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Peter Crane / 6545 27th Avenue NW / Seattle, WA 98117 / kinderhook46@yahoo.com / 206-819-2661

July 20, 2013

Chairman Allison Macfarlane
Commissioner Kristine L. Svinicki
Commissioner George Apostolakis
Commissioner William D. Magwood, IV
Commissioner William C. Ostendorff
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Macfarlane and Commissioners:

In April, the Environmental Protection Agency published for public comment a draft "PAG Manual," subtitled "Protective Action Guides and Planning Guidance on Radiological Incidents." (78 FR 42071, April 15, 2013). One of the major issues it deals with is the use of potassium iodide (KI) for thyroid protection in the event of a radiological emergency.

As I described in comments filed with EPA on July 4, 2013 (see attached copy), the single most significant fact about KI is that it is, to my knowledge, the only aspect of American life where we have in recent years **decreased** protection against terrorism, whereas everywhere else, protection has been increased. I am referring to the removal of KI from the Strategic National Stockpile in 2009. That action was a consequence of a 2008 decision by the President's Science Advisor, in which the NRC staff played a key role, effectively nullifying an Act of Congress that sought to increase the availability of KI for nuclear accidents and acts of terrorism. While we hope that this country never experiences a major radiological disaster, it is a certainty that if one does occur, and KI is needed but unavailable, that failure will be laid at NRC's door, given its record of having "fought relentlessly" against KI, in the words of Professor Frank von Hippel of Princeton University.[1] If the Commissioners do nothing else with respect to KI, they should take steps to see that it is restored to the Strategic National Stockpile at the earliest possible moment.

In my comments, I described grave problems in the draft PAG manual, both of omission and commission. Most notably, the draft, which was prepared by an interagency writing committee that included NRC staff participation, failed to discuss, mention, or cite the preeminent government study of KI: *Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident*, authorized by Act of Congress, conducted by the National

[1] *New York Times*, March 23, 2011.

Academies of Science, and published in 2004. Nor did it cite the key peer-reviewed journal article on the safety of KI when administered on a mass scale: the paper by Drs. Janusz Nauman, of Warsaw, and Jan Wolff, of NIH, on the Polish experience with KI after Chernobyl: "Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks." *Am J Med* 1993; 94: 524-532. In addition, on the question of contraindications for taking KI, the draft PAG offered advice that conflicted significantly with the Food and Drug Administration's 2001 guidance, *Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.* (66 FR 64046, Dec. 11, 2001).

I ended my July 4 comments by urging EPA to extend the comment period, then set to expire on July 15, 2013, by sixty days. I am happy to report that it did so four days later, by order of EPA Assistant Administrator Gina McCarthy, who in the meantime has been confirmed as the agency's Administrator. (78 FR 42071, July 15, 2013.) As a result, the Commission now has a generous window of time in which to offer its comments on the EPA guidance. I hope it will do so, and present the Commission's own considered views on the subject to EPA, rather than delegating the issue to the NRC staff.

For a quarter of a century, I have been reiterating a very simple point: that potassium iodide is comparable to the life preservers on a ferryboat, *i.e.*, neither a panacea nor the first line of defense in an emergency, but rather a reasonable and prudent supplementary protection, and a cheap one. The opponents of KI stockpiling would have you believe not only that the drug poses unacceptable health risks – a proposition untenable in light of the data on the 18 million Poles dosed during Chernobyl – but also that it could cause the public to doubt the safety of nuclear power plants, and could produce a "false sense of security," leading people to disobey evacuation orders in an actual emergency. The opposition to KI stockpiling has come principally from the Nuclear Energy Institute, outside the Government, and the NRC staff, within it.

Though these arguments against KI are in my view specious and sometimes mendacious,[2] the purpose of this letter is not to debate the merits of KI. Rather, it is to make a jurisdictional point: that federal agencies need to recognize the limits of their expertise and authority, and refrain from intruding into each other's business.

Drug safety is the exclusive responsibility of the Food and Drug Administration, which in this case determined KI to be "safe and effective" for use in nuclear emergencies some 35 years ago.

[2]Following this line of reasoning, the presence of life jackets on ferryboats could cause passengers to doubt the safety of ferryboats, and in an emergency, to refuse orders to enter lifeboats.

(43 FR 58798, Dec. 15, 1978.) FDA's 2001 guidance on KI, cited above, is definitive. On the question of who should and should not take KI in an emergency, FDA's word must be accepted as final by the rest of the Federal community. Second-guessing by other agencies on instructions for use of a drug, of the sort we see in EPA's draft PAG Manual, is not helpful and can only do harm.[3] The last thing this country would need in a radiological emergency is for conflicting information to be coming from different federal agencies on the conditions under which a radioprotective drug should be taken.

In 2008, when the longest-serving member of the present Commission arrived at White Flint, the battles over KI within the agency had already been going on for 25 years. Because my perspective on the institutional history of the issue goes back to 1983, it may be helpful to the Commissioners to describe some of the KI-related events that preceded their tenure at NRC. To keep this letter from being overlong, I will do so in an appendix.

Thankfully, KI is a unique case: a bureaucratic Thirty Years' War that has often seen the NRC and other agencies at odds, and has sometimes pitted the NRC staff and the Commissioners against each other. Having joined NRC ten weeks after it opened its doors in 1975, I can assure you that no other issue in the NRC's 38-year history has given rise to so much ill feeling toward NRC on the part of other agencies. Time and again, we have seen complaints that the NRC has provided inaccurate information on KI, impeded the efforts of other agencies to do their jobs, and failed to honor its commitments. Certainly it is the only subject on which NRC Commissioners have ever opened the newspaper to find themselves described by an official of a sister agency – whether with good cause, readers can decide for themselves – as "those rascals." (*New York Times*, April 24, 1999. See the appendix for details.)

With respect to the draft PAG Manual issued by EPA, it is troubling that there was no mention either of the NAS Report or the Nauman/Wolff paper. At the very least, their absence

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[3] I can think of only one instance in which the NRC was on the receiving end of so major an intrusion into its prerogatives by a sister agency. Early in the Carter Administration, the *Wall Street Journal* reported that the Interior Department, supported by the Justice Department, was bringing suit against the NRC to stop construction of the Bailly nuclear plant, because of harm allegedly occurring to the nearby Indiana Dunes National Lakeshore. As OGC's lawyer on Bailly, I sought to learn the nature of the alleged harm, so that NRC could investigate and take any necessary action, but was told by DOI and DOJ that to disclose this information would reveal litigation strategy. Finally, at an interagency meeting in Indianapolis, it was explained that DOI believed that construction and operation of the plant would interfere with its goal of letting the National Lakeshore revert to its condition during the Pleistocene Era. Soon afterwards, the NRC Solicitor met with high officials in DOJ to press the argument for exclusive NRC jurisdiction in this area, and the planned lawsuit was dropped. (The Bailly plant was later cancelled, for different reasons, when construction was less than one percent complete.)

suggests that the NRC participants could have done more to make sure that the draft included references to key documents in this field. I recommend that in commenting on the draft PAG Manual, the Commission should draw EPA's attention to these critical omissions, and also urge EPA to give absolute deference to FDA's 2001 guidance on the conditions under which KI should be used, and by whom.

I am enclosing, for the Commission's information, a copy of a paper that I delivered at an international conference on radiation and thyroid cancer at Cambridge University in 1998. (The conference was co-sponsored by the European Commission, DOE, the National Cancer Institute, and Cambridge University.) It describes the U.S. Government's handling of the KI issue between 1978 and 1998, and is included in a 1999 volume, *Radiation and Thyroid Cancer*, edited by G. Thomas, A. Karaoglou, and E. D. Williams, and published by the European Commission.

Sincerely,

/s/

Peter Crane
Counsel for Special Projects, USNRC (retired)

APPENDIX – DETAILS ON HISTORY OF NRC CONSIDERATION OF KI

Between 1997 and 2002, the Commission on four occasions rejected, as unfit for publication, staff documents on the subject of KI: first SECY-97-124, in 1997, and then three successive drafts of NUREG-1633, the staff's "technical analysis" of KI. At last the Commissioners lost patience, and by a 4-1 vote barred the staff from further work on NUREG-1633.[4] Commissioner Diaz's vote on the third and last version of NUREG-1633 was blunt:

> Congress has asked the National Academies of Science to look at issues of KI distribution. The Food and Drug Administration has issued its guidance on the safety and effectiveness of KI. In addition, the NRC has provided its own guidance in its Federal Register notice on the new rule. In my opinion, the NUREG and the brochure at best can add little to what states and the public already know. At worst, they can confuse the public and the states. These projects have gone on too long, and cost too much, to be continued. In my opinion, it's time to pull the plug.

Sometimes, however, these rejected staff documents on KI have enjoyed a second life. In 2004, the Department of Health and Human Services, acting pursuant to the 2002 statute that sought to expand the availability of the drug, issued draft guidelines on KI, only to discover afterwards that what it had published was a recycled version of SECY-97-124, with all the flaws of omission and commission that had caused the NRC Commissioners to turn it down in 1997. HHS withdrew the draft and started from scratch.

Likewise, NUREG-1633, though rejected for the third and last time by the Commissioners in 2003, wound up being cited with evident approval in the 2008 decision of the President's Science Advisor, the late Dr. John Marburger III. Based on technical support from the NRC staff, that decision ignored a principal recommendation (on stockpiling beyond the Emergency Planning Zone) of the 2004 National Academies of Science report on KI; effectively nullified the 2002 statute; and resulted in the removal of KI from the Strategic National Stockpile (SNS).

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[4] http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2002/2002-0089vtr.pdf#pagemode=bookmarks It is indicative of the problems with NUREG-1633 that the first version failed even to mention the FDA's "safe and effective" finding, as though trying to wish it out of existence. Nor did it mention the Polish experience with KI during Chernobyl. The authors, instead of citing peer-reviewed journal literature on the safety of KI, chose to rely on an outdated edition of the *Physician's Desk Reference*, and what was more, to misrepresent it, claiming that it declared KI to be unsafe for children and pregnant women. The criticisms from states and others were so blistering, and so obviously sound, that the Commission had to order the document, which had already been published, to be withdrawn from circulation. (63 FR 55653, Oct. 16, 1998.)

It is no exaggeration to say that the KI issue poisoned NRC's relationship with FEMA in the 1990's. In 1995, the Federal Radiological Preparedness Coordinating Committee (FRPCC), which operates under FEMA's aegis, came under heavy pressure from the NRC staff to reaffirm a 1985 federal policy on KI, the crux of which was the phrase "not worthwhile" to describe a KI requirement. Assured by NRC that there was "no new information" warranting a reexamination of the 1985 policy, the FRPCC's KI Subcommittee had already disbanded, believing its work done, and the FRPCC was on the verge of reaffirming the policy.

Almost at the last moment, however, FEMA Director James Lee Witt discovered that far from there being "no new information" on KI, there was abundant and highly important data from Chernobyl, documented in such papers as the Nauman/Wolff study referred to earlier. He reconstituted the KI Subcommittee and told it to review this new information, with the result that the FRPCC in 1996 called for a new federal policy that would give KI to any state requesting it. (The NRC staff would spend the next five years working to block or delay its adoption.)

The problems between NRC and FEMA on KI only grew. Responding to a complaint from FEMA that SECY-97-124 had incorrectly described FEMA as being opposed to any change in federal KI policy, an NRC official admitted in an open Commission meeting, attended by FEMA, that the NRC staff had "misrepresented" FEMA's position. (Transcript, November 5, 1997, at 78.)

On July 1, 1997, the NRC, then headed by Chairman Shirley A. Jackson, issued a press release, saying that the NRC intended to offer KI to any state requesting it, and declaring explictly, "The NRC will provide the funding."[5] In reliance on this promise, other agencies, federal and state, began to make plans, which meant expending resources. But in April 1997, after 20 months of what could be called resolute inaction, the Commission, still under Chairman Jackson, withdrew its promise, citing budgetary constraints, and suggested that regional stockpiles of the drug could be created instead, paid for by FEMA.[6] The problem with this

[5] A few hours earlier, a reporter from CBS News, accompanied by a camera crew, had interviewed me outside NRC headquarters.

[6] Given that KI is a time-critical drug, which should ideally be administered before exposure to radiation, and failing that, as soon as possible afterwards, this posed an obvious question: how, in an emergency, could the KI be brought from regional stockpiles in time to do any good? In answer to this question, one Commissioner was quoted in his hometown newspaper as proposing that "fighter jets" could deliver the KI, though he later assured me personally that he had never said any such thing.

idea was that FEMA had long opposed regional stockpiles of KI, believing that they would do more harm than good.

The NRC's turnabout and the reaction to it were described in an April 24, 1999, article by Matthew Wald in the *New York Times*, headed "Atom Agency Tries to Avoid Financing Fallout Drug." It began:

> The Nuclear Regulatory Commission has quietly backed away from its offer to give states with nuclear power plants stockpiles of a drug that cuts the risk of thyroid cancer in people exposed to fallout in an accident.
>
> The commission decided in July 1997 to pay for the drug, potassium iodide. But on Thursday it approved a document that calls for trying to shift the cost to the Federal Emergency Management Agency.
>
> "They were going to fund the purchase, and repurchase when the shelf life ran out," William F. McNutt, a senior policy adviser at the emergency management agency and chairman of a multi-agency subcommittee on potassium iodide, said of the N.R.C. "Those rascals."
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> In Ohio, which has held hearings on whether to expand its stockpile, officials said they were surprised. "Everything Ohio has been doing was based on the premise that the N.R.C. was going to pay for the potassium iodide," said Randy Hertzer, a spokesman for the state's Health Department.

Writing to the NRC on April 29, 1999, FEMA Director Witt made no effort to hide his anger:

> Your abrupt retreat from repeated promises to the Federal community, states and the public is apparent based on a misapprehension of FEMA's authorizing legislation and a disregard of our view – and that of other FRPCC agencies – that regional potassium iodide stockpiles will not enhance radiological emergency preparedness. ... FEMA has always opposed the notion that Federal regional stockpiles of potassium iodide would be effective in the event of a release from a nuclear power plant. ... Regional stockpiles of potassium iodide would complicate, not strengthen radiological emergency preparedness.

Just a few months later, NRC still had not got the message, or at least professed not to have done so. On September 10, 1999, the agency responded to questions from Chairman Joe Barton of the Subcommittee and Power of the House Commerce Committee. One question quoted Director Witt's letter of April 29, and asked why NRC disputed FEMA's position. The NRC's reply included the following:

> The NRC believes that regional stockpiles may be a reasonable and prudent approach.... The NRC is confident, based on a long record of coordination and cooperation between the two agencies, that the NRC and FEMA staffs will successfully resolve the KI stockpile issue.

There were more aggrieved letters from FEMA on KI, but these should be enough to make my point.

Earlier, I described how HHS had to withdraw draft guidance on KI in 2004, after learning that it was an edited version of a rejected NRC staff paper, SECY-97-124. In addition, HHS Secretary Michael Leavitt wrote the Commission on March 27, 2006, essentially rebuking it for having used selective quotations to distort the findings of the National Academies of Science report on potassium iodide.[7] Leavitt made clear his exasperation with NRC's delaying tactics, and declared his intent to proceed with implementation of the 2002 law providing for expanded distribution of KI. Soon afterwards, President Bush stripped him of his authority over the 2002 law and transferred it to the President's Science Advisor and NRC, with the entirely predictable result that implementation of the law was disapproved, and the law effectively nullified. The group responsible for the Strategic National Stockpile then felt that it had no choice, in view of that decision, to remove KI from the SNS.

[7]That letter was not registered in the NRC's ADAMS system until July 16, 2013, more than seven years after it was received, and more than two years after I had pointed out its omission from ADAMS. It is only thanks to NRC's Secretary that it is there at all.

POTASSIUM IODIDE PROPHYLAXIS AND THE UNITED STATES GOVERNMENT: A CASE STUDY

PETER G. CRANE[1]
4809 Drummond Avenue, Chevy Chase, MD 20815
Tel :301-656-3998
E-mail : pgcrane@erols.com

On July 1, 1998, the U.S. Nuclear Regulatory Commission (NRC) announced that it had voted to grant a petition for rulemaking that will require states to consider potassium iodide (KI) prophylaxis, along with evacuation and sheltering, in emergency planning for nuclear power plant accidents. This decision, by a 3-1 vote of the Commissioners, represents a major step in the U.S. Government's 20-year consideration of the KI issue. A review of the NRC's actions over this 20-year period points up serious deficiencies in the handling of the issue by the NRC and its technical staff, with the result that the United States is now far behind other developed countries in ensuring comprehensive protection for its citizens, especially its children, in the event of a major release of radioiodines. The review suggests that in governmental decision making concerning public health effects of nuclear power plant emergencies, the views of public health agencies and emergency management agencies should be given dominant weight.

On July 1, 1998, the U.S. Nuclear Regulatory Commission (NRC) announced that it had granted a petition for rulemaking, filed by me, that would require states to consider the drug potassium iodide (KI) as part of their emergency plans for radiological mishaps at nuclear power plants2. In voting to begin rulemaking, NRC Chairman Shirley A. Jackson and Commissioners Nils J. Diaz and Edward McGaffigan, Jr., rejected the recommendation of the NRC's own technical staff that the petition be denied3. KI stockpiling is also bitterly opposed by the U.S. nuclear power industry. The rule change will be coupled with a new U.S. policy, not yet final, under which stocks of KI will be given to any U.S. state that requests it.

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1 Counsel for Special Projects, Office of the General Counsel, U.S. Nuclear Regulatory Commission; former Member, Nuclear Claims Tribunal, Republic of the Marshall Islands. This paper, submitted in the author's private capacity, represents his personal views only.

2 See NRC Press Release of July 1, 1998.

3 The vote was 3-1. Commissioner Greta J. Dicus, whose term expired June 30, 1998, sided with the NRC staff.

The grant of the petition did not bring an instant change in the NRC's rules. Before that can happen, the NRC must publish a proposed rule, receive and analyze comments from the public, and issue a final rule. Thus the three Commissioners' commendable decision represents not the end, but perhaps the beginning of the end, of the U.S. Government's protracted consideration of the KI issue, a process that began some 20 years ago.

To the international community, it is well known by now that KI stockpiling is routine throughout the developed world; that some nations, notably France and Switzerland, go further, with house-to-house predistribution4; that KI has long had the backing of the World Health Organization5 and the American Thyroid Association; that it is an element of the International Basic Safety Standards6 sponsored by the International Atomic Energy Association and other organizations; and that its safety in actual use was proved in Poland, as Drs. Janusz Nauman and Jan Wolff described in their seminal 1993 paper7. The question that an international audience may be asking is how the United States could contrive to spend 20 years resolving an issue so straightforward and obvious that 20 weeks should have been more than enough time for a reasoned decision.

I will try to offer an answer to that question, through a case study of the handling of the KI issue by the United States Government. My purpose is to suggest the problems that can arise when public health decisions relating to radiation are placed in the hands of an agency whose primary expertise is not health, but nuclear technology.

I should interject that I am a lawyer, not a physician or a scientist. I make no pretensions to medical expertise, except insofar as I have gained it as a patient with thyroid cancer, presumably radiogenic.[8] My 15-year involvement in the KI issue stems from my conviction, born of experience, that thyroid cancer is a disease well worth preventing, especially if prevention can be achieved easily and cheaply.

4 Electricité de France and the Swiss Government both publicize their KI policies through Internet sites.

5 World Health Organization, EUR/ICP/CEH 102(S), § 4.3.3. (1991).

6 International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (interim edition), International Atomic Energy Agency (Vienna, 1994).

7 J. Nauman & J. Wolff, "Iodine Prophylaxis in Poland after the Chernobyl Reactor Accident: Benefits and Risks," American Journal of Medicine, Vol. 94, p. 524 (May, 1993).

8 I was part of the cohort of some 5000 children who, some 50 years ago, received head and neck radiation -- in my case, 750 rads of x-ray to my enlarged tonsils and adenoids -- at Michael Reese Hospital in Chicago, Illinois. In 1973, I had a partial thyroidectomy for papillary thyroid cancer; in 1983, had the thyroid remnant ablated; in 1988, was diagnosed with a recurrence; and in 1992, after five courses of radioiodine therapy, totaling 700 millicuries of I-131, was given a clean bill of health.

Benjamin Franklin once wrote, "A child thinks that 20 shillings and 20 years can never be spent." Let me offer now a brief chronology of where the last 20 years went in the U.S. Government's consideration of KI.

-- 1978: The U.S. Food and Drug Administration (FDA) declares KI "safe and effective" for use in nuclear power plant emergencies, and approves its over-the-counter sale.[9]

-- 1979: During the Three Mile Island accident, federal and state officials, fearing a major release, search for supplies of KI and discover none exist. Later, the President's Commission investigating the TMI accident castigates the Government's failure to stockpile KI and recommends stockpiling for the public and radiation workers.[10] A month later, the NRC announces its agreement, declaring its intent to make the availability of KI a "necessary part of an acceptable State emergency response plan."[11]

-- 1982: The NRC technical staff recommends that the Commissioners approve an interagency U.S. Government policy endorsing the use of KI as a "useful ancillary protective action."[12] Nineteen days later, without explanation, the NRC technical staff withdraws that recommendation, saying that it plans to prepare a new paper that will recommend against stockpiling and distribution of KI on cost-benefit grounds.[13]

-- 1983: The NRC technical staff briefs the Commission in a public meeting on its new, anti-KI position. The gist of the NRC staff's argument is that though KI is cheap, it will be even cheaper in the long run to treat radiation-caused illnesses after an accident than to spend even a small amount to prevent them with

9 Food and Drug Administration, "Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency," 43 Federal Register 58798 (Dec. 15, 1978).

10 Report of the President's Commission on the Accident at Three Mile Island ("Kemeny Commission"), at 41-42.

11 NUREG-0632, "NRC Views and Analysis of the Recommendations of the President's Commission on the Accident at Three Mile Island" (November, 1979).

12 SECY-82-396, "Development of a Federal Policy Statement on the Distribution and Use of Potassium Iodide for Thyroidal Blocking in the Event of a Nuclear Power Plant Accident" (September 27, 1982), Attachment 3, at 3-4.

13 SECY-82-396A, "Withdrawal of SECY-82-396 (Federal Policy Statement on Use of Potassium Iodide)" (October 15, 1982). The memorandum notes that the Federal Emergency Management Agency (FEMA) has just dropped plans to buy a large amount of KI for stockpiling. Unlike the NRC, which is an independent regulatory agency, FEMA is part of the Executive Branch, *i.e.*, under Presidential control.

KI. The comparison is exclusively in dollar terms: dollars for KI pills vs. dollars for medical treatment, as though illness had no burdens other than the expense involved. The briefers mention neither cancer nor the possibility of fatalities.[14]

-- 1985: The U.S. Government issues a national policy on KI.[15] Referring to the NRC's "cost-benefit analysis," it dismisses the idea of requiring KI as "not worthwhile."

-- 1989: As NRC internal rules allow, I file a "Differing Professional Opinion," challenging the agency's KI policy. I argue that new information warrants reconsidering the KI issue, and that existing policy was tainted from the start by NRC staff misinformation to the Commissioners and the public.

-- 1994: The NRC staff, while not addressing the issue of misinformation, recommends to the Commissioners that stockpiling KI in the vicinity of nuclear plants "appears prudent."[16] It proposes a new federal policy to buy KI and encourage states to establish stockpiles. The staff estimates that it would cost less (a few hundred thousand dollars) to buy a national stockpile of KI than go on studying whether to do so. But the Commissioners then in office tie 2-2, so the old policy remains in place.

-- 1995: Acting as a private citizen, on my own time, I file a petition for rulemaking, asking the NRC to require that KI be among the "range of protective actions" included in state emergency plans. I also write to the Director of the Federal Emergency Management Agency, which chairs the interagency committee responsible for overall KI policy.

-- 1996: At a public meeting called by FEMA, several state officials describe KI stockpiling as undesirable and unnecessary. An Illinois official explains, "Loss of the thyroid is not life-threatening."[17] Several months later, the

14 The briefers refer instead to "nodules." They convey the impression that any thyroid illness resulting from an accident would be trivial: "There's a few days loss from -- it's a relatively simple operation that's involved in removing the thyroid or removing the nodules." Transcript of November 22, 1983 meeting, at 52-53. When the NRC Chairman suggests that if he survives an accident because of KI, he will think the $.20 cost of the pills to be money well spent, the NRC staff corrects him, telling him that "the surviving question is not the question." Transcript at 63.

15 "Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent," 50 Federal Register 30258 (July 24, 1985).

16 SECY-94-087, "Addendum to SECY-93-318 Re-evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant" (March 29, 1994), at 2.

17 The identical sentence appears in a separate statement filed by a South Carolina official. Later, the Illinois Department of Nuclear Safety, offended by my criticism of it, writes to the NRC that the State of Illinois "stands firmly behind its contention that hundreds of thousands of people live normal, healthy lives without functioning thyroid glands." Letter from Thomas W. Ortciger, Director, January 8, 1998.

interagency committee headed by FEMA calls for a new federal policy that would give KI at federal expense to any state requesting it.[18]

-- 1997: The NRC staff proposes a draft federal policy statement on KI to the Commissioners.[19] While the policy would make KI available to states requesting it, the notice includes no recommendation that they do so. It does not refer to Chernobyl or the Polish experience with KI; states that there is "no new information" warranting a change in existing policy; and mentions only near the end of the notice that the purpose of using KI is to prevent cancer. After a protest from FEMA, the NRC staff apologizes in a public Commission meeting for having "misrepresented" FEMA's position on KI in its June 1997 paper.[20]

-- 1998: The NRC staff recommends to the Commission that it deny my petition.[21] It offers a 40-page "technical assessment" of KI, offering its own highly equivocal judgment of the drug's safety. Although the obvious starting point for any such analysis by a U.S. Government agency is the Food and Drug Administration's finding that KI is "safe and effective," the NRC staff "technical assessment" omits even to mention it.

The "technical assessment" appears calculated to raise alarm that KI will have severe side effects, and that these side effects will expose state governments to legal liability. For example, it warns: "In the U.S., the implementation of a protective action *may entail litigation and liability for long after the accident*. The TMI accident is a case in point. One can expect that *administration of KI on a*

18 Despairing of persuading the Government to provide the states and the public with accurate and up-to-date information on KI, I decided in early 1996 to try to reach the public directly through newspaper articles. The first, in the New York Times, was designed to coincide with the tenth anniversary of Chernobyl. Other articles followed. (I did not accept payment for them.) They helped stimulate citizen action at the state level, which in turn led to state meetings, in which I participated, in Maine, Ohio, and New York. Maine and Ohio have decided in favor of stockpiling, and the issue remains under active consideration in New York State. In each of these states, great weight has been given to the advice of thyroid cancer experts from the American Thyroid Association.

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

20 At this meeting, believing that I did not have the votes to gain approval of my petition as written, I stated that I would be satisfied if states are required by rule to "consider" KI in developing their emergency plans. At the Commission's request, I submitted an amended petition a week later.

21 SECY-98-061, "Staff Options for Resolving a Petition for Rulemaking," March 31, 1998.

mass basis would certainly entail litigation in this country, whereas the government of Poland, which administered KI on a mass-basis, did not appear to be faced with such litigation." [Emphasis added.][22]

The authors of the "technical assessment" evidently recognize that the strongest empirical evidence for the safety of KI is the very low incidence of adverse medical reactions observed in Poland. Accordingly, in an apparent effort to disparage Nauman and Wolff's report, the NRC "technical assessment" says of it in passing, "to the extent that we believe the report...."[23] The authors of the "technical assessment" cast this aspersion upon two internationally renowned medical experts without offering any evidence to support the insinuation that the report should not be believed.[24]

While the staff's paper is pending before the Commission, a FEMA official writes to the NRC to point out an erroneous statement about FEMA's position on KI by the NRC staff and "misleading" comments by a nuclear industry lobbying group and an Illinois state agency.[25] Her letter refers to the FDA's 1978 approval of KI, and adds pointedly, "This FDA approval was empirically reinforced by the experience in Poland with KI, subsequent to the Chernobyl accident." It appears to be an implicit warning to the NRC that FEMA will not be a party to withholding key information on the safety of KI from the public.

22 Technical assessment, at p. 22. Why a legal judgment of this kind has any place in what purports to be a technical assessment of a particular medication, and what qualifications the authors have to offer any legal opinion -- particularly one as sweeping as that just quoted -- are unexplained. The authors' effort to invoke the specter of legal liability may help explain the absence from the "technical assessment" of any reference to the Food and Drug Administration's finding on KI. If state governments were made aware that the FDA had approved KI as "safe and effective," that fact would be doubly reassuring to them. First, it would indicate that the drug was safe. Second, it would mean that even if, as the NRC staff confidently predicts, use of KI in a radiological emergency were to lead to lawsuits over side effects, states could defend themselves by showing that they had relied on the FDA's finding. The NRC staff "technical assessment" is careful not to address the point, often made by supporters of KI stockpiling, myself included, that states concerned about possible exposure to lawsuits relating to KI should probably worry most about a different type of lawsuit: those that would be brought if an accident occurred and children developed thyroid cancer because KI had *not* been stockpiled.

23 *Id.* at 11.

24 The NRC, which has made the "technical assessment" public, should withdraw the document and offer Drs. Nauman and Wolff a deep and contrite apology.

25 Letter from Kay C. Goss, FEMA Associate Director, April 9, 1998.

As I mentioned at the outset, the Commissioners rejected the staff recommendation and directed the NRC staff to begin a rulemaking that would incorporate into the NRC's rules a requirement that states "consider" iodine prophylaxis as a part of radiological emergency planning. This requirement would be coupled with an offer of free KI from the Federal Government. As of late July, 1998, Commission action on the draft policy statement was expected shortly.

Thus in the end, the Commissioners decided wisely, and the United States may no longer be at odds with the rest of the civilized world on whether it is "worthwhile" to protect children from thyroid cancer. In such cases, it is common to declare that "the system worked." But did it? To be sure, it speaks well for the American democracy that the citizen's right to seek redress of grievances is not an empty phrase. Likewise, it reflects no small credit on the NRC that it tolerated with such good grace the campaign that an NRC employee was conducting in his spare time.

By any other measure, however, the system did *not* work. First and foremost, there is no excuse for American children still to have second-class protection, so many years after the recommendations of the WHO. When nations rich and poor, from Japan to Armenia, can afford to buy KI, surely the U.S. can do the same. It is or should be a reproach to the richest nation on earth that its policy on protecting children from cancer should be based on the notion -- a fallacious notion at that -- that cure is cheaper than prevention.

The safety of American children should also not depend on citizens hammering on their Government to do what it promised to do almost 20 years ago. Moreover, a system for allowing interested citizens to seek regulatory change that takes nine years even to approach fruition cannot be said to be working satisfactorily. Finally, the record shows too many instances in which the NRC staff provided information to the Commissioners and the public that lacked balance, accuracy, and completeness.[26] I have offered examples of the way in which facts that did not support the desired result have disappeared down the "Memory Hole," in George Orwell's well-known phrase. The NRC staff's treatment of pro-KI comments, including those from internationally known medical experts representing the American Thyroid Association, is another example. The

26 FEMA is to be commended for having brought some of these lapses to the NRC Commissioners' attention.

opportunity to submit views to a federal agency is of little value if the technical staff ignores those comments it finds difficult to rebut.[27]

I have high confidence in the NRC staff to make sound, well-supported and intellectually honest judgments about nuclear safety hardware, conditions of reactor operation, and the like. Sadly, the record does not permit a similar statement about the NRC staff's past handling of the KI issue.[28]

One can speculate that part of the underlying problem may be that the technical experts involved in nuclear safety decisions do not in their hearts view major accidents as credible, at least in the United States, and therefore regard all emergency planning as no more than a political concession to the public's irrational fears of nuclear power. If one starts from the premise that emergency planning is a pointless charade, then any upgrading of planning, even one as inexpensive as KI, may seem worth resisting. By the same token, it may seem unnecessary to be overly punctilious in how one analyzes a health issue that one believes will never arise.

The cause of the phenomenon is beside the point, however; the issue is what to do about it. I believe that one part of the answer is to ensure a proper division of governmental responsibilities among different agencies. The primary responsibility for radiological emergency planning must be placed (or kept) in the hands of agencies whose mission is emergency preparedness, not nuclear regulation. In the U.S. context, this means FEMA. Such agencies know from experience that accidents can happen and can develop unpredictably, and they plan accordingly.

Likewise, decisions affecting human health should be made in the first instance by health agencies and health professionals. It seems unlikely, for example, that any medical doctor, answerable to his or her peers, would ever discuss the consequences of radiation-caused thyroid disease in a public meeting without mentioning cancer. Nor would medical doctors presume to discuss the safety of a drug without reference to the Food and Drug Administration's judgment that it is "safe and effective." The line between nuclear regulation and nuclear

27 The NRC staff's recent memoranda to the Commissioners on the KI issue illustrate how essential it is that Commissioners and their personal staffs read the actual comments that are submitted to the NRC on controversial issues, rather than relying on the NRC staff to summarize the comments for them.

28 Now that the Commissioners have voted, it is reasonable to expect that the highest levels of NRC staff management will loyally accept the direction they have received. The more problematic issue concerns NRC staff management below the highest levels. Suffice it to say that the deficiencies of the "technical assessment" are of such a nature that it would be prudent to excuse the individuals principally responsible for that document from any further involvement with the KI issue.

promotion is not an easy one to maintain, and needs to be guarded vigilantly, as must the line between science and propaganda. Here, something went seriously wrong, not once but repeatedly.

Thanks to the three NRC Commissioners now in office, the U.S. Government's long mishandling of the KI issue may now be nearing its end. Nevertheless, it should be an object lesson within the U.S. and for authorities in other countries as well.

Peter Crane / 6545 27th Ave. NW / Seattle WA 98117 / kinderhook46@yahoo.com / *206-819-2661 (cell)*

July 4, 2013

Air and Radiation Docket and Information Center
Environmental Protection Agency
Mail Code: 6102T
1200 Pennsylvania Ave., NW
Washington, DC 20460

Attn: Docket ID No. EPA-HQ-OAR-2007-0268

To the Docket:

Introduction and Summary

I appreciate the opportunity to comment on EPA's draft PAG Manual, "Protective Action Guides And Planning Guidance For Radiological Incidents." I will limit myself to the portions of the document that relate to potassium iodide (KI).

The EPA draft has serious defects, both of omission and commission, that require correction. Regrettably, it conforms to a pattern all too familiar to those who have followed the KI issue over the past 30 years, when agencies with no special expertise in drug safety venture into this area.

On the subject of KI, EPA should simply have deferred to the Food and Drug Administration. It has expert knowledge both about drugs in general and KI in particular, having declared it "safe and effective" for use in radiological emergencies as long ago as 1978. Instead, EPA's draft includes warnings about contraindications for using KI that conflict significantly with FDA's.

Moreover, the EPA PAGs fail to mention two of the most significant studies of the safety and effectiveness of KI: the National Academies of Science report, commissioned by Act of Congress and published in 2004, and the paper, co-authored by Drs. Janusz Nauman and Jan Wolff, that described the Polish experience in administering KI after Chernobyl. These striking omissions demand correction.

Discussion

Potassium iodide is to my knowledge the sole aspect of American life in recent years in which the Government has made a conscious decision to weaken rather than strengthen public protection against terrorism. As the *Washington Post* reported on April 7, 2011:

> The U.S. Strategic National Stockpile stopped purchasing the best-known agent to counter radioactive iodine-induced thyroid cancer in young people, potassium iodide, about two years ago and designated the limited remaining quantities "excess," according to information provided by the U.S. Centers for Disease Control and Prevention to ProPublica. Despite this, the CDC Web site still lists potassium iodide as one of only four drugs in the stockpile specifically for use in radiation emergencies.

Why was KI removed from the Strategic National Stockpile? Apparently, the committee that maintains the stockpile felt that it had no choice, in view of the 2008 decision of the late John Marburger III, Science Advisor to President Bush, refusing to implement the 2002 law that provided for distribution of KI beyond the 10-mile radius around nuclear plants in which the Nuclear Regulatory Commission (NRC) was offering it to states.[1]

Marburger's decision, which relied on technical support from the NRC staff, failed to heed the advice of a definitive National Academies of Sciences study, commissioned by Congress and published in 2004, which had concluded that in an accident, KI might in some cases be needed beyond the 10-mile radius. Produced by a committee consisting of 13 distinguished experts from the United States and abroad, and published in book form in 2004 as *Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident*, its 248 pages constitute the definitive Government-sponsored study of the drug. (President Obama's Science Advisor, John Holdren, has so far refused to disturb his predecessor's ill-advised decision, despite pleas for reconsideration from the

[1]In the interest of full disclosure, I should mention that the rule change under which NRC agreed in 2001 to provide KI to states for populations within the 10-mile radius was in response to a petition for rulemaking filed by me in 1995. The grant of that petition was a decision of the NRC Commissioners, made over the bitter opposition of the NRC technical staff.

American Thyroid Association, Congressman Ed Markey, and others.)[2]

The question that readers new to this subject may be asking is this: what is the basis for the opposition to KI? What is so wrong with having it available in emergencies?

Perhaps the clearest and most forthright answer came from the NRC's senior adviser for preparedness, quoted in an October 22, 2007 article in USA Today ("White House may stop plan for anti-radiation pills") as saying that the NRC "opposes broad distribution of the pills because the best way to eliminate risk is to make sure people don't eat contaminated food." The article continued:

> She also says the NRC is concerned about undermining the reputation of the nuclear industry. "It's always a concern that if you expand the distribution (of the pills), you don't have confidence in the plants," she says. "We have studies that show the safety of our plants."

Thus the need to send a message of confidence in the safety of nuclear power plants trumps preparedness for possible acts of radiological terrorism.[3] We just have to hope

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[2]If readers consulted the NAS report, they would recognize the factual problem with one statement on page 22 of the EPA document: "**Although the size of the EPZ is based on the maximum distance at which a PAG might be exceeded**, the actual boundary of an EPZ should be demarcated by features readily identifiable by people within that area." [Emphasis added.] This strongly implies that the 10-mile EPZ provided by NRC regulations is adequate to ensure that PAGs will not be exceeded. However, the NAS report was clear in saying that under some accident conditions, KI would be needed beyond the boundaries of the EPZ – a finding that the NRC staff refused to acknowledge. See the March 27, 2006, letter to NRC from HHS Secretary Michael Leavitt, sharply criticizing the NRC for mischaracterizing the findings of the NAS report in a letter to HHS, in which it had used selective quotation to create the inaccurate impression that the NAS saw no need for KI beyond the 10-mile EPZ. (See joint letter of September 26, 2007, from Professor Frank von Hippel and Peter Crane to Senator Joseph Lieberman, accessible here: http://pbadupws.nrc.gov/docs/ML0728/ML072831363.pdf) For his earnest desire to ensure better radiation protection for American children, his major concern, Secretary Leavitt was stripped of authority over KI in July 2007. That authority was transferred to the President's Science Advisor and NRC, with the entirely foreseeable result that the statute was effectively nullified a few months later.

[3]There are easy answers to these arguments. First, KI is a supplement to other measures, not a substitute for them. We are better off having more arrows in our quiver in an emergency than fewer. As to the notion that having KI would suggest that nuclear plants are unsafe, the same rationale would support removing life jackets and lifeboats from ferry boats, lest the public see them as implying that the boats are unsafe. The NRC position, incidentally, corresponds exactly to that expressed by NUMARC, a nuclear trade association (forerunner of today's Nuclear Energy Institute), which declared in a 1993 White Paper

that the day never comes that KI is needed, and the nation learns that the drugs that once were in the Strategic National Stockpile were disposed of as "excess."

In an op-ed published in the *New York Times* on March 23, 2011, as the Fukushima accident was unfolding, Professor Frank von Hippel of Princeton University commented that the Nuclear Regulatory Commission had "fought relentlessly" against the stockpiling of KI. This was by no means an exaggeration. As though to prove his point, an NRC staffer was quoted in an Associated Press article of March 31, 2011, as saying that the agency was "absolutely confident" that a 10-mile radius for KI distribution was sufficient. Whether right or wrong, it was plainly premature, with the accident still in progress, for NRC to reach any such conclusion.

All too often, the NRC has used interagency consultative processes to press its deeply held policy views on other agencies, sometimes to their later regret.[4] I wish to stress in the strongest terms, however, that I have no knowledge that this occurred here.

Invariably, in the various defective Government issuances on KI, we see a suppression of pertinent and valuable information on the one hand, coupled with the introduction of erroneous and misleading information on the other. This EPA document is no exception. The most egregious omission is the absence of any discussion or citation of the National Academies of Science report on KI referred to earlier. This is as incomprehensible as if a Government agency published a document on the causes and effects of nuclear accidents without mentioning the Kemeny Commission report on Three Mile Island, or on the risks of space flight without mentioning the Rogers Commission report on the Challenger disaster.

To take another example, the best empirical data on the safety of KI when used on a

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that if KI were stockpiled, "public confidence in the technology could be affected."

[4] For example, in 2004, HHS issued draft KI guidelines, pursuant to the 2002 statute. It discovered only afterwards that what it had published was a recycled version of an NRC staff paper from 1997, SECY-97-124, which the NRC Commissioners had rejected at that time, for good reason. In the HHS notice, as in the NRC staff paper, there was no mention of Chernobyl or of the FDA "safe and effective" finding, and the reader had to get many pages into the notice to find out that the purpose of KI was to prevent cancer. A rueful HHS withdrew the guidelines and started again from scratch.

mass scale is the Chernobyl accident, in which Polish authorities, under the direction of Dr. Janusz Nauman, gave out 18 million doses of the drug, 10 million of them to children, within a short time. The total number of persons with adverse reactions requiring hospitalization, and that only briefly, was two. Both were adult males who took the drug despite knowing that they were allergic to iodine.[5]

Dr. Nauman co-authored a paper on the Polish KI experience with Dr. Jan Wolff, an American scientist at the National Institutes of Health: Nauman J, Wolff J. "Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks." *Am J Med* 1993; 94: 524-532. It is a seminal, basic work in the field, and is cited in the FDA guidance on KI and innumerable other studies in this area. I cannot think of a single journal article or government study on KI in nuclear emergencies that does not refer to it – with the sole exception of these draft PAGs, which neither mention nor cite it.

Why the omission? Surely it is important for readers of the PAGs to know that the risks of KI administration on a mass scale, while not negligible, are extremely small.[6] As I was preparing these comments, I telephoned the EPA contact on the PAGs paper to

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[5]Dr. Nauman once told me, "We asked them why they had taken it, after they had been warned not to, and they said, 'We thought it was a matter of life and death.'"

[6]It is worth noting that in the 1990's, the NRC technical staff was deeply displeased by the Nauman-Wolff paper, since it undercut the staff's argument that the risks of KI administration were unacceptably high for the drug to be stockpiled. In a 1998 technical assessment of KI (Draft NUREG-1633, "Assessment of the Use of Potassium iodide (KI) As a Public Protective Action During Severe Reactor Accidents), the NRC staff even made a disparaging reference to the Nauman-Wolff article, saying of it, "to the extent we believe the report...." I drew attention to this slur in a paper I gave at Cambridge University in the summer of 1998, "Potassium Iodide Prophylaxis and the United States Government: A Case Study,"which can be found in book form in *Radiation and Thyroid Cancer*, published in 1999 by the European Commission, DOE, the National Cancer Institute, and Cambridge University. Criticizing this "aspersion upon two internationally renowned medical experts," I urged the Commissioners to withdraw the document and issue a "deep and contrite apology" to Drs. Nauman and Wolff. The NRC Commissioners did in fact order the report withdrawn from circulation (63 FR 55653, Oct. 16, 1998), and in an implicit apology, Dr. Nauman was invited to NRC headquarters to address the relevant staff. Twice in the next several years, the NRC staff sent revised drafts of NUREG-1633 to the Commission for approval. Both were rejected. At last the Commissioners lost patience, and by a 4-1 vote, ordered work on the project to cease. Officially, therefore, the document does not exist, except as an attachment to a rejected staff proposal. But rather than being consigned to the dumpster, as the Commissioners seem to have intended, it was given new life when it was cited with evident approval in the Marburger decision referred to earlier.

ask the reason for the omission of the NAS study, and was informed that the authors of the draft felt that the FDA guidance from 2001 was so useful that it should be emphasized.

Leaving aside for the moment that a citation to the NAS report would hardly have detracted from whatever emphasis was given to the FDA guidance, the difficulty with this argument is that the PAGs actually **conflict** with the FDA guidance. They offer warnings about the risks of KI that are quite at odds with what the FDA said in 2001.

If we carefully compare the two, on the critical question of medical contraindications for KI use, we see subtle but extremely significant differences. First, here is the 2001 FDA guidance, at page 5:

> Short-term administration of KI at thyroid blocking doses is safe and, in general, more so in children than adults. The risks of stable iodine administration include sialadenitis (an inflammation of the salivary gland, of which no cases were reported in Poland among users after the Chernobyl accident), gastrointestinal disturbances, allergic reactions and minor rashes. In addition, persons with known iodine sensitivity should avoid KI, as should individuals with dermatitis herpetiformis and hypocomplementemic vasculitis, extremely rare conditions associated with an increased risk of iodine hypersensitivity.
>
> Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis, which is more common in older people and in iodine deficient areas but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects more common in iodine sufficient areas, but they require chronic high doses of stable iodine (Rubery 1990). In light of the preceding, individuals with **multinodular goiter**, Graves' disease, and autoimmune thyroiditis **should be treated with caution, especially if dosing extends beyond a few days**. The vast majority of such individuals will be adults. [Emphasis added.][7]

[7] I am grateful to Professor von Hippel for pointing out to me that the guidance on KI currently posted on the FDA website includes a line not found in the 2001 guidance: "People with nodular thyroid with heart disease should not take KI." See

Now let us look at EPA's draft PAGs, at p. 20:

> **Some people should not take KI.** As a rule, individuals with known allergy to iodine or with pre-existing thyroid disease (e.g., Graves' disease, **thyroid nodules**, Hashimoto's thyroiditis) that might predispose them to adverse reactions should avoid KI. [Emphasis added.]

Thus there are at least two noteworthy differences. First, "multinodular goiter," in the FDA document, has been changed to "thyroid nodules." Second, instead of saying that these patients should be "treated with caution," as FDA does, EPA tells us they should "not take" and should "avoid" KI.

To fully appreciate the pernicious impact of these changes, one must know the prevalence of thyroid nodules among the American population. Here is the first paragraph of "Nonpalpable Thyroid Nodules—Managing an Epidemic," an article by Dr. Douglas S. Ross of Massachusetts General Hospital and Harvard Medical School, published in the Journal of Clinical Endocrinology & Metabolism on May 1, 2002 (vol. 87 no. 5 1938-1940):

> **Thyroid nodules are extraordinarily common.** The prevalence of palpable thyroid nodules in two non-biased population-based studies—Framingham, Massachusetts, and Whickham, England—was 4.2 and 3.2%, respectively (1, 2). In the Framingham study, the prevalence was 6.4% in women and 1.5% in men (1). The true prevalence of thyroid nodules, however, requires autopsy data. A 1955 study at the Mayo Clinic found thyroid nodules in 50.5% of 821 consecutive autopsies of patients with clinically normal thyroid glands (3). Because 7.4% of autopsies were excluded from analysis because of premortem thyroid disease, **the true prevalence is slightly higher than half the population.** Even in an unlikely group of patients to have thyroid nodules, men in the military aged 18–39 yr, the prevalence of thyroid nodules at autopsy was 13% (4). [Emphasis

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http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm072265.htm. However, in the population sought to be reached by a KI program – those below the age of 40, and above all children – there will presumably be very few individuals with both thyroid nodules **and** heart disease.

added.]

Whether or not by design, the effect of these selective omissions and insertions is thus to create a document that would serve as a perfect tool for persuading state, local, and federal authorities that to stockpile and administer KI is unwise, because so large a fraction of the population would be placed at risk. And as noted earlier, there will be no references to the NAS report, or to the Polish experience with KI, that might lead anyone to realize that there may be a good case for stockpiling the drug after all.

Conclusion

During the Fukushima accident, when some on the West Coast were opportunistically peddling KI to frightened citizens at high prices, I went on television in Seattle to condemn their "irresponsible scaremongering." I thought it reprehensible of these entrepreneurs to exaggerate the benefits of KI in a situation where there was no need for anyone in the United States to be taking it. But it is every bit as reprehensible, in my view, for opponents of KI to exaggerate the risks of using the drug in potential future situations where the need for it actually **does** exist or **may** exist. One form of alarmism and disinformation is no better than the other.

Rather than drafting its own list of cautions for those taking KI, EPA should simply incorporate the FDA guidance verbatim. With respect to the omission from the draft of any mention of the NAS report and the Nauman/Wolff journal article, EPA should in its revision of the draft draw attention to these documents and discuss their findings, given their central importance to a proper understanding of the KI issue.

Fortunately, no radiological event requiring KI administration has ever occurred in this country, and we hope one never does. But we know that it **could**. That makes it incumbent on government agencies and on all of us to address these issues on the basis of sound, honest, complete information: the truth, the whole truth, and nothing but the truth. Regrettably, these guidelines in their present form do not meet that test.

Nearly 20 years ago, Senators Joseph Lieberman and Alan Simpson, a Democrat and a

Republican, wrote to the NRC in an effort, futile at the time, to persuade that agency to support stockpiling of potassium iodide. (Letter of April 20, 1994.) In it, they pointedly reminded the NRC Commissioners of their "moral responsibility to provide the public with complete and accurate information" on the KI issue. Today, that moral responsibility rests with EPA, and I trust the agency will rise to it.

Finally, I recommend that EPA extend the comment period by an additional 60 days, to enable commenters to give the draft PAGs the careful scrutiny they plainly require.

Ms. Mary Lampert of Pilgrim Watch has advised me that she agrees with these comments and wishes to be associated with them.

Sincerely,

/s/

Peter Crane
NRC Counsel for Special Projects (retired)

Remsburg, Kristy

From:	Peter Crane <kinderhook46@yahoo.com>
Sent:	Saturday, July 20, 2013 9:00 PM
To:	Vietti-Cook, Annette
Subject:	Letter to NRC Commissioners on EPA and KI
Attachments:	img416.jpg; img417.jpg; img418.jpg; img419.jpg; img420.jpg; 2013.EPAdocketKIJuly4version.doc; 2013.Commission,KI.letter.July.doc

Dear Annette,

Hope you had a pleasant weekend. Attached is a letter to the Chairman and Commissioners, attaching comments that I filed with EPA on July 4, as well as a talk I gave at Cambridge University in 1998. Could you please circulate this to them? If there are any problems with the transmission, please let me know.