DOJ Demonstrates Continued Focus on Opioid Crisis with $600 Million Criminal and Civil Settlement Against Indivior Solutions, Indivior Inc., and Indivior plc

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The Department of Justice's ("DOJ") most recent settlement with Indivior Solutions, Inc., Indivior Inc., and Indivior plc (together, "Indivior") demonstrates not only that the DOJ is continuing its pursuit of claims and settlements related to the opioid crisis, but also that the DOJ is searching for creative penalties beyond large monetary payouts.

In a July 24, 2020 press release, the DOJ announced a $600 million civil and criminal settlement against Indivior related to marketing the opioid-addiction-treatment drug Suboxone. This settlement follows a larger, $1.4 billion settlement with Rickeitt Benckiser Group PLC, Indivior's former parent company, inked in 2019. The DOJ touts the combined $2 billion value of the 2019 and 2020 settlements as the largest-ever resolution in a case brought by the DOJ involving opioid drugs.

The civil settlement resolves claims from six qui tam lawsuits brought against various combinations of the Indivior entities under the False Claims Act ("FCA"). *United States ex rel. Finkelstein v. Reckitt Benckiser Pharms., Inc.*, No. 14-cv-00059 (W.D. Va.); *United States ex rel. Williams v. Reckitt Benckiser, Inc.*, No. 13-cv-00036 (W.D. Va.); *United States ex rel. Lemons v. Reckitt Benckiser Pharms.*, No. 15-cv-00016 (W.D. Va.); *United States ex rel. Kruszewski v. Reckitt Benckiser Pharms., Inc.*, No. XX-cv-XXXX [UNDER SEAL] (D.N.J.); *United States ex rel. Scott v. Reckitt Benckiser Pharms, Inc.*, No. XX-cv-XXXX [UNDER SEAL] (N.D.J.); *United States ex rel. Greene v. Indivior PLC*, No. XX-cv-XXXX [UNDER SEAL] (D.N.J.). Under the civil settlement, Indivior Inc. and Indivior plc agreed to pay $300 million, with $209.3 million going to the federal government and $90.7 million going to certain participating states. The amount awarded to the individual whistleblowers has yet to be determined.

While Indivior did not admit fault in its civil settlement, the settlement resolves three main allegations. First, the DOJ alleged Indivior knowingly promoted the sale and use of Suboxone to physicians who were writing prescriptions not for a medically-accepted indication, lacked a legitimate medical purpose, were issued without counseling or

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psychosocial support, were for unsafe, ineffective, and medically-unnecessary uses, or were often diverted. Second, the DOJ alleged that Indivior knowingly promoted the sale or use of Suboxone Film to physicians and state Medicaid agencies using false and misleading claims that Suboxone Film was less susceptible to accidental pediatric exposure than Suboxone Tablets. And third, the DOJ alleged that Indivior tried to delay the entry of generic competition to control the price of Suboxone—including pricing to federal healthcare programs. Such actions allegedly included the improper submission of a petition to the Food and Drug Administration ("FDA") claiming that Suboxone Tablet had been discontinued "due to safety concerns" about the tablet formulation of the drug. As part of the criminal resolution, Indivior Solutions pleaded guilty to a one-count felony criminal information charging false statements related to health care matters, in violation of 18 U.S.C. § 1035. *See United States v. Indivior Solutions, Inc.*, 19-cr-00016-JPJ-PMS (W.D. Va.). The plea included an admission that Indivior Solutions made false statements to promote the film version of Suboxone to the Massachusetts Medicaid programs regarding the safety of Suboxone Film around children. The settlement includes a criminal fine, forfeiture, and restitution in the combined amount of $289 million.

The criminal resolution also includes novel, non-monetary components, requiring that Indivior Inc. permanently disband its entire Suboxone sales force and a prohibition from using data obtained from surveys of health care providers for marketing, sales, or proposal purposes. Indivior's CEO will also be required to annually certify—under penalty of perjury—either that: (1) Indivior was complaint with the Food, Drug, and Cosmetic Act and did not commit health care fraud; or (2) list all of Indivior's non-compliant activity and the steps taken to remedy it. Finally, Indivior Inc. is also required to remove health care providers from its promotion programs at high risk of inappropriate prescribing. Neither the press release nor settlement materials explain how Indivior is supposed to identify high-risk providers. Failure to meet the above requirements will cause contempt sanctions and a reinstatement of the dismissed charges.

Besides the civil and criminal settlements, Indivior also agreed to a five-year Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General, under which Indivior will implement numerous accountability and auditing provisions, including a yearly compliance certification by Indivior executives and Board of Directors, annual risk assessments and other monitoring, and multi-faceted audits conducted by an independent review organization.

These cases serve as a reminder that the DOJ continues to aggressively pursue both civil and criminal claims related to the opioid crisis and provides insight into the non-monetary, compliance-based penalties the DOJ may pursue as part of global civil and criminal resolutions. As the stated by Elton Malone, Assistant Inspector General for Investigations with the Office of Inspector General of the U.S. Department of Health and Human Services, "[t]his resolution, along with our law enforcement partners' work, should serve as a warning that large companies will face prosecution if they break the law."