



January 7, 2019

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

Dear Member of the Massachusetts Delegation:

On behalf of the Massachusetts Biotechnology Council (MassBio), I respectfully request that you **not** sign-on to Congressman Doggett’s measure entitled “The Medicare Negotiation and Competitive Licensing Act of 2018.”

MassBio represents more than 1100-member organizations, including companies, teaching hospitals, and academic institutions, the majority of which are directly engaged in research, development, and manufacturing of innovative products that improve the lives of people around the world. The Commonwealth’s vibrant biomedical research and development community, by most accounts, ranks first in the world for medical discovery and innovation.

Medicare Part D is a highly successful program which leverages its competitive, market-based structure to provide access to affordable drug coverage while keeping costs low for both beneficiaries and taxpayers. The “Medicare Negotiation and Competitive Licensing Act of 2018” would repeal this framework by enabling government interference and price setting of drugs in Part D. Importantly, the bill would also take the unprecedented act of permitting the U.S. Government to unilaterally bypass existing patent and exclusivity protections to grant ‘compulsory licenses’ to generic or biosimilar manufacturers.

Issuing compulsory licenses would create significant uncertainty for the biopharmaceutical industry and undermine incentives for future research. Patent protection and statutory exclusivity rights are the lynchpin that enable innovative manufacturers to invest in the substantial R&D needed to bring new products to market. Giving the government free reign to unilaterally choose to ignore patents and exclusivity would destroy this lynchpin, effectively gutting incentives for future innovative research—particularly in areas of significant unmet need affecting elderly Americans, such as Alzheimer’s Disease.

Compulsory licensing could largely nullify the Hatch-Waxman Act and Biologics Price Competition and Innovation Act (BPCIA), two laws intended to strike the balance between innovation and competition. Both the Hatch-Waxman Act and the BPCIA rely on patent protection and statutory exclusivity rights to encourage innovation. Without the incentives for innovation afforded by these statutes, the U.S. will risk losing its position as a global leader in biomedical innovation.

Thank you for your time and consideration of this request. If you have any questions or need additional information, please do not hesitate to contact me. I look forward to working with you and other stakeholders to enact public policy that will improve and preserve patient care in Massachusetts, around the country and the world.

Sincerely,

Robert K. Coughlin
President & CEO