Natalizumab-associated melanoma: A report of 139 cases from the southern network on adverse reactions (SONAR)

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Natalizumab is an effective immunosuppressive therapy for multiple sclerosis that received its initial FDA approval in 2004. Its most notable toxicity is progressive multifocal leukoencephalopathy (PML); an opportunist infection that is the focus of an FDA mandated Registry (the Tysabri Outreach Commitment to Health (TOUCH) Outcomes Registry). The Southern Network on Adverse Reactions identified a fatal case of Natalizumab associated urethral melanoma and undertook an extensive evaluation of all cases of Natalizumab-associated melanoma included in the FDA's Adverse Event Reporting System (FAERS) (between 2005 and 2014). Characteristics of these patients and report quality were analyzed. Report quality was based on a 15 point scale of various components. The mean patient age at the time of diagnosis of melanoma was 46 (s.d. 11). Seventeen patients were diagnosed with cutaneous melanoma developing in non-sun-exposed areas. We found that cases reported through the TOUCH registry were of lower quality (mean score 7.7) compared to others that reported outside of the USA (mean score 8.5, p<0.008). Our findings suggest that in the United States, the TOUCH Registry should be expanded to require clinicians to report details of Natalizumab-associated melanoma, an opportunistic illness that frequently develops in immune-compromised persons. Also, the FDA-approved product label for Natalizumab should be revised to include information on occurrences of melanoma among Natalizumab-treated MS patients, particularly those who have cutaneous nevi prior to Natalizumab initiation. Natalizumab-treated MS patients and their physicians should be vigilant for changes in nevi's appearances and development of new cutaneous lesions (particularly in non-sun-exposed cutaneous areas).

Biography
Virginia Noxon is a PhD candidate at the University of South Carolina in Clinical Pharmacy and Outcomes Sciences. She joined SONAR last year and contributed to several of their publications over the past year.

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