Insight

Post-Chevron Impacts on Health: Three Case Studies

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Executive Summary

- The Supreme Court's decision to overturn *Chevron* deference in *Loper Bright v. Raimondo*, which requires courts to independently interpret ambiguous and silent statutes rather than deferring to federal agencies, is likely to significantly impact the health care industry.
- With agencies no longer given automatic deference in the event of ambiguous statute, courts are now likely to weigh-in on such longstanding as the definition of "same drug" and "medical device," as well as Medicare reimbursement rates and coverage determinations.
- To ensure effective health care regulation, Congress should take measures to clarify statutory ambiguities and potentially delegate additional authority to agencies in fields requiring technical expertise.

Introduction

Last month, in a landmark decision, the Supreme Court overturned the 40-year precedent of *Chevron* deference , a doctrine under which courts deferred to federal agency interpretations of ambiguous or silent statutes in federal law. In its *Loper Bright Enterprises v. Raimondo* decision, the Court held that whenever disputes arise over statutory ambiguity, it is the role of the courts, not federal agencies, to interpret the meaning of that ambiguity. As such, courts have regained a key role in judicial review concerning federal agency regulations. *Loper Bright* poses opportunities to challenge potentially expansive agency interpretations of their regulatory authority and for congressional action to clarify statutory ambiguities, potentially even expanding agency authority in certain relevant areas.

This decision will likely have major impacts on the health care industry. Statutory ambiguities and silent statutes are found throughout the Code of Federal Regulations and other federal laws establishing agency roles. This paper examines three cases where the *Loper Bright* decision could be pivotal: the definition of "same drug" and the classification of "medical device" in relevant statute, as well as potential challenges to Medicare reimbursement rates, limits, and coverage determinations.

"Same Drug"

The first case centers around the definition of the term "same drug." Dispute over this term arose when the Food and Drug Administration (FDA) approved biopharmaceutical company Avadel's narcolepsy treatment "Lumryz" during the exclusivity period for company Jazz's narcolepsy treatment "Xywav," which had received orphan drug designation in 2020. Orphan drug designation, which was established by the Orphan Drug Act (ODA), grants companies a seven-year exclusivity period to produce treatments for rare diseases, disorders, and conditions. During this period, the FDA may not approve the "same drug" for the treatment of the same condition from a rival company. Because Jazz's Xywav and Avadel's Lumryz have the same active moiety – and are thus arguably the same drug – Jazz filed suit against the FDA.

Why did the FDA approve Lumryz during Jazz's exclusivity period? The ODA only allows for orphan drug exclusivity to be broken under a narrow set of circumstances. To break this superiority, a rival company must establish the clinical superiority of its own product. Clinical superiority can be established in three ways : Applicants must prove that a drug is safer, more effective, or otherwise makes a major contribution to patient care. Under these conditions, Avadel set out to establish the clinical superiority of Lumryz. Avadel argued that Lumryz's single-dose regimen provided a significant benefit to patient health when compared with Jazz's Xywav, which requires two doses. Despite Avadel's efforts to prove Lumryz's clinical superiority due to its single-dose regimen compared to Xywav's two doses, its requests were repeatedly rejected. Yet after more than five years of repeatedly rejecting Lumryz' request, the FDA Review Board reversed course and granted approval to Lumryz. The FDA at that point held that Lumryz's superior dosing regimen rose to a level that "makes a major contribution to patient care," as required by 21 CFR § 316.3(b)(14).

The FDA further argued that its determination of Lumryz's clinical superiority meant that it was not the same drug as Jazz's Xywav. Under this reasoning, FDA wrote in a response to Jazz's complaint that "Lumryz is clinically superior to Xywav and is thus not considered to be the 'same drug' as Xywav within the meaning of 21 CFR § 316.3(b)(14) and section 527(a) of the FD&C Act."

In response, Jazz argued that the term "same drug" is only defined by a drug's active moiety. In filing its lawsuit, Jazz argued that there is no ambiguity in the term "same drug." Jazz contended that, "Because the active moiety of a product is an objective and knowable fact, the statutory phrase 'the same drug' just means 'the same active moiety.' There is no ambiguity that requires clarification from FDA." The FDA, on the other hand, contended that the term "same drug" is defined by active moiety except when there is established clinical superiority. Of note, Jazz's lawsuit was filed before the *Loper Bright v. Raimondo* decision.

In light of the *Loper Bright v. Raimondo* decision, the dynamics of the case have changed. Jazz's initial legal complaint maintained that the term "same drug" is not ambiguous. Under *Chevron* deference, the Court was only involved in interpreting a statute if the wording was determined to be unambiguous. Thus, Jazz needed to establish that this term was clear to avoid the application of *Chevron* deference. Under post-*Chevron* jurisprudence, however, courts are now required to actively interpret ambiguous statutes. This shift in jurisprudence strengthened Jazz's chances of legal success, as the courts may rule in favor of either party regardless of the determination of ambiguity for the term "same drug."

Courts must now determine what constitutes a "same drug." If courts find the term to be unambiguous, this would establish legal precedent for future rulings. If courts find the term to be ambiguous, they will decide which party's interpretation is correct and potentially set a precedent for future legal battles centering around the term "same drug."

What Is a Medical Device?

A second case where *Loper Bright v. Raimondo* could have implications for health care is over the definition of the term "medical device." This dispute arose when the FDA decided to classify laboratory testing services known as laboratory developed tests (LDTs) as medical devices. LDTs are diagnostic tests that are designed, manufactured, and used within a single laboratory to diagnose diseases or other conditions. They are developed by clinical laboratories in-house, rather than being manufactured and sold as kits by external companies.

The FDA argues that LDTs are medical devices and claims that it has exercised enforcement discretion with respect to LDTs over the past several decades. In other words, the FDA is claiming that it has had the authority to regulate these testing services all along and simply chose not to do so. The FDA further states that modern LDTs are more widely used and present higher risks than those used in the past, thus necessitating the agency's regulatory oversight.

In response to the FDA's new decision, the American Clinical Laboratory Association (ACLA) filed a lawsuit against the agency. The ACLA argues that Congress never granted the FDA the authority to regulate LDTs, or in their words, "the professional testing services that laboratories provide." The ACLA argues that laboratory testing services including LDTs do not fall within FDA's jurisdiction. It argues that the regulatory authority concerning these services falls under the jurisdiction of the Centers for Medicare and Medicaid Services (CMS). In 1988, Congress passed the Clinical Laboratory Improvement Amendments explicitly granting CMS that regulatory authority. The FDA has never been explicitly granted authority to regulate LDTs.

Another layer to the case is the "people and processes" argument. Laboratory testing services encompass elements beyond the physical tests themselves. The FDA will need to demonstrate that these further elements can be included under its regulatory authority over medical devices.

Last, there is a potential role for Congress to add clarity in this case. For example, in 2023, Representatives Larry Bucshon (R-IN) and Diane DeGette (D-CO) introduced legislation that would grant the FDA greater authority over laboratory testing services. The legislation would establish an electronic FDA review process for laboratory tests. The legislation additionally includes provisions to grandfather in previously in-use laboratory tests

Should the term "medical device" be deemed ambiguous, courts may not automatically defer to the FDA's interpretation, as they would have under *Chevron* deference. Regulatory policy experts have previously suggested that within the *Chevron* framework, courts would likely defer to the FDA's definition of "medical device." In the post-*Chevron* landscape, however, the likelihood of a court ruling in favor of the ACLA has substantially increased.

Medicare and Medicaid

A final potential area where *Loper Bright v. Raimondo* could exert significant influence pertains to Medicare and Medicaid reimbursement rates, limits, and coverage determinations. Historically, the *Chevron* decision conferred upon agencies considerable discretion when statutes were deemed ambiguous or "silent." The term "silent statutes" refers to legislative areas where federal law has conferred a broad directive to an agency without specifying the precise methods by which the agency should achieve that objective. Consequently, this grants agencies substantial rulemaking authority. In the context of Medicare and Medicaid reimbursement rates, limits, and coverage determinations, the Department of Health and Human Services (HHS) and CMS have established specific processes for these determinations.

For the determination of Medicare reimbursement rates, CMS defers to the recommendations of a select American Medical Association

committee of 32 specialists known as the Relative Value Scale Update Committee in over 90 percent of cases . Information about this committee is generally not made publicly available, along with information from other committees within CMS and HHS.

Under post-*Chevron* jurisprudence, HHS and CMS decisions concerning reimbursement rates, limits, and coverage determinations would be open to potential challenges in court. To avoid this, Congress could take measures to more explicitly grant agencies regulatory authority within these spheres. If Congress does not act, it is possible that courts could still reject potential challenges to determinations by HHS and CMS.

Conclusion

The Supreme Court's decision to overturn *Chevron* deference in *Loper Bright v. Raimondo* marks a major shift in regulatory oversight within the health care sector. By requiring courts to independently interpret ambiguous statutes, this ruling affects key areas such as drug and device definitions and reimbursement determinations. As a result, Congress now faces the imperative to provide clear legislative guidance and potentially even expand agency authority in technically complex domains to foster effective health care regulation. The outcomes of ongoing legal battles will further shape the future landscape of health care policy and regulation after *Chevron*.