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Justice Department Obtains \$1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History

Global consumer goods conglomerate Reckitt Benckiser Group plc (RB Group) has agreed to pay \$1.4 billion to resolve its potential criminal and civil liability related to a federal investigation of the marketing of the opioid addiction treatment drug Suboxone. The resolution – the largest recovery by the United States in a case concerning an opioid drug – includes the forfeiture of proceeds totaling \$647 million, civil settlements with the federal government and the states totaling \$700 million, and an administrative resolution with the Federal Trade Commission for \$50 million.

Suboxone is a drug product approved for use by recovering opioid addicts to avoid or reduce withdrawal symptoms while they undergo treatment. Suboxone and its active ingredient, buprenorphine, are powerful and addictive opioids.

“The opioid epidemic continues to be a serious crisis for our nation, and I’m proud of the work the Department of Justice and our partners are doing to address this epidemic,” said Principal Deputy Associate Attorney General Claire Murray.

“We are confronting the deadliest drug crisis in our nation’s history. Opioid withdrawal is difficult, painful, and sometimes dangerous; people struggling to overcome addiction face challenges that can often seem insurmountable,” said Assistant Attorney General Jody Hunt for the Department of Justice’s Civil Division. “Drug manufacturers marketing products to help opioid addicts are expected to do so honestly and responsibly.”

Resolution of the Criminal Investigation

Until December 2014, RB Group’s wholly owned subsidiary, Indivior Inc. (then known as Reckitt Benckiser Pharmaceuticals Inc.) marketed and sold Suboxone throughout the United States. In

December 2014, RB Group spun off Indivior Inc., and the two companies are no longer affiliated. On April 9, a federal grand jury sitting in Abingdon, Virginia, indicted Indivior for allegedly engaging in an illicit nationwide scheme to increase prescriptions of Suboxone. The United States' criminal trial against Indivior is scheduled to begin on May 11, 2020, in the United States District Court in Abingdon, Virginia. Indivior is presumed innocent until proven guilty.

To resolve its potential criminal liability stemming from the conduct alleged in the indictment of Indivior, RB Group has executed a non-prosecution agreement that requires the company to forfeit \$647 million of proceeds it received from Indivior and not to manufacture, market, or sell Schedule I, II, or III controlled substances in the United States for three years. In addition, RB Group has agreed to cooperate fully with all investigations and prosecutions by the Department of Justice related, in any way, to Suboxone.

"Today's announcement demonstrates that this office will work tirelessly to address all facets of the opioid epidemic," First Assistant United States Attorney Daniel P. Bubar of the Western District of Virginia said. "This historic resolution is the product of a continued partnership with the Virginia Medicaid Fraud Control Unit, FDA, HHS, and the U.S. Postal Service."

"This is a landmark moment in our fight to hold drug companies responsible for their role in the opioid crisis," said Virginia Attorney General Mark Herring. "We will not allow anyone to put profits over people, or to exacerbate or exploit the opioid crisis for their own benefit. The Virginia Medicaid Fraud Control Unit's expertise, capacity, and diligent investigation, combined with strong relationships with local, state, and federal partners, helped make this resolution possible."

"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 Acting FDA Commissioner Ned Sharpless, M.D. "Providing misleading information about product benefits puts the public at risk. We also are particularly concerned with schemes to game the drug approval process to prevent generic competition for important medicines. The FDA, including criminal investigators in our Office of Regulatory Affairs and the lawyers in our Office of Chief Counsel, 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."

"The U.S. Postal Service spends billions of dollars per year in workers compensation-related costs, most of which are legitimate," said Kenneth Cleevly, Special Agent in Charge of the Eastern Field Office for the U.S. Postal Service Office of Inspector General. "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 our special agents at www.uspsaig.gov or 888-USPS-OIG.”

According to the indictment, Indivior—including during the time when it was a subsidiary of RB Group—promoted the film version of Suboxone (Suboxone Film) to physicians, pharmacists, Medicaid administrators, and others across the country as less-divertible and less-abusable and safer around children, families, and communities than other buprenorphine drugs, even though such claims have never been established.

The indictment further alleges that Indivior touted its “Here to Help” internet and telephone program as a resource for opioid-addicted patients. Instead, however, Indivior used the program, in part, to connect patients to doctors it knew were prescribing Suboxone and other opioids to more patients than allowed by federal law, at high doses, and in a careless and clinically unwarranted manner.

The indictment also alleges that, to further its scheme, Indivior announced a “discontinuance” of its tablet form of Suboxone based on supposed “concerns regarding pediatric exposure” to tablets, despite Indivior executives’ knowledge that the primary reason for the discontinuance was to delay the Food and Drug Administration’s approval of generic tablet forms of the drug.

The indictment alleges Indivior’s scheme was highly successful, fraudulently converting thousands of opioid-addicted patients over to Suboxone Film and causing state Medicaid programs to expand and maintain coverage of Suboxone Film at substantial cost to the government.

The Civil Settlement

Under the civil settlement, RB Group has agreed to pay a total of \$700 million to resolve claims that the marketing of Suboxone caused false claims to be submitted to government health care programs. The \$700 million settlement amount includes \$500 million to the federal government and up to \$200 million to states that opt to participate in the agreement. The claims settled by the civil agreement are allegations only and there has been no determination of liability.

The civil settlement addresses allegations by the United States that, from 2010 through 2014, RB Group directly or through its subsidiaries knowingly: (a) promoted the sale and use of Suboxone to physicians who were writing prescriptions without any counseling or psychosocial support and for uses that were unsafe, ineffective, and medically unnecessary and that were often diverted for uses that lacked a legitimate medical purpose; (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 in order to improperly control pricing of Suboxone, including pricing to federal healthcare programs.

“With the nation continuing to battle the opioid crisis, the availability of quality addiction treatment options is critical. When treatment medications are used, it is essential they be prescribed carefully, legally, and based on accurate information, to protect the health and safety of patients in federal healthcare programs,” said Gary L. Cantrell, Deputy Inspector General for Investigations at the U.S. Department of Health and Human Services. “Along with our federal and state law enforcement partners we will continue working to protect these vulnerable beneficiaries.”

“Opioid manufacturers – like all drug manufacturers – have a duty to market their products both truthfully and safely,” said Craig Carpenito, U.S. Attorney for New Jersey. “Opioid manufacturers have an additional and critically important duty to maintain effective controls to prevent their highly dangerous products from being abused and diverted.”

“The opioid crisis has caused devastation throughout the country, including in the lives of Federal employees, annuitants, and their families,” said Thomas W. South, Deputy Assistant Inspector General for Investigations for the Office of Personnel Management. “The OPM OIG is committed to working with the Department of Justice and our other law enforcement partners to combat this epidemic. As always, patient safety is our number one priority.”

The civil settlement resolves the claims against RB Group 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.

FTC Resolution

Under a separate agreement with the Federal Trade Commission (FTC), RB Group has agreed to pay \$50 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 is filing a complaint in the United States District Court for the Western District of Virginia alleging anticompetitive activities by RB Group designed to impede competition from generic equivalents of Suboxone. RB Group no longer manufactures or markets drug products. As part of a consent decree, RB Group agreed that it would notify the FTC if it began marketing drug products in the United States. RB Group further agreed that 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. RB Group 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.

“Buprenorphine products are approved for use in the treatment of Americans struggling to overcome opioid addiction, and, in the middle of the nation’s opioid crisis, RB Group allegedly sought to deny those consumers a lower-cost generic alternative to maintain its lucrative monopoly on the branded drug,” said Gail Levine, a Deputy Director of the FTC’s Bureau of Competition.

A Multilateral Effort

The criminal resolution with RB Group was handled by the U.S. Attorney’s Office for the Western District of Virginia and the Department of Justice’s Consumer Protection Branch based on an investigation 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 the Civil Division’s Commercial Litigation Branch, the U.S. Attorney’s Office for the Western District of Virginia, and 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. 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.

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