



HAYSTACK PROJECT

The Voices of Rare & Ultra Rare

January Call Summary



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Housekeeping Items

New Haystack CEO: Deanna Darlington joined the call to introduce herself and share her excitement in joining HP.

100% Participation: Our work is 100% driven by our 90+ patient group members. And policymakers need to see our groups are vested in us.

TAKE JUST 5 MINS TO HELP WITH 100% PARTICIPATION:

- 1) Pay your dues [here](#)
- 2) Follow us on social media! [Facebook](#) - [Twitter](#) - [LinkedIn](#)
- 3) [Email](#) us for a list of dates/times for your 30-min 1:1 listening session
- 4) [Download](#) our new “Proud Haystack Project Member Seal” to display on your website or social media!



Education

Don't miss **February 10th** AEI Speaker: Sarah Shapiro, legislative director for Congressman Swalwell, will discuss her Congressman's bill on insurance coverage for genetic testing. Send us any questions you'd like raised in the discussion with Sarah and register [here](#) to attend. **NEW IN 2022 -- YOU MUST REGISTER TO ATTEND.**

Our Patient-Oriented Value (POV) Report on Uveal Melanoma is out! Thank you to Melanoma Research Foundation and Amgen for their partnership. If you would like to work with Haystack on a POV for your rare condition, let us know. Check out the press release [here](#) and read the entire report [here](#).



Legislative Update

Build Back Better: We discussed a status update and several BBB scenarios on what may come next. We also continue to meet with key Hill offices about a BBB provision that would disincentivize companies from adding new rare indications to labels and encourage them to study the *largest* orphan condition rather than the ultra-rare ones. We are following up this month. Stay tuned!

FDA Accelerated Approval Pathway: We discussed the likelihood of Congressional "reform" and our efforts at HP to develop guardrails to protect our community's access to this pathway. **Ask your industry partners to reach out** if they have ideas, and want to participate in developing of a solution that protects rare and ultra rare. [Here](#) and [here](#) are two articles to learn more about FDA's AA pathway.

Rare Disease Week: Haystack is planning two in-person panel discussions on various aspects of the **Access to Rare Indications Act** (H.R. 6160) and the **HEART Act** (H.R. 1184). Welcome your ideas on panelists and timing (during/after Rare Disease Week)



Regulatory Update

We discussed Haystack's comments to CMS' annual proposal for changes to the ACA Obamacare plans (about 23 million people are enrolled in these

plans today). As we discussed, our [letter](#) focuses on (i) CMS' proposal to use peer-reviewed literature and clinical guidelines as reliable data sources for designing non-discriminatory benefit designs in ACA plans, and (ii) reminding CMS that 'network adequacy' isn't just about giving patients access to nearby doctors, but to doctors with expertise in our rare diseases.

Next up - Haystack will comment on CMS' proposal on access to Alzheimer's treatments. No, Alzheimer's isn't rare! But CMS' focus on use of the accelerated approval pathway to deny patients access makes this a dangerous precedent for our community.



Advocacy

Voter Voice is live! Our new grassroots advocacy tool is here! Visit our TAKE ACTION webpage [here](#) to: (1) send your senators/ representatives an email asking them to cosponsor the Access to Rare Indications Act and the HEART Act!! (2) use your social media to ask your patients, caregivers, friends and family to do the same, and (3) [ask us](#) about placing Voter Voice on your org's website; LET'S GET THE WORD OUT!!

Haystack Virtual Hill Day: Member groups expressed interest in exploring bandwidth and resources for a mid-year Haystack Project virtual Hill Day.

One of our member patient groups (Marc Yale from IPPF) will highlight our Access to Rare Indications bill (HR 6160) at RDLA's Feb 17 monthly webinar! Register [here](#) to attend and highlight your support for the bill in the chat function as Marc presents!

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! This month, we call out Aurinia, Biomarin, and bluebird bio for their support! If you work with a company that doesn't know about Haystack, please help make the connection.

Partners



[Haystack Project](https://www.haystackproject.org) | haystack@haystackproject.org

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