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Making Sense of the New Landscape for Health Policy After Recent Supreme Court Decisions

A series of recent Supreme Court decisions has reshaped the regulatory landscape, further shifting power away from the executive and legislative branches to the judiciary branch. Taken together, the decisions intensify an ongoing trend of lawsuits challenging administrative agency actions. These rulings are expected to lead to a dramatic increase in litigation, which will make it even harder for agencies to regulate. The tumultuous policy environment will likely create uncertainty among industry, which may complicate business decisions.

Congress can help mitigate these effects by passing more prescriptive legislation that explicitly gives agencies deference in certain circumstances, however, there are still outstanding questions around the language lawmakers must use to protect against legal challenges and misinterpretation. The potential lame duck health care package could be the first meaningful test for Congress to legislate without *Chevron* deference, i.e., judicial deference to agency interpretations of ambiguous statutes. The Lower Costs, More Transparency Act (H.R. 5378) is a prime candidate for inclusion in such a package, passing the House with a large bipartisan majority (320-71). It is unclear if the bill requires more specificity to avoid potential legal challenges, but House lawmakers are unlikely to revisit it, particularly given the long list of issues Congress still needs to address before the end of the year.

Overview of Recent Decisions

Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce

The Supreme Court jointly decided two cases that relied on *Chevron* deference, striking down the 40-year-old doctrine and asserting that it should never have been used to begin with. While the opinion states that it does not call into question prior cases that relied on the *Chevron* framework, the Court's *Corner Post* decision (see details below) opens long-finalized regulations to new legal challenges. Moving forward, deference to federal agencies will now be permitted only on factual determinations and technical judgments when Congress has expressly delegated authority. This means that any statutory interpretation will be left to the courts to determine "the single, best meaning."

- Implications for Health Policy: Policies not explicitly detailed in statute are at risk in a post-*Chevron* world. This includes an array of regulations stemming from the Affordable Care Act such as those implementing the coverage of preventive health services as well as technical changes to risk adjustment and network adequacy standards for the individual market, or annual policies defining Medicare rates and reimbursement limits, services, and coverage determinations. Within this broader context, there are several types of policy that may be particularly ripe for litigation, including:

    1. Policies already facing legal challenges, such as the reliance on, and calculation of, the Qualified Payment Amount (QPA) in the implementing regulations for the No Surprises Act;

2. Policies that change from one administration to the next like the regulations governing short-term limited duration (STLD) health plans and prohibiting discrimination in health care; and
3. Agency actions in response to executive orders like the nursing home staffing rule.

In each of the above scenarios the agency's position has been made weaker with the overturning of *Chevron*.

Corner Post, Inc. v. Board of Governors of the Federal Reserve System

The decision in this case significantly expands opportunities to bring challenges under the Administrative Procedures Act. Specifically, it changes the period in which plaintiffs can challenge agency action, allowing entities to bring a lawsuit for six years after being injured even if more than six years have passed since the Federal regulation took effect. Meaning, entities formed within the last six years can challenge long-standing regulations.

- Implications for Health Policy: This decision opens the door to challenging longstanding agency policies that have been presumed relatively safe from judicial review. For example, the decision could bolster arguments in an ongoing challenge to reverse the Food and Drug Administration's 2000 approval of mifepristone, also known as the abortion pill.

Securities and Exchange Commission v. Jarkesy

In this case, the Supreme Court determined that defendants facing civil monetary penalties (CMPs) from the U.S. Securities and Exchange Commission (SEC) have a right to a jury trial under the Seventh Amendment. Previously, it was understood that Federal agencies could both enforce and resolve penalty proceedings administratively, without the need for protracted litigation in Federal Courts. According to concurring opinions by Justices Gorsuch and Thomas, the administrative procedures *Jarkesy* faced in the underlying SEC administrative proceeding lacked "many of the procedural protections our courts supply in cases where a person's life, liberty, or property is at stake."

- Implications for Health Policy: The Department of Health and Human Services' (HHS') administrative proceedings similarly do not provide defendants with the procedural protections they enjoy under the rules that govern the introduction of evidence at civil trials in Federal trial courts. The decision in *Jarkesy* casts doubt on HHS' ability to continue to rely on these administrative procedures. Considering the ruling, health care and life sciences companies facing the potential for CMPs imposed by HHS may decide to challenge the agency's ability to seek compensation through these means in lieu of a trial by jury.

What to Expect Moving Forward

Judiciary

Collectively, the Supreme Court's decisions this term invite many more legal challenges to agency regulations, both past and present, for "injured" entities. Policymaking through the judiciary will result in slower resolution of issues and increased uncertainty around regulations as legal challenges play out. Further, the overturning of Chevron deference will likely reduce the probability that a court will find in favor of an agency in a regulatory dispute. An analysis of cases where Chevron was referenced in a published opinion found that agency interpretations were significantly more likely to prevail under *Chevron* (77.4%) than *Skidmore* (56.0%) or a de novo review (38.5%). Similarly, for CMPs, different verdicts may be reached in a jury trial as opposed to one with an administrative law judge.

As mentioned above, Courts may shift towards citing Skidmore Doctrine in their decisions. This approach affords deference to an agency's interpretation only if the agency's technical or scientific expertise on the matter is persuasive to the court. It is important to note, however, that when relying on *Skidmore*, there is nothing that would compel the court to side with an agency.

Courts will likely need more technical assistance to understand the policies they are adjudicating. It is not yet clear what that will entail, but amicus briefs may hold more weight in informing opinions and judges may seek informal education through seminars or other means.

Congress

The overturning of Chevron puts more pressure on Congress to pass much more detailed legislation to ensure policies are enacted as intended and are not held up in litigation or misinterpreted in future court cases. Congress may delegate authority to HHS through legislation, but it must be explicit about what that entails as the current Supreme Court has made clear that it will look only to the statute and will not consider other contextual information, such as legislative history, in its decisions. There are still open questions about how Congress can ensure the language it uses is sufficiently specific in granting agencies power.

The need for specificity could make it more difficult for Congress to address policy issues as legislation will be more complicated, take longer to draft, and consensus may be harder to reach on details. Congress may also have to revisit "old" issues to address litigation, limiting action on new priorities. For example, the No Surprises Act, a law that passed with bipartisan support, continues to face implementation hurdles. In a letter to HHS after *Chevron* was overturned, Senator Cassidy asked the Department to respond to several questions about the QPA, which has been the subject of multiple lawsuits.

Senator Cassidy also asked HHS to respond to requests for Congressional technical assistance and policy briefings. Like the courts, Congressional staff will need more support and a detailed understanding of policy issues to be able to effectively write legislation that accomplishes what is intended and meets new judicial standards.

Administration

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Both parties benefited from *Chevron* when in power, for example, the Trump Administration used the flexibility granted under *Chevron* deference to expand STLDs and the Biden Administration used that same flexibility to limit them. Overturning *Chevron* restricts the ability of any administration to change interpretations of policy over time, resulting in greater stability on contentious issues but also limiting the ability to act in response to future changes in understanding. This means agencies may be less willing to engage in policymaking to address stakeholder concerns going forward, depending on the policy.

While Chevron may have helped both Democrats and Republicans pursue their agenda when in control of the executive branch, the overturning of *Chevron* is arguably more helpful to a potential second Trump Administration than a Biden Administration, as policies which seeks to deregulate or minimally regulate would generally not require deference to the agencies. A second Biden Administration would have a harder time making proactive regulatory changes through innovative interpretations of Federal law that advance its goals, such as lowering health costs, without a direct mandate from Congress. Ongoing legal challenges from President Biden's first term will likely hamper efforts as well.

Regardless of who is in power, the regulatory process will slow down as agencies divert resources to prevent and defend against more frequent legal challenges and take time to ensure decisions are positioned as findings of fact rather than interpretations of law. Regulators are also likely to shy away from taking bold action or making dramatic shifts in policy and may instead issue non-binding guidance. Ultimately, more litigation means that some regulations may not take effect in a timely manner or ever, increasing uncertainty for stakeholders.

States

States have their own administrative law regime, so while there will be no uniform result or immediate impact at the State level, State Courts may begin to follow the Supreme Court's lead. Additionally, Federal statutory law which delegates some portions to States to implement, such as elements of the No Surprises Act, could be at risk as State agencies are also unlikely to be granted deference post-*Chevron*.