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October 31, 2005

Dr. Robert G. Claypool
Deputy Assistant Secretary
U.S. Department of Health and Human Services
Office of Public Health and Emergency Preparedness
200 Independence Ave., SW, Room 638-G
Washington, DC 20201

Dear Dr. Claypool:

I am writing to express concern regarding the "Federal Guidelines for Requesting, Stockpiling, Distributing Potassium Iodide (KI) from the Strategic National Stockpile", issued by the Office of Public Health Emergency Preparedness, HHS, on August 29, 2005.

As you know, the DHS guidelines have been issued to implement the requirements of Section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. I was the author of the amendment which added this Section to the bill. The Markey amendment requires that the President shall make available to State and local governments sufficient quantities of KI to provide for the population within a 20 mile radius around a nuclear power plant. Further, the law requires that the President establish guidelines for the stockpiling of KI tablets and for the distribution and utilization of KI tablets in the event of a nuclear incident.

The bill to which this amendment was attached passed with overwhelming support in both houses of Congress, as illustrated by a vote of 425-1 in the House on May 22, 2002 and by 98-0 in the Senate on May 23, 2002. Support for the amendment and the distribution of KI was broad and bipartisan in nature. The amendment was accepted by the Chairman of the Energy and Commerce Committee, Rep. Tauzin, and approved by voice vote. It was accepted by the Senate conferees, following bipartisan consultations and discussions of which I was a part. The President also supported the idea, as was apparent in a White House statement issued on June 6, 2002 announcing the President's proposal to create a Department of Homeland Security. At that time, the President's proposal stated that KI is a "crucial" drug, and that "one Department would be responsible for distributing Potassium Iodide to citizens exposed -- no matter where they live. There would no longer be an artificial ten-mile barrier to treatment." The President signed the Bioterrorism bill into law on June 12, 2002. In light of that history, I am perplexed by the bureaucratic footdragging and resistance that has characterized the Administration's subsequent implementation of my amendment.

Evidence for the efficacy and safety of KI in the event of a nuclear incident is clear. The 1999 Guidelines for Iodine Prophylaxis following Nuclear Accidents published by the World Health Organization state that "Stable iodine administered before, or promptly after, intake of radioactive iodine can block or reduce the accumulation of radioactive iodine in the thyroid." Furthermore, the U.S. Food and Drug Administration in their guidance document entitled "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies" states that "KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified conditions of use, and thereby obviate the risk of thyroid cancer in the event of a radiation emergency". KI pills are available for approximately 18 cents a pill, making them a cheap and effective way to protect our citizens.

Timeline for implementation of Public Law 107-188

The first step in implementing the law was for the President to ask the National Academy of Sciences (NAS) to conduct a study to determine the most effective and safe way to distribute and administer potassium iodide tablets on a mass scale. It took the President many months to even request the NAS study, and the NAS consequently did not even begin the study until March 27, 2003, which meant that the final NAS report was not issued until in January 2004.

During the delays in implementation, I twice wrote the President to request information on what actions were being taken to implement the requirements of my amendment. The first letter was sent on February 28, 2003. I never received a response to this letter. I subsequently wrote the President again on April 7, 2004.

My staff also contacted the White House staff to request information about who had been placed in charge of carrying out this program, and they indicated that my letter had been referred to the Department of Homeland Security (DHS) for response. When my staff contacted DHS, however, the DHS staff could not identify who within the Department actually was responsible for the program. My staff then contacted HHS to inquire into the status of implementation of my amendment, at which time they were provided a copy of HHS's draft KI guidelines. My amendment required that the guidelines be issued not later than one year after the date of enactment of the Act, making the draft guidelines over 18 months late.

On December 14, 2004, I sent a letter to then-Secretary Tommy Thompson, responding to the draft guidelines. In this letter I pointed out seven major flaws in the HHS Draft Guidelines. These flaws were:

- 1) The draft guidelines failed to follow the requirements of the law.
- 2) The guidelines did not even mention the threat of terrorism.
- 3) Basic information regarding the use of potassium iodide was omitted.
- 4) The guidelines appeared to have ignored the recommendations of the NAS.
- 5) The guidelines contained misleading or incomplete information.

- 6) HHS did not consult with local governments or other experts as it developed its guidelines (as required by the amendment).
- 7) HHS has not provided sufficient time for the public to review and comment on the draft guidelines.

On December 14, 2004, I also finally received a response to my second letter (April 7, 2004) to the President about the KI program. This response came from Stewart Simonson, Assistant Secretary for Public Health Emergency Preparedness in HHS. Again, I found the Department's response unsatisfactory, and in some places there was a fundamental misunderstanding of the purpose and intent Congress had when it enacted the law. I conveyed these concerns in a letter to then-Secretary Tommy Thompson, dated January 18, 2005.

On June 1, 2005, I received a letter from William Raub, Principal Deputy Assistant Secretary for HHS, in response to my January 18, 2005 letter to HHS. In this letter I was told that HHS was reviewing my comments and suggestions on the draft Guidelines in preparation for issuing the final draft. The guidelines were re-issued in the Federal Register on August 29, 2005. The new draft guidelines still contains many flaws and do not properly implement the intent of my amendment.

Problems with HHS Federal Guidelines for Requesting, Stockpiling, Distributing Potassium Iodide (KI) From the Strategic National Stockpile (SNS)

1) The Guidelines Do Not Provide Guidance on the Stockpiling and Distribution of KI

My amendment requires the establishment of "guidelines for the stockpiling of potassium iodide tablets and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident." However, there does not appear to be very much actual guidance within the document issued by HHS.

Section B of Stockpiling, Distribution, Public Education of the guidelines should give clear directions to state, local and tribal governments on how to develop methods for stockpiling and distributing KI. Instead, the section merely refers to Chapter 6 of the NAS report. I agree that local governments should refer to the NAS report, however the federal guidelines should outline options for the stockpiling and distributing KI.

Section A of Stockpiling, Distribution, Public Education of the guidelines gives considerations for KI Utilization. Among these considerations, state and local governments are asked "How will KI be stockpiled and distributed?" I don't know how state and local governments will answer this question, when the government does not provide them with clear guidance regarding options for stockpiling and distribution.

2) The Guidelines Are Not Clear About the Provisions of the Law

The guidelines invite “comments as to whether or not employing measures of prophylaxis other than KI or continuing reliance upon established preventive measures without expanding the area of KI coverage would render the deployment of this expanded KI distribution unnecessary”. Section (f) of Public law 107-188 states that the President would no longer be required to make KI available if “the President determines that there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.” KI is a safe, effective, proven and cheap way to prevent thyroid cancer and disorders resulting from the exposure to radioactive iodine. There is no alternative drug available at this time which could be substituted for KI. This particular part of my amendment was crafted to address the possibility that there might someday be an alternative and more effective prophylaxis available. It was never conceived of as a mechanism for negating the obligation to make KI available based upon arguments relating to the efficacy of reliance on sheltering or evacuation. It is not the duty of State and Local governments to find other prophylaxis measures. Although I support comments from local government and other relevant agencies and associations, these should be with respect to the stockpiling and distribution plan. The language used in the invitation for comments does not emphasize the importance of KI.

Furthermore, in the section entitled “Stockpiling, Distribution, Public Education”, section A “Considerations for KI Utilization” the following questions are posed “What is the cost-benefit of the program? Are there better uses of the funding and resources that would result in a greater reduction in risk?” The law *requires* the President to make KI available for free. The benefits of doing so are quite clear, and have been substantiated by both the FDA and the NAS. I see little value in calling for state and local governments doing a cost-benefit analysis, and the suggestion that there may be better uses for any local funds betrays HHS’s fundamental hostility to the provision, notwithstanding the fact that it is law. I urge that this language be deleted.

3) The Guidelines Are Misleading by Implying that Evacuation Is a Substitute for KI

In the event of a nuclear incident, areas surrounding the incident should be evacuated and KI should be administered. One response does not preclude the other. If those exposed to radioactive iodine have access to KI, their risk of contracting thyroid cancer will be minimized. As illustrated recently when Hurricanes Katrina and Rita hit the Gulf Coast, evacuation can take hours, and during this time, the evacuating population may be exposed to radioactive iodine. Given these recent examples of the difficulty of evacuation, I do not understand why your report includes the following statement “...people closest to the facility are evacuated before significant releases of radioactive materials occur”. Recent evacuations in the Katrina and Rita Hurricanes suggest that the Department’s confidence that those living nearest to a nuclear facility can always be evacuated are wildly optimistic. If an event like a hurricane, where the approach of the

storm is known well in advance and people may have at least a day to get out results in a huge traffic jam and many left behind, what would happen in the event of a sudden attack on a nuclear plant, where the citizens may have no warning, little time to evacuate, and there may be a panic to leave the area? It would seem to me that this experience only strengthens the case for making KI available as a supplement to evacuation and sheltering..

Further, the guidelines state that “The use of KI as a supplemental action to evacuation and sheltering is also sometimes recommended to protect the public. However, the use of KI should not be adopted as an alternative for the implementation of an effective evacuation strategy.” The guidelines should stress the use of KI and they should never imply that evacuation is a substitute for KI. These are not evacuation guidelines but guidelines for stockpiling and distribution of KI.

4) The Guidelines Are Misleading Regarding the Safety of Nuclear Power Plants

The guidelines go on at length about the design features of U.S. nuclear power plants and their safety. Regardless of these safety features, nuclear power plants can not be 100% failsafe. Further, the plants are targets for terrorist attacks. A report by the Congressional Research Service on August 9, 2005 entitled “Nuclear Power Plants: Vulnerability to Terrorist Attack” states that “Nuclear power plants have long been recognized as potential targets of terrorist attacks, and critics have long questioned the adequacy of the measures required of nuclear plant operators to defend against such attacks.” The Department’s guidelines need to recognize that threat of attack is clear and there is a need to prepare for it, both by defending nuclear power plants and, in the event such defenses fail, by providing citizens with emergency measures such as KI in case of an incident should be a priority.

5) The Guidelines Are Not Clear About the Benefits of KI

Section A of “Stockpiling, Distribution, Public Education” discusses “Considerations for KI Utilization”. I suggest the deletion of the question “What is the benefit to public health and safety from incorporating KI into emergency response plans?” This suggests that the benefits are somehow unknown or questionable, while in fact the benefit has already been established by the World Health Organization, the U.S. Food and Drug Administration, the Nuclear Regulatory Commission (which has made KI available for free for states who request it within their 10 mile emergency planning zone) and the National Academy of Sciences. The NAS recommended that “1) KI should be made available to everyone at risk of significant health consequences from accumulation of radioiodine in the thyroid in the event of a radiological incident.” and “2) KI distribution should be included in the planning for comprehensive radiological incident response programs for nuclear power plants.”

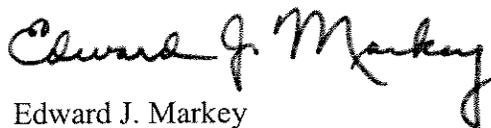
Furthermore, in the background section on potassium iodide, the guidelines include the following language “It (KI) is not a panacea for protection from radiation injury.” No one has ever suggested that it is a panacea. There is no

miracle pill to prevent against all the disastrous health effects that are possible in the event that a nuclear power plant is compromised. However, KI can prevent some of the health side-effects. I suggest that this phrase also be removed.

In summary, I am disappointed that this draft of the guidelines clouds the important health benefits of KI by including text on the safety of nuclear power plants, evacuation planning, and even by questioning the benefits of KI. The guidelines also provide very little guidance as to how KI should be stockpiled, distributed and administered. A clearer plan needs to be laid out for state and local governments.

Given the real threat of a terrorist attack on our nuclear power plants, it is imperative that we do everything we can to protect our citizens. Providing KI is a step in this direction. This should be clear in the guidelines. I look forward to working with the Department to ensure that the final guidelines emphasize the benefits of KI and clearly describe how KI can be distributed in the event of any compromise to a nuclear power plant. Thank you for your assistance and cooperation in this matter.

Sincerely,

A handwritten signature in black ink that reads "Edward J. Markey". The signature is fluid and cursive, with the first name "Edward" and last name "Markey" clearly legible.

Edward J. Markey

References:

"Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident", *National Academy of Sciences*, January, 2004.

"Guidelines for Iodine Prophylaxis following Nuclear Accidents," World Health Organization, Geneva, 1999. (http://www.ki4u.com/WHO/guide_pageii.htm)

"Potassium Iodide as a Thyroid Blocking agent in Radiation Emergencies", U.S. Food and Drug Administration Guidance Document, December 10, 2001. (<http://www.fda.gov/cder/guidance/4825fn1.htm>)

"Nuclear Power Plants: Vulnerability to Terrorist Attack", CRS Report for Congress, August 9, 2005.