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Does SCOTUS Chevron Decision Tip The Scales In Favor Of Industry?

by Brian Bossetta

With the reversal of the *Chevron* doctrine in June, lower courts will now have more say in deciding regulatory statutes when the language is murky. But will that open the door to more legal challenges from the healthcare industry against government regulations it finds unfavorable? A pair of legal experts recently discussed the potential implications of the Court's decision.

During a recent webinar hosted by the Washington Legal Foundation, partners Brenna Jenny and Sean Griffin of law firm Sidley Austin discussed the Supreme Court's 6-3 ruling in *Loper Bright Enterprises et al. v. Raimondo et al.* — which overturned a 40-year legal precedent that favored US regulators.

The *Chevron* doctrine was established in the 1984 case, *Chevron v. Natural Resources Defense Counsel, Inc.*, in which the Supreme Court handed down a landmark decision giving US agencies the final say in gray areas concerning regulatory matters.

Specifically, the 1984 decision created a two-step framework for judicial review of agency interpretations of statute. It first required courts to determine if the language was clear. If so, courts had to apply that language. If unclear, then the second step was to defer to the agency's reading.

Now, under the new *Loper Bright* doctrine, as penned for the majority by Chief Justice John Roberts, the courts "must exercise their independent judgment in deciding whether an agency has acted within its statutory authority" under the federal Administrative Procedure Act (APA).

"*Chevron* insists on more than the 'respect' historically given to executive branch

interpretations; it demands that courts mechanically afford binding deference to agency interpretations, including those that have been inconsistent over time," Roberts wrote.

As Griffin and Jenny explained, in deciding *Loper Bright*, the conservative majority found that the deference previously afforded to administrative agencies under *Chevron* is inconsistent with the APA, which tasks federal courts with interpreting constitutional and statutory provisions and determining "the meaning or applicability of the terms of an agency action."

This is why the Court's ruling could have significant implications on the healthcare industry as well as the Department of Health and Human Services (HHS), the industry's chief regulatory body. With the *Chevron* precedent gone, US agencies will no longer receive the benefit of the doubt when statutory language is unclear, which removes one potential barrier from industry prevailing in lawsuits against the government.

But the question as to whether industry will become more trigger-happy in filing lawsuits now that barrier is removed remains an open one.

To Be (a device) Or Not To Be. That's The Legal Question

By Brian Bossetta

08 May 2024

Now that the US FDA has published its final rule regulating lab developed tests, litigation challenging the rule and the FDA's authority to enact it is sure to follow. And the central argument will likely focus on whether the tests are defined as medical devices, which the agency regulates without question.

Read the full article here

One area in which that question could be answered, however, concerns the Food and Drug Administration's final rule on lab-developed tests, or LDTs. The rule phases out the FDA's general enforcement discretion of LDTs over four years, placing them under the same regulatory purview as other in vitro diagnostics (IVDs) by classifying them as medical devices. (Also see "*It's Official: FDA Drops Final Rule On LDTs*" - Medtech Insight, 29 Apr, 2024.)

And there's the rub.

While the FDA says the tests are devices, opponents say no.

So based on the *Chevron* principle, the courts would defer to the FDA's interpretation. Case closed. But with *Loper Bright*, the Court has now turned that on its head.

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> *"Chevron's presumption is misguided because agencies have no special competence in resolving statutory ambiguities. Courts do."*
> *— Chief Justice John Roberts*

As Griffin explained, the conservative majority based their *Chevron* ruling primarily on APA text that governs cases brought against federal agencies directly and is broadly applicable.

"In the APA there's a review provision that specifically says that the court shall decide all relevant questions of law and interpret statutory provisions," Griffin said, adding the Court basically ruled that lower courts must step in when language is not clear.

"The majority essentially said to the courts, 'It's your job to decide, even if you think that statute is ambiguous,'" he said. "The courts have to pick which [interpretation] is correct. They can't just stop and say the agency wins because it's close enough."

Further complicating matters for the FDA potentially is the Court's majority finding the *Chevron* doctrine "misguided because agencies have no special competence in resolving statutory ambiguities" — even concerning "technical" matters.

For example, courts can call on subject matter experts in deciding technical questions, as Griffin noted. However, courts will determine which interpretation of a vague statute is right even after weighing input from industry or government experts.

So, does this mean a chemist's testimony that LDTs are not medical devices and therefore outside the FDA's jurisdiction could sway a court? Perhaps.

But Michael Werner, a public policy and regulatory attorney with the DC firm Holland & Knight, who spoke to *Medtech Insight* recently about the impact of Chevron, was skeptical.

In Werner's view, the definition of what constitutes a medical device under federal law is not ambiguous at all, rendering the argument weak at best. (Also see "*Could SCOTUS Chevron Reversal Reverse FDA's Final Rule On LDTs?*" - Medtech Insight, 30 Jul, 2024.)

However, that does not mean attempts to stop the final rule won't be successful.

Challenges

Prior to *Loper Bright*, the American Clinical Laboratory Association (ACLA), filed a lawsuit

challenging the FDA's rule. In the suit, ACL claimed that LDTs are not devices, but rather clinical services, which the FDA does not have the authority to regulate.

The Association for Molecular Pathology (AMP) also filed a lawsuit to block the rule, arguing that LDTs "are not manufactured, packaged, nor commercially distributed as medical devices."

How, or if, the dynamics of those lawsuits will change due to the Court's *Chevron* reversal remains to be seen.

While the Court overturned the long-standing precedent established by *Chevron*, the ruling did not nullify agency discretion altogether, Griffin noted. In fact, one of the caveats included in the decision was that courts may still consider agency interpretations when those interpretations reflect the agency's technical expertise. So, while an agency's interpretation of a statute may not be binding, it may still be informative.

In other words, while courts are no longer required to defer to agencies when language is unclear, they still may.

What is a Device?

But as Jenny noted, ACLA's position against the FDA may have gotten stronger in light of the Court's decision. That's based, in her view, on language in the complaint which states that LDTs are "a series of processes and tasks undertaken by trained laboratory professionals using instruments and other tools to derive information that may be useful to a treating physician."

She further noted that US law's definition of a device— known as the instrument clause — says a device is "an instrument, apparatus, implement, machine, contrivances, implant, in vitro reagent, or similar or other related article, including any component, part, or accessory."

"The question then becomes whether a series of processes and tasks fits within any of those nouns, running from instrument to article," Jenny said. "And the argument that ACLA and AMP are making in their cases is that no, those nouns all mean physical things."

And this is where, in Jenny's estimation, *Loper Bright* becomes relevant.

She cited past cases, such as *Genus Medical Technologies v. FDA*, in which the question centered around whether barium sulfate — a contrast agent used to examine the esophagus, stomach, and bowels — was a device. In that case, the court said it was uncertain if the chemical could meet the definition of a device.

Following that case, the FDA *sought* public comment regarding whether and how to shift the classification of products that have been uniformly regulated as drugs for decades to medical

devices. The agency also said it intended to regulate products that meet the definitions of both devices and drugs "as devices." (Also see "*Genus Triumphs Over FDA In Barium Sulfate Product Classification Suit*" - Medtech Insight, 21 Apr, 2021.)

In the past, courts have generally been guided by Chevron to default to the agency's interpretation, such as in the *Genus* case, Jenny emphasized.

"Now they can't do that, so at least at that level, one of the ways FDA could have won this fight is gone," she said, "and the plaintiff's position becomes that much stronger."