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FDA in the Era of Trump: How the Agency and the Products it Regulates Could Fare

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SUMMARY

On April 11, 2017, White House Budget Director Mick Mulvaney announced that the Trump administration would be lifting (http://bit.ly/2oulpTQ) a federal hiring freeze, which the President instituted (http://bit.ly/2jqMG6f) on January 23, 2017. Unfortunately for current and prospective federal employees, the memo lifting the freeze provides little hope that jobs are safe or that vacancies will be filled. The memo outlines the Trump administration's plans to make government "lean, accountable, and more efficient." It requires federal agencies to: (1) take actions to reduce the federal workforce and achieve cost savings, including planning for the President's FY '18 Budget Blueprint; (http://bit.ly/2nvjrBO) (2) develop a plan to maximize employee performance; and (3) submit an agency reform plan to the Office of Management and Budget (OMB).

The proposal is particularly bleak for the U.S. Department of Health and Human Services (HHS), of which the U.S. Food and Drug Administration (FDA or the Agency) is a part. The budget calls for a nearly 18 percent decrease in HHS's budget, from $84.1 billion to $69 billion. President Trump has referred (http://bit.ly/2lTsvBM) to FDA's approval process as being "slow and burdensome," and has indicated that "in a constrained budget environment, industries that benefit from FDA's approval can and should pay for their share." Accordingly, the President is calling for a more than doubling of FDA medical product review user fees. It is not clear what impact such increased fees would have on Agency reviews given the reforms and reductions discussed above. Moreover, the President's budget is merely a proposal and scores of congressional Republicans and Democrats are opposed to many of the cuts.

Aside from the cuts and reform and reduction plans, FDA, like other agencies, is grappling with how to comply with the President's "one in, two out" executive order (http://bit.ly/2obOxhW). Under the executive order, whenever an agency proposes a new regulation, it must identify at least two existing regulations to be repealed. It is not clear whether an agency proposing a new regulation has to identify two of its own rules to repeal or whether it could target another agency's rules. Since President Trump issued the order, there has been a noticeable but expected decline in federal agency regulatory actions.

The reform and reduction plans and the proposed budget cuts could have a profound impact on all federal agencies, but in particular, FDA. An open question is how the President's nominee for FDA Commissioner, Dr. Scott Gottlieb, would shape the Agency's work, if confirmed, particularly in a constrained budget and reform environment. On March 10, 2017, President Trump nominated Gottlieb, a physician and conservative health policy expert. Gottlieb, who served as deputy FDA Commissioner under President George W. Bush, has longstanding ties to the pharmaceutical and biotech industries. Notably, he "favors deregulation and loosening the agency's requirements for the approval of medical products," (http://bit.ly/2pB9Vx1) and has suggested that FDA could tolerate a bit more uncertainty when it evaluates the effectiveness of a new drug.

On April 5, 2017, the Senate Health, Education, Labor, and Pensions (HELP) Committee held a confirmation hearing on Gottlieb's nomination. HELP Chairman Lamar Alexander (R-Tenn.) expressed (http://bit.ly/2oceHks) concerns regarding the federal hiring freeze and its impact on FDA's ability to implement the 21st Century Cures Act. Ranking Member Patty Murray (D-Wash.) called attention to Dr. Gottlieb's "'unprecedented financial entanglement with industry,'" and indicated her desire to learn more about his plans for "increasing competition through generics and biosimilars and reducing drug costs." Other topics addressed included opioid addiction, which Gottlieb assessed as "'the biggest crisis facing the agency,'" (http://nyti.ms/2oyF0UA) the President's contention that vaccines may be linked to autism, with which Gottlieb disagrees (http://nyti.ms/2o17RPn), e-cigarettes and vaping, which Gottlieb acknowledged as having a role in helping established smokers quit, and FDA medical product review. Gottlieb indicated that there should be a "balance between speeding new products to market and making sure that good science continues to guide the FDA's decisions." Moreover, he rejected the "'false dichotomy that [FDA review] all boils down to a choice between speed and safety'" but expressed a desire to ensure that "'we're getting the most bang for our regulatory buck.'"

During the hearing, Gottlieb said (http://bit.ly/2o4ufJr) he would be open to delaying FDA's rule that overhauls the Nutrition Facts label in order to align with the U.S. Department of Agriculture's (USDA) GMO labeling rule. Gottlieb's response was welcome news to the leading food and beverage groups that sent a letter (http://bit.ly/2pAXlxV) to HHS Secretary Dr. Tom Price on March 14, 2017 requesting delay of the Nutrition Facts rule from July 2018 until May 2021.

The National Association of Convenience Stores (NACS) and the National Grocers Association (NGA) are hoping that Gottlieb responds similarly to their Citizen Petition (http://bit.ly/2ocejSV), which requests a stay and reconsideration of FDA's Menu Labeling Rule (http://bit.ly/2mGKJaJ). The Rule, which has a compliance date of May 5, 2017, requires restaurants and "similar retail food establishments" (e.g., convenience stores and grocery stores) that are part of a chain of 20 or more locations and that sell similar menu items to post on menus and menu boards: (1) calorie information; (2) a statement on suggested daily caloric intake; and (3) a statement that written nutrition information is available upon request.

NGA and NACS argue that:

- Their members cannot comply with the current Rule;
- FDA underestimates compliance costs, especially for retailers; and
- The Rule violates the First Amendment.

Finally, some tobacco companies are similarly hoping that Gottlieb will roll back or delay portions of FDA's Deeming Rule (http://bit.ly/2fYevVC), which subjects e-cigarettes, cigars, hookah tobacco, and pipe tobacco, to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Per the Deeming Rule, "new tobacco products" must obtain premarket authorization from the Agency via (1) substantial equivalence (SE); (2) exemption from SE; or (3) premarket tobacco product application (PMTA) approval. Unless a product was on the market as of the Rule's "grandfather date" (i.e., February 15, 2007), or unless a sponsor is able to demonstrate SE to a grandfathered product, the sponsor would have to submit a PMTA. Because virtually all e-cigarettes and vapor products came on the market after February 15, 2007, such products will have to go through the most onerous PMTA pathway. This will result in major industry consolidation because of the $1 million-plus cost involved in preparing a PMTA.

If confirmed, Dr. Gottlieb will certainly have his hands full. It remains to be seen how a Gottlieb-led FDA will fare at the confluence of proposed budget cuts, reform and reduction plans, increased user fees, and restrictions on regulatory action, all while attempting to implement the 21st Century Cures Act, in addition to navigating the issues discussed above and myriad others.

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