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To: Zimmerman, NSIR

AUTHOR: Peter Crane
AFFILIATION: WA
ADDRESSEE: Sen. Joseph Lieberman
SUBJECT: Potassium Iodide (KI)

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September 26, 2007

Senator Joseph I. Lieberman, Chairman
Committee on Homeland Security and Governmental Affairs
United States Senate
340 Dirksen Senate Office Building
Washington, D.C. 20510

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COMMUNICATIONS SECTION

Dear Senator Lieberman:

The issue of potassium iodide (KI) for the prevention of childhood thyroid cancer in the event of nuclear terrorism or reactor accidents is one for which you have long played a leadership role. Indeed, letters that you wrote on this subject in the 1990's were instrumental in bringing about long overdue changes in Federal policy, helping ensure that American children are better protected against possible catastrophic harm.

Today, the subject of potassium iodide is still controversial, and it is relevant to your Committee's jurisdiction in two respects:

1. The Nuclear Regulatory Commission (NRC) staff's so far successful efforts to undermine a post-9/11 law intended to improve the nation's preparedness to deal with nuclear terrorism, and
2. The continuing refusal of the NRC's Inspector General to investigate the deceptive tactics that the NRC staff has used in pursuing this objective.

It was more than 13 years ago, on April 20, 1994, that you and Senator Alan K. Simpson wrote a compelling and eloquent letter to the NRC, urging it to ensure that KI be available to protect the thyroids of American children in the event of a large release of radioactive iodine resulting from an accident or terrorist attack at a nuclear power plant. At the time, the NRC staff had been stalling for many years, avoiding a decision on the merits of KI, and also refusing to confront well-documented allegations that the NRC had disseminated misinformation on the subject when Federal policy on the subject was under review in 1983. Your letter not only marshaled the medical, scientific, and policy arguments in favor of stockpiling this over-the-counter drug; it also pointedly emphasized the "moral responsibility to provide the public with complete and accurate information." A copy of that letter, still a powerful explanation of the necessity of KI

stockpiling, is attached.

Having no good answers to the substantive points you made, the NRC Commissioners' response was a curt note saying that all the issues raised in your letter had been considered by the Commission. In January 1998, you again wrote to the NRC on the subject of KI. That year, your championing of the KI issue was the subject of editorial praise in *The Day*.

The NRC staff continued to drag its feet, however, preserving the status quo by refusing to reach a decision. Not until April 2001, seven years after your first letter, did a new NRC rule go into effect, requiring states to consider KI as part of their nuclear emergency plans. This was coupled with a commitment by the NRC to supply KI, at NRC expense, to those states electing to stockpile KI, for the population within a 10-mile radius around nuclear plants.

In the aftermath of 9/11, Congress enacted the Bioterrorism Act of 2002. Section 127 of this Act provided for expanding the availability of KI to a 20-mile radius. Reflecting Congress's lack of confidence in the NRC, based on its past handling of the KI issue, the National Academies were given the task of studying how to implement KI distribution and HHS was instructed to implement the statute, with the broader distribution of KI beginning in 2003. However, the NRC staff, which fought the legislation when it was before Congress, objected to KI distribution guidelines developed by the Department of Health and Human Services (HHS) and has so far succeeded in preventing the law from taking effect.

On July 3 of this year, President Bush signed an order published in the *Federal Register* on July 10, 2007, that stripped HHS of its authority for implementing the law and transferred that authority to NRC. In one key subsection of the law, authority is given to the White House Office of Science and Technology Policy, but NRC has been given the lead in drafting the opinion of the head of that office, the White House Science Advisor, Dr. John Marburger III. The likely result is a finding that KI is unnecessary beyond the 10-mile radius, followed by a refusal by the President to proceed with broader distribution of the drug. This will mean the de facto nullification of the law. This White House is all the more inexplicable given that, on June 10, 2002, in promoting the idea of creating a Department of Homeland Security, the White House declared that KI was "crucial" and "critical," and said that henceforth, it would be available where needed, not just within what it termed the "artificial 10-mile barrier."

The decades-long pattern of NRC staff misstatements on the subject of potassium iodide, and of the NRC Inspector General's steadfast refusal to look at them, continues unabated. Below, this letter lists some of the numerous instances in which NRC has distorted the record. A recent

example is a November 1, 2005, letter from William F. Kane, NRC Deputy Executive Director for Reactor and Preparedness Programs, to Dr. Robert Claypool of the Department of Health and Human Services, which seriously misstates the findings of the report on KI issued in 2004 by the National Academy of Science's National Research Council (NAS). The gist of Mr. Kane's letter is that in the event of a radiological emergency that releases radioiodines, the only pathway of concern beyond the 10-mile radius would be the ingestion pathway, something that could be addressed by interdiction of foodstuffs, and that distribution of KI beyond the 10-mile radius was therefore unnecessary. The NRC staff letter claimed to base its conclusions on the NAS report, and even declared falsely that "the Academy raised questions about the usefulness of expanded distribution of KI."¹

Before going further, it may be helpful to explain the context:--In enacting Section 127 of the Bioterrorism Act, Congress directed the President to make KI available in the zones between and 10 and 20 miles from U.S. nuclear power plants, but provided an escape clause, which says that these requirements cease to apply "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." This provision, intended by Congress to allow for the development of new and better measures for thyroid protection, is interpreted by the NRC staff to mean that the President can decide that the law was unnecessary, and choose not to implement it. Since there is no alternative to KI for thyroid prophylaxis, it therefore suits the NRC's purposes to assert that KI is unnecessary beyond the 10-mile limit. Rather than simply continuing to make that argument on behalf of the NRC, Mr. Kane claimed that this represented the findings of the NAS.

¹The misleading way in which the NRC letter was crafted is well illustrated by its quotation from p. 159 of the NAS report. The NRC letter quoted one sentence, while omitting the four preceding sentences, which were essential if the meaning of the quoted sentence was to be understood correctly. Here is the sentence that was quoted in the NRC letter:

"KI is also effective for protection against the harmful thyroid effects of radioiodine ingested in contaminated milk and other food, but food testing and interdiction programs in place throughout the United States are more effective preventive strategies for ingestion pathways."

The four preceding sentences are as follows:

"In the event of nuclear accidents or as a result of nuclear terrorism, radioiodine could be released to the environment. Because iodine concentrates in the thyroid gland, exposure to radioiodine by inhalation of contaminated air or ingestion of contaminated milk and other foods can lead to radiation injury to the thyroid, including risk of thyroid cancer and other thyroid diseases. Thyroid radiation exposure from radioiodine can be limited by taking stable iodine. KI is a chemical compound that contains iodine and can be used to protect the thyroid gland from possible radiation injury by reducing the amount of radioiodine concentrated by the thyroid after inhalation of radioiodine."

In reality, the NAS report, far from having “raised questions regarding the usefulness of expanded distribution of KI,” made clear that depending on site-specific factors, KI might be desirable beyond the 10-mile EPZ, since the 10-mile radius does not necessarily bound the actual risk presented. On this point, Recommendation 2, from p. 160, of the section of the NAS report on “Benefits of and Risks Posed by Potassium Iodide Distribution” states that:

“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.” [Boldface in the original.]

And here, on p. 161 of the report, the full conclusion on “Implementation Issues Related to Potassium Iodide Distribution and Stockpile Programs” states that:

“Conclusion

“A strategy is needed whereby local planning agencies could develop geographic boundaries for a KI distribution plan based on site-specific considerations because conditions and states vary so much that no single best solution exists. [Boldface in the original.] KI distribution planning in the United States has focused on the Nuclear Regulatory Commission's early-phase Emergency Planning Zone (EPZ) of a 10-mile radius. However, the EPZ provides only a basis for planning. A specific incident might call for protective actions to be restricted to a small part of the EPZ or require that they be implemented beyond the EPZ as well. See Chapters 5 and 7 for details.”

In saying that “no single best solution exists,” the NAS report was stating, in unmistakable terms, that applying the standard 10-mile radius to all situations is inappropriate. But the NRC letter strove to give exactly the opposite impression.

The deceptiveness of the NRC's letter was brought to the attention of the NRC Commissioners in April 2006 (e-mail from Peter Crane, April 25, 2006). The NRC staff's response, signed by NRC Executive Director for Operations Luis Reyes a few weeks later, neither admitted nor denied that Mr. Kane's letter had been untruthful.² The NRC's Inspector General declined to

²“The Chairman has asked me to respond to your April 25, 2006, e-mail to the Chairman and the Commissioners, in which you expressed concerns with a November 1, 2005, letter from William Kane to Dr. Robert Claypool of the Department of Health and Human Services (HHS) on expanded distribution of potassium iodide. Among other things, you stated your belief that the U.S. Nuclear Regulatory Commission (NRC) should revise its letter to HHS and post it on the NRC website with an explanation that the previous letter was found to be inaccurate. The

investigate, explaining that it was not a federal crime to mislead another Federal agency.³

Whether or not deceiving HHS was a crime, the NRC letter was evidently a source of considerable irritation, as HHS Secretary Michael Leavitt made clear in a March 27, 2006, letter to NRC Chairman Nils J. Diaz (attached). While couched politely, his quotations from what the NAS report actually said were an implicit rebuke to the NRC for mischaracterizing the NAS report on those points.

At this point, the Presidential order transferring authority over Section 127 from HHS to NRC, and the four-year delay in implementing the statute, raise serious questions about whether the nation will be adequately protected if ever there is a major release of radioiodines from a nuclear power plant. Congress acted wisely in trying to transfer responsibility for KI distribution beyond the 10-mile Emergency Planning Zones to another agency but the NRC staff has succeeded in making a mockery of its efforts.

None of this would be possible, however, without the continuing abdication of responsibility by the NRC's Office of Inspector General and its predecessor, the Office of Inspector and Auditor. As long ago as 1990, the then Inspector General, David Williams, when asked to investigate the NRC staff's misrepresentations on KI, quashed the allegation without making a written record, in apparent violation of the chapter of the manual governing his activities, and without even informing his deputy, Leo Norton, who headed the investigations unit of the office, that the allegation had been received. It was, Norton agreed, "an off-the-books investigation," unique in his experience.

Again and again, the Inspector General either refused to look at issues relating to the NRC staff's handling of the KI matter or did so in a perfunctory fashion. Each new instance in which the NRC staff provided misleading, inaccurate, or seriously incomplete information (including to the Congress) was treated in isolation, rather than in relation to similar past occurrences. OIG's refusal to connect the dots between these related data points enabled it never to find the all too obvious pattern.

Commission believes that Mr. Kane's letter reflected the NRC's well-considered, scientifically-based position on expanded distribution of KI. Therefore, it will not be necessary to supersede his letter with another to HHS. Sincerely, Luis Reyes, Executive Director for Operations."

³Telephone conversation between George Mulley, Senior Level Assistant for Investigative Operations, and Peter Crane.

The data points, moreover, were numerous. The following is only a partial list:

1. 1995: The NRC staff attempted to induce the Federal Radiological Preparedness Coordinating Committee (FRPCC), chaired by the Federal Emergency Management Agency, to reaffirm a 1985 Federal policy that was extremely negative toward KI (it used the words “not worthwhile”), that had been adopted nine months before the Chernobyl accident. The NRC urged that there was “no new information” undercutting the 1985 policy, although there is in fact a wealth of new data resulting from Chernobyl on the safety of KI in actual use and the hazards to children’s thyroids if it is unavailable.
2. 1997: The NRC staff apologized to FEMA in a November 5 public meeting for having “misrepresented” (the staff’s word) FEMA’s position on KI. The NRC staff had told the NRC Commissioners that FEMA was opposed to any change in federal policy on KI, whereas the opposition actually came from the NRC staff, not FEMA.
3. 1997: The NRC staff prepared and submitted to the Commissioners a draft Federal Register notice on the subject of KI.⁵ Its lengthy discussion of KI included no mention of Chernobyl, or the epidemic of childhood thyroid cancer that it had caused in the former Soviet Union, or the special susceptibility of children to radiogenic disease, or the “safe and effective” finding on KI by the Food and Drug Administration. Instead, it offered a less than accurate account of how the FRPCC almost reaffirmed the 1985 Federal policy. (See item #1 above.) Most revealingly, this draft Federal Register notice does not mention thyroid cancer at all until its eighth page, which is comparable to a notice on Sabin vaccine that waited until page 8 to mention polio. The NRC Commissioners reject this draft.
4. 1998: The NRC staff prepared a report, “NUREG-1633,” a 40-page purported technical assessment of KI. This report ignored published literature and the Food and Drug Administration finding that KI was “safe and effective,” nor did it acknowledge the published findings on the safe use of KI in Poland after the Chernobyl accident. In making the case that KI is hazardous, the authors claimed to be relying on an old edition of the Physician’s Desk Reference, but they cited it inaccurately. Where the Physician’s Desk Reference says that KI is safe for pregnant women and children, the NRC staff quoted it as saying that KI is unsafe for pregnant women and children. (In reality, it is pregnant women and small children who benefit most from the drug.) The NRC Commissioners acceded to the NRC staff’s request for authorization to publish the document. A few weeks later, however, having become aware of its many defects, they ordered it withdrawn from circulation and taken off the NRC website.⁶

⁵ SECY-97-124, “Proposed Federal Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant,” June 16, 1997.

⁶ A large task force, headed first by Mr. Aby Mohseni and later by Ms. Patricia Milligan, then spent several years and

5. 1998: The NRC apologized to Rep. Ed Markey for providing inaccurate information on the cost of a nationwide KI program.
6. 2001: After the NRC Commissioners finally changed the NRC's emergency planning rules, and declared their willingness to provide KI to any state that wants it, the NRC staff failed to provide the states with information that is timely and complete. Though the Commission's decision was made in January 2001, and the rule change became effective three months later, the NRC staff's notification of the states did not come until December, and notwithstanding the then recent attacks on 9/11, said nothing about the risk of terrorism as a reason for stockpiling KI.

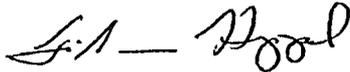
For all these reasons, we are deeply troubled that President Bush has once again given the NRC the dominant role within the Executive Branch in determining policy on the potassium iodide issue. We urge you and the Committee on Homeland Security and Governmental Affairs to take a hard look at the handling of the KI issue, especially in the years since Congress enacted the Bioterrorism Act. The functioning of the NRC's Office of Inspector General is a significant but distinctly secondary issue; the truly critical issue is why our nation's children are not receiving the protection that Congress thought it had provided for them in 2002.

considerable funds revising the document to try to bring it up to publishable standards. They failed twice, however, as their redrafts were submitted to the NRC Commissioners and rejected. In 2002, after rejecting the second redraft, the Commissioners had had enough, and directed that no further effort be expended on the report.

Sincerely,



Peter Crane
Counsel for Special Projects, U.S.N.R.C. (retired)
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Attachments:

Letter from Sens. Joseph I. Lieberman and Alan K. Simpson to Ivan Selin, NRC, April 20, 1994
Letter from Secretary Michael O. Leavitt, HHS, to Nils J. Diaz, NRC, March 27, 2006

cc: Senator Susan M. Collins, Ranking Member

Dr. John Marburger, III, Director, White House Office of Science and Technology Policy
Secretary Michael O. Leavitt, Department of Health and Human Services
Dale Klein, Chairman, U.S. Nuclear Regulatory Commission
Gregory B. Jaczko, Commissioner, U.S. Nuclear Regulatory Commission
Peter B. Lyons, Commissioner, U.S. Nuclear Regulatory Commission

¹ Von Hippel was a member of the American Physical Society's Study Group on Light Water Reactor Safety that originally brought the value of KI for thyroid protection to the attention of the Nuclear Regulatory Commission in 1974. When the accident at Three Mile Island occurred in 1979, he brought it to the attention of the White House Office of Science and Technology and, when the Chernobyl accident happened, he brought it to the attention of President Gorbachev's science advisor. He served as the Assistant Director for National Security in the White House Office for Science and Technology Policy in 1993-1994. He has written numerous articles on the subject, three of which are reprinted in a collection of his articles published by the American Institute of Physics in its Masters of Modern Physics series.

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United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6176

PETER L. BAKER, STAFF DIRECTOR
STEVEN J. SHENBERG, MINORITY STAFF DIRECTOR AND CHIEF COUNSEL

April 20, 1994

The Honorable Ivan Selin
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Chairman Selin:

We are writing to urge the Nuclear Regulatory Commission (NRC) to revise its current policy regarding the availability and use of potassium iodide (KI) in the event of an emergency at a nuclear power plant.

The NRC's current policy is that state and local governments should consider stockpiling KI for emergency use by emergency workers and institutionalized persons, but not for the general public. This policy was established in the early 1980's. Since that time, however, new information has arisen and additional experience has been gained on the costs and benefits of the prophylactic use of KI by the general population. We believe that this new information and experience requires a new approach to this issue.

It is well-established scientifically that KI is extremely effective in preventing the uptake of radioactive iodine by the thyroid. If taken in the proper dose prior to exposure to radioactive iodine, KI can completely block the uptake of the radioactive iodine.

The distribution of KI to the general population in the event of a nuclear emergency is a widely accepted protective measure. The World Health Organization has recommended its use for people living near a nuclear power plant if radiation levels are expected to exceed a predetermined dose. A number of foreign governments--including the United Kingdom, the Czech Republic, Switzerland, Canadian provinces with nuclear power plants, and the former Soviet Union--stockpile KI for distribution to and use by the general public in the event of a nuclear emergency. In the U.S., three states--Alabama, Tennessee, and Arizona--have plans to distribute or already have distributed KI to people living near one or more nuclear power plants within those states.

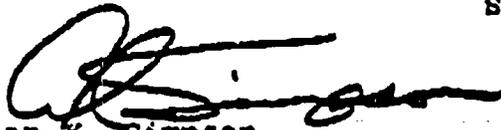
A recent cost-benefit study of this issue conducted for the NRC indicates that the costs of stockpiling KI for people who live within five miles of a nuclear power plant are minimal-- approximately ten cents per person per year. This means that for a typical population of 10,000 people living within five miles of a nuclear power plant, it would cost approximately \$1,000 to make KI available for distribution. The NRC staff projects that the cost of stockpiling KI for everyone in the country within five miles of a nuclear power plant would be on the order of several hundred thousand dollars per year. This is only a small fraction of the expenses already spent on emergency planning. As the NRC staff has noted, "[c]osts in this range present no significant barrier to stockpiling and are probably less than the cost of the continued studies."

Some concern has been expressed that public education on the use of KI may result in a potentially significant negative public perception. However, no evidence has been provided that any of the existing policies in other nations or in the states that provide for the use of KI by the general population has caused any undue panic or apprehension to the general public. Moreover, the federal government has a moral responsibility to provide the public with complete and accurate information regarding the risks from federally-licensed activities and ways in which those risks may be reduced.

In sum, therefore, KI can be an extremely effective countermeasure to prevent damage to the thyroid in the event of a radiological emergency. It can also be made available for the general population living near a nuclear power plant for minimal costs. The NRC should revise its policy to provide this additional potential protective measure for nuclear emergency planning.

We thank you for your time and consideration.

Sincerely,



Alan K. Simpson
Ranking Minority Member
Subcommittee on Clean Air
and Nuclear Regulation



Joseph I. Lieberman
Chairman
Subcommittee on Clean Air
and Nuclear Regulation



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 27 2006

The Honorable Nils J. Diaz
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Chairman Diaz:

Thank you for your letter in which you expressed concern about the publication of proposed guidelines to States, local governments, and tribal authorities regarding Federal provision of Potassium Iodide (KI). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires the President, through the Strategic National Stockpile (SNS), to provide KI to communities within 20 miles of nuclear power facilities. The Department of Health and Human Services (HHS) has agreed to fulfill this role through the SNS, an HHS asset.

I appreciate your concerns about expanding the distribution of KI for populations beyond the 10-mile radius of the Emergency Planning Zone (EPZ) surrounding commercial nuclear power plants and your recommendation to apply subsection 127(f) of the Bioterrorism Preparedness and Response Act of 2002. We agree that the current NRC established protective actions within the EPZ from 10 to 50 miles are very important measures to deal with the accidental or terrorist-related release of radioactive iodine from a nuclear power plant. We also agree with the National Academy of Sciences' conclusions regarding the need for KI. Specifically, in its 2004 KI report it recommended that "*Potassium iodide (KI) should be available to everyone at risk of significant health consequences from accumulation of radiiodine in the thyroid in the event of a radiological incident.*" The National Academy of Sciences went on to conclude that

KI distribution planning in the United States has focused on the Nuclear Regulatory Commission's early-phase Emergency Planning Zone (EPZ) of a 10-mile radius. However the EPZ provides only a basis for planning. A specific incident might call for protective actions to be restricted to a small part of the EPZ or require that they be implemented beyond the EPZ as well. (for emphasis.)

Section 127 of the Bioterrorism Preparedness and Response Act of 2002 requires the President to make KI available to State and local governments for stockpiling and distribution, and to establish guidelines for the stockpiling of KI and for its distribution and utilization in the event of a nuclear incident. Additionally, subsection 127(f) states that these requirements "*cease to apply as requirements if the President determines that there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions...*" The President has not made the necessary determination here. Rather, as the President stated in 2002 when

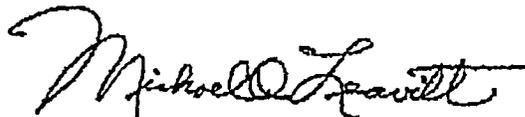
forming the Department of Homeland Security, "...one Department would be responsible for distributing Potassium Iodide to citizens exposed - no matter where they lived. There would no longer be an artificial ten-mile barrier to treatment." Currently, we do not believe there are "alternative and more effective... measures" than to make KI available up to 20 miles from a nuclear facility, in conjunction with the protective measures established by the NRC.

If states, local governments, or tribal authorities wish to apply for a federal program to provide KI as another layer of thyroid protection in the additional area of 10-20 miles, their plans should prescribe KI utilization in a way that complements rather than compromises the Nuclear Regulatory Commission's primary protective measures of avoiding consumption of contaminated food and water. We have drafted the guidelines as required by Section 127 with this principle in mind; where the draft guidelines state

The 10-mile EPZ has been reviewed and accepted by the Environmental Protection Agency (EPA), NRC, and FEMA as the appropriate EPZ size for commercial nuclear power plant licensees to use in developing emergency plans in cooperation with State and local governments. These guidelines do not question the appropriateness of the 10-mile EPZ under NRC regulations or their legal or regulatory basis, and nuclear power plant licensees will not be expected to modify their emergency plans because of these guidelines.

Your thoughts on making the KI guidelines consistent with the NRC protective actions and delineating any confusion between the two joint strategies is greatly appreciated. Thank you for your continued support of the American people and the public health activities that protect them.

Sincerely,



Michael O. Leavitt