

Clinical Trials and Translational Research Advisory Committee (CTAC)

M.K. Holohan, J.D.

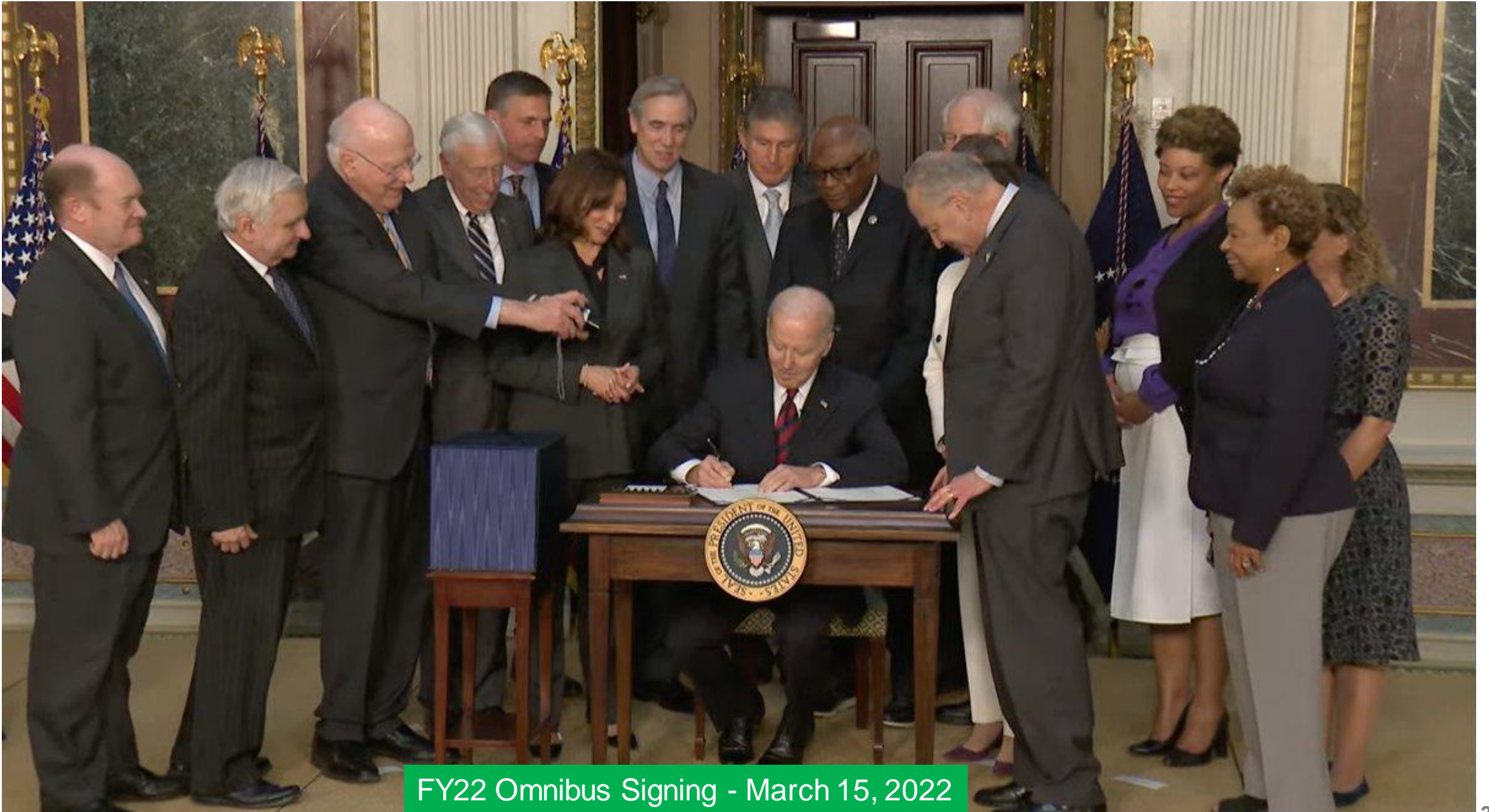
Office of Government and Congressional Relations

FY22 (and FY23) Appropriations

COVID Funding

Legislation & Issues to Watch

- Telehealth bills (50+ bills)
- Cures 2.0 & Advanced Research Projects Agency for Health Act
- PREVENT Pandemics
- COMPETES Act (Endless Frontiers Act, USICA, Make it In America)



FY22 Omnibus Signing - March 15, 2022



Senate confirms Shalanda Young to lead OMB

BY JENNIFER SCHOLTES | 03/15/2022 04:49 PM EDT

The Senate on Tuesday confirmed Shalanda Young to be White House budget director, filling President Joe Biden's last vacant Cabinet position more than a year after he withdrew Neera Tanden's nomination.

In a 61-36 vote, the Senate approved Young to head the Office of Management and Budget, the agency she has led in an acting capacity after earning [Senate approval a year ago](#) to serve as deputy director. Lawmakers have been pleased with Young's leadership at OMB, easing her confirmation to the top post.

FY22 Appropriations

CR #1: 10/1-12/3 CR #2: 12/4-2/18 CR #3: 2/19-3/11 CR #4: 3/12-3/15

	President's Budget Request	House passed 7/29/21 (219-208)	Senate DRAFT released 10/18/21	FY2022 Omnibus Appropriations Act Passed 3/10/22
NIH	\$52 B (+\$9 B)	\$49.4 B (+\$6.5 B)	\$47.9 B (+\$5 B)	\$ 45B (+\$ 2.25B)
ARPA-H	\$6.5 B	\$3.0 B	\$2.4 B	\$ 1B (in HHS Section)
NCI	\$6.73 B (+\$174 M)	\$6.99 B (+\$434 M)	\$6.77B (+\$212 M)	\$6.9 B (+\$353 M)

COVID funding

- **1st version of Omnibus - \$15.6B (removed before passage)**
- **White House Request - \$22.5B (renewed 3/15/22)**

CQ NEWS

Mar. 15, 2022

White House sees immediate cuts to virus response absent more funds

March 15, 2022 – 1:03 p.m. By Ariel Cohen, CQ

The White House said it is preparing to make cuts to the country's COVID-19 response effort if Congress doesn't provide additional funds to deal with the pandemic, warning that the U.S. is running out of money to test, treat and vaccinate Americans against the virus.

As parts of Europe and Asia experience virus spikes and scientists monitor for a similar surge in the U.S., senior administration officials said Tuesday the Health and Human Services Department and the National Institutes of Health won't be able to research and develop next-generation vaccines that protect against multiple variants without additional funds. The officials also said the government needs more money to conduct genomic surveillance of potential new variants and to purchase enough doses for all Americans if a fourth COVID-19 shot is needed.

Telehealth Proposals: 50+ introduced this session

- Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act
 - *61 bipartisan cosponsors in the Senate, 120 in the House*

- Selected additional bills:
 - Protecting Access to Post-COVID–19 Telehealth Act
 - Ensuring Telehealth Expansion Act
 - Advancing Connectivity during the Coronavirus to Ensure Support for Seniors (ACCESS) Act
 - Rural and Frontier Telehealth Expansion Act

Note: The FY22 Omnibus extends Medicare telehealth flexibilities for 151 days past the end of the COVID-19 public health emergency. It does not make these changes permanent.



Cures 2.0

117TH CONGRESS
1ST SESSION

H. R. 6000

To continue the acceleration of the discovery, development, and delivery of 21st century cures, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 17, 2021

Ms. DEGETTE (for herself and Mr. UPTON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, the Budget, Science, Space, and Technology, Agriculture, Education and Labor, Armed Services, Natural Resources, Veterans' Affairs, Homeland Security, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To continue the acceleration of the discovery, development, and delivery of 21st century cures, and for other purposes.

- 1 *Be it enacted by the Senate and House of Representa-*
- 2 *tives of the United States of America in Congress assembled,*
- 3 **SECTION 1. SHORT TITLE.**
- 4 This Act may be cited as the “Cures 2.0 Act”.



- Introduced November 2021
- Authorization of appropriations for ARPA-H and several other research efforts (Long COVID, antibiotic resistance)
- Aims to address clinical trial diversity/ access, and improve access to diagnostics and treatment
- Proposes telehealth expansion and calls for additional research
- Calls for additional patient and caregiver training and education

DeGette, Eshoo, Upton join forces to advance Cures 2.0, ARPA-H Act

Feb 8, 2022 | Press Release

WASHINGTON, D.C. – U.S. Reps. Diana DeGette (D-CO), Anna Eshoo (D-CA) and Fred Upton (R-MI) have joined forces to advance two critical health care bills aimed at revolutionizing America's biomedical research capabilities and creating a new advanced research agency for health modeled after the Department of Defense's highly successful DARPA program.

The move became clear during a key congressional subcommittee hearing today in which the lawmakers all expressed support for each other's legislation and vowed to work together to get both bills approved by the full House as soon as possible.

Once approved, the measures – the Advanced Research Projects Agency for Health Act (H.R. 5585), introduced by Eshoo, and Cures 2.0 (H.R. 6000), introduced by DeGette and Upton – would not only create a new Advanced Research Projects Agency for Health, known as ARPA-H, to find new cures and treatments for some of the world's most difficult diseases, but would also provide the new agency the framework it needs to be successful.



Chair
Anna Eshoo (D-CA)



Ranking Member
Brett Guthrie (R-KY)



Dr. Keith Yamamoto,
UCSF

Dr. Geoffrey Ling,
On Demand Pharm.

Dr. Brian Miller,
JHU



Esther Krofah,
FasterCures



Adm. Brett Giroir

Senate panel advances sweeping pandemic readiness, research bill

March 15, 2022 – 3:35 p.m. By Lauren Clason, CQ



The Prepare for and Respond to Existing Viruses, Emerging New Threats, and (PREVENT) Pandemics Act- Introduced March 10, 2022, reported out to the Senate floor March 15

- Seeks to strengthen the medical supply chain, improve management of the strategic national stockpile, strengthen FDA's enforcement authority against counterfeit medical devices
- Directs CDC to work with public health departments to develop best practices for improving data availability, quality, and completeness
- Would commission reviews of the COVID-19 response
- **Would establish ARPA-H within NIH**
 - President appoints Director to a 4-year term
 - Prohibits location in the Washington, D.C. area or near any NIH campus
- Sec. 502: Modernizing Clinical Trials
 - Requires HHS to provide guidance on remote data collection methods; improve access to clinical trials for underrepresented communities

American Competitiveness Legislation

SENATE:
**U.S. Innovation and
Competition Act of
2021 (USICA)**
passed June 8, 2021

- Focus on increasing competitiveness with China
- Increases to NSF, DOE, NASA, Commerce Department (establishment of regional tech hubs), U.S. semiconductor industry
- Double DARPA budget over a 5-year period
- NIH provisions: data sharing, “gain of function” research

HOUSE:
**America
COMPETES Act**
passed Feb. 4, 2022

- Reauthorization of SBIR/STTR programs through FY27
- Support for low-dose radiation research at DOE
- Boost U.S. competitiveness in the semiconductor industry
- Climate provisions
 - Improve interagency collaboration
 - Increase State Dept. focus
 - Foster partnerships between financial institutions investing in clean energy

**Conference
Package TBD**

CASUALTY LIST
117th Congress
(As of 03/03/2022)

SENATE
Dems - 1
GOP - 5

HOUSE
Dems - 31
GOP - 15



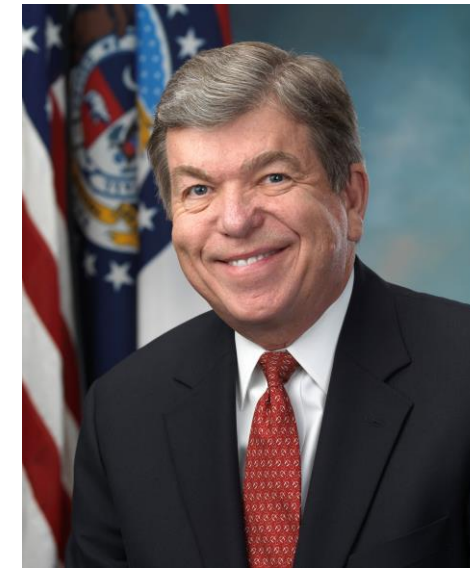
Senator Richard Burr



Senator Patrick Leahy



Senator Richard Shelby



Senator Roy Blunt



Rep. Jackie Speier



Rep. GK Butterfield



Rep. David Price



Rep. Lucille Roybal-Allard



Rep. Kevin Brady



Rep. Adam Kinzinger

Questions?

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