COBTH
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Submitted electronically via cures2@mail.house.gov

The Honorable Diana DeGette
Chair, Subcommittee on Oversight & Investigation
Committee on Energy and Commerce
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
Ranking Member, Subcommittee on Energy
Committee on Energy and Commerce
2183 Rayburn House Office Building
Washington, DC 20515

RE: 21st Century Cures 2.0 Discussion Draft

Dear Representative DeGette and Representative Upton:

The Conference of Boston Teaching Hospitals, on behalf of our 12 member hospitals, appreciates the opportunity to comment on the recently released discussion draft of 21st Century Cures 2.0 (Cures 2.0). COBTH and its members deeply appreciate the considerable work you and your colleagues have put into accelerating medical research and improving patient access to novel therapies. Countless Americans have benefited from the investments and policy changes made as part of the 21st Century Cures Act. We are excited that you are pursuing Cures 2.0, as the medical research landscape has changed considerably in the short time since the original law's enactment.

First, we are grateful for your inclusion of the Research Investment to Spark the Economy (RISE) Act (H.R. 869/S. 289). As you know, this legislation would provide a one-time infusion of resources to federal research agencies to address lost research progress caused by the COVID-19 pandemic. During the pandemic, much of our members' research activity slowed or came to a complete stop. This funding is needed to limit the lost progress as a result of this slowdown, which is particularly important for early-career researchers, women researchers, and researchers of color, who were most likely to experience the negative impacts of the pandemic.

We also appreciate your inclusion of public health and pandemic preparedness measures related to surveillance, testing, and vaccination. It is critical to ensure that we take the lessons learned from the COVID-19 pandemic to respond more effectively to the next public health crisis.

In addition to research, ensuring patient access to the most appropriate and efficient form of care is also critical as we move forward. That is why we were glad to see your inclusion of the Telehealth Modernization Act (H.R. 1332/S.368) in the discussion draft. Elimination of Medicare's geographic and originating site restrictions will help ensure Medicare beneficiaries can continue to access telehealth regardless of where they live when it is appropriate. Patient and provider satisfaction with telehealth has been consistently high throughout the pandemic, and making this flexibility permanent will reduce travel time and cost for patients, reduce no-show rates for providers, and ensure telehealth remains an option for patients.

Finally, we especially appreciate your request for information as it relates to President Biden's proposal to create an Advanced Research Projects Authority for Health (ARPA-H). While we are excited by the prospect of considerable additional investments in medical research, which are sorely needed, we do have some questions and concerns about the new agency's implementation. Below, we outline a few questions about ARPA-H that we believe must be carefully considered and addressed as you move forward with the proposal.

Where should ARPA-H be housed?
President Biden proposes making ARPA-H part of the National Institutes of Health (NIH), which makes sense given the two agencies' focus on medical research. However, it also made clear in the proposal that ARPA-H have a different culture and organizational structure than NIH so that it can pursue different types of research objectives. We agree that is important that ARPA-H coordinate closely with NIH and other federal research agencies to ensure that no duplicative research is conducted, and meaningful collaboration can be pursued when appropriate, but we do have some concerns about housing ARPA-H within NIH's existing structure. If the impetus for the creation of this new agency is that NIH cannot do the things that ARPA-H will be able to do, we question whether it makes sense to create it outside of NIH's structure entirely. An example of such an initiative is the Biomedical Advanced Research and Development Authority (BARDA), a division of HHS created in 2006 to promote research, innovation and development of medical countermeasures to respond to chemical, radiological, and nuclear accidents, pandemic flu, and other emerging infectious diseases. BARDA's creation outside of an existing federal research agency gave it independence and the ability to pursue its unique mission in a new way. Using a similar structure for ARPA-H could provide clarity of vision and avoid confusion about specific program requirements associated with the NIH.

How do we avoid confusion for investigators?
Per our comments above, another specific concern we have is that the existence of ARPA-H could create confusion for investigators who are applying for federal research funding. ARPA-H will need clear and coherent guidelines for investigators that indicate when projects are appropriate for ARPA-H versus the traditional NIH funding mechanisms. We do not want to create a system where investigators feel that they need to apply for funding twice, especially if the metrics and application processes for the two agencies are significantly different. If ARPA-H will not be using NIH's existing grant types (i.e., R01s, etc.), how will these new opportunities be communicated to researchers in a way that can be easily understood and matches their expertise?

How do we ensure all promising investigators have the opportunity to work with ARPA-H?
When it comes to applying for federal funding, more sophisticated and mature research programs are well resourced with staff and experience attracting federal investment. We are concerned that with a whole new agency and funding application structure, some research programs may not have an adequate opportunity to be considered for ARPA-H awards because they may struggle to adapt to new requirements or bring on additional staff to help handle new applications. COBTH is comprised of diverse research programs across our institutions, and we think it is important to ensure that every potential and promising applicant has a fair shot at this new funding opportunity. This could be achieved in part through clear submission guidelines that do not create unnecessary burdens to apply, as well as providing technical assistance to institutions and organizations that may not typically be considered for grants of this type.

How do we protect NIH funding and avoid a funding cliff?
We were pleased to see President Biden propose the creation of ARPA-H with significant funding for three years in addition to an increase for the NIH's budget in FY22. If the nation's medical research enterprise is to be successful, it is critical that ARPA-H's funding needs cannot be met at the expense of funding for the NIH's existing institutes and centers. We think Congress must consider these two funding line items separately and should not take funding from one at the expense of other, including in out-years. We are also concerned that only three years of funding are proposed for ARPA-H. NIH's typical grant cycle is five years, and while we understand ARPA-H will not be operating the same way as NIH, we are concerned this is not adequate time to assess the success of the new agency, and could lead to a funding cliff and the loss of early research gains made through the ARPA-H program.

The American Recovery and Reinvestment Act (ARRA) provided $10.4 billion for the NIH, leading to $8.97 billion for over 21,500 research projects. While this is more funding than is contemplated for ARPA-H, it is worth noting that when the ARRA funding ran out, the cliff experienced by researchers and research institutions was significant. Increased staff and improved infrastructure to spend the new resources were no longer needed, leading to budget cuts, staff reductions, and decreased opportunities for promising research conducted by new investigators. Avoiding a research funding cliff and committing to long-term, sustainable research funding is necessary for the long-term stability of our research enterprise. Congress must think now about what to do with ARPA-H funding in year four and beyond. Regardless of the enormous potential for ARPA-H's success, keeping increased funding within the federal research ecosystem will help minimize disruptions to investigators and their home institutions.

Thank you for your consideration of our comments and for your tireless work to advance medical research and discovery. Please do not hesitate to be in touch with any questions or if we can provide additional information on these or other matters.

Sincerely,

Patricia McMullin
Executive Director
Conference of Boston Teaching Hospitals