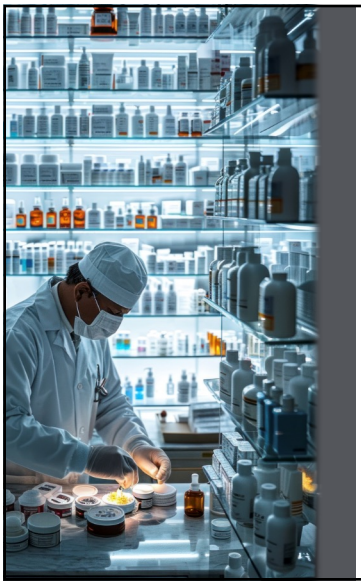

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Regulatory Rundown:
What Compounders Need to Know

Presented by:

Rachael G. Pontikes

March 6, 2025

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Changes at FDA under the Trump Administration

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A Smaller FDA

Large scale Reduction in Force (RIF) for FDA (Executive Orders)

- Allow one new employee to be hired for every four who leave
- Require career FDA appointment hire to be done in conjunction with the Department of Governmental Efficiency (DOGE) team

Two phases of RIF

- Phase 1: FDA to identify which staff are performing work functions that are statutorily required (March 2025)
- Phase 2: FDA to identify which departments are statutorily required and how to consolidate (April 2025)

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New Rules for Rules

(including guidance, memoranda, inter-agency agreements, and policy statements)

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Regulatory Freeze (Presidential Memorandum)

- No proposal or issuance of any rules without a Trump appointed agency head or designee reviews
- Immediately withdraw any rule sent to the federal register but not yet published until Trump-appointed official can review
- Postpone for 60 days the effective date of any rule not yet effective and consider further notice and comment

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10-1 Deregulation Initiative (Executive Order)

For 2025, for every one rule that FDA proposes for notice and comment, it must identify ten that will be repealed

The cost of all repealed and new regulations together must be "significantly less than zero"

For 2026 and beyond, for regulations that increase incremental costs, FDA must identify on an aggregated basis the ten cost offsetting regulations

Office of Budget Management (OMB) is directed to work on a process to implement

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Deregulatory Initiative (Executive Order)

- FDA directed to rescind any regulation that is based on anything other than the best reading of the underlying statutory authority or prohibition, implicated matters that are not authorized by statute, excessively costly and overly burdensome for small business and entrepreneurs, and harmful to national interest
- FDA is permitted to deprioritize any enforcement of regulations that are based on anything other than the best reading of the statute or goes beyond what the Constitution allows
- FDA must consult with the DOGE Team leads and head of Office of Information and Regulatory Affairs before promulgating any new regulations

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Impact on Compounding

- Smaller FDA
  - Inspections/ Enforcement Actions
  - FMD-145 Letters

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Impact on Compounding

- New Rules for Rules (including guidance, memoranda, inter-agency agreements, and policy statements)
  - Sunset of Categorizations for bulk (503A and 503B)— finalized 1/6/2025)
  - Draft Guidance on Prohibition on Wholesaling under Section 503B
  - Proposed Rule for Demonstrably Difficult to Compound
    - Proposed additions of Semaglutide/Tirzepatide to the list
  - Peptides (*Evexias Medical Centers v. FDA*)
    - Removed from Category 2 and put through the PCAC process
    - October /December regulatory meeting
    - Next step—proposed rule
  - Proposed ingredients for the 503A and 503B positive list
    - Tirzepatide (503B)
    - Semaglutide (503B)
  - Proposed regulation setting out definitions of dispense, distribute, inordinate amount under MOU

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GLP-1s—Drug Shortage

- 503A and 503B can compound commercially unavailable drugs, which are drugs that are on drug shortage
- A shortage is:
  - "a period of time when the demand or projected demand for the drug within the Untied States exceeds the supply." 21 U.S.C. § 356c.
- FDCA requires FDA to keep an update list of drugs in shortage. 21 U.S.C. § 356(a)

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Tirzepatideepatide Shortage—Timeline

- Shortage began in December 2022
- FDA declared shortage resolved in October 2024
- OFA sued FDA in October 2024
- FDA decided to reevaluate the resolution of the Tirzepatide shortage and allowed compounding in the interim
- FDA determined shortage resolved in December 2024 via an adjudication
- FDA allows compounding of Tirzepatide until the court rules on the preliminary injunction

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Challenge to FDA's Resolution Of The Tirzepatide Shortage—*OFA v. FDA*

- OFA sued FDA requesting a preliminary junction, claiming the removal of TirzepatideTirzepatideepatide from shortage was:
  - A rule requiring notice and comment;
  - Arbitrary and capricious

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Challenge to FDA's Resolution Of The Tirzepatide Shortage—*OFA v. FDA*

- District Court denied the preliminary injunction finding:
  - Removal of Tirzepatide from shortage is not a rule requiring notice and comment:
    - FDCA requires the list be "up to date"—notice and rule making takes too long
    - Be careful what you wish for—if it is a rule, it will also require notice and comment for drugs to be put on shortage
    - Drug shortage determinations are case by case factual determination that immediately bind parties
  - Removal of Tirzepatide from shortage not arbitrary and capricious
    - The record demonstrates a rational relationship between the facts and FDA's decision to end the shortage
    - FDA did take the compounders' data into consideration and was not unreasonable

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What now?

- Tirzepatide shortage has been resolved
- OFA has appealed
- For a 503A pharmacy, the period of enforcement discretion has ended
- For outsourcing facilities, FDA will exercise enforcement discretion until March 19, 2025.

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Semaglutide Shortage—Timeline

- Shortage began in March 2022
- FDA determined shortage resolved via adjudication February 2024
- Via adjudication, FDA is allowing compounding with Semaglutide for 503As and 503Bs for a ramp down period
- OFA sued FDA
- Ramp down period will run until:
  - the Court rules on OFA's forthcoming preliminary injunction, or
  - April 22, 2025 for 503A and May 22, for 503B

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Challenge to FDA's Resolution of the Semaglutide Shortage —*OFA v. FDA*

- Filed as a related case—same judge and same district court
- OFA challenges resolution of the Semaglutide shortage on the same grounds, claiming the resolution of the Semaglutide shortage is:
  - A rule requiring notice and comment
  - Arbitrary and capricious

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What now?

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