National MS Society

March 5, 2006

An open letter to the membership of the National Multiple Sclerosis Society from Joyce Nelson, President & CEO

People with multiple sclerosis must have more choices for safe and effective treatments. The National MS Society is relentless in our pursuit of this goal.

It is our strongest hope that the FDA, after considering the safety issues associated with Tysabri®, will determine that such issues are manageable and that Tysabri can return to the market.

To that end, the National Multiple Sclerosis Society has worked on multiple fronts to assist the FDA with its work:

We advocated for the speediest possible review of Tysabri. As a result, the FDA accelerated the process to the fastest extent the law would permit.

In order to assure that the FDA received feedback from every individual who wished to be heard on this issue, we dedicated a month-long front-page link from our website, which attracts over 14.5 million visits a year, to the FDA comment page. We also provided information on submitting testimony and participating in the hearings in person. As a result of the outpouring from all comments received, the FDA extended its hearing proceedings from one day to two, and expanded its usual one to two hour public comment period to six.

In order to make sure that the hopes and concerns of people with MS were being heard in the FDA process, in December 2005, the National MS Society commissioned an online survey of people with MS to better understand their views concerning Tysabri and its possible return to market. The Society shared the comprehensive results of that survey with the FDA, who will include these results in their deliberations.

In order to assure that the best possible reviewers serve on the FDA panel, the National Multiple Sclerosis Society met with FDA officials and submitted a recommended list of reviewers who, in our opinion, bring to the table a comprehensive and balanced understanding of the issues associated with the return of Tysabri to the market. We do not know if any of these candidates will ultimately sit on the review panel, but the FDA accepted these recommendations for consideration.

Dr. John Richert, Vice President of Research and Clinical Programs, will present testimony at the hearings March 7-8 and will attend the full deliberations, along with other Society officials. Dr. Richert's statement will be made available on our website after his testimony on March 7.

Since Tysabri's initial introduction to the market and its subsequent recall, the Society has provided the most current and comprehensive information available to its membership on this important issue.

During this time, a number of Society members have become actively engaged in advocating for specific outcomes. We encourage and support each of our members in their right to take an individual stand on this issue, and we support the rights of members to form ad hoc groups to support their opinion.

We have maintained respectful communications with these members. For example, as a result of the work of MS Patients for Choice, Society members had the opportunity to register for the webcast of the hearing at a fraction of the full cost.

The Society has a responsibility to give voice to all people affected by MS—those hoping for more rapid availability of effective new treatments and those concerned with having the safest treatment choices. Thus, despite the urgings of individuals, industry representatives and ad hoc groups representing all points of view on this matter, the National Multiple Sclerosis Society has not, and will not, dictate to the FDA what its answer should be.

Having provided the best possible information and feedback to the FDA, we support the process that has been designed to review Tysabri. If, after this safety review is complete, the FDA recommends Tysabri's return to the market, we will applaud the addition of this treatment to our arsenal. If the FDA does not approve Tysabri's return to the market, or if it does so with significant restrictions, we will work tirelessly to find ways to satisfy the safety concerns so that more effective treatments can be readily available for the benefit of people with MS.