The Legal Update

A Profile in FDA Overreach

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Alliance for Pharmacy Compounding

What is FDA Overreach?

- FDA operating outside the authority granted to it by Congress in its governing statute (Section 50A or 503B of the FDCA)
- FDA violating the Administrative Procedure Act (APA)
- FDA violating federal obligations (Federal Advisory Committee Act)

So what?

What's the big deal?

Recent Examples of FDA Overreach

- FDA disregarded Section 503A in issuing the Final Standard MOU
- FDA will violate the Federal Advisory Committee Act (FACA) if FDA adopts or uses the NASEM report on cBHRT

Federal Court Finds FDA Overreached in Issuing The MOU – *Wellness Pharmacy Inc. v. Becerra*

Background

- Seven plaintiff pharmacies (Belmar, ChemistryRX, Hartley, Medquest, VLS Pharmacy, Wellness, Women's International Pharmacy) filled suit against FDA
- Plaintiffs alleged FDA overreach—FDA failed to follow Section 503A and the Regulatory Flexibility Act in issuing the MOU
- How?
  - FDA failed to follow the "shall issue regulations" command in Section 503A and promulgate the MOU via regulation;
  - FDA failed to conduct a Regulatory Flexibility Act analysis (analyzing the MOU's impact on small business entities) which is required for legislative rules;
  - FDA exceed its statutory authority by defining the statutory terms "distribution" and "inordinate amount" to include dispensing.

Federal Court Finds FDA Overreached in Issuing The MOU – *Wellness Pharmacy Inc. v. Becerra*

Court Ruling (Holding)—Part I

Plaintiffs are entitled to be in Court

- Plaintiffs' claims are ripe;
  - The dispute is not hypothetical or remote;
  - So, the Court can hear the Plaintiffs' claims.
- Plaintiffs have standing
  - Plaintiffs are impacted by FDA issuing MOU;
  - So, the Court can proceed.

Federal Court Finds FDA Overreached in Issuing The MOU – *Wellness Pharmacy Inc. v. Becerra*

Court Ruling (Holding)—Part II

FDA Overreached In Issuing the MOU

- The MOU is a legislative rule
  - The MOU defines key terms in 503A (distribution to include dispensing);
  - Draws the line in a statute that carries both civil and criminal penalties.
- FDA failed to comply with the Regulatory Flexibility Act (RFA) and do an analysis of the MOU's impact on small business
  - Legislative rules requires compliance with RFA;
  - No analysis of MOU impact on small business was done;

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Court Ruling (Holding)—Part II (Continued)

FDA Overreached In Issuing the MOU

- MOU remanded to FDA to:
  - Prepare a regulatory flexibility analysis OR
  - To certify that the MOU will not have a "significant impact on small entities."
  - "Small business" in this context means that a pharmacy is considered "small" if it has $30 million or less in annual gross receipts, according to the standard established by the Small Business Administration.
- FDA to submit a progress report to the Court by November 22, 2022

FDA will violate FACA if it adopts or uses NASEM's Report on cBHRT

What is FACA?

- FACA is a federal statute that formally recognizes the importance and value of federal advisory committees to agencies;
- FACA allows agencies the benefit of the expertise of the public on a broad range of issues;
- FACA puts restrictions on recommendations from the National Academy of Sciences.

FDA will violate FACA if it adopts or uses NASEM's Report on cBHRT

What are FACA's restrictions?

- FACA prohibits an agency from using any advice or recommendation that was developed a committee that was subject to ***actual management or control by an agency***;
- FDA cannot use any conclusion or recommendation by NASEM if they are the result of a NASEM committee that was unduly influenced by FDA.

FDA will violate FACA if it adopts or uses NASEM's Report on cBHRT

FDA unduly influenced the NASEM report

- Ms. Axelrad former, lead on pharmacy compounding evidenced that FDA had strong command over the outcome;
- FDA submitted its own data and forced NASEM to evaluate cBHRT under new drug approval standards;
- FDA and NASEM collaborated consistently over substance aspects of the report;
- FDA was handed the pen to revise the report before it was published—also violating NASEM rules.

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Rachael's broad experience covers the full range of issues that arise for health care companies in life sciences, most prominently with entities involved in the compounding of drugs across both the human and animal health spheres. Rachael has notable strength in representing health care facilities in high-stakes Federal Food and Drug Administration, (FDA), Drug Enforcement Administration (DEA), and state agency investigations and related litigation, as well as acting as regulatory counsel for large-scale, high-profile transactions involving major healthcare players in the compounding space. Widely regarded as a thought leader on current issues facing the compounding sector, Rachael is called upon to represent coalitions of compounding pharmacies and outsourcing facilities to challenge FDA, state regulators, or other regulatory bodies on critical issues defining the industry.

A recognized national authority, Rachael is the leading health care partner in our Chambers-ranked Illinois Health Care group, and is personally ranked by Chambers USA in Band 1 for the Illinois Healthcare: Pharmaceutical/Medical Products Regulatory category. Clients describe her as "quick to understand and support the perspective of the business, allowing her to help formulate business solutions that fit into the regulatory framework of our industry" and say "[h]er intellect, measured responses, written expertise and work ethic are unsurpassed."