

# HAYSTACK PROJECT

## The Voices of Rare & Ultra Rare

JUNE RECAP / NEWSLETTER

JUNE 2022

## HOUSEKEEPING

### 1. Please pay 2022 dues today!

Thank you to the patient groups that have already paid.

Help us reach our 100% participation goal!

[Pay dues](#)

2. Have you given Haystack a list of how many patients you have in each state? Not patient names/addresses, but simply how many in TX, CA, etc. Your fellow patient groups have benefitted from Haystack keeping an aggregated list and are now helping us coordinate. Learn more about why this is such a critical tool for all our patient groups and share your data!

[Email Kara](#)

## ADVOCACY MANAGER NEEDED!

For a complete list of current responsibilities, please visit the job posting below.

Please submit resumes to [Haystack1@HaystackProejct.org](mailto:Haystack1@HaystackProejct.org)

[View posting](#)



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## LEGISLATIVE UPDATE

### DISCUSSION THIS MONTH CENTERED AROUND:

#### 1. HEART Act (HR 6888/S 4071) Progress:

WE MADE IT! Parts of the HEART Act are in the both the House and Senate versions of the FDA user fee bill. Senator Casey (D-PA) introduced two amendments for us strengthening the Senate language, **so PLEASE TWEET your thanks TODAY to @SenBobCasey for his leadership on the HEART Act!**

[Tweet](#)  
[@SenBobCasey](#)

#### 2. Access to Rare Indications Act (HR 6160):

If you represent patients that need off-label treatments (for their rare condition, side effects, or symptoms, etc.), please join our efforts to pass H.R. 6160. Join the very active work group on planning Congressional visits when Members of Congress are home in August, and email Marc Yale if you have patients/doctors in CA, MI, & PA.

[Email Marc](#)

Also, STAT News ran [this great op-ed](#) on the bill in June.

#### 3. Accelerated Approval Pathway:

Please join us in thanking Sen. Kaine (D-VA) for creating an AA Pathway Council whose mission will now include oversight and consistency of FDA's use of the pathway. **BUT ask his help to put the Rare Disease Review Division on the Council** (NOT the Office of Orphan Products). And [email us](#) if your organization has worked with the Rare Review Division.

[Tweet](#)  
[@TimKaine](#)



## REGULATORY

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Haystack's Response to CMS' proposals for reimbursement changes in the inpatient setting (IPPS Rule) are posted [HERE](#). Please note in particular the section on the Rare RFI, the result of years of hard work at Haystack to bring attention to this issue.

Next up: CMS' proposals for the outpatient setting (emergency room, clinic, doctor's office, etc.) will be released any day now. Our July call will focus on our analysis and we look forward to your insights and discussion then.



## FOR THOSE PARTICIPATING IN RARE ACROSS AMERICA

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Unsure how to schedule meetings during Rare Across America, and to use the materials from the Haystack website?

Your fellow patient group, Marc Yale at IPPF, recommends this approach and offered to email with any group interested to learn more.

[Email Marc](#)

Please use Haystack Project's one-pager [HERE](#)



# WORKGROUPS

## HP50/State Activities

(led by Dean Suhr, MLD Foundation)

Dean reports the work group is closing in on how best to support Haystack patient groups in the states. If you have ideas, email Dean.

Meets second Tuesdays @ 3pm ET

[Email Dean](#)

## HEART & Accelerated Approval

(led by Kara Berasi, CDG Cares and Dottie Caplan, Applied Therapeutics)

Kara and Dottie report workgroup discussion on the differences between Heart Act provisions in the House and Senate bills, the request for industry input in new Senate language in the Heart section, and more...

Meets second Mondays at 3pm ET

[Email Kara](#)

## HR 6160/Medical Necessity

(led by Marc Yale, IPPF)

Marc reports the work group is organizing a couple of 'homestate' meetings in MI and CA, with patients and doctors.

If you are/have patients or doctors in either state, please reach out to Marc. Or if you'd like to help host a meeting in a 3rd/4th state too....

Meets first Wednesdays at 4:30pm ET

[Email Marc](#)

## First Look Workgroup

(led by Michelle Davis, IFOPA and Julie Boyd, Ultragenyx)

This work group is looking for contacts at the American Academy of Pediatrics and the American College of Medical Genetics – if you know someone at one/both, please email Michelle.

Meets third Wednesdays at noon ET.

[Email Michelle](#)

**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!



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.

All Copays Count Coalition



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BRAIN  
COALITION

