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Indivior Solutions Pleads Guilty To Felony Charge And Indivior Entities Agree To Pay \$600 Million To Resolve Criminal And Civil Investigations As Part Of DOJ's Largest Opioid Resolution

Resolutions Follow CEO Guilty Plea and \$1.4 Billion Settlement with Former Corporate Parent

Indivior Solutions today pleaded guilty to a one-count felony information and, together with its parent companies Indivior Inc. and Indivior plc, agreed to pay a total of \$600 million to resolve criminal and civil liability associated with the marketing of the opioid-addiction-treatment drug Suboxone. Together with a \$1.4 billion resolution with Indivior's former parent, Reckitt Benckiser Group PLC (RB Group), announced in 2019, and a plea agreement with Indivior plc's former CEO, Shaun Thaxter, announced last month, the total resolution relating to the marketing of Suboxone is more than \$2 billion — the largest-ever resolution in a case brought by the Department of Justice involving an opioid drug.

Suboxone is a drug product approved for use by recovering opioid addicts to avoid or reduce withdrawal symptoms while they undergo treatment for opioid-use disorder. Suboxone contains buprenorphine, a powerful opioid.

"Combatting the opioid crisis is a Department of Justice priority," said Principal Deputy Associate Attorney General Claire M. Murray. "Today's announced resolution and related actions hold accountable entities and individuals that unlawfully marketed opioid-addiction products."

"The opioid crisis is a public health emergency. Prevention and access to effective treatments for opioid addiction are critical to fighting this epidemic," said Deputy Assistant Attorney General Michael D. Granston for the Justice Department's Civil Division. "When a drug manufacturer claims to be part of a solution for opioid addicts, we expect honesty and candor to government officials, as well as to the physicians and patients making important treatment decisions based on those representations."

Resolution of the Criminal Investigation

Indivior Solutions pleaded guilty today to a one-count felony criminal information charging false statements relating to health care matters. In connection with its guilty plea, Indivior Solutions admitted to making false statements to promote the film version of Suboxone (Suboxone Film) to the Massachusetts Medicaid program (MassHealth) relating to the safety of Suboxone Film around children. The resolution includes a criminal fine, forfeiture, and restitution totaling \$289 million. On June 30, 2020, Indivior plc's former CEO Shaun Thaxter pleaded guilty to a one-count misdemeanor information related to Indivior's false and misleading representations to MassHealth.

In 2002, Indivior Inc. received approval to market Suboxone tablets for use in the treatment of opioid addiction and dependence. At that time, Indivior Inc. was an RB Group subsidiary known as Reckitt Benckiser Pharmaceuticals Inc. In December 2014, RB Group spun off Indivior Inc., and the two companies are no longer affiliated. Thereafter, Indivior Inc. became a subsidiary of Indivior plc. On April 9, 2019, a federal grand jury sitting in Abingdon, Virginia, indicted Indivior Inc. and Indivior plc for allegedly engaging in an illicit nationwide scheme to increase prescriptions of Suboxone.

In its guilty plea today, Indivior Solutions, which employed marketing and sales personnel for the Indivior group of companies, admitted to an aspect of the scheme alleged in the indictment. Specifically, Indivior Solutions admitted that, in October 2012, it sought to convince MassHealth to expand Medicaid coverage of Suboxone Film in Massachusetts and sent MassHealth false data indicating that Suboxone Film had the lowest rate of accidental pediatric exposure (*i.e.*, children taking medication by accident) of all buprenorphine drugs in Massachusetts, when in fact, it did not. Indivior Solutions further admitted that sending the false and misleading information occurred in the context of marketing and promotional efforts directed at MassHealth, which were overseen by top executives. MassHealth announced it would provide access to Suboxone Film for patients with children under the age of six shortly after Indivior provided the false and misleading information to agency officials.

“During the nationwide opioid epidemic, Indivior Solutions made false statements about Suboxone’s safety to increase its sales. In doing so, Indivior Solutions misled government health care officials and is being held accountable today for its felonious conduct,” said First Assistant U.S. Attorney Daniel P. Bubar of the Western District of Virginia. “This resolution is the culmination of years of work by prosecutors and agents and demonstrates that we will continue to work tirelessly to hold pharmaceutical manufacturers responsible for illegal conduct.”

In addition to its financial aspects, the agreement with Indivior Inc. includes novel provisions that:

- Require Indivior Inc. to disband its Suboxone sales force and not reinstate it;
- Require Indivior Inc.’s CEO to personally certify, under penalty of perjury, on an annual basis that during the prior year (a) Indivior was in compliance with the Food Drug and Cosmetic Act and did not commit health care fraud or (b) list all non-compliant activity and the steps taken by Indivior to remedy these acts;
- Prohibit Indivior Inc. from using data obtained from surveys of health care providers for marketing, sales, and promotional purposes;
- Require Indivior Inc. to remove health care providers from their promotional programs who are at a high risk of inappropriate prescribing; and
- Make Indivior subject to contempt sanctions by the court and reinstatement of the dismissed charges if it violates the agreement.

“The opioid crisis has devastated families and communities across the Commonwealth and drug manufacturers must be held accountable for their role in creating and prolonging this crisis,” said Virginia Attorney General Mark R. Herring. “I want to thank my Medicaid Fraud Control Unit for their work on this important case, as well as our local, state and federal partners for their continued collaboration. My team and I will continue to do everything in our power to hold pharmaceutical companies accountable for their role in the opioid crisis and help to ensure justice for those families who have been effected by the opioid crisis.”

“Parties that contract with the government will be held to the letter of the contract,” said Kenneth Cleevly, Special Agent in Charge of the Eastern Field Office for the U.S. Postal Service Office of Inspector General. “The U.S. Postal Service spends billions of dollars per year in workers compensation-related costs, most of which are legitimate. However, when medical providers or companies choose to flout the rules and profit illegally, special agents with the USPS OIG will work with our law enforcement partners to hold them responsible. To report fraud or other criminal activity involving the Postal Service, contact USPS OIG special agents at www.uspsig.gov or 888-USPS-OIG.”

U.S. District Judge James P. Jones accepted the guilty plea but deferred acceptance of the plea agreement until after the preparation of a presentence report. He scheduled sentencing for Oct. 20, 2020 at the U.S. Courthouse in Abingdon, Virginia.

The Civil Settlement

Under the civil settlement, Indivior Inc. and Indivior plc have agreed to pay a total of \$300 million to resolve claims that the marketing of Suboxone caused false claims to be submitted to government health care programs. The \$300 million settlement amount includes approximately \$209.3 million to the federal government and \$90.7 million to states that opt to participate in the agreement.

The civil settlement resolves allegations by the United States that, from 2010 through 2015, Indivior companies knowingly (a) promoted the sale and use of Suboxone to physicians who were writing prescriptions that were not for a

medically accepted indication and that lacked a legitimate medical purpose, were issued without any counseling or psychosocial support, were for uses that were unsafe, ineffective, and medically unnecessary, and were often diverted; (b) 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 diversion and abuse than other buprenorphine products and that Suboxone Film was less susceptible to accidental pediatric exposure than tablets; and (c) submitted a petition to the Food and Drug Administration on Sept. 25, 2012, claiming that Suboxone Tablet had been discontinued “due to safety concerns” about the tablet formulation of the drug and took other steps to delay the entry of generic competition for Suboxone to improperly control pricing of Suboxone, including pricing to federal healthcare programs.

“Prescription opioids are both addictive and dangerous when diverted for improper use or prescribed without accurate information about the risks that they pose,” said U.S. Attorney Craig Carpenito for the District of New Jersey. “This resolution holds Indivior to account for placing profit above patient and community safety.”

The civil settlement resolves claims against Indivior in six lawsuits pending in federal court in the Western District of Virginia and the District of New Jersey under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery. The False Claims Act also permits the government to intervene in such actions, as the government previously did in the three lawsuits pending in the Western District of Virginia. The whistleblower share to be awarded in this case has not yet been determined.

“Opioid addiction and abuse is an immense public health crisis and taking steps to address it is one of the FDA’s highest priorities,” said FDA Commissioner Stephen M. Hahn, M.D. “Medication-assisted treatments incorporating drugs like Indivior’s Suboxone, in combination with counseling and behavioral therapy, are an important tool in combating opioid use disorder but can quickly become part of the problem if not used responsibly. When companies encourage the use of powerful drugs where not medically necessary and provide misleading information about relative product benefits, they can ultimately risk more misuse, abuse, diversion, and accidental exposure to opioid drugs as well as make treatment more difficult to obtain for those suffering from this crisis. We will continue to work with the Department of Justice to investigate and hold accountable those who devise and participate in schemes to the detriment of the public health.”

Non-monetary Provisions of the Corporate Integrity Agreement

In addition to the criminal and civil resolutions, Indivior executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The CIA requires that Indivior implement numerous accountability and auditing provisions. On an annual basis, top executives and the Board of Directors must certify about compliance, Indivior must conduct annual risk assessments and other monitoring, and an independent review organization will conduct multi-faceted audits.

“Addressing the opioid crisis is a top priority for OIG, and we will continue to work closely with the Department of Justice to hold corporations and individuals accountable when they use illegal tactics to promote and sell opioids,” said Gregory E. Demske, Chief Counsel to the Inspector General, HHS-OIG. “Among other things, our CIA with Indivior imposes accountability on the Board and top executives, subjects the company to internal and external auditing, and ensures that the company will separate itself from its prior top leadership.”

“The opioid epidemic has ravaged this nation,” said Elton Malone, Assistant Inspector General for Investigations with the Office of Inspector General of the U.S. Department of Health and Human Services. “This resolution, along with our law enforcement partners’ work, should serve as a warning that large companies will face prosecution if they break the law.”

FTC Resolution

Under a separate agreement with the Federal Trade Commission (FTC), Indivior has agreed to pay \$10 million to resolve claims that it engaged in unfair methods of competition in violation of the Federal Trade Commission Act, 15 U.S.C. § 53(b). The FTC filed a complaint in the U.S. District Court for the Western District of Virginia alleging anticompetitive activities by Indivior designed to impede competition from generic equivalents of Suboxone. As part of a consent decree, Indivior agreed that it would notify the FTC if it filed a Citizen Petition with the FDA in connection with

a drug product, it would simultaneously disclose to both the FDA and the FTC all studies and data relevant to that Citizen Petition. Indivior further agreed not to withdraw a drug from the market or otherwise disadvantage a drug after obtaining approval to market another drug containing the same active ingredient.

“As alleged in the FTC’s complaint, in the midst of the nation’s opioid crisis, a critical opioid-addiction treatment was about to become more affordable,” said Gail Levine, a Deputy Director of the FTC’s Bureau of Competition. “But Indivior prevented that. It kept its drug prices high by unlawfully impeding generic manufacturers from competing effectively.”

A Multilateral Effort

The criminal case against Indivior was prosecuted by Randy Ramseyer of the U.S. Attorney’s Office for the Western District of Virginia, Albert P. Mayer and Carol Wallack of the Department of Justice Civil Division’s Commercial Litigation Branch, Charles J. Biro and Matthew J. Lash of the Department of Justice Civil Division’s Consumer Protection Branch, Kristin L. Gray, Joseph S. Hall and Janine M. Myatt of the Virginia Medicaid Fraud Control Unit of the Office of the Virginia Attorney General, and Garth W. Huston of the Federal Trade Commission. This matter was investigated by the Virginia Attorney General’s Medicaid Fraud Control Unit; FDA - Office of Criminal Investigation; United States Postal Service – Office of Inspector General; and Department of Health and Human Services - Office of Inspector General.

The civil settlement was handled by Edward Crooke of the Civil Division’s Commercial Litigation Branch, Sara Bugbee Winn of the U.S. Attorney’s Office for the Western District of Virginia, and Andrew A. Caffrey III of the U.S. Attorney’s Office for the District of New Jersey. Assistance was provided by representatives of the HHS Office of Counsel to the Inspector General; the HHS Office of the General Counsel, CMS Division; FDA’s Office of Chief Counsel; the U.S. Attorney’s Office for the Eastern District of Virginia; the U.S. Department of Agriculture Office of the General Counsel; the National Association of Medicaid Fraud Control Units; the Defense Criminal Investigative Service; the Office of Personnel Management - Office of Inspector General; the Department of Veterans’ Affairs Office of Inspector General; the Department of Labor - Office of Inspector General; and TRICARE Program Integrity.

The joint effort advances the goals of the Department’s Prescription Interdiction & Litigation (PIL) Task Force to deploy all available criminal, civil, and regulatory tools to hold opioid manufacturers accountable for unlawful practices and to ensure that prescription opioid products are marketed truthfully.

Except to the extent admitted as part of the criminal resolution, the claims resolved by the civil settlement are allegations only. There has been no determination of liability in the civil case.

For more information about the U.S. Attorney’s Office for the Western District of Virginia, visit its website at <https://www.justice.gov/usao-wdva> . Additional information about the Consumer Protection Branch and the Civil Fraud Section and their enforcement efforts may be found at <http://www.justice.gov/civil/consumer-protection-branch> and <http://www.justice.gov/civil/fraud-section> . Tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement, can be reported to the Department of Health and Human Services at 800-HHS-TIPS (800-447-8477).

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