Comments on 2nd group of proposed PDAB regulations by James Gutman, member of Stakeholder Council **(COMMENTS ARE PERSONAL AND NOT REPRESENTATIVE OF ANY ORGANIZATION)**

Thank you for the opportunity to comment on another group of the PDAB's well-crafted proposed regulations. As with the first batch I commented on, I agree with the approach and the thorough manner by which the PDAB would take actions under the rules and appreciate the greater specificity in the revisions. But I have some comments and suggestions about specific provisions.

My only general comment, which refers to several references in the proposed rules, is that it is important to get the most specific information feasible regarding insulin products. In this way, Maryland can take any needed steps to complement those provisions in the new federal Inflation Reduction Act to ensure that its residents can afford insulin drugs, including new ones. Insulin products should qualify for special treatment, as the drug itself does in the federal law, because the prevalence of diabetes in Maryland and elsewhere is rising sharply. Another reason is that many insulin drugs remain unaffordable for large numbers of state residents, which impacts such other vital areas of general public concern as hospital emergency department wait times, which now typically are very long in Maryland. It is commendable and important that the PDAB is acting forcefully and with all feasible speed along with other entities in the state to ensure that unemployed Maryland residents will have an insulin affordability program. However, it is equally vital that the PDAB rules themselves have specific provisions that apply to any insulin product. It's good that there will be a process to allow requests to add other insulin products, but it would be even better if such an added-time step is not necessary.

Here are the specific comments, listed and identified in the order (with numbered sections as they appear in the proposed regulations), all of which are from COMAR 14.01:

From 01:04A: The new criteria for selecting drugs for referral to the Stakeholder Council (SC) are very good. So is the new section authorizing the PDAB to develop a list of therapeutic alternatives for each Rx drug product referred to the SC and authorizing the PDAB to determine the therapeutic alternative for each Rx product selected for a cost-review study.

The movement of the provisions regarding direct-to-consumer advertising spending seems okay, but it is important that the board has the authority to consider these data when making determinations on Rx drugs that will undergo cost reviews.

As on the prior set of regulations, I think, as PDAB member Gerard Anderson has said, that 60 days is too long a period from the date of a PDAB data request for the entity involved to submit information in most cases. If the 30 days suggested by Dr. Anderson is not enough time, please consider 45 days instead.

Also, I understand that the provision that the Rx drug manufacturer would not have to break out price concessions, discounts and rebates in its responses to PDAB data requests does not prevent the PDAB from asking for such information later. But it is important that the PDAB be able to obtain this information if it is needed for specific determinations during the period of a cost/price review.

The provision that an Rx drug manufacturer would be required, for foreign sales, to furnish only the "invoice price per unit" rather than the price actually paid creates the possibility that the price specified may not be meaningful. But the other change in this section to limit the price data to four industrialized foreign countries seems acceptable.

The provisions governing insurers seem good, particularly those requiring them to provide information on the number of covered lives for each formulary and the net cost incurred by the insurer for each prescription drug product involved. Similarly, the provisions requiring PBMs to furnish gross and net PBM revenues for the Rx drug product under review in both Maryland and the U.S. as a whole are excellent.

I am not clear on the reasons for the changes in the closed-session provisions or for taking out "trademark" information in what the PDAB may consider. But if the PDAB is convinced that it will still be able to get the information it needs with the revised phrasing and via closing an open session rather than having a closed session from the beginning, as the proposed rules formerly stated, this seems okay.

From 04:01:05: The elimination of "all insulins" from the drugs to be studied on the basis of patient out-of-pocket costs relates to my opening comments about insulin. I understand the reluctance to single out products, but I would urge the PDAB to reconsider whether this will leave it with the authority to do what is needed and permissible under the law with this important product category.

The new section on Therapeutic Alternatives authorizing the board staff to develop, post, and, if necessary, "modify" a list of therapeutic alternatives for each Rx product referred to the SC seems to be a very good addition. The revised provisions regarding cost reviews allowing the PDAB to identify all NDCs "marketed under the same ANDA, NDA or BLA" along with unapproved generics to be included in the cost review seems well thought out and appropriate.

The cost-study review provisions' revised language allowing requesting information only on the net price received by the manufacturer rather than also obtaining data on price concessions, discounts and rebates (CD&R) will limit potentially illuminating and relevant information. But if there are legal reasons for making this change and the PDAB is satisfied it can get what it needs on CD&R, this may be acceptable. Similar provisions that limit these data to net costs now also would apply also to insurers, PBMs and distributors and therefore raise the same issues. And the proposed rules do allow the board to seek this same additional information for therapeutic alternatives, raising the question of why this can't be provided for the drug under review.

The added language to allow consideration of costs to health plans based on patient access consistent with "standard medical practice" is good. But it is somewhat puzzling why "peer-reviewed journal articles" are stricken as a source for data and analysis.

Finally, it was reassuring to see that if the PDAB, after a review, still is unable to determine whether an Rx product will produce or has produced an affordability challenge for the state health care system that the PDAB — as originally proposed — will be able to look at such other important considerations as federal support for research and development of the product and pricing data from other countries.