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Legal Insights for Manufacturing: Regulatory & Compliance

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GREGG N. SOFER
AUSTIN:
202.378.2383
WASHINGTON:
202.378.2300
GREGG.SOFER@
HUSCHBLACKWELL.COM

REBECCA FURDEK
MILWAUKEE:
414.978.5348
REBECCA.FURDEK@
HUSCHBLACKWELL.COM

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In prior reports we have noted how federal and state regulation falls most heavily on manufacturers, particularly those in the middle market. According to an October 2023 study from the National Association for Manufacturers, the per-employee cost of compliance with federal regulation exceeds $50,000 for manufacturing firms with less than 50 employees, more than double the cost for large firms.

Additionally, the intensity of regulatory oversight is growing. Over 90,000 pages—filled with new rules, regs, and guidance—were added to the Federal Register in 2023, the second-highest figure in history. As one might imagine with such a large—and largely uncoordinated—expansion of oversight, agencies frequently issue rules that are ambiguous, duplicative, or contradictory, adding significant complexity to the compliance function.

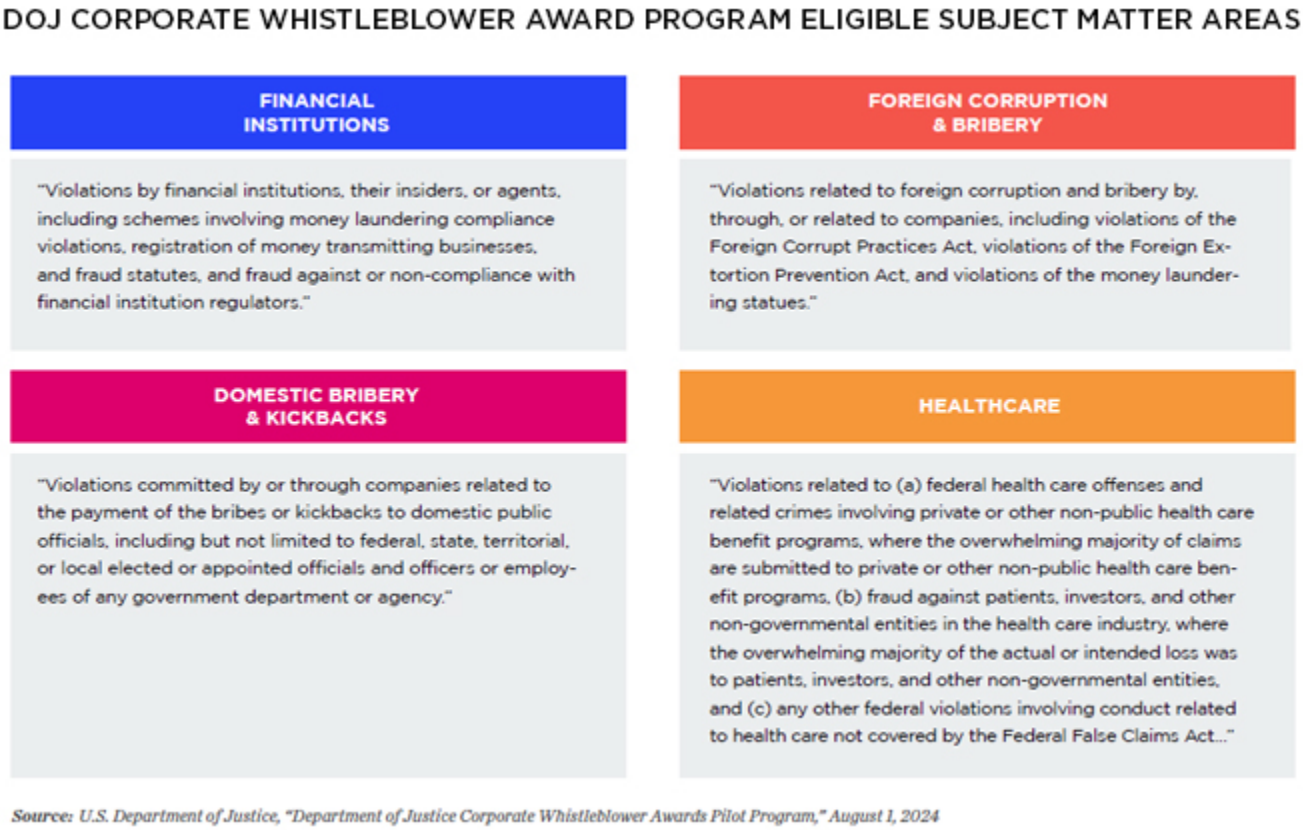
DOJ's New Whistleblower Program

Speaking of duplication and contradiction, the U.S. Department of Justice (DOJ) announced a new whistleblower pilot program in August 2024 after a soft launch in a March speech by Deputy Attorney General Lisa Monaco. The program purports to fill "gaps" between existing government whistleblower programs, but even before the program was finalized over the summer, private businesses voiced concerns about how it could undermine previous efforts by DOJ to encourage voluntary self-disclosure.

In 2023 DOJ's Criminal Division revised its Corporate Enforcement Policy (CEP) to incentivize companies to self-disclose illegal conduct. At its core, the update used the Department's prosecutorial discretion as a bargaining chip

with private businesses. Declinations would depend on three factors: voluntary self-disclosures of misconduct, full cooperation, and timely remediation of the misconduct. This framework energized corporate compliance teams to establish processes and procedures to ensure timely self-reporting inside organizations, and it largely cohered both with DOJ's recent focus on individual responsibility and building properly resourced and fully functioning compliance programs.

The whistleblower pilot program cuts in the opposite direction, providing employees with incentives to bypass internal compliance programs altogether and take information to the government in the first instance, but there are notable limitations. Whistleblowers must be individuals; no companies or other entities are eligible. The individual must voluntarily offer "original information," which is defined as "derived from the individual's independent knowledge or independent analysis." The disclosure cannot be founded in publicly available information and cannot be already known by DOJ, and whistleblowers must fully cooperate with DOJ after divulging information.



Source: *U.S. Department of Justice, "Department of Justice Corporate Whistleblower Awards Pilot Program," August 1, 2024*

The Department has signaled its awareness of the tension between the CEP update and the new whistleblower program, crafting certain incentives and requirements in the latter accordingly. For instance, the program does not set forth a requirement that whistleblowers first alert a company's

internal compliance department prior to blowing a whistle to the government; however, DOJ attempts to balance this misplaced incentive by increasing potential whistleblower awards in those instances where an attempt was made to notify the company first and, correspondingly, to decrease awards when whistleblowers bypass internal compliance. Much, then, is left to the discretion of DOJ in applying such factors, and many compliance professionals have concerns about how such a distinction works in the real world where time is of the essence in self-disclosing misconduct. Internal investigations and compliance procedures take time to execute; whistleblowers need only pick up a phone.

This leads to a second important source of tension between DOJ's CEP and new whistleblower program: declinations. A major incentive within the CEP is the notion that properly disclosed information will in many cases result in the government declining to prosecute, but the policy strongly suggests that declinations depend on the disclosure of new information. Whistleblowers, too, are on the clock, as the new program only awards those who volunteer information not already known. These policies create what is in effect a race to be first. Recognizing that this is less than ideal, DOJ has attempted to mitigate the negative aspects of the policy by creating a 120-day window during which a company can still qualify for a presumption of a declination after a whistleblower reports misconduct to the company and to DOJ.

The disclosure window notwithstanding, DOJ has stated explicitly that a company is "only eligible for the presumption of a declination…if it reports to the Department before the Department contacts the company." As a practical matter, then, the new whistleblower program does not really diminish a company's prior efforts to develop state-of-the-art processes for internal reporting and intake; however, it might change the methodology employed in voluntary self-disclosure and declination analyses. If the process regarding how and when to escalate a matter is muddy, companies could run the risk of failing to timely disclose.

While the Department has pitched this as a program to fill enforcement gaps, there is much about it that is unique; both whistleblowers and compliance teams will need to carefully consider the implications. First, it is a product of DOJ's Criminal Division, and one imagines that it will be deployed to abet criminal prosecutions. Many of the government's existing whistleblower initiatives, such as the False Claims Act, are aimed at bringing civil lawsuits. This distinction carries with it serious questions of due process, as well as concerns in connection with whistleblower anonymity and confidentiality.

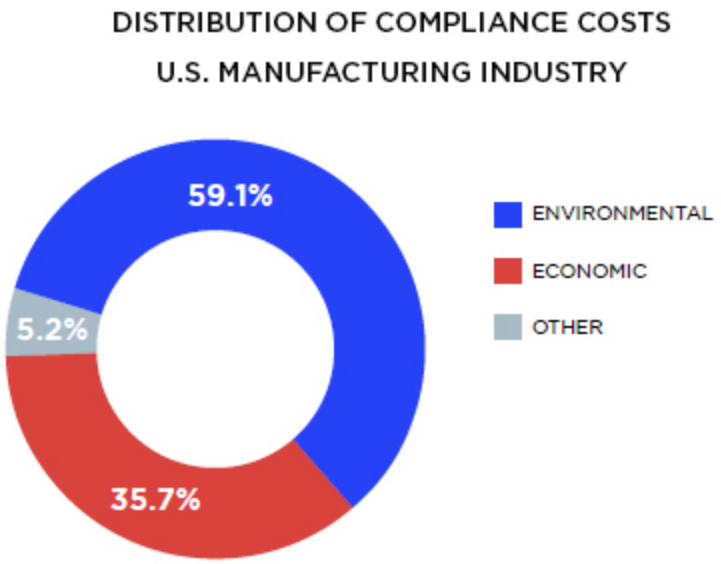
It also presents a couple of practical problems for the government of which corporate defendants should be aware. When the government is pursuing parallel proceedings with both criminal and civil components, the Criminal Division's whistleblower program could create challenges for interagency cooperation. The disclosure and dissemination of evidence collected in a criminal proceeding is

guided by a very different set of rules than those in civil cases. Additionally, should the program wildly succeed, and the government lands a windfall of information regarding potential corporate malfeasance, there is still a necessity for the DOJ to sift and sort the information. The only thing worse than a lack of information is the inability to make use of information at hand. The former is a policy problem; the latter is a political problem and could backfire on the Department if information regarding a major corporate scandal was found to be sitting on a desk after the fact.

Supreme Court Seeks to Rebalance Federal Power

In a major development with broad implications for regulatory law, the October 2023 term of the U.S. Supreme Court featured two decisions that could recalibrate how federal agencies promulgate rules and enforce them. These decisions addressed very different questions of law, but taken together, they consistently signal the Court's desire to reallocate federal power away from the executive branch and administrative agencies and toward the legislature and judiciary.

The first of the decisions—*Securities and Exchange Commission v. Jarkesy*—ruled on the question of whether the U.S. Securities and Exchange Commission could employ its own in-house venue when seeking civil penalties against a defendant. Ultimately, the Supreme Court ruled that such a practice violated the Seventh Amendment's right to a jury trial and remanded the case to be tried again on that basis. It is expected that *Jarkesy* will have implications for numerous federal administrative agencies that use in-house venues to impose civil penalties. In her dissent, Justice Sonia Sotomayor listed several such agencies—including the Environmental Protection Agency (EPA)—whose ability to enforce civil penalties could be greatly impacted by *Jarkesy*. Given the costs associated with environmental law compliance for the manufacturing industry, compliance teams should pay close attention to how EPA adapts to a post-*Jarkesy* world, both in terms of the enforcement actions it brings and the remedies sought.



Source: *Nicole V. Crain and W. Mark Crain, "The Cost of Federal Regulation to the U.S. Economy, Manufacturing and Small Business: A Study Conducted for the National Association of Manufacturers," October 2023.*

Following closely on *Jarkesy*, the Supreme Court then decided *Loper Bright Enterprises v. Raimondo*, which involved arguments that struck at the heart of the so-called *Chevron* deference doctrine. For nearly 40 years, *Chevron*—named after a 1984 Supreme Court case upholding a Reagan-era EPA rule—required federal courts to defer to administrative agencies' interpretations of ambiguous statutes whenever the agencies' interpretations are reasonable or permissible. The Court unambiguously ended this practice in *Loper Bright*, determining that *Chevron* deference cannot be squared with the Administrative Procedure Act (APA), which requires that courts reviewing agency actions "decide all relevant questions of law."

One of the main complaints with *Chevron* over the years has been the wildly vacillating nature of regulatory law from administration to administration, making compliance more costly and complex than it needs to be. It is believed that, by relocating the adjudication of "questions of law" to the judiciary, *Loper Bright* might bring greater certainty to the law, but that remains to be seen, as does whether such certainty is desirable. After all, some agencies have done commendable jobs in some areas of law, and not all heavily regulated industries may welcome the decision. Business-friendly agency rules and decisions will receive the same neutral adjudication on questions of law, and not all judges view administrative law as do the six justices of the Supreme Court who formed the majority in *Loper Bright*.

Contact Us

If you have any questions related to this article, please contact Gregg Sofer, Rebecca Furdek, or your Husch Blackwell attorney.