



March 3, 2015

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20015

Dear Chairman Upton:

NCHC is a coalition of more than 80 member organizations—representing health care providers, purchasers, payers, and consumers—committed to promoting an affordable, high-quality health system in the United States. We are pleased to have the opportunity to comment on the 21st Century Cures Act Discussion Draft, released on January 27, 2015.

NCHC commends the Committee for its efforts to encourage innovation in pharmaceuticals and medical devices. New medical technologies and therapies have dramatically improved patients' prognoses and quality of life, and, in some cases, have even offered the possibility of a cure. Precision Medicine, in particular, promises significant breakthroughs in the treatment of a range of diseases, including cancer. Therefore, we are pleased that the discussion draft included an array of provisions to ensure a faster, more efficient path for new medical innovations. NCHC supports in principle the Committee's efforts to promote surrogate endpoint qualification and utilization, an improved data sharing network, and broader application of adaptive trial designs. When combined with adequate support for basic and translational research and careful attention to patient safety, these bipartisan proposals can help speed new treatments to the market.

However, the speedier introduction of treatments will mean nothing if patients and our health system cannot afford them. NCHC is gravely concerned that the discussion draft ignores the fundamental challenge of affordability.

In fact, some provisions of the discussion draft would sacrifice the affordability of prescription drugs in the name of promoting innovation. For example, the Dormant Therapies provision (Subtitle L) grants a full fifteen years of monopoly power to any drug applicant whose product meets an "unmet need" and has no

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competitor with the same moiety. As Columbia University Professor Scott Hemphill, Ph.D. stated before the Subcommittee on Health on June 11, 2014, “It is hard to think of a new chemical entity that would fail this test.” Enactment of such a broad and lengthy extension of monopoly power would shatter the incentives for strong generic competition which have helped hold down prescription drug costs in Medicare Part D and the private sector.

Fortunately, granting a long-term monopoly to a brand name manufacturer is not the only option to promote innovation. Other tools, such as increased funding for basic and translational research, public private cooperation, and provision of tax credits or other prizes can help promote the development of dormant therapies without crippling competition. Therefore **NCHC urges the Committee to reject any long-term or broad-based extensions of market exclusivity.**

Ultimately, however, it’s not enough to merely avoid worsening the current cost trajectory for prescription drugs. Following years of relatively stable drug expenditures, drug costs are already on the rise, climbing at 10.9% clip in 2014. By 2020, CVS projects that specialty drug costs alone projected to reach \$400 billion. If consumers and taxpayers are to afford the growing cost of prescription drugs over the long term, Congress must take proactive steps to enhance price competition now. **NCHC strongly recommends that any final 21<sup>st</sup> Century Cures legislation include the following pro-competition provisions:**

- **Pass the FAST Generics Act:** This bipartisan legislation, introduced as HR. 5657 by Rep. Steve Stivers (R-OH) and Rep. Peter Welch (D-VT) during the 113<sup>th</sup> Congress would end the misuse of Risk Evaluation and Mitigation Strategies (REMS) to deny drug samples to potential generic competitors- both for biologic and chemical drugs.
- **Assure Adequate Reimbursement for Biosimilars:** The biosimilar pathway established by the Biologics Price Competition and Innovation Act is vital to affordability of biologic medications- for both consumers and taxpayers. But appropriate reimbursement policies are needed to ensure the expected savings from biosimilar competition are realized. In Medicare Part B, for example, Congress should instruct CMS to promptly clarify that biosimilars, like other generic drugs, will be reimbursed under the same Healthcare Common Procedure Coding System (HCPCS) codes as the originator drug.

Just nine months after its launch last June, the 21<sup>st</sup> Century Cures Initiative has helped bring the stakeholder community, lawmakers of both parties, executive branch agencies, and the White House together in a common effort to support innovation. But moving forward with legislation that fails to address affordability would not be reflective of the spirit of cooperation which has characterized the 21<sup>st</sup> Century Cures effort previously. We urge the Committee to remove counterproductive, long-term extensions of monopoly power from this bill and instead take steps to expand competition. When that occurs, NCHC will be eager to advance down the road to 21<sup>st</sup> Century Cures.

Yours truly,



John Rother  
President and CEO