



## FDA Update, Fetus/Newborn Infant, News Articles

### Newborn screening test for lysosomal storage disorders can be marketed

by from the Food and Drug Administration Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health, and Center for Devices and Radiological Health

The Food and Drug Administration (FDA) has permitted marketing of the Seeker System (Baebies Inc., Durham, N.C.), the first newborn screening test for four rare lysosomal storage disorders (LSDs) - Gaucher disease, Fabry disease, mucopolysaccharidosis type 1 and Pompe disease. Estimated prevalence of LSDs is between one in 1,500 and one in 185,000 people, depending on the disease.

Newborn screening is offered to parents of all babies in the U.S. to identify conditions that are treatable but not clinically evident at birth, and for which early intervention may improve long-term clinical outcomes. A delay in treatment of LSDs may lead to permanent damage of multiple organs, neurological disability, bone abnormalities and/or death.

The Seeker System measures the activity of four lysosomal storage enzymes using the dried blood sample collected from a newborn heel prick. Reduced enzyme activity detected by the device indicates the potential presence of a disorder and must be confirmed using additional diagnostic methods.

A clinical study of 105,089 newborns, including 39 with LSD diagnoses, demonstrated the Seeker System was safe and effective for newborn screening. On Aug. 10, 2016, the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee recommended allowing the Seeker System to be marketed. The panel noted the lack of approved devices and said the benefit of potentially improving timely detection of LSDs using the Seeker System outweigh the risks, including false-positive and false-negative results.

Marketing authorization of the Seeker System will enable greater access to LSD newborn testing for state public health programs.

#### Resources

- [Additional information on mucopolysaccharidosis](#)
- [Additional information on Pompe disease](#)
- [Additional information on Fabry disease](#)
- [Additional information on Gaucher disease](#)
- [FDA news release on marketing approval for Seeker System](#)
- [Decision summary](#)
- [Panel meeting website \(meeting held Aug. 10, 2016\)](#)