Time is NOW to Modernize the US Innovation Ecosystem

*National Health Council urges Congress to pass the MODDERN Cures Act*

Washington, DC (June 11, 2014) – The National Health Council (NHC) strongly urged the House Energy and Commerce Committee’s Health Subcommittee to address head-on the difficult challenges faced by people with unmet medical needs and pass the MODDERN Cure Act, HR 3116, which would update the nation’s innovation ecosystem and advance the development of new treatments.

The subcommittee held a hearing today to gain a better understanding of whether current economic and regulatory incentives are sufficient to encourage robust investment in the research and development of innovative drugs, biologics, and medical devices.

The Executive Vice President and Chief Executive Officer of the NHC, Marc Boutin, provided the oral testimony below.

- To learn more about the MODDERN Cures Act: www.puttingpatientsfirst.net/moddern
- To read Boutin’s formal written testimony: http://ow.ly/xSo8X
- For more information about the NHC: http://ow.ly/xSoX
- Contact: Nancy Hughes, nhughes@nhcouncil.org, 703-608-9709

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**Testimony of Marc Boutin, JD**

*Executive Vice President and Chief Operating Officer, National Health Council*

**21st Century Cures Initiative Hearing - June 11, 2014**

Good morning Chairman Pitts, Ranking Member Pallone, and members of the sub-committee.

There are more than 133 million people living with one or more chronic conditions – that's more than 40% of the population. Effective treatments are available for some. But for many patients – all they have is hope.

My name is Marc Boutin, and I am the Executive Vice President and Chief Operating Officer at the National Health Council. We provide a united voice for people with chronic diseases and disabilities and their family caregivers. We welcome all stakeholders into membership, but our governance is controlled by the CEOs of our patient advocacy organizations.

As a child I remember growing up in a tiny town in northern Maine. Every surface of my home was covered in floral wallpaper – including the light switches. You actually had to rub the wall to find the light switch.
The wallpaper, rugs, furniture – everything – was covered in flowers. And when my mom sat perfectly still – in her floral dress – you couldn’t see her.

In my thirties, I remember the day I sat in the doctor’s office when my father was told he had incurable cancer. My mom became his primary caregiver – even though she had health issues.

I held my father’s hand when he took his final breath. My mom died soon after – on my birthday.

Dismantling our family home was difficult – all the memories – and all that wallpaper. Getting the house ready to sell was not easy, but it had to be done.

Nearly every person in this room has been touched by the burden of disease. Michael Gollin, sitting behind me, is an intellectual property lawyer. He is also living with ALS or Lou Gehrig’s disease – which progressively robs you of your ability to walk, talk, swallow and even breathe.

Thirty years ago Representative Waxman co-authored – the Hatch Waxman Act – which updated our innovation ecosystem and made medications affordable for millions of people.

But as Senator Hatch recently wrote, "we cannot rest on our laurels ... We have an obligation to periodically reevaluate and adjust to account for the sweeping changes in the health sector."

Our current innovation ecosystem was built decades ago – long before we mapped the human genome, had super computers or advanced diagnostics.

Much like my family home, this ecosystem has not kept pace with time. No one is to blame for this – it just happens – you get used to the wallpaper.

The 21st Century Cures: Call to Action provides an opportunity to update. While we may not yet agree on specific solutions – consensus is emerging on some of our most pressing challenges:

First, we all know that you need a patent to develop a new medicine – but less known is the fact that many of the most promising treatments don't qualify for a patent. Just because you cure Parkinson's or lupus doesn't mean you get a patent.

Some of the best science is not translated into treatments – simply because they don't meet the technical requirements for a patent.

From a patient perspective – this makes no sense – and Congress can fix it.
Second, our current system encourages the fastest, least expensive innovation – not necessarily the treatments that are most important to society or to individual patients.

As you know, patents run concurrently with pre-clinical, clinical and regulatory review, the best and most promising medicines receive the shortest protection from generic competition. For example, conditions that are not well understood or progress slowly – like Alzheimer’s – come to the market with the shortest period of protection.

This also encourages the development of treatments for late stage cancers rather than early stage cancers – despite the huge social and economic value of addressing or preventing disease early.

From a patient perspective – this makes no sense – and Congress can fix it.

The MODDERN Cures Act introduced by Representative Lance with bipartisan support is the first legislative attempt to address these two barriers. It promotes the best science – not the best patent – but only for drugs that address an unmet medical need as defined by the FDA.

On behalf of my dad, my Mom, Mr. Gollin and nearly everyone in this room affected by disease – thank you for including the patient community in this multi-stakeholder approach. We stand ready, willing and able to help solve these and other complex challenges.

It’s time to take down the wall paper – it’s time to update our innovation ecosystem.

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