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Massachusetts Biotechnology Council
300 Technology Square, Eighth Floor
Cambridge, MA 02139

February 7, 2020

The Honorable Cindy Friedman
The Honorable Dan Cullinane
Joint Committee on Health Care Financing
State House
Boston, MA 02133

**Re: House Bill 4268, An Act to create a Massachusetts Rare Disease Advisory Council
House Bill 4211, An Act to Improve Patient Access to Cancer Clinical Trials**

Dear Members of the Health Care Financing Committee:

On behalf of MassBio and our 1,200+ members, I write in favor of **House Bill 4268, An Act to create a Massachusetts Rare Disease Advisory Council**, and **House Bill 4211, An Act to Improve Patient Access to Cancer Clinical Trials**, both bills sponsored by Representative Hannah Kane.

MassBio represents a wide range of member organizations, including biotech companies, teaching hospitals, and academic institutions, the majority of which are directly engaged in cutting-edge research, development, and manufacturing of innovative products that improve the lives of sick people around the world.

House Bill 4268 - An Act to create a Massachusetts Rare Disease Advisory Council - support

Rare disease affects fewer than 200,000 individuals in the United States and over 90% of those living with a rare disease do not have an FDA-approved treatment.

H4268 will establish a rare disease advisory council in Massachusetts to advise the Governor, General Court, and Department of Public Health on the incidence and status of rare disease in the state. The bill will bring together a group of expert stakeholders, including (2) representatives from the biotech community (who are engaged in rare disease research, including but not limited to, a medical researcher with experience conducting research on rare diseases), to share perspectives and discuss innovative ways to improve the quality of life for all affected by rare disease.

The Council will create a rare disease plan that will provide a framework for tackling rare disease in the Commonwealth. The Council will bolster education and raise awareness of those living with rare disease. If passed, Massachusetts would join 8 other states, including our neighbors Rhode Island and Connecticut, in having established a Rare Disease Advisory Council. The creation of this Council will further advance the great research that is being done in the Commonwealth, enhance Massachusetts' ability to remain the #1 place for the life sciences industry, and ultimately, improve the lives of patients.

House Bill 4211, An Act to Improve Patient Access to Cancer Clinical Trials - support

Increasing the overall participation in cancer clinical trials improves outcomes for future patients by bolstering the value of the scientific research. However, while direct healthcare costs are covered in cancer trials, the ancillary costs of lodging and transportation associated with participating in a trial are not and can serve as an insurmountable financial barrier for willing participants.

The FDA recently issued guidance stating that the “*FDA does not consider reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence.*” However, there is reluctance among foundations and charitable organizations to provide financial support to participants unless a similar clarification is enshrined in state law. H.4211 aims to detail the difference between “inducement” for participation in a cancer clinical trial and reimbursement of expenses for participation in a clinical trial. This clarification will ensure that insufficient financial means does not prevent a willing participant from being eligible to participate in a clinical trial and that reimbursement of ancillary costs may be provided.

The increased diversity of people involved in cancer clinical trials has substantive scientific value in the trial results. Currently, only 5% of eligible people participate in cancer trials and the percent of people who are minority is less than 1%. States that have adopted similar legislation have seen a tremendous increase in minority participation in cancer clinical trials. Passage of H4211 will expand the diversity of populations that enroll in cancer trials and positively broaden the scope of the scientific research.

Thank you for your time and consideration of this testimony. I look forward to continuing to work with you and other stakeholders to improve patient care in Massachusetts and I hope that you will report H4268 and H4211 favorably from Committee. If you have any questions or need additional information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "RK Coughlin". The letters are fluid and cursive, with the first letters being larger and more prominent.

Robert K. Coughlin
President & CEO, MassBio