



Susan Eik Filstead Stroke & Epilepsy Foundation, Inc.

A cure is at the ♥ of our mission.

July 26, 2004

2004 N-0181 C 20

Nancy Myers
Docket #2004-N-0181
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Critical Path Project and Epilepsy

On behalf of the 2.3 Americans living with epilepsy, including myself, I am writing to encourage members of the Critical Path Project to consider selecting epilepsy as the disease which merits elevation in priority for clinical research.

Unlike thousands of others living with intractable epilepsy, I know how wonderful life can be without epilepsy. I lived 38 years without a seizure, without debilitating side effects of seizure medication and without any horrific brain surgeries.

At the age of 38, I had a catastrophic stroke the morning after the birth of my son. At that time, I couldn't imagine anything worse than not being able to hold my newborn son. I quickly discovered things could be worse when I had my first seizure. After my second seizure I was told I had epilepsy resulting from the significant damage caused by the stroke.

Thus began my ongoing battle with epilepsy. More than my stroke, epilepsy has robbed me of precious time with my son. Fortunately, my son is not aware of all the times I wasn't able to respond to his needs because of hospitalizations, doctor's visits and side effects from seizure medications. My son is now 11 years old and has become painfully aware of the risks I face everyday. Numerous times he has witnessed paramedics rush me to the ER. He has faced the responsibility of calling 911 to get help while I was having a seizure which wouldn't stop. His heroic action saved my life and was acknowledged by the Boy Scouts of America.

Elevating epilepsy to the top of the list for clinical research would offer much needed hope to the individuals and their families struggling with this debilitating disease.

Thank you in advance for your time and consideration.

Sincerely,

Susan Eik Filstead

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Re: Critical Path Proposal and Epilepsy

I am writing this letter in support of epilepsy being placed on the list of diseases/conditions for consideration by the Critical Path Program of the FDA.

You are probably well versed in the scope of this problem: 2.3 million Americans have epilepsy; 55 million worldwide; about 1/3 to 40% of those who have epilepsy do not have any effective way to manage it. In these cases, epilepsy is refractory. It has been suggested that stroke is the leading cause of epilepsy in individuals over 50 years of age.

Numbers pale in comparison to the personal devastation this illness can have on an individual and their family. Epilepsy discriminates against no one, but to know someone with epilepsy is to be privy to the horrendous suffering it causes.

My wife, Susan, has epilepsy. Epilepsy began at 38 years of age the result of a stroke the day after our son was born and the subsequent development of an infection in her brain. The bleed caused damage; surgery to save her life added to the damage (the scaring); the infection left its mark- all eventually leading to epilepsy surgery in hopes of reducing or eliminating the seizures. Surgery was unsuccessful.

Having tried all drugs available to treat epilepsy and having undergone unsuccessful epilepsy surgery – the latest suggestion for addressing the relentless seizing is a functional right hemispherectomy. In short, the proposal is to disconnect the right side of her brain.

The current array of medications are a mixed blessing in that while they may contain or minimize the seizing activity, they leave the person in a “brain fog” – unable to clearly think, concentrate or use cognitive/intellectual faculties to their capacity. Not taking the medication risks uncontrolled seizing (status) and potentially sudden death.

So the choices are: brain fog from medications; status from uncontrolled seizures; or disconnection/removal of parts of her brain. There certainly must be better options.