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

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MK Holohan, J.D.

Director, Office of Government and Congressional Relations

National Cancer Institute

Building 31-10A48

mholoha@mail.nih.gov

240-781-3410

Visit the Office of Government and Congressional Relations website at:

https://cancer.gov/about-nci/legislative/

COVID-19 Response Update

In contrast to quick Congressional action earlier this year (passage of four emergency funding bills providing a total of $2.7 trillion within just two months), protracted negotiations for a fifth supplemental bill have yet to produce a deal. Speaker Nancy Pelosi and Treasury Secretary Stephen Mnuchin have engaged in intermittent but intense negotiations over the past few months, but major policy differences and fundamental disagreement about the size of the supplemental package have derailed talks multiple times.

Legislators have largely agreed upon the need for further coronavirus relief, but there are significant policy differences between the leadership of the House and Senate, and Sec. Mnuchin, representing the Administration. Speaker Pelosi has consistently rejected "piecemeal" legislation, in favor of a single, large infusion of funding (Dems' lowest offer was $2.2 trillion, down from $3.2 trillion). The Senate and White House have pushed for a "skinny" bill, with a top-line number of no more $1.5 trillion. The House passed a scaled-back $2.2 trillion version of The Heroes Act (H.R.8406) on Thursday October 1st on a party line vote (original $3.2 trillion bill passed in May). The Senate twice tried to pass smaller aid packages ($300 billion and $500 billion) in September and October, respectively, but were unable to get 60 votes to proceed on either measure. Majority Leader Mitch McConnell adjourned the Senate on October 26th, virtually eliminating any possibility of passing a COVID relief bill before the election. Negotiations are expected to resume in November.

Congressional authorizers are also seeking to provide emergency funding to federal science agencies like NIH. In late June, bipartisan legislation was introduced by House Energy & Commerce Health Subcommittee Chair Diane DeGette (D-CO), along with Eddie Bernice Johnson (D-TX), Fred Upton (R-MI), Frank Lucas (R-OK), Anna Eshoo (D-CA), and Anthony Gonzalez (R-OH). The bill, the Research Investment to Spark the Economy (RISE) Act, would authorize $26 billion in emergency relief for federal science agencies, allow grants extensions to cover time lost due to COVID-19, extend the training of a graduate student or post-doctoral researchers for up to two years, and enable graduate students, post-doctoral researchers, and Principal Investigators to complete work that was disrupted by COVID-19, or extend the training or employment of researchers on an existing research project for up to two years because of the disruption of the job market.

In the early days of the pandemic, Congress provided a total of $2.7 trillion in emergency funding through four coronavirus relief bills (three of which included funding for NIH). Overall, NIH has received $3.587 billion in emergency supplemental funding, as noted below.

			NIH Institute Funding *(dollars in millions)*									
Bill Number	**Bill Title**	**Date Enacted**	**NIAID**	**NIEHS**	**NHLBI**	**NCATS**	**NLM**	**NID OD**	**NBIB**	**NCI**	**NIMH**	**Total NIH**
H.R. 6074	Coronavirus Preparedness and Response Supplemental Appropriations Act	3/6/2020	$ 826	$ 10	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 836
H.R. 748	Coronavirus Aid, Relief, and Economic Security (CARES) Act	3/27/2020	$ 706	$ -	$ 103	$ 36	$ 10	$ 30	$ 60	$ -	$ -	$ 945
H.R. 266	Paycheck Protection Program and Health Care Enhancement Act	4/24/2020	$ -	$ -	$ -	$ -	$ -	$ 1,000	$ 500	$ 306	$ -	$ 1,806
			$ 1,532	**$ 10**	**$ 103**	**$ 36**	**$ 10**	**$ 1,030**	**$ 560**	**$ 306**	**$ -**	**$ 3,587**

In the last of these bills, the Paycheck Protection Program and Health Care Enhancement Act (H.R. 266, enacted April 24, 2020), NCI received $306 million in supplemental funding to "develop, validate, improve, and implement serological testing and associated technologies." The legislation also provides

$1 billion to the NIH Office of the Director and $500 million to NIBIB for coronavirus testing and contact tracing efforts.

NIH also received funding through two coronavirus-related emergency spending bills enacted in March 2020. The Coronavirus Preparedness and Response Supplemental Appropriation Act (H.R. 6074) provided NIAID $826 million to support vaccine, therapeutics and diagnostic research, and provided NIEHS $10 million for worker-based training for reduction of risk of exposure to coronavirus. The Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748) provided NIH with $945 million in funding for coronavirus related activities, distributed across NHLBI, NIAID, NIBIB, NLM, NCATS, and the NIH OD.

FY 2021 Appropriations Update

The House, Senate, and White House reached an agreement on a continuing resolution on Tuesday, September 22nd, and the measure was signed into law in the early hours of October 1, 2020, narrowly avoiding a government shutdown. The bill provides funding at FY2020 levels for federal agencies through December 11th.

The FY 2021 President's Budget was released February 10, 2020. The budget proposal for NCI is $5.9 billion, a 9% decrease from the enacted FY 2020 budget. Included in the $5.9 billion is $195 million for the Cancer Moonshot. The total NIH decrease in the budget proposal is about 7%, and the total HHS decrease is about 9%. Dr. Ned Sharpless accompanied NIH Director Dr. Francis Collins to the House Labor-HHS Appropriations Subcommittee Congressional hearing on the FY 2021 NIH budget request on March 4, 2020. A Senate hearing on the FY 2021 NIH budget request tentatively scheduled for March 26 was postponed indefinitely due to COVID-19.

The House released their Labor, Health and Human Services, Education and Related Agencies (L-HHS) appropriations bill on Monday, July 6, 2020. Unusually, the bill includes emergency funding (which is outside the budget caps) along with regular appropriations. The bill includes $47 billion to NIH, an increase of $5.5 billion: $50 million in regular appropriations and $5 billion in emergency funding. Of the $5 billion, at least $2.5 billion must be transferred to Institutes and Centers proportionately, and all institutes would receive at least a 7% increase over the FY20 enacted levels through a combination of regular and emergency funding. The bill states that the $5 billion in emergency funding "**may** be used for lost productivity due to coronavirus" but does not specify an amount for that purpose. Importantly, the bill does not say the funds need to be used for coronavirus-related work. The bill would require the NIH Director to provide a briefing to House and Senate appropriators at least a week prior to obligating emergency funds. For NCI, the bill includes a total of $6.908 billion for NCI under the bill through a combination of $6.299 billion in regular appropriations, $414 million in emergency funding, and $195 million in Cancer Moonshot funding.

The House passed a six-bill minibus, H.R. 7617, which includes appropriations for the Departments of Labor-Health and Human Services-Education, Defense, Commerce-Science-Justice, Energy and Water, Financial Services, Homeland Security, and Transportation-HUD, on Friday, July 31st, by a vote of 217-197.

The Senate has not released an FY21 spending bill for Labor-HHS. Earlier this year, it was reported that the Senate Appropriations Committee was going to begin marking up spending bills in late June, but a partisan disagreement between Senate Appropriations Chair Richard Shelby (R-AL) and Ranking Member Patrick Leahy (D-VT) regarding a plan to add amendments on coronavirus funding and police reform

measures to the spending bills derailed the process. It is likely that the Senate Appropriations Committee will release its FY21 spending proposals early in November, which will provide an idea of the starting points for negotiations with the House.

Recent Legislative Highlights

Privacy Concerns

Congress has introduced three contrasting bills in recent months in response to privacy concerns surrounding digital COVID-19 contact tracing. On April 30, 2020, GOP Senators Roger Wicker (R-MS), John Thune (R-SD), Jerry Moran (R-KS), and Marsha Blackburn (R-TN) introduced the COVID-19 Consumer Data Protection Act (S. 3663). On May 14, 2020, Democrats in both the House and Senate introduced the Public Health Emergency Privacy Act. The bill is sponsored by Representatives Jan Schakowsky (D-IL), Anna Eshoo (D-CA) and Suzan DelBene (D-WA) in the House and by Senators Richard Blumenthal (D-CT) and Mark Warner (D-VA) in the Senate. A bipartisan group of Senators introduced the Exposure Notification Privacy Act on June 1, 2020. Sponsors are Senators Maria Cantwell (D-WA), Bill Cassidy (R-LA), and Amy Klobuchar (D-MN).

In general, these pieces of legislation aim to secure personal data obtained through COVID-19 contact tracing apps and to ensure that data is used for public health purposes only. The bills aim to safeguard personal data by making it unlawful for covered entities to collect and/or disclose data without express consent of individuals. However, there are major differences in the bills regarding the parties covered, the scope of protection, allowances for commercial use, preemption of state law, and provision of a private right of action.

The COVID-19 Consumer Data Protection Act (S.3663, Senate GOP bill) defines a "covered entity" as any entity that is subject to the Federal Trade Commission Act or is a nonprofit entity that collects, processes, or transfers covered data. The Public Health Emergency Privacy Act (the House bill) applies to organizations that collect, use, or disclose emergency health data, and the bipartisan Senate Exposure Notification Privacy Act applies to non-public health authorities that operate an automated tracing contact apps and exposure notification service. The Senate GOP bill specifically excludes employees of covered entities from being considered "covered individuals."

The bills also differ in what they consider "covered data" – the House bill is the most expansive in its definition, including several more specific demographic indicators than the other bills. Both the House bill and the bipartisan Senate bill prohibit entities from using covered data for purposes such as marketing of goods or dissemination of services. The Senate GOP bill does not allow a private right of action, and unlike the other two bills, includes a preemption clause that would prohibit actions under state laws that could provide more extensive privacy protections.

All three bills require congressional reporting, though the time periods and purposes vary. The Senate GOP bill requires public reporting of the aggregate data collected and its purpose 30 days after passage of the law and every 60 days thereafter. The House bill requires similar reporting 90 days after passage and every 90 days thereafter. The bipartisan Senate bill requires reporting on the impact on privacy and civil liberties of government activities one year after passage of the bill.

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, HHS leaders have indicated that the changes may become permanent. CMS Administrator Seema Verma stated, "I think the genie's out of the bottle on this one. I think it's fair to say that the advent of telehealth has been just completely accelerated, that it's taken this crisis to push us to a new frontier, but there's absolutely no going back."

Congress has introduced a number of bills recently focused on telehealth. The Temporary Reciprocity to Ensure Access to Treatment "Treat" Act (S.4421) was introduced by Sen. Christopher Murphy (D-CT) and co-sponsored by Sen. Roy Blunt (R-MO) on August 4, 2020, and would allow healthcare providers to use telehealth to treat patients in any state during the coronavirus pandemic. The Telehealth Expansion Act of 2020, introduced by Ron Wyden (D-OR), the Telehealth Modernization Act, introduced by Lamar Alexander (R-TN) and the Telehealth Act, introduced by Ann Wagner (R-MO-2) 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. Members of Congress are also exploring legislative approaches to evaluate the implementation of the expansion of telehealth services. Rep. Robin Kelly (D-IL), along with nine House Democrat colleagues, introduced the Evaluating Disparities and Outcomes of Telehealth During the COVID-19 Emergency Act (H.R. 7078) on June 1, 2020, which aims to study the effects of these recent changes to telehealth under the Medicare and Medicaid programs during the COVID-19 emergency.

Other Legislation of Interest

The following bills and resolutions were selected for inclusion in this update due to anticipated interest among the Clinical Trials and Translational Research Advisory Committee. Status and/or co-sponsorship updates are provided in bold font.

Selected Bills – 116th Congress

CLINICAL TREATMENT Act (S.4742/H.R. 913)

- The legislation was introduced by Sens. Richard Burr (R-NC) and Ben Cardin (D-MD) on 9/29/2020. Reps. Ben Ray Lujan (D-NM) and Gus Bilirakis (R-FL) introduced this bill in the House on 1/30/2019 and the bill has 57 co-sponsors.
- The full title of the bill is: "Covering Life-saving Investigations Needed In Cancer And other Life-threatening conditions through Timely use of Resources for Easy and Affordable Treatment from Medicaid for Enrollees in Need Today Act" (CLINICAL TREATMENT Act)
- The bill would amend title XIX of the Social Security Act to require Medicaid coverage of routine patient costs for items and services furnished in connection with participation in qualifying clinical trials, including all NIH-funded clinical trials. The bill aims to ensure that Medicaid (as Medicare is already required to) covers routine care costs for trail participants such as regular physician's visits, hospital stays, imaging and laboratory tests.

The Temporary Reciprocity to Ensure Access to Treatment (TREAT) Act (S.4421)

- The legislation was introduced by Sens. Chris Murphy (D-CT) and Roy Blunt (R-MO) on 8/4/20. There are currently 2 cosponsors.
- 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.

Research Investment to Spark the Economy (RISE) Act (H.R.7308)

- The legislation was introduced by Rep. Diana DeGette (D-CO-1) on 6/24/20 and currently has 123 sponsors.
- The bill would authorize $26 billion in emergency relief for federal science agencies, allow grants extensions to cover time lost due to COVID-19, extend the training of a graduate student or post-doctoral researchers for up to two years, and enable graduate students, post-doctoral researchers, and Principal Investigators to complete work that was disrupted by COVID-19, or extend the training or employment of researchers on an existing research project for up to two years because of the disruption of the job market.

SECURE CAMPUS Act of 2020 (H.R.7033)

- The legislation was introduced by Rep. David Kustoff (R-TN-8) on 5/27/20 and currently has 3 sponsors.
- The legislation would give the Secretary of State the authority to deny visas to Chinese citizens if they seek to enter the U.S. to participate in graduate or post-graduate coursework or academic research in scientific fields, and would ban Chinese citizens from receiving federal grants in science, technology, engineering, or mathematics.
- The legislation would require Federal agencies to ensure that entities receiving federal assistance do not employ any individual who is a participant in a foreign talent recruitment program of the People's Republic of China.

COVID-19 Consumer Data Protection Act (S. 3663)

- The legislation was introduced by Sen. Roger Wicker (R-MS) on 5/7/20 and currently has 4 cosponsors.
- The bill would prohibit covered entities (businesses, common carriers, and certain non-profit organizations) from collecting, processing or transferring an individual's personally identifiable information (PII) for contact tracing related to COVID-19 without obtaining prior consent from the individual.

Gabriella Miller Kids First Research Act 2.0 (H.R. 6556)

- The legislation was introduced by Rep. Jennifer Weston (D-VA) on 4/17/20 and currently has 6 cosponsors.
- The bill would require certain civil penalties to be transferred to a fund at NIH for the Gabriella Miller Kids First Pediatric Research Program.

Reversing the Youth Tobacco Epidemic Act of 2019 (H.R. 2339, S.3174)

- The legislation was introduced by Rep. Frank Pallone (D-NJ) on 4/18/19.
- The legislation proposes to raise the minimum age of tobacco sales to 21, prohibit the flavoring of tobacco products (including e-cigarettes), prohibit the marketing of tobacco products to individuals under 21, and establish tax parity across tobacco products.
- Language raising the federal minimum age to purchase all tobacco products from 18 to 21 was included in the Further Consolidated Appropriations Act of 2020, which was signed into law on 12/20/19.
- The Energy and Commerce Committee passed H.R. 2339 out of Committee on 11/19/19; **H.R. 2339 passed the House on 2/28/20.**

Endometrial Cancer Research and Education Act of 2020 (H.R. 5794)

- The legislation was introduced by Rep. David Scott (D-GA) on 2/6/20 and currently has 30 cosponsors.
- The bill authorizes funding for NIH to support endometrial cancer research.

Global Hope Act of 2019 (H.R. 5338)

- The legislation was introduced by Rep. Michael McCaul (R-TX) on 12/6/19. It passed the House by voice vote on 1/28/20. There has been no further action in the Senate.
- The bill would authorize and encourage the State Department and other relevant Federal agencies to pursue public-private partnerships, innovative financing mechanisms, research partnerships, and coordination with international organizations to address global childhood cancer.

Medical Innovation Act of 2020 (S. 3163)

- The legislation was introduced by Sen. Elizabeth Warren (D-MA) on 1/8/20.
- The bill was referred to the Committee on Health, Education, Labor, and Pensions. It currently has 4 cosponsors.
- The bill would authorize the HHS Secretary to collect supplemental payments to increase congressional investments in medical research. Amounts would be distributed to FDA and NIH for research that fosters radical innovation, research related to diseases that disproportionally account

for Federal health care spending, research that advances fundamental knowledge and technology, and early career scientists.

National Biomedical Research Act (H.R. 5400, S. 3161)

- The legislation was introduced in the House by Rep. Yvette Clark (D-NY) on 12/11/19 and in the Senate by Sen. Elizabeth Warren (D-MA) on 1/8/20. It currently has 1 cosponsor in the House and 12 cosponsors in the Senate.
- The bills would establish a Biomedical Innovation Fund in the Treasury Department whose funds would be transferred to the NIH & FDA. $10M would be transferred to the agencies each year and would be used to support basic research as well as research that fosters disruptive innovations.

Elijah E. Cummings Lower Drug Costs Now Act (H.R.3)

- The bill was introduced by Rep. Frank Pallone (D-NJ), Chair of the House Committee on Energy and Commerce, on 9/19/19 and passed the House on 12/12/19.
- The legislation would cap what Medicare beneficiaries pay out of pocket for medicine and allow Medicare to negotiate drug prices.
- The Prescription Drug Pricing Reduction Act of 2019 (S. 2543) was introduced in the Senate by Sens. Chuck Grassley (R-IA) and Ron Wyden (D-OR) and passed out of the Senate Finance Committee on 9/25/19. This legislation would also cap what Medicare beneficiaries pay out of pocket, but does not allow Medicare to negotiate drug prices.
- The Administration issued a Statement of Administration Policy on H.R. 3 on 12/10/19 noting their intent to veto and a strong preference instead for S. 2543.

Henrietta Lacks Enhancing Cancer Research Act of 2019 (H.R. 1966, S. 946)

- The bills were introduced on 3/28/19 by Rep. Elijah Cummings (D-MD-7) in the House and Sen. Chris Van Hollen (D-MD) in the Senate. After the death of Rep. Cummings, Rep. Kweisi Mfume, who now serves the 7th District of Maryland, became the leas sponsor of the House version of the bill.
- **The House bill currently has 62 cosponsors and the Senate bill currently has 7 cosponsors**.
- The legislation instructs the Government Accountability Office (GAO) to complete a study that reviews actions taken by federal agencies to help to address barriers to participation in federally funded cancer clinical trials by populations that have been traditionally underrepresented in such trials. The legislation also instructs the GAO to identify additional actions that can be taken by federal agencies to address these barriers and to submit a report to Congress on the results of the study, including the GAO recommendations.
- The legislation notes that the study should include review of cancer clinical trials that are largely funded by Federal agencies, including the NIH.