CAPITOL STREET

March 31, 2025

FDA Staff Cuts, PDUFA & Peter Marks' Departure

"What It Means" Biopharma and MedTech Webinar Tues April 1 at 11 am ET

Relevant Companies: ALL HEALTHCARE

Our Take & Next Up

We believe FDA review times will slow for non-novel therapies, there will be more requests for data (CRL) as reviewers buy time. In the fact sheet announcing a major staffing cut to the department of Health & Human Services (HHS), it notes FDA layoffs “will not affect drug, medical device, or food reviewers, nor will they impact inspectors." The cuts are allegedly to administrative, communications and "redundant" staff in "high-cost regions," such as the Washington DC region. Reviewers and manufacturing (inspectors) are said to be exempt.

Key Points

We are hosting a "What It Means" webinar on HHS/FDA restructuring, impact on reviews, PDUFA outlook and other ripple effects on April 1 at 11 am ET. We will circulate details ASAP. Please join us (RSVP here)

Morale is clearly an issue: with the ongoing RIF (reduction in force) and brain drain, FDA talent is (and will continue) to walk out the door. When personnel have less expertise, particularly in niche areas such as orphan drugs, rare cancers, gene editing, they are likely to ask for more data versus making a hasty decision. Complete response letters (CRLs) are the likely outcome. Over time, more rushed decisions may be made to meet deadlines, with potentially a lower bar for supplemental applications and/or indication expansions.

Product reviews will naturally slow ... FDA is likely to prioritize therapies, first in class, novel tech. We could see “me toos” and line extensions likely being placed at the bottom of the priority (review) list.

Dr. Peter Marks (CBER) announced his departure on Friday (effective April 5). BIO CEO John Crowley (reportedly via *BioCentury*) advocated for Marks to remain in place as head of CBER (Center for Biologics Evaluation and Research). In the end the back-and-forth over vaccine policy prompted Marks to resign late Friday. He shared a letter with FDA Acting Commissioner Sara Brenner. Marks has been in his role since 2016.

What does the new FDA Commissioner Makary do, walking into a low morale, gutted organization? The new FDA Commissioner takes his seat this week. Makary has asked Michelle Tarver to stay (CDHR), a well-regarded Center for Devices senior leader, providing some stability for the Device group, near term.

We would anticipate ~10-15% additional staff are likely to leave in this tumultuous environment. We understand that backfilling/rehiring with new employees is unlikely. The announcement calls for the following major items.

- The RIF is estimated to save $1.8 B per year through ~10,000 full-time employees who are part of this most recent transformation.
- Restructuring results in a total downsizing from 82,000 to 62,000 FTEs.
- 3,500 job cuts will occur at FDA.
- The restructuring plan will consolidate from 28 to 15 new divisions, including a new A*dministration for a Healthy America,* or AHA, and will centralize core functions such as (1) Human Resources, (2) Information Technology, (3) Procurement, (4) External Affairs, and (5) Policy.
- Regional offices will be reduced from 10 to 5.
- The re-org will implement the new HHS priority of ending America's epidemic of chronic illness by focusing on safe, wholesome food, clean water, and the elimination of environmental toxins.
- HHS will be "more responsive and efficient, while ensuring that Medicare, Medicaid, and other essential health services remain intact".

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