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VIA Electronic Delivery

November 20, 2023

Mr. Van Mitchell, Chair
Maryland Prescription Drug Affordability Board (PDAB)
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Upper Payment Limit Framework Under Consideration by the Prescription Drug Affordability Board

Dear Chairman Mitchell:

The Biotechnology Innovation Organization (BIO) and the Maryland Tech Council (MD Tech Council) are writing to offer comments regarding Upper Payment Limit (UPL) Framework that is currently under consideration by the Prescription Drug Affordability Board (PDAB) and Stakeholder Council.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

Maryland Tech Council is a collaborative community that is actively engaged in building strong technology and life science industries by supporting the efforts of our individual members. We are the largest technology and life sciences trade association in the state of Maryland and we provide value by giving members a forum to learn, share, and connect.

General Comments on the UPL Framework

BIO and the Maryland Tech Council have concerns regarding the UPL Framework that has been discussed by the PDAB. First and foremost, we are concerned that such a proposal is being considered at this time when there are unresolved legal issues that must be addressed, including but not limited to the MD PDAB's statute effect on hindering interstate commerce, interfering with federal price reporting structures, and obstructing the exclusivity made available by federal patent law.

Secondly, BIO and the Maryland Tech Council remain committed to policy solutions that will help patients and strongly oppose any policies that will sacrifice access to medicines and

future innovation. Accordingly, we continue to encourage the Board to consider other affordability solutions and examine plan benefit designs to help ensure patients are able to afford their medicines. For instance, it is critical that the Board protect patient assistance programs from diversion schemes such as accumulators, maximizers, non-EHB maximizers, and alternative funding programs. Accumulator and maximizer programs prevent patient cost-sharing relief from accruing toward patient cost sharing responsibilities, while alternative funding programs eliminate patient coverage for specialty drugs. These diversion schemes increase financial burden for patients and should be banned.

Finally, BIO and the Maryland Tech Council continue to have serious concerns regarding the underlying UPL structure that remain unaddressed. The Board has not fully considered the negative ramifications UPLs will have on patient access to life-saving and life-altering biopharmaceuticals. Since distribution and dispensing of some drugs are limited to specialty providers, patient access could also be harmed by UPLs if those providers cannot, or will not, access these drugs anymore because reimbursement for associated services is limited. We continue to urge the Board to consider the adverse impact UPLs have on patient access to critical drugs and treatments.

Below, we highlight some of our specific concerns with the framework's approach.

Specific Comments on the UPL Framework

Lessons from Other Drug Payment Systems (p.7)

Setting a UPL on drugs that have no therapeutic alternative may disproportionately impact patients with diseases where there is a high unmet need and where low-cost treatment options are not available (e.g., rare diseases). A two-part assessment – used to first evaluate whether there are existing therapeutic alternatives and then whether the drug is an improvement over existing therapies – fails to fully consider the value that an innovative therapy. It fails to consider the value it can have to an individual patient—especially one who may have no other recourse—or the societal impact innovative technologies can have, including increased productivity and decreased overall healthcare costs due to fewer hospitalizations, surgical interventions, and physicians' office visits.

Dealing with Market Power (p.4)

The Example Framework suggests that the Board is attempting to "curb[] monopoly pricing" through UPLs. This misleading language fails to consider Congress' intent to encourage pharmaceutical innovation by granting inventors a limited period during which they have the exclusive right to market and sell their drug. We caution the Board against any approach that contradicts the legal protections of exclusivity made available by federal patent law.

An Example Framework for UPLs (p.10)

The Example Framework suggests that an "efficiency frontier" is able to determine a UPL by comparing price and effectiveness of a drug with therapeutic alternatives. Our concern with this approach is that it can mislead policymakers and other stakeholders to believe that arbitrary spending caps can improve patient care and stem healthcare costs, when in fact the opposite is true. The UPL's biased focus on cost containment could lead to restrictions on patient access to treatments for rare diseases, which would be especially devastating on these populations. We strongly recommend the Board solicit meaningful stakeholder

feedback to consider the comparative clinical effectiveness of available treatments, unmet needs, the severity of disease, and other factors that inform the full value of the product, such as the impact on quality of life, the spread of disease, and the impact on population health. Without considering any access metrics for patients, such comparison of price and effectiveness is misleading and may lead to adverse consequences. For example, if the Board applies a UPL to high-value drugs with large spend across a broad set of patients but without affordability challenges, then the return to patients is marginal – and the state's drug spend will likely shift toward lower-value drugs. In addition, it is critical that the Board recognizes that a true examination of patient affordability and value depends heavily on individual plan benefit designs.

Board Feedback (p.14)

The Board is considering against using a specific methodology to suggest an upper payment limit. We remain concerned that a case-by-case approach would create ad hoc and arbitrary decision-making and additionally make it impossible to predict the methodology that would be used for any particular drug. In addition, we urge the Board to provide stakeholders with opportunities to meaningfully respond to proposals through both written submissions and on-the-record hearings. Consequently, the Board should explain how it has considered stakeholder input in its decision-making process.

Appendix (p.25-28)

The Framework provides examples of price control calculations in other countries including Canada, France, Germany, and the United Kingdom. As shared in previous comments to the MD PDAB, BIO strongly opposes the use of international drug prices as consideration in the Framework. International drug markets are extremely different than the United States and are not governed by federal patent and healthcare laws. According to one study, 40% of medicines to treat rare diseases between 2002 and 2014 were rejected for coverage in the United Kingdom.[1] In another study comparing drug price regulations in different countries, it was found that countries with greater price regulations inhibited competition among generics.[2] Furthermore, Canadian and many other countries' prices are governed by price controls that are based on the use of quality- adjusted life years (QALYs). The federal government recognizes that QALYs are inherently discriminatory to patients with chronic disease and disability. In its November 2019 report on QALYs, the National Council on Disability (NCD) "found sufficient evidence of QALYs being discriminatory (or potentially discriminatory) to warrant concern[3]." It is evident that international drug pricing systems are not a model for the United States and have a discriminatory and chilling effect on innovation.

Additional Questions to Consider (p.12)

[1] Mardiguian, S., Stefanidou, M., et al. "Trends and key decision drivers for rejecting an orphan drug submission across five different HTA agencies." Value in Health Journal. 2014.
[2] Danzon, Patricia M. and Chao, Li-wei. "Does Regulation Drive Out Competition in Pharmaceutical Markets?" University of Pennsylvania. 2000.
[3] "Quality-Adjusted Life Years and the Devaluation of Life with Disability." National Council on Disability, November 6, 2019. https://ncd.gov/newsroom/2019/federal-study-finds-certain-health-care-cost-effectiveness-measures-discriminate

The Board poses an example proposal that staff conduct an analysis of existing literature and manufacturers can submit new information that is Maryland-specific.

We urge the Board to freely allow the sharing of critical information within the scope of the U.S. pharmaceutical market and healthcare space. Within this scope, manufacturers should be permitted to present all relevant information concerning pricing and value, rather than being limited to submitting "new information" or Maryland-specific data.

In addition, we urge the Board to fully consider how the state will ensure that the statutory prohibition on duplicate discounts is not violated by the UPL. The sharing of adequate claims-level detail is essential to enforce this statutory prohibition.

Should you have any questions, please do not hesitate to contact 202-962-9200 or at jgeisser@bio.org.

Sincerely,

/s/

Jack Geisser
Senior Director, Healthcare Policy
Medicaid, and State Initiatives

Kelly Schulz
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Maryland Tech Council