University of Colorado
Anschutz Medical Campus

August 1, 2024

The Honorable Diana DeGette
United States House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon, MD
United States House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Bucshon,

On behalf of the University of Colorado Anschutz Medical Campus (CU Anschutz), we appreciate the opportunity to respond to your request for information regarding the future Next Generation Cures Bill.

CU Anschutz is a world-class medical destination at the forefront of transformative science, medicine, education and patient care. The campus encompasses the University of Colorado health professional schools, more than 60 centers and institutes, and two nationally ranked independent hospitals – UCHealth University of Colorado Hospital and Children's Hospital Colorado – which see more than 2 million adult and pediatric patient visits yearly. Innovative, interconnected, and highly collaborative, the University of Colorado Anschutz Medical Campus delivers life-changing treatments, patient care and professional training and conducts world-renowned research fueled by $700 million in research grants.

Over the past eight years, programs authorized by the 21st Century Cures Act (Cures, P.L. 114-255) have spurned biomedical research innovation and have advanced health outcomes for all Americans. CU Anschutz is especially proud that our faculty is engaged in many initiatives from the law, including the Cancer Moonshot, the BRAIN Initiative, and the Regenerative Medicine Innovation Project. Our clinicians and researchers have also been the beneficiaries of important Cures priorities such as electronic health record interoperability, streamlining of FDA regulation of regenerative medicines, and the inclusion of socio-economic status in CMS penalties for patient readmission.

Additionally, since the passage of Cures, Congress has taken additional action to address the need to advance our nation's biomedical research, such as passing the RECOVER Initiative and the Advanced Research Projects Agency for Health (ARPA-H). CU Anschutz, with its ongoing involvement in these initiatives, continues to be a key player in advancing our nation's biomedical research. Furthermore, Congress continues to increase investment in crucial biomedical research agencies such as the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Administration for Strategic Preparedness and Response (ASPR), have helped spurn advances in

biomedical science. These initiatives were crucial in addressing some of the gaps in our healthcare delivery and research into novel diseases and issues.

With COVID-19 pulling back the curtain on the gaps in our biomedical and healthcare infrastructure, we applaud your efforts to introduce the Next Generation Cures Act. This effort would enable our country to continue to be at the forefront of care delivery and developing cures. CU Anschutz remains committed to developing treatments for Coloradans and patients nationally. We look forward to commenting on ways federal partnerships can build on our past successes.

Investing in improved clinical trials

Clinical trials are imperative in developing new ways to prevent, detect, or treat disease for patients across the country. In Colorado, CU Anschutz is currently conducting over 3,000 clinical trials, reaching patients across the Centennial state. As physicians and researchers conducting clinical trials start to utilize new and emerging technologies and continue efforts to ensure that trials represent all populations, federal policies must exist to allow these trials to deliver cures to all Americans.

Allowing for robust recruitment of clinical trial participants
To ensure that future treatments, detection efforts, and prevention initiatives meet the needs of all Americans, researchers and clinicians performing clinical trials need to recruit patients from all backgrounds. This includes patients from rural, urban, and suburban communities, children, adolescents, middle-aged and senior age brackets, and patients from different racial and ethnic backgrounds. Patients from different backgrounds can respond differently to treatments, so having a diverse range of backgrounds in a trial is necessary.

CU Anschutz supports efforts at NIH to ensure that federally funded trials are representative of all patient populations and is committed to helping their efforts. However, there is a need to recruit more patients from all backgrounds, which can be challenging – especially for patients from rural and underrepresented backgrounds who may be reluctant to participate in a clinical trial. We encourage Congress to establish and enhance current programs that are aimed at building trust between health care and patients' communities by establishing programs that promote collaboration between academic medical centers and organizations that have long-standing connections to local communities.

Reducing financial and administrative barriers to clinical trials
Currently, there are financial barriers to enrolling patients in clinical trials, especially those who may be uninsured or underinsured. Researchers and clinicians conducting trials at CU Anschutz find challenges in getting coverage for patients covered by the Centers for Medicare and Medicaid Services (CMS). We encourage Congress to enact policies that allow CMS to streamline coverage of all incurred expenses for patients enrolling in clinical trials and install a process that will enable them to approve new therapies in trials for reimbursement swiftly. The

current administrative backlog and burden have reduced the speed at which trials can get to underserved patient populations.

Additionally, there needs to be increased coordination between CMS and the FDA in allowing trials to proceed, especially when enrolling patients who have third-party insurance providers. Under the current system, researchers and research sites spend a large amount of administrative effort to coordinate research-related medical procedures with both CMS and private, adding to administrative costs and delaying medical advances. Establishing clear processes and guidance on requests to bill third-party payers for investigational devices that are administered to patients under compassionate use regulations with FDA permission for use.

Utilizing new and emerging technologies

Over the past eight years, CU Anschutz has seen increased utilization of new and emerging technologies such as telehealth, artificial intelligence, and advances in electronic health records. These technologies will continue to change the way medical research and healthcare delivery is conducted. The Next Generation Cures legislation is an opportunity way to create continuity investments and provide guidance on the use of these technologies, leading to increased health outcomes for patients across the country.

Investing in Telehealth Services
Since the COVID-19 pandemic, we have seen exponential growth in telehealth usage from our providers at CU Anschutz. Much of the increased usage has been from patients in rural or other unserved communities, especially those seeking mental health treatments. Over the past four-plus years, we have seen telehealth as one of the best ways for CU Anschutz—as the only academic medical center in Colorado—to reach our patients across the entire Centennial state.

The telehealth waivers for Medicare and Medicaid services that were established during the COVID-19 public health emergency and extended by Congress were the catalyst in our increased use of telehealth by providers affiliated with CU Anschutz. With the waivers set to expire at the end of 2024, CU Anschutz supports the Telehealth Modernization Act (S. 3967) and urges Congress to make these services permanent, which will enable our providers to set up comprehensive telehealth practices.

Additionally, telehealth has proven to be a useful tool for conducting research and clinical trials for patients in rural locations. For research participants in rural and remote locations, telehealth serves as a useful way to connect them with lead scientists at academic centers without forcing long-distance travel for participants. We encourage Congress to allow the use of telehealth for patients in clinical trials, allowing our faculty and researchers to enroll patients from all locations.

Establishing standards for artificial intelligence (AI) in healthcare
The CU Center for Health AI within the CU School of Medicine at the Anschutz Medical Campus is at the forefront of utilizing AI to increase research outcomes and better deliver care utilizing this new technology. AI is being used to develop personalized medical treatments for patients, creating consistency in research and data entry and utilizing our faculty's ability to answer patients in a timely manner. With AI being known as a new frontier of technology, Congress has the opportunity to create standards and regulations to make sure it is being utilized to improve patient and research outcomes.

As Congress looks to legislate on this new technology, we urge you to include broad-based investments in foundation AI models for biology and health care and ensure all Americans, including children, rural, and other represented patients, are built into all models.

Strengthening ARPA-H and Long COVID programs

Over the past few years, we have appreciated Congress' efforts to create ARPA-H and invest in Long-Term COVID-19 programs. Strengthening our investments in these programs is crucial in ensuring that all Americans have access to highly skilled, advanced biomedical research and ways to combat the long-term impacts of the COVID-19 virus.

Maintaining ARPA-H's mission
First passed in the Consolidated Appropriations Act, 2021 (P.L. 117-103), ARPA-H is tasked with performing accelerated biomedical research. Since its establishment, ARPA-H has made strides to start performing crucial studies and has been swiftly awarding grants.

In fact, in March 2024, CU Anschutz, in partnership with CU Boulder and Colorado State University, received an ARPA-H award aiming to find a cure for osteoarthritis in five years. This joint disease impacts over 32.5 million people. CU Anschutz is also part of a larger nationwide grant to investigate oral delivery of electroceuticals and mRNA therapies, with the hopes of treating metabolic disorders such as obesity and diabetes.

Over the past few years, ARPA-H has lived up to its intentions by establishing grant programs to conduct accelerated research to address many pressing needs of Americans. As intended in its authorization, awards provided by ARPA-H operate outside of the current NIH procedures, which is allowed due to its independence as an institute. We urge Congress to maintain ARPA-H's independence as an institute or independent agency within HHS to allow for accelerated research.

Reinforcing Long-COVID Programs
With COVID-19 being a novel condition, we must study the long-term impacts it may have on people who have been infected – especially for those with pre-existing medical conditions and other respiratory conditions. The Colorado Clinical and Translational Sciences Institute (CCTSI) at CU Anschutz serves as a RECOVER site investigating Long-COVID and performing clinical

trials of novel therapeutics for patients across Colorado. Additionally, the CCTSI has taken a leadership role in the Agency for Healthcare Research and Quality (AHRQ) Long-COVID Care Network, addressing the statewide response to Post-COVID Care Delivery within the state.

Since their founding, Long-COVID initiatives within HHS have made strides in studying its impacts on patients; however, coordination of all efforts within the agency must be improved to reduce redundancy and increase the impact of the programs. This includes coordinating efforts between the RECOVER initiatives, programs conducting research into Long-COVID at NIH, and other efforts from AHRQ, CDC, and additional agencies aimed at training providers to treat patients impacted by Long-COVID and improve health outcomes for patients across the country.

As you consider ways to better streamline our nation's Long-COVID strategy, we urge you to look at states such as Colorado, which has been successful in advancing its initiatives throughout our state. Led by Lieutenant Governor Primavera, Colorado has successfully created initiatives to increase access and coverage for Long-COVID patients within the state, as well as making sure pediatric and adult providers – including those in rural areas---– are best equipped to help treat patients from all backgrounds.

Additionally, many initiatives in tracking Long-COVID, such as the National Clinical Cohort Collaborative (N3C), can be applicable to other diseases and health tracking needed for patients across the country. We urge Congress to use the technologies established through the Office of Long-COVID to improve health outcomes for patients suffering from a variety of complex chronic diseases and disorders.

Sustaining crucial medical research programs

Increased support for basic science medical research programs has been crucial to delivering up-to-date treatments and cures for patients in the country. For example, the mRNA technology used to develop the COVID-19 vaccine rapidly was due to decades of basic science medical research. To ensure that our nation is protected against all biomedical threats, increased investment in NIH and other biomedical research agencies conducting scientific research is crucial to the defense of our country.

Cures built on the need to invest in our biomedical research by establishing research programs such as the Cancer Moonshot, BRAIN Initiative, and Regenerative Medicine Innovation Project (RMIP)– all of which have allowed for new cures and treatments to be established by CU Anschutz faculty. As part of the Cancer Moonshot and RIMP initiatives, CU Anschutz faculty were able to produce CAR-T immunotherapy treatment for children with acute lymphocytic leukemia (ALL) and acute myeloid leukemia (AML) that is less susceptible to drug resistance – thus reducing the number of children who suffer a life-threatening re-occurrence of cancer after their treatment.

Programs like the ones stated in the 21st Century Cures Innovation Fund had their funding sunset in the Further Consolidated Appropriations Act, 2024 (P.L. 118-47), providing a setback for the success of these initiatives over the past few years. We urge Congress to provide permanent funding streams for these initiatives and to make sure any new programs and initiatives established in the Next Generation Cures legislation do not have sunsetting provisions, ensuring that important biomedical research programs can continue in the decades to come.

We also encourage Congress to extend the authorization for the Research Policy Board, which is intended to advise the federal government on the effects of federal regulations and reporting requirements and recommend ways to modify, streamline, and harmonize research across agencies.

Developing our biomedical research workforce

To safeguard our nation's biomedical research infrastructure, we must continue to invest in our biomedical research pathway. With the number of health scientists declining and the average age of NIH grantees increasing, developing the next generation of research scientists is a necessary investment to ensure our nation is at the forefront of biomedical discoveries.

Institutionally, CU Anschutz has partnered with the NIH and other partners to invest in training future biomedical research workforce. For example, through a grant from the National Center for Advancing Translational Sciences, CCTSI at CU Anschutz has established the Clinical Research Workforce Development Program, which fosters opportunities for collaboration, communication, and connection with the clinical research community, expands the diversity of the profession and provides clarity of the promotion and career path of research service professionals. Additionally, the Ludeman Family Center for Women's Health Research provides mentorship programs to support the next generation of scientists whose cutting-edge research focuses on issues that pose a significant threat to women's health.

Programs like the Clinical Research Workforce Development Program are important partnerships in developing our biomedical research workforce. However, the federal government can do more to assist in training future health scientists. We urge Congress to allow modular budgets on any grants, which will allow for increased compensation for young researchers and retain talent already working on grants. Additionally, we encourage Congress and the NIH to continue initiatives that support postdoctoral researchers, ensuring they remain in the biomedical research workforce pipeline.

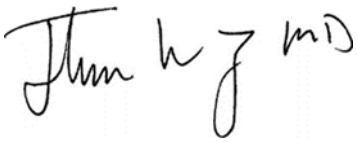
Finally, biomedical workforce programs should focus on training future researchers who are able to support patients from historically underrepresented backgrounds, such as women, children, rural, and underrepresented minority patients. For example, the CU-supported Pediatricians Accelerate Childhood Therapies (PACT) Act (H.R. 4714, S. 2345) would establish training awards for early-career researchers focusing their careers on pediatrics. CU Anschutz encourages Congress to establish workforce programs, such as what would be developed in the PACT Act,

for researchers who will be focused on all of these historically underrepresented groups in biomedical research.

As you continue your efforts for the Next Generation Cures legislation, please utilize our campus experts for advice and opinions. For further questions, don't hesitate to contact Brett Roude, Assistant Vice President of Federal Relations and Health Policy, at brett.roude@cu.edu or 202-281-9301.

Sincerely,

Donald Elliman
Chancellor



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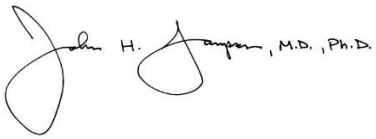

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cc: Senator Michael Bennet
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