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March 4, 1994
Rockville, MD

Hugh L. Thompson, Jr. (17G-21)
Deputy Executive Director for
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U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Thompson:

Re: KI Issue

I was instrumental in establishing the current NRC position regarding KI. I have a whole box full of the early papers on the subject. But that's not the point - I'm merely establishing credentials for the following.

Please hold the bottom line: do not require that utilities distribute KI to the general public as a license condition. This was my bottom line over many years of discussions of the subject at the staff and commission levels. As I said to Peter Crane at one time: If I lived near a nuclear power plant, I'd have some KI for my family (it's so cheap!), but I think it would be legally obscene to require KI predistribution to the public as a condition of a license. If Peter wants KI available in the schools, then let the PTAs run car washes and buy some! At the time they cost only 2-3 cents apiece. Peter never did say just exactly what he wants. Neither did Richard Wilson, with whom I had some words on the subject, also.

Regarding the joint NRC/FEMA position paper of some years ago: I did not fight it because of one word: 'national' pre-distribution was specifically discouraged in a FR Notice. At the staff level I argued for a different position, to wit: that stockpiling of KI in schools, fire stations, hospitals, etc. within or just beyond the 10 mile EPZ made some sense, so a positive position statement was preferable. The control bureaucracy is already well established and the pills are cheap, so why not? I lost. But I knew that the position paper would not be the end of the matter.

The major technical basis document at the time was the Blond & Aldrich report on the efficacy of KI. Indeed, it showed that a 'national' KI predistribution program would not be cost effective in terms of cancers avoided (half or more of the calculated cancers arise beyond 50 miles at most sites - all except for IP, as I recall - so the emphasis must be on the area beyond 50 miles, for the cancer issue). However, the report also showed that, for people nearby, taking KI in the early time frame reduced the number of thyroid ablations to zero, for even the worst reactor accident conceivable! Avoiding injuries and fatalities are the first objectives of emergency response, of course, which should be reflected in the emergency preparedness. Unfortunately, nothing

much was ever made of this part of the report - except by me, I guess.

At the time, I published the attached Note in the HP Jr., and distributed a draft to peers in the NRC, FEMA, and EPA, in hopes that I could prompt a more enlightened discussion. As you are now well aware, I hope, KI has to be readily availably for it to be potentially beneficial. Moreover, in the early response phase, you'd need to take only <u>one</u> pill! So a big stockpile isn't necessary. But the FR position paper was published before my Note was published. It's interesting to note that the Russian paper I quoted was coauthored by Prof. Il'in, who was prominent in the Chernobyl response as deputy head of the U.S.S.R. National Academy of Sciences. The graph in the Note is rather notorious nowadays.

Good luck! Hang in there. Judging from the recent Post article (on the financial page, yet), you're on the right track, even if this is an FDA (not NRC) problem. (I'd recommend that the Commission tell the staff to quit bugging them on this, it's not the Commission's problem. It's odd to me that engineers and lawyers want to give expert advice on a medical, nay, pharmaceutical issue.)

Sincerely,

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P.S. You don't have to reply to this. But if you'd like to see my box full of papers on this, give me a call.

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NOTES

Potassium Iodide: Predistribution or Not? The Real Emergency Preparedness Issue

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A RECENT review article provided a broad sample of literature regarding the administration of potassium iodide (KI) to reduce thyroid dose upon inhalation of radioiodine (Cr84). Unfortunately, the article failed to address a fundamental point, to wit: for emergency preparedness, the KI issue reduces to the question: Should KI be predistributed or not? This note will shed some light on this narrow, yet fundamental question.

The potential efficacy of KI is illustrated in Fig. 1 (Il72). Ingestion of 130 mg of stable KI either some hours before intake of radioiodine, or within 2–3 h afterward, provides an effective block to the uptake of the radioiodine by the thyroid. A thyroid dose reduction factor of about 20 is possible if the KI is taken at the time of a slug (short, rapid) intake of radioiodine. Beyond 3 or 4 h after a slug intake, the benefit of the KI would be markedly reduced for many people, although one subject in the study benefitted to the extent of about 10% after such a delay. Only a few subjects were involved in this study, so the spread in individual responses would be expected to be greater in the public at large.

Two other significant observations by Il'in *et al.* (as translated from the original Russian) are:

(i) with regard to a slug intake of ^{131}I:

> "It is important to emphasize that the acceleration of the elimination of radioiodine which enters the body on a one-time basis cannot be achieved more by increasing the frequency of administration of large amounts of iodide than by a single administration of a large dose of iodides." (Il72, p. 234)

and (ii) with respect to the chronic intake case:

> "Thus, the result of studies involving repeated administration of ^{131}I convincingly show that quite a high value of protective effect can be reached only by administering to the body relatively large amounts of iodides (100 mg or more per administration) simultaneously with or several hours before the administration of ^{131}I. In our studies the protective effect . . . was reliably at a maximum upon daily administration of 200 mg of stable iodide . . . ." (Il72, p. 229)

Equal amounts of ^{131}I were administered daily in the latter experiments.

Thus, in either the slug or chronic intake case the initial dose of KI is most important, but for the slug exposure case the initial dose of KI is the *only* important one and it must be taken within 2–3 h to be of substantive benefit after a slug intake of ^{131}I. For the chronic intake (of ^{131}I) case, daily administration of KI would be necessary to maintain thyroid blockage. At any rate, the initial dose of KI must be immediately available to be of potential benefit, i.e. with or near a person or in numerous local distribution centers.

A decision against predistribution or local stockpiling would be tantamount to a decision to be unprepared for the administration of KI at a time when it would be most beneficial. This could well be a defensible position based on the low probability of an accidental release for which administration of KI would be warranted, the costs of a 40-y preparedness program and the limited benefits the drug would provide (US80a; US80b). On the other hand, the drug is quite inexpensive (about 10¢ each, capital cost). As an alternative, the preparedness matter could be left to the individual where the drug is available for purchase.

The number of persons selected to be involved in a preparedness program would depend on the radiation protection objectives of the authorities. A point often missed is that for an atmosphere release, a significant reduction in collective dose (and total numbers of adverse health effects) can be achieved only by reducing doses over long ranges, i.e. 50–200 km for most nuclear power plant sites in the United States (US83). Thus, a preparedness program would have to be broadcast to be potentially beneficial in this regard. By the same token, during an emergency response, the numbers of people who would have to respond to achieve this benefit would be quite large. This would raise the possibility of a small number of the low probability adverse reactions to KI described by Crocker (Cr84).

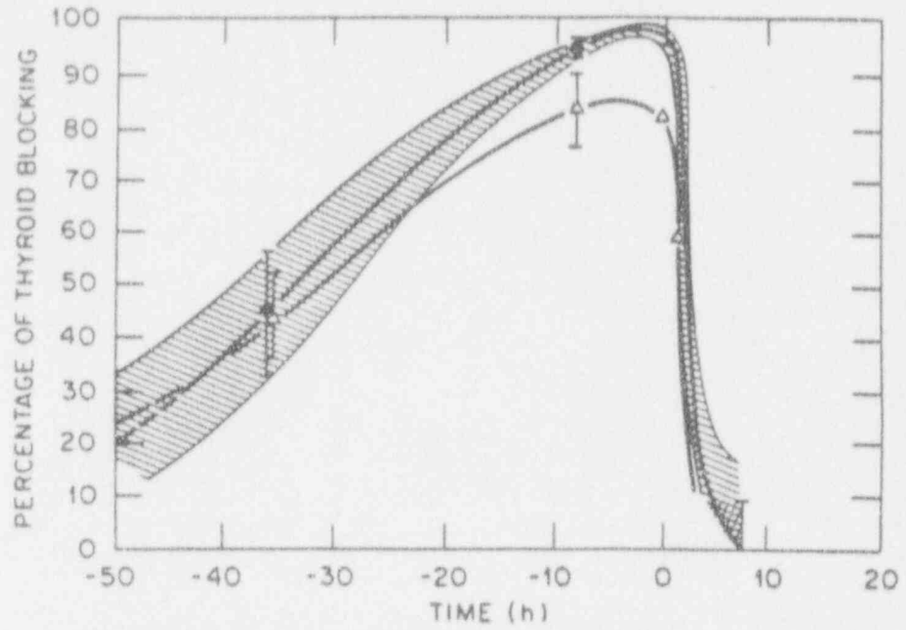

FIG. 1. Percent of thyroid blocking afforded by 100 mg of stable I as a function of time of administration before or after a 1 μCi slug intake of ^{131}I. Data points are for different subjects, of which only a few (3–5) were involved (I172).

In contrast to collective dose, which would increase with distance, individual risks of thyroid ablation and latent cancer decrease monitonically with distance (I172; US80a; US80b). Thus, a preparedness program which has the objective of reducing individual risks could be limited to a short range, e.g. 5 km, and fewer people, with a lower potential for adverse reactions to KI.

In the United States, the Nuclear Regulatory Commission and the Federal Emergency Management Agency recommend that KI be stockpiled in or near nuclear power plants for the use of plant personnel, emergency workers and inhabitants of certain local institutions during a radiological emergency (US80c). The U.S. Food and Drug Administration has determined that ingestion of KI would be warranted at a projected thyroid dose of 25 rem and has authorized the non-prescription sale of the drug (US82).

The remaining issue in the United States is whether or not KI should be predistributed to the public for immediate use in the event of the release of significant quantities of radioiodines to the atmosphere. The KI issue has been debated for many years in the United States but only recently has the focus been on the predistribution issue (US83; US84). The matter is unresolved at this time in the United States.

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