Fentora® (fentanyl) – First-time generic (authorized generic)

- On June 13, 2019, Mayne Pharmaceuticals launched an authorized generic version of Teva's Fentora (fentanyl) buccal tablets.
    - Fentora is a scheduled II controlled substance.
- Fentora is approved for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.
- Fentanyl is also available generically as an injection, oral transmucosal lozenge, and transdermal system; and as brand sublingual tablet (Abstral®), an iontophoretic transdermal system (Ionsys®), nasal spray (Lazanda™), and a sublingual spray (Subsys®).
    - The injection is indicated as an analgesic prior to, during, and after anesthesia.
    - The lozenge, Abstral, Lazanda, and Subsys carry the same indication as Fentora except the lozenge is approved for patients 16 years of age and older.
    - The transdermal system is for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
    - Ionsys is indicated for the short-term management of acute postoperative pain severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate.
- Fentora carries a boxed warning for life-threatening respiratory depression; accidental ingestion; risks from cytochrome P450 3A4 interaction; risks from concomitant use with benzodiazepines or other central nervous system depressants; risk of medication errors; addiction, abuse, and misuse; risk evaluation and mitigation strategy; and neonatal opioid withdrawal syndrome.