

I. Pennsylvania Supreme Court Affirms Preclusion of Evidence of Compliance with Industry Standards

On December 22, 2023, the Pennsylvania Supreme Court affirmed that defendants in strict products liability cases may not introduce evidence of a product's compliance with industry and government standards. While many states consider this "compliance evidence" admissible, Pennsylvania does not.

In the underlying case, a carpenter sued the manufacturer of a scaffolding platform after the carpenter was injured when the platform collapsed. The carpenter sued under the risk-utility theory. The manufacturer proffered evidence that the product complied with both industry and government standards, but the trial court precluded the evidence. Following a verdict for the carpenter, the manufacturer appealed to the Superior Court, which affirmed the trial court. The Pennsylvania Supreme Court upheld the lower courts.

Sullivan resolved questions about the impact of the Supreme Court's 2014 decision in *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014). *Tincher* implemented two new tests for finding defect in strict products liability cases: (1) the consumer expectations test and (2) the risk-utility test, the test at issue in *Sullivan*. Under the risk-utility test, a product is in a defective condition "if a 'reasonable person' would conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of taking precautions." Further, *Tincher* overruled earlier case law aimed at preventing "negligence concepts" from creeping into strict products liability cases. However, *Tincher* did not address the status of *Lewis v. Coffing Hoist Div., Duff-Norton Co., Inc.*, 528 A.2d 590 (Pa. 1987), which relied on earlier case law in banning defendants from introducing industry and government standards in strict products liability cases. As a result, some judges believed that industry and government were admissible.

The Supreme Court found that *Tincher* did not overrule *Lewis*, leaving the bar on compliance evidence intact. The plurality reiterated existing concerns that compliance evidence shifts juries' focus away from the characteristics of the product and onto the manufacturer's conduct, which invites consideration of negligence concepts such as fault or due care.

Importantly, while *Sullivan* severely limits a defendant's ability to introduce compliance evidence in strict products liability cases, defendants may still introduce compliance evidence in products liability claims sounding in negligence. A plaintiff may also "open the door" by introducing compliance evidence through its own witnesses. *See Gaudio v. Ford Motor Company*, 976 A.2d 524, 544 (Pa. Super. Ct. 2009). If the plaintiff opens the door, the defense may use compliance evidence to deny or rebut the evidence presented by plaintiff. *See id.* Therefore, defense counsel should monitor for an opportunity to introduce compliance evidence, even for strict products liability claims.

II. Loper Bright Enterprises: The End to Agency Authority? And What does this mean for FDA?

On June 28, 2024, the Supreme Court of the United States jettisoned the *Chevron* doctrine, overruling a 40-year-old case that had long served as the foundation for American administrative law. In the consolidated opinion in *Loper Bright Enterprises, Inc. v.*

Raimondo and Relentless, Inc. v. Department of Commerce, the Supreme Court declared that, instead of deferring to agency interpretations of ambiguous statutes, courts now must exercise their “independent judgment” to determine whether an agency acted within its statutory authority.

Although the Court held that *Loper Bright Enterprises* does “not call into question prior cases that relied on the *Chevron* framework,” it will still likely create waves for every federally regulated industry in the United States. How much of an impact this decision will have will likely be discussed for years to come. In the meantime, companies are encouraged to review any recently issued regulations to determine if the agency acted within its statutory authority under this post-*Chevron*, nondeferential analysis.

A. The *Chevron* Doctrine

In 1984, the Supreme Court decided *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.* In that case, the Court held that where a “statute is silent or ambiguous with respect to the specific issue” before an agency, courts “may not substitute [their] own construction of a statutory provision for a reasonable interpretation made by” the agency. In so holding, the principle of “*Chevron* deference” was born. *Chevron* deference required courts to analyze an agency’s construction of a statute using a two-step test. In step one, courts determined whether the statutory language at issue was “clear” or “ambiguous.” If it was clear, that language controlled, and an agency could not deviate from it. But if it was ambiguous, in step two, courts were to defer to the agency’s interpretation of the statutory scheme that Congress “entrusted [it] to administer,” as long as that interpretation was “permissible.” *Chevron* deference gave federal agencies significant discretion to pass rules based on their reasonable interpretations of arguably ambiguous federal statutes.

B. The Regulation Involved in *Loper* and *Relentless*

Both *Loper* and *Relentless* challenged a regulation promulgated by the National Marine Fisheries Service (NMFS) under the Magnuson-Stevens Fishery Conservation and Management Act (MSA). That statute gives the Secretary of Commerce and the NMFS the authority to require commercial fishing vessels to “carry” federal observers on the vessel to ensure that the vessel is complying with federally approved fishery management plans.

Using its regulatory power, NMFS issued a regulation that requires herring fishermen to carry federal observers on approximately 50 percent of their fishing trips. The regulation also provided that, while the federal government would cover the daily salary of some observers, the vessel owners would be required to pay the salaries of the other, nonfunded observers.

Herring fishermen challenged the regulation, arguing that the NMFS lacked authority to require the vessel owners to pay the salaries of the mandated observers. In the two cases in which the Supreme Court granted certiorari, the U.S. Courts of Appeals for the First Circuit and for the District of Columbia disagreed. In *Relentless*, the First Circuit held that the MSA authorized the NMFS’s regulation without deciding whether the statute was ambiguous, implicating *Chevron* step two. In *Loper Bright Enterprises*, the D.C. Circuit held that the statute was ambiguous, meaning the NMFS’s regulation was lawful because it was reasonable.

C. The Supreme Court Overruled *Chevron* for Future Regulatory Challenges

In *Loper Bright Enterprises*, the Supreme Court held that *Chevron* deference is inconsistent with the judiciary's constitutional authority to say what the law is. Deference is also inconsistent with the Administrative Procedure Act's (APA) requirement that courts "exercise their independent judgment" to decide if an agency has acted pursuant to its statutory authority. The Court leaned on the APA's provision that "courts, not agencies will decide 'all relevant questions of law'" touching on agency action. Neither the Constitution nor the APA allows courts to abdicate that role just because a statute is ambiguous.

To reach this conclusion, the Court analyzed decades of precedent before and after *Chevron*, both to demonstrate that *Chevron* was an aberration at the time it was issued and to show its subsequent unworkability.

The Court held that the fatal flaw in the *Chevron* principle was the assumption that statutory ambiguity is a delegation of authority to the agency. It rejected that assumption. The Court also explained that an agency's subject matter expertise does not make it more qualified than the federal judiciary to interpret a statute.

Although the Court has left *Chevron* behind, it expressly held that regulations previously upheld under the *Chevron* framework are subject to *stare decisis*.

The Court also recognized that Congress may still confer discretionary authority on agencies to prescribe rules. In such circumstances, the role of a reviewing court is to ensure that the agency has acted within the boundaries of that delegated authority and has engaged in the reasoned decision-making required by the APA.

Finally, although courts will no longer automatically defer to an agency's interpretation, courts can still treat the agency's interpretation as persuasive, particularly if it is thorough, well-reasoned and consistent with other agency pronouncements.

III. Implications

The Court's decision to overrule *Chevron* is a momentous change in how American courts approach issues relating to administrative law. Given the large number of regulated industries in the United States, the Court's decision has the potential to affect every federally regulated industry, including education, healthcare, tax, automotive, environmental, farming and securities, to name a few. The decision will have a major impact on administrative agencies' ability or appetite to regulate in areas that are not obviously within their statutory authority and may embolden businesses who are interested in challenging agency actions affecting their respective industries.

A. Post *Loper Bright*—How are the Courts Applying the Doctrine

As of August 8, 2024 Westlaw shows 74 cases citing *Loper Bright*.

These cases show many courts are relying on *Skidmore* deference, which *Loper Bright* permits, and other courts are giving no deference to agencies, but rather using "every tool at their disposal" or "all relevant interpretative tools. So far there is no clear correlation between the

approach and whether or not the result favors the agency's interpretation or a broadening of agency authority.