

November 3, 2016

Re: Do not pass the 21<sup>st</sup> Century Cures Act during lame duck

Dear Majority Leader McConnell, Minority Leader Reid, Speaker Ryan, Minority Leader Pelosi, Chairman Alexander, Ranking Member Murray, Chairman Upton and Ranking Member Pallone:

We, the undersigned organizations representing healthcare providers, clinical researchers, public health experts, and consumer advocates across the country, urge you not to advance the 21<sup>st</sup> Century Cures Act, H.R. 6 (Cures Act) in the lame duck session. We understand that this package has received considerable support, given the desire to increase funding for the National Institutes of Health (NIH) and accelerate the development of cures for patients. Unfortunately, the Cures Act would create new problems that significantly outweigh the legislation's benefits in terms of added public funding for medical research. During a time when more than three quarters of Americans are outraged by high drug prices, the Cures Act could raise healthcare costs by extending needless exclusivities for pharmaceutical corporations.<sup>1</sup> Further, it includes costly and potentially harmful regulatory changes and financial incentives for pharmaceutical and medical device companies that would put patient safety at risk and undermine public health. We therefore are unable to support the legislation.

The Cures Act fails to ensure a comprehensive and scientifically valid approach to drug and medical device regulation that supports patients' access to affordable treatments. Instead, it would allow for unsafe and ineffective drugs and medical devices to enter the market while further limiting the public's access to effective medicines. One assessment indicates the Cures Act could cost taxpayers an estimated \$12 billion over 10 years by extending monopolies on brand-name blockbuster drugs that receive additional approval to treat orphan diseases.<sup>2</sup>

We are concerned that a final package could include proposals that endanger the lives of patients and curb access to affordable treatments. Specifically, the House-passed Cures Act and, in some instances, Senate counterparts would –

- bar generic entry of medicines for a longer period and allow for continued drug price gouging, denying patients access to affordable, life-saving medicines (H.R. 6 Section 2151)
- further undermine the FDA's ability to ensure the safety and effectiveness of medical devices (H.R. 6 Sections 2201, 2222 and 2221, S. 1077)
- allow for antibiotics and antifungals (and possibly other drugs) to be approved based on lower FDA standards, putting patients at risk of being treated with unsafe and ineffective drugs (H.R. 6 Section 2121, S. 185)
- hasten the rise of resistant superbugs by providing hospitals with financial incentives to use new antibiotics rather than reserving them for appropriate use (H.R. 6 Section 2123)

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<sup>1</sup> Kaiser Health Tracking Pool: September 2016. <http://kff.org/health-reform/report/kaiser-health-tracking-poll-september-2016/>

<sup>2</sup> Public Citizen Report: House Orphan Drug Proposal. [www.citizen.org/hrg2289](http://www.citizen.org/hrg2289)

- weaken the reporting requirements under the Physician Payment Sunshine Act, allowing for secret influence from pharmaceutical and medical device companies on the practice of medicine and medical education (H.R. 6 Section 3041)

We also understand that the pharmaceutical industry is pushing for a diluted version of the CREATES Act (S. 3056) – a measure that would help ensure timely generic entry – to be included in the CURES Act, and that it may be considered to offset the costs of NIH funding. The CREATES Act is estimated to save \$3.2 billion in taxpayer dollars over the next decade, but a weaker version would limit those savings and the underlying goal to make medicines more accessible. We oppose diluting the CREATES Act. And furthermore, although we strongly support the Senate-introduced version of the CREATES Act and increases in NIH funding, we do not believe adding those items to the Cures Act would overcome or justify the harmful provisions highlighted above.

The sweeping 21st Century Cures Act that passed the U.S. House of Representatives contains provisions that would put lives at risk and worsen the growing crisis around drug price gouging. Therefore, we urge you not to move forward with the legislation in the lame duck session.

Sincerely,

American Medical Student Association  
Annie Appleseed Project  
Consumers Union  
Culinary Health Fund  
Health GAP  
MedShadow Foundation  
National Physicians Alliance  
Public Citizen  
Social Security Works  
Treatment Action Group  
Universities Allied for Essential Medicines (UAEM)  
Washington Advocates for Patient Safety  
Young Professionals Chronic Disease Network