



National
Multiple Sclerosis
Society

Please Support Adequate Funding for the Food and Drug Administration (FDA)

What is multiple sclerosis (MS)?

- MS is an unpredictable, often disabling disease of the central nervous system.
- MS interrupts the flow of information within the brain, and between the brain and body.
- Symptoms range from numbness and tingling to blindness and paralysis.
- The progress, severity and specific symptoms of MS in any one person cannot yet be predicted.

Role of the FDA

- The FDA is the country's pre-eminent public health agency and is responsible for regulating the country's pharmaceutical, biotech and device industries.
- The FDA ensures that drugs and devices are safe and effective for public use.
- The FDA plays a key role in ensuring that older, lower-cost generic products are reviewed and approved for public use.

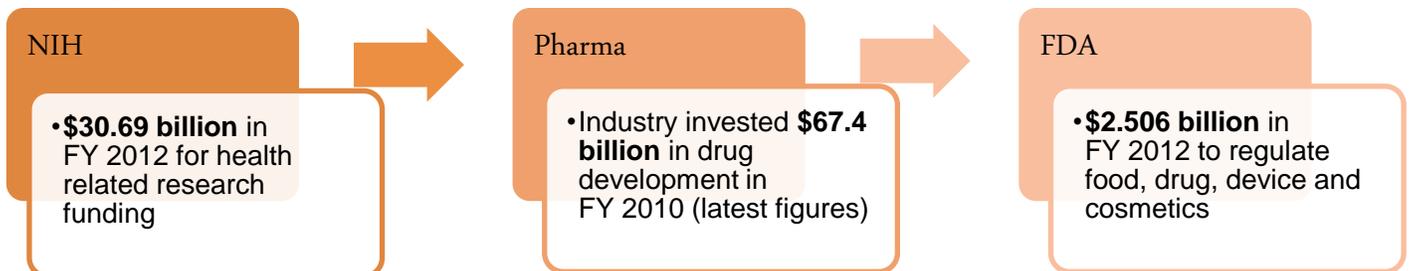
Request

Due to the tremendous impact the FDA has on the development and availability of drugs and devices for individuals living with MS and other disabilities, the National MS Society **supports \$2.6 billion for the FDA in FY 2014.**

FDA's Impact on People Living with MS

- Additional funding from the user fee program allowed FDA to hire more staff and in turn lower the new drug approval time from a median of 19.0 months in FY 1993 to less than 9.9 months today.
- Over the past two decades, the FDA has been instrumental in regulating and approving 10 disease modifying drugs for MS, as well as other drugs that manage symptoms.
- In an effort to lower the cost of biologics, FDA has been granted the authority and is developing a biosimilars pathway. This could potentially benefit those with MS save money as other generic-like biologics are approved in the future.
- The FDA Safety and Innovation Act, passed July 9, 2012, included a number of provisions that could benefit people living with MS including reevaluating the benefit-risk structure and expanded use of biomarkers and patient-reported outcomes in clinical trials.

Funding Levels: An Example of the Drug Pipeline



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In her late 30s, Maria Coté was busy with a full-time career and raising three teenage children. Her husband also worked full-time, and family life was constantly busy with sports, school projects, pets and more. But soon, based on years of unexplained spasticity in her arm, numbness in her toe and ankle pain, Maria's general practitioner referred her to a neurologist. In the months leading up to her 40th birthday, magnetic resonance imaging (MRI) and many other tests added to Maria's already busy schedule. "My neurologist was running all these tests and I had no idea what she was looking for," said Maria. "Then she said it was multiple sclerosis – which I had never heard of – and I asked, 'is that fatal?'"

Maria's neurologist educated her about MS and recommended starting treatment immediately – there were several options, all of which were injected or intravenously infused. Maria tried four different therapies over the next several years, but her fear of needles affected her mental outlook, and the various side effects were intolerable. "I gave up. I didn't take any treatments for about a year," she remembers. When Maria's neurologist mentioned an upcoming clinical trial for an oral medication, Maria was very interested.

In 2008, Maria was selected for a clinical trial of fingolimod. She said that two years in the blind study was "a lot of work" due to scheduled blood draws, MRIs and doctor's visits. However, she says it was worth it. "That I wasn't getting poked once a week made a **big** difference," declares Maria, who was motivated to keep participating. Participation in a clinical trial, which is an integral part of the process required by the Food and Drug Administration (FDA) to approve any new treatments, would allow Maria to help make the first oral medication for MS available to people living with the disease, herself included.

Once the trial was finished, Maria and other participants waited to find out if and when the treatment would become widely available. With data from the trial, the FDA would now determine if the drug was safe and effective. The review seemed to take an extraordinary amount of time; Maria remembers that "people in my support group were anxious to have it approved!" While the review period can still feel lengthy to people like Maria, it has improved in the last 20 years. With additional dedicated funding, the FDA reduced wait time from an average of 19 months in 1993 to less than 10 months today. And the wait was rewarded: People with MS across the country were granted access to fingolimod (brand name, Gilenya) when it was approved by the FDA in September 2010.

Maria now works part-time in information technology, and in 2009 started her own non-profit dog rescue organization. She continues to have symptoms such as vertigo, numbness, pain, "pins and needles" in her legs, and spasticity in her arms. "Stress is a trigger for me," she says. "At times I can't walk, but I keep a positive attitude. I feel like a strong person – not always – but that's what I like to show to the world."

Many people like Maria who experience side effects or who have issues with injections anxiously await approval of each new potential therapy that might slow disease progression. The wait for patients could grow if the FDA is not adequately resourced; cutting current levels of funding would make it extremely difficult for the FDA to achieve even current evaluation and approval times. As the government and country weigh priorities, please remember the millions like Maria who shouldn't have to wait any longer than necessary for potentially life-altering drugs.