

# DOJ and Compliance: Great Expectations and Even Greater Consequences Ahead

## WRITTEN BY

Abigail A. Hazlett | Christen Tuttle | Tiffany N. Bracewell

---

As 2020 drew to a close, Indivior PLC, a global pharmaceutical company and manufacturer of the opioid treatment Suboxone, was sentenced in the U.S. District Court for the Western District of Virginia for making false statements to the Massachusetts Medicaid program about the relative safety of Suboxone Film around children to increase its sales, in violation of 18 U.S.C. § 1035. The Indivior sentencing closed out yet another significant, multifaceted investigation led by the U.S. Department of Justice (DOJ or the Department) that resulted in \$2 billion in civil and criminal penalties, as well as multiple felony guilty pleas by the company and individual executives. Though DOJ's ability to extract hefty monetary settlements may no longer be newsworthy in light of its banner 2020 year, pointed comments by prosecutors on Indivior's sentencing in an [interview with Law360's Jeff Overly](#) offer a warning to other pharmaceutical companies. Just as we explained [here](#), the prosecutors' remarks emphasized that DOJ has high and clear expectations for compliance programs, and that the consequences for compliance failures are increasingly punitive.

As a condition of Indivior's plea agreement, for instance, its CEO must personally certify to the U.S. Attorney's Office (USAO) and DOJ's Consumer Protection Branch (CPB) the company's compliance with the Federal Food, Drug, and Cosmetic Act (FDCA) and health care fraud prevention laws annually for five years. As Managing Assistant U.S. Attorney Randy Ramseyer emphasized, this "forces the CEO to know what's going on with the company. And if he doesn't know, then he's got a problem." Similarly, for five years, Indivior's board of directors or a designated committee must submit an executed resolution to the USAO, CPB, and court certifying the effectiveness of Indivior's compliance program over the preceding 12 months. Although DOJ has long expected a demonstrable commitment from the top of the company to drive compliance messaging through all levels — often referred to as the "tone at the top" — the CEO and board certifications demand "tone setting" and personal accountability. This is no small task in the face of ever-changing legal landscapes and industry standards, as well as the tumultuous and unprecedented business environment caused by COVID-19.

Notably, under the terms of Indivior's plea agreement, if the USAO or CPB determine in their sole discretion that the CEO or board falsely certified compliance with the FDCA and health care fraud prevention laws — or knowingly and intentionally violated any other provision of the agreement — they could pursue sanctions for contempt against the company or reinstatement of the dismissed charges. The burden then shifts to Indivior to demonstrate, within 45 days, that no violation occurred or that any violation should not result in adverse action. Acting U.S. Attorney for the Western District of Virginia Daniel Bubar characterized this formula as DOJ "trying to think outside the box a little bit about ways that could [achieve] some meaningful compliance. We really tried to have some teeth here[.]" That is, DOJ was not concerned with just punishing and remediating the past misconduct, but also ensuring that compliance remains a preeminent focus going forward.

Unsurprisingly, in response to the question whether the government is “making a concerted push toward resolving cases in ways that more aggressively try to ensure future compliance,” DOJ’s CPB Director Gustav Eyster responded with an unequivocal “yes.” He added, “[t]he department has put out a fair bit of guidance and had a good deal of industry engagement with respect to what makes for a meaningful compliance program, and how the department will consider those compliance programs if an investigation does begin.”

In other words, DOJ believes that it has made its expectations clear and has expended considerable resources to do so. DOJ expects companies to understand the value of meaningful compliance, to ingrain compliance into business operations, and to require corporate executives to take personal accountability for compliance. Companies that successfully do so will have a better chance at avoiding or limiting court-imposed repercussions. If companies’ compliance programs are not in shape, expect DOJ to exercise “creative thinking” to develop potentially onerous terms that, in the Department’s view, will satisfy its expectation of continuous monitoring and improvement — the hallmarks of an effective compliance program.

## **RELATED INDUSTRIES + PRACTICES**

- [Health Care + Life Sciences](#)
- [White Collar Litigation + Investigations](#)