CORAR

Council on Radionuclides and Radiopharmaceuticals, Inc.

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Henry H. Kramer, Ph.D., FACNP
Executive Director

Commissioner Mark B. McClellan
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner McClellan:

CORAR COMMENTS TO FDA ON PRUSSIAN BLUE

The Council on Radionuclides and Radiopharmaceuticals[1] (CORAR) is seriously concerned about a recent posting (January 31, 2003) on the FDA's Center for Drug Evaluation and Research website[2] linking Tl-201 with Cs-137 and dirty bombs. Tl-201 is a diagnostic radiopharmaceutical that has been used for 3 decades for heart scans that improved the treatment of patient with heart problems without adverse patient reactions. Linking any diagnostic radiopharmaceutical with the physical harm that may result from a dirty bomb in a Government announcement or publication gives the impression that the Government considers any amount of radiation, regardless of the amount, harmful. The technical basis that associates Tl-201 with Cs-137 and dirty bombs was not revealed in the posting. Any declaration by any Government agency should be based on facts in order not to stimulate unwarranted public panic, especially about a proven aid in the treatment and management of the public's health.

This letter is to clarify CORAR's position that the FDA announcement is based on faulty or incomplete reasoning, contains numerous omissions of fact and inaccuracies and is potentially damaging to the practice of Nuclear Medicine. Consider the following facts:

1. Thallium-201 has a short 73-hour half-life. Therefore, this radionuclide cannot be stockpiled and accumulated over time. Cesium-137, on the other hand, has a half-life of 30 years.

2. Thallium-201 is routinely administered to people undergoing nuclear medicine scans at activity levels of 3-5 millicuries, with no detrimental effects. The mass of thallium involved in a 3 millicurie dose is less than 20 millionths of a gram. Any toxic effects from non-radioactive thallium require masses on the order of a thousand times higher. It would take more than 1,000 patient vials in a single configuration to create an amount of thallium that may have a toxic effect on a single person. This is a physical impossibility.

[1] CORAR members include the major manufacturers and distributors of radiopharmaceuticals, radioactive sources and research radionuclides used in the United States for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

[2] http://www.fda.gov/cder/graphics/CDER-LogoNu1inch.JPG

[3] Taken from the EPA chemical profile for thallous chloride located at the following web URL: http://www.epa.gov/swercepp/ehs/profile/7791120p.txt

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3. The mass of thallium-201 produced by a major radiopharmaceutical manufacturing facility is less than 1 milligram per week. The entire industry output of thallium-201 in a year has a mass of just 0.13 grams. Based on an LD_{50} value of 24 mg/kg[3], the mass of thallium that would pose a 50% risk of death for a 70 kg adult would be 1.68 grams. It would take the entire industry output for 13 years to produce this much mass of thallium-201.

4. Due to it's short half-life, relatively low hazard radiations, and rapid biological excretion, thallium-201 has a very low radiotoxicity when introduced internally to a human. Such facts assist the NRC in establishing occupational intake limits which lists thallium-201 as two hundred times less restrictive than cesium-137 (20,000 microcuries for thallium-201 vs. 100 microcuries for cesium-137).

5. Almost all thallium-201 is shipped to the end-users or local radiopharmacies immediately after manufacture, in single or multi-dose vials containing anywhere from 15 to 60 millicuries of activity at the time of manufacture. To intercept these shipments and combine hundreds to thousands of vials quickly enough to make and deliver any kind of a dirty bomb before the thallium-201 decayed away is extremely implausible.

6. Although it is interesting that prussian blue can be used to discorporate thallium, and theoretically possible to use it to hasten the removal of thallium-201, it has never been used in the treatment of patients.

Based on the above data, it is implausible that anyone would considering using thallium-201 for a dirty bomb, due to it's short half life, limited supply, very low radiotoxicity, and rapid biological excretion. CORAR strongly recommends that the FDA modify their announcement to remove thallium-201 from the list of potential ingredients of a dirty bomb. It does no one any good, but only leads to public panic, to pick a demonstrated useful radiopharmaceutical as a harmful agent as well as having a government agency implicitly indicate that all radiopharmaceuticals are harmful and should be avoided.

Sincerely yours,

L R Smith

Leonard R. Smith, CHP
CORAR Chairman