

# HAYSTACK PROJECT

## The Voices of Rare & Ultra Rare

JUNE RECAP

JUNE 2023

**DUES, DUES, DUES!** Pay your 2023 dues [here](#). Please help us keep up all the good work you've come to count on us for!

### SPEAKER SERIES

On July 18, 2023, at 1 pm ET, Juliette Cubanski discussed the IRA – and encouraged patient groups to engage with CMS in the coming months.

Who would you like to see Haystack host next month on our Speaker Series? Send your suggestions [HERE!](#)



### SPEAKER SERIES CONTINUED

Our guest speaker in June 2023, Jodi Daniel from Crowell Health Solutions, talked about Decentralized Clinical Trials - trials in which some or all of the services can be performed off site from the main clinical trial site (e.g. primary care doctor's office or a local phlebotomy laboratory. Watch [here](#).

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# LEGISLATION

**Does your group have experience with treatments approved overseas/EU but not in the U.S.?**

This has been enough of a trend to warrant a study by the National Academy of Sciences to help Congress identify needed changes at FDA. LET'S MAKE SURE THE RARE DISEASE EXPERIENCE IS INCLUDED. Email us -- either confidentially or to join us in our discussions with National Academies.

# REGULATORY

Haystack continues to invest heavily in responding to CMS' requests for input. [Click here](#) to read our letter on ensuring Medicare drug prices reflect a treatment's value in the negotiation process...

Haystack Project signed onto a group letter urging consistent guidelines, criteria, and a process for exceptions/appeals/grace period for the "smoothing" provisions in the IRA. The letter also noted plans shouldn't require patients exceed their OOP commitments to trigger eligibility for smoothing. Finally, signatories asked CMS to (i) evaluate if utilization management is appropriate for negotiated drugs, and (ii) mitigate potentially misaligned market incentives that may undermine the IRA's statutory intent. [Click here](#)

[Click here](#) for Haystack's Inpatient PPS comments, calling on CMS to move beyond the 'monitoring' of access problems caused by DRGs that include but don't reflect the cost of rare treatments. The agency's monitoring announcement was a decade ago, and patients have yet to see actionable changes to preserve access to rare disease treatments.

Haystack Project recently expressed its support of Senator Cassidy's (R-LA) Discussion Draft on State Integrated Care Programs for Dual Eligible Individuals, but also asked the draft address hardships to patients unable to access a disease-specific specialist because the provider is out-of-state. This has been a longstanding barrier to timely diagnosis and appropriate care for our patient communities. [Click here](#) to read our letter.

[Click here](#) for Haystack's response to CMS' proposal to improve access to care, quality, and health outcomes in managed care Medicaid/CHIP. CMS focuses on four sets of services, that while important, don't look at rare disease needs. Even as our patients face unique and pervasive struggles with access, Haystack expects MCOs will redirect resources to the four services, further diverting limited resources away from rare diseases.

## MEDICAID

[Click here](#) for Haystack's letter expressing urgent concern that rare/ultra-rare patients have been left out of recent CMS proposals to protect Medicaid patient access. CMS' proposal would allow states to drastically cut payment for services like specialist office visits, which rare disease patients disproportionately rely on, without triggering additional regulatory scrutiny. Haystack urges instead that CMS review any payment reductions in excess of 5% for any given service or CPT code if patient access is at risk. CMS should also require states to perform a payment adequacy analysis of a specified percent of Medicaid services rather than an analysis of a specified set of services that exclude services relevant to rare diseases.

## WORK GROUPS

Updates were provided on the several work groups underway, including:

**PROTECT Rare/Access to Rare Indications** – This work group announced upcoming introduction of the newly named PROTECT Rare Act in the House.

**First Look Project** – This work group is focused on phenotypes/"tell-tale signs" of rare diseases.

**HP50** – This work group has a pilot underway to improve advocacy at state Medicaid departments – three states and two patient groups with recent/near approvals.

**Do you have these on your calendar?**

Please email Tiara Logan at [tiara.logan@haystackproject.org](mailto:tiara.logan@haystackproject.org).

## HOUSEKEEPING

**DUES, DUES, DUES!** Pay your 2023 dues [here](#). Please help us keep up all the good work you've come to count on us for!

Do you have calendar invitations for our standing monthly calls?

**3rd Tuesdays 1-2 pm ET** - Speaker Series – Invite includes required registration link.

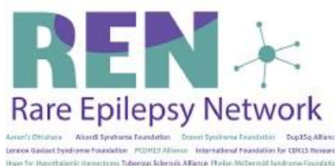
**3rd Wednesdays 1-2 pm ET** - Member calls with patient groups

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Any questions, contact [Tiara.Logan@haystackproject.org](mailto:Tiara.Logan@haystackproject.org)

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Please check the website for the growing list of Haystack sponsors, whose support allows us to do what we do!



Haystack Project is grateful to all of our Alliance Partners for lending their insights and perspectives, as well as for combining their efforts with ours to better serve the rare and ultra-rare communities.