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April 22, 2021

The Honorable Aaron Michlewitz  
Chair, House Committee on Ways and Means  
Massachusetts State House, Rm 243  
Boston, MA 02133

Dear Chairman Michlewitz,

On behalf of MassBio, our Board of Directors, and our members, we appreciate the opportunity to provide comment on three amendments made to the House's FY2022 budget proposal that are of interest to the life sciences industry. MassBio represents over 1,400 life sciences companies, academic institutions, service providers, and patient organizations, the majority of which are directly engaged in the research, development, and manufacturing of innovative products that solve unmet medical needs for patients around the world.

Thank you for putting together a thoughtful, responsible budget proposal, especially in such a time of uncertainty and change. We applaud you for not including Governor Baker's proposal seeking to penalize drug manufacturers and set price controls on certain medicines. However, this same proposal has been filed as an amendment (#1128). We remain strongly opposed to this policy, as we outline further below.

**Amendment #376 – Clinical Laboratory Improvement Amendments (CLIA)-Waived Tests (Decker) – SUPPORT**

All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. Amendment #376 would align Massachusetts law with the Food and Drug Administration (FDA) and the Center for Disease Control (CDC) policies related to CLIA-waived tests by substantially expanding the type(s) of tests that can be performed in the physician offices. These changes eliminate current flaws in Massachusetts law that were especially exposed by the COVID-19 pandemic, and that impeded bringing CLIA-waived diagnostic testing to the market quickly in Massachusetts.

MassBio supports Amendment #376.

**Amendment #795 – Prescription Drug Coupon Task Force (Jones) – OPPOSE**

This amendment seeks to create a task force to study the use and impact of prescription drug coupons. This amendment is unnecessary as the Health Policy Commission was previously charged (via Chapter 363 of the 2018 Session Laws) with creating such a report, which HPC submitted to the Legislature in July of 2020 (<https://www.mass.gov/doc/prescription-drug-coupon-study/download>).

MassBio opposes Amendment #795.

**Amendment #1128 – Price Gouging Penalties (Malia) – OPPOSE**

This amendment mirrors Outside Section 42 of Governor Baker’s FY2022 budget proposal. We agree with the decision by the House to exclude this misguided policy from its budget proposal. We encourage the House to continue to pass over this unnecessary proposal and instead consider policies that would have a direct, positive impact to patients at the pharmacy counter.

MassBio opposes Amendment #1128.

Thank you for your consideration of these issues and MassBio’s positions. Please don’t hesitate to reach out to me with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Zachary A. Stanley", written over a light-colored rectangular background.

Zachary Stanley  
Executive Vice President, MassBio