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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: (Docket No. 00D-1681) Revisions to FDA Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies – Comments

To whom it may concern:

The December 2000 Draft Guidance document on use of potassium iodide (KI) contains new information that wasn't available when formulating the 1982 guidance. Based on the new information from Chernobyl, FDA can, with a greater degree of confidence, balance the potential risks and benefits of using KI as a thyroid blocking agent in radiation emergencies. There is no question that in controlled situations use of KI as recommended by FDA is safe and provides a health benefit. However, an analysis of the clinical questions based on the Chernobyl accident may not answer all the questions that need to be dealt with when considering use of KI for the general public.

- The guidance recommends that KI be made available for the early phase of an accident to prevent uptake by inhalation. Availability of KI in the early phase of the Chernobyl accident would have accomplished little, since the vast majority of radioiodine uptake resulted from ingestion in the weeks after the release.

  The early response philosophy of nuclear plant emergency planners in the United States focuses on early precautionary evacuations prior to significant releases taking place. This philosophy obviates the need for use of KI to prevent inhalation during a release.

  Distributing and administering KI to the general public before or during a plant release is impractical and will risk causing greater exposure to the public. Few people will have predistributed KI at hand and many will waste time looking for it when they should be leaving. Attempts to distribute KI to all individuals during evacuation risk disrupting the orderly movement of people out of the area. Some individuals will not evacuate because they feel they are protected by the KI. Providing KI to people at reception centers or shelters will reduce exposure for only a small percentage of the population at risk..

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Longer term response will include interdiction of contaminated food products, milk, water and other drinks. Chances for intakes of radioiodine similar to those at the Chernobyl incident are vanishingly small.

- The recommendations reflected in the table showing thresholds and recommended dosages of KI are far too complex to be effectively communicated to the public. Attempting to communicate the myriad of dosage recommendations during an emergency will cause confusion and inappropriate administration of KI. Tablets are not available in the lower dosages, and there is no easy method for dividing the tablets to create the recommended dosages.

  The guidance recommends that pregnant or lactating women continue to take a full dose (130 mg.) daily until there is no longer a risk of uptake. Yet the document warns that potential problems may arise if pregnant or lactating women take KI for extended periods of time. The guidance with respect to pregnant or lactating women needs clarification, but that will only add to the already excessive complexity of the recommendations.

- The populations studied near Chernobyl and in Poland to determine thyroid cancer risk and side effects of KI, respectively, are probably more homogeneous than populations around most U.S. nuclear plants. There may be ethnic and racial variations in susceptibility to radiation induced thyroid cancer and possible reactions to KI. The implications of the diversity factor are difficult to predict, but the resultant uncertainty should be addressed in the analysis and recommendations.

- U.S. nuclear power plant design and the design of the Chernobyl reactor are so dissimilar that the nature and magnitude of the release at Chernobyl is not indicative of what is probable or even possible in a severe accident at a U.S. plant. Recommendation that KI be made available to the public for the emergency phase of an accident based on events at Chernobyl is inappropriate.

In summary, we feel FDA needs to simplify their guidance and reconsider their recommendation to make KI available to the general public during nuclear power plant accidents. The analysis and recommendations also need to take into account some complicating factors that may not have been considered.

Thank you for the opportunity to comment on the guidance. If you have questions about our coments, please call John Lorenz (608) 267-4794.

Sincerely

John Lorenz

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