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FDA's Califf Is 'Very Worried' About Judges Overruling Agency Decisions

by Brenda Sandburg

Commissioner says more judges have recently stepped in and 'acted like they were FDA.' Concern is heightened as Supreme Court is to rule on whether to overturn or limit *Chevron* deference to agency decisions.

The US Food and Drug Administration is routinely sued by companies who object to its decisions, but Commissioner Robert Califf is concerned that judges are now more willing to overrule FDA's scientific judgements.

Califf commented on the change in FDA's position before the courts during a recent Healthcare Unfiltered podcast focused on the agency's accelerated approval regulatory pathway. Moderator Chadi Nabhan asked Califf if he was concerned about the ability of companies to sue FDA if they don't agree with a decision, such as a request to withdraw a drug's accelerated approval.

"I'm very worried about that right now," Califf said. He noted that until the last couple of years, when someone appealed a decision, courts yielded to the FDA as a science-based agency.

"Judges are obviously not scientists and not trained to adjudicate clinical outcome data or biomarker data to make these kinds of decisions. So, usually it's only a matter of if the FDA violated a procedure. It's sort of a technical issue," he stated.

"But recently, more judges have stepped in and, I don't know, acted like they were FDA. And I'm worried about that because if we ended up with every decision of FDA ending up with a judge potentially overruling the FDA, this would be extremely disruptive to the entire system."

The podcast was recorded in late December and posted on 16 January, the day before the US Supreme Court heard oral argument in two cases challenging the *Chevron* deference given to federal agencies. The questioning by the majority of justices indicated that the court is likely to eliminate or narrow this deference, which is expected to result in more litigation against the

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FDA.

'Inviting A Flood Of Litigation'

The Supreme Court cases – Loper Bright Enterprises v. Raimondo and Relentless v. Department of Commerce – seek a ruling on whether the court should overrule or clarify its 1984 decision in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc. That ruling held that if courts find that a statute is ambiguous, they should defer to a federal agency's interpretation of it.

The cases, brought by two groups of fishing vessels, involve a statute governing fishery management in federal waters that permits the National Marine Fisheries Service to require vessels to carry federal observers onboard to enforce the agency's regulations.

During oral argument in the Relentless case, Justice Amy Coney Barrett suggested that the outcome could lead to the relitigation of cases. She questioned the claim of Roman Martinez, a partner at Latham & Watkins who argued on behalf of Relentless, that overruling *Chevron* would not effect many cases that get to *Chevron* step two.

"Isn't the door then open for litigants to come back" and challenge the meaning of a specific term in the statute? she asked. "So, isn't it inviting a flood of litigation even if for the moment those holdings stay intact?"

Axinn, Veltrop & Harkrider partner Chad Landmon and associates Aaron Savit and Ian Swan commented in a blog post on the oral arguments that it seems even *Chevron* proponents recognize that judges should take a more active role in interpreting statutes and limit broad deference to agency interpretations.

"As the Supreme Court prepares to narrow or eliminate the *Chevron* doctrine, a decision in these cases will likely define how administrative agencies function over the coming decades. An outcome that narrows or eliminates *Chevron* deference will undoubtedly lead to an uptick in litigation challenges and greater scrutiny of administrative decisions," they wrote.

Other lawyers have said that elimination of *Chevron* deference will result in the agency spending more time and resources to provide justification for its decisions and interpretations to lay the foundation for legal battles. (Also see "*What Will FDA Do If Supreme Court Curtails Chevron Deference?*" - Pink Sheet, 22 May, 2023.)

Battle Over Mifepristone Access

The ability of courts to overrule FDA's scientific judgment is directly at stake in litigation over mifepristone. The Supreme Court is to consider whether the Alliance for Hippocratic Medicine has standing to challenge the FDA's actions on the abortion pill, whether the agency's actions easing restrictions on its conditions of use were arbitrary and capricious, and whether the district

court's order suspending the effective date of FDA's actions was improper.

The court has not set a date yet for oral argument in the case, which has been consolidated with that of Danco Laboratories, manufacturer of Mifexprex, the brandname mifepristone. The court granted both of their petitions for a writ of certiorari in December. (Also see "*Supreme Court Could Curtail Mifepristone Access, Lay Out 'Road Map' To Challenge FDA Approvals*" - Pink Sheet, 13 Dec, 2023.)

The Alliance, a group of doctors and associations of doctors who oppose abortion, filed suit against FDA in November 2022 challenging FDA's approval of mifepristone, changes to the REMS, and the approval of generic mifepristone. In April 2023, US District Judge Matthew Kacsmaryk of the Northern District of Texas granted Alliance's motion for a preliminary injunction.

The Supreme Court stayed the district court order pending appeal.

In August, the US Court of Appeals for the Fifth Circuit ruled that the medical organizations and doctors have standing to sue FDA and concluded that mifepristone should remain available under the restrictions in effect prior to 2016. (Also see "*Mifepristone REMS Modifications Likely Violated Administrative Procedure Act, Appeals Court Says*" - Pink Sheet, 16 Aug, 2023.)

"To the government's knowledge, this case marks the first time any court has restricted access to an FDA-approved drug by second-guessing FDA's expert judgement about the conditions required to assure that drug's safe use," the FDA argued in its 23 January *brief* asking the Supreme Court to reverse the ruling. "The Fifth Circuit reached that unprecedented result through a series of errors that contradict this Court's precedents and violate black-letter Article III and administrative-law principles."

Danco Laboratories asserted in its *brief* that the Fifth Circuit's standing analysis would give medical organizations standing to challenge virtually every government regulation that touches on health or safety. "And its merits analysis threatens to destabilize the pharmaceutical industry, which relies both on FDA's ability to make predictive judgments and on courts not second-guessing those scientific judgments," Danco stated.

Attorneys general from Missouri, Idaho and Kansas filed a *motion to intervene* in the case to resolve the question of standing. They contend that they have standing so if the court finds that Alliance does not, the FDA would not be freed from the district court's preliminary injunction order.

They argue that they can assert many harms the private plaintiffs cannot, including direct monetary harm to state-run insurance programs and hospitals, and harm to the states' sovereign

interests in creating and enforcing laws.

Emitting Emotion

In another case, the Fifth Circuit issued a ruling reining in the FDA's ability to express emotion or humor in its communications.

Three doctors who prescribed the human version of ivermectin for treatment of COVID-19 sued the FDA, Califf, and HHS Secretary Xavier Becerra over the agency's Twitter posts warning people not to take ivermectin intended for livestock. They claimed FDA's messaging interfered with their own individual medical practice and that the posts violate the Administrative Procedure Act.

One of the posts stated: "You are not a horse. You are not a cow. Seriously, y'all. Stop it." The post included a link to a consumer update noting that the agency had received multiple reports of patients who required medical attention, including hospitalization, after self-medicating with the veterinary product.

The US District Court for the Southern District of Texas dismissed the suit, Apter v. HHS, holding that sovereign immunity protects the agencies and officials. But in September, the Fifth Circuit reversed the dismissal and remanded the case for further proceedings.

The court said FDA "has the authority to inform, announce, and apprise – but not to endorse, denounce, or advise" and that the doctors plausibly alleged that FDA's posts fell "on the wrong side of the line between telling *about* and telling *to*."

FDA and HHS filed a renewed motion to dismiss the case and US District Judge Jeffrey Brown granted their request for the filing to be sealed. He noted that one of the plaintiffs in the case is a party to a separate, state-level confidential proceeding and FDA's reply references confidential information in that proceeding.

Califf alluded to the Fifth Circuit's ruling at the UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (CERSI) summit earlier this month, noting that the one time the agency expressed emotion in its communications a court said it could not do so. (Also see "*Combatting Misinformation: FDA's Califf On Use Of Facts, Opinion And Emotion*" - Pink Sheet, 24 Jan, 2024.)

Bypassing Exclusivity Decision

Courts have ruled against the FDA in other cases that have rankled the agency. In a case involving the agency's award of orphan drug exclusivity, the US Court of Appeals for the Eleventh Circuit found that the district court erred in finding that that the language in the Orphan Drug Act is ambiguous and deferring to the FDA's interpretation of the phrase "same

disease or condition."

The agency approved *Jacobus Pharmaceutical Co. Inc*'s Ruzurgi (amifampridine) for treatment of Lambert-Eaton myasthenic syndrome (LEMS), a rare autoimmune disorder, in pediatric patients even though *Catalyst Pharmaceuticals, Inc.* already had orphan exclusivity for Firdapse (amifampridine) for treatment of adults with LEMS.

After the 11th Circuit ruled that it was wrong for the agency to have approved Ruzurgi, legislation was sought to override the decision. A policy rider was attached to the House user fee reauthorization bill with a provision supporting FDA's position that orphan drug exclusivity only applies to the specific indication or use for which the drug is approved, not the entire disease. The Senate version of the bill did not include this provision and it was not included in the omnibus government funding bill enacted in December 2022.

While the FDA set aside its approval of Ruzurgi, it declined to adopt the *Catalyst* ruling and announced it would continue to tie exclusivity to the uses or indications for which a drug was approved. (Also see "*Orphan Drug Exclusivity: In Narrow Application Of Catalyst Ruling, FDA Retains Its Existing Regs*" - Pink Sheet, 23 Jan, 2023.)

Sue Sutter contributed to this article.