY 2018 and requests that they also include a preliminary estimate of the total costs or savings associated with each planned significant regulatory action for FY 2018 and their offsetting deregulatory actions.

The memorandum underscores the importance of monitoring the semi-annual Unified Agendas. Going forward, they will not only forecast the new rulemakings each agency plans to undertake, but also will provide advance notice of the regulations agencies are considering for repeal to comply with EO 13771.

Executive Order Calls for Plan for Executive Branch Reorganization

On March 13, President Trump issued EO 13781 directing OMB to develop a plan for reorganizing the governmental functions of the executive branch and eliminating unnecessary agencies, components of agencies, or agency programs. Within 180 days of the EO, the head of each agency 5/ must submit to OMB a proposed plan to reorganize the agency, as appropriate, to improve its efficiency, effectiveness, and accountability. Additionally, OMB must solicit public comments on suggested improvements in the organization and function of the executive branch. Within 180 days following the completion of the public comment period, OMB must submit a proposed plan for reorganizing the executive branch, including recommendations to eliminate unnecessary agencies, agency components, or programs; merge existing agency functions; and for any legislation or administrative measures needed to execute the reorganization.

When developing the plan, OMB must consider the following factors:

- Whether some or all of the agency/component/program functions would be better left to state or local governments or to the private sector;
- Whether some or all of the agency/component/program functions are redundant, including with functions of another agency/component/program;
- Whether administrative capabilities necessary for operating an agency/component/program are redundant with those of another agency/component/program;
- Whether the costs of continuing to operate an agency/component/program are justified by the public benefits it provides; and
- The costs of shutting down or merging agencies/components/programs, including the costs of addressing the equities of affected agency/component/program staff.

It is too soon to tell if or how the EO may affect the operation or structure of FDA or USDA. It is certainly possible that previous discussion of establishing a single food safety agency may be revisited, as well as discussion of how to reduce regulatory overlap between FDA and USDA (e.g., so-called "dual jurisdiction" facilities regulated by both FDA and USDA). Companies with suggestions for reducing overlapping regulations, or that wish to emphasize the value of regulating particular issues at a federal level (as opposed to by state or local governments), should consider submitting information in response to OMB's forthcoming request for public comment.

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We will continue to monitor the Trump administration's actions and developing policy agenda. Please contact us if you have any questions.

5/ Note that "agency" is not defined, but likely includes departments (e.g., Department of Health and Human Services (HHS) and USDA) as well as agencies (e.g., FDA and Food Safety Inspection Service).