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November 9, 2007

The Honorable Jim Nussle
Director
Office of Management and Budget
725 17th Street, N.W.
Washington, D.C. 20503

Dear Director Nussle:

We are writing in concern that more than five years have passed since the Public Health Security and Bioterrorism Preparedness Act of 2002 (the Act) (Public Law 107–188) was enacted, yet, as required under Section 127 of that law, the crucial anti-radiation drug — potassium iodide (KI) — has yet to be distributed to populations living within 20 miles of a nuclear power plant. It is essential to our system of government that when Congress legislates national policy, the laws enacted are not ignored by Executive Branch officials.

Unfortunately, that appears to be the case with respect to Section 127 of the Act, which requires the President to make potassium iodide available to State and local Governments for stockpiling and distribution to protect populations within 20 miles of a nuclear power plant. The consequence is that people living within a 20-mile radius of a nuclear power plant are at unnecessary risk from the uptake of radiation should a release occur.

In addition to the 103 operating civilian reactors, the Nuclear Regulatory Commission (NRC) is expected to receive applications to license an estimated 28 new reactors. We are also concerned that public confidence in NRC's plans to license new nuclear power plants will be weakened by the failure to implement this measure to protect the public in the event of a radiation release.

The science supporting KI distribution and utilization in the event of a nuclear release is well established and unambiguous:

- The American Academy of Pediatrics has noted that, "if administered right before exposure to radioiodines, KI can be 100 percent effective in preventing radiation-induced effects, including thyroid cancer."

- The American Thyroid Association has found that, "KI prevents thyroid cancers arising in individuals exposed to the radioactive iodine that can be released in a nuclear reactor incident, such as might be caused by terrorist action."

- The National Academy of Sciences (NAS) has concluded that "in the event of an accidental or intentional release of radioactive iodine into the environment, radiation doses to the thyroid from radioiodine can be limited by appropriate administration of stable iodine such as KI … KI should be available to everyone at risk of significant health consequences from accumulation of radioiodine in the thyroid in the event of a radiological incident."

- In the Administration's proposal for the establishment of the Department of Homeland Security, KI was called a "crucial drug" that "helps prevent thyroid cancer in the event of exposure to radiation."

Recent Developments

On July 3, 2007, the White House issued a memorandum transferring authority to implement this long-delayed program from the Department of Health and Human Services (HHS), which supported its implementation, to the Nuclear Regulatory Commission, which has repeatedly stated its opposition to expand the distribution and stockpiling of KI beyond the NRC's 10-mile radius "Emergency Planning Zone."

Most recently, NRC argued against distribution of KI in an October 23, 2007, *USA Today* article entitled "White House May Stop Plan for Anti-Radiation Pills." In it, NRC staff were quoted, "It's always a concern that if you expand the distribution [of the pills], you don't have confidence in the plants." We are disappointed that NRC would allow public relations concerns to trump public health protections, which are required by law.

We were encouraged when HHS Secretary Michael Leavitt issued draft implementation guidance in February 2006, which was based on the findings of the National Academy of Sciences. It is our understanding, however, that these guidelines were subsequently held up by the Office of Management and Budget (OMB).

We are disappointed that the NRC has tried to second-guess the decision by Congress to establish a 20-mile distribution zone. More troubling are NRC statements that seem to "cherry

pick" scientific studies to support its opposition to expanding KI distribution to populations living and working between 11 and 20 miles from a nuclear reactor.

For example, in a November 1, 2005, letter commenting on the HHS draft KI distribution guidelines, William F. Kane, the Deputy Executive Director for Reactor and Preparedness Programs at NRC, selectively quoted the National Academy of Sciences report regarding intermediate phases of a radiation release:

> "Removing contaminated products from the market and isolating contaminated products until the radioactive iodine decays to safe levels are the most effective way to eliminate radiation exposure and damage to the thyroid. That also eliminates the need for the use of KI by the general public as a protective action."

What Mr. Kane omitted, however, is that during the initial stages of a radiation release, where exposure predominantly occurs through inhalation, NAS advises:

> "Potassium iodide should be available to everyone at risk of significant health consequences from accumulation of radioiodine in the thyroid in the event of a radiological incident. KI should be available to infants, children, and pregnant and lactating women."

The NAS recommendations accounted for all phases of radiation release—including the primary phase when KI is recommended, and the secondary phase when removing contaminated foodstuffs is recommended. NRC's position which limits distribution of KI inside of the 10-mile Emergency Planning Zone around a reactor is squarely at odds with NAS, which calls for expanding KI distribution outside of the Emergency Planning Zone. NAS states:

> "KI distribution should be included in the planning for comprehensive radiological incident response programs for nuclear power plants. KI distribution programs should consider predistribution, local stockpiling outside the emergency planning zone (EPZ), and national stockpiles and distribution capacity." (emphasis added)

Dubious Reassessment on the Utility of KI

The Administration has recently initiated another scientific review of Section 127, which while permitted by law, has the appearance of even further delaying Congressional intent. John H. Marburger, III, Director of the Office of Science and Technology Policy (OSTP). announced that:

> "...my office will convene an interagency group to examine the issues raised by Section 127(f), and I will use the technical input from this interagency process to inform a decision on Section 127(f). Because the criteria for Section 127(f)'s applicability involve highly technical questions, the President has delegated the authority to invoke Section 127(f) to me."

Section 127(f) is a safety-valve clause allowing for the cessation of the KI stockpiling and distribution requirement "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."

The Administration's decision to convene another interagency process and reopen the scientific debate is curious considering that HHS Secretary Leavitt responded to NRC's objections in 2006 stating "We do not believe there are 'alternative and more effective ...measures' than to make KI available up to 20 miles from a nuclear facility, in conjunction with protective measures established by the NRC." We are not aware of any new scientific findings that would contravene HHS's 2006 determination, which raises questions about why the Administration is convening yet another interagency process. At a minimum, it adds another delay.

The recent experiences of Hurricanes Katrina and Rita indicate that evacuations in emergencies can lead to paralyzing traffic gridlock, which in a radiation release scenario would leave large populations unable to evacuate and require them to shelter in place. Measures to limit exposure to radiation should never be relied on alone as a means to prevent widespread harm from radiation release. That is why Congress enacted provisions to distribute KI, because it is a proven means to prevent adverse consequences.

Requests for Information

Given the failure to implement Section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 for five years, the Committee on Energy and Commerce has initiated an investigation. Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee requests documents and answers to the following questions:

1. Why does the requirement for KI stockpiling and distribution remain unimplemented five years after the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002?

2. Section 127(c) of the Act requires the President to establish guidelines for stockpiling, distribution, and utilization of KI by no later than June 12, 2003. The guidelines have yet to be established.

    a. Did HHS develop draft KI distribution guidelines?

    b. Were these draft guidelines sent to OMB in February 2006 for final approval?

    c. What is the basis for failing to finalize these HHS guidelines?

    d. When will the final guidelines be published?

e. Please provide a list of names and titles of all White House, OMB, and other Executive Branch officials who were responsible for the review of the HHS distribution guidelines and involved in decisionmaking on whether to finalize them.

3. Please provide a timeline of what happened to the draft HHS guidelines after they were provided to OMB in February 2006, and identify each step in the administrative review process. Please provide copies of all records held by the Office of Management and Budget related to its review of the HHS Guidelines for KI distribution, including all memoranda, analyses, meeting records, and e-mail correspondence.

4. The Secretary of HHS stated in 2006: "We are not aware of any 'alternative and more effective prophylaxis or preventive measures' that could be offered in place of potassium iodide in conjunction with other protective measures." Given this position, why did the White House direct the creation of an interagency group to re-examine this issue?

5. Why was a decision made to delegate the reassessment authority in Section 127(f) to OSTP? Please provide all documents, including any memoranda, analyses, meeting records, and e-mail correspondence, relating to the decision to transfer the authority under Section 127(f) from HHS to OSTP.

6. Please explain the rationale for transferring authority for implementation of Section 127 from HHS to NRC. Please provide a list of the names and titles of individuals involved in developing this decision. Please provide copies of all documents, including any memoranda, analyses, meeting records, and e-mail correspondence, relating to the decision to transfer the authority to implement Section 127 from HHS and to NRC.

7. When will the OSTP-led interagency group complete its work? Please provide a schedule for its work and estimated dates for a draft and a final decision.

Please respond to the questions and provide copies of documents requested above within 21 days of the receipt of this letter. If you have questions, please contact us or have your staff contact Will Huntington (Rep. Markey's office at (202) 225-2836) or Richard Miller (Committee on Energy and Commerce at (202) 226-2424).

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Edward J. Markey
Chairman
Subcommittee on Telecommunications and the Internet

Frank J. Pallone, Jr.
Chairman
Subcommittee on Health

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Fred Upton, Ranking Member
Subcommittee on Telecommunications and the Internet

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable John H. Marburger, III, Ph.D., Director
Office of Science and Technology Policy

The Honorable Michael O. Leavitt, Secretary
Department of Health and Human Services

The Honorable Dale E. Klein, Ph.D., Chairman
Nuclear Regulatory Commission

The Honorable Michael Chertoff, Secretary
Department of Homeland Security

The Honorable Samuel W. Bodman, Secretary
Department of Energy