**Delalutin** (hydroxyprogesterone caproate) – First-Time Generic

- **McGuff announced** the FDA approval of the generic version of Bristol-Myers Squibb’s Delalutin (hydroxyprogesterone caproate) injection.
  - McGuff’s generic hydroxyprogesterone is therapeutically equivalent to Delalutin injection.

- Delalutin is indicated for use in non-pregnant women for the treatment of advanced adenocarcinoma of the uterine corpus (stage III or IV); management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer; as a test for endogenous estrogen production and for the production of secretory endometrium and desquamation.

- Delalutin was initially approved in 1956 for use in pregnant women for the treatment of habitual and recurrent abortion, threatened abortion, and postpartum after pains.
  - At the request of Bristol-Myers Squibb, the FDA approval was withdrawn in 2000 because the product was no longer being marketed.

- Hydroxyprogesterone caproate is a long-acting, progestational steroid ester.
  - Hydroxyprogesterone caproate is also available as Makena®, indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

- Hydroxyprogesterone caproate is contraindicated in patients with known or suspected carcinoma of the breast, other hormone-sensitive cancer, or history of these conditions; undiagnosed abnormal vaginal bleeding; liver dysfunction or disease; missed abortion; as a diagnostic test for pregnancy; and in patients with a current or history of thrombotic or thromboembolic disorder.

- Other warnings of hydroxyprogesterone caproate include allergic reactions and glucose tolerance.

- The recommended dose of hydroxyprogesterone caproate injection varies by specific indication.

- McGuff plans to launch generic hydroxyprogesterone caproate in 2016. Generic hydroxyprogesterone caproate will be available as 1,250 mg per 5 mL vials.