CAPITOL STREET

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SCOTUS Chevron Decision Impacts Healthcare

Lawsuits to Abound as Agencies (FDA, CMS, NIH) Face Scrutiny

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Today, the Supreme Court overturned the Chevron framework (here). The decision focuses on the role of the federal courts to independently review agency actions consistent with the Administrative Procedure Act. Agency interpretations of federal laws will *not* be entitled to deference moving forward. Now, courts will have significantly greater authority in reviewing and challenging policy choices made by federal agencies, which impacts the ability of CMS, FDA, NIH to enact executive policymaking (particularly under Executive Orders). Ongoing regulatory work that may be impacted includes CMS Drug Negotiation program, various value-based care (VBC) initiatives, FDA oversight of laboratory developed tests (LDTs), and CMS nursing home staffing mandates.

Key Points

Now What?

- **"Negotiated rule making" is a likely result**. As a reminder, negotiated rule making, formalized by Congress in 1990 with the passage of the Negotiated Rulemaking Act (NRA) to supplement the APA, involves stakeholders in agencies' rulemaking process (usually in the drafting of proposed rules text), which can foster stakeholder buy-in -- leading to easier implementation & less litigation once rules are finalized. Its use has waned, although Congress has enacted specific requirements for some agencies, i.e. the HHS under the ACA for several provisions (42 U.S.C. §254b), to use negotiated rule making. Agencies like CMS may begin to turn back to negotiated rulemaking to protect regulations from an onslaught of litigation.

- **FDA drug/device/biologic decision making could be at risk**. During oral arguments, Justice Kagan noted the overhang that would remain over the FDA's ability to approve and regulate products if Chevron is overruled. With Chevron overruled, there is an increased risk for FDA regulatory guidances to be open to litigation challenges. The FDA has seen several recent court challenges to policies, including their approval of mifepristone (SC decision here), their regulations on laboratory developed tests (complaint

here), and their authority to issue a consumer update via social media (lawsuit here).

- **The decision opens the door for yearly CMS payment challenges.** As a reminder, CMS engages in rulemaking every year to set payment rates for covered healthcare services including MA plans, hospitals, home health, dialysis, rehab hospitals, and skilled nursing facilities (SNF). With payment rules, the agency often dictates reimbursement. The weakening of agency authority could lead to yearly litigation on final CMS payment rules, particularly from sectors that may see annual cuts, e.g. MA, home health, physicians.

- **Ongoing Medicare drug negotiation litigation is likely to be impacted**. As a reminder, CMS took major interpretations of the IRA through their guidance of grouping different products together under different NDAs as a Qualifying Single Source drug and through implementing a Bona Fide marketing requirement for generics and biosimilars. Both AZN and NVO lawsuits contend that CMS had no authority to group different products together under different NDAs. These arguments will likely hold more weight with the overturning of Chevron, increasing manufacturer odds of the desired split decisions.

- **New march-in guidance could be challenged**. In December 2023, the Department of Commerce (DOC) released draft guidance on how the agencies should determine when to exercise march-in rights across agencies. Key to the guidance is the inclusion of price and availability as a new criterion for march-in for therapies. This change in stance by the agency has been another headwind for the biopharma sector, and we may see litigation upon finalization.

The highest court in the land today ruled to overturn Chevron in a 6-3 majority decision. The majority opinion highlighted the role of the courts in exercising independent judgement and stated that the deference Chevron requires of courts reviewing agency action cannot be squared with the APA. As a result, the Justices found that courts may not defer to agency interpretations in their oversight of their policies, even if the law is ambiguous.

Past cases that used the Chevron framework are not invalidated. But without deference given to agencies under Chevron, agencies will likely soon face a slew of litigation. Medicare/Medicaid reimbursements rates and coverage determinations, FDA decisions, and ACA insurance regulations -- all of which rely on Chevron deference -- may soon face challenges due to the increased odds of agency decisions to be vacated.

Under Chevron, courts have previously deferred to expert federal agencies' interpretation of the laws, provided their reading is reasonable. This allowed the agencies significant flexibility in implementing legislation in utilizing their subject matter expertise to guide regulations.

CMS has relied on Chevron for upholding regulations in the past. Some instances include *Baptist Memorial Hospital v. Azar* (here), when Chevron was applied to uphold a Medicaid rule clarifying that hospitals' "cost incurred" for purpose of calculating disproportionate share hospital (DSH) payments are net payments from third parties, and *Resident Councils of Washington v. Leavitt*, when Chevron was applied to uphold a rule clarifying that the provision of feeding assistance to nursing home patients without complicated feeding problems did not constitute the provision of nursing services.

The decision impacts the ability of all agencies to enact federal regulations. The cases under review involved a challenge to a federal regulation that requires herring fishing boat operators to pay for third-party private observers to conduct federally required compliance checks. Previously, lower courts found that the agency regulations were reasonable under Chevron precedent. But now, the odds of an agency rule being vacated increases.

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