

# 21st Century Cures Act signed into law



## Legislation provides funding for brain research and data collection.

by Marcella Durand

Frank Austin, diagnosed with multiple sclerosis in 1999, calls the 21st Century Cures Act a “game changer.”

Austin, a National MS Society district activist leader in Pennsylvania, helped get the act in front of Congress, where it received a bipartisan 94–5 vote in the U.S. Senate, following a 392–26 vote in the U.S. House of Representatives. Former President Barack Obama signed the bill into law on Dec. 13, 2016. Austin says he is most excited about the “big data” that will be collected on MS as a result of the act. “[Big data] gives us the best chance of getting the government’s focus on MS.”

### What it is

The act contains several provisions important to people affected by MS, including:

- **The National Neurological Conditions Surveillance System**, which will help establish a data collection system to track the incidence and prevalence of neurological conditions such as MS, allowing researchers to better track and study factors such as the geography of MS diagnoses or variances in gender;
- **New funding** for the National Institutes of Health (NIH) directed toward the **Precision Medicine Initiative**, which aims to incorporate individual genetic information and personal environment and lifestyle factors into treatment decisions; and toward the **Brain Research through Advancing Innovative Neurotechnologies (BRAIN)**

**Initiative**, which will explore how individual brain cells and complex neural circuits interact, allowing for a deeper understanding of how the brain works.

- **New funding** for the Food and Drug Administration (FDA) to bring new treatments to clinical actuality.
- **Protection** for access to complex rehabilitation technology wheelchair accessories, such as tilt-and-recline systems and customized seat cushions, which allow people with MS to remain mobile and independent.

Other provisions of the act will also support many people living with MS. For instance, the act requires the FDA to establish a framework for using “real-world” data collected outside of clinical trials to support approval of new indications for previously approved drugs. It requires the Centers for Medicare and Medicaid Services to provide data on how care might be improved for Medicare beneficiaries by telehealth services; this should include those with MS who live far from MS treatment centers.

For people with MS facing emotional challenges, the act’s provision, Helping Families in Mental Health Crisis, will strengthen coordination of mental health resources, support mental health workers and increase early access to mental health services. And, under the new law, individuals with disabilities can also create special needs trusts, which will promote financial security and access to long-term services.

### **Getting the big data**

“The passage of the act is such a big deal,” says Weyman Johnson, diagnosed in 1990. As the son and nephew of people with MS—and as a parent himself—Johnson knows firsthand how important it is to understand MS, particularly who can develop it.

“When I was a youngster, we really did not have a clear idea about who has the disease and how many people have it,” he says. He and his family had already participated in genetics surveys led at University of California, San Francisco, but in 2013, he joined the National MS Society’s MS Prevalence Workgroup to address what many people felt was a lack of data regarding the prevalence of the disease. “We decided it would be a very good idea to figure out ways we could get a better angle on incidence and prevalence.”

Johnson says the workgroup helped pave the way toward the inclusion of the National Neurological Conditions Surveillance System in the 21st Century Cures Act and lays great groundwork for the data collection system. “The [system] really does go to the history of the disease and the way families have dealt with it over the years,” he explains. “This is why this is such a big leap forward.”

For Dr. Seth Morgan, a district activist leader who helped drive the act’s passage, the new legislation also feels personal. “As a practicing physician, I was intellectually aware of the limitations in our knowledge about MS,” he said in a news release about the act. “But the impact of MS really hit home when I was diagnosed with it.”

He identifies two “linchpins” to finding a cure for MS: “First, we need to create an environment that will foster the next great medical discoveries by investing more money in research and creating incentives for scientists to remain dedicated to their field. Second, we need more information about the faces of MS and what factors predispose people to MS, which are currently a mystery because of a lack of data.”



**Frank Austin, shown above with Society CEO Cyndi Zagieboylo, is thrilled about the law’s provisions regarding big data.**

Austin couldn’t agree more. He says when he was first diagnosed, he was “not an activist” and “not that kind of guy,” and yet, the more he got involved, the more passionate he became in driving MS research. After what he calls a “unique evolution,” he found himself participating in a congressional roundtable. “Our congressman was taking input on what was happening in research—what government was and wasn’t doing,” Austin remembers. “He asked us all the same question: If we could only get one thing out of the 21st Century Cures Act, what would it be? I responded, ‘Big data,’ and that is the National Neurological Conditions Surveillance System.”

### **Studying the brain**

While the National Neurological Conditions Surveillance System is a big step toward gathering that necessary information on disease prevalence, the NIH’s BRAIN Initiative—which the law is designed to help fund—could help researchers look at the brain itself.

“The BRAIN Initiative provides a forum for targeted research on brain diseases like MS,” says Dr. Robert Fox, managing director of the North American Research Committee on Multiple Sclerosis (NARCOMS), a global registry of 37,500 people with MS, which has provided data to more than 80 published research papers on MS. “And part of that research [involves work] to identify biomarkers for neurological diseases.”

He adds that we have a “great” biomarker for relapsing-remitting MS, namely new lesions and active lesions, which are also “very effective for screening anti-inflammatory therapies to identify which to take forward to phase 3 studies.” However, we don’t have an equivalent biomarker for progressive MS. “That has been a huge impediment to developing therapies for progressive MS,” he says. “We need biomarkers that can evaluate the value of therapies for progressive MS in much shorter, focused trials.”

### **Making it happen**

However, the law’s passage doesn’t mean MS activists’ work is done—yet. The next step is to advocate for funding for the programs in the 21st Century Cures Act. At present, funding for the National Neurological Conditions Surveillance System is scheduled to begin in 2018, but Congress has to allocate and appropriate that funding first.

“We are urging Congress to allocate money to the Centers for Disease Control and Prevention so that the agency can implement the law and build the system,” says Laura Weidner, the National MS Society’s senior director of federal government relations. “There was significant bipartisan support in Congress to establish the neurological diseases data collection system, and we are hopeful that this support continues for the funding needed to get the system up and running.”

“We have to make sure the funding is there for the NIH, the FDA and for the neuro data system in particular,” agrees Austin. “We passed the law! Now there needs to be a lot of action.”

**Marcella Durand is a freelance writer in New York City.**

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