



June 30, 2015

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODXL
8701 Morrisette Drive
Springfield, Virginia 22152

Submitted Electronically

Re: Docket No. DEA-415; Schedules of Controlled Substances; Removal of [123I]Ioflupane from Schedule II of the Controlled Substances Act

The American College of Radiology (ACR)—a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists— supports the removal of [123I]Ioflupane (DaTscan) from schedule II of the Controlled Substances Act. We believe this action will improve patient access to this important diagnostic radiopharmaceutical, thus improving the quality of care our patients receive.

DaTscan was approved by the US Food and Drug Administration (FDA) in January 2011 as a radiopharmaceutical agent intended for use with single photon emission computed tomography imaging (SPECT) for the detection of dopamine transporters in the brains of adults with suspected Parkinsonian Syndromes. The first FDA-approved diagnostic agent to help physicians evaluate neurodegenerative movement disorders, DaTscan assists in the visualization of dopamine transporters in the brain and may help decrease diagnostic uncertainty in patients with suspected Parkinson's, especially to differentiate idiopathic Parkinson's syndrome from essential or drug induced tremor, a feature that can be critical in selecting the appropriate management for these patients. There is also evidence to suggest that DaTscan may help doctors predict which patients with Parkinson's are at risk of more severe disease affecting motor and non-motor symptoms.

Indeed, the FDA granted DaTscan Priority Review due to an unmet clinical need for an imaging agent to assist physicians in managing patients according to their dopaminergic status. With earlier and more accurate diagnoses and characterization of Parkinson's, doctors are better equipped to anticipate and treat symptoms early in the course of the disease. However, under Schedule II status, clinical access to DaTscan has been seriously impeded, with only a fraction of sites in the country currently administering it.

As DEA recognizes, this impediment to access is certainly not warranted by the risk for abuse posed by DaTscan. With only miniscule amounts of ioflupane in the product, as many as 6000 injections of the agent would be required to induce a pharmacologic effect. This, along with the fact that the agent

contains a radioactive material, renders the potential for abuse as a narcotic agent a virtual impossibility. As further evidence, Europe has a decade of experience with the agent without the type of controls currently imposed by DEA, and there are no recorded instances of product abuse in the European medical literature.

ACR appreciates DEAs actions in declassifying this important diagnostic tool. Please feel free to contact Gloria Romanelli, Senior Director, Legislative and Regulatory Relations at ACR, to discuss this issue further. She can be reached via e-mail at gromanelli@acr.org or via phone at 703-716-7550.

Sincerely,



Bibb Allen, Jr., MD, FACR
Chair, Board of Chancellors
American College of Radiology



M. Elizabeth Oates, M.D.
Chair, Commission on Nuclear Medicine
and Molecular Imaging
American College of Radiology