

the political costs of gutting the entire ACA is too high, states may be the ones crafting the future of federal health care reform. Reforms undertaken by Massachusetts in 2006 greatly influenced federal reforms in the ACA. State-driven reforms enacted under innovation waivers could similarly foreshadow the future of U.S. health care reform.

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The 21st Century Cures Act — A View from the NIH

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The Cures Act, formally known as H.R. 34 or the 21st Century Cures Act,¹ passed overwhelmingly in the U.S. House of Representatives and Senate in the waning days of the 114th Congress and was signed into law by President Barack Obama on December 13, 2016. Weighing in at nearly 1000 pages, this bipartisan bill is the product of years of hard work by Republican and Democratic lawmakers, in collaboration with a broad array of diverse stakeholders. As with any landmark piece of legislation, the complex negotiations leading up to its passage were challenging and intense. But the final provisions are well worth heralding, including increased support for state efforts to combat opioid abuse, new steps aimed at improving mental health services, and important changes affecting the Food and Drug Administration and the National Institutes of Health (NIH).

Here, we focus on aspects of the Cures Act that are directly relevant to the NIH's mission — measures that will provide the

agency with critical tools and resources to advance biomedical research across the spectrum from basic, curiosity-driven studies to advanced clinical trials of promising new therapies. Affecting everyone from researchers to research participants to patients suffering from numerous conditions, these measures will cut bureaucratic red tape that slows the progress of science, enhance data sharing and privacy protections for research volunteers, improve support for the next generation of biomedical researchers, exhort the NIH to extend its efforts to ensure inclusion of diverse populations, and provide the NIH with a bolus of additional funding over 10 years for key biomedical research initiatives.

Some key measures reduce red tape. Policies generated with the best intentions sometimes have serious adverse consequences for research. Two needlessly obstructive policies have been undone by the Cures Act — one dealing with paperwork and the other with scientific meetings.

The first, the ironically titled

Paperwork Reduction Act,² was enacted when the Internet was nascent and paper still ruled. Its purpose was to limit government's ability to ask Americans to fill out endless forms, especially when those forms were required to receive government services or benefits. Minimizing needless paperwork and bureaucracy is an admirable goal. However, as applied to biomedical research, the law requires multiple levels of government review and public comment on any set of questions that NIH researchers propose to ask of 10 or more persons in a scientific study supported by contracts, the Intramural Research Program, and many cooperative agreements. This process rarely results in substantive changes, but it delays the start of research for 9 months, on average — dissuading investigators, especially trainees, from undertaking important studies. Through the Cures Act, lawmakers have now liberated science from this red tape by eliminating Paperwork Reduction Act requirements for NIH research — a step that

will help speed the initiation of research and the generation of new knowledge.

The Cures Act's second major red-tape-cutting measure provides much-needed relief from restrictions on support for scientific meetings. Because of a few well-publicized extravagant meetings attended by members of other federal agencies, restrictions were placed on federal employees' travel to meetings. Those restrictions applied to government scientists' travel to scientific meetings, severely hampering their ability to present their research and exchange ideas with other scientists.³ Scientists could not be confident that their travel applications would be approved, and requests for meeting attendance were sometimes denied. These travel restrictions generated senseless paperwork and, owing to the resulting delays in processing requests from multiple agencies, actually increased costs to the government. The Cures Act has removed these restrictions.

Other measures in the bill relate to data sharing and privacy protection. Sharing data is essential for progress in biomedical research. Rapid data sharing was key to the success of the Human Genome Project, and that same commitment has been spreading across biomedicine in the past two decades, as advances in technology and "big data" have enabled an entirely new level of data sharing and inquiry.⁴ Despite the clear value of sharing data, the NIH has been constrained from requiring in a straightforward way that NIH-funded investigators share their data. The Cures Act solves this problem by allowing the NIH director to require that data from NIH-supported research be shared, giving all scientists the opportuni-

ty to use these data as quickly as possible to advance biomedical research.

This new era of rapid and facile exchange of data also requires redoubled efforts to protect the privacy and confidentiality of information about research participants. People who volunteer for research need to be confident that scientists will do everything in their power to protect their private information. The Cures Act contains what we believe are the most significant advances in research privacy protections in two decades. Certificates of confidentiality, previously available to researchers upon request, will now be provided to all NIH-funded scientists conducting research that involves the collection of identifiable, sensitive information. The certificates will provide stronger protections against the disclosure of the names of participants or any other identifiable data gathered during research. In addition, the Cures Act will allow the NIH to withhold biomedical information about individuals that could be used to reidentify them through requests for records filed under the Freedom of Information Act.⁵

Cures Act provisions also support early-stage researchers. Today, the average age of a researcher receiving his or her first independent research grant from the NIH is 42. The NIH has been working hard to create additional opportunities for younger researchers, including dedicated awards for new and early-stage investigators. Though such efforts have proven valuable for encouraging individual researchers, they have not resulted in a lowering of the average age of independent investigators within the full NIH research portfolio. Provisions in the

Cures Act will establish an office at the NIH to promote policies aimed at improving coordination and analysis of opportunities for new and early-stage investigators, as well as at attracting, retaining, and developing emerging scientists in priority research areas. Such efforts will include strategies for developing early-stage researchers who are women or members of other groups that are traditionally underrepresented in biomedical research careers. To provide further support to early-stage researchers, the Cures Act authorizes the establishment of additional programs to assist in the repayment of student loans and raises the cap on the repayment assistance available to researchers.

It is essential that biomedical research reflect, and provide a benefit to, the entire U.S. population. The Cures Act encourages diversity by setting out a path for the NIH to continue and expand its efforts to allow Americans of all stripes to participate in and benefit from NIH-funded biomedical research. These efforts will be aided by the NIH's collection and posting of more detailed information about the participants in NIH-funded research, specifically the inclusion of key demographic groups defined by characteristics including sex, age, and minority status. The NIH is also encouraged by the legislation to carry out focused efforts to improve research related to sexual and gender minority populations, as well as work aimed at understanding and reducing health disparities between different populations.

The Cures Act provides multi-year funding for three highly innovative scientific initiatives launched by the Obama administration: the Brain Research through Advanc-

ing Innovative Neurotechnologies (BRAIN) Initiative, the Precision Medicine Initiative (PMI), and the Beau Biden Cancer Moonshot. It also includes a promising new research initiative focused on regenerative medicine (see table).

Each of these initiatives has its own set of audacious goals, but their basic aims are as follows. BRAIN is a sweeping effort to build technology and knowledge across an array of disciplines to elucidate how circuits in the brain function in real time and what goes wrong in disease. PMI is a transformative research infrastructure that will enable and simplify research across all diseases. Its centerpiece, dubbed All of Us, is a longitudinal cohort study involving 1 million or more Americans. The Beau Biden Cancer Moonshot is an ambitious plan to double the rate of progress in the fight against cancer, making more therapies available to more patients, while also improving our ability to detect and prevent cancer. The Cures Act regenerative medicine program is focused on clinical research using adult stem cells, including autologous stem cells. It features an innovative funding mechanism that requires a match from the grant or contract awardee.

Congress has made it clear that these focused investments are not intended as a substitute or offset for supporting NIH research through the regular appropriations process. Although the decision about the overall fiscal year 2017 funding level for the

| Funding for NIH Innovative Research Initiatives under the Cures Act.* | | | | |
|-----------------------------------------------------------------------|-----------------------|-------|-----------------|-----------------------|
| Fiscal Year | BRAIN | PMI | Cancer Moonshot | Regenerative Medicine |
| | <i>millions of \$</i> | | | |
| 2017 | 10 | 40 | 300 | 2 |
| 2018 | 86 | 100 | 300 | 10 |
| 2019 | 115 | 186 | 400 | 10 |
| 2020 | 140 | 149 | 195 | 8 |
| 2021 | 100 | 109 | 195 | |
| 2022 | 152 | 150 | 194 | |
| 2023 | 450 | 419 | 216 | |
| 2024 | 172 | 235 | | |
| 2025 | 91 | 36 | | |
| 2026 | 195 | 31 | | |
| 10-Yr total | 1,511 | 1,455 | 1,800 | 30 |

* BRAIN denotes Brain Research through Advancing Innovative Neurotechnologies, and PMI Precision Medicine Initiative.

federal government to support all NIH research across disciplines and disease areas has been postponed until April 2017, the Cures Act funding is available now and will be used right away to support groundbreaking research. We remain optimistic that strong support for the NIH budget will be reflected in the ultimate decisions about the fiscal year 2017 budget and beyond.

In the meantime, Congress has provided an enormous gift to science in the form of the Cures Act, a gift that reflects a deep confidence in the promise of biomedical research to make discoveries and develop cures in the 21st century. All those who made this gift possible — the President and Vice President, lawmakers, stake-

holders, and most of all, patients — deserve our heartfelt thanks.

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