Cassipa® (buprenorphine/naloxone) – New drug approval

- On September 7, 2018, the FDA announced the approval of Teva's Cassipa (buprenorphine/naloxone) sublingual film, for the maintenance treatment of opioid dependence.
    - Cassipa should be used as part of a complete treatment plan to include counseling and psychosocial support.
    - This approval provides a new dosage strength of buprenorphine and naloxone compared to currently marketed agents.
    - Cassipa is a Schedule 3 controlled substance.
- Buprenorphine and naloxone is also available generically as a sublingual tablet, as well as the branded products Bunavail® buccal film, Suboxone® sublingual film and Zubsolv® sublingual tablet.
    - All of these products are indicated for the treatment of opioid dependence.
- The approval of Cassipa was supported by the FDA's finding of safety and efficacy for Suboxone sublingual film. Cassipa-specific pharmacokinetic data was provided to establish the safety and efficacy of this higher dose formulation for its approved use.
- Warnings and precautions of Cassipa include addiction, abuse, and misuse; risk of respiratory and central nervous system (CNS) depression; managing risks from concomitant use of benzodiazepines or other CNS depressants; unintentional pediatric exposure; neonatal opioid withdrawal syndrome; adrenal insufficiency; risk of opioid withdrawal with abrupt discontinuation; risk of hepatitis and hepatic events; hypersensitivity reactions; precipitation of opioid withdrawal signs and symptoms; risk of overdose in opioid naïve patients; use in patients with impaired hepatic function; impairment of ability to drive or operate machinery; orthostatic hypotension; elevation of cerebrospinal fluid pressure; elevation of intracholedochal pressure; and effects in acute abdominal conditions.
- The most common adverse events with the sublingual administration of buprenorphine and naloxone sublingual film were oral hyposthesia, glossodynia, oral mucosal erythema, headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema.
- The recommended dose of Cassipa for the treatment of opioid dependence is one film administered under the tongue as a single daily dose.
    - Cassipa should only be used after induction and stabilization of the patient, and when the patient has been titrated to a dose of 16 mg buprenorphine using another marketed product.
    - Under the Drug Addiction Treatment Act (DATA), prescription use of this product is limited to healthcare providers who meet certain qualifying requirements.
    - Cassipa is not appropriate as an analgesic and cannot be used in opioid-naïve patients.
    - Cassipa must be administered whole. Do not cut, chew, or swallow Cassipa.
- Teva's launch plans for Cassipa are pending. Cassipa will be available as a sublingual film containing 16 mg of buprenorphine and 4 mg of naloxone.