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Client Alert Commentary

Latham & Watkins FDA Regulatory Practice

September 6, 2024 | Number 3295

New FDA Brief in Supreme Court Tobacco Case Puts Spotlight on Post-*Chevron* Regulatory Landscape

FDA says its authority to implement the TCA is not limited by* Loper Bright, *but suggests that future guidance documents may be limited.

On August 26, 2024, the US Food and Drug Administration (FDA or the Agency) filed its opening brief in the Supreme Court proceedings for *FDA v. Wages and White Lion Investments, LLC*,[1] publicly taking a position for the first time on the enforcement of the Family Smoking Prevention and Tobacco Control Act (TCA), following the potentially paradigm-shifting decision earlier this summer in *Loper Bright Enterprises v. Raimondo,* which overruled the *Chevron* doctrine.[2] (See our Client Alert, US Supreme Court Overrules *Chevron* Deference to Agencies in *Loper Bright* and *Relentless*.)

This brief is the first clear indication that *Loper Bright* may affect how the Agency issues non-binding regulatory guidance documents across all-regulated product areas and how regulated industries may seek to challenge FDA's decision-making moving forward.

FDA's Brief

As background, earlier this year, the Supreme Court granted a petition seeking review of a ruling by the US Court of Appeals for the Fifth Circuit, which set aside FDA's orders denying applications to market new e-cigarette products.[3] In its brief, FDA asserts that *Loper Bright* does not place meaningful limits on the Agency's ability to enforce the TCA. Specifically, FDA argues that "[i]n the Tobacco Control Act, Congress recognized FDA, not federal courts, as 'the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products.'"[4]

The Agency's argument centers on its interpretation of the TCA's "appropriate for the protection of the public health" (APPH) standard.[5] FDA asserts that "Congress directed FDA to judge whether authorizing a new product would be" APPH "and the word 'appropriate' leaves FDA with significant 'flexibility.'"[6] FDA therefore concludes that the wording of the APPH standard affords it the ability to continue to enforce the TCA using its reasonable discretion without departing from the pre-*Loper Bright* standard.

Although FDA generally takes the position that its authority and approach in implementing and enforcing the TCA is not limited by *Loper Bright*, FDA cautions the Court that its decision may play a significant role in shaping the incentives for executive agencies, including, but not limited to, FDA, to issue guidance documents.

Among the matters at issue in *Wages* is the Fifth Circuit decision's treatment of FDA's regulation of flavored tobacco products. In its brief, FDA frames the Fifth Circuit decision such that the court "concluded that FDA had an affirmative obligation to issue specific guidance that gave applicants 'fair notice' of how it would evaluate flavored products, and that an applicant's 'good faith' reading of an agency's guidance is controlling even if that reading is wrong."[7]

FDA argues that the Fifth Circuit's *Wages* decision is inconsistent with the *Loper Bright* framework generally: "As this Court recently held [in *Loper Bright*], the [Administrative Procedure Act] requires reviewing courts to 'determine the best reading' of the law 'by applying their own judgment.' That holding forecloses any contention that courts should accord controlling effect to a private party's purportedly reasonable but incorrect reading of a guidance document."[8]

The crux of FDA's argument invokes language from *Loper Bright* and asserts that "because of 'the limits of human language and foresight,' any guidance document will contain ambiguities. By automatically resolving all such ambiguities against the agency, the Fifth Circuit's approach discourages agencies from providing guidance in the first place — an outcome that, in the long run, harms rather than helps regulated parties."[9] FDA concludes by noting that, if the Fifth Circuit's *Wages* decision is upheld, executive agencies will be discouraged from issuing guidance documents, which may be to the detriment of regulated parties.

FDA's Tobacco Regulatory Authority After *Loper Bright*

While FDA takes the position that the decision in *Loper Bright* will not limit FDA's ability to enforce the TCA given the inherent "flexibility" of the APPH standard, an alternative reading of the *Loper Bright* decision is that it requires Congress to be more direct in its delegation of authority to executive agencies — a mandate that is arguably not present in the TCA.

As the tobacco industry is well aware, FDA has taken significant actions in guidance documents and other non-binding methods to regulate the industry. The Agency's opening *Wages* brief suggests that *Loper Bright* may force FDA to focus its regulatory activity on the notice-and-comment process. Latham & Watkins will continue to monitor FDA's regulatory strategy post-*Loper Bright*. We also await the respondents' brief, which is due on or before October 7, 2024, and may address how one regulated party believes *Loper Bright* affects its regulator.

Effects of *Loper Bright* on Other FDA-Regulated Products

Looking beyond tobacco products, the short- to medium-term effects of *Loper Bright* in the FDA-regulated space will continue to unfold, particularly with regard to some more-vulnerable regulatory schemes and product categories. Specifically, while the core drug and device approval processes may not face serious challenges, other areas have potential for statutory interpretation disputes that may be resolved by the federal courts, such as product classifications (e.g., combination products that could be regulated as a drug or a device).

Additionally, we expect that the regulatory frameworks for certain product categories may face increased scrutiny, particularly those categories where FDA arguably has limited statutory authority. FDA's recent final rule for laboratory developed tests is already facing legal challenges filed in Texas earlier this year, including arguments that FDA does not possess statutory authority to regulate such products under the device authority granted to it by the FDCA.[10]

There is potential for similar challenges to the regulatory frameworks for digital health products, dietary supplements, cosmetics, new foods, and other novel product categories. In particular, given the entirely novel and potentially paradigm-shifting nature of artificial intelligence, we are keeping an eye on any efforts by FDA to regulate the use of artificial intelligence to develop FDA-regulated products, seek FDA authorizations, and interact with patients and physicians.

We will continue to monitor challenges to FDA's authority post-*Loper Bright* and FDA's issuance of guidance documents.

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Endnotes

[1] No. 23-1038 (U.S. 2024).

[2] 144 S. Ct. 2244 (2024).

[3] *See* Petition for Writ of Certiorari, *Wages*, No. 23-1038 (cert. granted Jul. 2, 2024).

[4] Brief for Petitioner at 16, *FDA v. Wages and White Lion Investments, LLC*, No. 23-1038 (FDA Brief) (internal citations omitted).

[5] *See* 21 U.S.C. § 387j(c)(2)(A).

[6] *Id*. (internal citations omitted).

[7] FDA Brief at 25 (internal citations omitted).

[8] Brief for Petitioner at 29 (internal citation omitted).

[9] Brief for Petitioner at 30 (internal citation omitted).

[10] *See American Clinical Laboratory Association et al. v. FDA et al*., No. 4:24-cv-479 (E.D. Texas 2024); *Association for Molecular Pathology et al. v. FDA et al*., No. 3:24-cv-00241 (S.D. Texas 2024).