

March 17, 2021*

**Legislative Update:
Clinical Trials and Translational Research Advisory Committee (CTAC)**

*Content current as of March 15, 2021

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I. 117th Congress

The 117th Congress was sworn in on Sunday, January 3, 2021. Democrats retained their majority status in the House, with a reduced margin of 219 Democrats and 211 Republicans.¹ Democrats also won control of the Senate, with Vice President Kamala Harris breaking the tie between an equally divided chamber of 50 Democrats² and 50 Republicans. This 50/50 split of the Senate has only happened three other times in history, leading to weeks of discussions between Senate Majority Leader Chuck Schumer (D-NY) and Senate Minority Leader Mitch McConnell (R-KY), who brokered a power-sharing deal.

With a deal in place, Senate leaders joined the House in appointing committee and subcommittee chairs and completing committee assignments, which are detailed below. Changes are marked in red.

Congressional Leadership

Rep. Nancy Pelosi (D-CA) was re-elected as the Speaker of the House, marking her third session in this role. Sen. Chuck Schumer (D-NY) is serving as Senate Majority Leader for the first time in his career.

Chamber	Position	Member
House	Speaker of the House	Rep. Nancy Pelosi (D-CA)
	Majority Leader	Rep. Steny Hoyer (D-MD)
	Majority Whip	Rep. James Clyburn (D-SC)
	Assistant Speaker of the House	Rep. Katherine Clark (D-MA)
	Democratic Caucus Chair	Rep. Hakeem Jeffries (D-NY)
	Minority Leader	Rep. Kevin McCarthy (R-CA)
	Minority Whip	Rep. Steve Scalise (R-LA)
	Republican Conference Chair	Rep. Liz Cheney (R-WI)
Senate	Republican Committee Chair	Rep. Gary Palmer (R-AL)
	Majority Leader	Sen. Chuck Schumer (D-NY)
	Majority Whip	Sen. Dick Durbin (D-IL)
	Republican Conference Chair	Sen. John Barrasso (R-WY)
	Republican Policy Committee Chair	Sen. Roy Blunt (R-MO)
	Minority Leader	Sen. Mitch McConnell (R-KY)
	Minority Whip	Sen. John Thune (R-SD)
	Assistant Democratic Leader	Sen. Patty Murray (D-WA)

House Appropriations Committee

Rep. Rosa DeLauro (D-CT) was named the new Chair of the full committee, following the retirement of Rep. Nita Lowey (D-NY). Rep. Kay Granger (R-TX) will remain as the Ranking Member. Rep. DeLauro (D-CT) will retain her Chairmanship of the Labor, Health and Human Services, Education and Related Agencies (L-HHS) Appropriations Subcommittee, and Rep. Tom Cole (R-OK) will remain the Ranking Member. New members of the L-HHS subcommittee are Reps. Brenda Lawrence (D-MI), Josh Harder (D-CA), Chuck Fleischmann (R-TN) and Ben Cline (R-VA). Full roster below.

¹ As of March 15, 2021, there are five vacant seats in the House.

² The 50 Democrat seats in the Senate include two Independent members who caucus with Democrats: Sens. Bernie Sanders of Vermont and Angus King of Maine.

House Appropriations Committee Leadership & L-HHS Subcommittee Roster	
Majority	Minority
Rosa DeLauro (D-CT) – Full Committee Chair	Kay Granger (R-TX) – Full Committee Ranking Member
Rosa DeLauro (D-CT) – L-HHS Subcommittee Chair	Tom Cole (R-OK) – L-HHS Subcommittee Ranking Member
Lucille Roybal-Allard (D-CA)	Andy Harris, M.D. (R-MD)
Barbara Lee (D-CA)	Chuck Fleischmann (R-TN)
Mark Pocan (D-WI)	Jaime Herrera Beutler (R-WA)
Katherine Clark (D-MA)	John Moolenaar (R-MI)
Lois Frankel (D-FL)	Ben Cline (R-VA)
Cheri Bustos (D-IL)	
Bonnie Watson Coleman (D-NJ)	
Brenda Lawrence (D-MI)	
Josh Harder (D-CA)	

Senate Appropriations Committee

Sen. Patrick Leahy (D-VT) is the Chair of the Senate Appropriations Committee, and Sen. Richard Shelby (R-AL) is the Ranking Member. With the flip in Senate leadership, Sen. Patty Murray (D-WA) is the new L-HHS Subcommittee chair, and Sen. Roy Blunt (R-MO) is the ranking member. Sen. Mike Braun (R-IN) is a new member of the L-HHS subcommittee. *Full roster below.*

Senate Appropriations Committee Leadership & L-HHS Subcommittee Roster	
Majority	Minority
Patrick Leahy (D-VT) – Full Committee Chair	Richard Shelby (R-AL) – Full Committee Ranking Member, Member of Subcommittee
Patty Murray (D-WA) – Subcommittee Chair	Roy Blunt (R-MO) – Subcommittee Ranking Member
Richard Durbin (D-IL)	Lindsey Graham (R-SC)
Jack Reed (D-RI)	Jerry Moran (R-KS)
Jeanne Shaheen (D-NH)	Shelley Moore Capito (R-WV)
Jeff Merkley (D-OR)	John Kennedy (R-LA)
Brian Schatz (D-HI)	Cindy Hyde-Smith (R-MS)
Tammy Baldwin (D-WI)	Mike Braun (R-IN)
Chris Murphy (D-CT)	Marco Rubio (R-FL)
Joe Manchin (D-WV)	

House Energy and Commerce Committee

Rep. Frank Pallone (D-NJ) retains Chairmanship of the full House Energy and Commerce (E&C) Committee, while Rep. Cathy McMorris Rodgers (R-WA) replaces retired Rep. Greg Walden (R-OR) as the Ranking Member. Within the Health Subcommittee, Rep. Anna Eshoo (D-CA) remains Chair, and Rep. Brett Guthrie (R-KY) was named Ranking Member, replacing Rep. Michael Burgess (R-TX), who will continue to serve as a member of the Subcommittee in the new Congress. New members of the health subcommittee are Reps. Angie Craig (D-MN), Kim Schrier, M.D. (D-WA), Lori Trahan (D-MA), Lizzie Fletcher (D-TX), Neal Dunn (R-FL), John Curtis (R-UT), Dan Crenshaw (R-TX), and John Joyce (R-PA). *Full roster below.*

E&C Health Subcommittee Roster	
Majority	Minority
Frank Pallone (R-NJ) – Full Committee Chair, Ex Officio Member of Subcommittee	Cathy McMorris Rodgers (R-WA) – Full Committee Ranking Member, Ex Officio Member of Subcommittee
Anna Eshoo (D-CA) – Health Subcommittee Chair	Brett Guthrie (R-KY) – Health Subcommittee Ranking Member
G.K. Butterfield (D-NC)	Fred Upton (R-MI)
Doris Matsui (D-CA)	Michael Burgess, M.D. (R-TX)
Kathy Castor (D-FL)	H. Morgan Griffith (R-VA)
John Sarbanes (D-MD)	Gus Bilirakis (R-FL)
Kurt Schrader (D-OR)	Billy Long (R-MO)
Tony Cárdenas (D-CA)	Larry Bucshon, M.D. (R-IN)
Peter Welch (D-VT)	Markwayne Mullin (R-OK)
Raul Ruiz, M.D. (D-CA)	Richard Hudson (R-NC)
Debbie Dingell (D-MI)	Earl “Buddy” Carter, B.S.Pharm. (R-GA)
Ann Kuster (D-NH)	Neal Dunn (R-FL)
Robin Kelly (D-IL)	John Curtis (R-UT)
Nanette Diaz Barragán (D-CA)	Dan Crenshaw (R-TX)
Lisa Blunt Rochester (D-DE)	John Joyce (R-PA)
Angie Craig (D-MN)	
Kim Schrier, M.D. (D-WA)	
Lori Trahan (D-MA)	
Lizzie Fletcher (D-TX)	

Senate Health, Education, Labor and Pensions (HELP) Committee

Leadership of the HELP Committee has changed to reflect the Democratic control of the Senate as well as the retirement of previous chair, Sen. Lamar Alexander (R-TN). Sen. Patty Murray (D-WA) now serves as chair with Richard Burr (R-NC) serving as ranking member. New members include Sens. Ben Ray Luján (D-NM), John Hickenlooper (D-CO), Roger Marshall, M.D. (R-KS), Tommy Tuberville (R-AL), and Jerry Moran (R-KS). *Full roster below.*

HELP Committee Roster	
Majority	Minority
Patty Murray (D-WA) – Chair	Richard Burr (R-NC) – Ranking Member
Bernie Sanders (I-VT)	Rand Paul, M.D. (R-KY)
Robert Casey, Jr. (D-PA)	Susan Collins (R-ME)
Tammy Baldwin (D-WI)	Bill Cassidy, M.D. (R-LA)
Chris Murphy (D-CT)	Lisa Murkowski (R-AK)
Tim Kaine (D-VA)	Mike Braun (R-IN)
Maggie Hassan (D-NH)	Roger Marshall, M.D. (R-KS)
Tina Smith (D-MN)	Tim Scott (R-SC)
Jacky Rosen (D-NV)	Mitt Romney (R-UT)
Ben Ray Luján (D-NM)	Tommy Tuberville (R-AL)
John Hickenlooper (D-CO)	Jerry Moran (R-KS)

II. Budget and Appropriations

FY 2021 Appropriations Update

The Fiscal Year 2021 Omnibus and COVID Relief and Response Act was signed into law on December 27, 2020. The bill provides \$6.56 billion for NCI, including the \$195 million authorized for the Cancer Moonshot in the 21st Century Cures Act, in addition to \$50 million, as requested, for the second year of the Childhood Cancer Initiative. The FY21 NCI funding level is approximately \$119 million over the FY20 enacted level, representing an approximately 1.8% increase.

FY 2022 Appropriations Update

As is customary during the first year of a presidential transition, the release of the President's Budget was delayed beyond the traditional early February release date. This year's budget and appropriations process is also complicated by parallel efforts in Congress to develop and pass the \$1.9 trillion COVID aid package. In addition, the debt limit suspension will expire on July 31, triggering the need for legislation to increase the debt limit.

III. Recent Congressional Events

Less Cancer Prevention Workshop (February 4, 2021): Dr. Vikrant Sahasrabudhe, Program Director, Breast and Gynecologic Cancer Research Group, Division of Cancer Prevention, participated in a discussion with Dr. Thomas Uldrick, Deputy Head, Global Oncology Program, Fred Hutchinson, regarding virally-induced cancers as part of Less Cancer's annual Prevention Workshop. This year's virtual event included remarks from a number of members of Congress, featuring members of the House Energy and Commerce Committee, including Ranking Member Cathy McMorris Rodgers (R-WA), Rep. Michael Burgess (R-TX), and Rep. Fred Upton (R-MI); Senate HELP Committee member Sen. Maggie Hassan (D-NH); House L-HHS Appropriations Subcommittee member Rep. Jaime Herrera Beutler (R-WA); and members of Congress with an interest in cancer research and prevention, including Reps. Debbie Dingell (D-MI), Don Beyer (D-VA), Dan Kildee (D-MI), Ro Khanna (D-CA), Chris Pappas (D-NH), and Madeleine Dean (D-PA).

IV. Special Legislation

COVID-19 Response

On January 14, 2021, shortly before taking office, President Biden released a broad-ranging \$1.9 trillion COVID-19 relief plan. Republicans countered with a more targeted \$618 billion proposal, which was discussed between Congressional leaders and White House officials on February 2, 2021. Despite reports that the meeting was productive, the Democratically controlled Congress ultimately made the decision to move the President's plan through using the fast-track budget reconciliation process.

The House began that process by approving a budget resolution on Wednesday, February 3rd by a vote of 218-212. In the early morning hours of Friday, February 5th, following 15 hours of votes on amendments, the Senate approved a budget resolution by a vote of 51-50, with Vice President Kamala Harris breaking the tie. The Senate approval of the resolution allowed the House to complete the first stage of the budget reconciliation process. Once the budget blueprint was approved, House Authorizing committees worked quickly to fill in the details of the \$1.9 trillion relief package, drafting legislative text, considering amendments, and advancing the bills out of committee during the week of February 8th.

The House passed the reconciliation package in the early hours of Saturday, February 27th by a vote of 219-212, with only two Democrats voting against the bill, and zero Republicans voting in favor of the measure. It is unlikely that the package would have been able to move forward in the Senate without facing a filibuster, but

Democrats needed only a simple majority vote, as reconciliation bills are not subject to filibuster in the Senate. The Senate passed the package on Saturday, March 6th by a vote of 50-49, after certain provisions were amended after being flagged by the Senate Parliamentarian as ineligible for the budget reconciliation process. Most notably, a provision which would have instituted a federal minimum wage of \$15 per hour was cut from the package, and a subsequent effort to add the provision back as an amendment during the Senate vote failed.

The revised bill passed the House on Wednesday, March 10th largely along party lines by a vote of 220-211, with one Democrat joining Republicans in voting against the bill, and it was signed into law on Thursday, March 11th, meeting the Democratic goal of enacting legislation by March 14th, when enhanced unemployment benefits provided by previous COVID-19 relief packages were set to expire.

The American Rescue Plan Act builds upon the Administration's initial plan, with the \$1.9 trillion in relief addressing several priority areas to support the ongoing COVID-19 response and economic recovery. The bill includes additional funding to fight COVID-19 through an increase in testing as well as support for vaccine production and distribution, treatment, and prevention. Economic recovery provisions include direct relief to Americans through stimulus payments and increased unemployment insurance benefits; aid to state, local, tribal, and territorial governments; and small business assistance, among other provisions. The plan also prioritizes a return to in-person learning, proposing additional funds to help schools reopen safely.

Telehealth

The Centers for Medicare and Medicaid Services (CMS) issued a number of [temporary waivers and new rules](#) at the beginning of the pandemic to minimize the risk of patients and providers contracting COVID-19 during the course of medical care. Under the public health emergency, all Medicare beneficiaries can receive services through telehealth. Providers may see new or returning patients, and they can waive copayments for non-face-to-face services. In addition, CMS has created an easier process for providers to temporarily become Medicare providers.

These flexibilities extend not just to physicians, but to all Medicare providers, such as clinical social workers, psychologists, physical therapists, and occupational therapists. Clinicians requiring physician supervision, such as nurse practitioners and residents, may receive guidance virtually. The new rules cover a wide variety of services, including COVID-19 diagnostic testing, remote evaluations (both computer-aided and over the phone), behavioral health and education services, remote patient monitoring, and remote patient care for Medicare patients with End Stage Renal Disease.

Prior to these flexibilities being put in place, approximately 13,000 Medicare beneficiaries received telemedicine in a week. Almost 1.7 million beneficiaries received telehealth services in the last week of April 2020.

[State and territorial Medicaid agencies](#) are encouraged to assess their needs and request the flexibilities outlined in the Medicaid and CHIP Disaster Response Toolkit. [Private insurers have followed suit](#), with many carriers covering telehealth services.

While these flexibilities are only guaranteed to be in place until the end of the public health emergency is declared, there is significant interest in Congress as well as the public health and research communities in making permanent changes in support of telehealth flexibilities. Congress introduced a number of bills in the 116th Congress focused on telehealth, and members have reintroduced several of these bills in the new Congress already. The Temporary Reciprocity to Ensure Access to Treatment "[Treat](#)" Act (S.168) was reintroduced by Sen. Christopher Murphy (D-CT) and co-sponsored by Sen. Roy Blunt (R-MO) on February 2, 2021, and would allow healthcare providers to use telehealth to treat patients in any state during the

coronavirus pandemic. The Advancing Connectivity during the Coronavirus to Ensure Support for Seniors (ACCESS) Act, introduced by Sens. Shelley Moore Capito (R-WV) and Amy Klobuchar (D-MN), Protecting Access to Post-COVID-19 Telehealth Act, introduced by Rep. Mike Thompson (D-CA-5), and the Ensuring Telehealth Expansion Act, introduced by Rep. Roger Williams (R-TX-25) are several other recently introduced bills aimed at making telehealth expansion permanent.

These changes join flexibilities already in effect as of January 1, 2020, which were implemented in response to the Bipartisan Budget Act of 2018 (BBA). Under the BBA, certain Accountable Care Organizations (ACOs) are able to [expand the use of telehealth](#), utilizing special coverage for these services. The new policies removed geographic limitations imposed under normal fee-for-service rules and allowed Medicare beneficiaries to receive telehealth services from their home.

Other Legislation of Interest

The following bills were selected for inclusion in this update due to anticipated interest among CTAC members.

Selected Bills – 117th Congress

Prostate-Specific Antigen Screening for High-risk Insured Men (PSA Screening for HIM) Act (H.R.1176)

- The legislation was introduced by Rep. Bobby Rush (D-IL-1) on 2/18/2021.
- The bill would waive deductibles, copayments, and coinsurances for prostate cancer screenings for men who have a family history of prostate cancer or who are African-American.

Research Investment to Spark the Economy (RISE) Act (S.289)

- On 2/5/2020, Senators Edward J. Markey (D-MA), Thom Tillis (R-NC), Gary Peters (D-MI), and Susan Collins (R-ME) reintroduced the RISE Act to authorize nearly \$25 billion in emergency relief funds for federal science agencies, including \$10 billion for the NIH. The legislation was also introduced in the 116th Congress.
- Reps. Diana DeGette (D-CO), Fred Upton (R-MI), Eddie Bernice Johnson (D-TX), Anna A. Eshoo (D-CA) and Anthony Gonzalez (D-OH) introduced the legislation in the House, with 77 original co-sponsors. (H.R.869)
- More than 300 organizations have signed on to support the legislation.

The Temporary Reciprocity to Ensure Access to Treatment (TREAT) Act (S.168)

- The legislation was originally introduced by Sens. Chris Murphy (D-CT) and Roy Blunt (R-MO) on 8/4/20 and reintroduced in the 117th Senate on 2/2/2021.
- The bill would provide temporary licensing reciprocity for all practitioners and health professionals for all types of services (in-person and telehealth) during the COVID-19 response and for future national emergencies.
- A House version of the bill (H.R.708) was also introduced on 2/2/2021 by Reps. Bob Latta (R-OH-5) and Rep. Debbie Dingell (D-MI-12).

Gabriella Miller Kids First Research Act 2.0 (H.R. 623)

- The legislation was introduced by Rep. Jennifer Wexton (D-VA) on 1/28/2021 and currently has 22 cosponsors.
- The bill would require certain civil penalties collected from pharmaceutical, cosmetic, supplement, and medical device companies to be transferred to a fund at NIH for the Gabriella Miller Kids First Pediatric Research Program.
- This bill aims to provide new and ongoing funding to support the research program and would transition the program out of the NIH Common Fund to the NIH Division of Program Coordination, Planning, and Strategic Initiatives.

Comprehensive Breast Reconstruction Act of 2021 (H.R.469)

- The legislation was introduced by Rep. Alcee Hastings (D-FL-20) on 1/25/2021.
- The bill would provide for Medicare, Medicaid, and private health insurance coverage of certain tattooing services in connection with post-mastectomy breast reconstruction, and aligns the scope of Medicare and Medicaid coverage of such breast reconstruction with that of private health insurance.

Protecting Access to Post COVID-19 Telehealth Act (H.R.366)

- The legislation was introduced in the House by Rep. Mike Thompson (D-CA) and colleagues on the Congressional Telehealth Caucus on 1/19/2021.
- The bill would allow for the expanded use of telehealth after the Coronavirus public health emergency by eliminating restrictions on telehealth services in Medicare. These restrictions have been waived during the COVID-19 pandemic, and this piece of legislation is one of numerous pieces of recently introduced legislation that would make the expanded flexibilities permanent.

Katherine's Lung Cancer Early Detection and Survival Act of 2021 (H.R. 238)

- This legislation was introduced in the House by Rep. Brendan Boyle (D-PA) on 1/11/2021. It was referred to the House Committee on Energy and Commerce.
- This bill requires private health insurance plans to cover, without cost sharing, screenings for the detection of lung cancer for individuals 40 years of age or older without regard to such individuals' smoking history.

Triple-Negative Breast Cancer Research and Education Act of 2021 (H.R.113)

- The legislation was introduced by Rep. Sheila Jackson Lee (D-TX-18) on 1/4/2021.
- The bill would provide for research and education with respect to triple-negative breast cancer, and for other purposes.
- The legislation would authorize funds for NIH to expand, intensify, and coordinate programs for the conduct and support of research with respect to triple-negative breast cancer.

Lung Cancer Screening Registry and Quality Improvement Act of 2021 (H.R. 107)

- The legislation was introduced in the House by Rep. Brian Higgins (D-NY) on 1/4/2021. The bill was referred to the House Committee on Energy & Commerce and the Committee on Ways and Means.
- The bill aims to provide funds for FY2022-FY2026 for grants to help entities establish free lung cancer screening registries and requires registries to be interoperable in order to receive federal funds. The bill also directs the Secretary of the Department of Health and Human Services to award grants to support the development of related quality measures for lung cancer screenings.

Selected Resolutions – 117th Congress

This section highlights resolutions introduced to raise awareness about specific diseases or issues. It is important to note that resolutions are different than bills, in that they are used to express the sentiment of one chamber (House or Senate) on an issue. As such, resolutions do not require concurrence of the other chamber or approval by the president, and they do not have the force of law.

Expressing support for designation of March 3, 2021, as National Triple-Negative Breast Cancer Day. (H.Res.185)

- The resolution was introduced by Rep. Joseph Morelle (D-NY) on 3/3/2021.
- The resolution expresses support for the designation of National Triple-Negative Breast Cancer Day.

Expressing support for the designation of the last day of February each year as "Rare Disease Day". (H.Res.167 & S.Res.74)

- The resolution was introduced in the House by Rep. Andre Carson (D-IN) on 2/26/2021 and in the Senate by Senator Sherrod Brown (D-OH) on 2/24/2021.
- The resolution expresses support for the designation of Rare Disease Day.

Expressing support for the designation of February 4, 2021, as "National Cancer Prevention Day". (H.Res.96)

- The resolution was introduced by Rep. Debbie Dingell (D-MI) on 2/4/2021.
- This resolution expresses support for the designation of National Cancer Prevention Day.