

## BACKGROUND & OBJECTIVE

- The Inflation Reduction Act of 2022 (IRA) established the Medicare Drug Price Negotiation Program (DPPNP), which requires the Centers for Medicare and Medicaid Services (CMS) to determine “maximum fair prices” (MFPs) for selected drugs.
- Ten listen-only patient-focused listening sessions, one for each selected drug, were broadcast virtually on the CMS website in Fall 2023 as part of the Agency’s evaluation of selected drugs.
- This study aimed to describe the breadth and depth of patient and stakeholder input at CMS’s patient-focused listening sessions for the first 10 drugs selected to the DPPNP.

## METHODS

- This study conducted a sentence-level, time-based content analysis of the publicly broadcasted patient-focused listening sessions.
- Audio recordings of the listening sessions were transcribed and time-stamped using AssemblyAI, with manual accuracy review.
- The six-category coding framework was designed to reflect the key areas of interest for the DPPNP, including CMS’s optional discussion topics for speakers,<sup>1</sup> DPPNP goals,<sup>2</sup> and potential unintended consequences of the IRA expressed in response to CMS’s initial guidance on DPPNP implementation<sup>3</sup> (Table 1).

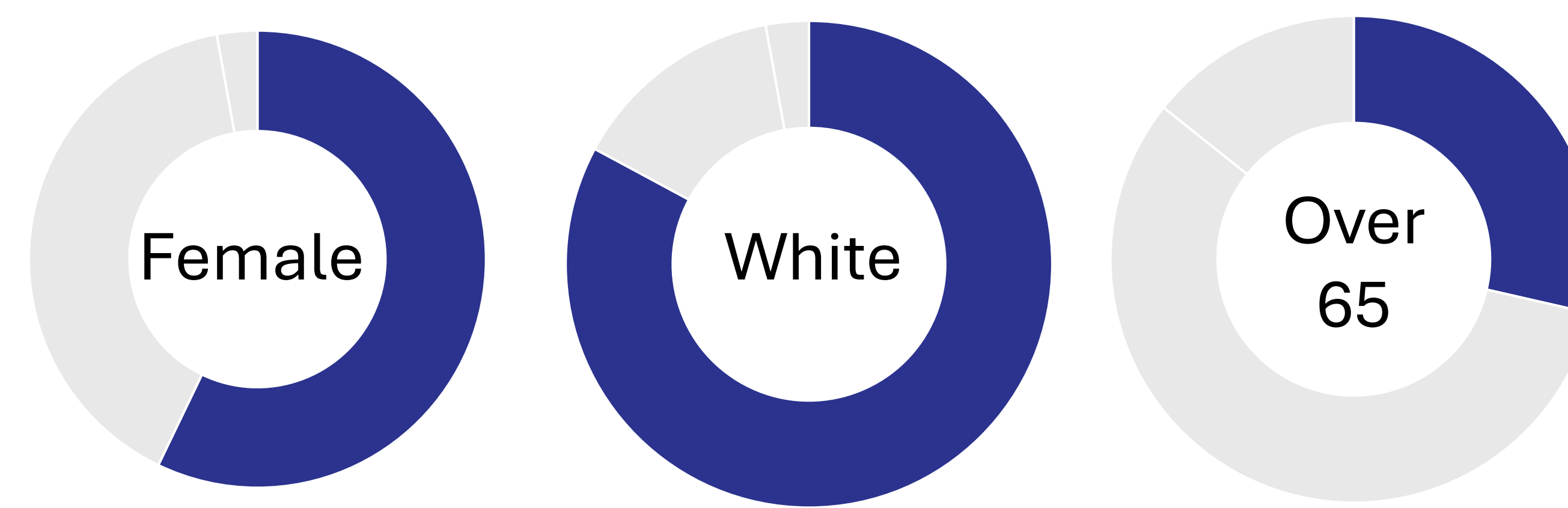
**Table 1.** Examples of Six Included Categories

Category	Examples
Speaker Background	Name, demographics, professional background, affiliated organization
Evidence about Selected Drugs and Therapeutic Alternatives	Patient experience, unmet needs, benefits, side effects, health equity considerations concerning the condition, selected drug, or a therapeutic alternative
Drug Prices	Prices of selected drugs, therapeutic alternative(s), or the conditions they treat; patient assistance programs, financial implications of these drugs for CMS
Access/Benefit Design	Benefit structures, utilization management, formulary coverage, challenges with pharmacy benefits managers, issues with affordability and access
Therapeutic Advancement	The broad role of – or potential impact of the IRA on – new drugs or indications
Other	Remarks outside of above topics

CMS should **prioritize** opportunities to hear a greater amount of **patient-centered evidence** directly from patients and their advocates, caregivers, and providers.

## RESULTS

- Out of an anticipated 200 speaker slots, there were 106 total speakers (median: 10 participants per session; range: 5-17).
- A median of 5.5 patient advocacy representatives (range: 1-10; IQR: 3-8) and 2.5 patients (range: 0-10; IQR: 1-7) participated in each session.
- A total of 70 unique speakers participated in the sessions (Figure 1).

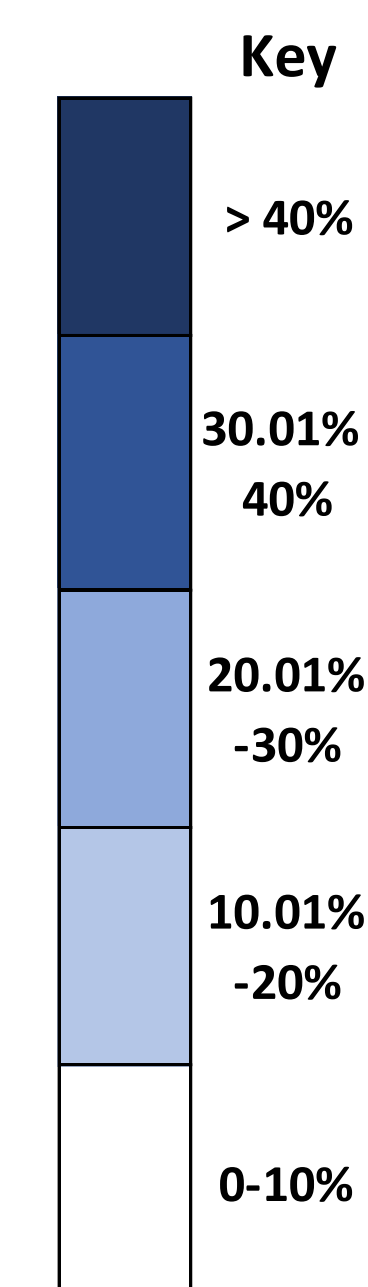


**Figure 1.** Speaker Demographics among Unique Participants in the Fall 2023 Patient-Focused Listening Sessions hosted by CMS

- Most speaker time focused on evidence about the selected drugs and therapeutic alternatives (median per slot: 36.5% of time) and patient access/benefit design (median per slot: 12.1%) (Figure 2).
- Patients devoted the highest proportion of time to drug evidence (49.4%).

**Figure 2.** Heat Map of Variation in Median Proportion of Speaker Time Spent on Each Category during the Patient-Focused Listening Sessions, by Speaker Type

Category	Overall (n = 106)	Patient (n = 38)	Health Care Provider (n = 11)	Patient Advocacy Organization (n = 48)	Other (n = 11)
Background	7.7%	2.9%	11.4%	11.6%	14.2%
Evidence about Selected Drugs and Therapeutic Alternatives	36.5%	49.4%	25.3%	27.3%	26.4%
Drug Prices	0.0%	21.8%	24.7%	0.0%	6.1%
Access/Benefit Design	12.1%	12.6%	4.0%	14.3%	21.5%
Therapeutic Advancement	0.0%	0.0%	0.0%	9.8%	0.0%
Other	9.4%	7.1%	2.0%	14.1%	5.4%



## RESULTS

- The total duration of speaker time per drug session ranged from 13.9 to 48.3 minutes (median per session: 31.4; IQR: 27.0-41.1 minutes) (Figure 3).

**Total Speaker Time Per Session** 31.4 min (27.0-41.1 min)

**Total Patient Speaker Time Per Session** 7.3 min (4.7-18.3 min)

**Total Time on Evidence per Session** 12.3 min (9.9-15.5 min)

**Figure 3.** Total Time per Drug Listening Session, Overall and by Selected Characteristics, Median (IQR)

## CONCLUSIONS & DISCUSSION

- CMS took important steps towards facilitating patient engagement with the DPPNP by introducing “patient-focused listening sessions” to its evaluations.
- Speakers often focused their time on patient experience and evidence; still, the median duration of input on patient-focused evidence about therapeutic alternatives per drug listening session was less than 15 minutes.
- A median of only 2.5 patients participated per session, providing CMS with a median of only seven total minutes of patient input per selected drug.
- Patient engagement may have been hampered by a lack of transparency or framework surrounding how input would be used in the price determination process.<sup>4</sup> In the future, CMS should delineate the process by which clinical benefits and patient impacts would be considered and influence MFPs.

## REFERENCES

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