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ROB BONTA

Attorney General

Attorney General Bonta Announces \$102.5 Million Settlement Against Maker of Opioid Addiction Treatment Drug Suboxone

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California receiving over \$7.1 million of settlement funds

OAKLAND – California Attorney General Bonta today joined a coalition of 42 attorneys general in announcing a settlement against Invidior Inc. (Indivior) to resolve allegations that the global pharmaceutical company violated state and federal antitrust laws by attempting to maintain market exclusivity over Suboxone. As part of the settlement, Indivior will pay \$102.5 million to the states and be prohibited from engaging in future anticompetitive conduct. Manufactured and marketed by Invidior, Suboxone is a

prescription drug approved for use by recovering opioid addicts to avoid or reduce withdrawal symptoms while they undergo treatment. California will be receiving over \$7.1 million of the multistate settlement funds.

"The cost of prescription drugs is a tremendous problem for many Californians, and Indivior contributed to that problem by preventing lower cost generics from competing with Suboxone, their branded opioid addiction treatment drug," **said Attorney General Bonta**. "Opioid addiction treatments should be accessible to everyone — especially our most vulnerable populations that need them for their recovery. With today's settlement, we're holding Indivior accountable and ensuring it doesn't engage in similar anticompetitive conduct in the future."

In addition to requiring Indivior to pay \$102.5 million, under the settlement:

- Indivior must provide the states with information and reasons for any reformulated versions of Suboxone;
- If pharmaceutical companies file for Food and Drug Administration (FDA) approval of generic versions of Suboxone, Indivior must leave the original product on the market for a limited period to allow doctors and patients to choose which formulation they like better; and
- If Indivior files an FDA Citizen Petition in an attempt to delay generic competition in the future, it must also submit any data or information underlying that petition to the FDA and the states.

Indivior received FDA approval for Suboxone in 2002, along with exclusive rights to sell the drug for seven years based on representations that it was otherwise unlikely to recover its investment in the drug. Suboxone originally came in tablet form. However, in 2010 — a year after Indivior's exclusive right to the Suboxone tablet had expired and generic manufacturers were set to enter the market — the company switched from tablet to sublingual film, falsely citing safety concerns. Sublingual film is a dissolving film.

In response, the California Attorney General's office and fellow attorneys general sued Indivior in 2016, alleging that Indivior engaged in a “product-hopping” scheme to block competition to Suboxone. In such a scheme, pharmaceutical companies try to maintain profits generated via a monopoly by slightly reformulating their product in a way that blocks generic competitors without offering any significant medical or therapeutic advantages to patients.

In April 2021, Attorney General Bonta announced a separate \$300 million settlement against Indivior resolving claims that Indivior falsely and aggressively marketed Suboxone, resulting in improper use of state Medicaid funds. California was a part of the team of states that negotiated the settlement which was paid to all 50 states, the District of Columbia, and Puerto Rico.

Attorney General Bonta is joined in today's settlement by the attorneys general of Alabama, Alaska, Arkansas, Colorado, District of Columbia, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

A copy of the agreement, which was submitted to the United States District Court for the Eastern District of Pennsylvania for approval, can be found **here**.

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