Sidney Rep. Ex. #13

THE WHITE HOUSE

WASHINGTON

April 3, 1979

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MEMORANDUM FOR GOVERNOR THORNBURG

FROM: JACK WATSON

I am sending you the attached memorandum from Secretary Califano for your information and guidance. We stand ready to assist you in any manner needed.

FOR IMMEDIATE TRANSMITTAL TO THE GOVERNOR.

THE SECRETARY OF HEALTH, EDUCATION AND WELFARE
WASHINGTON, D.C. 20201

April 3, 1979

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MEMORANDUM FOR THE HONORABLE JACK WATSON

Enclosed are recommendations of the Surgeon General with respect to thyroid blocking. Both the Director of the National Institutes of Health, and the Director of the National Cancer Institute, and the Commissioner of the Food and Drug Administration support these recommendations. These recommendations are:

1) Have workers in the plant and others on the island begin taking blocking doses now.

2) Have potassium iodide now personally available to all persons whose proximity to the site is such (perhaps up to ten miles distant) that they will not have as much as 30 minutes advance warning of I131 exposure.

3) Have potassium iodide available at convenient distribution points for distribution to other persons who may be exposed, such that they can have the medication at least 30 to 60 minutes in advance of possible exposure.

4) Accompany all distribution with notification to the effect that: All persons may take potassium iodide safely for a short time. All persons who: a) have goiter or known thyroid disease, or b) are pregnant or c) are breast-feeding a child should notify their physician when they start taking iodide and after they have stopped.

5) Preparations must be made for reducing the iodide dose after two weeks of administration of the amount on the labels. We will help you devise instructions for this if you wish.

6) Those in immediate touch with the local situation should assess these recommendations in light of knowledge about current risks and about the likelihood of advance warning of releases.

I also concur in these recommendations and urge that you provide this information to the state authorities as the basis for their action.

Joseph A. Califano, Jr.

Enclosure

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : The Secretary
Thru: ES_____

DATE: APR 3 1979

FROM : Assistant Secretary for Health
and Surgeon General

SUBJECT: Request for a Federal Advice on Thyroid Blocking

On April 2 we were asked by Gene Eidenberg to provide guidance from Federal health officials for the Governor's staff in Pennsylvania on the advisability of providing precautionary iodine blocking for residents of the Three Mile Island area. The following is based upon consultation with Dr. Donald Frederickson, Director, NIH, and three of his staff (Drs. Rall, Robbins, and Wolff, NIAMDD) and Commissioner, FDA, his staff (Dr. Richard Crout, Dr. Jerome Halperin and Dr. Paula Botstein, Bureau of Drugs) and Dr. Arthur Upton, Director, NCI. Dr. Frederickson had already consulted with his own advisory group on the morning of April 2.

The recommendation of the group is that workers in the plant and others on the island begin receiving blocking doses now. Persons farther from the facility, perhaps up to 10 miles distant, should have the solution made personally accessible and be given instructions for its use, but should not receive precautionary doses as long as the dose can be given at least 30 minutes before a significant exposure to I^{131} becomes probable. Persons at greater distances should have the solution available at convenient distribution points that can be reached within a time adequate to allow blocking doses to be administered at least 30 minutes before significant exposure. It is not possible for us to give recommendations in terms of precise distances from the facility, because the logistics of distribution and the probability of release affect those determinations.

Our advice is based upon the following considerations:

Blocking Effectiveness and Kinetics. Guidance on these subjects has been provided by the National Council on Radiation Protection and Measurement, Ad Hoc Committee on Thyroid Blocking, Report #55, recently published in the Federal Register (Dec. 15, 1978; copy attached). The blocking effect depends upon the action of non-radioactive iodine, provided as a saturated solution of potassium iodide (SSKI) at an adult dose of about 100 mg/day in competitively displacing I^{131} in the uptake mechanism of the thyroid. In experiments in which the interval between pulses of I^{131} and of KI was varied, blocking was fairly complete when the

blocking dose and the radioactive iodine were given simultaneously. About 50% blocking was seen when the KI followed the radioactive dose by 3-4 hours. Of course in real situations the exposure to radioactive iodine is continuous and the thyroid steadily accumulates it, so the blocking solution is effective even if doses of the KI ~~should be~~ follow the exposure. They should be commenced and continued even if the exposure has begun hours or even days before. The kinetics of this interaction do argue, however, that the largest effect will be obtained if the KI solution is administered before the radioactive dose. If, however, the thyroid has been exposed to elevated levels of iodine by the administration of KI over several days — as would be likely in a continuous precautionary dosage regimen — there may be "escape" from protection against a subsequent dose of radioactive iodine.

Possible Side Effects. The possible side effects of continuous administration of KI at high dose levels include some skin rashes (not serious), or (in a few cases per 100,000 population) hypothyroidism or hyperthyroidism. The latter effect, which is treatable, is especially likely in persons with goiter — a condition detectable in more extreme cases by bisible swelling of the neck. Persons with this condition should be advised to consult their physicians while taking and advised KI dosages, and to continue consultation after the regimen has been discontinued. Pregnant and lactating women also may be subject to some elevated risk from continued KI administration. Like those persons with thyroid disease, pregnant and nursing women should take KI when the rest of the population is advised to do so, but should consult their physicians during and after the regimen.

Other Risks and Benefits. The psychological effects on the population that may associated with an official program of protective medication are difficult to assess, but obviously should not be ignored. To some it may appear that hitherto unrevealed difficulties are now foreseen by the authorities. On the other hand, a successful program might well provide some reassurance that those responsible are displaying foresight and solicitude. It may also generate some positive sense of control on the part of residents over a situation in which they have been relatively powerless to affective outcomes up to now. We believe that only those directly in touch with the behavior and mood of the population at risk can make such judgments — and then only with difficulty.

It should also be pointed out that the decision depends critically upon information about the likelihood of a loss of containment at the site, about the nature of the accidents that might be anticipated, and about the intervals by which warnings might be expected to precede significant exposure at varying distances from the site. We believe that the benefits of protective dosing clearly outweigh the risks close to the site, where sufficient time to anticipate the exposure does not exist. Whether this zone extends to 2 miles or to five miles we cannot say.

We would emphasize that instructions will also need to be given to the population receiving blocking doses about how to discontinue the regimen after the need for it has passed. The dose must be tapered, presumably by a programmed decrease in the frequency of taking the medication.

It is our understanding that Dr. Neil Wald of the University of Pittsburgh is consulting with State health officials on this matter. Dr. Wald is highly knowledgeable in this area, and has been in regular communication with members of the NCRPM subcommittee and other experts.

Julius B. Richmond, M.D.