National Health Council
1730 M Street NW, Suite 500, Washington, DC 20036-4561 · 202-785-3910 · www.nationalhealthcouncil.org · info@nhcouncil.org

Modernizing Our Drug and Diagnostics Evaluation and Regulatory Network: The MODDERN Cures Act of 2011

21st Century Regulatory Science for 21st Century Cures

More than 133 million Americans – over 40% the U.S. population – live with a chronic disease or disability. But for some people there are no treatments, there are no cures, and the drug approval process is not providing patients what they need fast enough.

In an era of increasingly scarce resources for health research, it is critical that the limited research dollars available are spent most effectively to meet the needs of patients. The status quo is not yielding the treatments to address the growing epidemic of chronic disease in this country.

U.S. Representative Leonard Lance (R-NJ) has introduced legislation that would "modernize our drug and diagnostics evaluation and regulatory network" – the MODDERN Cures Act, H.R. 3947. The lead cosponsor is U.S. Representative Jay Inslee (D-WA).

The MODDERN Cures Act…..

- **Advances personalized medicine by getting the right medicines to the right people.** The development and approval of breakthrough diagnostic tests would identify patients most likely to benefit from a particular medication or treatment. The MODDERN Cures Act encourages partnerships between drug and diagnostics makers and dramatically increases private investment in the development of tools that help determine the most appropriate treatment options for patients. It also ensures immediate access to new tests once approved by the Food and Drug Administration (FDA).

- **Advances the discovery of therapies for unmet medical needs.** Drug companies pursue drugs that are likely to have long periods of patent protection when the product reaches the market. Because drug patents run concurrently with the development and federal approval process, companies invest in medicines that can be brought to market quickly. Unfortunately, drugs that might address unmet medical needs, such as neurological conditions, autoimmune diseases, cancer, or rare diseases, often take substantially longer to develop, and by the time the medicines come to market the patent has expired. The MODDERN Cures Act creates a new class of drugs called "dormant therapies" – medicines that address complex conditions with limited or no treatment options. The bill grants dormant therapies an additional period of regulatory protection, thereby encouraging more complex research and development initiatives, while also establishing a predictable timeline for the introduction of low-cost generic equivalents.

This game-changing legislation matters for <u>all</u> people with chronic diseases. It would fundamentally transform the delivery of care in this country. A truly MODDERN regulatory system benefits all patients by encouraging the development of new, more targeted treatments and the efficient use of health care resources. The legislation will transform the development process for drugs that slow or stop disease progression for degenerative conditions, such as Alzheimer's and ALS (Lou Gehrig's Disease), for autoimmune diseases, such as lupus and Sjögren's Syndrome, and for cancer.

To get modern medical miracles, we need the MODDERN Cures Act.
To learn more and read a copy of H.R. 3497, visit www.puttingpatientsfirst.net/moddern.

TITLE I — ADVANCING DIAGNOSTICS FOR PATIENTS

Sec. 101 – DEVELOPING A COMMON LEXICON TO FACILITATE PROGRESS ON DIAGNOSTICS

Most of the terminology in the diagnostics space is not statutorily defined, which has led to inconsistent definitions for many important concepts. This section outlines a process to establish clear and consistent definitions related to diagnostics.

Sec. 102 – CREATING INCENTIVES FOR INNOVATIVE DIAGNOSTICS

This section puts forth the factors that should be considered in setting payment for a new test. In addition, in determining the payment rates, it requires the Secretary of Health and Human Services to seek the advice of an independent advisory panel that is comprised of individuals with expertise in diagnostic tests.

This section also allows developers of a new diagnostic test to apply for a temporary Healthcare Common Procedure Coding System (HCPCS) code until a permanent code is established, allowing for more timely access to new diagnostic tests. The assignment of temporary codes would occur on a quarterly basis.

Sec. 103 – PROMOTING THE DEVELOPMENT OF INNOVATIVE DIAGNOSTICS

This section encourages the development of corresponding diagnostic tests that could help predict the appropriate patient population for the therapy and provides that a drug or biologic will be eligible for an additional 6-month period of data exclusivity if a diagnostic test is developed after a drug or biologic is already on the market. An additional 12-month period of data exclusivity is provided for a drug or biologic if a diagnostic test is developed concurrently with the development of a drug or biologic. Data exclusivity is a period of time during which a generic manufacturer cannot rely on the research data of the original manufacturer for purposes of gaining FDA approval of the generic equivalent.

TITLE II — CAPTURING LOST OPPORTUNITIES FOR PATIENTS

Sec. 201 – DESIGNATION OF DORMANT THERAPIES

This section creates a new class of drugs, named "dormant therapies." A dormant therapy is a new drug or biological product that has insufficient patent protection and meets the FDA definition of "unmet medical need." The Secretary is required to establish a methodology and criteria for this designation. In its request for designation as a dormant therapy, the manufacturer must provide a list of all patents and applications for patents to which the manufacturer has rights, and must agree to waive those rights in order to receive the designation.

Sec. 202 – PROMOTING THE DEVELOPMENT OF DORMANT THERAPIES

This section provides for a 15-year period of data exclusivity after FDA approval to encourage the development of dormant therapies. The Secretary is required to make its determinations available to the public. This bill will establish a predictable pathway for introducing low-cost generic equivalents to dormant therapies.

To learn more and read a copy of H.R. 3497, visit www.puttingpatientsfirst.net/moddern.