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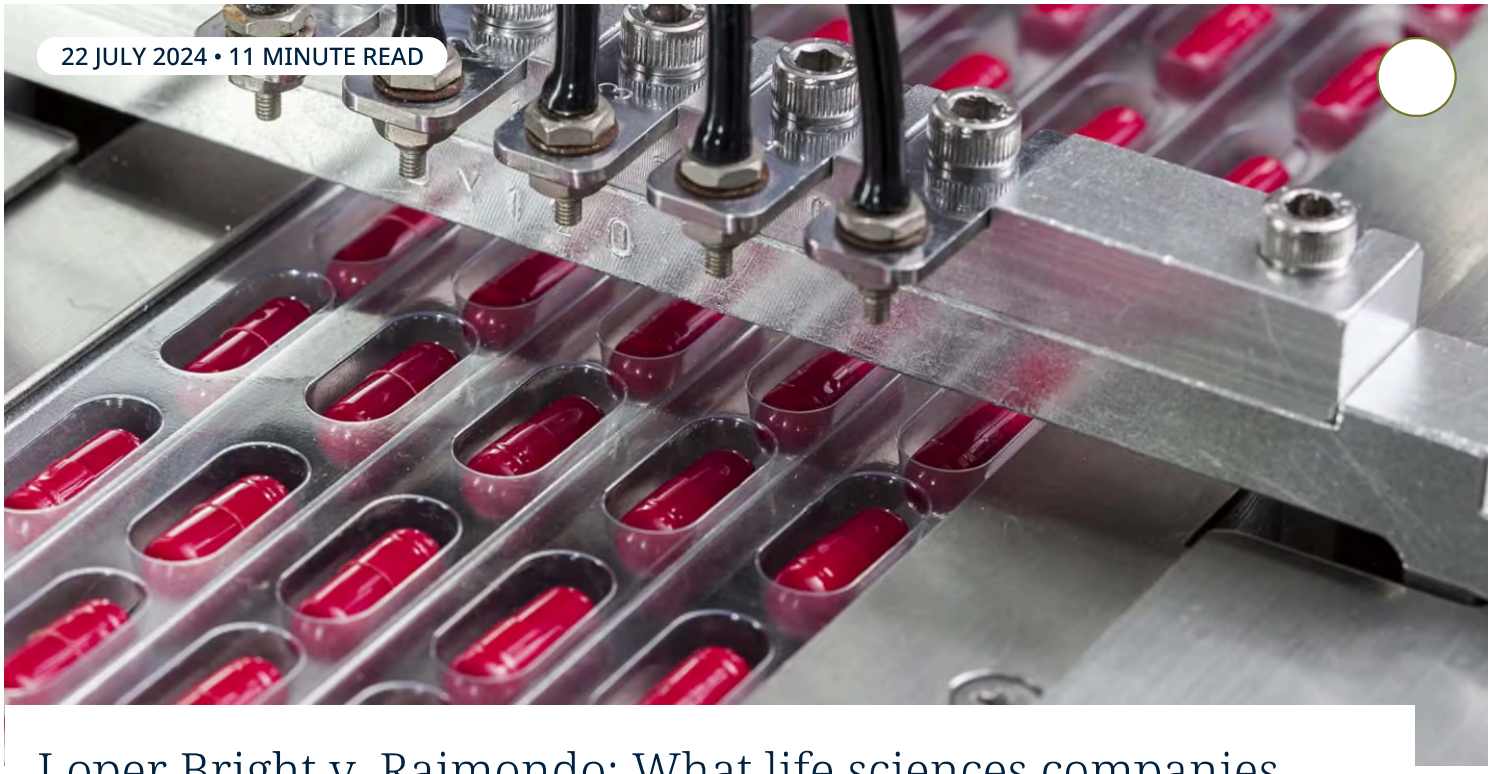

Loper Bright v. Raimondo: What life sciences companies should consider

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We at DLA Piper recently wrote about how the Supreme Court's ruling in the consolidated cases, *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce*, (*Loper Bright*), reshapes the regulatory landscape by overruling the *Chevron* deference doctrine, an administrative law precedent that provided the framework for judicial review of federal agencies' formal interpretations of statutes for the past 40 years.

We explained how the Court's ruling has major implications for the operations of all three branches of government and for regulated entities, including but not limited to:

- Charging courts with supplying the interpretation of ambiguous statutory provisions, even where technical and scientific expertise may be implicated
- Increasing the likelihood of success of those challenging federal regulations
- Limiting executive agencies' ability to fill gaps in the laws or to address situations not expressly anticipated by Congress, and potentially leading agencies to proceed more cautiously and narrowly in adopting certain regulations
- Placing pressure on Congress to legislate with greater specificity (or at least make express delegations of interpretive authority, where permissible), and

- Potentially increasing regulatory uncertainty and limiting the ability of business to confidently act in reliance on agency pronouncements – particularly in the near term as both agencies and courts adjust to the post-*Chevron* legal landscape.

In the short time since the *Loper Bright* opinion was made public, a member of Congress has already sent a letter to the Food and Drug Administration urging the agency to comply with the decision, pointing out that FDA has "unilaterally asserted jurisdiction over laboratory developed tests (LDTs) without Congress granting FDA that authority" and "has ignored multiple court rulings on the Orphan Drug Act."

A similar letter was sent to the Department of Health and Human Services (HHS), focused on its implementation of the No Surprises Act (regarding billing calculations and patient notice requirements) and its involvement with an effort to "reinterpret the Bayh-Dole Act's criteria for the use of march-in rights to apply to drug prices."

Here, we analyze what life sciences companies should be on the lookout for in light of *Loper Bright*'s major implications.

FDA product approvals and authorizations

For drug approvals, the Federal Food, Drug and Cosmetic Act (FDCA) requires applicants to provide "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." Courts have found this provision to be ambiguous, and deferred to FDA's interpretation of the provision, allowing the agency to impose additional requirements not specified in the statute. One example is FDA requiring that a drug's intended use have medical significance in order to be "effective in use." Siding with the FDA, the DC Circuit specifically declined to examine "whether the statute compels the agency's … reading," and "turn[ed] directly to the question whether the agency's interpretation, as applied to this case, is permissible under the second step of Chevron."

After *Loper Bright*, courts are required to determine what "the statute compels," rather than simply determining whether FDA's interpretations are "reasonable" – giving rise to more opportunities for unsuccessful applicants to challenge FDA's drug approval analysis. Similar challenges could arise under FDA's interpretation of "adequate directions for use" for drug labeling, where FDA has required that a label must provide "directions under which the layman can use a drug safely and for the purposes under which it is intended."

Importantly, *Loper Bright* is not expected to impact areas where the FDCA authorizes the FDA to engage in factfinding or expressly grants FDA discretion. For example, with tobacco products, the FDCA requires that a finding that "permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations." Yet, unlike the standard for drug approvals, the FDCA specifically gives FDA discretion to determine "that there exists valid scientific evidence," other than well-controlled investigations, "which is sufficient to evaluate the tobacco product."

FDA's jurisdictional decisions

FDA must often make decisions about how to regulate a particular product. These decisions often involve FDA interpreting the FDCA to determine whether a product will be regulated as, for example, a drug or a dietary supplement. In a 2004 case, the US Court of Appeals for the DC Circuit sided with FDA's interpretation of the FDCA to regulate "saw palmetto" as a drug due to what FDA declared to be "drug claims," as opposed to "health claims," about the product. Whitaker v. Thompson, 353 F.3d 947 (D.C. Cir. 2004).

Employing *Chevron*, the Court upheld FDA's interpretation, despite concluding that not one of FDA's justifications was "a knock-down argument" and expressing "doubt that any of them would be sufficient to overcome a strong textual or structural inference in favor of a different interpretation." Id. at 951.

With pending challenges to FDA's recent decision to regulate laboratory-developed tests (LDTs) as devices underway, FDA's interpretations of the FDCA will likely not receive similar treatment under *Loper Bright*.

FDA's exclusivity and forfeiture determinations

The FDCA provides market exclusivity for manufacturers in a number of situations, including orphan drug exclusivity, generic drug exclusivity, and what is known as "pioneer" drug exclusivity.

FDA's determinations concerning the applicability and duration of these exclusivity periods may have significant financial consequences for manufacturers and competitors. Given these financial stakes, FDA's exclusivity determinations have frequently been challenged in court, with FDA's success often hinging on *Chevron* deference upon a finding of ambiguity in the statute.

One example of many is the appellate decision in *Otsuka v. Price*, 869 F.3d 987 (D.C. Cir. 2017) (upholding FDA's approval of a competitor drug product in the face of pioneer company's assertion of market exclusivity, concluding that pioneer exclusivity is only infringed by a drug with the same "active moiety.")

Because FDA's exclusivity and forfeiture determinations are based largely on statutory interpretation, these decisions will be particularly vulnerable to legal challenges under the new *Loper Bright* paradigm, and new challenges to FDA's exclusivity and forfeiture determinations may have increased chances of success.

Drug negotiation policy under the IRA

Under the Inflation Reduction Act's (IRA) Drug Price Negotiation Program (DPNP), the Centers for Medicare and Medicaid Services (CMS) are authorized to directly negotiate the price the government pays for certain prescription drugs and biologics.

While the DPNP is codified in statute, CMS's negotiation parameter requires subjective agency determinations. Per CMS's parent agency, HHS, "[t]he negotiation process will consider the selected drug's clinical benefit, the extent to which it fulfills an unmet medical need, and its impact on people who rely on Medicare, among other considerations, such as costs associated with research and development as well as production and distribution for selected drugs."

Thus far, lawsuits challenging the program have focused on the constitutionality of the underlying IRA provision. But now, drug companies with products that have been selected for negotiation may also be encouraged to challenge CMS's assessment of these factors, and whether those assessments are, as stipulated by the IRA, "in accordance with" the IRA's intent.

Moreover, neither agency rules nor guidances have outlined how these determinants would factor into the negotiation program, offering only that "CMS intends to consider research on and real-world evidence relating to Medicare populations," thus inviting further court intervention.

So, for example, a drug's clinical benefit relative to its price is a key factor in determining whether a drug is subject to the DPNP, but there is no fixed metric by which CMS makes this assessment. The agency may rely on any number of subjective factors to determine whether the drug's clinical benefit relative to its price is so questionable as to warrant inclusion in the program.

Similarly, determining the impact on people who rely on Medicare is entirely open to agency interpretation, while per-drug estimates of research and development (R&D) costs vary widely based on what costs are included and excluded: A 2014 report by the Tufts Center for the Study of Drug Development found the cost to bring a new drug to market at $2.6 billion in 2013, while more recent numbers from business consulting firm Deloitte peg the number at $2.3 billion.

Others have suggested that the methodology used to reach these numbers is flawed and that the real number is as low as $1.1 billion. Thus, even if CMS defines these criteria by rule, would-be litigants could now challenge those rules in court.

Drug coverage determinations by CMS

While the Supreme Court has not relied on *Chevron* since 2016, lower federal courts have leaned on it in upholding Medicare coverage determinations. So, for example, when a rural black lung clinic challenged CMS's denial of benefits for services CMS believed were due to be paid from the federal black lung benefits program rather than Medicare, the DC Circuit's analysis rested on *Chevron* deference, holding that not only did *Chevron* apply, but that CMS was due "particular deference … given the tremendous complexity of the Medicare statute."

Two years later, when Los Angeles County joined several hospitals in challenging payment denials, the DC Circuit invoked that previous finding, holding that "[i]n marking off the metes

and bounds of our review under the second step of Chevron, we accord particular deference to the Secretary's interpretation of [the Medicare Act] 'given the tremendous complexity of the Medicare statute.'"

Were these cases to be heard today, the Court would not be compelled to apply this kind of deference, leaving it an open question as to how future coverage determination cases will be decided.

CMS is empowered by Congress to determine whether a service or product is "reasonable and necessary." While that power is enshrined in statute, the criteria for "reasonable and necessary" is not. It is fair to assume that the use of such broad terminology was deliberate, but even broad authorities have limits and with courts unencumbered by the parameters of *Chevron*, the subjective nature of "reasonable and necessary" could invite striking down of coverage restrictions.

General rulemaking at FDA and CMS

Loper Bright may have a chilling effect on the FDA's future rulemaking. The agency has always been required to base its rules on a robust administrative record that includes analysis of public comments, resulting in rulemaking taking three to five years from draft to final. After this decision, the agency is likely to take even longer to issue final rules to help ensure against future challenges.

In conjunction with the Supreme Court's decision in *Corner Post, Inc., v. Board of Governors of the Federal Reserve System*, these challenges may come long after regulations are issued. While there is a six-year statute of limitations for most Administrative Procedure Act challenges, *Corner Pos*t held that the right of action accrues when the plaintiff actually suffers an injury, not when the regulation becomes final. The result opens the door to facial challenges to rules long after the six-year mark, and while rules upheld by under *Chevron* remain good law under stare decisis, broadly speaking, the *Loper Bright* decision is further destabilizing for regulations issued by FDA and CMS, as well as for industry that has to rely on them.

While *Chevron* deference never applied to guidances or general policies, federal law requires any policy "that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits" to be "promulgated by the Secretary by regulation." This functionally makes the most consequential CMS decisions subject to new *Loper Bright* framework, where courts must determine the "single, best meaning" of statutes.

Among others, fee schedules, payment adjustments, nursing home staffing requirements, and nondiscrimination requirements are largely determined through CMS and HHS rulemaking, and have been the subject of substantial differences of opinion among stakeholders and federal decisionmakers. Given the high stakes of these decisions, the elimination of *Chevron* deference is sure to invite new litigation.

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