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Suboxone Manufacturer Indivior's Former Chief Executive Officer Sentenced to Jail Time in Connection with Drug Safety Claims

ABINGDON, VIRGINIA – Shaun Thaxter, the former chief executive officer of Indivior PLC, was sentenced today in U.S. District Court in Abingdon to 6 months in federal prison. He was also ordered to pay a fine of \$100,000 and forfeit \$500,000. Thaxter pleaded guilty to a one-count misdemeanor information on June 30, 2020 for his role in causing the introduction into interstate commerce of misbranded shipments of the opioid drug Suboxone Film, a violation of the Federal Food, Drug, and Cosmetic Act. Acting United States Attorney Daniel P. Bubar announced the sentence today.

Thaxter served as Indivior's top executive from 2009 until shortly before his guilty plea. This includes the time period prior to December 2014 when Indivior was known as Reckitt Benckiser Pharmaceuticals. When Indivior was known as Reckitt Benckiser Pharmaceuticals, it was a subsidiary of British conglomerate Reckitt Benckiser Group (RB Group). RB Group paid \$1.4 billion in 2019 to resolve its liability to the United States related to the marketing of Suboxone. On July 24, 2020, an Indivior subsidiary called Indivior Solutions pleaded guilty to a one-count felony information for false statements related to health care matters, and together with Indivior, agreed to pay an additional \$600 million to resolve liability to the United States related to the marketing of Suboxone. On August 26, 2020, Indivior's former medical director, Timothy Baxter, pleaded guilty to a one-count misdemeanor information for a violation of the Federal Food, Drug, and Cosmetic Act related to the marketing of Suboxone. Indivior Solutions and Baxter have not yet been sentenced.

Suboxone Film is a drug product approved for use by recovering opioid addicts to avoid or reduce withdrawal symptoms while they undergo treatment. Suboxone's active ingredient, buprenorphine, is a powerful and addictive opioid. Thaxter was charged in connection with Indivior's misrepresentations regarding the safety of Suboxone Film.

“While Thaxter served for years as Indivior’s chief executive, he was in a position to ensure that doctors, patients, and insurers were dealt with honestly,” Acting United States Attorney Bubar said today. “Instead, Thaxter failed to prevent efforts to build profits through misleading safety claims, which led to millions of dollars in ill-gotten gains for Indivior. As the Court recognized today, this sentence should serve as a deterrence to other pharmaceutical executives. Today’s sentencing is also the product of years of work and could not have happened without the close federal and state law enforcement partnerships, for which we are grateful.”

“Families and communities across the Commonwealth continue to feel the devastating effects of the opioid epidemic,” said Virginia Attorney General Mark Herring. “Opioid manufacturers and their executive leadership must be held accountable for taking advantage of this country’s opioid crisis and putting profits over people. I want to thank my Medicaid Fraud Control Unit for their terrific work on this case as well as our local, state, and federal partners for their continued partnership on these cases.”

“Misrepresentations made about the drug, while Thaxter ran the company, misled MassHealth about the potential risk of accidental opioid exposure. It is inexcusable to willfully disregard requirements that treatment medications be prescribed carefully in order to protect patient health and safety,” said Elton Malone, Assistant Inspector General for Investigations with the Office of Inspector General of the U.S. Department of Health and Human Services. “With our law enforcement partners, we will continue investigating and bringing to justice those placing profits over patients in government healthcare programs.”

“Opioid addiction is a significant public health crisis and addressing opioid abuse continues to be one of FDA’s top priorities. Misleading information about relative product benefits undermines efforts to provide affordable treatment to those suffering from opioid addiction,” said Judy McMeekin, Pharm.D., Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration. “We will continue to investigate and bring to justice those whose schemes jeopardize public health and put Americans at risk.”

“The U.S. Postal Service spends billions of dollars per year in workers compensation and health care-related costs, most of which are legitimate,” said Kenneth Cleevely, 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 USPS OIG special agents at www.uspsoig.gov or 888-USPS-OIG.”

According to court documents, Thaxter had authority over Indivior's marketing and sales of Suboxone Film which, along with other Suboxone products, generated nearly all the company's revenue. In 2012, Thaxter oversaw and encouraged Indivior's efforts to secure formulary coverage for Suboxone Film from the Massachusetts Medicaid agency called MassHealth. Thaxter asked Indivior employees under his direction to devise a strategy to win preferred drug status for Suboxone Film and counteract a non-opioid competitor MassHealth was considering for opioid-addiction treatment. Certain Indivior employees subsequently shared false and misleading safety information with MassHealth officials about Suboxone Film's risk of accidental pediatric exposure. Two months after receiving that false and misleading information, MassHealth announced it would provide access to Suboxone Film for Medicaid patients with children under the age of six.

The criminal cases against Thaxter, Indivior, and Baxter are being prosecuted by attorneys from the U.S. Attorney's Office for the Western District of Virginia and the Department of Justice's Civil Division, including Albert P. Mayer, Randy Ramseyer, Kristin L. Gray, Joseph S. Hall, Janine M. Myatt, Garth W. Huston, Carol Wallack, Charles J. Biro, and Matthew J. Lash. The criminal investigation of Thaxter was handled by the Virginia Medicaid Fraud Control Unit; FDA's Office of Criminal Investigations; United States Postal Service - Office of Inspector General; and U.S. Department of Health and Human Services - Office of Inspector General.

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