Suggested Talking Points
Other PDAB Concerns
Affordability Reviews Are Advancing With ONLY Limited Stakeholder Input

Major Concern with the PDAB Process – Limited Ability for Stakeholders to Provide Input:

- As the PDAB has moved forward in 2023 with implementation, numerous issues have become apparent which need to be immediately addressed.

- One significant concern is that the PDAB is making decisions without any significant or meaningful input from patients, caregivers and providers.

- The main cause – due to the current statutes, regulations and policies governing the PDAB - the opportunities for stakeholder input are extremely limited, complicated to navigate and simply not user-friendly.

- The PDAB staff created and dictates much of the framework for stakeholder participation.

- This must change in order to protect patients.

- Patients, providers and others **repeatedly** stated in letters and their public comments that the process for providing input is NOT user-friendly and has prevented many from sharing their concern.

- The PDAF staff has ignored these issues **and NO significant changes were made to make the process easier to navigate or facilitate greater stakeholder participation.**

- The numbers speak for themselves!

- The draft affordability review materials from the October 27, 2023 PDAB meeting and the recent February 16th PDAB meeting CLEARLY demonstrate that the poorly constructed process for obtaining stakeholder input created a significant lack of participation by patients, caregivers and medical providers.

- The process MUST be changed before any other drugs are reviewed.

According to PDAB data (10/27/23 Affordability Review Presentation, in 2022 there were 461 individuals who used Trikafta in CO:

- Prior to the beginning of the affordability review for Trikafta, 41 voluntary comments were submitted, and 47 patient/caregiver survey responses were turned in due in large part to the considerable mobilization of the CF community.

- Ironically, the Trikafta affordability report claims that having 47 surveys turned in was a "robust" response rate-about 10% of the population. What about the other 90% of our CF population? Colorado doesn't care about those individuals?

- Access to Trikafta is a life and death issue for many CF patients and the PDAB forged ahead with the review even though only 10% of the population had engaged in the process. Is this how CO cares for individuals with serious health conditions?

- And only eight HCPs were able to attend the stakeholder meeting which was set for a single day in September—without asking providers if this day was convenient.

<u>According to PDAB data, in 2022, there were 879 individuals who used Genvoya in CO:</u>

- Prior to the beginning of the affordability review for Genvoya, only 3 voluntary comments were submitted and only 16 patient/caregiver survey responses were turned in. Only 3 individuals participated in the Genvoya stakeholder meeting.
- Based upon these numbers only 2.5% of those using Genvoya were able to participate in the process (3 + 16 + 3 = 22, then divided by 879 -those using the medication in 2022).
- Is this sufficient stakeholder input? Clearly not. More must be done to reach the community of patients that will be affected by the affordability decision.
- Eight HCPs attended their stakeholder meeting and zero completed their survey. The issue of stigma has been raised as a possible contributing factor and the need for anonymous vehicles to gather input.

<u>According to PDAB data, in 2022, there were 3406 individuals who use Enbrel in CO</u>

- Prior to the beginning of the affordability review for Enbrel, only 3 voluntary comments were submitted and only 11 patient/caregiver survey responses were turned in. Only 3 individuals participated in the Enbrel stakeholder meeting.
- Based upon these numbers only 0.5% (yes, less than 1%) of individuals prescribed Enbrel were able to participate in the process (3 + 11 + 3 = 17, then divided by 3406-those using the medication in 2022).
- Again, is this how Colorado wants to be known? We impose policies that have a dramatic impact on access to essential medications without hearing from the patients who need these therapies?
- Seven individuals, HCPs or those with scientific/medical training attended their stakeholder meeting and 2 completed the medical survey.
- This process is moving forward without any true or measurable representation from patients using Enbrel.

- During the December 8th PDAB meeting, the lack of provider input was raised by the PDAB members and discussed. Chair Mizner acknowledged input from clinicians working for manufacturers but wanted additional input. She suggested that having 2 independent physicians and 2 independent pharmacists would be sufficient input?

- TWO? Is this really how low our standards are that we only care if we hear from 2 MDs and 2 pharmacists before moving ahead and making decisions that will impact every patient, every MD and every pharmacist that touches the medications being reviewed?

- So, it is clear that there is a real problem with stakeholder engagement; let's consider some of the reasons why.

- The sixty-day period for obtaining public input is not sufficient and should be extended to a minimum of 6 months for any future reviews – including for Stelara and Cosentyx.

- The meeting to determine the affordability of Genvoya and Enbrel should be delayed until more patient, caregiver, and provider input is gathered and considered.

- Besides the rushed timeline, numerous other factors also contribute to inadequate stakeholder input being incorporated into the PDAB information gathering and review process.

- The average patient or provider does not know how or where to find information about the PDAB process.

- An individual must go to the insurance website and follow several screens and tabs to get to the proper place to register to receive information about the PDAB.

- The opportunities for stakeholder input, such as submitting written comments, completing a survey and attending meetings, were extremely limited and not adequately publicized or explained by the PDAB staff.
    - Patients affected by the first 3 drugs reviewed have serious chronic illnesses that can be debilitating and may simply be unable to type a letter or obtain the information about the submission process.
    - The surveys to gather insights from patients, caregivers and providers were developed by the PDAB staff and did not reflect the questions and issues of importance to patients, caregivers and providers.
    - Stakeholder meetings for each drug reviewed were limited to **only 1 day** with **only 2 hours for patients and caregivers** and **2 hours for medical professionals to attend and provide information**.
    - PDAB staff office hours were extremely limited – **ONE** hour **each** week.
    - Patients with conditions, such as Cystic Fibrosis, HIV/AIDS and autoimmune disorders may not be well enough to attend on one specific day.
    - Caregivers may have to work and providers have hectic schedules or simply may not have been aware of these very limited opportunities to provide input.
    - PDAB members were noticeable absent from ALL of the originally scheduled stakeholder meetings and only attended the second Trikafta meeting after extensive public outcry.

<u>Recommendations:</u>

- The PDAB should be repealed.
- If that is not possible, the PDAB affordability review and decision-making process should be immediately halted.
- The votes on the affordability of Genvoya and Enbrel should be postponed until more patient, caregiver, and provider input is gathered and considered.
- IF the PDAB is not repealed, the following statutory changes are necessary to ensure that decisions only occur after significant input is obtained from patients, caregivers and providers with in-depth knowledge of the medications being reviewed.
    - The stakeholder input process should be extended to a minimum of 6 months.
    - The PDAB staff must meet with patient groups and providers on a day/time that is convenient for patients and caregivers, to develop any surveys.
    - The PDAB staff must conduct outreach to patient groups as well as clinicians and those with medical expertise to identify days/times (PLURAL) for meetings.
    - The PDAB staff must have multiple stakeholder meetings for patients and caregivers as well as clinicians and those with medical expertise, not just one.
    - The PDAB staff should then be required to proactively distribute the surveys to several state professional associations and patient advocacy groups.

    - PDAB staff need to extend their office hours.
    - Affordability reviews should only progress if a minimum of 50% of the affected patient population have participated in the process and contributed their input.
    - Affordability reviews should only progress if a minimum of %20 of the medical professionals that specialize in the condition treated by the medication have participated in the process and contributed their input.
    - The PDAB must be expanded to include a voting member that is a patient who uses, or has used the medication being reviewed. The patient representative will obviously change with each drug reviewed.
    - The PDAB must be expanded to include a voting member that is a medical specialist who cares for individuals that use the medication being reviewed and prescribes the medication being reviewed. The medical specialist representative will obviously change with each drug reviewed.

- The PDAB continues to push forward and make decisions without any significant stakeholder input.

- PDAB affordability decisions have life and death consequences for the affect patients – many of whom do not know how or are unable to participate in the current process which is difficult to navigate and not user friendly.

- Statutory changes are immediately needed to ensure greater stakeholder input in order to protect patients.