



May 9, 2024

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Written comment on list of prescription drugs referred to the Stakeholder Council

Dear Members of the Prescription Drug Affordability Board,

I write today as both the CEO of the Maryland Tech Council (the “Tech Council”) and as the biotechnology representative on the Prescription Drug Affordability Board (“PDAB”) Stakeholder Council. The Tech Council is a community of nearly 800 Maryland member companies that span the full range of the technology sector. Our vision is to propel Maryland to become the number one innovation economy for life sciences and technology in the nation.

Maryland is one of the leading states in the nation for the concentration of life sciences companies and jobs. The State is rich in assets that make life sciences innovation possible – with 54,000 life sciences jobs, 2,700 life sciences and biotechnology companies, world class universities, and government agencies. These companies are a critical asset to Maryland’s economy. We consistently urge policymakers to bear this in mind when considering new policies that could harm our life sciences ecosystem. As a Stakeholder Council member and on behalf of the life sciences community, I am writing to note several overarching concerns about the initial list of drugs referred to the Stakeholder Council for cost reviews by the PDAB.

Principally, I want to echo several of the comments submitted to the Stakeholder Council about the lack of transparency and specificity as to how the initial eight drugs referred for cost reviews were selected. While we understand that each satisfies certain eligibility criteria from the adopted regulations, it is not clear why these drugs were selected among dozens of others that were not. Not having the methodology, additional criteria, data, or other context makes it difficult for the manufacturers of those products to respond to concerns about affordability. Publishing supplemental information about the selection process would bring additional transparency and credibility to the process.

Additionally, we urge the PDAB to consider the full picture of a patient’s out-of-pocket costs when making determinations on the affordability of a drug. In discussions during April 29th Stakeholder Council meeting, it was stated that factors like patient co-pay assistance programs were not considered in the selection of these eight drugs. We do understand that it is the intent of the PDAB to consider patient assistance programs as part of the cost review process. However, we feel that not considering this information on the front end may result in companies having to undergo a burdensome cost review process and the possible imposition of an upper payment limit (“UPL”) where it may not be warranted under the circumstances.

On behalf of Tech Council members in the life sciences industry, I also want to share that there is a high level of concern about what happens once a drug is considered unaffordable. Life sciences companies are spending an inordinate amount of time attempting to assess how a UPL would impact their businesses and the patients that they serve. It has been stated during multiple PDAB Stakeholder Council meetings that UPLs are just one potential tool to use if a drug presents an affordability challenge. What is unclear are what types of

other measures could be considered by the PDAB that are an alternative to UPLs. Selecting drugs without first knowing how a UPL will be applied, or what alternatives might be pursued, makes it very difficult for manufacturers to consider any unintended consequences of affordability measures and any impacts on patients and providers.

Lastly, I am taking this opportunity to again call on the PDAB to post the recordings of PDAB Board and Stakeholder Council meetings on the PDAB website for both future and prior meetings. This request has been made by me and other Stakeholder Council members on multiple occasions. To date, the PDAB has not directly addressed whether it will make prior recordings available. Publicly posting the prior recordings of these meetings would help increase transparency surrounding the PDAB's proceedings and will allow concerned patients, providers, and members of the public the opportunity to learn more about the process. We respectfully request a response on whether these recordings will be made publicly available.

Thank you for the opportunity to submit these comments.

Sincerely,

A handwritten signature in black ink that reads "Kelly M. Schulz". The signature is written in a cursive style with a large, prominent "K" and "S".

Kelly Schulz
CEO, Maryland Technology Council