Legal Opinion Letter

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MULTIPLE SCLEROSIS PATIENTS V. FDA OVERCAUTION

by
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I am a 51-year-old multiple sclerosis (MS) patient. My MS started out 30 years ago with only mild symptoms – numb hands and a slight drop foot on the right. Despite my MS, I was able to remain a productive member of society, working as a paralegal for 26 years at a Los Angeles law firm. I was fairly active, swimming 25 laps a day, hiking, camping, and dancing.

Due to the worsening cognitive problems from my MS, however, I had to retire on disability in 2001, and in the past two years, my symptoms and disability have progressed very rapidly. MS has taken away my ability to work and destroyed my finances. I don't want anyone's pity, though. I just want to be able to take the medicine that will help me fight my MS, and which the Food and Drug Administration (FDA) is keeping out of my hands and the hands of thousands of other desperate patients while decision-makers ponder and dawdle.

A drug called Tysabri, approved by the FDA in November of 2004, stopped my attacks and improved my condition. My doctor and I discussed the available therapies and I tried many of them, but my MS was progressing despite those medications. Tysabri was the first and only therapy that helped me. Within two weeks of my first infusion, I started to notice that my balance and speech were improving. I was thrilled to be able to walk with just a cane, with no limp, and to be to able speak normally for the first time in over a year. I was delighted. Then came the bombshell: The manufacturer, under pressure from the FDA, took it off the market four months later. Tysabri was thought to have caused PML (progressive multifocal leukoencephalophy), a fatal brain disease, in three patients – three patients out of *8,000* patients receiving the medicine.

No drug is without risk – including aspirin – and Tysabri is no exception. The *New England Journal of Medicine* placed the risk of developing PML at just 0.01%, or one in a thousand. It isn't even certain that Tysabri was responsible in these cases, since two of the patients with PML had been treated with Tysabri in combination with another medication and the third already had a compromised immune system from other medications. *Not one patient with a confirmed diagnosis of MS and a non-compromised immune system who received Tysabri as their sole therapy was ever reported to have contracted PML.*

Lauren Roberts is a multiple sclerosis patient living in California.

In a situation like this, who should weigh the risks vs. benefits for individual patients and make the decisions? We, the patients, in consultation with our doctors? We, who have our lives, health, and independence at stake? Or FDA officials who have nothing more at stake than the prospect of an unpleasant congressional grilling if they make the wrong decision?

Well, you can guess how the FDA has come out on *that* question. After Biogen Idec Inc. and Elan Corp., Tysabri's manufacturers, petitioned the FDA for reapproval of the drug, the FDA disregarded the unanimous recommendation of its own Advisory Committee in March in favor of reapproval. Instead, the FDA granted itself a 90-day extension to consider the Tysabri application further. How many more extensions the FDA will give itself is anyone's guess.

MS progresses on its own timetable, not the FDA's. In the course of 90 days, there will be, on average, 2,160 more people who hear the words, "You have multiple sclerosis." My own MS continues to ravage my body. I now have optic neuritis, zero balance, increased muscle cramps (legs and hands), slurred speech, and an overall decline in strength and coordination. My legs are now useless. I have lost the ability to write legibly or cook for myself and I can barely feed myself.

The worst damage that MS inflicts is physical deterioration of brain tissue. The longer Tysabri remains off the market, the more brain damage that MS patients like me will suffer – possible permanent damage that no drug can reverse. This, in turn, will drive up the cost of health care. With so many younger MS patients joining us and the current availability of largely ineffective therapies, the unmet medical needs of MS patients are staggering.

I know firsthand of the benefits of Tysabri. From what I've experienced (and many others have experienced), and from the judgment of clinical researchers, supporting data of safety and superior efficacy, including improvements in the quality of life of the patient, it is a travesty that the FDA is withholding this drug from us. A federal law intended to protect patients from quack cures and dangerous compounds has been perverted to the extent that it is now wielded as a sword against the very patients it was meant to protect. It is literally a case of paralysis by analysis – their analysis, my paralysis.

In short, the small risk from Tysabri pales in comparison to the risks created by *not* having Tysabri available to us as a choice. Patients deserve to have access to Tysabri *now*, not later, after months of further progression of their disease. As for me, I am willing to take that risk, in exchange for having an improved quality of life, *my* life, back.

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