Robert Hussey Waterville LD 416

The Joint Standing Committee of Appropriations and Financial Affairs Testimony from Robert Hussey P.E. Co-Founder of Hussey Medical, LLC

In Support of LD 416

LD 416

An Act to Authorize a General Fund Bond Issue for Research and Development and Commercialization

24 April 2023

Senator Pierce, Representative Millett, and members of the Joint Standing Committee on Appropriations and Financial Affairs:

My name is Robert Hussey and I am one of three co-founders of Hussey Medical, LLC, formed in 2019 and is located in Waterville, Maine. I am submitting this written testimony in support of LD 416.

I am a Licensed Mechanical Engineer in the State of Maine and spent 38 years as a senior level automation and machine design engineer solving complex manufacturing and product design issues for international corporations.

Due to a personal medical emergency, I have an ostomy and discovered an issue commonly faced by ostomy patient issue that did not have a solution. My sons, a physician and an electrical engineer, and I formed Hussey Medical, LLC and created a device that solved this issue which resulted in improved quality of life and preservation of my personal dignity. I use our patent-pending prototype every day and have benefited for the past 2 plus years.

Unfortunately, there is a paucity of available funding required to fully comply with FDA regulations, which is preventing us from bringing our device to other ostomy patients. FDA compliance would also allow us to satisfy hospital Institutional Review Board (IRB) requirements that are responsible for ensuring patient safety during human trials. We need to complete these trials prior to bringing the final design to market.

Hussey Medical has experienced that the financial burden of complying with FDA regulations is underappreciated by funding organizations, such as MTI. Even with Hussey Medical's relatively simple FDA-regulated class I medical device, estimates from consulting firms exceed \$250,000 for us to fully comply with the FDA regulatory requirements.

For these reasons, I urge you to support LD416 so that Maine can become a competitive, world-class biotech destination. Thank you for the opportunity to submit this written testimony.

Sincerely,

Bob Hussey P.E. Hussey Medical, LLC bob@husseymedical.com