21st CENTURY CURES 2.0

Discussion Draft Section-by-Section

TITLE I: PUBLIC HEALTH

Sec. 101. Further Understanding the Implications of Long COVID:

- **Sources of Coverage Survey:** directs the Secretary of Health and Human Services (HHS) to conduct a large national survey of patients who self-identify as having long-COVID to assess sources of health coverage, long-term care coverage, and disability coverage.
- **Learning Collaborative:** directs the Secretary of HHS to convene a series of national meetings (virtually) to serve as the basis of an ongoing long-COVID learning collaborative with individuals and organizations representing key sectors of the health care community. This should include health plans, providers (including hospitals, physicians, nurses, etc.), medical and scientific researchers, patient and consumer advocates, data scientists, service providers, and developers of diagnostics and therapeutics).

Sec. 102. National Testing and Response Strategy for Future Pandemics: requires a national strategy, based off lessons learned, and best practices developed, as a result of the COVID-19 pandemic, that addresses testing, data sharing infrastructure, administration of vaccines and therapeutics, and medical supply readiness to mitigate future pandemics and public health emergencies.

Sec. 103. Pandemic Preparedness Rare Disease Support Program:

- requires the Secretary of HHS to develop a plan to help rare disease patients overcome challenges in public health emergencies; and
- establishes a federal grant program for organizations implement the plan.

Sec. 104. Vaccine and Immunization Programs: improves the education of all Americans on the importance of vaccines and strengthens and supports the capacity of the Immunization Information System (IIS) within the Centers for Disease Control and Prevention.

Sec. 105. Developing Antimicrobial Innovations: collaborating with Sens. Bennet (D-CO) and Young (R-IN) and Reps. Doyle (D-PA) and Ferguson (R-GA) to include the Pioneering Antimicrobial Subscriptions to End Up surging Resistance (PASTEUR) Act. This policy would establish a subscription model to pay for critically-needed novel antimicrobial drugs. HHS would provide companies with a federal payment, that is delinked from the sales or use of those newly-developed antibiotics, to ensure a predictable return on investment and improve appropriate use of the drug. The policy contains investment in programs to address antimicrobial resistance, which is critical for patient care and public health.

TITLE II: PATIENTS AND CAREGIVERS

Sec. 201. Educational programs and training for caregivers: funds educational programs and training for caregivers to learn skills which would allow them to augment a care team and complement, not compete with, a clinical visit.

Sec. 202. Increasing Health Literacy to Promote Better Outcomes for Patients: requires the Centers for Medicaid and Medicare Services (CMS) to solicit input on how the agency can work with federally subsidized health care program stakeholders to encourage and promote greater health literacy.

Sec. 203. Increasing Diversity in Clinical Trials:

- requires an update from FDA on efforts to improve diversity in clinical trials;
- requires a GAO study on barriers to clinical trial participation;
- requires the Department of HHS to conduct a public awareness campaign to increase awareness and understanding, particularly in minority communities, of clinical trials;
- and establishes a task force on making clinicaltrials.gov more user- and patient-friendly.

Sec. 204. Patient Experience Data:

- requires drug manufacturers/sponsors to collect and report on patient experience data as part of the clinical trial;
- requires FDA to fully consider all patient experience data collected during the clinical trial; and
- requires reporting of patient experience data in a transparent manner that is uniform, meaningful and informative to patients and providers

Sec. 205. Ensuring Coverage for Clinical Trials Under Existing Standard of Care: allows Medicare to cover the costs of their beneficiaries in PCORI-funded clinical trials.

TITLE III: FOOD AND DRUG ADMINISTRATION

Sec. 301. Report on Collaboration and Alignment in Regulating Digital Health Technologies: requires the HHS Secretary to submit a report to Congress on the efforts to ensure collaboration and alignment across the centers and offices of the Food and Drug Administration with respect to the regulation of digital health technologies

Sec. 302. Grants for Novel Trial Designs and Other Innovations in Drug Development: provides grants in the area of innovative clinical trial design and patient experience data to further build the science in these areas.

Sec. 303. FDA Cell and Gene Therapy: requires the HHS Secretary to submit a report to Congress re: the current state of cell and gene therapy regulation and foreseeable regulatory challenges for the FDA in the future.

Sec. 304. Increasing Use of Real-World Evidence: builds on FDA's efforts by

- requiring HHS to outline approaches to maximize and expand the use of RWE; and
- establishing a task force to develop recommendations on ways to encourage patients to engage in real-world data generation.

Sec. 305. Improving FDA-CMS Communication Regarding Transformative New Therapies: establish an automatic communication requirement between FDA and CMS for Breakthrough Therapy drugs.

Sec. 306. Establishment of Additional Intercenter Institutues at the Food and Drug Administration: directs the Secretary of HHS to establish two additional FDA Centers of Excellence.

Sec. 307. IND Application Not Needed to Initiate Accelerated Approval: remedies unforeseen impediments to sponsors which will allow them to get designations for investigational drugs if they meet proper criteria**.**

Sec. 308. Guidance Regarding Development and Submission of Chemistry, Manufacturing, and Controls Information for Expedited Approval: Requires FDA to publish guidance on the standards and factors it will employ regarding CMC data development and review for expedited programs, and specifically breakthrough and RMAT.

Sec. 309. Post-Approval Study Requirements for Accelerated Approval: Allows for use of other evidence, such as clinical evidence, patient registries, or other real-world evidence, to fulfill post-approval study requirements to confirm the predicted clinical benefit of a therapy.

TITLE IV: CENTERS FOR MEDICARE & MEDICAID SERVICES

Sec. 401. GAO Study and Report: requires a GAO report on recommendations to enhance Medicare coverage and reimbursement for innovative health technologies

Sec. 402. Strategies to Increase Access to Telehealth under Medicaid and Children's Health Insurance Program: collaborating with Reps. Blunt Rochester (D-DE) and Burgess (R-TX) to include the Telehealth Improvement for Kids' Essential Services (TIKES) Act. This policy would provide guidance and strategies to states on effectively integrating telehealth into their Medicaid program and Children's Health Insurance Program (CHIP), review the impact of telehealth on patient health and encourage better collaboration.

Sec. 403. Extending Medicare Telehealth Flexibilities: working with Reps Carter (R-GA) and Blunt Rochester (D-DE) to include the Telehealth Modernization Act. This policy would permanently remove Medicare's geographic and originating site restrictions which require a patient to live in a rural area and be physically in a doctor's office or clinic to use telehealth services. It would also allow the Secretary of HHS to permanently expand the types of health care providers that can offer telehealth services and the types of services that can be reimbursed under Medicare.

Sec. 404. Coverage and Payment for Breakthrough Devices Under the Medicare Program: working with Rep. DelBene to include the Ensuring Patient Access to Critical Breakthrough Products Act. This policy would codify the current Medicare Coverage of Innovative Technology pathway at CMS.

Sec. 405. Secretary of Health and Human Services Report on Coverage for Innovative Technologies: requires the Secretary of HHS to submit a report on the viability of establishing alternative coverage pathways for innovative technologies.

Sec. 406. Secretary of HHS Report on CMS Computer Systems: requires the Secretary of HHS to submit a report on the current capabilities and deficiencies of CMS's computer systems.

Sec. 407. Expanding Access to Genetic Testing: working with Reps. Swalwell (D-CA) and Peters (D-CA) to include policy provisions to increase access to genetic diagnostics. This policy would provide federal support for the use of genetic and genomic testing for pediatric patients with rare diseases.

Sec. 408. Medicare Coverage for Precision Medicine Consultations: Requires the Secretary of HHS to create a pilot grant program within the Center for Medicaid and Medicare Innovation to test approaches to delivering personalized-medicine consultations

Sec. 409. Prohibiting the Use of Geographic Tracking Features and Biometrics within Medicare Electronic Visit Verification Systems: Prohibits the use of geographic tracking features and biometrics within EVV systems.

TITLE V: RESEARCH

Sec. 501. Advanced Research Projects Agency for Health: authorizes the creation of ARPA-H.

- The mission of ARPA-H is to speed transformational innovation in health research and speed application and implementation of health breakthroughs by funding projects that could:
    - Tackle bold challenges requiring large scale, sustained coordination;
    - Create new capabilities (e.g., technologies, data resources, disease models);
    - Support high-risk exploration that could establish entirely new paradigms; and/or
    - Overcome market failures through critical solutions, including financial incentives.
    - Complement NIH's existing research portfolio and mission and the private sector's research initiatives.

Sec. 502. Research Investment to Spark the Economy: Provides $25 billion to independent research institutions, public laboratories and universities throughout the country to continue their work on thousands of federally-backed projects.