FDA announces decision to withdraw Makena (hydroxyprogesterone caproate)

- On April 6, 2023, the FDA announced the final decision to withdraw approval of Makena (hydroxyprogesterone caproate). **Makena and its generics are not shown to be effective** for reducing the risk of preterm birth in women with singleton pregnancy who have a history of singleton spontaneous preterm birth. Additionally, Makena and its generics have not been shown to be effective for any subgroup of this population, including in women at high risk of preterm birth. The benefits of Makena do not outweigh the risks.
  - The provider notification advises health care practitioners to consider the FDA's conclusion that these drugs are not shown to be effective and that the benefits do not outweigh their risks to patients.
- Makena was approved under an accelerated approval pathway in 2011. As a condition of this approval, the sponsor was required to conduct a confirmatory clinical trial to demonstrate the predicted clinical benefit to newborns.
  - The confirmatory trial, which was nearly four times larger than the trial that supported Makena's accelerated approval, did not show improvement in the health of the babies born to mothers who were treated with Makena. It also failed to show that Makena reduced the risk of preterm birth.
- While the approvals of Makena and its generics have been withdrawn, the FDA recognizes that there is a supply of product that has already been distributed, including to health care providers' offices and pharmacies.
- Some health care providers might continue to prescribe or administer the limited remaining supply to their patients. However, the FDA recommends health care providers consider the FDA's conclusion that these drugs are not shown to be effective for the indication for which they were approved and do not have benefits that outweigh their risks to patients.
- A health care practitioner considering whether to prescribe compounded drug products containing hydroxyprogesterone caproate should be aware of the FDA's determination that Makena and its generics are not effective.
- See here for more information about the FDA's decision.