

October 26, 2016

Dear Leader Harry Reid, Leader Nancy Pelosi, Ranking Member Patty Murray, and Ranking Member Frank Pallone:

We write to urge you not to move forward with the 21st Century Cures Act during the lame duck session and instead work to improve this legislation in the next session. Over the last year, a series of instances of price gouging by pharmaceutical corporations has led various congressional committees to look into these practices; these efforts included several high-profile hearings and Senate Finance Committee investigations. While the Cures Act's funding for the National Institutes of Health is a priority for many, it is critical that any legislation making changes to drug policies take steps to rein in the cost of prescription drugs.

We have several concerns about the legislation's provisions to speed FDA approval based on limited information and to extend exclusivity periods for certain drugs. Such provisions may undermine the agency's ability to ensure the safety and quality of products and could reduce access to prescription drugs. Moreover, these policies are generally unnecessary, given that the FDA already approves a significant share of drugs through expedited pathways. In fact, the FDA's current extensive use of such pathways is already raising serious safety concerns.¹

But notwithstanding these provisions, moving forward with this legislation now would be a missed opportunity to address unaffordable prescription drug prices. There is no justification for moving forward with legislation that provides substantial benefits to the drug industry without asking for something in return.

Mylan's price gouging on EpiPens is just the latest example of a systemic problem. Excessive drug pricing will continue to be an issue of pressing national concern next year. Moving forward with this legislation now will undermine efforts to act on an issue next year that is the highest health care priority for the vast majority of Americans – Republicans and Democrats alike.²

We respectfully urge you to delay action on this legislation until it can be included as part of a package that also addresses the high cost of prescription drugs.

Sincerely,

Center for American Progress
AFL-CIO
Alliance for Retired Americans
American Federation of State, County and Municipal Employees
American Federation of Teachers

¹ Center for American Progress, "The FDA Is Not the Problem: Why Undermining the Drug Approval Process Is Not the Answer To High Drug Prices," March 9, 2016, available at: <https://cdn.americanprogress.org/wp-content/uploads/2016/03/09143833/FDA-briefv2.pdf>.

² Kaiser Family Foundation, "Kaiser Health Tracking Poll: October 2015," October 28, 2015, available at: <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/>.

Center for Medicare Advocacy, Inc.
Consumers Union
Doctors for America
National Committee to Preserve Social Security and Medicare
Public Citizen
Service Employees International Union
Social Security Works
Unite HERE Health