Suggested Talking Points
Colorado's PDAB Drug Evaluation Process –
Rushed, Lacks Transparency & Utilizes Flawed Discriminatory Data

Major Concern - the Drug Evaluation Process is Rushed, Lacks Transparency & Utilizes Flawed Discriminatory Data:

- The affordability review process has been rushed, lacks transparency and is based upon flawed data.
- Collectively these issues raise questions about integrity and accuracy of the affordability review information that PDAB members must use to make decisions which will have dramatic consequences for patients, caregivers, medical providers, pharmacists, hospitals and the entire pharmaceutical distribution system.

RUSHED:

- While the statute does not set any specific timeline for reviewing drugs and making recommendations about affordability, the **staff** (which represents the Administration) are moving very quickly and forcing the PDAB to make decisions which have life and death consequences for patients with Cystic Fibrosis, HIV/AIDS and autoimmune disorders.
- While PDAB decisions will affect patients, caregivers and medical providers, not enough time or effort has been spent to gather input from patients, caregivers and providers.
- The affordability reviews document this problem:
    - The patient caregiver survey only captures input from about 10% of the CF
    - 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).
    - 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).
- The public and even members of the PDAB have admitted to not being able to review and digest all of the information in the affordability review documents before meetings occur and decisions are being made.
- Why is the PDAB staff in such a hurry? Lives will be adversely impacted by these decisions!

LACK of TRANSAPARENCY:

- The PDAB **staff** is conducting literature reviews, evaluating information and interpreting the data being used to compile the affordability summaries for each drug. Staff have NO CLINCIAL expertise!
- If outside consultants are being used, and we know that to be the case, the names and credentials, as well as amount of compensation, of these individuals should be provided publicly.

- Fifteen affordability components must be analyzed and considered for each drug review and summary.
- The conditions treated by the 3 drugs in the first review cycle (autoimmune disorders, HIV and CF) are chronic, complex debilitating illnesses.
- The medications also are very different in dosing, monitoring, drug interactions and sequencing in the course of a patient's treatment.
- What are the credentials of those evaluating the data?
- Did the PDAB staff bring in specialists that treat each of these conditions to help review the provided information? An internist should not be making decisions about how to treat patients with HIV/AIDS or autoimmune disorders.
- In light of the short timeline, it is VERY unlikely that specialists with in-depth knowledge of the medications and the indicated conditions have been involved in creating the affordability review documents.
- Once again, the PDAB staff compiling and presenting the affordability review summaries to the PDAB members are NOT medical professionals, they are state bureaucrats.

<u>FLAWED DATA SOURCES – Much of which is based upon discriminatory metrics, such as QALYs:</u>

- Since the very first discussions focused on identifying drugs to be reviewed, numerous questions have been raised by members of the PDAAC, the PDAB as well as patients, providers and others about the lack of complete data, poor data integrity/quality and improper data analysis methods being used by the staff.
- These concerns have been ignored!
- The state is spending significant resources on PDAB staff and external consultants. Why not take the time to resolve the data issues and be sure the information used to make decisions by the PDAB is accurate?
- Additionally, PDAB affordability recommendations are prioritizing foreign sources of data and external consultants instead of listening to patients, caregivers and providers who live and work in Colorado.
- Why would the PDAB place greater value on the input of individuals and resources from outside of Colorado instead of using the state's own experts and information?
- Even worse, most of these US and foreign data sources being referenced in the affordability reviews rely upon discriminatory evaluation metrics, such as Quality Adjusted Life Years (QALYs).
- Since passage of the Affordable Care Act (ACA) 2010, Medicare has prohibited the use of QALYs or any similar measures to make decisions related to coverage, reimbursement and incentive programs.
- Efforts are underway in Congress to expand the QALYs prohibition to all federal programs.
- Why is CO using data sources and evaluation metrics that the federal government has deemed as discriminatory?
- Some of the other data sources cited in the affordability reviews are from countries with reference pricing and different standards of medical care.
- Why should CO patients have the quality of care they receive be compromised and reduced to the lower medical standards that exist in foreign countries with reference pricing?
- Patients in countries with price controls wait longer or lack complete access to new therapies – especially for cancers and rare conditions; as a result, people become sicker and or succumb to their diseases.
- Is this how Colorado wants to be known? For devaluing the state's most vulnerable patients affected by very complex health conditions by denying them access to innovative life essential therapies?

- The integrity of the data sources and clinical accuracy of the information being delivered to PDAB members is flawed, unreliable and includes discriminatory evaluation metrics.
- This is nothing for Colorado to be proud of. Patients' lives are at stake with every PDAB decision being made.

Recommendations:

- This entire PDAB effort needs to slow down and be paused to ensure that decisions being made are actually based upon sound information that is relevant to Colorado's patients and incorporate additional insights and knowledge from medical experts for each respective disease state.
- Full disclosure of all consultants and individuals involved in the review process and their credentials and compensation must be made public before any affordability decisions are made.
- The PDAB staff must solicit input from patients and provider groups to identify a minimum of 5 clinical experts per disease condition to be significantly involved with developing the affordability review document for each drug;
    - These specialists should be compensated for their time and clinical experience and be the individuals shaping the development of the affordability reviews INSTEAD of PDAB staff and external consultants who lack appropriate credentials related to the medical condition.
    - These individuals should be nominated by patient and specific provider groups for each condition.
- Use of any data sources and HTA assessments that incorporate QALYs should be prohibited – which is consistent with federal government policy.
- Instead of bringing in outside vendors and foreign information, experts on Colorado's Rare Disease Advisory Council (RDAC) should have been involved in the PDAB process *from the onset* - **but were not**.