New drug for use in bone scans approved

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The FDA has approved a New Drug Application (NDA) from the National Cancer Institute (NCI), part of the National Institutes of Health, for a new strength of a previously approved drug, Sodium Fluoride F18, for use in bone scans. In contrast to Technetium-99m (Tc-99m), which has been the only approved radioactive tracer for bone scans, Sodium Fluoride F18 is not subject to the supply problems that have led to recent nationwide shortages of Tc-99m.

Many diagnostic imaging tests, including bone scans that utilize Single Photon Emission Computed Tomography (SPECT), require the use of Tc-99m. Bone scans are essential tools in the diagnosis of bone metastases in cancer patients, especially those with cancers (such as breast and prostate) that tend to metastasize to bone. Sodium Fluoride F18 was approved in 1972 but withdrawn in 1975, when the less expensive tracer Tc-99m became available. Tc-99m is derived from an isotope called molybdenum-99 (Mo-99), which is made mostly in highly enriched uranium nuclear reactors. Because both Mo-99 and Tc-99m have fairly short half-lives (66 hours and six hours, respectively), these drugs cannot be stockpiled.

Seven nuclear reactors worldwide currently produce Mo-99 for medical use, with much of the United States' supply coming from a nuclear reactor in Canada that has had frequent outages, the latest one lasting more than a year. Although Sodium Fluoride F18 is more expensive than Tc-99, it can be produced in medical cyclotrons, which are available at many academic universities and commercial suppliers in the U.S. This drug also provides better images because it uses Position Emission

Tomography (PET) instead of SPECT imaging, allowing for improved, earlier detection.

The previous strength of Sodium Fluoride F18 was discontinued for market reasons, not for reasons of safety or efficacy. NCI hopes that multiple companies and institutions will submit Abbreviated New Drug Applications (ANDAs) so that generic versions of the drug can be produced, allowing for a reduction in cost. A decision by the Centers for Medicare & Medicaid Services regarding coverage for Sodium Fluoride PET scans was posted on February 26, 2010. It allowed Coverage with Evidence Development (CED), and a formal registry is being established by the National Oncologic PET Registry (NOPR) that should help facilitate this coverage.

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