PUBLIC HEALTH DIVISION
Oregon State Public Health Laboratory
Kate Brown, Governor

Oregon Health Authority

3150 NW 229th Ave
Hillsboro, Oregon 97124
Voice: 503-693-4100
FAX: 503-693-5605
TTY: 971-673-0372

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TO: The Honorable Senator Laurie Monnes Anderson, Chair
Senate Committee on Health Care

FROM: Dr. John Fontana, Director
Oregon State Public Health Laboratory
Public Health Division
Oregon Health Authority
971-693-4100

SUBJECT: SB 808, Newborn Screening

Chair Monnes Anderson and members of the committee: I am John Fontana, the Director of the Oregon State Public Health Laboratory. Thank you for the opportunity to provide information about the Northwest Regional Newborn Screening Program at the state laboratory. Senate Bill 808 proposes that health screen testing services may conduct federally recommended newborn screening tests, that rules specifying testing for the disorder must be adopted within two years of federal recommendation, and establishes a committee to review health screen testing for newborns.

This bill references health screen testing services, defined in ORS 438.010, which perform limited, easy-to-perform tests without a physician's order in temporary locations. Newborn screening tests are classified as highly complex and generally are outside the scope of health testing services and are governed by ORS 433.285.

The Oregon Health Authority maintains authority to add new tests to the newborn screening panel. The Newborn Screening Program began in 1963 and Oregon was one of the first states to provide screening, initially on two disorders, PKU and galactosemia. We are currently testing for 29 primary disorders and 22 secondary disorders.

Since 2005 the US Health and Human Services Secretary's Advisory Committee on Heritable Disorders in Newborns and Children has made recommendations for disorders to be tested by newborn screening programs. Currently there are 32 disorders on the

recommended uniform screening panel (RUSP). The most recent additions approved by the Secretary of HHS are severe combined immunodeficiency or SCID (2010), Pompe (2015), mucopolysaccharidosis type I or MPS-1 (2016) and adrenoleukodystrophy or X-ALD (2016). A RUSP recommendation does not imply that a Food and Drug Administration (FDA) approved test is available, which is why it is not practical to mandate test adoption within two years of recommendation. SCID was added to Oregon's testing panel in 2014. In February 2017, the FDA approved a test kit for Pompe, MPS-1 and two other similar lysosomal storage disorders that are not on the RUSP. Currently there is no FDA-approved test kit for X-ALD.

Now that there are FDA approved tests, we will follow our standard process for adding new disorders to our newborn screening panel. With the guidance of an ad hoc committee of experts, we will review several considerations, including:

- That the disorder has some form of treatment,
- That the disorder can be identified soon after birth by testing dried blood spots, and
- That there is a test with sufficient specificity and sensitivity to detect the disorder.

Our laboratory capacity is another consideration. The Northwest Regional Newborn Screening Program is fee based and when expanding testing, fees need to be increased to cover the additional costs, additional staffing and adaptation of the laboratory. Work is underway to assess these operational needs. An ad hoc committee to provide guidance will be convened once the feasibility of testing has been determined.

Thank you for the opportunity to share information with you. If you have any additional questions, please do not hesitate to contact me.