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Testimony before the FDA's Pharmacy Compounding Advisory Committee about Hydroxyprogesterone Caproate

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I am Robert Steinbrook, Director of Public Citizen's Health Research Group. We have no financial conflicts of interest.

Public Citizen's Health Research Group supports the FDA's recommendation for the addition to the Withdrawn or Removed List of "all drug products containing hydroxyprogesterone caproate to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth." [1]

In April 2023, soon after the FDA withdrew approval of Makena and all related generic products, Public Citizen and co-petitioner Dr. Adam Urato, a maternal-fetal medicine physician in Massachusetts, filed a Citizen Petition with the FDA. The petition called for the prompt initiation of the regulatory process to add hydroxyprogesterone caproate injection for prevention of preterm birth to the list of drug products that were withdrawn or removed from the market for reasons of safety or effectiveness and therefore may not be compounded under the exemptions provided in FDA regulations.[2] As the petition argued, the lack of evidence that hydroxyprogesterone caproate was effective for its labeled indication as well as a benefit-risk balance that was not favorable for Makena, provided a strong basis for the FDA to initiate regulatory action to prevent pharmacy compounding of the drug for prevention of preterm birth.

Public Citizen is concerned that unless hydroxyprogesterone caproate is added to the Withdrawn or Removed list some obstetricians and maternal-fetal medicine physicians may continue to prescribe compounded versions of the drug, either now or in the future. Regardless of how frequently compounded versions of hydroxyprogesterone caproate are currently prescribed, the FDA should promptly take the necessary regulatory action to prohibit pharmacy compounding. We urge the advisory committee to fully support the FDA's recommendation to add hydroxyprogesterone caproate for the prevention of preterm birth to the Withdrawn or Removed List.

Thank you for the opportunity to comment.

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[1] FDA Briefing Document. Pharmacy Compounding Advisory Committee (PCAC) Meeting. October 29, 2024. https://www.fda.gov/media/182090/download Accessed October 28, 2024.

[2] Carome MA, Wolfe SM, Urato AC. Public Citizen. Petition to Amend 21 C.F.R. § 216.24 to include hydroxyprogesterone caproate injection. April 27, 2024. https://www.citizen.org/wp-content/uploads/2655.pdf Accessed October 28, 2024.