

Subject:

FW: Edwards PAC July Newsletter: NEW Design, Same Great Info!

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Edwards PAC

EDWARDS PAC NEWSLETTER - JULY 2024

Voice. Action. Impact.

New Look! Welcome to the new Edwards PAC Newsletter.



One of your benefits as an Edwards PAC member is to receive our bi-monthly newsletter including political updates, policy updates, events, and the occasional odds and ends. We have updated our look and hope you find this enjoyable and easier to read.

Upcoming Event: Edwards PAC Midyear Spending Review -

August 12, 11:00 a.m. PT.

Edwards is committed to transparency in its political activities. The company discloses its political activities to appropriate state and federal government agencies, in accordance with applicable laws and regulations. Twice a year, we hold a public forum with Edwards' employees who contribute to the PAC to listen to an activity report from our Government Affairs Team, complete with an opportunity for Q&A. Look out for a calendar invitation to register to attend and feel free to reach out to the team with any questions!

June 25 Election Results in Utah

Toplines:

- Based on the Republican make-up of the state, Governor Spencer Cox should sail to reelection in November.
- Similarly, having won the Republican primary, Rep. John Curtis will likely be the next Senator from Utah (replacing Senator Mitt Romney) in January. Edwards has an extremely warm and productive relationship with Rep. Curtis.



Results of Utah Primary Election

Governor: Incumbent Republican Governor **Spencer Cox** defeated Phil Lyman with 57% of the vote. Cox will take on Democrat Brian King, who ran unopposed in the democratic primary, in the general election.

Senate: **Rep. John Curtis** (R-UT-3) defeated Riverton mayor Trent Staggs in a contentious 4-way race for the Republican nomination 51% - 30%. Curtis, who had initially declined to run for the seat being vacated by Sen. Mitt Romney and overcame former president Trump's endorsement of Staggs, will have a strong advantage over Democrat Caroline Gleich, who ran unopposed in her primary, in the general election.

House of Representatives

- **Utah – 01:** Incumbent Republican Congressman **Blake Moore** defeated Paul Miller 72% - 28%. Moore will face Democrat Bill Campbell, who ran unopposed in the primary, in the general election.
- **Utah – 02:** Incumbent Republican Congresswoman Celeste Malloy is leading challenger Colby Jenkins by just 214 votes, and on July 29th, Jenkins officially filed a

request for recount. The winner of the primary race will face Democrat Nathaniel Woodward in the November general election.

- **Utah – 03:** In Rep. John Curtis’s **open House seat**, state Senator Mike Kennedy has won a 5-way race with 37% of the vote, while his closest opponent Case Lawrence has received 22%. Kennedy is a lawyer and general practice physician who had previously run against Mitt Romney for U.S. Senate. Kennedy will face Democrat Glenn Wright, who previously ran against incumbent John Curtis in 2022, in the general election.
- **Utah – 04:** Incumbent Republican Congressman **Burgess Owens** ran unopposed, and will face Democrat Katrina Fallick-Wang, who also ran unopposed, in the general election this November.

Team Edwards on Capitol Hill



Stephanie Badeaux in TMTT GHER came to Washington to help educate policymakers on EVOQUE and our current engagement with CMS to coverage the technology, which helps patients with tricuspid regurgitation, through a National Coverage Decision (NCD).



Stephanie Badeaux, TMTT GHER, joined Brian Looser of the DC team on Capitol Hill to help educate members of congress and staff about EVOQUE and our ongoing engagement with CMS. They are pictured here with staff for Rep. Blake Moore (UT-R).



Leah Kegler, SVP - Government Affairs, participated as a panelist to discuss H.R. 1691 during an AdvaMed sponsored briefing on Capitol Hill entitled “Ensuring Patient Access to Critical Breakthrough Products Act of 2023.”



The Government Affairs Team had an opportunity for a photo op on the Speaker's Balcony during Hill visits!

Brian Looser demonstrated the EVOQUE Transcatheter Tricuspid Valve Replacement system to staff on Capitol Hill during the AdvaMed MedTech Showcase – part of the Q2 AdvaMed Board Meeting.

House W&M Advances Accelerated Coverage for Breakthrough Technologies

Last month, the House Ways & Means Committee passed an amended version of HR 1691, the “Ensuring Patient Access to Critical Breakthrough Products Act of 2023”, with a strong bipartisan vote of 36 yeas to 5 nays.

[Click here to read the amended version of the bill](#)

H.R. 1691, as Amended – Summary

The legislation establishes a pathway by which FDA-approved devices would receive temporary coverage (up to four years from the date of FDA approval) under CMS, wherein:

- After an 18-month implementation period, CMS coverage of the device would begin within 6 months of FDA approval;
- The Secretary determines the device meets “breakthrough” status, based on assessment criteria resembling that of FDA;
- The Secretary has authority to deny coverage in cases where “undue harm” based on evidence could come to patients;
- At the request of the sponsor, shall complete a National Coverage Determination before the conclusion of the temporary coverage period, provided that the sponsor makes such request no less than 9 months prior to the end of the temporary coverage period;
- An additional \$10 million/year from 2025 until 2030 will be provided for the establishment of such temporary coverage pathway;
- Includes breakthrough designated 510(k)s with a specified level of clinical data as eligible to receive temporary coverage.

This is an important step in the legislative process that makes the bill eligible for consideration by full House, though it’s unclear when that will happen, especially in an election year. Edwards’ Government Affairs Team is hopeful that chances are high for the bill’s inclusion in an end-of-year omnibus legislation.

In a related matter, 47 bipartisan Members of Congress sent a letter to HHS Secretary Becerra and CMS Administrator Brooks-LaSure seeking answers to questions regarding proposed guidance entitled “Transitional Coverage for Emerging Technologies” (TCET), which would establish a coverage pathway under which CMS would provide temporary coverage of FDA-approved ‘Breakthrough’ devices, allowing Medicare beneficiaries access while the agency works with manufacturers to identify and fill any gaps in evidence necessary to satisfy CMS’ standard for a National Coverage Determination (NCD). Edwards strongly supports finalization of the TCET guidance.



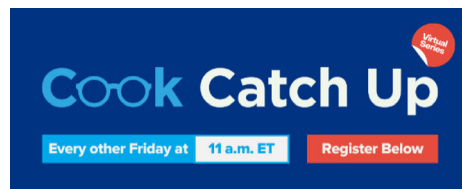
Teams Town Hall with Rep. Mariannette Miller-Meeks

On July 22nd, Edwards PAC hosted its monthly “Teams Town Hall” meeting with Rep. Mariannette Miller-Meeks (R-IA-01). Over 50 Edwards employees joined the call in which the congresswoman discussed her experience as a physician, military veteran, and her priorities in Congress.

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Edwards PAC Perks!

As a member of Edwards PAC, we are delighted to offer several perks to keep you informed on political and policy updates in Washington.



[Click Here](#)

If you would like to receive daily policy and politics news, sign up to receive the Edwards Political and Policy News blog!

[Click Here](#)

Join Charlie Cook as he provides his recap of the week, shares his latest outlook on the political landscape, and answers your questions.



[Click Here](#)

If you truly are a political junkie or want to learn more about politics, the GA Team has expanded the Edwards Lifesciences National Journal subscription to allow access to certain events to Edwards PAC members.

Hotline Power Hour

[Click Here](#)

Step into the Hotline newsroom as the team discusses the latest from the campaign trail and analyzes races up and down the ballot.

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