



MODDERN Cures Act

Position: We urge you to support the reintroduction of *Modernizing Our Drug and Diagnostics Evaluation and Regulatory Network Act (MODDERN Cures Act: H.R. 3497 112th Congress)*; or to support the introduction of similar legislation in the Senate. The MODDERN Cures Act would accelerate the search for treatment options by removing barriers that limit medical innovation and by encouraging the development of new treatments and diagnostic tools that can improve, prolong and, ultimately, save lives. The Epilepsy Foundation supports the MODDERN Cures Act as a way to accelerate the development of new diagnostic tools and treatments for epilepsy.

Background: Approximately 25 to 30 percent of the epilepsy patient population lives with seizures that cannot be controlled by existing drugs or surgery. Even when seizures are controlled, the quality of life for some people with epilepsy is severely affected by the long- and short-term side effects of medication or surgery. Doctors call epilepsy that is not responsive to treatment intractable (treatment-resistant) epilepsy. In some cases, people with epilepsy could develop brain damage or other life threatening effects from seizures. Many epilepsy syndromes, such as infantile spasms, Dravet syndrome, Lennox-Gastaut syndrome, Rasmussen's encephalitis, and Landau-Kleffner syndrome are rare conditions that begin in childhood. They can often have devastating impacts on brain development and, because smaller groups of people are affected, treatment options and research can be very limited.

Just as there are different kinds of seizures, there are different kinds of epilepsy. A minority of these syndromes appear to be hereditary. For most of the epilepsy syndromes, the cause is unknown. Recent studies have significantly improved our understanding of how age and gender affect the response to epilepsy therapy. **Because both the efficacy and side effects associated with specific epilepsy medications vary greatly from person to person, one way to improve epilepsy treatment is to develop ways to predict individual responses to medications.** Personalized treatment could give individuals better symptom relief, fewer side effects, and advances could lead to better treatments for those whose seizures are not controlled (or well-controlled) by current therapeutic options.

Patent & Diagnostic Issues that Can Impede Innovation:

- **Patents:** Patent protection and the ability to make a treatment available without competition for a period of time helps drive drug development and reduce risk. The Orphan Drug Act is an example of how protection can spur innovation. However, there are hundreds of thousands of potential treatments that either have either weak, expired, or expiring patents. These potential treatments that could save lives are sitting on the lab shelf and never will be developed simply because they lack patent protection. Moreover, the patent system can create disincentives to pursue treatments where the time it takes to develop a therapy can exceed 15 or more years. That's because the patent clock starts at the beginning of the development process, leaving only a limited amount time after approval for a company to recoup its costs before the patent expires.

- **Delays in coding and reimbursement for advanced diagnostics:** It can take a year or longer for a diagnostic to receive a reimbursement code. These delays not only discourage development of diagnostics, but also further delay patient access to vital diagnostics tools.
- **Outdated system for reimbursing advanced diagnostics:** Currently, advanced diagnostics are reimbursed at a rate similar to diagnostic tests that were available in the 1980s. These rates poorly reflect the value that newer advanced diagnostics provide to patients and the greater health care system.

The MODDERN Cures Act:

Addresses Unmet Medical Needs and Facilitates the Development of Treatments

The MODDERN Cures Act would create a new category of drugs called “dormant therapies,” which are those that are deemed to have insufficient patent protection and also show promise for treating diseases where there are limited or no treatments. The bill would encourage development of dormant therapies by providing a 15 year period of data exclusivity, which offers incentives for therapy development similar to those afforded by patent protection. However, unlike patents, the period of data exclusivity would begin at the time of FDA approval so that manufacturers are not penalized for pursuing treatments that can take longer to develop.

Removes Barriers for Developing New Diagnostics and Personalized Medicine

The MODDERN Cures Act would ensure prompt coding and reimbursement for new diagnostic tests by defining improvements to the process for determining payment rates and developing a system for assigning temporary HCPCS codes to new tests until a permanent code is established. HCPCS codes are necessary to ensure reimbursement, coverage and patient access to new diagnostics.

- The bill would update the process for determining the reimbursement rate for advanced diagnostics in a way that better rewards innovation and improvement in patient care.
- The bill would encourage the development of companion diagnostics that accurately predict for whom a medicine will work by prolonging the period before which generics may enter the market by an additional 6 to 12 months.
- The MODDERN Cures Act would establish a council to develop educational tools and programs to promote a common understanding of the terminology and definitions related to the development and use of diagnostics.

The MODDERN Cures Act could help speed the development of new treatments and diagnostic tools that may improve the lives of people living with epilepsy.