Testimony before the House Select Committee on Step Therapy

Submitted to House Select Committee on Step Therapy
Representative David R. Lewis, Chair

February 24, 2016

Submitted by John Scagnelli, MD,
[redacted]

Good Morning Chairman Lewis and Members of the Committee. Thank you for the opportunity to give you my perspective on how Step Therapy affects the practice of Neurology and more specifically the field of Multiple Sclerosis.

I am Dr. John Scagnelli of Raleigh, NC. I am a board-certified, practicing neurologist and multiple sclerosis specialist for 6 years.

Today I am representing myself, Raleigh Neurology Associates, the National Multiple Sclerosis (MS) Society, the North Carolina Neurologic Society and the Alliance for Patient Access. AfPA is a national network of physicians dedicated to advocating on behalf of patient access to approved therapies and appropriate clinical care.

I have a Bachelors in Science from Cornell University and received my MD from The University of Miami. For the last four years I have been in practice here in Raleigh, North Carolina at Raleigh Neurology Associates where I am the director of the Multiple Sclerosis Clinic. At Raleigh Neurology, we have the largest MS clinic in the state with over 3,000 patients suffering from this disease. Step therapy affects our patients and our practice greatly.

Today, I will explain to you how Step Therapy is dangerous to patient's lives, damaging to the physician-patient relationship and costly to the medical system and to individual practices.

As you are aware and will hear from other providers today, step therapy, also known as "fail first," is a process used by health insurers to control costs. It requires patients try one or more medications specified by the insurance company, to treat a health condition. Patients must then fail on the medication(s) before allowing a "step up" to another medicine. In theory, an insurer's step therapy protocols do not prevent prescribers from writing prescriptions as they see fit.

However, in practice, patients are not able to afford prescriptions on their own. Therefore, step therapy gives the insurer a prominent role in determining patient's treatment, a role they should not be playing.

As this Select Committee studies step therapy and develops policy to improve access to treatments, I would like this committee to understand how step therapy protocols interfere with the treatments of Multiple Sclerosis (MS) patients, in particular.

Multiple sclerosis is a chronic autoimmune disease of the central nervous system. There are thirteen FDA approved medications for the treatment of this disease. These drugs have shown efficacy in stopping damage in the brain and slowing the development of disability in patients from the earliest stages of this disease. These medications each act differently in the immune system. Often we will find patients either responding to or tolerating only one of these medications. It is for these reasons that the National MS Society and the American Academy of Neurology have issued statements recommending initiation of MS treatment at the time of diagnosis, no restrictions on medication selection and switching medications without access restriction if a particular drug is failing.

When patients are required to cycle through and document a "step" (or in some cases, more than one step) this delays treatment. This may affect patients' ability to immediately start treatment, or their ability to continue their current treatment. In MS, delaying access to the right treatment can result in irreversible disability.

I have seen first-hand the harmful effects of Step Therapy in patients. One of my patients, a 45 year old woman, was not tolerating her treatment with a medication called Tysabri. She came to me in October of 2013 and we decided to switch her from Tysabri to Gilenya. Because of Prior Authorization and Step Therapy we had to go through months of appealing, faxing and re-faxing paperwork. In February she was treated for a disease relapse, presenting with cognitive and walking difficulty. In March she returned with severe cognitive issues, right sided weakness and inability to speak. She required multiple admissions to the hospital and multiple treatments including chemotherapy before we could stop her MS from progressing. If you look at exhibit XX, you can see the progression of abnormalities seen on her Brain MRI. This was avoidable.

Now this woman, who was previously working, is completely disabled, cannot work, drive a car or live independently.

In addition to being unsafe, the process of Step Therapy is costly to the medical system, individual practices and in the end ineffective at forcing physicians to follow such a rubric.

My practice is the largest group of neurologists in the state of North Carolina. We see over 150,000 patients per year. We currently have 3 full time employees whose only job is to deal with prior authorizations and appeals regarding step therapy. Additionally, my nurses estimate that about 25% of their time is spent reviewing this paperwork and discussing this issue with patients. Our providers spend hours each week preparing appeal letters and engaging in so-called "peer-to-peer" discussions with medical professionals employed by insurance companies. Adding to the scope of this is that all of this paperwork has to be printed, faxed, and in many cases re-faxed multiple times, phone calls are cumbersome – often requiring multiple transfers to get to the correct individual. Lastly, the peer-to-peer procedure is a complete farce because none of the so called "peers" have experience in neurology, let alone subspecialty training in multiple sclerosis. This process requires an enormous amount of time - such time that would be spent with patients.

Step therapy has no basis in the science of medicine. Each insurance company has its own formulary and as a practice we deal with over 100 different insurance companies! Step therapy policies receive little oversight and are upheld with minimal proof by insurers of the effectiveness of their step therapy policies in ensuring quality patient care.

This causes rather inane situations, such as the current case with Avonex. Avonex is a medication that has been used effectively for MS since 1996. Avonex was a "First Step" choice for most insurance companies until January of 2016. We had scores of patients on this medication for years now receiving letters that in January 2016, it is no longer a preferred medication. Let me be clear, there is nothing in existence suggesting Avonex was no longer an effective treatment, this was a business decision and did not take into account patient stability on the medication.

In response to this, we at Raleigh Neurology have been appealing, writing letters and engaging in Peer to Peer discussions. We have not lost a single case and our patients have ultimately, after months of aggravation and anxiety been able to stay on Avonex. Why did we have to go through this much work to keep patients on their current and effective medication?

Adding to the frustration in this case, patients were told they would have to come off Avonex in November 2015, however, we unable to appeal this decision until the last week of December because the insurance companies did not have the new formularies in their computers until that time. This affected our relationship with our patients, who were concerned that we were not working on their appeals in a timely fashion. This decision forced the practice and our patients to jump through unnecessary hoops and caused a lot of aggravation. The outcome of all of this frustration has been the status quo – not one patient has ultimately had to change their medication.

The Avonex story is not alone. We have an 85% success rate in winning our case for breaking step edits. While this is great, realize that this has come at the expense of reams of paperwork, hundreds of hours of work and many more hours of patient and provider frustration. Why are we successful at winning these cases? We are fortunate to be a large enough practice to employ 3 full time employees to do all of this work – this is not the case for the average neurologist out there – they simply cannot afford to fight these battles and they should not have to.

Therefore, I would ask you to think about policies that would offer clear pathways for physicians to make reasonable decisions about care for their patients. This can be achieved by limiting the scope of step therapy.

What is also needed is a streamlined and uniform process - both for initial approvals of the patient's medication as prescribed and requests for exceptions to a step therapy process. An expedited, clear, transparent and uniform process for exceptions would vastly improve patient care and limit time spent by providers and their staff.

The positive outcome of such guidelines is: patients are not delayed in accessing appropriate treatments and ineffective treatments are not prolonged. Both delay and ineffective treatments can cause significant disease progression in MS patients.

To conclude, I believe you would find the support of many providers for legislation that places the patient-physician relationship first and allows physicians and their patients the ability to determine and pursue the best course of treatment.

I wish to thank the members of this committee for their deliberation of this critical issue and dedication of time to improve the lives and living conditions of patients in North Carolina.

Thank you for the opportunity to share my experience with this committee today.

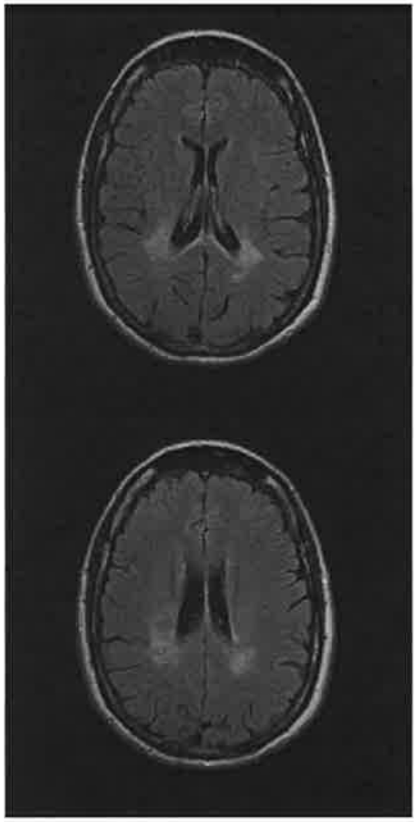
Respectfully Submitted,

John R. Scagnelli, MD

Neurologist

Raleigh Neurology Associates

Patient SB



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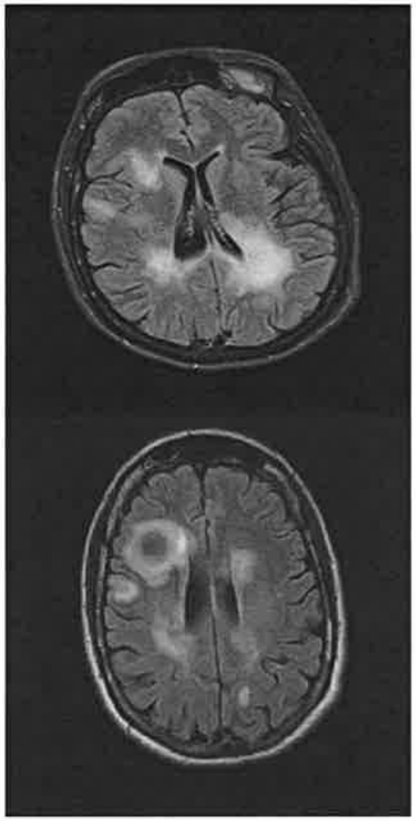

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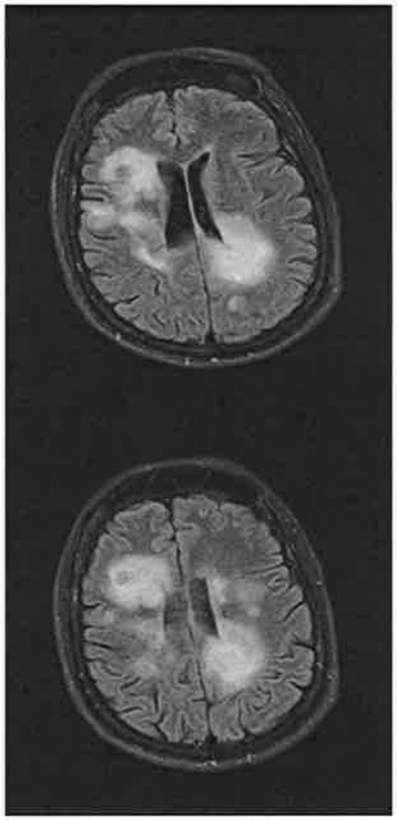

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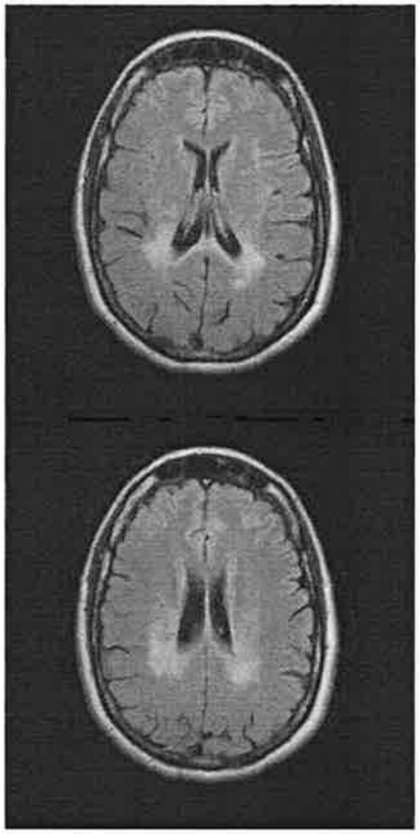
Patient SB



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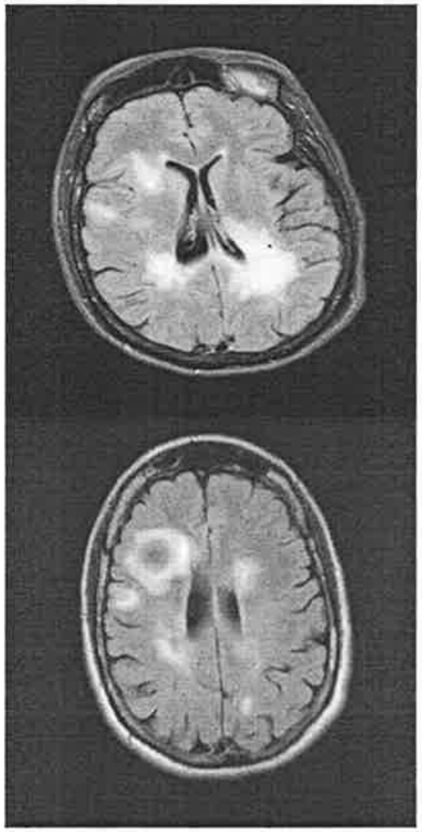

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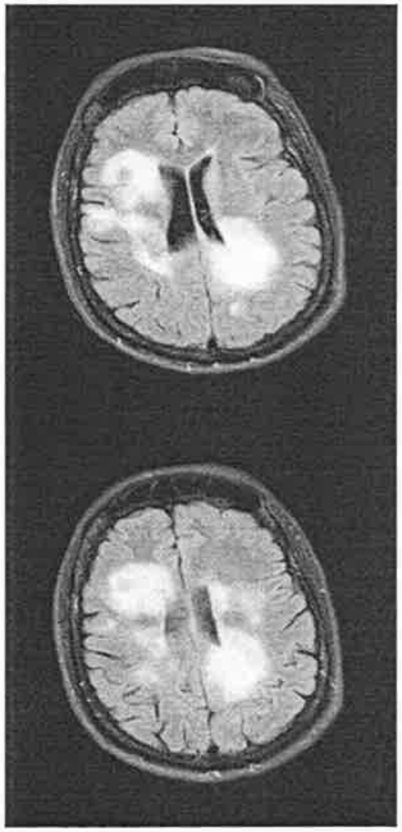

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