



# MARYLAND TECH COUNCIL

**TO:** The Honorable Shane E. Pendergrass, Chair  
Members, House Health and Government Operations Committee  
The Honorable Karen Lewis Young

**FROM:** Pamela Metz Kasemeyer  
J. Steven Wise  
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**DATE:** March 9, 2021

**RE:** **OPPOSE** – House Bill 1256 – *Maryland Department of Health – Gene Synthesis Providers and Manufacturers of Gene Synthesis Equipment – Certification*

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The Maryland Tech Council (MTC) is a collaborative community, actively engaged in building stronger life science and technology companies by supporting the efforts of our individual members who are saving and improving lives through innovation. We support our member companies who are driving innovation through advocacy, education, workforce development, cost savings programs, and connecting entrepreneurial minds. The valuable resources we provide to our members help them reach their full potential making Maryland a global leader in the life sciences and technology industries. On behalf of MTC, we submit this letter of **opposition** for House Bill 1256.

House Bill 1256 requires the Maryland Department of Health to develop guidelines that include requirements for gene synthesis providers and manufacturers of gene synthesis equipment. It also requires the Department to develop a process to certify that gene synthesis providers and manufacturers of gene synthesis equipment comply with guidelines, are certified by the State, or are subject to penalty.

MTC understands the sponsor's intent. In fact, MTC and its members believe that this issue should in fact be carefully regulated. However, MTC is concerned about unintended consequences associated with legislating the requirements of this bill in State law. The members of MTC that are potentially affected by this legislation are already required to adhere to the existing federal guidelines and regulations that apply to this matter. NIH Guidelines can be found here: <https://osp.od.nih.gov/biotechnology/nih-guidelines/>. It is unclear how this legislation will align with those existing federal guidelines. MTC is concerned that state legislation could be redundant and confusing.

For example, House Bill 1256 provides an exemption for a scientist doing gene synthesis research, yet it is unclear how the exemption would apply in a practical sense. It appears that a scientist, making the material for use by another research scientist, is exempt, but it is not clear how that exclusion would be applied to a core lab that does gene synthesis. Since the core lab will be staffed and run by a facility director and technicians who may not be considered research scientists, does this mean the proposed regulation would apply to these core labs or to individuals?

There is also a lack of clarity on how the provisions of this legislation may affect the essential partnerships between industry start-ups, research laboratories, research institutions, and a variety of

academic and non-academic partners that may collaborate, both inside and outside of the State of Maryland.

While MTC appreciates that the sponsor is open to amendments, we respectfully contend that it is not possible to easily amend this legislation to address the risk of unintended consequences associated with regulation at the State level. This matter requires federal regulation, rather than a patchwork of state laws and regulations that may differ state by state and may not align with federal regulations. If the State should choose to enact regulation at the State level, MTC believes the framework for that legislation should involve a collective dialogue of affected stakeholders to ensure all potential questions and issues are thoroughly vetted. MTC would welcome an opportunity to participate in such a dialogue but it has not yet occurred. For these reasons, we urge the committee's unfavorable report of House Bill 1256.

**For more information call:**

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