SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

January 26, 2015

Joseph Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

**Re: The Drug Enforcement Administration's Classification of DaTscan™ (I-123 FP-CIT Ioflupane) as a Schedule II Substance Under the Controlled Substances Act (CSA) – Docket No. DEA-394**

Dear Mr. Rannazzisi:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) appreciates the opportunity to respond to the Drug Enforcement Administration's (DEA) request for comments on amending its regulation to waive the registration requirements for persons licensed or permitted to administer DaTscan™ (ioflupane iodine-123 injection). SNMMI's more than 18,000 members set the standard for nuclear medicine through the creation of clinical guidelines, sharing evidence-based medicine through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy research and practice. SNMMI is pleased to offer comments on specific topics detailed below.

**Benefits of DaTscan™**

On January 17, 2011, the Food and Drug Administration (FDA) approved DaTscan™. DaTscan™ is a single photon emission computed tomography (SPECT) radiopharmaceutical used to differentiate between essential tremor and Parkinsonian syndromes, including Parkinson's disease, progressive supranuclear palsy, and multiple system atrophy. Scanning with ioflupane iodine-123 aids doctors by differentiating benign tremor from tremors caused by Parkinsonian syndromes, with significant implications for both clinical therapy and predicted prognosis. In published clinical trials of the ability to detect a true Parkinsonian syndrome, DaTscan™ has been shown to be a very accurate imaging test, with a sensitivity of 78-97% and a specificity of 93-100%.

**Risks of Diversion or Abuse to DaTscan™ Patients**

SNMMI respects the DEA's mission to prevent, detect, and eliminate the diversion of controlled substances under the Controlled Substances Act (CSA). However, no potential for substance abuse has been observed to date with DaTscan™. DaTscan™ was approved in Europe in 2000, and there have been no reports of any diversion in the 15 years since. DaTscan™, as well as other commonly used radiopharmaceuticals, contains an extremely small amount (non-pharmacologic dose) of active drug substance in the vial. An entire vial of DaTscan™ contains 0.325 micrograms of ioflupane iodine-123, which is impossible to convert back into cocaine. In order to produce any pharmacological effect, a DaTscan™ patient would need 6,000 injections, which is an extremely unlikely occurrence because ioflupane iodine-123 is manufactured at a maximum of 80 doses per day. Furthermore, DaTscan™ is not available to patients through prescription, further eliminating the potential for abuse.

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**Schedule II Classification Limiting Patient Access**

In March 2014, the Parkinson's Action Network reported that only 200 out of a potential 5,000 imaging centers administer DaTscan™. For various reasons, including the DEA's license requirement, smaller facilities are unwilling to administer DaTscan™ to their patients. Due to the small number of facilities willing to administer DaTscan™, patients have to travel an average of 90 minutes to be scanned in larger medical centers. DaTscan's status as a Schedule II substance is preventing patients from receiving appropriate care. With more than 90,000 Americans living with an uncertain diagnosis, allowing greater access by patients by decontrolling DaTscan™ would not only allow earlier detection of patients suffering from Parkinsonian syndromes, but also decrease the number of misdiagnosed illnesses and their associated costs.

SNMMI appreciates the opportunity to comment on this regulation. The Society is ready to discuss any of its comments or meet with the DEA on the above issues. In this regard, please contact Sue Bunning, Director, Health Policy and Regulatory Affairs, by email at sbunning@snmmi.org or phone at 703-326-1182.

Respectfully Submitted,

Virginia Pappas, CAE
Chief Executive Officer