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Deference No More: More Suits Against US FDA Coming After High Court Tosses Chevron Doctrine?

by Sue Sutter

The Supreme Court's 6-3 ruling is expected to have a minimal impact on drug approvals and other scientific determinations, but matters steeped in the interpretation of regulation and statute, such as marketing exclusivity, could face a heightened risk of challenge, legal experts say.

The US Supreme Court's elimination of the *Chevron* doctrine of judicial deference is expected to invite more legal challenges to US Food and Drug Administration decisions based primarily on interpretations of regulation or statute, but have less impact on the agency's scientific determinations, such as drug reviews.

However, the agency will spend more time thoroughly documenting decisions, such as those involving marketing exclusivity, and may need congressional clarity of its ability to interpret ambiguous statutory terms, legal experts said.

In a 6-3 *decision* announced 28 June, the Supreme Court overruled the doctrine of judicial deference to a "permissible" agency interpretation of a statute that is ambiguous. The doctrine was established in a 1984 case, *Chevron v. Natural Resources Defense Council*.

"*Chevron* is overruled," Chief Justice John Roberts wrote for the majority. The Administrative Procedure Act requires

Key Takeaways

- The Supreme Court overturned the *Chevron* doctrine, which allowed courts to award deference to federal agency decisions that are a permissible interpretation of an ambiguous statute.

courts to exercise their independent judgment in deciding whether an agency has acted within its statutory authority, he said. "But courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous."

- The move is expected to result in more lawsuits against FDA decisions that are based on interpretations of statute or regulation, such as marketing exclusivity awards.
- The agency may consider seeking explicit authority from Congress to interpret ambiguous statutory terms.

The court's ruling came in a pair of cases challenging a rule issued by the National Marine Fisheries Service. The court heard oral arguments in January and was widely expected to either significantly narrow the doctrine or eliminate it entirely. (Also see "*FDA's Califf Is 'Very Worried' About Judges Overruling Agency Decisions*" - Pink Sheet, 25 Jan, 2024.)

Removing The Thumb From The Scale

The high court's decision "left no uncertainty as to where *Chevron* stands. It very explicitly overturned *Chevron*," Stephanie Webster, a partner at Ropes and Gray in Washington DC, said in an interview. "There was a lot of conjecture about how far the court would go and it went all the way."

"All agencies, including the FDA, are going to probably be more focused on litigation prospects as they are making decisions," Webster said. Under *Chevron* "the thumb used to be on the scale in favor of the government."

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"While government views will certainly be informative to the court, and the court has made clear that even under its new decision it's still going to consider the agency views on matters, it's going to be more difficult for the government to prevail in actions challenging its decision-making," she said.

Gerald Masoudi, a partner at Covington and Burling in Washington DC and former FDA chief counsel, said the decision "dramatically changes the balance of power between courts and administrative agencies in deciding what Congress means."

"Even though FDA has not relied on *Chevron* deference regularly in its rulemakings, the agency has engaged in rulemaking knowing that *Chevron* can serve as backstop even when the agency does not expressly rely on it," Masoudi said.

On highly technical issues, courts may as a practical matter still defer to the FDA's views, although such deference is not automatic, Masoudi said. "These decisions on the *Chevron* doctrine will not affect FDA's case-by-case decisions on scientific issues, like product approvals. But rules underlying these processes may be open to broader challenge."

Experts pointed to the recent final rule on lab-developed tests, which already is facing a court challenge, as an example of regulation potentially at risk in the absence of *Chevron* deference.

Taking Aim At Exclusivity Decisions

Chad Landmon, a partner at Axinn, Veltrop and Harkrider in Hartford, CT, said the high court's decision is likely to create a flood of litigation against the FDA and other federal agencies.

"This will likely slow down agency decision-making generally and may slow down policy shifts between administrations," he said.

FDA decisions that are heavily premised on interpretation of the statute or regulations will be more susceptible to challenges, Landmon predicted.

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"For example, their decisions as to various marketing exclusivities, such as orphan drug, 180-day exclusivity, and other exclusivities will likely be subject to closer court scrutiny," he said. "It remains to be seen how courts will treat FDA decisions grounded in scientific evaluations, such as conclusions about safety and efficacy. We will likely need to wait to see how that plays out over the coming months and years before the lower courts."

Although the majority opinion appears to have left deference intact for the FDA's scientific decision-marking, "it can be very hard to disaggregate questions of law from questions of fact in the FDA world," Eva Temkin, a partner at Arnold and Porter in Washington DC and former FDA associate chief counsel, said in an interview.

Over the decades the FDA has undertaken a lot of big, complicated issues through regulation, Temkin said, such as good manufacturing practice requirements, labeling and exclusivity.

This is "not to say that they'll necessarily get overturned," she said. "I don't think that this is a race to the courthouse in which we will see all of FDA's regulations toppled. I do think we might see more challenges to some programs that exist largely in regulation."

Temkin was among several experts who predicted the agency would move further away from rulemaking in favor of guidance.

"As a practical matter FDA will pivot to doing almost everything in guidance," Temkin said. "They already almost do everything in guidance, and lately they've been doing things in memos that don't even look like guidance … Rulemaking is a big undertaking, and without the incentive of deference I worry that that will go away."

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Stacy Cline Amin, a partner at Morrison Foerster in Washington DC and a former FDA chief counsel, said the agency will have to divert a lot more resources into how it documents its decisions, including decision memos that take a lot of time and effort, going forward. (Also see "*What Will FDA Do If Supreme Court Curtails Chevron Deference?*" - Pink Sheet, 22 May, 2023.)

Amin and other experts also suggested the FDA seek congressional assistance to clarify its authority.

If Amin were still chief counsel, "I would be advising the commissioner to be working closely with Congress to get explicit authority to interpret ambiguous terms," she said in an interview.

Courts Should Handle Statutory Questions …

In the majority opinion, Chief Justice Roberts said *Chevron* cannot be reconciled with the APA by presuming statutory ambiguities are implicit delegations to agencies. Furthermore, "*Chevron*'s presumption is misguided because agencies have no special competence in resolving statutory ambiguities. Courts do."

The court acknowledged the government's argument that Congress must generally intend for agencies to resolve statutory ambiguities because they have subject matter expertise regarding the statutes they administer, deferring to agencies promotes uniform construction of federal law, and resolving statutory ambiguities can involve policy-making best left to political actors, rather than courts.

"But none of these considerations justifies *Chevron*'s sweeping presumption of congressional intent," Roberts wrote.

"Even when an ambiguity happens to implicate a technical matter, it does not follow that Congress has taken the power to authoritatively interpret the statute from the courts and given it to the agency," the opinion states. "Congress expects courts to handle technical statutory questions."

> ***By leaving Chevron behind, "we do not call into question prior cases that relied on the Chevron framework. The holdings of those cases that specific agency actions are lawful … are still subject to statutory stare decisis despite our change in interpretive methodology." – Chief Justice John Roberts***

The high court has not deferred to any agency interpretation under *Chevron* since 2016, Roberts said.

"But *Chevron* remains on the books," he said. "So litigants must continue to wrestle with it. And lower courts, bound by even our crumbling precedents … understandably continue to apply it."

Notably, the majority sought to limit its decision to prospective application, closing off the possibility of retrospective readjudication.

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framework," the majority said. "The holdings of those cases that specific agency actions are lawful, including the Clean Air Act holding of *Chevron* itself, are still subject to statutory *stare decisis* despite our change in interpretive methodology."

Associate Justices Clarence Thomas, Samuel Alito, Neil Gorsuch, and Amy Coney Barrett joined in the majority opinion, with Thomas and Gorsuch filing separate concurring opinions.

… But Judges Lack Agencies' Scientific Expertise

In a dissenting opinion, Associate Justice Elena Kagan highlighted the impact that the majority's opinion will have on scientific agencies such as the FDA.

The *Chevron* doctrine "has formed the backdrop against which Congress, courts, and agencies, as well as regulated parties and the public, all have operated for decades," Kagan wrote. "It has been applied in thousands of judicial decisions. It has become part of the warp and woof of modern government, supporting regulatory efforts of all kinds – to name a few, keeping air and water clean, food and drugs safe, and financial markets honest."

Some interpretive issues arising in the regulatory context involve scientific or technical subject matter, the dissent states.

"Agencies have expertise in those areas, courts do not," Kagan wrote. "Some demand a detailed understanding of complex and interdependent regulatory programs. Agencies know those programs inside-out, again, courts do not."

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Kagan cited a 2020 US District Court decision in a *Teva Pharmaceutical Industries Ltd.* lawsuit challenging the FDA's regulation of Copaxone (glatiramer) as a drug under the Food and Drug Cosmetic Act as an example of a "typical *Chevron* question." (Also see "*Copaxone Legal Fight May Finally Be Over As Court Finds The MS Treatment Is Not A Biologic*" - Pink Sheet, 5 Jan, 2021.)

"Agencies often know things about a statute's subject matter that courts could not hope to," the dissent states. "The point is especially stark when the statute is of a 'scientific or technical

nature.' Agencies are staffed with 'experts in the field' who can bring their training and knowledge to bear on open statutory questions."

She again referenced the Teva lawsuit related to the Biologics Price Competition and Innovation Act's transition provisions.

"When does an alpha amino acid polymer qualify as a 'protein'?" Kagan asked in the dissent. "I don't know many judges who would feel confident resolving that issue. (First question: What even is an alpha amino acid polymer?) But the FDA likely has scores of scientists on staff who can think intelligently about it, maybe collaborate with each other on its finer points, and arrive at a sensible answer."

"At its core, *Chevron* is about respecting that allocation of responsibility, the conferral of primary authority over regulatory matters to agencies, not courts," she wrote.

Associate Justice Sonia Sotomayor joined in the dissenting opinion. Associate Justice Ketanji Brown Jackson joined in the dissent as it related to one of the cases, and took no part in the decision on the other case.

Boon Or Bust For Industry?

As the Supreme Court and lower courts increasingly have eschewed *Chevron* in recent years, it has been widely asserted that eliminating the doctrine would be an advantage for life sciences companies, who would find it easier to challenge the FDA's decision-making.

However, the absence of deference could have a destabilizing effect on the regulatory paradigm that supports investment decisions made years in advance, experts said. Furthermore, the absence of *Chevron* deference also could lead to court-by-court differences in rulings on similar lawsuits against the agency.

"This creates more uncertainty for regulated industry, but also more opportunities for companies that feel like they have been wronged by an agency decision," Landmon said.

"You'll have the opportunity to sue on a decision that you don't like and may have a better chance of winning," Amin said. "The flip side of that is that having deference for agency rulemaking provides a more reliable, uniform, regulatory regime that companies can make investment decisions based around."

"Like many, we are cautiously watching what this decision will mean to future litigation and regulatory decision-making," the Biotechnology Innovation Organization said in a statement.