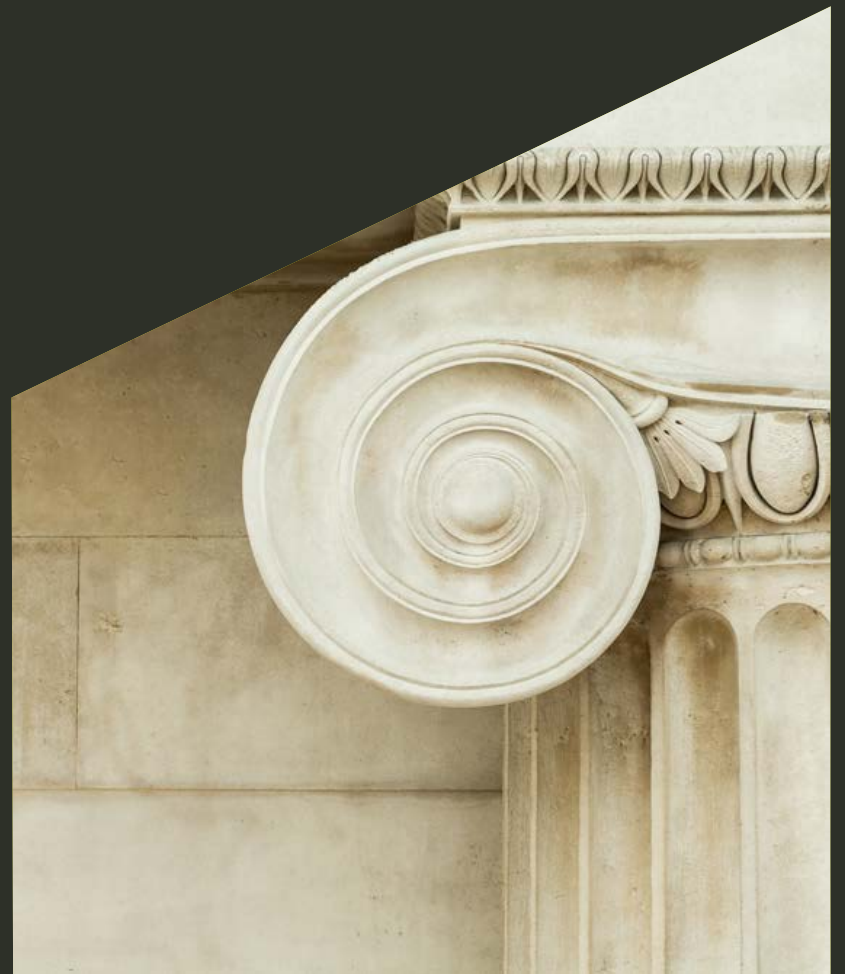
REGULATORY DISPUTES WITH HHS: WHEN TO NEGOTIATE AND WHEN TO LITIGATE

BRIAN J. MALKIN, PARTNER

BRIAN R. STIMSON, PARTNER



McDermott Will & Emery

March 25, 2021

mwe.com

AGENDA

- Legal Framework
- Practical Perspectives
- Case Studies
- The Next Four Years

LEGAL FRAMEWORK

ADMINISTRATIVE PROCEDURE ACT (APA)

- Defines “adjudication” and establishes adjudication process
- Defines “rule” and establishes rulemaking process
- Establishes parameters for hearings for adjudications and rulemakings
- Creates statutory right to judicial review
- Addresses form and venue of proceeding for judicial review
- Defines agency actions subject to review

ADJUDICATION

- "'[O]rder means the whole or part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of any agency in a matter other than rule making but including licensing[.]" 5 U.S.C. § 551(6).
- "'[A]djudication' means agency process for the formulation of an order[.]" 5 U.S.C. § 551(7).
- "The Agency shall give all interested parties opportunity for—
  - (1) the submission and consideration of facts, arguments, offers of settlement, or proposals of adjustment when time, the nature of the proceeding, and the public interest permit; and
  - (2) to the extent that the parties are unable so to determine a controversy by consent, hearing and decision on notice and in accordance with sections 556 and 557 of this title." 5 U.S.C. § 554(c)(1)-(2).

RULEMAKING

- “A ‘rule’ means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency … ” 5 U.S.C. § 551(4).
- “A ‘rulemaking’ means an agency process for formulating, amending, or repealing a rule[.]” 5 U.S.C. § 551(5).
- The notice-and-comment requirement does not apply to “interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice[,]” or when an agency for good cause finds that compliance would be “impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(3)(A)-(B).
- “Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.” 5 U.S.C. § 553(e).

JUDICIAL REVIEW

- "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.
- "Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. *A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action*." 5 U.S.C. § 704 (emphasis added).
- " The reviewing court shall—
  - (1) compel agency action unlawfully withheld or unreasonably delayed; and
  - (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
    - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law …" 5 U.S.C. § 706(1)-(2)(A).

PRACTICAL PERSPECTIVES

ADMINISTRATIVE V. JUDICIAL FORUM

Administrative Forum

- Transparency may vary
- Myriad factors may drive time frame
- Often many stakeholders and interests
- Law, policy, or politics may drive outcome
- Less adversarial with agency

Judicial Forum

- High level of transparency
- The Court drives time frame
- Often fewer stakeholders and interests
- Law, policy, or venue may drive outcome
- More adversarial with agency

ADVOCACY CONSIDERATIONS

- Specific administrative process
- Policy priorities of the Administration
- Institutional interests of federal departments
- Interests of individual political and career personnel
- Long-term institutional relationship
- Likelihood of success

INSTITUTIONS

- The Unitary Executive Branch?
  - White House may disagree with Departments
  - Departments may disagree with their sub-agencies
  - Sub-agencies of Departments may disagree with one another
  - Departments may disagree with one another
- Example: U.S. Food and Drug Administration (FDA) and
  - Executive Office of the President (EOP)
  - U.S. Department of Health and Human Services (HHS)
  - U.S. Department of Justice (DOJ)

INDIVIDUAL DECISION-MAKERS

Political Leadership

- Drive policy change
- Government experience varies
- Length of government service varies
- Serve at pleasure of POTUS
- Incentives

Career Staff

- Implement policy
- More government experience
- Serve across multiple administrations
- Civil service protections
- Incentives

TIPS

- Know the process
- Focus on substance first
- Avoid unnecessary provocation
- Build a record and preserve arguments
- Remember that litigation is not against a private party
- Assess likelihood of success by working backwards from appeal

CASE STUDIES

ADJUDICATION

Facts

- Company seeks FDA approval of Drug B
- FDA issues letter decision concluding that Drug B is not yet eligible for final approval because has not demonstrated clinical superiority to “same drug”
- Company believes that FDA has:
  - Misinterpreted the statute
  - Departed from legal precedent

Considerations

- FDA advocacy
  - Meet with FDA
  - Seek supervisory review
- Strategic decisions
  - File a citizen petition
  - Pursue litigation
- Litigation assessment
  - Chevron I or II
  - Remedy if successful

RULEMAKING

Facts

- HHS/FDA considers citizen petition, and proposes rule on product labeling that would amend interpretation of terms in FDCA
- Company files comments:
  - Disagreeing with views of other stakeholders on underlying science
  - Raising First Amendment concerns
- HHS finalizes rule as proposed

Considerations

- FDA advocacy
  - Petition for reopening rulemaking
- Litigation assessment
  - Chevron I or II
  - Strength of record
  - Remedy if successful
- Congressional engagement

ENFORCEMENT

Facts

- FDA issues compliance guidance related to product manufactured by Company
- FDA issues a warning letter concerning product manufactured by Company
- FDA, however, has not yet taken any further action
- Company asserts that compliance guidance and warning letters misinterpret the law

Considerations

- FDA Advocacy
  - Submit comments on guidance
  - Meet with FDA / Seek supervisory review
- Litigation Assessment
  - Article III standing
  - Final agency action
  - Venue

THE NEXT FOUR YEARS

POLICY CHANGES

- Recent drug pricing litigation raises policymaking questions
  - MFN IFR, Rebate Rule, Drug Importation Rule
- The Executive Branch may change policies if it:
  - States good grounds and considers reliance interests
  - Follows the appropriate process when doing so
- Policy changes may prompt litigation

ADDITIONAL INTEREST AREAS

- COVID-19 product-related challenges
- Product exclusivity challenges
- Food labeling/traceability
- Cannabis
- Tobacco

SPEAKERS

BRIAN J. MALKIN

Partner
McDermott Will & Emery
+1 202 756 8045 | bmalkin@mwe.com

NAME

Partner
McDermott Will & Emery
+1 202 756 8477 | bstimson@mwe.com

THANK YOU / QUESTIONS?

mwe.com