

HAYSTACK PROJECT

The Voices of Rare & Ultra Rare

MARCH NEWLETTER

MARCH 2022

Please take 5 minutes today to....

- 1) Pay your annual dues [here](#)
- 2) Follow us on Social Media!



HOUSEKEEPING

1. Dues: Still not even halfway there. Please don't forget!
2. Beta testers for telehealth survey needed ASAP! Please volunteer!
3. College level interns needed: Send us resumes!
4. Workgroups:

Sign up for topics of interest. And remember to forward the invite to a medical or scientific advisory board member, industry partners, etc.

Email us at haystack@haystackproject.org to indicate your workgroup preference and/or let us know if you don't see a topic of interest.

- First Look Project
- HEART Act
- Rare Indications Act
- COVID/Telehealth/Network Adequacy
- Accelerated Approvals
- Bundled Payments
- HP50 (State Work)
- Testing

[Pay dues](#)

[Email us](#)

LEGISLATIVE

ACCELERATED APPROVALS

We are educating both Republican and Democratic committee staff and other committee offices about our patients' experiences at FDA and our "asks" of:

- (i) cross center collaboration
- (ii) review division oversight
- (iii) FDA progression biomarker identification and
- (iv) limiting payer flexibility on coverage under the pathway.

Several patient groups have joined us at these meetings and it clearly makes a difference!

DRG BUNDLED PAYMENTS

A request for an HHS OIG report on the need to recognize rare patients in a hospital payment system based on "averages" is progressing.

If you have patients interested in helping, please email us. Timing is important and constituents can make a difference!

SIGN ON LETTER

There is a sign-on letter circulating in support of the PIE Act (HR 7008), to let payers review drug applications while they are still pending at the FDA.

Payers say this will help them make coverage decisions and assess the value of the drug and compare it to competing treatments. We continue to evaluate the bill for implications and unintended consequences. Please let us know if you are interested in learning more.

HEART ACT

The HEART Act made it through the E&C Health subcommittee hearing yesterday.

We are cautiously optimistic! Our very own FCS Foundation has put a lot of work into the bill and the group was mentioned by Rep. Tonko during the hearing.

[View Press Release](#)

BUILD BACK BETTER

Build Back Better Provision on Out of Pocket (OOP) Cap:

- We continue to discuss prospects of some, most, or all of the BBB package progressing. Last month, we focused on the cap on OOP costs.
- We shared a recent study, noting that only 890K out of 50 million enrolled beneficiaries in the Medicare Part D plan would be helped with a \$2000 annual OOP cap.

Of the 890K patients paying < \$2,000:

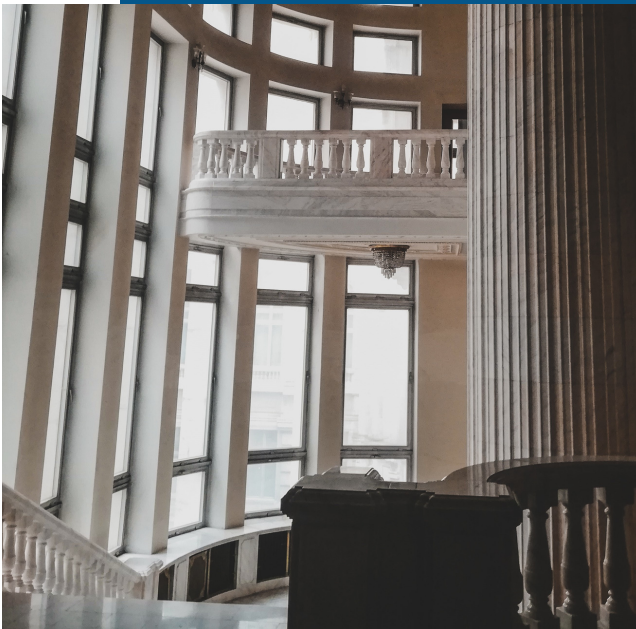
- 40% spend \$2,000-\$2,500
 - 30% spend \$2,500-\$3,000
 - 12% spend \$3,000-\$3,500
 - 18% spend >\$3,500
- We suspect rare patients are, of course, captured in that 18%, and per the discussion, will follow up to see if the authors captured any greater granularity on these numbers. It would be helpful to see if a relatively low-cost provision disproportionately helps rare patients!



REGULATORY

Haystack is reviewing and/or drafting input on these comment opportunities and RFIs:

- Oregon 1115 waiver
- Medicaid flexibilities winding down
- FTC has an RFI on PBMs



Take Action



Please Support the Access to Rare Indications Act (See Dear Colleague)

The lead co-sponsors of the Access to Rare Indications Act have circulated a letter to their fellow Representatives asking for support of HR 6160. Please share this letter to help encourage your elected official to co-sponsor the bill.



Support the Helping Experts Accelerate Rare Treatments Act (HEART)

The Helping Experts Accelerate Rare Treatments Act of 2022 will ensure that FDA is transparent and open when it reviews medications to treat rare disorders. It will require FDA to publish an annual report summarizing its actions related to designating and reviewing drugs...

Sign Up for Alerts

Enter your information below to sign up.



Find Legislation

View and search for legislation.



[View key legislation](#)

Find Officials

Elected Officials Candidates

HOW YOU CAN HELP

Please visit HaystackProject.org/TakeAction and tell your Representatives that you support the Access to Rare Indications Act (HR 6160) and the HEART Act (HR 6888).

[Take Action](#)



WE ARE LOOKING FOR AN INTERN

Research legislation, draft memos, talking points, advocacy materials, compile data, provide event and meeting support, and track/report on advocacy and lobbying efforts.

If you know of anyone, please let us know!

[Email us](#)

THANK YOU TO OUR SPONSORS

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



Mitsubishi Tanabe Pharma



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

