UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

March 7, 1990

MEMORANDUM FOR: Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

FROM: Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

SUBJECT: NRC POSITION ON POTASSIUM IODIDE: DIFFERING PROFESSIONAL OPINION

On July 7, 1989, a Differing Professional Opinion (DPO) was filed regarding the stockpiling of potassium iodide for use during a radiological emergency. By memorandum dated June 23, 1989, I assigned lead responsibility for informal review of the DPO to RES. As part of that informal review, a DPO review panel was formed and met with Mr. Peter Crane to clarify points of the DPO. Following that meeting, the panel compiled additional information and performed a simplified cost-benefit analysis. In a December 14, 1989 memorandum, the review panel presented its findings and recommendations. In a January 4, 1990 memorandum, Mr. Crane responded noting several concerns.

According to DPO procedures, the next step is for the responsible Office Director to review the DPO review findings and recommendations of the panel report and meet with Mr. Crane to see if his concern has been addressed to his satisfaction. If the DPO is resolved with the party through the report, no further action is necessary and the DPO is considered closed. If there are differences between the DPO and the findings, the Office Director should specify the differences in a memorandum to the EDO. The EDO will then make a final determination of the issues involved.

This memorandum requests you to review the DPO review panel report and provide an opinion of the findings and recommendations. In addition to the documents discussed above, appropriate background documents are enclosed.

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosures:
As stated

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MAR 1 5 1990

MEMORANDUM FOR: Hugh L. Thompson, Jr.
Deputy Executive Director for Nuclear Materials Safety,
Safeguards & Operations Support

FROM: Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

SUBJECT: POTASSIUM IODIDE DPO OF PETER CRANE

Pursuant to your March 7 letter, I have reviewed the DPO and related correspondence, and I met with Mr. Crane on March 13, 1990.

In summary there are two main points in the DPO as follows:

1. NUREG/CR-1433 presents an analysis of the costs and benefits of stockpiling potassium iodide for treatment to prevent uptake of radioactive iodine in the event of a nuclear accident with a large release. The analysis is flawed.

2. On November 22, 1983 the staff briefed the Commission on Commission paper SECY-83-362 (Emergency Planning - Predistribution/Stockpiling of Potassium Iodide for the General Public), and on NUREG/CR-1433, which was the basis for the Commission paper. The presentation emphasized thyroid therapy following an exposure, but did not make clear that 4% of the nodules resulting from an accident would be fatal.

Mr. Crane believes that the NUREG/CR-1433 should be withdrawn, that the Commission's record should be updated and revised, and that Federal agencies, states, localities, and the public should likewise be advised of the updated and revised information.

The review of the DPO prepared by the panel consisting of Messrs. Speis, Congel, Roecklein, and Soffer addressed the first point, and speaks for itself. In summary it evaluated stockpiling rather than predistribution, utilized the insights of NUREG-1150 for accident releases, included the effect of hypothyroidism, and considered benign thyroid nodules, cancerous nodules, and fatalities, and the current cost of potassium iodide. It considered the available information from the Soviets on Chernobyl. In the revised analysis the benefit of potassium iodide is substantially increased from the NUREG/CR-1433 basis, but it still falls short of breaking even by more than a factor of 10. The panel is strongly convinced that potassium iodide has limited efficacy as a public protection measure, because it addresses one organ through one pathway, and because its effectiveness depends on its use before or within a few hours of exposure. The panel recommends that existing Federal guidance should not be changed. In effect the panel updated the NUREG/CR-1433 analysis, and concluded that the new information should be transmitted to other Federal agencies and states.

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Thus it appears to me that the panel has addressed Mr. Crane's first point. He nevertheless believes that a cost/benefit analysis is not determinate, and should not be the sole basis for judging this issue. With respect to his view on thyroid cost/benefit analysis, there are two important aspects on which I make further comment below.

The panel did not address Mr. Crane's second point, and I conclude on this basis that the DPO is not resolved.

My suggestion to resolve the issue is to revise and broaden the NUREG/CR-1433 analysis, along the lines that the panel did on the basis of new information. The revised analysis could then be presented to the Commission and issued to other Federal and state authorities. Based on this revised analysis, the Commission could then decide whether or not to revisit the policy question. If the Commission should decide to do, it would be necessary to coordinate with all the Federal agencies that participated in developing current the policy. This action would address Mr. Crane's concerns.

The two aspects that relate to Mr. Crane's view on cost/benefit analysis noted above are (1) due consideration of thyroid dysfunction health effects, and (2) the role of cost/benefit analysis in decision making. With regard to thyroid dysfunction, it will be important in any future consideration of the issue to gather in the best possible medical opinion on the subject. I am not able to judge from the DPO case documents that such opinion was a part of the 1983 decision; nor am I able to judge that it was not. There are a number of ways to read the 1983 transcript attached to Mr. Crane's DPO. Part of the testimony compares potassium iodide as a means of averting an illness to cost-ineffective auto insurance. On the other hand, the transcript also makes it clear that the Commissioners were aware of the views of other Government agencies on the subject.

The second aspect, the role of cost/benefit analysis in decision making is also important. I do not mean to suggest that cost/benefit should be followed blindly. When properly used with due regard for important considerations, cost/benefit analysis is a powerful tool, especially helpful in establishing priorities for needs, and commitment of resources. Mr. Crane argues that potassium iodide stockpiling is a good idea, and should therefore be adopted, regardless of cost/benefit. The problem as I see it is that, without any reference to or inference for this case, the idea that may be good for one person may be valueless to another. It is therefore essential to analyze health and safety proposals in a disciplined way to examine the conclusions broadly, i.e., from many points of view, and scientifically, in order to assure that resources are used wisely. Careful cost/benefit analyses have proven their usefulness in many health and safety decisions. In short, I am not sympathetic to the idea of dismissing cost/benefit considerations in the agency's decision making.

With regard to revising the thyroid analysis, the only problem is the availability of experienced people to do the required work; people who are now committed to other Commission priorities. If you wish, I will see what can be done and on what schedule.

Eric S. Beckjord

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

cc: James M. Taylor, EDO
Peter G. Crane, OGC

March 20, 1990

MEMORANDUM FOR: Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety,
Safeguards & Operations Support

FROM: Peter Crane

SUBJECT: MEMORANDUM OF MARCH 15, 1990,
FROM ERIC BECKJORD REGARDING
MY DPO ON POTASSIUM IODIDE

Eric Beckjord's memorandum to you of March 15, 1990, contains several points to which I would like to respond.

1. Dr. Beckjord states that my DPO of June 16, 1989, made two major points, and that the review panel did not address the second point; thus he "conclude[s] on this basis that the DPO is not resolved." I am obviously gratified that he has reached this conclusion, but in all frankness, it comes as no surprise, since no other rational conclusion could conceivably have been reached. Indeed, it was self-evident when the review panel issued its report on December 14, 1989 that it had failed to mention, much less to address, the portion of the DPO dealing with the accuracy of the information provided to the public and the Commission in 1983. I had also pointed out that omission in my comments to you of January 4, 1990. Thus my sense of gratification that Dr. Beckjord has acknowledged the review panel's omission is tempered by regret that three months should needlessly have been lost in coming to grips with the underlying issues -- and this in a process that is designed to put a premium on timeliness.

2. Dr. Beckjord writes of me that I "nevertheless believe... that a cost/benefit analysis is not determinate, and should not be the sole basis for judging this issue." This statement is not inaccurate, but it requires some qualification and explanation.

I do not dismiss the usefulness of cost-benefit analysis generally, nor do I argue that it should play no role whatsoever in considering whether the stockpiling of potassium iodide is sensible and prudent. My point is that when one is talking about health effects, one has to use the cost-benefit approach with a modicum of common sense, and in any case, the collection of valid data about the actual costs and benefits involved must <u>precede</u> the balancing of costs and benefits. It may be tempting, when the costs of a program seem greatly to outweigh its benefits, to think that one need not look too closely at the accuracy of the data on

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costs and benefits. But if the data is defective, the cost-benefit balancing may be defective as well.

The approach taken by the staff in 1983 was based solely on the cost of treating a thyroid nodule. (For the moment, let us put to one side the fact that the staff mischaracterized the seriousness of the medical problems caused.) The staff's reasoning went as follows: "If a potassium iodide program costing $20,001 could result in averting one case of thyroid nodules, and that case of thyroid nodules could be treated for a maximum of $20,000, then it is more cost-effective for society to allow the thyroid nodule to develop than to prevent it."

The DPO review group, conscious of the criticisms of the earlier analysis, went back and factored in thyroid malignancies and fatalities. They nevertheless concluded, Dr. Beckjord reports, that the benefit of potassium iodide "still falls short of breaking even by more than a factor of 10." (I might interject that this is quite a difference from the factor of 500 that the Commission was told about in 1983, but that is beside the point for the moment.) But what does it mean to have factored in malignancies and fatalities? I would submit that apart from the $1 million figure assigned to fatalities, the DPO panel made no effort to estimate -- other than in dollar costs of treatment, as before -- the actual costs (i.e., disruption of the quality of life) that thyroid disease brings to patients and their families. Thus the DPO panel was looking essentially through the same lens through which the staff had looked in 1983.

The old maxim, "an ounce of prevention is worth a pound of cure," comes to mind here. It should be self-evident that it is better for individuals to live their lives free from disease than to develop diseases and have to be cured of them. Yet the staff's approach, at least as presented in 1983, seems to treat the two states (disease averted and disease treated) as exactly equivalent, regardless of the discomfort and anxiety (if nothing worse) that illness brings.

It should be obvious that society may wish to spend more to prevent some kinds of illness than it would cost to treat those illnesses if they occur. Let us deal for a moment with a disease most of us are familiar with, polio. Let us suppose that with a vaccination program costing $100 million dollars, society can avert a number of cases of polio that in the aggregate would cost $50 million dollars to treat. Does anyone think that such a program would be regarded as non-cost-effective by a factor of two? Does anyone think that the only elements that would fall in the "benefit" column would be the money saved on braces and doctor bills?

Only if the illness in question were as trivial as the common cold could anyone doubt for a moment that to equate dollars for prevention and dollars for treatment is absurd. It is at this point that the staff briefing of November 22, 1983 becomes so significant. At that briefing, the staff presented so rose-colored a version of the significance of radiation-caused thyroid problems as to bear no relation to reality. Fatalities were not the issue, the Commission was told, the issue was averting an illness that might mean "a few days loss." All of this you will find in the DPO and the attached excerpts from the meeting transcript.

Decisionmakers cannot make intelligent judgments about the costs and benefits of averting a particular health effect if they are provided inaccurate information about the nature of that health effect. Only at such time as the staff gets around to telling the Commission about the consequences of radiation-caused thyroid disease will the Commission be in a position to judge how much it may be worth to society to prevent such disease.

On this point, Dr. Beckjord's memo refers euphemistically to whether the cost-benefit analysis gave due consideration of "thyroid dysfunction effects." Euphemisms can sometimes lead to misunderstanding. The central issue is not thyroid dysfunction, it is thyroid nodules and tumors, benign and malignant, and the fatalities that sometimes result from the latter. Dr. Beckjord goes on to say that he cannot determine from the DPO case documents whether or not the 1983 decision reflected "the best possible medical opinion on the subject." I can assure him that it did not. To establish that, he need look no further than DeGroot's 1977 work, Radiation-Caused Thyroid Carcinoma, available in the National Library of Medicine. But a hundred other sources, readily found in any medical library, would yield the same result. The American Thyroid Association could and doubtless would be happy to contribute to the process of providing the Commission with accurate information in this area. A copy of their letter of November 27, 1989 is attached.

I have no desire to elaborate here on my own experience with thyroid disease. The Commission has ample sources from which to obtain information on the consequences of thyroid disease without needing to rely on my personal testimony, and I would like to keep this issue on a professional, not a personal, basis. I trust that when the staff revisits this issue, it will seek its information on the conequences of thyroid disease from doctors and perhaps also from patients. So far, there seems no indication of input from either group, at least on the issue of what thyroid disease entails for the quality of life. I submit that what the Commission needs now on the potassium iodide issue is more in the way of accurate and appropriately documented information,

including information on the error bands in the state of our knowledge; less in the way of avoidance of hard issues; and a complete end to the substitution of wishful thinking for scientific data. Then and only then will it be possible to have a meaningful balancing of costs and benefits -- and to that sort of cost-benefit analysis I do not object at all.

3. Dr. Beckjord's suggestion is to "revise and broaden the NUREG/CR-1433 analysis," with a view to providing the revised information to the Commission and other Federal and state authorities. This approach may be sound in principle, but it may also be time-consuming. The proposed approach does not answer the question whether the Commission has an obligation to correct the record now for the misinformation provided in the November 1983 briefing. I believe that issue has to be faced. Given that other Federal agencies are apparently interested in revisiting the Federal guidance in this area, and that the Centers for Disease Control will be conducting a new study, I think it would be in the Commission's best interest to have corrected the record before the record is corrected for us.

4. Some weeks ago, you asked me what I would do in your position. I replied with a draft memo from you to the Commissioners, a copy of which is attached. While it does not go as far as I personally would like, I believe that it would solve a number of problems for the Commission if adopted.

Attachments: Letter, American Thyroid Association to
Dr. Alan Roecklein, Nov. 27, 1989

Draft Memorandum, Thompson to Commissioners

cc: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
The General Counsel
Dr. Eric S. Beckjord

1988 1989

THE AMERICAN THYROID ASSOCIATION
GRAVES 1796-1853
INCORPORATED
FOUNDED 1923

27 November 1989

Alan Roecklein, M.D.
Radiation Protection-Health Effects Branch
USNRC
5650 Nicholson Lane
Rockville, MD 20852

Dear Dr. Roecklein:

The American Thyroid Association has for some time monitored the problem of potential radioiodine contamination of the atmosphere in the event of a nuclear reactor core melt accident. There has been concern about the possibility of radioiodine in the fallout accumulating in the thyroid gland and irradiating it, with the potential of causing thyroid neoplasms and hypothyroidism.

Potassium iodide (KI), by blocking radioiodine uptake by the thyroid gland, has a radioprotective effect. However, there are a number of significant difficulties in using KI for this purpose.

The American Thyroid Association has re-examined the issues involved in stockpiling KI for use in the event of a reactor accident. The attached statement is an update of a previous published analysis of this complex situation (Journal of the American Medical Association, 1984; 252:659). It is hoped that this statement will generate renewed consideration of this complex problem.

Sincerely yours,

John Wilber, M.D.
President, A.T.A.

Leonard Wartofsky, M.D.
Secretary, A.T.A.

Chairman, Public Health Committee
David S. Cooper, M.D.
Johns Hopkins University

David Becker, M.D.
Cornell University

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Statement on Potassium Iodide Stockpiling

American Thyroid Association

The recent reactor accident at Chernobyl in which large amounts of radioactive iodine were released into the atmosphere again raised questions about proposed methods of protecting those at risk of exposure. In a previous statement (JAMA 1984, 252:659), the American Thyroid Association (ATA) reviewed the scientific information available about the usefulness of potassium iodide (KI) as a blocking agent to prevent radioactive iodine from entering the thyroid gland of those exposed to fallout. It also reviewed available data about the possible effects on the thyroid of low level radiation from radioiodine as well as the potential toxic side effects of distribution of potassium iodide to large unsupervised populations.

It was concluded at that time that information necessary for the development of a suitable public health strategy required risk/benefit data (ratio of the risk of the hazards of radioiodine to those of stable iodine administration) but that such information was not then available. The ATA is aware of no new information altering the issues raised at that time.

It was concluded in that report that, although the general distribution of KI was not recommended except in special locations and under special circumstances, advanced planning for possible distribution was advisable and it urged that a national task force of specialists be convened to review the issues in KI distribution and to develop alternate national distribution strategies for consideration.

As best as can be determined at this time, no substantial stockpile of potassium iodide is available for public use. Despite the unlikely event of an emergency requiring its use, the ATA believes that the option of potassium iodide distribution should be available for consideration to those responsible for public health measures. To this end, the ATA believes that it would be prudent to have available at central locations a suitable stockpile of KI for possible distribution should its use be contemplated.

(DRAFT BY PETER CRANE)

MEMORANDUM FOR: The Commissioners

FROM: Hugh L. Thompson, Jr.
Deputy EDO

SUBJECT: DIFFERING PROFESSIONAL OPINION
ON STOCKPILING POTASSIUM IODIDE

As you know, the staff has under review a differing provessional opinion filed by Peter Crane of the Office of the General Counsel. That DPO made essentially two points: (1) that the cost-benefit analysis which the staff performed on KI in the early 1980's was flawed, and (2) that in 1983, there were inaccuracies in the information provided by the staff to the Commission and the public on the medical significance of radiation-caused thyroid abnormalities if and when they do occur.

I have had the opportunity to review the report of the panel convened to review Mr. Crane's DPO, as well as his comments on the report. My initial review indicates that the cost-benefit analysis relied upon by the Commission in the 1984 time frame did in fact contain flaws, and that it seriously overstated the ratio of costs to benefits of a KI program. It also appears that the information provided to the Commission and the public regarding the consequences of radiation-caused thyroid abnormalities was deficient in several respects.

The fact that the analysis performed in the early and mid-1980's may have been flawed does not, of course, mean that the result reached -- i.e., a recommendation that stockpiling of potassium iodide is not worthwhile -- is therefore necessarily incorrect. We are not yet in a position to make that judgment. However, we are conscious that the NRC is in the position of have provided information to states, localities, and other federal agencies -- information on which those entitites may well have relied for their own determinations on the desirability of stockpiling KI -- that may be deficient in important respects. The cost-benefit analysis is in fact referenced in the Federal Government's current Policy Statement on potassium iodide.

We are aware that because of recent interest in the potassium iodide issue in other areas of the Federal Government, the Centers for Disease Control will shortly be coordination a new examination of the matter. The question now facing the Commission is the position that the NRC should take publicly in the interim. We recommend that the Commission be straightforward about the problems identified in the agency's past handling of the potassium iodide

question. Under this approach, a brief notice in the Federal Register would state that the Commission has become aware of deficiencies in its earlier analysis; is currently reexamining its position in light of new information; recommends that its earlier guidance on the potassium iodide issue be regarded as in abeyance pending further guidance from NRC; and urges interested parties to look to the forthcoming Centers for Disease Control Study for additional guidance on this issue.

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APR 16 1990

MEMORANDUM FOR: Eric Beckjord, Director
Office of Nuclear Regulatory Research

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: POTASSIUM IODIDE (KI) DPO OF PETER CRANE

I am responding to your memorandum of March 15, 1990, to Hugh L. Thompson, Jr., concerning the panel review on the subject DPO and your suggestions. I agree with your proposed approach, i.e., to update NUREG/CR-1433 by publication of a supplement to add current information.

It is my understanding that the Federal Radiological Preparedness Coordination Committee (FRPCC) of the Federal Emergency Management Agency (FEMA), intends to review the Federal position on KI stockpiling and distribution. A revision of the Federal position may result from this effort. .NRC, through its NRR and AEOD membership in the FRPCC will fully participate in this evaluation and keep us informed. NRR will have the lead on this issue and will coordinate the NRC review with RES and AEOD.

In addition to updating the NUREG, you are requested to prepare a Federal Register Notice informing the public of the revision of our previous analysis, announcing the publication of the NUREG/CR-1433 supplement, and noting our participation in the FRPCC reevaluation of the Federal position on stockpiling KI.

James M. Taylor
Executive Director
for Operations

cc: P. Crane

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UNITED STATES
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APR 16 1990

MEMORANDUM FOR: Edward Jordan, Director
Office for Analysis and Evaluation
of Operational Data

Thomas Murley, Director
Office of Nuclear Reactor Regulation

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: NRC POSITION ON THE POTASSIUM IODIDE (KI) DIFFERING PROFESSIONAL OPINION (DPO) OF PETER CRANE

Attached are memoranda on the KI DPO of March 15, 1990 from Eric Beckjord and of March 20, 1990 from Peter Crane. The Office of Research has been tasked to work on the resolution of most of the issues raised by Mr. Crane.

We understand that the American Thyroid Association (ATA) asked the Federal Radiological Preparedness Coordination Committee (FRPCC) of the Federal Emergency Management Agency to reexamine the issues in stockpiling KI. A subcommittee of the FRPCC has been established to review the issue and is expected to begin review sometime this year. ATA made the same request to the Food and Drug Administration which conveyed the request to its Center for Disease Control (CDC) in Atlanta. CDC has agreed to evaluate the U.S. and foreign experience in KI stockpiling and distribution.

I request that NRR and AEOD, through your membership in FRPCC, fully participate in this evaluation. I will keep the Commission informed. As part of the FRPCC subcommittee, NRR will have the lead in reexamining whether it is warranted to stockpile KI in the vicinity of nuclear power plants. NRR should coordinate the NRC review on this issue with RES and AEOD.

The Office of Research is updating our previous cost-benefit analysis on stockpiling (NUREG/CR-1433). In addition, RES has been requested to prepare a Federal Register Notice informing the public of the revision of our previous analysis; announcing the publication of the NUREG/CR-1433 supplement; and noting our participation in the FRPCC reevaluation of the Federal position on stockpiling KI.

Once all the above is completed, I will request that the Commission review the new analysis and decide whether the current policy should be changed.

James M. Taylor
Executive Director for Operations

- cc: Eric Beckjord, RES

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UNITED STATES
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MAR 1 5 1990

MEMORANDUM FOR: Hugh L. Thompson, Jr.
Deputy Executive Director for Nuclear Materials Safety,
Safeguards & Operations Support

FROM: Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

SUBJECT: POTASSIUM IODIDE DPO OF PETER CRANE

Pursuant to your March 7 letter, I have reviewed the DPO and related correspondence, and I met with Mr. Crane on March 13, 1990.

In summary there are two main points in the DPO as follows:

1. NUREG/CR-1433 presents an analysis of the costs and benefits of stockpiling potassium iodide for treatment to prevent uptake of radioactive iodine in the event of a nuclear accident with a large release. The analysis is flawed.

2. On November 22, 1983 the staff briefed the Commission on Commission paper SECY-83-362 (Emergency Planning - Predistribution/Stockpiling of Potassium Iodide for the General Public), and on NUREG/CR-1433, which was the basis for the Commission paper. The presentation emphasized thyroid therapy following an exposure, but did not make clear that 4% of the nodules resulting from an accident would be fatal.

Mr. Crane believes that the NUREG/CR-1433 should be withdrawn, that the Commission's record should be updated and revised, and that Federal agencies, states, localities, and the public should likewise be advised of the updated and revised information.

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Eric S. Beckjord

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

cc: James M. Taylor, EDO
Peter G. Crane, OGC

March 20, 1990

MEMORANDUM FOR: Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety,
Safeguards & Operations Support

FROM: Peter Crane

SUBJECT: MEMORANDUM OF MARCH 15, 1990,
FROM ERIC BECKJORD REGARDING
MY DPO ON POTASSIUM IODIDE

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costs and benefits. But if the data is defective, the cost-benefit balancing may be defective as well.

The approach taken by the staff in 1983 was based solely on the cost of treating a thyroid nodule. (For the moment, let us put to one side the fact that the staff mischaracterized the seriousness of the medical problems caused.) The staff's reasoning went as follows: "If a potassium iodide program costing $20,001 could result in averting one case of thyroid nodules, and that case of thyroid nodules could be treated for a maximum of $20,000, then it is more cost-effective for society to allow the thyroid nodule to develop than to prevent it."

The DPO review group, conscious of the criticisms of the earlier analysis, went back and factored in thyroid malignancies and fatalities. They nevertheless concluded, Dr. Beckjord reports, that the benefit of potassium iodide "still falls short of breaking even by more than a factor of 10." (I might interject that this is quite a difference from the factor of 500 that the Commission was told about in 1983, but that is beside the point for the moment.) But what does it mean to have factored in malignancies and fatalities? I would submit that apart from the $1 million figure assigned to fatalities, the DPO panel made no effort to estimate -- other than in dollar costs of treatment, as before -- the actual costs (i.e., disruption of the quality of life) that thyroid disease brings to patients and their families. Thus the DPO panel was looking essentially through the same lens through which the staff had looked in 1983.

The old maxim, "an ounce of prevention is worth a pound of cure," comes to mind here. It should be self-evident that it is better for individuals to live their lives free from disease than to develop diseases and have to be cured of them. Yet the staff's approach, at least as presented in 1983, seems to treat the two states (disease averted and disease treated) as exactly equivalent, regardless of the discomfort and anxiety (if nothing worse) that illness brings.

It should be obvious that society may wish to spend more to prevent some kinds of illness than it would cost to treat those illnesses if they occur. Let us deal for a moment with a disease most of us are familiar with, polio. Let us suppose that with a vaccination program costing $100 million dollars, society can avert a number of cases of polio that in the aggregate would cost $50 million dollars to treat. Does anyone think that such a program would be regarded as non-cost-effective by a factor of two? Does anyone think that the only elements that would fall in the "benefit" column would be the money saved on braces and doctor bills?

Only if the illness in question were as trivial as the common cold could anyone doubt for a moment that to equate dollars for prevention and dollars for treatment is absurd. It is at this point that the staff briefing of November 22, 1983 becomes so significant. At that briefing, the staff presented so rose-colored a version of the significance of radiation-caused thyroid problems as to bear no relation to reality. Fatalities were not the issue, the Commission was told, the issue was averting an illness that might mean "a few days loss." All of this you will find in the DPO and the attached excerpts from the meeting transcript.

Decisionmakers cannot make intelligent judgments about the costs and benefits of averting a particular health effect if they are provided inaccurate information about the nature of that health effect. Only at such time as the staff gets around to telling the Commission about the consequences of radiation-caused thyroid disease will the Commission be in a position to judge how much it may be worth to society to prevent such disease.

On this point, Dr. Beckjord's memo refers euphemistically to whether the cost-benefit analysis gave due consideration of "thyroid dysfunction effects." Euphemisms can sometimes lead to misunderstanding. The central issue is not thyroid dysfunction, it is thyroid nodules and tumors, benign and malignant, and the fatalities that sometimes result from the latter. Dr. Beckjord goes on to say that he cannot determine from the DPO case documents whether or not the 1983 decision reflected "the best possible medical opinion on the subject." I can assure him that it did not. To establish that, he need look no further than DeGroot's 1977 work, Radiation-Caused Thyroid Carcinoma, available in the National Library of Medicine. But a hundred other sources, readily found in any medical library, would yield the same result. The American Thyroid Association could and doubtless would be happy to contribute to the process of providing the Commission with accurate information in this area. A copy of their letter of November 27, 1989 is attached.

I have no desire to elaborate here on my own experience with thyroid disease. The Commission has ample sources from which to obtain information on the consequences of thyroid disease without needing to rely on my personal testimony, and I would like to keep this issue on a professional, not a personal, basis. I trust that when the staff revisits this issue, it will seek its information on the conequences of thyroid disease from doctors and perhaps also from patients. So far, there seems no indication of input from either group, at least on the issue of what thyroid disease entails for the quality of life. I submit that what the Commission needs now on the potassium iodide issue is more in the way of accurate and appropriately documented information,

including information on the error bands in the state of our knowledge; less in the way of avoidance of hard issues; and a complete end to the substitution of wishful thinking for scientific data. Then and only then will it be possible to have a meaningful balancing of costs and benefits -- and to that sort of cost-benefit analysis I do not object at all.

3. Dr. Beckjord's suggestion is to "revise and broaden the NUREG/CR-1433 analysis," with a view to providing the revised information to the Commission and other Federal and state authorities. This approach may be sound in principle, but it may also be time-consuming. The proposed approach does not answer the question whether the Commission has an obligation to correct the record now for the misinformation provided in the November 1983 briefing. I believe that issue has to be faced. Given that other Federal agencies are apparently interested in revisiting the Federal guidance in this area, and that the Centers for Disease Control will be conducting a new study, I think it would be in the Commission's best interest to have corrected the record before the record is corrected for us.

4. Some weeks ago, you asked me what I would do in your position. I replied with a draft memo from you to the Commissioners, a copy of which is attached. While it does not go as far as I personally would like, I believe that it would solve a number of problems for the Commission if adopted.

Attachments: Letter, American Thyroid Association to Dr. Alan Roecklein, Nov. 27, 1989

Draft Memorandum, Thompson to Commissioners

cc: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
The General Counsel
Dr. Eric S. Beckjord

1988 1989

THE AMERICAN THYROID ASSOCIATION
GRAVES (1796-1853)
INCORPORATED
FOUNDED 1923

27 November 1989

Alan Roecklein, M.D.
Radiation Protection-Health Effects Branch
USNRC
5650 Nicholson Lane
Rockville, MD 20852

Dear Dr. Roecklein:

The American Thyroid Association has for some time monitored the problem of potential radioiodine contamination of the atmosphere in the event of a nuclear reactor core melt accident. There has been concern about the possibility of radioiodine in the fallout accumulating in the thyroid gland and irradiating it, with the potential of causing thyroid neoplasms and hypothyroidism.

Potassium iodide (KI), by blocking radioiodine uptake by the thyroid gland, has a radioprotective effect. However, there are a number of significant difficulties in using KI for this purpose.

The American Thyroid Association has re-examined the issues involved in stockpiling KI for use in the event of a reactor accident. The attached statement is an update of a previous published analysis of this complex situation (Journal of the American Medical Association, 1984; 252:659). It is hoped that this statement will generate renewed consideration of this complex problem.

Sincerely yours,

John F. Wilber, M.D.
President, A.T.A.

Leonard Wartofsky, M.D.
Secretary, A.T.A.

David S Cooper, M.D.
Chairman, Public Health Committee
David S. Cooper, M.D.
Johns Hopkins University

David Becker, M.D.
Cornell University

4 pp.

Statement on Potassium Iodide Stockpiling

American Thyroid Association

The recent reactor accident at Chernobyl in which large amounts of radioactive iodine were released into the atmosphere again raised questions about proposed methods of protecting those at risk of exposure. In a previous statement (JAMA 1984, 252:659), the American Thyroid Association (ATA) reviewed the scientific information available about the usefulness of potassium iodide (KI) as a blocking agent to prevent radioactive iodine from entering the thyroid gland of those exposed to fallout. It also reviewed available data about the possible effects on the thyroid of low level radiation from radioiodine as well as the potential toxic side effects of distribution of potassium iodide to large unsupervised populations.

It was concluded at that time that information necessary for the development of a suitable public health strategy required risk/benefit data (ratio of the risk of the hazards of radioiodine to those of stable iodine administration) but that such information was not then available. The ATA is aware of no new information altering the issues raised at that time.

It was concluded in that report that, although the general distribution of KI was not recommended except in special locations and under special circumstances, advanced planning for possible distribution was advisable and it urged that a national task force of specialists be convened to review the issues in KI distribution and to develop alternate national distribution strategies for consideration.

As best as can be determined at this time, no substantial stockpile of potassium iodide is available for public use. Despite the unlikely event of an emergency requiring its use, the ATA believes that the option of potassium iodide distribution should be available for consideration to those responsible for public health measures. To this end, the ATA believes that it would be prudent to have available at central locations a suitable stockpile of KI for possible distribution should its use be contemplated.

(DRAFT BY PETER CRANE)

MEMORANDUM FOR: The Commissioners

FROM: Hugh L. Thompson, Jr.
Deputy EDO

SUBJECT: DIFFERING PROFESSIONAL OPINION
ON STOCKPILING POTASSIUM IODIDE

As you know, the staff has under review a differing provessional opinion filed by Peter Crane of the Office of the General Counsel. That DPO made essentially two points: (1) that the cost-benefit analysis which the staff performed on KI in the early 1980's was flawed, and (2) that in 1983, there were inaccuracies in the information provided by the staff to the Commission and the public on the medical significance of radiation-caused thyroid abnormalities if and when they do occur.

I have had the opportunity to review the report of the panel convened to review Mr. Crane's DPO, as well as his comments on the report. My initial review indicates that the cost-benefit analysis relied upon by the Commission in the 1984 time frame did in fact contain flaws, and that it seriously overstated the ratio of costs to benefits of a KI program. It also appears that the information provided to the Commission and the public regarding the consequences of radiation-caused thyroid abnormalities was deficient in several respects.

The fact that the analysis performed in the early and mid-1980's may have been flawed does not, of course, mean that the result reached -- i.e., a recommendation that stockpiling of potassium iodide is not worthwhile -- is therefore necessarily incorrect. We are not yet in a position to make that judgment. However, we are conscious that the NRC is in the position of have provided information to states, localities, and other federal agencies -- information on which those entitites may well have relied for their own determinations on the desirability of stockpiling KI -- that may be deficient in important respects. The cost-benefit analysis is in fact referenced in the Federal Government's current Policy Statement on potassium iodide.

We are aware that because of recent interest in the potassium iodide issue in other areas of the Federal Government, the Centers for Disease Control will shortly be coordination a new examination of the matter. The question now facing the Commission is the position that the NRC should take publicly in the interim. We recommend that the Commission be straightforward about the problems identified in the agency's past handling of the potassium iodide

question. Under this approach, a brief notice in the Federal Register would state that the Commission has become aware of deficiencies in its earlier analysis; is currently reexamining its position in light of new information; recommends that its earlier guidance on the potassium iodide issue be regarded as in abeyance pending further guidance from NRC; and urges interested parties to look to the forthcoming Centers for Disease Control Study for additional guidance on this issue.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

APR 16 1990

MEMORANDUM FOR: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: NRC POSITION ON POTASSIUM IODIDE: DIFFERING PROFESSIONAL OPINION

This memorandum provides the Commission with information on the status of the Differing Professional Opinion (DPO) regarding the stockpiling of potassium iodide as a protective measure for radiological emergency. The DPO addressed two basic points: 1) that the cost-benefit analysis contained flaws and omissions, and 2) that inaccurate information was provided to the public and the Commission on the significance of radiation-caused thyroid abnormalities. The DPO suggested prompt withdrawal of NUREG/CR-1433, "Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents;" notification of States, localities, other federal agencies and the public of the flaws and omissions in the cost-benefit analysis; and affirmative steps be taken to ensure potassium iodide is stockpiled for possible emergencies.

After the DPO was filed on July 7, 1989, the DPO review panel met with the submittor, Mr. Peter Crane on June 24, 1989, to clarify points in the DPO. Subsequent to the meeting, the DPO review panel compiled additional information and prepared a simplified cost-benefit analysis incorporating the new information. The findings and recommendations of the DPO review panel were documented in a memorandum dated December 14, 1989. The results of the cost-benefit analysis differed from the results of the previous analysis in that the previous analysis overstated the ratio of costs to benefits of a potassium iodide program. However, the results still indicated stockpiling of potassium iodide is not cost beneficial. Additionally, the report indicated the panel's strong conviction that potassium iodide has a very limited efficacy as a public protective measure. The panel felt that this is not only due to the fact that it is useful for only one organ, one nuclide of interest and one exposure pathway, but also because its efficacy is dependent upon its being available either before or within a few hours after exposure. The DPO review panel recommended the current Federal guidance not be changed, and the information developed as a result of pursuing the DPO be transmitted to the States and other interested Federal agencies for their information.

By memorandum dated January 4, 1990, Mr. Crane responded to the DPO review panel report. Mr. Crane stated that although the panel performed a cost-benefit analysis, it was not the entire point of the DPO. The crux of the DPO was that the information on potassium iodide given to the Commission and the

public in 1983 (in part the basis for the Commission decision), was misleading and should be corrected by publishing the latest analysis. Additionally, Mr. Crane discussed other areas he felt were not addressed by the DPO review panel. Namely, that the 1983 report did not make clear that 4% of the accident-caused nodules would be fatal (as assumed in WASH-1400).

By memorandum of March 15, 1990, the responsible office director, Mr. Eric Beckjord, submitted his analysis of the DPO review panel report. As mentioned above, some aspects of the DPO were not resolved by the review panel. The staff is working on their resolution as suggested by Mr. Beckjord. In addition, Mr. Beckjord proposed to publish a supplement to NUREG/CR-1433 based on the new information complied by the DPO review panel.

We understand that the American Thyroid Association (ATA) asked the Federal Radiological Preparedness Coordinating Committee (FRPCC), of the Federal Emergency Management Agency (FEMA), to reexamine the issues in stockpiling KI. A Subcommittee of the FRPCC has been established to review the issue and is expected to begin review sometime this year. ATA made the same request to the Food and Drug Administration which conveyed the request to its Center for Disease Control (CDC) in Atlanta. CDC has agreed to evaluate the U.S. and foreign experience in KI stockpiling and distribution.

I have directed that NRR and AEOD, through their membership in the FRPCC, fully participate in this evaluation. I will keep the Commission informed. NRR will have the lead in reexamining whether it is warranted to stockpile KI in the vicinity of nuclear power plants. As part of the FRPCC Subcommittee, NRR will coordinate the NRC review with RES and AEOD on this issue.

Once all the above is completed, I will request that the Commission review the new analysis and decide whether the current policy should to be changed.

Original Signed By:
James M. Taylor
James M. Taylor
Executive Director
for Operations

cc: SECY
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

APR 16 1990

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