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President-elect Trump Makes More HHS Personnel Moves: Dr. Marty Makary Tapped to Lead FDA

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In recent days, President-elect Trump has made progress in announcing the names of various individuals he intends to nominate to serve in some of the most senior and influential leadership positions at the Department of Health and Human Services (HHS) and which also require Senate confirmation. The first of these announcements was that President-elect Trump intends to nominate RFK Jr. to serve as HHS Secretary. The HHS Secretary is responsible for overseeing all 13 of the Department's Operating Divisions, including the FDA, in addition to the Department's staff divisions. President-elect Trump also recently announced his intent to nominate physician and former Representative Dave Weldon (R-FL) to serve as the next Director of the Centers for Disease Control and Prevention and Dr. Janette Nesheiwat as the next Surgeon General.

President-elect Trump announcing his intent to nominate Dr. Makary to serve as the next Commissioner of Food and Drugs is the first step in the Senate confirmation process. Once the 119th Congress commences early next year, his nomination would be expected to be taken up by the Senate Health, Education, Labor and Pensions (HELP) Committee, including the HELP Committee holding a hearing on his nomination during which senators on both sides of the aisle who serve on that the Committee would likely delve into Dr. Makary's previous health policy commentary. He will likely be asked a range of questions about how he would approach the role of Commissioner. Dr. Makary's previous criticism of the FDA appears to be more nuanced than some of the other HHS nominees named by President-elect Trump thus far. His confirmation is subject to a 50-vote threshold, and with a

Republican majority of 53 Senate seats, it is likely to be more of a question as to when, not if, Dr. Makary is confirmed to serve as the next Commissioner of Food and Drugs.

The Commissioner of Food and Drugs is one of the most anticipated political appointee nominations, given the breadth of the FDA's mission to protect and promote public health. FDA is responsible for ensuring the safety, efficacy and security of human and veterinary drugs, biological products and medical devices. The agency is also charged with ensuring the safety of our nation's food supply, cosmetics and products that emit radiation. In addition, FDA regulates the manufacturing, marketing and distribution of tobacco products. FDA ensures the security of the food supply and fosters development of medical products to respond to public health threats whether naturally occurring, like an emerging infectious disease, or deliberate.

The agency's regulatory responsibilities are vast and impacts are not limited to patients and public health but also extend to the economy: FDA-regulated products account for 20 cents of every dollar spent by U.S. consumers. Even though FDA does not have a direct role in medical product pricing, how the agency's regulatory frameworks are structured and implemented does impact the timing its takes for products to reach the market, whether they are new innovations for unmet public health needs or those like generic drugs, and medical devices cleared under 510(k) as substantially equivalent, which may expand choices for consumers and thereby foster competition.

Marty Makary, M.D., M.P.H., a board certified surgeon, is Chief of Islet Transplant Surgery at The Johns Hopkins University. He has written extensively on health care, including publishing two *New York Times* bestsellers, scientific peer-reviewed articles and commentary for national publications like the *Washington Post*, *Wall Street Journal* and *New York Times*, in addition to Fox News appearances. While Dr. Makary would be new to FDA, he is not new to Washington, D.C.'s policy scene, having served as an advisor to the health care think tank Paragon Health Institute. Dr. Makary would also bring experience having advised life sciences companies and served in leadership at the World Health Organization.

As Commissioner, Dr. Makary would assume the role of leading an agency comprised of more than 18,000 employees spanning the agency's medical product centers, human foods program, and tobacco products center and implementing regulatory frameworks that rely upon billions in taxpayer dollars and industry collected user fees to sustain regulatory certainty for the premarket review of products overseen by FDA and related performance goals. As the

commissioners who have come before him, Dr. Makary would have the opportunity to chart his priorities for the agency in assuming its helm. However, he is destined to face the Goldilocks dilemma inherent to leading the agency: no matter the time and approach the agency takes, there will likely be those that say the agency moved too fast, too slow, too far or not far enough. Indeed, FDA's actions are consistently an area of intense focus by patients, consumers, the public health community, clinicians, industry stakeholders and Congress. Yet, the scrutiny Dr. Makary may have to navigate as Commissioner may set a new high watermark as he would be entrusted with carrying out the agency's public health mission against the backdrop of an incoming administration expected to prioritize government-wide deregulatory action and the first administration to establish its regulatory agenda post the *Loper Bright* decision, and alongside administration colleagues who have criticized the agency and may have varying expectations as to what they would view as success for it over the next four years.

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