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Press Release

Attorney General Frosh Announces \$700 Million Settlement Allegations with Drug Distributor for Allegations of Improper Marketing and Sale of Suboxone

BALTIMORE, MD (November 7, 2019) – Maryland Attorney General Brian E. Frosh announced today that Maryland and other states have reached an agreement with pharmaceutical distributor Reckitt Benckiser Group (Reckitt) to settle allegations that Reckitt improperly marketed and otherwise promoted the drug Suboxone, causing the improper expenditures of state Medicaid funds. Suboxone is a drug approved for use by recovering opioid addicts to avoid or reduce withdrawal symptoms while they undergo treatment. Suboxone contains a combination of buprenorphine and naloxone.

"Suboxone has been critical in helping individuals addicted to opioids through withdrawal and recovery," said Attorney General Frosh. "But Reckitt misled the public about Suboxone's risks, promoted its use to physicians, and defrauded state Medicaid programs out of hundreds of millions of dollars to increase its bottom line."

Under the settlement, Reckitt has agreed to pay \$700 million collectively to the federal and state governments. The participating states will share \$400 million of the total settlement. Maryland will receive \$28,230,748, a portion of which will be shared with the federal government and whistleblowers who filed the original cases.

The settlement resolves the following allegations:

- (a) Reckitt knowingly promoted the sale and use of Suboxone to physicians who were writing prescriptions (1) to patients without any counseling or psychosocial support, such that the prescriptions were not for a medically accepted indication; and (2) for uses that were unsafe, ineffective, and medically unnecessary and that were often diverted for uses that lacked a legitimate medical purpose.
- (b) Reckitt knowingly promoted the sale or use of Suboxone Sublingual Film based on false and misleading claims that Suboxone Sublingual Film was less subject to diversion and abuse than other buprenorphine products and that Suboxone Sublingual Film was less susceptible to accidental pediatric exposure than Suboxone Sublingual

Tablets. Physicians relied on these false and misleading claims in prescribing Suboxone Sublingual Film, and state Medicaid programs relied on these false and misleading claims to their detriment in making formulary and prior authorization decisions.

(c) Reckitt knowingly submitted a petition to the Food and Drug Administration in 2012 fraudulently claiming that it had discontinued manufacturing and selling Suboxone Sublingual Tablet "due to safety concerns" about the tablet formulation of the drug, and took other steps to fraudulently delay the entry of generic competition for various forms of Suboxone in order to improperly control pricing of Suboxone, including pricing to state Medicaid programs.

Reckitt is an English public limited company headquartered in Slough, England, the United Kingdom. Until December 23, 2014, Reckitt's wholly owned subsidiary Indivior, Inc. (then known as Reckitt Benckiser Pharmaceuticals, Inc.) distributed, marketed, and sold Suboxone Sublingual Tablets and Suboxone Sublingual Film in the United States. In 2014, Reckitt spun off Indivior, Inc. The settlement described is with Reckitt, alone. Reckitt has entered into a separate non-prosecution agreement to resolve its potential criminal liability stemming from conduct alleged in the indictment of Indivior, Inc.

The civil settlement included all 50 states, the District of Columbian, and Puerto Rico, and resolves the claims against Reckitt brought in six whistleblower lawsuits pending in federal courts in the Western District of Virginia and the District of New Jersey.

Attorney General Frosh thanked the Medicaid Fraud Control Unit for its work on the case, specifically Assistant Attorney General Adam Sampson, Chief Investigative Auditor Ruth Jarrell, Senior Investigative Auditor Carol Kelly, and Investigator Aaron Stewart. Attorney General Frosh also thanked the National Association of Medicaid Fraud Control Units team that participated in the investigation and settlement of the case.