



March 13, 2019

The Honorable Michael Dembrow
Chair, Senate Environment and Natural Resources Committee
Oregon State Legislature
900 Court St. NE
Salem, Oregon 97301

RE: Senate Bill 892

Chair Dembrow and Members of the Committee:

The Infant Nutrition Council of America (INCA) offers this testimony in support of SB 892, which would amend the revised Oregon Bottle Bill to allow for the exemption of oral rehydration products, such as oral electrolyte solutions.

Beginning January 1, 2019 all “beverages” (except liquor, wine, dairy, plant based, meal replacement drinks, vinegar, syrup, and infant formula) are required to comply with Oregon’s revised Bottle Bill that charges a 10-cent deposit upon delivery to a store. Not explicitly included in the list of exempted products are oral rehydration products, which are used in cases of severe dehydration (like diarrheal illness) and are products regulated as “medical foods” by the U.S. Food and Drug Administration (FDA). Senate Bill 892 would appropriately add oral rehydration products that are classified as “medical foods” to the list of exempted products due to their federal classification and recommended use.

The oral rehydration products included in the exemption per Senate Bill 892, are regulated by the FDA as “medical foods” under the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). Medical foods are specially formulated products intended for patients who are seriously ill or require the product as a major treatment modality. Medical foods are subject to their own statutory and regulatory requirements, which are not applicable to conventional foods and beverages. Decades of preclinical and clinical research and product development have gone into the development of these formulas setting them apart from conventional foods and beverages. Oral rehydration products are specially formulated to prevent dehydration by restoring key electrolytes and fluids, which may be lost due to illness in infants, children or adults. Additionally, these products are used for the maintenance of fluids and electrolytes following corrective parenteral therapy, surgery, or illness. Unlike conventional foods and beverages, these products are intended exclusively for use under medical supervision (21 CFR 101.9(j)(8)). The decision whether to use these products should be driven by the nutritional adequacy of a formulation in the medical management of the specific disease or medical condition, as determined by the assessment of a healthcare professional.

Furthermore, federal and state agencies and health care practitioners recognize that these products are different from conventional foods and beverages (e.g., Gatorade, Vitamin Water). FDA plainly explains that they “consider the statutory definition to narrowly constrain the types of products that fit within this category”.ⁱ Therefore, such products such as sports drinks, soft drinks, juices, bottled waters and the like would fall outside of the scope of medical foods, as defined by FDA, and would not be included in the narrow exemption outlined in Senate Bill 892. Additionally, medical foods are specifically included in the Oregon Medicaid formulary and are reimbursable through Health Savings Accounts (HSA) and Flexible Spending Accounts (FSA). Conventional foods and beverages are not eligible for reimbursement with an HSA or an FSA as they do not address a specific medical need. INCA would like to note that Oregon is the only state that does not exempt products classified as medical foods from their Bottle Bill

requirements. We urge this Committee to consider the fact that these oral rehydration products can be reimbursed through HSA and FSA accounts and we encourage Oregon legislators and regulators to remain consistent with the other states that have implemented a Bottle Bill program to reduce confusion on behalf of consumers, regulators, distributors, retailers and manufacturers.

Thank you for your time and the opportunity to submit this testimony in support of SB 892.

Sincerely,

A handwritten signature in black ink, appearing to read "Mardi K. Mountford". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mardi K. Mountford, MPH
President
Infant Nutrition Council of America

ⁱ FDA Guidance about Medical Foods, Second Edition, May 2016. Available at <https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm500094.pdf>