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To: The Honorable Rachel Prusak
Chair, House Committee on Health Care

cc: Oliver Droppers, House LPRO
Brian Nieuburt, Senate LPRO

From: John Fontana, PhD, (HCLD) ABB
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Subject: Follow-up information on HB 2987 related to Newborn Screening

The Newborn Bloodspot Screening (NBS) Program and staff are dedicated to the health of infants and their families. As a public health screening program that serves and considers impacts to all infants and families, we are guided by national standards and the Northwest Regional Newborn Bloodspot Screening Advisory Board (NWRNBSAB).

A list of board members can be found in the board's reports to the Legislature at:
<https://www.oregon.gov/oha/ERD/Pages/Government-Relations.aspx>.

What is newborn screening?

Newborn bloodspot screening tests infants for serious but treatable conditions that may not be clinically evident in the first few days or weeks of life and that can lead to disability or death. Early detection allows the infant to be referred for diagnosis and appropriate treatment that can improve lifelong health outcomes.

What is the Northwest Regional Newborn Bloodspot Screening Advisory Board?

HB 2563 was passed in 2019, which created the Northwest Regional Newborn Bloodspot Screening (NWRNBS) Advisory Board. The board consists of representatives from different parts of the newborn bloodspot screening system, including parent and advocacy groups. The board advises the Newborn Bloodspot Screening (NBS) Program, including recommendations for the addition and removal of disorders to the Oregon panel. In addition, the board is mandated to provide reports to the Legislature.

Can you explain how the board determines adding and removing disorders?

The disorders on the Oregon panel are outlined in Oregon Administrative Rules. This allows the Newborn Bloodspot Screening (NBS) Program and the board the flexibility to implement new best practices, including the addition and removal of disorders.

The board has approved a procedure and criteria for recommending the additions of disorders to the Oregon panel that was included in the board's 2019 report to the Legislature, which can be found at: <https://www.oregon.gov/oha/ERD/Pages/Government-Relations.aspx>. There are three stages of the protocol, starting with whether the disorder has been reviewed by the National Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) and is added to the Recommended Uniform Screening Panel (RUSP). Then there is a set of 10 criteria for Newborn Bloodspot Screening (NBS) Program to evaluate. If those criteria are met there is an additional 9 criteria for the board to evaluate to inform their vote and recommendation.

Using approved protocol and criteria, the board reviewed two disorders on the Recommended Uniform Screening Panel (RUSP) which are not on the Oregon panel. The board recommended the addition of Spinal Muscular Atrophy (SMA) and X-linked Adrenoleukodystrophy (X-ALD).

In addition, the board approved a protocol and criteria for recommending the removal of disorders from the Oregon panel. Using this, the board reviewed Fabry and Gaucher, two disorders that were added to the Oregon panel before the board was formed and did not meet all established criteria. The board did not reach consensus for the recommendations to remove Fabry and Gaucher, which indicated the need for more consideration. This will be brought back to the board with additional evaluation of the national landscape for Fabry and Gaucher, including the national Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) and the Recommended Uniform Screening Panel (RUSP).

Why hasn't Krabbe been reviewed by the Northwest Newborn Bloodspot Screening Advisory Board in Oregon?

The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) was formed in 2003 to advise the Secretary of Health and Human Services (HHS) on newborn screening. The ACHDNC worked closely with the American College of Medical Genetics (ACMG), which was tasked with developing a recommended uniform core screening panel (RUSP) as a national standard. In 2005, the ACHDNC recommended the RUSP to the HHS Secretary as the national newborn screening standard. The Newborn Screening Saves Lives Act of 2007 expanded the responsibilities of the ACHDNC.

Among other charges, the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) is responsible for recommending new conditions to the Secretary of Health and Human Services (HHS) for approval. There is a nomination process for disorders to be considered for review by the ACHDNC. The ACHDNC includes nationally recognized experts for newborn screening and performs a comprehensive review for disorders that meet the review criteria.

Krabbe was reviewed by the national Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) and was not recommended for addition to the Recommended Uniform Screening Panel (RUSP). The national advisory board summarized that experts need to better understand how to define disease types, to determine the best screening methods, and due to the effectiveness of treatments. Due to these factors, and consistent with advisory board protocols and criteria, Krabbe has not been reviewed by the NWRNBS Advisory Board for recommendation to the Oregon panel.

Additional information about the ACHDNC, the RUSP, and the nomination and review process is available at: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

What are the costs of adding Krabbe to the panel in Oregon?

There are many components of newborn bloodspot screening programs, which include laboratory testing, second-tier testing, result reporting, case management, education, and medical consultation. Krabbe testing would require additional support for these activities. Additionally, there are other considerations for the larger newborn bloodspot screening system, which consists of birthing facilities, midwives, and insurance providers.

We hope this is helpful and are available for additional questions.