

October 28, 2020

## CEO Sentenced to Six Months in Prison After *Park* Doctrine Plea

On October 22, 2020, the former chief executive officer of Indivior PLC, Shaun Thaxter, was sentenced to six months of imprisonment for his conviction on one misdemeanor count of misbranding, in violation of the Federal Food, Drug, and Cosmetic Act (“FDCA”). For more than a decade, Mr. Thaxter was the highest-ranked executive at Indivior, which developed products to treat opioid dependence. Mr.

Thaxter’s conviction, which arises from Indivior’s marketing of its opioid-based product Suboxone Film, is particularly significant because it is based on the rarely used “responsible corporate officer” doctrine (also known as the “*Park* doctrine” based on the 1975 Supreme Court case, *United States v. Park*). Under the *Park* doctrine, Mr. Thaxter’s conviction is based on his role as a responsible executive who failed to prevent or correct Indivior’s illegal acts in violating the FDCA, instead of his direct involvement in those illegal acts. Additionally, the conviction did not involve any specific admission of criminal intent. While the vast majority of criminal statutes require the government to prove some level of criminal intent, the FDCA does not require criminal intent for a misdemeanor offense.

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The case against Mr. Thaxter arises from a multi-agency investigation into Indivior and its corporate affiliates that began in late 2013. In April 2019, a grand jury in the Western District of Virginia indicted Indivior on 28 felony counts for conduct from 2006 to 2015 that allegedly netted Indivior over \$3 billion in sales. The indictment asserted that Indivior engaged in a widespread illegal scheme to increase prescriptions of Suboxone Film, a drug prescribed in the treatment of opioid addiction. The active ingredient in Suboxone is buprenorphine, itself an opioid. Among other allegations, the government alleged that Indivior lacked any evidence to support its claims that Suboxone Film was safer and less susceptible to diversion than the tablet form of Suboxone. The government claimed that Indivior made those claims to health care providers and to state Medicaid administrators, developed misleading marketing materials, and encouraged providers to prescribe Suboxone Film in situations where it was not clinically warranted. For example, the government alleged that Indivior personnel were aware that physicians were overprescribing buprenorphine products, well in excess of the limits imposed by the federal Drug Addiction Treatment Act.

In July 2019, Reckitt Benckiser Group, which had been Indivior’s corporate parent until a spin-off in 2014, resolved all of its liability for a total of \$1.4 billion. That resolution included a non-prosecution agreement as well as civil settlements with the Department of Justice (“DOJ”), the Federal Trade Commission (“FTC”), and False Claims Act whistleblowers. Indivior itself entered into a global settlement on July 24, 2020; as part of that resolution, Indivior agreed to pay another \$600 million in penalties, and one of its subsidiaries pled guilty to one felony count of making false statements. The global resolution also included DOJ, FTC, and qui tam relators, and it required Indivior to agree to significant compliance certification and reporting requirements to DOJ for a five-year period.

Mr. Thaxter pled guilty to one count of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a), shortly before Indivior announced its global resolution. The Information to which Mr. Thaxter pled guilty charged that he failed to prevent and correct the distribution of false and misleading pediatric exposure data to the Massachusetts Medicaid program, MassHealth, in 2011 and 2012. The government alleged that the Medical Affairs Manager who was corresponding with MassHealth provided MassHealth with data that falsely suggested that Suboxone Film had the lowest rate of unintentional pediatric exposure in Massachusetts. Although the government charged that Mr. Thaxter had some early involvement in Indivior’s relationship with MassHealth, it did not allege that he played any personal role in the sending of false and misleading data. To the contrary, according to the Information, Mr. Thaxter approved sending a corrective letter to MassHealth in 2015.

On October 22, 2020, Judge James Jones sentenced Mr. Thaxter to six months of incarceration. Judge Jones also imposed one year of supervised release, a \$100,000 fine, and \$500,000 in forfeiture. Another Indivior executive,

Timothy Baxter, who served as the Global Medical Director, entered into a similar guilty plea based on the responsible corporate officer doctrine for the same incident involving MassHealth. Mr. Baxter's sentencing is scheduled for December 17, 2020.

The use of the *Park* doctrine in the Indivior cases is particularly noteworthy. DOJ prosecutors historically have been reluctant to charge individuals with strict liability FDCA misdemeanors based on their positions as responsible corporate officers rather than as a result of their personal involvement in the criminal misconduct at issue. That reluctance likely stems from the fact that a responsible corporate officer conviction brings a greater risk of reversal on appeal on due process grounds. Moreover, courts have endorsed its use in fairly limited circumstances. However, when the *Park* doctrine is available, it is a powerful weapon for the government, enabling charges against top-tier executives on a theory of negligence, for failing to prevent an offense, rather than for causing the offense through direct involvement in the misconduct. This means that executives can face jail time even when they have no personal knowledge or direct involvement in criminal conduct, making such charges a potent deterrent for illegal behavior and a strong incentive for executives to take extra measures to implement a culture of compliance within their organizations.

The Indivior individual plea agreements follow other recent high-profile misdemeanor convictions of executives. In 2014, in *United States v. DeCoster*, executives of Quality Egg LLC, which suffered a salmonella outbreak, were sentenced to three months' imprisonment following convictions under the *Park* doctrine. The U.S. Court of Appeals for the Eighth Circuit upheld those sentences on appeal, rejecting the defendants' argument that the prison sentences violated due process in light of the defendants' plea as responsible corporate officers. More recently, in *United States v. Facticeau*, Judge Allison Burroughs of the U.S. District Court for the District of Massachusetts upheld the convictions of two former Acclarent executives for ten counts of misdemeanor adulteration and misbranding on a strict liability theory. *Facticeau* is not a *Park* doctrine case, but the defendants raised post-trial arguments that their convictions without proof of intent violated due process. Although Judge Burroughs discussed *DeCoster* and expressed some concern about the potential scope of individual criminal liability where the defendant lacked knowledge of the wrongful conduct, she found that *Facticeau* did not present that issue because there was evidence that the defendants did personally participate in misconduct.

The Indivior individual prosecutions raise the question of whether the government will begin pursuing responsible corporate officer charges against executives in FDA-regulated industries more often, or whether the responsible corporate officer language in the Thaxter plea documents simply reflects the result of a negotiated settlement of a case where the non-public investigational record may reflect more direct involvement. While it is unclear whether the Indivior case reflects a significant change in the circumstances when DOJ will pursue FDCA criminal misdemeanor charges against individual corporate executives, the reminder that these charges can lead to actual jail time, even when based on a responsible corporate officer theory, gives DOJ significant leverage in plea discussions with corporations and their executives.