

06 Sep 2024 | Analysis

## Pink Sheet Podcast: Rare Pediatric Disease PRV Deadline, Potential Makena Compounding Ban

by Pink Sheet Team

Pink Sheet reporter and editors discuss the potential fallout if the US FDA's rare pediatric disease priority review voucher program is allowed to sunset, as well as an upcoming agency advisory committee meeting on potentially banning compounding of the active ingredient in the now-withdrawn preterm birth prevention drug Makena.

*Pink Sheet* Executive Editor Derrick Gingery, Senior Writer Sarah Karlin-Smith, Senior Editor Sue Sutter and Interim Editor-in-Chief Nielsen Hobbs consider the ramifications of ending the rare pediatric disease priority review voucher program, should Congress not renew it by the 1 October deadline (:30). They also discuss an upcoming advisory committee meeting and potential US Food and Drug Administration decision on banning compounding of the active ingredient in *Covis Pharma*'s preterm birth medication Makena (hydroxyprogesterone caproate), which was withdrawn from the market in 2023 (18:39).

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- US FDA Panel To Consider Compounding Ban For Makena's Active Ingredient

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