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July 16, 1981

Dr. Bernard Shleien  
Bureau of Radiological Health (HFX-4)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857



Dear Dr. Shleien,

I am sending this letter to you as my written comment on the FDA's Draft Recommendations on Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency (April 1981).

In brief, I find myself in complete agreement with your recommendations that potassium iodide be used to protect the thyroids of people who are in danger of receiving thyroid doses in excess of 10 to 20 rems from radioiodines. I think that the background discussion is incomplete at one point, however--on the relative biological effectiveness of X-rays and  $I^{131}$  in producing thyroid damage. And I think that the rejection in the accompanying background report\* of the usefulness of utility meters as storage points for potassium iodide tablets is at the very least premature. I expand on these two points below.

Comparison of the Long Term Effects on the Thyroid of X-rays and  $I^{131}$ :

Enclosed is a copy of my correspondence with the NCRP on this point. The following is a brief summary of its contents:

- On March 26, 1979 (Attachment #1) I wrote to the NCRP pointing out an error in a derivation in WASH-1400 (the NRC's Reactor Safety Study) of the ratio of the effects on the thyroids per rem of X-rays and internal irradiation by  $I^{131}$ . The NCRP report, Protection of the Thyroid Gland in the Event of Releases of Radioiodine (page 11), had fallen prey to this error when it quoted the conclusion drawn in WASH-1400 as follows:

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\* Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid-Blocking with Potassium Iodide (FDA 81-8158, March 1981, page 13).

"The ratios of  $I^{131}$  risks to external-irradiation (X-ray) risks are 1/67 for cancer and 1/53 for total nodules."

As is explained at some length in Attachment #1, the error in the WASH-1400 derivation was to compare the risks of nodules and cancer induction from  $I^{131}$  irradiation at very high--literally cell killing--doses of about 9000 rems with the corresponding risks from X-rays as determined at doses on the order of one hundred rems. The assumption that 9000 rems was in the linearly rising region of the dose response curve of the thyroid was obviously ludicrous and, to the extent that the references discussed by WASH-1400 dealt with the question of dose-response curves, they made clear that in this dose region the production of nodules and cancers is in fact a declining function of dose.

When I wrote Attachment #1, the error in WASH-1400 had already been pointed out in a report of an NRC advisory committee of which I was a member.\* My suggestion was that the NCRP issue an erratum to prevent this error from being propagated any further.

- The substance of the NCRP response (Attachment #2) when it came was contained in a letter dated October 15, 1979 from Dr. Eugene Saenger, the chairman of the committee which had written NCRP-55. According to an attachment to Dr. Saenger's letter, he was also a coauthor of the erroneous section in WASH-1400.

Dr. Saenger did not rebut my critique of that section but claimed that the conclusions derived there were nevertheless correct for other reasons.

- In my letter dated December 23, 1979 (Attachment #3) to Dr. Sinclair, President of the NCRP, I pointed out that Dr. Saenger's new arguments were also incorrect and I asked for "either a substantive response to my letter of March 26, 1979 by someone speaking for NCRP or a statement from you that Dr. Saenger in his letter did in fact speak for the NCRP".
- On January 22, 1980 Dr. Sinclair wrote back (Attachment #4) that "we are undertaking a further examination of this problem but...it may take some time for me to respond adequately to you". It is now 18 months since I received this response and I still have received no further communication from Dr. Sinclair despite at least one reminder (Attachment #5).

In light of this background I think that it is inappropriate for the FDA in its Draft Recommendations (page 8) to cite without comment the conclusions of the 1977 review article by Maxon, Thomas and Saenger in the American Journal of Medicine as follows:

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\* Risk Assessment Review Group Report to the U.S. Nuclear Regulatory Commission (NUREG/CR-0790, 1978, page 22.

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"Maxon et al., note that the available data suggest that for children  $^{131}\text{I}$  is about 1/70 as effective as external radiation in causing thyroid cancer and 1/50 as effective in causing nodules (15)."

Maxon et al., is, as Saenger pointed out to me in Attachment #2, "the contents of the thyroid section (Appendix H) of WASH-1400 in the open (referreed) literature". My criticisms of the treatment in WASH-1400 of the derivation of the relative biological effectiveness of  $^{131}\text{I}$  therefore apply also to the paper of Maxon et al. As noted above, these criticisms have been published in brief in NUREG/CR-0400 and, as noted in my letter to Dr. Sinclair of December 23, 1979 (Attachment #3), the 1972 National Academy of Science BEIR report had already rejected Saenger's arguments (then cited as Saenger, E.I. and Tompkins, E.A. personal communication).

I also note with some concern the following statement in the FDA's

Draft Recommendations (page 8):

"In a review of studies of persons exposed to internal irradiation from  $^{131}\text{I}$  for diagnostic purposes, 6 of 443 subjects developed benign thyroid lesions after 16 years follow-up. No cancers were found. This was reported by Maxon et al., based on personal communications from E. Tompkins and R. Hamilton relating to a group of persons less than 16 years of age who received a thyroid dose of 10 to 1900 rads (average 94 rads) (15). Both the prevalence of nodules and cancer were lower than expected in the general population."

On November 21, 1979 I wrote to E. Tompkins (Attachment #6) asking for any

"published or unpublished reports of your work on the effects of exposure of radioiodine on the thyroid gland. The data which you have collected in this area has been referenced in Appendix VI of WASH-1400 as only 'personal communication'."

As you will see, Tompkins' response to me (Attachment #7) indicates that she did not know what I was talking about. After ten years, perhaps it is time, therefore, to stop using Saenger's quotes of "personal communications" from E. Tompkins as a potential basis for public policy. If the FDA, nevertheless, insists on doing so, it should then also reference the much better documented refutations of Saenger's claims in the BEIR report, in NUREG/CR-400, and in my letters to the NCRP.

Utility Meters as Storage Points for Potassium Iodide:

The report, FDA 81-8158, which you coauthored dismisses (on page 13) in my view too cavalierly the usefulness of electrical utility meters as convenient storage points for potassium iodide tablets. Obviously, these locations are

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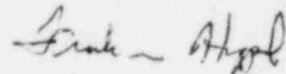
not suitable for all households but they may be suitable for a large fraction of households and, if the pre-distribution of the potassium iodide is made the responsibility of the electrical utilities, the electrical meter is a location to which the utility already has access. The problems which you cite of

"meters outside private houses, multiple meters in public area of apartment houses within reach of children, and even possible damage to the meter and electrical system by individuals trying to hurriedly secure tablets if they are stored inside glass covers"

could all be dealt with by placing the potassium iodide tablets in a child-proof, weatherproof, plastic bubble fixed with adhesive to the side of the meter.

Although I am not irreversibly committed to the idea that the utility meter approach is optimal, even as a partial solution to the potassium iodide predistribution problem, I believe that critics of the proposal should not feel that their duty is completely discharged before they come up with a better proposal.

Sincerely yours,



Frank von Hippel

cc: Representative Morris Udall  
Senator Paul Tsongas  
Nuclear Regulatory Commission  
Nuclear Safety Oversight Committee  
Dr. Warren Sinclair, President, NCRP

Attachments

FvH/zk