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Latest News from Haystack Project: Two New Board Members



Victoria brings over 20 years of leadership in government and industry, legislative expertise, and a wide breadth of knowledge around patient access to care. She recently retired from Amgen as Senior Vice President for Global Government Affairs, where she was responsible for federal and state legislative issues and managing relationships with U.S. agencies, legislatures, and governmental administrations. Previous work included senior Committee staff roles in both the House and Senate.



Lynn brings over 25 years of global policy and public affairs expertise to Haystack Project. She most recently served as Senior Vice President, Head of Healthcare Global Government & Public Affairs at Merck KGaA, where she led a team responsible for shaping government public policies to support innovation and access to medicines. Previous work included health outcomes research on a broad range of disease areas. Lynn currently serves on two other non-profit boards, Healthy Women and the Bryce Harlow Foundation.



“PROTECT RARE” ACT

Providing Realistic Opportunity To Equal [and] Comparable Treatment for Rare

What is “Medical Necessity” and Why Should Rare Disease Patients Care About It?

These two simple words allow your insurance company to **DENY coverage and payment** for the treatments your doctors say you need.

Only if your treatment is “Medically Necessary” – is it **covered by your insurance**.

DEFINITION: Treatment prescribed by your doctor must be “**on label or in compendia**” – just that and nothing else will count.

PROBLEM: *Rare Disease Treatments = Rarely On-Label or In Compendia*

RESULT: Payment Denied ... and a never-ending, time consuming, rarely successful APPEALS PROCESS





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Not a New Problem – Cancer patients faced this several years ago....And Congress solved it

PRECEDENT!!!

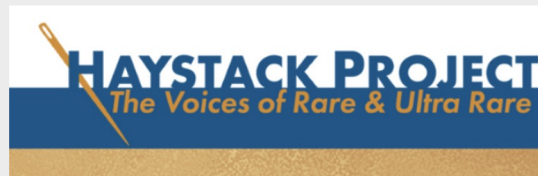
“MEDICAL NECESSITY” EXPANDED FOR CANCER:
ON-LABEL + *in Compendia or in Two Peer Reviewed Journal Articles*

We consulted with rare disease treating physicians, leading compendia in cancer (Dr. Robert Carlson, CEO, National Comprehensive Cancer Network), NIH, Journals, insurers, Hill offices...

Proposed solution: “Medical Necessity” EXPANSION FOR RARE: = On-Label, In-Compendia + *or in Clinical Guidelines or in Two Peer Reviewed Journal Articles*

Simple, Elegant Solution Based on Precedent ...

Expand Definition of “Medical Necessity” for rare diseases.



Current: On-Label, In-Compendia

Proposed Addition: “.... *or in Clinical Guidelines or in Two Peer Reviewed Journal Articles*”



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CONGRESS: HOUSE of REPRESENTATIVES

Energy & Commerce
Ways & Means
Committees

Reps. Matsui (D-CA)
and Dunn (R-FL) =
Energy & Commerce

Reps Kelly (R-PA) and
Thompson (D-CA) =
Ways & Means

Bill Introduction
forthcoming – next
week or Sept.

*What Can You Do To
HELP?*

*Ask Your
Representative to
call any of the four
to cosponsor the
bill...*

*If you/your group
would like help,
contact
[haystack@haystack
project.org](mailto:haystack@haystackproject.org)*



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CONGRESS: SENATE

Senate Finance
Committee

Two Finance
members ready to
introduce – one R and
one D

Hold up – CMS
feedback to
Committee staff

What Can You Do To
HELP?

Ask Your Senator to
contact Committee
staff to inquire about
the PROTECT Act

Ask any Senate
Finance Committee
member to help get
the bill introduced

*If you'd like help,
contact
[haystack@haystack
project.org](mailto:haystack@haystackproject.org)*

When you contact Haystack@HaystackProject.org...



Sign-on Letter for your group to thank the cosponsors in the House (they'll use in their press release...)



One-pager explaining the bill – to share with your patients, Senators, Representatives



“Script” for your patients so they’re comfortable **calling** their Representatives/Senators



“Script” for your patients to **email** their Representatives/Senators **directly**



“Script” for your patients to **tweet** to their Representatives/Senators



Add you to **distribution list** of folks who want to do more



Invite you to a **monthly call** to discuss progress, ideas for advancing the bill, etc.

Add Your Organization's Name to Letter Thanking PROTECT RARE's Leaders

Email haystack@haystackproject.org

The Honorable Doris O. Matsui
2311 Rayburn House Office Building
House of Representatives United States
Washington, DC 20515

The Honorable Neal Dunn
466 Canon Office Building United States
House of Representatives
Washington, DC 20515

The Honorable Mike Kelly
1707 Longworth House Office Building
United States House of Representatives
Washington, DC 20515

The Honorable Mike Thompson
268 Cannon House Office Building
United States House of Representatives
Washington, DC 20515

July 19, 2023

RE: PROTECT Rare Act

Dear Representatives Matsui, Dunn, Thompson, and Kelly:

We are writing to express our appreciation for your leadership in advancing the **Providing Realistic Opportunity to Equal and Comparable Treatment (“PROTECT Rare”) Act**. We stand ready to amplify your work to ensure that individuals with very rare conditions have the same intended benefit of health coverage as individuals with more common conditions – access to treatments our physicians know to be the standard of care for our medical conditions.

The bill will build on existing criteria for medically necessary care so that Medicare and Medicaid will be able to consider clinical guidelines and peer-reviewed literature to assess coverage of rare disease treatments. The bill aligns coverage of rare disease treatments to what Congress previously mandated in terms of Medicare coverage for cancer treatments. Importantly, the bill does not provide ‘special treatment’ for rare diseases; rather, it levels the playing field for access to those living with more common conditions.

It will also require private payers to create an expedited review pathway for formulary exception, reconsideration, and/or appeal of any denial of coverage for a drug or biological prescribed for a patient with a rare disorder.

Again, we appreciate your leadership in improving access to the treatments prescribed for rare and ultra-rare patients by their doctors. We appreciate the opportunity to support this important legislation and look forward to working with you to pass the PROTECT Act this year.

Respectfully,

Links

<https://haystackproject.org/access-to-rare-indications-act>

<https://static1.squarespace.com/static/5966cc2220099e91326caaec/t/641dd1ebdc28683756d4be7f/1679675883824/One+Pager+-+RARE+INDICATIONS+3-20-23.pdf>

<https://static1.squarespace.com/static/5966cc2220099e91326caaec/t/61afb2d1e111636bf718c82a/1638904529464/Press+Release+Access+to+Rare+Indications+Act+vf+%281%29.pdf>

<https://deepconnections.net/2023/05/30/protecting-rare-access-to-off-label-treatments/>

<https://static1.squarespace.com/static/5966cc2220099e91326caaec/t/620c42160878305675f815b2/1644970519149/6160+sign-on.pdf>



Email haystack@haystackproject.com for more info!

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