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The Future of FDA Policy: Reflections From the Summer of 'Chevron'

New York Law Journal
09.12.2024

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Sheppard Mullin attorneys discuss 'Loper Bright Enterprises v. Raimondo' and include the considerations stemming from the decision, both generally and with respect to FDA practice, specifically. They write: "Now, after having spent the summer pouring over cases, articles, and thought leadership on the matter, we're not sure the win is so sweeping—especially in the U.S. Food & Drug Administration arena."

Before June 28, unless you were a lawyer or federal agency employee, the term "Chevron" probably meant little more to you than a gas station. But on June 28, when the Supreme Court *overturned* the long-standing "Chevron Doctrine"—which previously directed lower courts to defer to a federal agency's reasonable interpretation of a silent or ambiguous statute—regulated industry notched what was hailed a sweeping win and "Chevron" became part of our daily vernacular.

Now, after having spent the summer pouring over cases, articles, and thought leadership on the matter, we're not sure the win is so sweeping—especially in the U.S. Food & Drug Administration ("FDA" or the "Agency") arena.

FDA Policy: Business As Usual

Loper Bright Enterprises v. Raimondo may not be the "sword" that we had initially assumed it would be against FDA policy. First, although the court formally eliminated the framework requiring *binding* agency deference, it did not eliminate the concept of agency deference altogether. Second, a significant portion of FDA policy is established through informal guidance, which was never subject to *Chevron* deference in the first place.

Agency Deference: Down But Not Out. While there is no doubt that, by eliminating *Chevron*, the court shifted some power from federal agencies back to the judiciary, agencies are not left powerless. First, *Loper* reserves a considerable amount of discretion for an agency's interpretation of *fact* (e.g., when an amino acid polymer qualifies as a "protein" under the regulatory framework for biological products)—what the opinion reels back is the binding deference previously afforded to agencies for *legal* interpretations (e.g., the meaning "same drug" under the Orphan Drug Act).

We could write a book on the complex and muddled distinction—or lack thereof—between fact and law (*see, e.g., Gray v. Powell*) but will just raise point for now and, instead, focus on the second caveat—the court's endorsement of the (albeit less deferential) Skidmore Doctrine.

Under *Skidmore,* courts are directed to "respect" agency expertise and are given the direction to grant agency interpretations of ambiguous legislation a degree of deference proportional to the persuasiveness of the agency's position. Unlike *Chevron*, *Skidmore* applies to all agency interpretations of ambiguous legislation—not only those agency interpretations that are legally binding—which is especially applicable to agencies like FDA that shape policy largely through informal guidance.

The majority and concurring opinions in *Loper* reference *Skidmore* ten times, signaling the Court's intent that *Skidmore* could serve as a framework for agency deference moving forward. However, given the historical inconsistency in *Skidmore*'s application among lower courts (*see, e.g., Smiley v. DuPont*), not to mention the sheer age of the *Skidmore* decision, lower courts may be hesitant to apply *Skidmore* until the Supreme Court provides more clarity—in fact, the majority of federal cases referencing *Loper* in the past month have not even mentioned the *Skidmore* framework (*see, e.g., Ryan LLC v. FTC)*. So, while *Skidmore* could be a useful tool for agencies to preserve some level of deference in legal interpretations, it remains to be seen how effective this tool will be in practice.

FDA's Off-Label Promotion Policy Illustrative of *'Chevron*'s' Limited Reach.

A key feature of FDA's so-called "off-label" or "inconsistent with label" promotion policy for drugs and devices may exemplify why *Chevron*'s fall and *Skidmore*'s potential rise may not be earth-shattering for FDA policy at large.

While off-label promotion is not explicitly prohibited by statute, FDA has effectively prohibited the practice—primarily through guidance—for decades by relying on its legal interpretation of Congress's vague *"misbranding" statute*. In fact, in the almost thirty years since the genesis of FDA's off-label policy (i.e., *the first draft guidance*), FDA has only promulgated a single rule on the topic, which was finalized back in 1998. Since that time, FDA has continued to shape its off-label promotion policy solely through informal guidance, including (i) *the "Reprint" Guidance;* (ii) *the "Unsolicited Requests" Draft Guidance*; (iii*) the "Consistent with Label" Guidance;* (iv) *the "Payor Communications" Guidance;* and (v) *the "Scientific Information Unapproved Uses" Guidance*.

As discussed, *Chevron* only ever afforded agencies deference in interpretations that carried the force of law—so, regulations and binding enforcement actions but not informal guidance or warning letters. *See United States v. Mead Corp.* at 230. This means that the bulk of FDA's off-label promotion policy has, all along, been entitled to *Skidmore* deference—not *Chevron*. Accordingly, revoking the Chevron Doctrine may have little, if any, effect on the way courts review administrative actions based on FDA's off-label promotion policy (i.e., its interpretation of the "misbranding" statute).

Business As Usual, Subject To Review

Although the jury is out on what exactly *Loper* means for FDA-regulated industry, we—like everyone else—are waiting to see how things play out in the courts and in policymaking moving forward.

FDA's LDT Rule: A Signal of What May Come. In the courts, there is no doubt that the fate of FDA's recent—and controversial—*rule* regulating Laboratory Developed Tests (LDTs) will serve as a litmus test. The rule, published on May 6, has been challenged by *the American Clinical Laboratory Association (the "ACLA")* and *the Association for Molecular Pathology ("AMP")* in two separate suits, which each dispute the Agency's interpretation of its authority to regulate "devices" under the Food, Drug, and Cosmetics Act. Interestingly, industry participants are not the only parties taking issue with FDA's decision to regulate LDTs—a group of Republican Congress

members recently sent a *letter* to FDA, praising the takedown of *Chevron* and criticizing what the group deems a "unilateral assertion" over LDTs.

Ultimately, thanks to the LDT rule's extensive administrative record—compiled in anticipation of the pushback it now faces—the Agency's position may be relatively defensible under *Skidmore*. However, all eyes are on the courts considering the ACLA and AMP challenges (i.e., the District Court for the Eastern District of Texas and the District Court for the Southern District of Texas, respectively) as to whether they will apply *Skidmore* and, if so, whether they will deem the discretionary difference between *Chevron* and *Skidmore* enough to invalidate the rule.

As part of the Fifth Circuit, these district courts are notorious for backing industry challenges to agency regulation and, accordingly, may use *Loper* as a sword to reel in what they could perceive as an overreach by FDA. So, even if the district courts do employ *Skidmore*, we may not necessarily see the same application of *Skidmore* to the LDT rule in other jurisdictions. We could end up with a circuit split on the matter, which would, in the short term, incentivize forum-shopping and, in the long term, necessitate clarity from the Supreme Court on how *Skidmore* should be applied.

Potential Increase in Defensive Rulemaking.

No matter how far up the chain the ACLA and AMP challenges make it, FDA will have to expend a significant amount of resources to defend the rule in court, on top of the considerable resources already spent not only packing the rule's preamble with analysis and objectivity, but now also responding to the Congressional inquiries noted above.

To carry out its chief mandate to protect public safety by ensuring that medical products are safe and effective for their intended uses in light of this considerable resource hemorrhage, FDA will be forced to triage and try to predict the new evidentiary standard under the post-*Chevron* framework. Accordingly, we may see the Agency engage in increasingly defensive rulemaking—ensuring that it comprehensively outlines support for legally binding decisions, such as rulemaking.

This significant diversion of resources presents something of an ethical quandary—at what point does the increasing demand for evidentiary justification no longer serve the patient safety mission? At what point is the diversion of resources unjustifiable? Ultimately, as with the effect of the *Loper* decision at large, we will have to wait and see.

Takeaways for Regulatory Practice

As we look ahead, we consider what all of these possibilities mean for FDA regulatory practice. In the short term, we expect that *Loper* will take up a considerable amount of space, as clients seek to understand the current and potential impact of *Chevron*'s demise. As counsel, it will be our job to guide clients through the contradiction that is regulation of an increasingly advancing technological landscape under an increasingly antiquated legal framework. Of course, litigation specialties, like administrative challenges, could see a relatively sustained increase, especially as forum shopping becomes a greater piece of the litigation strategy.

However, after the *Loper* dust settles, FDA regulatory counseling could return to business as usual, especially given agency's guidance-heavy policymaking framework and the potential resurgence of *Skidmore*.

We'll be keeping a close eye on the outcome of the ACLA and AMP challenges to the LDT rule—including the extent to which the courts apply *Skidmore* and how they interpret law versus fact—as well as FDA's evidentiary posture in future rulemaking. Although we currently face a lot of unknowns, one thing is clear—the need for thoughtful regulatory counseling is greater than ever.

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