Peter G. Crane / 4809 Drummond Avenue / Chevy Chase, MD 20815 / 301-656-3998

December 7, 1997

Mr. John C. Hoyle, Secretary
Nuclear Regulatory Commission
Washington, D.C. 20555

Re: PRM-50-63

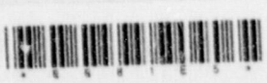
Dear Mr. Hoyle:

Enclosed, for inclusion of the docket on my petition for rulemaking, are two documents. The first is a statement that I submitted to the New York State Radiological Health Committee on November 15, 1997. The second is a response to a request from Mr. Roger Suppes, Chief of the Bureau of Radiation Protection in the Ohio Department of Health, for feedback on issues and concerns identified by participants in a meeting on KI that was held in Painesville, Ohio, on October 28, 1997. I would like these to be considered as additional comments on the petition and the amendment to the petition filed by me on November 12, 1997. As in the past, these were prepared at home, on my own time, using my own materials, etc.

Thank you.

Sincerely,

Peter Crane



D510

STATEMENT OF PETER CRANE
submitted to the New York State Radiological Health Advisory Committee
Meeting on Potassium Iodide (KI)
November 21, 1997

I appreciate the opportunity to submit a statement to this Committee's meeting on the radiation antidote potassium iodide (KI). I do so in my private capacity, as an interested citizen, not in my official capacity as Counsel for Special Projects at the U.S. Nuclear Regulatory Commission. I do not speak for the NRC or the U.S. Government.

This Committee recognizes, as the letter announcing the meeting made clear, that the threshold question about KI is medical: whether it is desirable as a public health matter to have KI on hand. Put another way, do the health benefits of the drug outweigh the health risks associated with its use? Only if the answer to that medical question is "yes" is it necessary to go on to address the logistical issues of where it should be stockpiled and how it should be distributed.[1]

Current Federal policy on KI uses strong words -- "not worthwhile" -- to discourage stockpiling and use of the drug. That policy was put in place in July 1985, just months before the Chernobyl accident. Since that time, we have a wealth of new information that illuminates both the effects of a major nuclear accident on human health, especially the health of children, and the safety and efficacy of KI in such an accident. Nevertheless, the opponents of KI continue to assert that there is "no new information" or "no new data" that would challenge the 1985 policy.

The physicians here today will have addressed the upsurge of childhood thyroid cancer in Belarus, Russia, and Ukraine since 1991; the Polish experience with KI following the Chernobyl accident in 1986; and the implications of those developments for the United States. I am not a physician, and would not presume to offer any medical advice to a committee of health experts except what comes from my own experience as a patient.

My patient's-eye view is that thyroid cancer, notwithstanding that it is usually curable, can be a very nasty disease. Fatality rates are not the only measure of whether an illness is serious and worth preventing. You also have to look at the impacts on the quality of life. By that standard, thyroid cancer is significant both for the patient and the family, especially when it recurs. The process of treating it can be an ordeal, in part because of the need to take the patient off medication and induce weeks of hypothyroidism, which means being exhausted, weak, and cold. Moreover, any cancer is frightening, and

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[1] This point may seem obvious, but for years, opponents of KI stockpiling, putting the cart before the horse, have argued that the logistical problems of getting KI to people in an emergency would be so insuperable that the decision should be made against stockpiling without ever reaching the question of the likely medical benefits of using the drug.

that takes an emotional toll as well.

There are, of course, many kinds of cancer (and many other diseases as well) that are statistically more dangerous than thyroid cancer, and that impose much greater burdens on the average patient. But that is irrelevant. The question is whether this disease is sufficiently dangerous and burdensome to be worth preventing, if prevention can be achieved with a dime's worth of medication. I would answer that question "yes," and so would my family.

You may be asking why anyone should feel it necessary to belabor the point that thyroid cancer is a serious, non-trivial illness. The answer is that too many states -- states where decisions on radiation protection are made by bureaucrats without the benefit of medical expertise -- seem not to know that. Just last year, for example, the Federal Emergency Management Agency held a meeting on KI at which the representative of a state with a population of about 12 million offered as one reason why his state saw no need to stockpile. "Loss of the thyroid," he said, "is not life-threatening."

Try telling that to Senator Tom Harkin of Iowa, who lost a brother to thyroid cancer last year.

In a narrow, technical sense, however, the state official I quoted was correct. Loss of the thyroid is not life-threatening in itself. Neither is loss of a breast, for that matter. But the cancer that causes you to lose your thyroid or your breast can take your life, and it is a grave disservice to the public to imply otherwise.

If many states are ill-informed about thyroid cancer and other radiogenic thyroid diseases, it is in large part because the Federal Government has done such a poor job, over the past 15 years, of giving them the information they need. In my petition for rulemaking and elsewhere, I have described how the current Federal policy on KI was grounded in misinformation provided to the NRC Commissioners and the public some 14 years ago. But all that is history. At this point, I would like to look forward, not back, and rather than concentrate on the errors of the 1980's, make sure that the Government does the right thing today.

The first thing the Government must do is to learn to speak clearly and straightforwardly on the KI issue. That means calling things by their right name, not using euphemisms or generalities that obscure from the states and the public the information they need.

For example, on July 1 of this year, the NRC announced that the Commissioners had decided to support a proposed new policy that would make supplies of KI available, paid for by the Federal Government, to any state that asked for it. That was major progress. Unfortunately, however, the press release on the NRC's decision never used the word "cancer" to explain what KI does, but instead referred in general terms to "thyroid diseases." To announce the availability of KI without mentioning cancer is like announcing the

availability of Sabin vaccine without using the word "polio." If you want states and the public to become aware of a public health issue and do something about it, you have to be a lot more direct than that.

The proposed new federal policy has yet to be put in place. A number of federal agencies are involved in the decision, not just NRC. Assuming they can arrive at a decision, a Federal Register notice will be issued, sooner or later. But the process is painfully slow. It has been more than a year since an interagency committee, the Federal Radiological Preparedness Coordinating Committee, voted to recommend that the Federal Government buy KI for those states that wanted it, and almost five months since the NRC Commissioners voted to endorse that recommendation. To date, however, no Federal Register notice has been published, the public and the states have received next to no information about these votes from the Federal Government, and officially, the status quo remains unchanged.

For the present, therefore, the official U.S. Government policy on KI is still the one adopted in 1985, nine months before Chernobyl. Its use of the words "not worthwhile" with regard to KI is based upon what purports to be a cost-benefit analysis. This analysis measures the cost of KI against the cost of curing "thyroid nodules," and concludes that instead of spending money on prevention -- cheap as prevention would be -- it would be even cheaper for society to put its resources into curing the thyroid disease if and when it occurs.

Let me interject at this point what I mean by prevention being cheap. The NRC staff calculated in 1994 that stockpiles sufficient for the vicinity of all nuclear plants would cost a total of $100,000 to at most a few hundred thousand dollars. That is for the whole country. The NRC staff also calculated that at that rate -- about $1100 for the average plant -- it would be cheaper to buy stockpiles than go on studying whether to do so. Isn't that the definition of a "no-brainer"? Only in Washington would we spend more money studying whether a medicine to protect our children is worth buying than the medicine itself would cost.

To return to the cost-benefit approach underlying the current policy, because it is based exclusively on economics, mechanistically balancing dollars for KI pills against dollars for medical bills, it does not take into account the possibility that people might have reasons other than saving money for preventing cases of disease. The policy turns the old adage about an ounce of prevention being worth a pound of cure and turns it upside down.

Eleven years after Chernobyl, it reflects little credit on our Government that this approach, of treating the disease after the fact rather than spending a tiny sum on prevention, should still be the basis of our policy for dealing with radiation-caused thyroid cancer. The result is that today, children in other countries, from Japan to Poland and from Canada to Switzerland, have a protection that American children don't have. In the United States, unbelievable as it sounds, we have KI to protect the sharks at Sea World but

not the children who come to see them.[2]

All over the world, countries know that if you are serious about being prepared to protect the public in nuclear emergencies, you should have three arrows in your quiver. Those are: (1) evacuation, which is the ideal solution -- when it is feasible; (2) sheltering, which means taking cover; and (3) potassium iodide. Having all three options gives you the flexibility to choose among them, or use them in combination, depending on the particular circumstances.

If you can evacuate the entire population before the radioactivity arrives, and don't need to use KI, so much the better. But in the real world, bad weather, congested roads, or changing winds can make a full evacuation impossible. In that case, it's better to be safe than sorry.

The French, Germans, Swedes, Slovaks, Austrians, Russians, Japanese, Canadians, and many more, all know this, and they stockpile KI. It's cheap enough, at about 10 cents per person protected, that the Poles keep 90 million doses on hand.

Let me emphasize that I am not an alarmist about nuclear power, any more than are Senators Joseph Lieberman and Alan Simpson, who wrote to the NRC in 1994 to urge it to embrace KI stockpiling. I think that a major release is unlikely, because, generally speaking, our plants are well built and well run. But we have emergency planning because we know that accidents <u>can</u> happen, and that their consequences can be serious. If we are going to have emergency planning at all, it might as well be done right. I have often compared KI to the lifejackets on a ferryboat. Ferryboat accidents are very rare, and if one does occur, it is better to be evacuated in a lifeboat than to jump into the sea in a lifejacket. But in the real world, the unexpected happens, so we have lifeboats <u>and</u> lifejackets. We know that there is no inconsistency between the two: there is nothing about having lifejackets as a backup protection that could interfere with evacuation by lifeboat. So we don't do fancy cost-benefit analyses, we don't study the issue for 15 years, we just do it, because it would be reckless and irresponsible not to.

Last December, when the Maine Advisory Commission on Radiation voted unanimously to support stockpiling, one of its members explained his vote in these words: "Ten years from now, if we have a release, I would rather say that we erred on the side of conservatism, <u>knowing what we know</u>." I think he

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[2] The 8-year-old daughter of Charles Pond, the director of Tennessee's program, having somehow learned that sharks in captivity require KI for their health, persuaded her father that as the state's KI reaches the end of its shelf life (5 years), it should be donated to Sea World, where it is added to the sharks' water. See her father's statement at p. 57 of the transcript of the public meeting on KI held at FEMA on June 27, 1996. Young Ms. Pond's accomplishment was written up in the "Kids Did It!" section of a recent issue of the children's magazine, "National Geographic World".

hit the nail on the head.

If the case for KI is as compelling as I have suggested, the question may be asked, what are the arguments against it? The arguments one hears against KI fall into two classes. First, there are those that are just plain invalid -- factually incorrect. The second are the objections that although they may be factually correct -- for example, that evacuation is generally the best option -- are still not a good reason to be without KI stockpiles.

I will start with the wholly specious arguments, which number six.

1. "There is no new data challenging existing policy."

I have dealt with that above.

2. "Loss of the thyroid is not life-threatening."

This issue also I have dealt with above. Thyroid cancer can be life-threatening, and Chernobyl-related disease has already claimed a few lives among children in the former Soviet Union. But even if it were true that thyroid cancer is never fatal, who says a disease has to be life-threatening to be worth preventing? That's not the standard we use when we have our kids immunized against mumps, measles, and chicken pox.

3. "KI is not cost-effective."

KI is an insurance policy -- backup protection in case of certain events that are unlikely but have serious consequences when they do occur. Is it "cost-effective"? The problem with framing the issue that way is that if by "cost-effective" you mean "likely to pay for itself over time," no insurance policy meets that test. The insurance companies would all be bankrupt if they didn't take in more from the average buyer than they pay out. Rational people, when deciding whether insurance is worthwhile, don't ask whether it is sure to pay for itself, but whether it provides valuable protection at a reasonable cost. Stockpiling of KI meets that test.

I should add that in 1992, the NRC commissioned a revised cost-benefit analysis. Whereas the old analysis had found an extremely high ratio of costs to benefits, the new study found that the costs and benefits were very close -- about 2 to 1 -- for the population within a 5-mile radius of reactors. Moreover, there is an error band of plus or minus two orders of magnitude when you are talking about the probability of severe accidents. Thus by the NRC's own calculations, KI might actually be cost-effective by a factor of 50 for close-in populations.[3]

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[3] Sometimes, even today, the opponents of KI will assert that there has been "no new information significantly challenging the basis of the 1985 policy," or similar words. What that means, when parsed out, seems to be this: that the cost-benefit analysis of the 1980's showed KI to be non-cost-effective; that

4. "KI could complicate evacuation."

You sometimes hear the argument that KI will diminish safety in an emergency, because people will ignore evacuation orders and go looking for KI instead. That's very farfetched. In fact, if you wanted to encourage evacuation, you might want to tell people over radio and television that when they get to the evacuation center, they will be checked out medically and given a medicine, potassium iodide, that will help protect them against radiation. And you add that this drug will not be available locally. So KI should not be a hindrance to an orderly evacuation; it might even be an incentive.

5. "KI carries a risk of serious side effects."

The best data on side effects comes from the Polish experience after Chernobyl, which is documented in a medical journal article co-written by Dr. Janusz Nauman, a Polish health official, and Dr. Jan Wolff, an NIH scientist. The Poles gave out 18 million doses. Two people were hospitalized, briefly. Both of them had known iodine allergies and took the drug in spite of being warned not to. Our own FDA says the benefit outweighs the side effects. The doctors of the American Thyroid Association were well aware of the side effects issue when they unanimously endorsed stockpiling in November 1996.

In addition, an NRC staff document issued in 1995[4] cites a study which looked for adverse reactions in people who took cough and cold medications containing the drug. It reported that "for the most current data involving 38 million equivalent doses of KI consumed, there were no reports of adverse reactions." [Emphasis in the original.]

6. "KI could increase a state's risk of liability."

Distribution of KI would take place only after an advisory from the federal government that it was appropriate. In that situation, with a state following federal directives and doing the best it could under emergency conditions, who would find a state liable? If I were a state, I would be much more worried about the consequences of not having a KI stockpile, given all that is known about the drug's value. If ever there were an accident, and it turned out a state had no KI to give out because it had taken its medical advice

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the reanalysis still showed KI to be non-cost-effective (though by a much narrower margin); and that accordingly, there has been no change. This kind of verbal sleight-of-hand creates the false impression that the Government has not learned anything casting doubt on the basis of the 1985 policy.

[4] Nuclear Regulatory Commission: An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident (NUREG/CR-6310, February 1995). Prepared by S. Cohen and Associates, Inc. and Scientech, Inc. for the NRC.

from lobbyists instead of doctors, that would be the time to worry about liability.

The following are eight arguments that are factually accurate, wholly or in part, but still are not persuasive reasons to forgo stockpiling.

7. "Evacuation is preferable."

The most common argument against KI is also the most meritless: that evacuation is better, so we don't need KI and shouldn't even have it around as a precaution. The problem is that evacuation isn't always feasible. The NRC and FEMA have never claimed it was. KI is backup protection -- Plan B -- for those situations where evacuation cannot be completed in time to avoid a substantial radiation dose to the thyroid -- for example because of adverse weather conditions, blocked roads, or widely dispersed radioactivity. Also, people may be exposed to radiation while they are evacuating -- automobiles don't afford much protection.

Moreover, it is not an either/or proposition. You don't choose between backing evacuation and backing stockpiling of KI; you do both. The question is whether you have three weapons in your arsenal -- evacuation, sheltering, and KI -- or only two, in a situation when the third weapon costs only a pittance.

8. "Big accidents are unlikely."

It is true that big accidents are unlikely. Generally speaking, a combination of good design, good operation, and good regulation makes American nuclear reactors quite safe. But there is a big difference between saying that accidents are unlikely and saying that they cannot happen. If we could be sure that accidents would not happen, then all emergency planning -- sirens, drills, and the like -- could go out the window. The cost of KI is a drop in the bucket by comparison to what is already spent on emergency preparedness. The reason we have sirens and drills and the rest is that we know that accidents can happen. (So can acts of terrorism.) If we accept the idea that emergency preparedness makes sense, then our preparedness ought to be first-rate, not second-rate.

9. "KI protects only one organ, whereas evacuation protects the whole body."

This is true, but nevertheless is not a valid reason to forgo stockpiling of KI. Evacuation is certainly the preferred protective action, when it is feasible, and when it can be accomplished in such a way as to avoid any exposure to radiation. But this may not always be the case. The Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA-400-R-92-001, published by the Environmental Protection Agency in May, 1992, makes clear that evacuation may be constrained by weather, floods, and road conditions. Moreover, there may be a danger to the public during an evacuation, since automobiles offer little shelter (about 10% protection). Thus

although potassium iodide protects only the thyroid gland, it can, when used in conjunction with sheltering, make evacuation unnecessary, thereby averting the risk of radiation exposure during evacuation.

The EPA Manual thus makes plain that choosing evacuation over sheltering during a radiological emergency does not mean zero radiation risk to the evacuees; on the contrary, it may sometimes mean higher radiation doses to the public, with pregnant mothers and their children at greatest risk of all. On this last point, the Manual explains that the particular danger to the unborn child is a risk of serious mental retardation so high, especially when the exposure occurs between the 8th and 15th week of gestation, that "induced abortion" may be indicated for any expectant mother who receives more than a relatively small dose of radiation (10 roentgen).[5]

Furthermore, the Manual makes clear that in a major accident, the dose to the thyroid may well determine whether the EPA Protective Action Guidelines are reached, and officials therefore have no choice but to evacuate. If people can be provided with KI while they shelter, and their thyroid dose thereby minimized, evacuation may be unnecessary, and the whole body dose that they would receive during evacuation can be averted.

Thus while it is true that KI protects only the thyroid, having the KI option may make it possible to avert the whole-body doses that would be received during evacuation. All the above makes plain how desirable it is for decisionmakers to have the option of giving out KI. Without stockpiles, this option as a practical matter does not exist.

10. "Public confidence in the technology could be affected."

That is a quotation from an industry "White Paper" on KI that was sent to the Nuclear Regulatory Commission in 1993. The same argument could be made to assert that we shouldn't have containments or emergency core cooling systems at nuclear plants, since both of those structures might remind people that accidents can happen.

You don't hear the ferryboat operators complaining that having lifejackets on board will diminish confidence in ferryboat technology. If I were the industry, I would be embracing KI, and making the point that even though it is very unlikely that it would ever be needed, the industry is committed to ensuring that Americans are protected to the highest standard in the world.

11. "The logistics of distribution need more study."

The opponents of KI stockpiling sometimes try to change the subject from

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[5] See pages B-11, B-18. To avoid misunderstanding, let me stress that EPA is not recommending abortion for pregnant women exposed to these levels of radiation, it is just reporting what the extensive journal literature on the subject says.

whether KI is a valuable protective measure (an argument they know they will lose) to the logistics of delivering the drug in an emergency. The idea is to make the delivery of KI sound just impossibly complicated, so as to put off, preferably forever, the question of whether it makes sense to have the drug at all. This is the cart-before-the-horse argument I referred to earlier. Those arguments were made at the June 1996 meeting at FEMA, and answered by Dr. Jacob Robbins of the National Institutes of Health, speaking for the American Thyroid Association. He observed that there were two issues: whether to stockpile KI, and how to deliver it to people in an emergency. He said:

> "You're sort of asking the question: Which should come first? If you remember back to the Three Mile Island incident, there was no stockpile. It was requested. With a great deal of difficulty, in a rather inadequate way, it was finally made available. And it was ready to be used but with a delay. I think we have to think of both aspects. And what the American Thyroid Association has said is, create the stockpiles, have them available, and then have expert groups developing the mechanisms of how to distribute this in time of need."

12. "<u>The states don't want it.</u>"

This is an argument you hear again and again at the federal level. The Federal Government has been giving the states inaccurate and incomplete information about KI for 15 years, and it is small wonder that many states therefore believe that KI is undesirable. Once states begin to get full and up-to-date information about KI, their attitude toward stockpiling is likely to change, as Maine's did. Nevertheless, you still find some in the Federal Government touting surveys that were conducted several years ago, before most states had even begun to focus on the KI issue, for the proposition that there is no point in offering the drug to the states because they would not accept it if it were offered.

13. "<u>People can buy it for themselves.</u>"

The argument can be made that people are free to buy the drug for themselves, and that the states and the Federal Government should not be involved. First, the drug is unlikely to be available locally. Second, people will know to buy the drug only if the authorities accept the obligation of informing them. It would probably be cheaper to buy a stockpile than to take on the task of telling people that they should consider buying it. Third, in an emergency, some people -- such as schoolchildren -- will not be at home. Fourth, do you really want to say that for the people who didn't have the foresight or money to buy the drug, it's their tough luck?

To leave it up to individuals would be like telling ferryboat passengers that they are free to bring their own lifejackets. It's simpler, fairer, and better health policy to stockpile KI and bring it out for the entire affected population in time of need.

14. "Because the Federal Government has recently decided to stockpile KI in 27 cities for acts of nuclear terrorism, states and localities can rely on the Government's stockpiles in an emergency, and need not consider stockpiling in the vicinity of nuclear plants."

The shift in U.S. policy by which KI will be stockpiled for terrorist events is a good thing, insofar as it represents a recognition that KI is valuable in radiological emergencies. If it is valuable for emergencies caused by acts of terrorism, then it is also valuable for emergencies caused by accidents. But these terrorism stockpiles are likely to be very limited in size -- a few thousand pills -- and in any case, we are talking about a medicine whose value is entirely dependent on time. Administering the drug before the exposure to radiation is better than after, one hour after is better than two hours after, and so on. Thus it makes sense to have the drug close at hand, and to have plans in place for its use, for if there is one thing we know about emergencies, it is that planning is always preferable to improvised, ad hoc responses.

* * * * *

In conclusion, Americans have a right, where nuclear hazards are involved, to expect their Government to ensure both that they are protected adequately and that they are given accurate and complete information. In the case of potassium iodide, the Government has so far done neither. As a result, though American children should enjoy radiation protection second to none, today they do not.

I hope the day will soon come that the Federal Government meets its responsibilities both to protect and to inform the public, where radiation and thyroid cancer are concerned. Until that day comes, states must rely on their own expertise, and on the expertise of those whom they consult, and decide for themselves how best to protect their citizens, especially the youngest ones.

Attachments:
Letter from Senators Joseph I. Lieberman and Alan K. Simpson, April 20, 1994
Letter from Dr. Jacob Robbins, July 8, 1996

United States Senate

[illegible]

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 liva 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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National Institutes of Health
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8 July 1996

William F. McNutt, Chairman
Federal Radiological Coordinating Committee
Ad Hoc Committee on Potassium Iodide
Federal Emergency Management Agency
Washington, D.C. 20472

Dear Mr. McNutt,

I very much appreciated the opportunity to participate in the 27 June meeting to consider stockpiling KI. I want to thank you for conducting an interesting and well run meeting, and also to reinforce my wish that those of us who recommended stockpiling convinced your committee that this is long overdue. The reasons are clear enough:

1. The Chernobyl experience has shown us that thyroid cancer is indeed a major result of a large reactor accident, even when evacuation is carried out;
2. The Polish experience has shown us that large scale deployment of KI is safe;
3. The Three Mile Island experience has shown us that it is not easy to obtain a good supply of KI in an emergency;
4. The shelf life of properly packaged KI is extremely long;
5. The advantage of having a supply on hand for immediate use far outweighs its moderate cost;
6. The problems attendant on predistribution are immaterial for the matter of creating a stockpile;
7. No one questions the ability of KI to protect the thyroid from exposure to radio iodine.
8. Even though KI administration before any exposure is ideal, the Chernobyl experience also has shown us that the exposure can

continue for days; institution of KI blockade at any time in this period is beneficial.

I sincerely hope that the subcommittee has been convinced by these arguments, and that the full committee will now devote its effort to creating one or more stockpiles and to developing the methodology for rapidly distributing the KI to a region where an accident is imminent or has already taken place.

I should add that the forgoing presents my personal opinion. I represent myself and the American Thyroid Association in this matter, but not the Public Health Service.

Sincerely yours,

J Robbins

Jacob Robbins, M.D.
Scientist Emeritus

Peter G. Crane / 4809 Drummond Avenue / Chevy Chase, MD 20815 / 301-656-3998

FAX FOR: ROGER SUPPES
OHIO DEPT. OF HEALTH
614-466-0831

FROM: PETER CRANE
301-656-3998 (telephone)

* * * * *

December 6, 1997

Mr. Roger L. Suppes, Chief
Bureau of Radiation Protection
Ohio Department of Health
246 N. High Street
Columbus, Ohio 43266-0118

Dear Mr. Suppes:

Thank you for the opportunity to comment on the summary, prepared by the Ohio Commission on Dispute Resolution and Conflict Management, of the concerns and issues raised by participants in the meeting on potassium iodide (KI) conducted in Painesville on October 28. I would also to reiterate my thanks to you and Mr. Lucia for inviting me to take part in the meeting. The meeting, I thought, was a fine example of democracy in action: a state and a local government, responding to citizen concerns by asking questions, giving the interested public an opportunity to be heard, and conducting its business in the open.

As in the past, in providing these comments I am writing in my personal capacity, not as an employee of the NRC, and this is written at home, on my own time.

First, I would like to inform you of some developments since the Painesville meeting, and then I will offer comments on the summary of the concerns and clarifications offered by the participants in the meeting.

A. **Recent Developments**

1. **NRC Staff Admits to "Misinforming" the Commission about KI**

On November 5, 1997, the Nuclear Regulatory Commission held a public meeting on potassium iodide -- the first such meeting in 14 years -- at which it received presentations from the Federal Emergency Management Agency (FEMA), the NRC

*technical staff, and me.[1] Among other things, the meeting was notable for the admission by the NRC staff that it had "misinformed" the Commission when it reported, in a June 1997 memorandum, SECY-97-124, that when the issue of KI was before an interagency group (the Federal Radiological Preparedness Coordinating Committee) in 1995, FEMA was the agency that opposed any change in the existing federal KI policy. In fact, said an NRC staff official, it was the NRC, not FEMA, that had opposed such a change. The NRC staff official stated that he had learned of this through a letter sent by me a few days earlier to the Federal Emergency Management Agency.[2]

The NRC staff did not explain, at the November 5 meeting, why it had misinformed the Commission; it is noteworthy that it did not claim that the error was inadvertent. Moreover, when a Commissioner asked about the assertion in my petition for rulemaking that existing policy was based on misinformation provided to the Commission and the public in the 1980's, the only staff member willing to admit to long familiarity with the KI issue said that he "had no answer."[3]

The tape of the October 28 meeting in Painesville shows the NRC staff representative making the identical statement which the NRC staff admitted was "misinformation" only a week and a day later. Thus to the extent that one of my major themes at the Painesville meeting was that the Federal Government has for many years been giving inaccurate and incomplete information to the states, the NRC staff seems to have demonstrated the validity of my contention in the Painesville meeting itself.

2. **Filing of Amended Petition**

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[1] The transcript of that meeting is available through the NRC's website (www.nrc.gov).

[2] The context suggests that FEMA was unwilling to allow the NRC staff to shift to FEMA the responsibility for having opposed a change in existing KI policy in 1995.

[3] It is somewhat extraordinary that at this late date, the NRC staff should have no answer to the question of whether the staff misinformed the Commission and the public about KI in the 1980's. This charge was a central element of my Differing Professional Opinion on KI, which the NRC staff first received in 1989 and spent the next four or five years evaluating. Attached to that document were extensive sections of the transcript of a November 22, 1983, Commission meeting in which, I claimed, the misinformation was provided. I made the same charge of misinformation in my 1995 petition for rulemaking, again with full documentation and lengthy quotations from the transcript of the November 1983 meeting. I also made this charge in my statements to a public meeting on KI held by FEMA in June 1996 and to a December 1996 meeting of the Maine Radiological Advisory Committee. At each step, the NRC staff was fully aware of the charges I was making against it, because it received copies of my statements.

At the Commission meeting on November 5, I was asked by Chairman Jackson exactly what it was that I wanted. I replied that I would be satisfied with a rule change under which the NRC would "require that consideration of potassium iodide be given in the formulation of emergency plans," but "would not ram potassium iodide down the throat of a state that emphatically rejected it." I made clear that I was asking for two things: a statement clearly recommending stockpiling of KI as a "reasonable and prudent" measure, and a rule change identifying what is meant by a "range of protective actions" (i.e., evacuation, sheltering, and KI) and requiring their consideration.

I was therefore asked to submit an amendment to my petition reflecting this approach, by which states would be required to consider, but not necessarily to adopt, KI stockpiling. I did so by a filing of November 12, 1997. In filing this amended proposal, I was changing only the bottom line of my 1995 petition -- and that only slightly -- but was not withdrawing the original petition or any of the arguments made in it for a change in policy. Thus any inference that I have retracted the 1995 petition would be erroneous. Rather, in the hope of a sound and expeditious (if less than ideal) resolution of a difficult and divisive issue, I was offering a compromise on the bottom line of the rule change that would result from granting the petition.[4]

I was also asked to provide a suggested markup of the draft Federal Register notice proposed by the staff in SECY-97-124.[5] In providing this as part of my November 12 filing, I offered some overview comments:

> [T]he staff's draft Federal Register notice, both in the selection of the facts it chooses to report and in its overall tone, ... is heavily slanted against KI.
>
> I would therefore be remiss if I did not candidly advise the Commission that the draft Federal Register notice, if issued in its present form, is likely to bring nothing but opprobrium to the NRC and to FEMA. In large measure, the notice's failings speak for themselves. What is one to say about a notice that does not get around until page 8 to mentioning that the prevention of cancer is the primary purpose of using KI? What is one to say about a purported history of the KI issue that describes how the FRPCC

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[4] So limited a change would mean no need for a new round of public comment on the amendment to the petition; instead, the agency could proceed directly to rulemaking.

[5] The document prepared by the Ohio Commission on Dispute Resolution & Conflict Management, and dated November 3, 1997, states in part, "Federal Register Notice has been issued -- contains current policy -- standing offer for NRC to fund." While the attendees at the Painesville meeting might well have received this impression, in fact no Federal Register notice has been issued. All that has been issued to date is the NRC's July 1, 1997, press release.

almost reaffirmed the 1985 KI policy two years ago, but does not mention Chernobyl, even though that accident has produced an extraordinary wealth of new data both on radiation-caused thyroid cancer and on the safety and efficacy of KI?

Can the NRC staff really mean to suggest that it is important that the public learn all about petty bureaucratic maneuverings that occurred in 1994 and 1995, but nothing about the upsurge of childhood thyroid cancer taking place now in the former Soviet Union? This is the way to court not merely criticism, but also ridicule and contempt.

The NRC staff has not yet replied to my filing of November 12.

3. **Meeting of New York State Radiological Health Advisory Committee**

On November 15, 1997, the New York State Radiological Health Advisory Committee met in Albany to consider the issue of KI stockpiling. The eight members of the panel were unanimous in support of having KI available for use in radiological emergencies. It deferred until a later date the logistical questions of how best to go about ensuring the availability of the drug. This recommendation will be passed on to the director of the New York Department of Health.

I think it is accurate to say that the members of the Committee were puzzled that the issue of KI was even controversial, and they asked what the arguments were against it. I quoted to them the comment of an Illinois state official that "loss of the thyroid is not life-threatening[6]," and at least several of the Committee members were -- so it seemed to me -- appalled at the depth of ignorance revealed by this comment. One member volunteered that he had a patient with thyroid cancer whom he considered terminal, and another said that in a child, even the surgery can be life-threatening. Another pointed out that thyroid surgery can also affect the parathyroids, which control the body's use of calcium.

The same day as the Albany meeting, an article in "USA Today" reported that Illinois has decided against KI stockpiling. I think it deeply regrettable that this decision was apparently made on the basis of woeful ignorance of the medical issues involved -- an ignorance which the NRC staff has done nothing to correct. (An NRC staff member was present at the 1996 FEMA meeting at which the Illinois state official made his comment, and said not a word to suggest that the official's grasp of the medical ramifications of thyroid cancer was deficient.) Again, as I stressed at the Painesville meeting, if states are ill-informed about KI and thyroid disease, the blame lies much less on the states than on the Federal Government, for its failure

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[6] Curiously, the identical words -- "loss of the thyroid is not life-threatening" -- appeared in the written statements of Illinois and South Carolina. This raises the question whether their misinformation came from the same source, and if so, from whom.

over 15 years to provide the states with accurate and complete information.

I am sure that the Illinois state official means the best according to his lights for the almost 12 million citizens of his state, but he has helped make Illinois a byword for ignorance and closemindedness when it comes to protecting the thyroids of our children from cancer. I hope and trust, therefore, that Ohio will follow the example of Maine and New York, not of Illinois.

B. Response to Concerns and Clarifications

1. NRC "Clarifications/Concerns"

I will deal briefly with some of the points attributed to the NRC.

a. It is true that under existing policy, distribution of KI is a state and local decision, and that states have had the opportunity to stockpile and distribute it if they so choose. It is also true, however, that federal policy, adopted in 1985, has tended strongly to discourage states from doing so, by using strong language -- "not worthwhile" -- with respect to KI.

b. As noted above, no Federal Register policy announcing the new policy has been issued.

c. As to whether the NRC (or the NRC staff) is or has been "anti-KI," I think I have said enough above.

d. On the point that "KI is site specific and only protects thyroid," this is true but beside the point. First, KI is not proposed as an alternative to those measures that protect the whole body, but as a complement to them. Moreover, there are circumstances in which KI can indirectly result in reducing whole body doses, even though the medicine itself protects only the thyroid gland. Although this sounds paradoxical, it is not. KI, by keeping radiation dose to the thyroid below the protective action guidelines at which evacuation is required, may make sheltering a viable option when it otherwise would not be. This in turn means averting the whole-body doses that might be received during evacuation, if the plume of radioactivity arrives before evacuation is complete. (Automobiles provide very limited protection against airborne fallout.) Whole-body doses are particularly dangerous to children in utero, especially during weeks 8 to 15 of pregnancy.

e. On the need of the state to deal with the FEMA local office, it is noteworthy that when asked by an NRC Commissioner at the November 5 meeting about the provisions made to move KI from terrorism stockpiles to nuclear power plant sites in the event of an accident, a FEMA official indicated that no consideration had yet been given to this issue. This seems to highlight the importance of having KI on hand locally if its distribution is to be a realistic possibility in the event of an accident.

2. Comments and Concerns of Other Participants

a. Liability seems to be a concern on the minds of many commenters. The short answer is the one offered by Connie Kline at the meeting: that states and localities should be more concerned about the lawsuits that would result from their failure to have stockpiled KI in an emergency than from anything that could go wrong from KI use during an accident. We know from the Polish experience during Chernobyl that wide-scale use of KI is safe. We know from the Soviet experience during Chernobyl that without KI, the result can be large numbers of aggressive thyroid cancers among children.

There is not and cannot be any guarantee that in an accident, it will be possible to get KI to everyone, even if planning is good and everything goes according to plan. It is in the nature of emergencies that the unexpected can and does occur. In such a case, it is possible that some people whom the KI did not reach would feel aggrieved. However, if there is no KI at all, then it can be guaranteed that no one will get the medicine, and that all of them -- with good reason -- will then feel aggrieved, especially the parents of small children.

A state that has done its best -- and that includes reasonable measures to screen out persons with known iodine allergies -- should have nothing to fear on liability grounds from having stockpiled KI. In any case, it would not be used (under the Federal Radiological Preparedness Response Plan) until the Federal Government had advised its use was warranted in the particular accident situation. Moreover, the drug was ruled "safe and effective" for use in radiological emergencies as long ago as 1978.

Liability, in short, is a bogeyman. States should not allow it to frighten them away from a reasonable, conservative safety measure widely used throughout the developed world.

b. Dr. Haler of the Ohio Department of Health raised concerns about whether there are elements in the population that might lack sufficient sophistication to use KI safely. Whether or not her premise is valid, this is not a reason to defer a decision on whether it makes medical sense to have the KI option in an emergency. Rather, the issue of how best to present KI to members of the public, like the issues surrounding distribution, is a question of implementation. As the New York State Radiological Health Committee observed, the first question is whether the drug is desirable medically, and only if that question is answered in the affirmative is it necessary to reach the questions of implementation.

To worry about details of distribution before a decision on whether the drug makes sense from a medical standpoint would be to put the cart before the horse. The first step is to make the decision to stockpile. This will assure that the medicine exists in sufficient quantity, sufficiently close to the people who may need it in an emergency. Meanwhile, federal, state, and local government officials can be addressing the question of what is the most effective way of getting this medicine to

the affected population in an actual emergency.

c. On the issue of whether there is "new data," it is important to cut through the fog of artfully worded and bewildering statements from the NRC staff. The NRC staff has been assuring the world for so long that there is "no new information" on KI that this point needs to be nailed down. First, is there new information since 1985 on the health impacts of a major nuclear accident? Yes, in the areas of former Soviet Union affected by fallout from Chernobyl we are seeing childhood thyroid cancer in greater numbers, and appearing sooner, than had previously been expected. Second, is there new information since 1985 on the safety and efficacy of KI? Yes, we have seen the Polish data on the use of KI during Chernobyl (18 million people received the drug), and there is also information on consumption of KI as an ingredient of over-the-counter cough and cold medications: 38 million equivalent doses of KI without a single adverse reaction reported, according to a 1995 NRC staff document.

What, then, does the NRC staff mean when it talks about "no new information that seriously challenges the basis of the 1985 policy"? Apparently, it means that the 1985 policy was based on a cost-benefit analysis that showed KI not to be cost-effective, and that no one has since demonstrated that KI <u>is</u> cost-effective. This leaves out two important considerations: (1) a reanalysis of costs and benefits in 1992 indicated that costs and benefits of KI were far closer than previously calculated, and for the closest-in populations were nearly equal; (2) the discussion of a change in KI policy in recent years has focused not on cost-benefit analysis but on prudency, so that it is irrelevant whether new information challenges the <u>basis</u> of the policy. The fact is that a great deal of new information has come to light in the last several years that seriously challenges the <u>soundness</u> of the policy, whether or not it challenges the <u>basis</u> of the policy -- whatever that means.

In matters affecting health and safety, words should be used to illuminate issues, not to obscure them. To create the impression that no new information bearing on the value and safety of KI has accrued since 1985 -- the year <u>before</u> Chernobyl -- is to do a grave disservice to the public.

Sincerely,

Peter G. Crane

Peter G. Crane

Attachment: Draft regulatory language and Statement of Considerations, from amended petition submitted to the Nuclear Regulatory Commission on November 12, 1997

PROPOSED RULE CHANGE

For the reasons set forth in the Statement of Considerations, the NRC is proposing to change the planning standard in 10 CFR §50.47(b)(10) by adding one sentence, as indicated by underlining:

> (10) A range of protective actions have been developed for the plume exposure EPZ for emergency workers and the public. <u>In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate.</u> Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

STATEMENT OF CONSIDERATIONS

The Nuclear Regulatory Commission is proposing to amend its emergency planning rules, codified at 10 CFR §50.47(b)(10), to clarify the requirement that emergency plans must demonstrate that "a range of protective actions has been developed" for protecting the public in the unlikely event of a radiological emergency.

As amended, the regulation will spell out that in developing emergency plans, states must consider the following: evacuation, sheltering, and the use of radioprotective drugs (i.e., potassium iodide, or KI).

Potassium iodide, if taken in time, can protect against radiation-caused thyroid cancer, as well as hypothyroidism and benign thyroid nodules. Children's thyroid glands are particularly sensitive to these effects. Since the efficacy of KI in protecting the thyroid depends on timing (i.e., administering it either before or within a few hours after the exposure to radioactive iodine), the NRC believes that stockpiling of KI in the vicinity of nuclear power plants is a reasonable and prudent measure.

This proposed rule change should not be taken to imply that the NRC believes that the present generation of nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has improved since the current emergency planning requirements were put in place after the Three Mile Island accident. Rather, the rule change primarily reflects lessons learned from the Chernobyl disaster of 1986, both about the consequences of an accident and about the safety and efficacy of KI.

The Chernobyl accident demonstrated that thyroid cancer can indeed be a major result of a large reactor accident. Moreover, although the Food and Drug Administration declared KI "safe and effective" as long ago as 1978, the drug had never been deployed on a large scale until Chernobyl. The experience of Polish health authorities during the accident has provided confirmation that large scale deployment of KI is indeed safe. Further reassurance about the safety of KI comes from a U.S. study of potential adverse reactions to KI, which is an ingredient in many cough and cold medicines. This study showed 38 million equivalent doses without a single adverse reaction being reported. According to the World Health Organization, children are even less likely than adults to experience allergic reactions to KI.

The NRC therefore recommends that states make KI stockpiling one of their tools to prepare for the unlikely event of a major nuclear accident with offsite releases of radioactivity. While NRC strongly encourages the stockpiling of KI by the states, it does not mandate it under this rule change. The rule change requires only that states consider KI stockpiling in developing the "range of protective actions" mandated by the NRC's emergency planning rules.

The NRC has previously decided (on June 30, 1997) to support a change in federal policy by which supplies of KI will be made available, paid for by the Federal Government, to states that request it. The rule change proposed in this notice is consistent with that change in policy, and clarifies the effect of the policy change on the NRC's emergency planning rules.

The use of potassium iodide is intended to complement, not to replace, other protective measures. This rule change thus represents no alteration in the NRC's

view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs, when that is feasible. (Evacuation protects the whole body, whereas potassium iodide protects only a single gland, the thyroid.) Depending on the circumstances, KI may offer additional protection if used in conjunction with evacuation and/or sheltering.

The approach taken in this rule change is consistent with International Basic Safety Standards issued by the International Atomic Energy Agency, et al.; with the Federal Radiological Emergency Response Plan, issued by the Federal Emergency Management Agency in 1996; and with recommendations of the President's Commission on the Accident at Three Mile Island, the World Health Organization, and the American Thyroid Association, which represents physicians specializing in thyroid disease. Stockpiling of the drug is currently the practice in numerous European countries, as well as Japan, Canada, and three U.S. states: Alabama, Tennessee, and Maine.

In the event that a state, having considered the NRC's recommendation to stockpile KI, nevertheless decides not to include KI stockpiling in its emergency plan, it would still have access, in the event of a radiological emergency, to the various stockpiles of the drug that have been created by the Federal Government as part of readiness for acts of "NBC" (nuclear, biological, and chemical) terrorism. These stockpiles will be available on an ad hoc basis for radiological emergencies of all kinds. However, because experience shows that pre-planning is more effective than ad hoc responses to emergencies, and because pre-positioning of KI is likely to mean quicker access to supplies of the drug in an emergency, the NRC believes that it is reasonable and prudent to maintain stockpiles in the vicinity of nuclear reactors and to include provisions for their distribution in emergency plans.

The NRC recognizes that the decision to stockpile KI presents issues of how best to position and distribute the medicine, to ensure, e.g., that optimal distribution takes place in an emergency, with first priority given to protecting children; that persons with known allergies to iodine not take it; that members of the public understand that KI is not a substitute for measures that protect the whole body; etc. To date, these issues have been addressed in different ways in the numerous countries that currently stockpile KI. The NRC intends to work with states and localities to develop guidance on these and other points relating to the use of KI. The NRC believes that these implementation issues are soluble, given the level of expertise in the relevant federal and state agencies.

It is expected that FEMA or the FRPCC will provide guidance to states to assist their consideration of the issue of KI stockpiling, and that it will offer technical assistance to help those states which decide in favor of stockpiling to incorporate it into their emergency plans. It is expected that states will inform FEMA and the NRC of the results of their consideration of whether or not to opt for stockpiling. This will enable the Federal Government to provide KI as expeditiously as possible to states which desire it, as well as to provide any further assistance that may be called for, and it will also allow the Government to engage in better contingency planning for states that decide against stockpiling KI.