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Opposition to Senate Bill 166 - "The Prescription Drug Ethics Act"

Thank you to Chairwoman Veiga and members of the Committee for providing me the opportunity to speak to you today regarding Senate Bill 166.

My name is Rob Clark and I represent Medtronic, the world's largest pure medical device company in the world and a company with operations in Louisville and Parker, Colorado. Medtronic's 450 Colorado employees and our 38,000 employees worldwide are focused on designing and marketing world class medical technologies to treat chronic diseases, such as heart disease, diabetes, and spinal and brain conditions.

I testify today to seek your opposition to Senate Bill 166 – The Prescription Drug Ethics Act. While Medtronic has been and continues to be a proponent of transparency and disclosure of physician and industry relationships, we believe this bill could serve to severely limit medical technology investment, innovation, research and education in the State of Colorado.

We are specifically concerned with provisions in the bill which would seemingly define certain critical engagements with health care practitioners – such as research and development, clinical trials and training and education activities - as "gifts" and then ban that activity. Furthermore, the proposed legislation would require detailed reporting on a whole of range of activities that will have minimal or no impact on patient care, while driving up health care costs.

Unlike pharmaceuticals, the collaboration between physician and industry is critical to innovation in the medical device industry. Our products are designed and tested with physician input and oversight as they are the ultimate users of these devices with patients. The industry can not create products of clinical and

therapeutic value without these interactions, nor should patients expect that devices used to treat their medical conditions have not had the benefit of physician insight and expertise.

Additionally, the medical device industry has a responsibility to provide education and training on our products to doctors, nurses and technicians, and is often directed and required by the U.S. Food and Drug Administration. The focus of these education initiatives is teaching healthcare professionals how these sophisticated instruments and devices function and operate, thereby ensuring patient safety.

This critical activity is not specifically allowed or exempted in the legislation and would, therefore, appear to be banned as a "gift" under SB166.

SB166 would also require manufacturers to publicly report a broad array of interactions with physicians, hospitals and other medical entities. This reporting will be costly to implement at a state-level, particularly when multiple states create varying standards and requirements. This cost will be particularly burdensome to small to mid-sized companies and will ultimately be absorbed by the health care system.

This legislation, if adopted, will create numerous questions regarding what interactions are and are not acceptable in the state of Colorado. To limit physician and industry concerns, certain research, development and educational activities will likely be ceased or curtailed in Colorado, creating a tangible impact on business development and investment in the state.

We agree with what appears to be the intent of this legislation, which is to put processes and a transparent reporting system in place to ensure that interactions between industry and physicians are appropriate and beneficial to the health care system. We believe that patients must have confidence and trust that the medical recommendations made to them by their physicians are based on sound medical judgment and are not inappropriately influenced by other factors. We believe, however, this objective is best achieved through existing voluntary Codes of Conduct and through a national compliance and reporting program currently being considered by Congress.

For these reasons, we ask that you vote no on Senate Bill 166.

Thank you again for the opportunity to speak today.