Topic	PREVENT Pandemics Act (HELP)	CURES 2.0 (H.R. 6000)
Review of the COVID-19 response and implementation of response strategy for future pandemics	**Sec. 101** – Establishes a Task Force with membership appointed by bipartisan Congressional and Committee leadership to examine the initial emergence of SARS-CoV-2 and to examine and assess the United States' preparedness for and response to the COVID-19 pandemic to identify gaps and make recommendations to the President and Congress. **Sec. 103** – Provides additional authority for the Secretary of HHS to coordinate with, and request support from, other departments and agencies in leading the Federal public health and medical response to a public health emergency and includes a GAO study on the use of existing authorities for related interagency agreements. Requires national- and state-level full-scale exercises every five years to identify and address gaps in preparedness and response, including the ability of SNS to appropriately support the response to a large-scale, long-term public health emergency. **Sec. 114** – Requires a GAO report on state and territorial preparedness and response plans to mitigate the spread of COVID-19 and technical assistance provided by the federal government to support such mitigation efforts over the course of the pandemic. **Sec. 211** – Updating the strategy and implementation plan to improve collaboration among Federal departments, implement lessons learned from previous public health emergencies.	**Sec. 102** – Requires a national strategy, based off lessons learned, and best practices developed, as a result of the COVID-19 pandemic to mitigate future pandemics and public health emergencies.
Strengthening public health communication and health literacy	**Sec. 104** – Requires the Secretary of HHS to establish a Public Health Information and Communication Advisory Committee to provide recommendations to the	**Sec. 202** – Requires CMS to solicit input on how the agency can work with federally subsidized

	Secretary on communication and dissemination of scientific and evidence-based public health information during public health emergencies. **Sec. 201** – Authorizes a grant program to support evidence-based or evidence-informed projects to reduce health disparities and improve health outcomes by increasing capacity to address social determinants of health within communities, such as through disseminating strategies to address social determinant of health, ways to use technology to improve coordination with social services, and implementing best practices for improving health outcomes. Authorizes grants to identify or facilitate the development of best practices to support improved health outcomes by addressing social determinants of health; provide technical assistance, training, and evaluation assistance to health departments; or establish or operate regional centers to develop, evaluate, and disseminate effective strategies to address social determinants of health. **Sec. 222** – Directs funds to be used to recruit, hire, and train community health workers; support community health workers in providing education and outreach in their communities; address social determinants of health and eliminate health disparities; and to educate community members. **Sec. 231** – Reauthorizes a network of Centers for Public Health Preparedness and Response to: (1) translate research findings or strategies into evidence-based practices to inform preparedness and response to public health emergencies; and (2) improve awareness	health care program stakeholders to encourage and promote greater health literacy.

	of these practices and other relevant scientific or public health information among health care and public health professionals and the public	
National Academies of Sciences study	**Sec. 202** – Requires a National Academies of Sciences, Engineering, and Medicine study on the effects of health disparities on health outcomes, including related to public health emergencies.	**Sec. 101** – Directs the National Academy of Medicine to conduct a study to evaluate disparities in long-COVID.
Centers of Excellence	**Sec. 212** – Requires the Secretary to establish Centers of Excellence to support innovation in pathogen genomics and molecular epidemiology.	**Sec. 306** – Directs the Secretary of HHS to establish two additional FDA Centers of Excellence.
Genomic sequencing	**Sec. 212** – Directs the CDC Director, in consultation with the Director of the NIH and heads of other departments and agencies, to strengthen and expand activities related to advanced molecular detection and genomic sequencing of pathogens, including the use of genomic sequencing technologies to inform surveillance activities, enhancing the sequencing and analytics capabilities of the public health workforce, and continuing partnerships with public and private entities for these activities.	**Sec. 407** – Increase access to diagnostic testing by providing federal support for the use of genetic and genomic testing for pediatric patients with rare diseases.
Supporting public health data availability and access	**Sec. 213** – Directs the Secretary to improve the access, exchange, and use of public health data by updating existing, and entering into new, memoranda of understanding or data use agreements with relevant federal agencies and other public and private entities. Allows the Secretary to work with public health departments to improve the availability of public health data, and information sharing between health. Authorizes a program to develop best practices to improve the quality and completeness of the collection of demographic data to support public health responses.	**Sec. 411** – Provides clinician-led clinical data registries with access to Medicare claims data for purposes of research to improve quality and cost efficiency by linking the data with clinical data in registries.
Vaccine programs	**Sec. 232** – Clarifies that existing authorities of the Secretary to track the initial distribution of federally	**Sec. 104** – Vaccine and Immunization Programs:

	purchased vaccines to inform decision-makers during an influenza pandemic also apply to other pandemics.	- Improves the education of all Americans on the importance of vaccines - Strengthens and supports the capacity of the Immunization Information System (IIS) within the Centers for Disease Control and Prevention.
Research and activities related to long-term health effects of COVID-19 infection	**Sec. 301** – Directs HHS to continue conducting or supporting basic, clinical, epidemiological, behavioral, and translational research on the long-term health effects of SARS-CoV-2 infection. Requires HHS to develop and inform recommendations, guidance, and provide educational materials for health care providers and the general public on the long-term effects of SARS-CoV-2 infection based on this research.	**Sec. 101** – Directs the Secretary of 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. Directs the Secretary of HHS to develop and disseminate: - Culturally-competent information to the public regarding long COVID - Up-to-date information regarding long COVID to health care providers to ensure providers remain informed on how to best provide care to patients.
Research program investment	**Sec. 302** – Requires the NIAID, in collaboration with ASPR and BARDA, to establish or continue a multidisciplinary research program with research centers to advance the discovery and preclinical development of medical products for priority virus families and other viral pathogens with the significant potential to cause a pandemic.	**Sec. 502** – Provides $25 billion to independent research institutions, public laboratories and universities throughout the country to continue their work on thousands of federally-backed projects.
Improving medical countermeasure research coordination	**Sec. 303** – Requires the NIH Director to consult with ASPR, BARDA, CDC, and the heads of other Federal agencies and offices regarding research needs to advance medical countermeasures for any agent or toxin that may cause a public health emergency, or other research needs related to emerging public health threats.	**Sec. 305** – Establishes an automatic communication requirement between FDA and CMS for Breakthrough Therapy drugs.
Accelerating product innovation	**Sec. 501** – Expands eligibility for the Qualified Infectious Disease Product (QIDP) designation to include biological	**Sec. 307** – Remedies unforeseen impediments to sponsors which will allow them to get designations

	products. Updates priority review eligibility for products that receive a QIDP designation to provide that the first application that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness receives priority review. **Sec. 503** – Codifies FDA's successful Coronavirus Treatment Acceleration Program to ensure expedited action for the development and review of countermeasures during future public health emergencies.	for investigational drugs if they meet proper criteria. **Sec. 309** – 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.
Modernizing clinical trials	**Sec. 502** – Requires FDA to issue three guidances to modernize and improve clinical trials, including on the use of: - Digital health technologies in clinical trials to help improve recruitment, participation, and data collection. - Decentralized clinical trials to improve trial participant engagement and advance the use of flexible and novel clinical trial designs. - Seamless, concurrent, and other innovative clinical trial designs to support the expedited development and review of drugs and biological products.	**Sec. 302** – Provides grants in the area of innovative clinical trial design and patient experience data to further build the science in these areas. **Sec. 310** – Directs the Secretary of HHS to convene a multistakeholder meeting to explore innovative ways and incentives to foster the adoption of decentralized trials.
Facilitating the use of real world evidence	**Sec. 505** – Requires FDA to issue or revise guidance on the use of real-world data and real-world evidence to support regulatory decision-making, including with respect to real-world data and real-world evidence from products authorized for emergency use.	**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 - Requires reporting of patient experience data in a transparent manner that is

		uniform, meaningful and informative to patients and providers **Sec. 304** – Builds on FDA's efforts by: - Requiring HHS to outline approaches to maximize and expand the use of real-world evidence - Establishing a task force to develop recommendations on ways to encourage patients to engage in real-world data generation **Sec. 309** – 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.
Improving FDA guidance and communication	**Sec. 508** – Requires publication of a report identifying best practices across the FDA and other applicable agencies for the development, issuance, and use of guidance documents and for communications with product sponsors and other stakeholders, and a plan for implementing such best practices.	**Sec. 308** – Requires FDA to publish guidance on the standards and factors it will employ regarding Chemistry, Manufacturing, and Controls (CMC) data development and review for expedited programs, and specifically breakthrough and regenerative medicine advanced therapy (RMAT) designation.