

CAPITOL STREET

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ALERT: Acting FDA Commissioner Possibilities

Leadership Changes Afoot

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»» Our Take & Next Up

An acting FDA commissioner is the most likely solution. Any permanent nominee would probably face a difficult path to Senate confirmation ahead of the midterm election in November. Names on our radar: Kyle Diamantas (Deputy Commissioner for Food), Lowell Zeta (Deputy Commissioner for Strategic Initiatives), Grace Graham (Deputy Commissioner for Policy, Legislation, and International Affairs), and Steven Kozlowski (Chief Scientist).

A leadership change at FDA is likely happening: Dr. Marty Makary is on the outs. President Trump has reportedly approved a decision to remove FDA Commissioner Marty Makary from his position, according to the WSJ. Allegedly, he has clashed with other officials in the administration over his refusal to approve flavored vapes and nicotine products, the increased publicity around rare disease product rejections, and his defense of former CBER director Prasad.

What's (been) happening from a review perspective at the FDA? On the CBER and CDER front, there has been a lack of reviewers, review staff who are scrambling to make sponsor meetings (often without an agenda provided ahead of time, as required), slowdowns in Pre-IND & Phase 2 to 3 meetings, as well as a paucity of scientific expertise overall. See our March analysis of the state of play at the FDA.

»» Key Points

Commissioner Makary could depart the agency sooner rather than later. The White House may be looking to reset the FDA's image. WSJ is reporting that President Trump has signed off on removing Makary as commissioner, although the decision is not yet finalized. We note that his absence would also come as the administration is trying to fill the CBER Director position and aiming to rehire career scientists (despite low morale) and reviewers at the FDA.

Acting FDA Commissioner prospects on our short list lack either drug approval or regulatory leadership experience. We note that potential acting replacements include Kyle Diamantas (Deputy Commissioner for Food), Lowell Zeta (Deputy Commissioner for Strategic Initiatives), Grace Graham (Deputy Commissioner for Policy, Legislation, and International Affairs), and Steven Kozlowski (Chief Scientist).

- **Kyle Diamantas J.D.** is the Deputy Commissioner for Food, and leads the FDA's Human Foods Program. He is a former food attorney by training. Previously, he advised food, cosmetic, dietary supplement, drug, and other life sciences and consumer goods clients (ex. he represented ABT in a lawsuit involving their infant formula). He has little experience in drug development or in drug review.
- **Grace Graham** is the Deputy Commissioner for Policy, Legislation, and International Affairs. She leads the Office of Policy, Legislation, and International Affairs (OPLIA), which serves as the FDA's focal point for Congress, Trump admin, global partners, and state policymakers. She comes from a legislative background with no experience in drug development, drug review, or in biotech. Prior to the FDA, she served as Chief Health Counsel for the House E&C Committee and worked on the 2022 User Fee Reauthorization.
- **Steven Kozlowski M.D.** is the FDA's Chief Scientist. We note that while he has extensive experience in drug review, he lacks leadership experience beyond the office level. Prior to assuming the role of Chief Scientist, Dr. Kozlowski has extensive experience in pharmaceutical review. He served as Director of the Office of Product Quality Assessment III (OPQA III) in CDER's Office of Pharmaceutical Quality (OPQ) and also served as Director of the Office of Biotechnology Products (OBP).
- **Lowell M. Zeta, J.D.** is the Deputy Commissioner for Strategic Initiatives at the FDA and serves as Special Counsel for FDA in the Office of the Chief Counsel (OCC) at HHS. He serves as a legal advisor and intermediary between FDA and HHS, and serves as the point-person ensuring that strategic initiatives and priorities fit within the FDA's statutory authorities. He previously served as a Senior Advisor to the Commissioner and advised on the Pandemic Recovery and Preparedness Plan (PREPP) initiative. He is experienced in FDA regulations, but lacks drug review or development experience.

Many acting FDA commissioners do not possess medical credentials, so don't rule out Grace Graham, for instance (and other folks listed above). Some other things to keep in mind when considering a potential Acting Commissioner:

- If someone within the FDA is considered as acting they need to have been in that senior role for a certain period of time (which leaves only a handful of individuals).
- Another option is someone becoming acting from another government agency.
- Example: Ned Sharpless went from NCI Director to acting FDA Commissioner. He was acting for about 8 months after Scott Gottlieb, MD, resigned in 2019.

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