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The Decision to Withhold Distribution of Potassium Iodide during The Three Mile Island Event: Internal Working Document

Gordon K. MacLeod, M.D., F.A.C.P.
Secretary of Health
Commonwealth of Pennsylvania
P. O. Box 90
Harrisburg, Pennsylvania
17120

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I. Background

For some period of time--perhaps 4 to 5 years--prior to the events of the nuclear reactor accident at Three Mile Island on March 28, 1979, at 3:56 a.m., Pennsylvania's Department of Environmental Resources had been pursuing the subject of the availability of a saturated solution of potassium iodide (SSKI) for prophylactic uses with the Food and Drug Administration and with the State Department of Health. Both John Willforth, Director of the Bureau of Radiation Health, and Jerome Halperin of the FDA had been parties to those discussions with the Department of Environmental Resources.

However, it was not until 1977, shortly after the release of the National Council on Radiation Protection and Measurement's NCRP Report #55, that the FDA actually approved the use of KI as a blocking agent against radioiodine. This approval, however, did not result in the increased availability of the medication to populations which were located in close proximity to nuclear reactors, for two reasons:

- The FDA was unable to identify a manufacturer who was willing to produce the drug in the large quantities necessary to protect all reactor sites and contiguous areas; and

2. There were no monies available under Federal programs to pay for the manufacture and stocking of a medication that "no one would need."

Nevertheless, the FDA and DER had a loose verbal agreement that if the State ever "needed" SSKI, the Federal Government would provide it. The mechanics of acquiring the drug were never fully explored beyond this assurance.

II. The Decision to Produce SSKI

Very shortly after the first indications of difficulty within the reactor at Three Mile Island on March 28th, Dr. Donald Frederickson, Director of the National Institutes of Health, conferred with scientists on his staff, many of whom had been involved in the primary research on the effects of SSKI as a blocking agent. Subsequently, NIH advised Secretary Califano, Department of Health, Education and Welfare, that as a precautionary measure there should be supplies of potassium iodide in the Harrisburg area. The Secretary accepted Dr. Frederickson's recommendation and directed the Food and Drug Administration to initiate steps to make the drug available to the State with all possible speed. This decision was conveyed by Secretary Califano to the FDA on Friday evening, March 30, 1979 [illegible] hours after the first incident at Three Mile Island.

The FDA quickly discovered, however, that no manufacturer in the country had sufficient amounts of KI on hand to supply the needs of the people in the greater Harrisburg area. It therefore re-contacted a number of the largest pharmaceutical firms in an attempt to find one which would agree to go into emergency production to fill the order. Mallinckrodt Corporation finally agreed, calling in some 50 of their employees at the Decatur, Illinois, plant when the order became an active project at approximately 1:00 a.m. on Saturday, March 31st.

The potassium iodide salt was turned into solution and sent from Mallinckrodt to Parke-Davis for bottling. An Air Force cargo jet from Scott Air Force Base picked up the delivery, and by 8:00 p.m. Saturday, the first 11,000 one-ounce bottles were on their way to Harrisburg, arriving at Harrisburg International Airport at 1:30 a.m. Sunday morning. The remainder of the order was flown to Harrisburg in six shipments by Petroleum Air Transport, a charter service out of St. Louis. The shipments were received as per the following schedule, and immediately transported to the General Services Administration warehouse in Harrisburg, where they were inventoried and secured:

		Time	Date	Quantity	Samples Drawn
Mallinckrodt	Shipment #1	1:30 a.m.	4-1-79	11,100	(14)
Mallinckrodt	Shipment #2	11:00 p.m.	4-1-79	24,000	(2)
Parke-Davis	Shipment #3	9:00 a.m.	4-2-79	26,000	(14)
Mallinckrodt	Shipment #4	10:00 a.m.	4-3-79	57,400	(1)

		Time	Date	Quantity	Samples Drawn
Parke-Davis	Shipment #5	1:30 p.m.	4-3-79	38,840	
Parke-Davis	Shipment #6	1:00 p.m.	4-3-79	30,994	1
Mallinckrodt	Shipment #7	9:00 a.m.	4-4-79	50,799	1

III. Assumption of Authority

On Saturday morning, March 31, 1979, a meeting was held at the Pennsylvania Emergency Management Authority's (Civil Defense) headquarters. Present were top PEMA officials, plus Clifford Jones and Thomas Gerusky from the Department of Environmental Resources, and Dr. Gordon MacLeod and Emmett Welch from the Department of Health. At this meeting, Dr. MacLeod was apprised of the discussion which had taken place between the FDA and the DER, and the decision to make KI available to Pennsylvania. Mr. Jones suggested, however, that jurisdiction over the medication and its possible distribution fell more logically within the purvue of the Health Department than within DER, and requested that Dr. MacLeod assume all future responsibilty for the handling and availability of the drug. Dr. MacLeod agreed, and at that point accepted the authority for all subsequent decision-making.

Immediately following this meeting, Dr. MacLeod contacted Dr. Paula Botstein, an endocrinologist with the FDA and discussed the clinical implications of a mass administration of prophylactic doses of potassium iodide.

IV. Quality Control Measures

As the medication began arriving in Harrisburg, Mr. Jack Ogun, Director of the Division of Drugs, Devices, and Cosmetics was assigned the responsibility for inspecting the bottles and sampling the solution for quality assurance. As a check of his division's work, a sample of bottles was pulled from each shipment and sent to the FDA laboratories in Rockville, Maryland, for their analysis.

A total of 237,000 bottles, manufactured under Lot Numbers J103N, J104N, and J105N, were received and inspected. During the inspection, it was noted that many of the bottles in the first shipment (J103N) contained hairlike filamentous material and other particulate matter, which indicated the possible use of unwashed bottles, poor filtration, or both. The white metal cap liners used on this lot also provided an improper seal and were rapidly absorbing fluid, resulting in some leakage.

Problems with this initial lot were discussed by Mr. Ogun with Mr. Halperin of the FDA in Washington, who indicated that quality control measures applied by the manufacturer may have been, or were, deficient due to the emergency conditions under which the drug was prepared. Both Mr. Ogun and Mr. Halperin felt, however, that the medicine's quality, while not in full

compliance with the FDA's standards, was acceptable for its intended use, and that the drug could be distributed with no resultant health hazards attributable to the noted defects.

Other minor difficulties surfaced during inspection of the bottles; these included part of the first shipment which arrived unlabelled (6,000 vials) and various sized medicine droppers which did not fit the bottles for which they were procured. Because of the emergency, these problems were also not deemed to be insurpassable if distribution and administration of the drug became necessary. A more serious problem resulted from improper dropper size, with each dropper yielding about half of the dosage recommended by NCRP Report #55. Again, it was suggested by the FDA that the drug could be administered in case of an emergency.

V. The Clinical Data

A. Nature of the Hazard

The 12 radioisotopes of iodine are among the most abundant of all fission products produced. These isotopes have half-lives ranging from I-140 at 1.5 seconds to I-129 at 16 million years, but the isotope in greatest abundance and thought of principal concern to the population near a nuclear reactor is I-131, with a half-life of 8 days. Our knowledge of the health effects I-131 comes primarily from

human and animal studies of high level radiation exposure of 50 rems (50,000 millirems) or more. We know that a large release of iodine I-131 into the atmosphere from a power reactor would result in the public's inhaling or ingesting amounts which could produce acute, continuing, or late thyroid effects. These effects would range from mild thyroiditis to hypothyroidism to benign thyroid neoplasms, nodules, and cancer. Fetal hypothyroidism is of particular concern due to the inverse relationship between iodine uptake and age.

Although we have much less direct evidence of the effects of continuous low level radiation, it is assumed that it, too, poses a health risk over a period of time. In testimony before the Senate Subcommittee on Health and Scientific Research (April 4, 1979) it was suggested that:

> "In a population of 10,000 persons--in which one may normally expect 1,600 cases of fatal cancer to occur naturally--exposure of each of the 10,000 persons to one rem of radiation may be expected to produce one additional case of fatal cancer."

It was cautioned, however, that this formula is still only the scientists' "best guess" of the additional risks associated with low-level radiation.

B. Countermeasures Against Radiation

Apart from prevention of radioactive iodine emissions, evacuation, and shelter, agents that block accumulation of radioiodine by the thyroid gland present the most complete protection against the hazards of inhaling or ingesting I-131. A supersaturated solution of potassium iodide (SKKI) has been found to be eminently suitable for thyroid blocking purposes. Potassium iodide blocks the uptake of I-131 almost immediately, with the onset of blocking having been demonstrated 30 minutes after oral administration. And when given in sufficient amounts, entry of radioiodine into the thyroid can virtually be prevented (1% in 24 hours).

An important factor in obtaining satisfactory blocking of I-131 uptakes is the speed with which KI is administered following exposure to radioidine. Standard uptake curves demonstrate that the bulk of the radioactive iodine from a single exposure will have entered the thyroid within 10 to 12 hours, and little benefit may be expected by blocking beyond that time. Further, significant benefit (a block of 50%) is attainable only during the first 3 to 4 hours. For a more prolonged exposure, however, KI will continue to be useful at any point during the exposure, thus it should be administered even if it was not initially received in a timely manner.

C. Dosage and Frequency

Various studies have established that for adequate suppression, an initial dose of 130 mg. of KI/day--equivalent to 100 mg. of iodide--is required. Because the decay of the inhibitory effects following each administration is relatively slow, continuation of a single daily dose appears to result in an adequate block. The National Council on Radiation Protection has suggested that daily doses be continued to an accumulated limit of between 1 and 1.5 grams of iodide, or for 8 to 10 days.

The NCRP also suggests that after 10 days of the iodide regimen, an "escape effect" occurs which prevents the thyroid from taking on or retaining further doses of potassium iodide. A hiatus of several days must then take place before the drug may be effectively readministered.

Although the possibility of an escape phenomenon is also mentioned in a memorandum from Secretary Califano to Jack Watson of the White House staff, some disagreement among the experts as to the legitimacy of this effect apparently exists. Dr. Reed Larson of Harvard Medical School most emphatically denied its existence in a telephone conversation to the Department of Health; Dr. Larson also suggested that Dr. Jan Wolff of NIH would concur with his assertion that KI could be taken indefinitely without loss

of effectiveness. Yet, Dr. Wolff's name appears among those cited by Secretary Califano as advising the opposite.

In any event, the following advisory was printed in volume by the Health Department on March 31, 1979, for distribution to the populace concurrent with the medication in case of an explosive catastropic nuclear event.

Emergency Advisory For Protection of the Thyroid Gland from Radio-Active Iodine (I-131)

I. Upon announcement of the imminent likelihood of significant radiation exposure, protect yourself by remaining in an area removed from the outdoors, such as a basement room or other such protected area. Anticipate the need for water and food supply.

II. Even if staying in a protected area, at the time of announcement of the imminent likelihood of significant radiation exposure, take liquid Potassium Iodide as recommended in III. below. Potassium Iodide will reduce the amount of radio-iodine taken into your thyroid gland if taken within 3 to 4 hours after radiation exposure, and will be of at least some value if the initial dose is taken up to 12 hours after radiation exposure.

III. Liquid Potassium Iodide Administration

1. Under one (1) year of age, put one (1) drop of Potassium Iodide liquid (saturated solution Potassium Iodide, SSKI) in a glass of water or juice.

2. Over one (1) year of age, put two (2) drops of Potassium Iodide liquid (saturated solution Potassium Iodide, SSKI) in a glass of water or juice.

3. Drink dosage recommended for appropriate age once a day for ten (10) to twenty (20) days (the latter advised by Department of Health, Education, and Welfare).

Gordon K. MacLeod, M.D., FACP
Secretary of Health
Commonwealth of Pennsylvania

March 31, 1979

D. Supply

The potassium iodide prepared for Harrisburg was packaged in one-ounce square, amber glass bottles or two-ounce round, amber glass bottles 1/2 full. Each bottle contained at least 30 cc's of KI solution. The droppers received were calibrated to deliver 30 drops per cc. of solution, thus each bottle would easily supply 900 drops.

Given the labelled daily dosage of two drops for adults and children, and one drop for infants, it was estimated that each bottle would provide 450 person-doses, or would supply 45 people for 10 days. The shipments of KI delivered to Harrisburg would, then, be more than enough to provide a full blocking regimen for all persons at risk of exposure if the vials could be distributed to persons who would assure their being shared with several other individuals during the ten day period. No more than a ten day treatment plan would be required if the

recipients were to be evacuated from the contaminated area following their single exposure from a burst.

I. Potential Side Effects of SSKI

Potassium iodide is a relatively stable, benign drug that has been used as an expectorant for many years in the treatment of asthma and other bronchial conditions with few, if any, side effects. In the treatment of respiratory insufficiencies, KI is administered in doses of 2 to 10 times the potency of those recommended for thyroid blocking; thus, few side effects are expected from prophylactic administration because of the low dosage and short regimen.

As with any drug, however, there is always some risk associated with its ingestion. The induction of thyrotoxicosis has been observed in the prophylactic treatment of iodine deficiency goiter, though it would be unlikely to occur in iodine sufficient areas such as the United States. Nevertheless, iodine-induced goiter may occur in areas of sufficient iodine intake and should be watched for in the 4% of the population with nodular goiter conditions.

Because iodides cross the placental barrier and are taken up by the fetal thyroid, respiratory obstruction by

an enlarged thyroid of infants delivered to mothers who have been taking KI during pregnancy is a possibility. Although the patient information instructions printed by the Department of Health, Education, and Welfare for distribution with the medication indicate that pregnant women may be administered KI prophylactically, they advise that these women be placed under a doctor's care.

The taking of iodides has been associated in a limited number of cases with either hypo or hyperthyroidism in patients who had no previous history of thyroid disease. These reactions would be unpredicted due to the lack of previous history, but may be expected to occur in 1 to 4% of the population.

Side effects may also occur which do not involve the thyroid gland. These include iodide parotitis, an uncommon complication resembling the swelling of the salivary glands as is found in mumps. Cutaneous iodism, a rare but extremely uncomfortable type of skin eruption, can occur in individuals who ingest large doses of iodine over long periods. Even less common are such systemic manifestations as fever generalized skin rash, arthralgia, swollen joints, changes in the hair and nails, and gastric upset and diarrhea.

These developments, according to the National Council on Radiation Protection, are all indications for discontinuing prophylactic iodine therapy. Evacuation of the subject from the I-131 contaminated area would then be required.

Since the undesired reactions to iodide vanish within a few days after discontinuing iodide ingestion, monitoring of the individual need only continue for that period of time.

The following paragraphs relating to potential risk were taken from the insert entitled "Patient Information Use of Saturated Solution of Potassium Iodide (SSKI) for Thyroid Blocking" which was developed by the FDA for distribution with the medication:

> Who Can Take Potassium Iodide? Unless you are allergic to iodide, you may take potassium iodide as directed. Even if you are taking a thyroid hormone drug product for an underactive thyroid gland, or taking an anti-thyroid drug for an overactive thyroid gland, you may still take potassium iodide, Pregnant women may also take it.
>
> Side Effects: On general, the side effects of potassium iodide have been seen when higher doses of potassium iodide have been taken for a long time. You should be especially cautious not to exceed the recommended dose or take potassium iodide longer than instructed. There are two kinds of side effects: those not

involving the thyroid gland and those involving the thyroid gland.

Side effects not involving the thyroid gland. The taking of iodide has been associated with skin rashes, swelling of the salivary glands ("iodide mumps"), and iodism (metallic taste, burning in the mouth and throat, soreness of the teeth and gums, skin rashes, symptoms of a head cold, and sometimes a gastric upset and diarrhea). Also, allergic reactions may produce symptoms such as fever and pains in the joints or, on rare occasions, swelling of various parts of the face and body with at times severe shortness of breath requiring immediate medical attention.

Side effects involving the thyroid gland: The taking of iodide has been associated with overactivity of the thyroid gland, under-activity of the thyroid gland, and enlargement of the thyroid gland (goiter). Goiter may occur also in infants born to mothers who took large doses of potassium iodide throughout pregnancy.

What to do If Side Effects Occur:
For side effects not involving the thyroid gland: If any of these side effects occur, call your physician or public health authority for instructions. If the symptoms are minor, you may be advised to continue taking potassium iodide. If you have an allergic reaction, discontinue taking potassium iodide and seek immediate medical attention.

For side effects involving the thyroid gland: Because these side effects are very unlikely, with short term use, they pose no immediate problem. However, the taking of iodide has been associated with overactivity of the thyroid gland in elderly persons with heart disease. The symptoms of an overactive thyroid gland are very similar to those associated with anxiety and include nervousness, sweating, and rapid heartbeat. Because in an emergency some anxiety is likely, it is difficult to determine whether these symptoms are caused by anxiety or an overactive thyroid gland. An overactive thyroid, however, would only occur after you had taken potassium iodide for several days. Thus, if these symptoms are persistent and severe, and particularly if the heartbeat is not only rapid but irregular, you should call your physician or public health authority

because medical attention is probably required.

I. The Pennsylvania Secretary of Health's Decision to Withhold Distribution of SSKI

Concurrent with the arrival in Harrisburg of the initial shipment of SSKI, the Secretary of Health was faced with the decision of whether to actually begin distribution of the medication to the populace or, conversely, to be prepared to distribute it to strategic locations within and around the city in anticipation of future need. Extensive consultation with Governor Thornburgh and Lt. Governor Scranton, plus Dr. Neil Wald, Professor and Chairman of the Department of Radiation Health of the University of Pittsburgh and Mr. Harold Denton, Director of Operations of the Nuclear Regulatory Commission, both of whom were on-site, resulted in a decision to strategically stockpile the medication, but to refrain from dispensing immediately. Justification for this decision was based upon the following concerns:

1) The threshold level for such actions--as spelled out by the feds themselves--is 10,000 millirems of I-131. At the time of the decision, the highest cumulative dose which was being estimated for any individual within a five mile radius was 80 millirems.

The general level of anxiety of the populace who had not already evacuated the area of their own volition was extremely high. Indeed, a great deal of the Administration's public information efforts were invested in maintaining an environment of relative calm within the extreme tenseness of the overall situation. It was felt that misinterpretation of the announcements of extremely low levels of radioactive iodine in milk could cause some people to administer the drug even though it were not necessary. The National Council on Radiation Protection had itself acknowledged the possibility of panic in their Report No. 55:

> "The short-term and long-term consequences of inhalation of radioactive iodine are far less than the possible injury that might result from individual or mass panic arising from efforts to obtain the blocking agent, and this modicum of common sense should be remembered by each person."

By Monday, April 2nd, the danger of an explosion from the accumulation of gases within the reactor's containment vessel had abated, if not disappeared. With each hour the possibility of a high-level release of radioactivity was diminishing. Mr. Denton was able to offer assurances of less likelihood of an imminent meltdown or explosion, and of greater and greater lead-time before a release of radioactive material as the days went on. With the increasing

certainty of hours-of-notice rather than minutes, the need to have the medication actually in-hand decreased proportionately.

4) The possibility of the existence of an "escape effect" made the timing of the drug's administration more complicated than if the regimen could be instituted and continued indefinitely. If the hazard, particularly to workers on the island, were to continue for a period of weeks or months, they would conceivably have to go through several cycles of protection/no-protection as they ingested, discontinued, then re-ingested the medication. Since no one could predict the timing of a high-level accident, it seemed more prudent simply to make the SSKI available on the island where it could be administered within 30 minutes of a release. Otherwise, the workers would have to be removed from the island during their "no-protection" phases, for the immediate availability of the drug would be of diminished use to them at that time.

5) The possibility of side effects, though admittedly small, presented the real potential for more public health problems as a result of ingesting the medication prophylactically than would certainly occur

if the medication were never needed. Given the fact that SSKI could be placed in everyone's hands in a matter of hours, and well within the lead-time available, it seemed unnecessary to risk even one serious or fatal complication resulting from the drug itself.

6) The inappropriate dropper sizes, the compromised quality of the solution of SSKI, and the conflicting recommendations for the length of administration were also factors.

VII. The Califano Directive

At a request from the White House on April 2, 1979, Dr. Julius Richmond, the Surgeon General, prepared a letter of "guidance" from Federal health officials unbeknownst to the the Department of Health. His recommendation on the advisability of providing precautionary iodine blocking was based upon his consultation with the directors and top staff of the National Institutes of Health, the Food and Drug Administration, and the National Cancer Institute.

Dr. Richmond's letter was forwarded to Secretary Califano, who encapsulated the recommendations in a memorandum of his own which was forwarded to Jack Watson of the White House

staff on Tuesday afternoon, April 3rd. Mr. Watson added his own cover memorandum to Governor Thornburgh, and all three pieces of communication were transmitted to Harrisburg that same afternoon. The Califano recommendations were:

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 I-131 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 sufficient advance warning of releases.

VIII. Decision Reaffirmed

The receipt on April 3, 1979, of Secretary Califano's letter in the Health Department occasioned considerable concern on the part of Dr. MacLeod and Dr. Wald, his consultant.

Because the "recommendations" were couched more in the language of a directive, there appeared to be only minimal leeway available to accomodate the judgment of the health and nuclear officials who were actually on the scene and presumably in the best position to evaluate the danger.

In light of the directive to "Have workers in the plant and others on the island begin taking blocking doses now"... Drs. MacLeod and Wald and Mr. Denton re-evaluated their original decision regarding the administration of potassium iodide. Their analysis of the situation--Federal recommendations notwithstanding--resulted in a reaffirmation of the original position. Dr. Wald documented his advice to Dr. MacLeod in the following memorandum:

> I have reviewed the memorandum of April 3, 1979, from Joseph Califano to the Honorable Jack Watson regarding thyroid blocking. The recommendations are very useful but may not fit our local circumstances optimally. My views about the subject area discussed in the recommendations were arrived at following a review of pertinent literature, including NCRP Report No. 55, "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," which was approved by all council members of the National Council of Radiation Protection and Measurement. I also held discussions with Dr. Eugene Saenger, the Chairman of the committee that prepared the report. In summary, my views are as follows:
>
> The thrust of the thyroid blocking concept is to protect the gland which is at real risk of receiving absorbed doses of at least 10 rads or more. This should be based on the dose estimates developed following a major accidental release of I-131, and the treatment should be given within a few hours after such an accidental release.

> In the case of plant workers, the KI administration should be considered at the beginning of any operation that have a significant likelihood of producing such an accidental release and such a thyroid exposure. In the case of the general population around the facility, when a sufficient supply of KI is in hand, it should be located in distribution points where it can be distributed to the persons who may be exposed, so that administration can begin within a few hours after an accidental release of sufficient magnitude to warrant its use. Despite the theoretical desirability of placing KI in the possession of individuals close to the location of a potential accidental release, it is not possible to draw a dividing line with any certainty between those who receive the KI medication and those who do not. In addition, the current announced presence of traces of I-131 in local milk could readily be mistaken as an indication for self-administration of KI, especially with the distribution of KI taking place at this particular time in the crisis period.
>
> The duration of KI treatment proposed in the memorandum, 20 days, is not in keeping with the 10 days upper limit of the period of need referred to by the NCRP Report No. 55, whose preparatory committee had the benefit of Mr. Harold Denton's participation as consultant.

Dr. Wald's opinion provided the final justification for for the Department of Health's standing firm on its decision.

April 13, 1979

Editor
Washington Post
Washington, D.C.

Dear Editor:

As Secretary of Health for the Commonwealth of Pennsylvania, I wish to comment on your April 6 article about the Health, Education and Welfare Secretary recommending the administration of potassium iodide to those in the immediate vicinity of the Three Mile Island (TMI) Plant. At the time we received the Secretary's recommendation, it seemed inappropriate to administer the drug when there was no scientific indication of any significant radiation. According to Secretary Califano's own testimony before the Senate Subcommittee on Health and Scientific Research on April 7, the maximum exposure to any person was no more than 85 millirems--a level considered by authorities in the field to be insignificant.

As potassium iodide was shipped into Pennsylvania, the Department of Health was in a constant state of readiness to distribute it to all people in the area, not only those at the site. For the first six days after the incident, we continuously sought advice from the National Council on Radiation Protection, HEW's Bureau of Radiation Health in the Food and Drug Administration (FDA), the Nuclear Regulatory Commission (NRC), the Department of Energy, and some of the country's leading medical specialists in radiation health. All agreed that we hold the drug in readiness and not administer it unless there was an expectation of imminent exposure to at least 10,000 millirems of radiation.

We had expert assurances that notice of any such likelihood would be sufficient to distribute and administer the drug. Other considerations which influenced our decision:

1) The possibility of a severe skin rash, plus side effects to those with thyroid diseases, to unborn children, and to the elderly with cardiac problems;

2) The possibility of precipitating unnecessary panic among the populace simply by announcing the distribution; and

3) The possibility that premature ingestion of the drug would diminish its effectiveness further into the incident, if prolonged, when the protection might actually be needed.

Each of these factors militated against distribution; consequently I felt obliged to advise Governor Thornburgh that the public's health and safety would best be served by withholding the potassium iodide.

Sincerely,

Gordon K. MacLeod, M.D., F.A.C.P.
Secretary of Health
Commonwealth of Pennsylvania

GKM:cmm

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