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TO: The Honorable Senator Monnes Anderson, Chair
Senate Committee on Health Care and Human Services

FROM: Michael Skeels, PhD, MPH
Director, Oregon State Public Health Laboratory
Public Health Division
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SUBJECT: SB 284

Chair Monnes Anderson and Members of the Committee:

My name is Michael Skeels and I am the director of the Oregon State Public Health Laboratory (OSPHL) within the Oregon Health Authority's Public Health Division. I am here today to provide the public health perspective on Senate Bill 284. We perform a wide array of communicable disease tests to support state and local public health efforts, and we also screen all newborn infants in six states (OR, ID, AK, NV, HI, NM) for disorders of body chemistry that can cause profound disability or death unless they are detected soon after birth.

Senate Bill 284 requires the Oregon Health Authority to adopt Oregon Administrative Rules (OARs) requiring all infants to be screened for lysosomal storage disorders (LSDs) by January 1, 2014. LSDs are a group of at least 50 diseases with a combined incidence of 1:5,000 to 1:10,000 live births. What they have in common is that they are caused by a genetic deficiency in some key enzyme that is necessary for the breakdown of biological molecules, which causes the accumulation of substances in lysosomes within the cell.

We hope that in the future we will be able to accurately screen infants for LSDs and refer them for effective treatment as part of our newborn screening program. However, there is a national consensus that screening infants for LSDs is neither feasible nor recommended at this time.

We have four specific concerns with this bill:

1. Three of the disorders mandated in Senate Bill 284 have been nominated, reviewed, and rejected by the Secretary of the United States Department of Health and Human Services (DHHS) because no validated laboratory screening method is available and/or medical treatments are not effective. The OHA relies on the Secretary and her advisory panel to evaluate and recommend disorders as part of the national Recommended Uniform Screening Panel (RUSP) for all newborns. Disorders are nominated and considered through a structured process of evidence-based review by national experts and practitioners. Criteria include the availability and validity of laboratory testing, plus the existence and efficacy of treatment. Laboratory screening methods and treatments are currently under development for LSDs, but these will not be widely available for at least 2-5 more years. Only two states (IL and NY) are screening all newborns for LSDs, with mixed results. Missouri is attempting to develop and validate a laboratory method for screening.

2. There is no FDA-approved commercial laboratory method for LSD screening, which means that each laboratory must develop and validate its own method, requiring considerable expertise, expense, and a large number of infants. Adding LSD screening for all infants would require a major increase in the newborn screening fees paid by health care providers and insurers, for two reasons. First, the laboratory methods currently being developed for LSDs are labor-intensive (non-automated) and therefore quite expensive compared with other disorders. Second, the OSPHL would have to bear the initial costs of test development/validation and clinical correlation, and then include these costs in its fees. This type of validation for "Laboratory Developed Tests" (i.e., non-FDA approved) is mandated by the federal government under the CMS Clinical Laboratory Improvement Amendments (CLIA) and by the College of American Pathologists, which accredits the OSPHL.

3. Even if the test adoption and validation costs could be justified, this kind of developmental work is beyond the current scientific capacity and population base of the OSPHL. The OSPHL does not have the expertise or staffing to conduct method development of this type. Also, because these disorders are rare, it is impossible for a state with just 44,600 births per year to find enough cases to validate and clinically correlate these screening processes on its own. Generally, these studies are done by larger state labs and academic research centers, often in multi-state collaborations to provide a large enough number of infants.

4. Naming specific disorders for the Oregon newborn screening panel in statute rather than allowing the OHA to add disorders through the rulemaking process is a concern,

because technologies and disorders change frequently. Currently, there is only one disorder named in statute – phenylketonuria (PKU) – which was the first disorder mandated in 1963. There are currently 28 disorders listed in OAR 333-024-0210, and we intend to propose the addition of Severe Combined Immunodeficiency Disorder (SCID) during 2013 because it was recently added to the national RUSP.

Thank you for allowing me to testify on Senate Bill 284. If there are any further questions, I will be happy to be a resource to the committee.