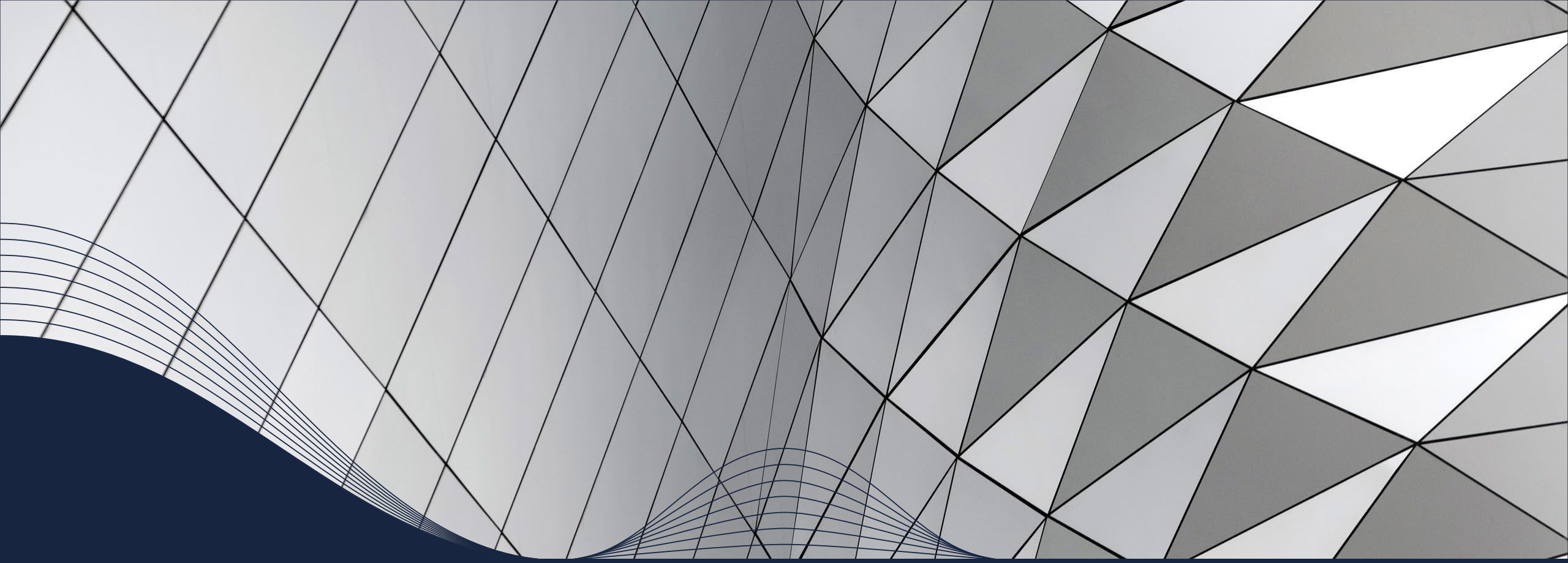

Regulatory Advocacy at the Local, State & Federal Levels

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Agenda

- Current regulatory environment
- Impact of *Loper Bright* decision
- Maximizing public policy efforts

Overview of Federal Regulatory Authority

Separation of powers between federal branches: legislative, executive, and judicial

- Legislative branch can grant some powers to administrative agencies
- Congress must establish an “intelligible principle” to govern the delegation

Federal Executive Agencies authority established by Congress

- Statutory language is not always precise
- Agencies endeavor to interpret statutory ambiguity by issuing regulations
- *Administrative Procedure Act of 1946 (APA)* governs the process by which federal agencies propose and establish regulations
  - Prohibits arbitrary and capricious agency action
  - Grants U.S. federal courts oversight over agency actions

Current Regulatory Environment

- Congress:
  - Majority highly deferential to administration
  - Will need to be more precise in legislative wording
- Trump Administration:
  - Shrink the executive agencies
  - Decrease regulations to remove barriers
  - Numerous federal Executive Orders and Actions
- Courts:
  - Less deferential to agency decisions
- States and Localities:
  - Increasingly active
  - Creating patchwork of regulatory requirements

Key Executive Orders and Actions

- The Trump Administration has issued more than 120 Executive Orders (EOs) and Actions since taking office on January 20, 2025.
- Key Executive Orders and Actions impacting the regulatory process:
  - Establishing And Implementing The President's "Department Of Government Efficiency“ (DOGE)
  - Imposing a hiring freeze (through July 15, 2025)and facilitating the firing of current federal employees in multiple agencies
  - Unleashing Prosperity through Deregulation including an initial regulatory freeze and requiring the elimination of 10 regulations or guidance documents prior to issuing new regulations.
  - Directing the Repeal of Unlawful Regulations without notice and comment rulemaking
  - Deregulation Suggestions Website to submit ideas on cutting existing regulations
- Numerous Executive Orders and Actions impacting industry
  - Broad: e.g., tariffs, AI, science/technology, federal procurement, DEI
  - Sector specific: e.g., energy, seafood, pharmaceuticals, steel, aviation

Supreme Court's *Loper Bright* Decision

- Under the doctrine established in *Chevron v. Natural Resources Defense Council* (1984), courts deferred to agency interpretations of ambiguous provisions in the statutes they administer.
  - The doctrine known as "*Chevron* deference" was triggered when a court would find ambiguity or silence in statute.
- With the rulings in *Loper Bright Enterprises v. Raimondo,* and *Relentless, Inc. v. Department of Commerce, Chevron* deference is now gone. As a result, courts must supply the interpretation of ambiguous statutory provisions, even where technical and scientific expertise may be implicated.
- One result of the elimination of *Chevron* deference, at least initially, will likely be heightened uncertainty regarding the legality of agency regulations. Another result is likely to be greater clarity and specificity from Congress in the statutes it enacts, since it can no longer assume accompanying rules will enjoy a presumption of validity.

Supreme Court's *Loper Bright* Decision (Cont'd)

- *Loper Bright* established a new framework for judicial review:
  - The "best reading" of each statute is the "one the court, after applying all relevant interpretative tools, concludes is best."
  - The Court held that "agencies have no special competence in resolving statutory ambiguities," but "[c]ourts do," even if it "happens to implicate a technical matter."
  - The Court rejected the "presumption" that ambiguity should be assumed to be a delegation of authority to the agency.
- Regulatory advocacy must account for this shift in responsibility.
- Bottom line: Successful regulatory strategies must account for the fact that an agency's reasonable interpretations of statutes set forth by regulation will no longer be granted a presumptive pass.

Implications of *Loper Bright* for Branches of Government

Executive (Agencies)

- Defend more litigation
- Increases likelihood of success of those challenging federal regulations
- Will limit agencies' ability to fill gaps in the law or address situations not expressly addressed by Congress
- Agencies may proceed more cautiously and narrowly in adopting regulations
- Will spend more time and resources to provide justification for decisions

Courts

- Shifts responsibility for interpreting statutes from the executive to the judicial branch
- A legislative strategy to complement regulatory strategies allows for more certainty.
- Courts charged with interpreting ambiguous statutory provisions, even where technical and scientific expertise may be implicated
  - Questions are likely to arise as to courts' capacity to adeptly interpret the law in specialized, scientific areas, absent clear and specific congressional direction

More on Congressional Implications

Congress

- *Loper Bright* places pressure on Congress to legislate with greater specificity
- Will have to employ processes to obtain greater expertise—heretofore, subject matter experts were primarily the domain of regulatory agencies.
- Bipartisan compromise and dealmaking becomes more important to regulatory implementation.
- Where legislative specificity proves politically impossible, Congress must take stronger consideration of prevailing judicial doctrines in how legislation is drafted, which in turn impacts regulatory implementation—this necessitates incorporating early legislative engagement to a successful regulatory strategy.

States

- Void in federal policy making will create more opportunity and room for states to advance their own regulatory initiatives
- State courts that previously adopted *Chevron*-like deference may reverse track and reach a *Loper Bright*-like decision rejecting deference to state agencies

Legislation Impacts Regulation More Than Ever

Textual ambiguity is now an issue for the courts

- As bills make their way through Congress, they are often stripped of specific language to keep sponsors from dropping off and different ideological and partisan interests from opposing.
- Legislators also often put ambiguous language in health legislation, counting on technical experts at regulatory agencies to interpret them properly.
  - The term “to the extent practicable” appears seventeen times in the Affordable Care Act. The qualifier “as possible” appears three times.
  - The Food, Drug, and Cosmetic Act requires applicants to provide “substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.” Under *Chevron*, courts deferred to the FDA’s interpretation of this provision—now they need not do so.
- Everything from drug negotiation provisions provided for in the Inflation Reduction Act to patient cost sharing limits in the Affordable Care Act is up for potential review by the courts.
- Congress can expressly delegate ***some*** powers to agencies to interpret statutes, but will they?

Regulatory Strategy in a Post-*Chevron* World

Agency rules no longer enjoy sweeping deference

- *Loper Bright* limits executive agencies' ability to fill gaps in the laws or to address situations not expressly anticipated by Congress, potentially leading agencies to proceed more cautiously and narrowly in adopting certain regulations.
- Under *Chevron*, a "permissible" agency interpretation of the statute was enough to confer deference. Now under *Loper Bright*, agencies utilize the "best reading."
- Contentious legislation has yielded contentious implementation.
  - Since the enactment of the Affordable Care Act (ACA) in 2010, more than 2,000 legal challenges have been filed in state and federal courts contesting the ACA.
  - ACA drug negotiations: limits on patient cost sharing, including patient assistance programs.
  - Stark & anti-kickback laws: what constitutes safe harbor?
- FDA often relies on guidances to establish agency policy—will other agencies do likewise?
- Jurisdiction and authority to regulate health products ranging from dietary supplements to laboratory-developed tests could shift from FDA to the courts.

Best Practice for Influencing Regulations

- May be less opportunity in this administration
- Stay informed about potential opportunities
- Participate in:
  - Public meetings
  - Requests for information
  - Notice and comment rulemaking:
    - Provide substantive information and data
- Meet with regulators to educate before and during the process to:
  - Educate
  - Propose solutions
  - Understand regulatory obstacles
  - Be prepared:
    - Research participants
    - Propose an agenda
    - Prepare presentation and provide in advance
  - Records of meetings may be made public through the Freedom on Information Act

Federal Advisory Committee Act (FACA) Restrictions

Take care not to trigger FACA

- FACA is a federal law that guides the establishment, operation, and termination of advisory committees
- FACA is intended to promote transparency and accountability to federal agencies
- Triggered when a "group" created by, or at the direction of a federal official, provides advice or recommendations to a federal agency
  - Group = 2+ individuals who are not full-time or permanent part-time federal employees who provide consensus opinion to the agency
  - Does not preclude a group meeting to provide individual opinions
- When triggered, a federal advisory committee must all FACA requirements, including:
  - Notice of meetings
  - Maintenance of public records
  - Conflict of interest requirements

Thank you