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### IN THIS ISSUE

Note: *Zolgensma* Data Manipulation ..... p 129

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## on Drugs and Therapeutics

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### NOTE

#### Zolgensma Data Manipulation

On August 6, 2019, the FDA issued a statement on data manipulation/inaccuracy issues with *Zolgensma*, a virus vector-based gene therapy approved for one-time IV treatment of children <2 years old with spinal muscular atrophy.<sup>1</sup> We reviewed *Zolgensma* in our July 29 issue.<sup>2</sup> According to the FDA statement, the manipulated data pertained to the production process for the product and did not affect the efficacy or safety results from the human clinical trials. It does not require any change in our review. ■

1. FDA Statement. Statement on data accuracy issues with recently approved gene therapy. Available at: [www.fda.gov/news-events/press-announcements/statement-data-accuracy-issues-recently-approved-gene-therapy](http://www.fda.gov/news-events/press-announcements/statement-data-accuracy-issues-recently-approved-gene-therapy). Accessed August 15, 2019.
2. *Zolgensma* – one-time gene therapy for spinal muscular atrophy. *Med Lett Drugs Ther* 2019; 61:113.

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