

HAYSTACK PROJECT

The Voices of Rare & Ultra Rare

MARCH RECAP

MAR 2024

Calling World Orphan Drug Congress Attendees!



Kara Berasi, Haystack's CEO, will be attending the WODC conference, and participating on a panel on April 25th from 3:45-4:35 PM called "How Policy Moves Forward with Patients at The Center"



If you are a patient group or company attending this conference, please reach out to Kara to meet up – come learn more about Haystack and our work! Kara.Berasi@haystackproject.org

ACCOMPLISHMENTS

Haystack Met with CMS: Listening Sessions Feedback



Haystack Project met with CMS in March to provide feedback on the initial 10 ListeningSessions to discuss what worked well and didn't, and specific changes our patient groups would need for rare disease drugs/sessions in the future. We discussed the definition of alternative treatments, multi-indication treatments, etc. as well as the need for CMS to correct, in real-time, the confusion or misinformation shared by patients and patient groups related to topics like the direct benefit of government price negotiations to patient out-of-pocket costs.

MEDICAID: Haystack Reported Out on CMS Meeting on Cell and Gene Therapy Model

Member groups participated in a meeting with CMMI staff last month. We compared the current model under development in sickle cell to upcoming approvals in ultra-rare cell and gene therapies. We shared our concerns about the precedent set in sickle cell, highlighted the different considerations CMMI will need to think through in rare, as well as incentives that companies and health plans may have to not have certain patients on the treatment, ability of patients to opt in or opt-out, the implications of fertility preservation in ultra-rare conditions, etc. Excellent feedback from CMS!



MARCH RECAP

MAR 2024

ACCOMPLISHMENTS CONTINUED

Haystack Project met with CMMI on their Accelerated Approval Pathway work. We will discuss more details at our next monthly session.



“SMOOTHING”/MPPP

Members discussed the pending Information Collection Request (ICR) from CMS with six ‘model’ documents intended for patient communication. Groups volunteered to ask their patients to review the documents for clarity/understanding ahead of the comment deadline to inform Haystack’s comments.

Some of our patient groups are interested in hosting webinars on the OOP cap and MPPP program. With some financial support, Haystack can support this need. Please email Kara.Berasi@haystackproject if you are with a company able to contribute.



SURVEY - 5 QS

MEDICARE: Haystack Member Patient Group Survey

Patient groups discussed the IRA’s 9 vs 13-year window before direct price negotiations. We discussed the need to survey patient groups about their marketed and pipeline products that fall into the ‘small molecule’ vs ‘biologics’ category. Haystack shared examples of prior/historic circumstances created by policies with the unintended impact on drug development. PLEASE RESPOND TO THE SURVEY WHEN IT HITS YOUR INBOX. It will help Haystack prioritize its IRA efforts on your behalf!



H.R. 6094

Members discussed getting physicians to participate in the efforts on H.R. 6094. If patient groups know of medical societies or individual doctors, nurses, etc. they would be interested in reducing barriers -- and their own staff/office time -- in getting insurance to cover/pay for rare-disease treatments -- please contact Tiara.Logan@haystackproject.org

Remember to ask your patient to write to their Representative [here](#).



NORD MEETING ON PROMISING PATHWAYS ACT

Groups shared learnings from NORD's meeting on Sen. Braun's bill, asked about the groups that appeared to support the bill, and sought Haystack insight. Good discussion. Compliments to NORD on what was a good presentation!



HOUSEKEEPING

DUES, DUES, DUES! Pay your 2024 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 Wednesdays 1-2 pm ET - Member calls with patient groups

Follow us on social media -- [LinkedIn](#), [Facebook](#), and [Twitter](#).
Any questions, contact Tiara.Logan@haystackproject.org



THANK YOU TO THE SPONSORS

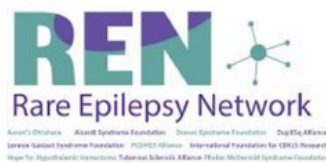
Please check the website for the growing list of Haystack sponsors, whose support allows us to do what we do!



All Copays Count Coalition



AMERICAN
BRAIN
COALITION



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.