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

DEC 14 1989

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

FROM: Themis P. Speis
Frank J. Congel
Alan K. Roecklein
Leonard Soffer

SUBJECT: REVIEW OF DIFFERING PROFESSIONAL OPINION (DPO) ON STOCKPILING POTASSIUM IODIDE

The review of the Differing Professional Opinion (DPO) (Enclosure 1) on stockpiling of potassium iodide (KI) has been completed. Under the direction of T. Speis, we met as a review panel with Mr. Crane on July 24 and November 21, 1989. At the first meeting there were broad discussions with Mr. Crane of his concerns. T. Speis' note of August 11, 1989 to you (Enclosure 2) summarized this meeting and also appended Mr. Crane's notes of the meeting. A major point of this DPO, which is directed solely to the merits of stockpiling KI, appears to be that previous staff analyses neither explicitly noted nor adequately treated the fact that a fraction of the thyroid nodules produced as a result of an accidental release of iodine could result in cancers, with a small fraction of these predicted to result in fatalities.

As a result of the first meeting, it was agreed that the panel would try to obtain the most recent information on the dose level needed to ablate the thyroid gland, the cost of thyroid nodule treatment and the cost of KI tablets. This information is summarized in a note from A. Roecklein to T. Speis, dated November 9, 1989 (Enclosure 3). Revised data on the incidence of thyroid cancer was also obtained (Enclosure 4).

The panel also agreed to utilize this information to prepare a simplified cost-benefit analysis directed at examining the merits of stockpiling KI. The panel utilized the insights of NUREG-1150 with regard to the magnitude of severe accident releases, and also specifically added the effects of hypothyroidism (an insufficiency of thyroid hormone production for carrying out normal physiologic function) as a fourth health effect not included in previous staff analyses in addition to considering benign thyroid nodules, cancerous nodules and fatalities. The panel met a second time with Mr. Crane on November 21, 1989 to inform him of the information

obtained and to discuss preliminary results of the cost-benefit analysis.

Although the cost-benefit analysis (Enclosure 5) is a best estimate analysis, it also provides additional calculations to show the sensitivity of the results to the assumptions made. On the basis of this analysis, the panel concludes that stockpiling of potassium iodide clearly is not cost-beneficial, and we recommend that present federal guidance should remain unchanged. While our present emergency planning regulations were never justified on any rigorous cost/benefit analysis, but rather on the basis of prudence, it is also important to note the panel's strong conviction that potassium iodide has a very limited efficacy as a public protective measure, in the event of a reactor accident compared to other available measures. This is due not only 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 crucially dependent upon its being available either before or within a few hours after exposure.

The panel also had the benefit of recent information obtained from Soviet sources on thyroid effects of the Chernobyl accident. The high thyroid exposure estimates provided by Soviet authorities, particularly for children, were stated to be primarily a result of ingestion of locally produced milk and dairy products which were contaminated by iodine deposition on grass and pasture areas, rather than from inhalation of iodine. The existence of a diversified nation-wide food distribution system in the U. S. which could readily provide alternative foodstuffs for those which might be contaminated represents a significant difference in this regard. Follow-up studies in this, as well as related areas, are planned as part of the U. S. - U. S. S. R. Joint Coordinating Committee on Nuclear Reactor Safety (JCCCNRS).

In view of the fact that federal policy, as stated in the Federal Register (FR Vol. 50, No. 142, page 30258) leaves the decision to use KI and/or other protective measures to the states and, if

appropriate, local authorities on a site specific basis, the panel recommends that the information developed as a result of pursuing this DPO be transmitted to the states and other interested federal agencies for their information.

Themis P. Speis

Frank J. Congel

Alan K. Roecklein

Leonard Soffer

Enclosures:

1. Memorandum, P. Crane to H. Thompson dated June 16, 1989, NRC Position on Potassium Iodide: Differing Professional Opinion

2. Note, T. Speis to H. Thompson dated August 11, 1989, NRC Position on KI-DPO-Mr. Peter Crane

3. Memorandum, A. Roecklein to T. Speis, dated November 9, 1989

4. Note, S. Yaniv to T. Speis dated December 8, 1989, Risks Associated with Thyroid Irradiation

5. Simplified Cost-Benefit Analysis Regarding Stockpiling of KI

cc: P. Crane
F. Congel
A. Roecklein
L. Soffer

ENCLOSURE 1

JRG file JPK

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June 16, 1989

MEMORANDUM FOR: Hugh L. Thompson, Jr.
Deputy Executive Director
for Operations

FROM: Peter G. Crane
Counsel for Special Projects

SUBJECT: NRC POSITION ON POTASSIUM IODIDE: DIFFERING PROFESSIONAL OPINION

I. Introduction

The NRC staff has recently obtained Commission approval of two staff documents, NUREG-1355 ("The Status of Recommendations of the President's Commission on the Accident at Three Mile Island") and NUREG-1251 ("Final Report on Chernobyl Implications"). Both documents address, among many other issues, the desirability of stockpiling potassium iodide for thyroid protection after nuclear accidents, and assert that a requirement to stockpile the drug "should not be required" because "it would not be worthwhile." Both documents rely on a 1980 cost-benefit analysis, NUREG-CR-1433, prepared jointly by NRC and DOE's Sandia National Laboratory, and on a 1985 federal policy statement which reflected the influence of NUREG-CR-1433 and cited it.

At least as it was presented to Commission by the NRC staff, NUREG-CR-1433 takes the position that when it comes to thyroid abnormalities resulting from a nuclear accident, society should put its resources into cure rather than prevention. What you have just read is not a typographical error. In urging the Commission to adopt and endorse NUREG-CR-1433 in 1983, the staff argued that it is more cost-effective for society to treat radiation-caused thyroid abnormalities after a nuclear accident than to seek to prevent such abnormalities by stockpiling potassium iodide for administration to the public during a nuclear accident. The staff made this argument very explicitly in a November 22, 1983 briefing. Excerpts from that transcript appear as Appendix A to this memorandum.

I do not pretend to find NUREG-CR-1433 easy to understand; I am not convinced that it is as clear-cut in its cost-benefit conclusions as the staff represented it in the November 1983 briefing. For purposes of this Differing Professional Opinion, however, I am proceeding on the assumption that NUREG-CR-1433 is as it was described to the Commission in November 1983. However, even if it is not as flawed as the staff briefing might suggest, I believe that its analysis does not provide an adequate basis for reasoned decisionmaking on health and safety issues.

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My reasons are as follows. Based on personal knowledge in this area, I believe that the information provided to the Commission in 1983 by the staff was erroneous in major respects. In a nutshell, both the risk of fatality from radiation-caused thyroid cancer and the adverse consequences for individuals of non-fatal thyroid abnormalities are vastly greater than the Commission was led to believe. Given that a stockpile of potassium iodide sufficient for the entire U.S. population could be purchased for less than the Government paid for the office building we work in, I think it is inappropriate for the NRC staff to be advising states and localities that the stockpiling of potassium iodide is not cost-effective.

I feel obligated to bring these facts to your attention so that appropriate corrective action can be taken. As NRC Manual Chapter 4125 states: "It is not only the right but the duty of all NRC employees to make known their best professional judgments on any matter relating to the mission of the agency." Differing professional opinions, according to the definition in Chapter 4125-041, "are not limited to the originator's area of expertise." In this case, the subject matter has nothing to do with law, which is my official area of expertise. I have discussed the matter with the General Counsel, who suggested that because it involves a technical matter under your jurisdiction, I direct my concerns to you.

I should add that I did not wait for the Commission to act on the papers before making my concerns known. As will be discussed below, I was the author in 1984 of a memorandum, signed by the then General Counsel, which pointed out a crucial flaw in the cost-benefit analysis. (SECY-84-161.) Although the then Executive Director for Operations acknowledged that flaw, in an April 30, 1984 intra-agency memorandum to the Commission, the staff never changed NUREG-CR-1433 accordingly. In March of this year, when I became aware that in two papers pending before the Commission, the staff was yet again preparing to endorse NUREG-CR-1433 publicly, I expressed my concerns to, among others, relevant staff members involved in the preparation of the papers, and, in a memorandum, to my immediate supervisor.

II. Background

At the risk of covering familiar ground, let me offer some factual background. The thyroid gland has two characteristics that make it of special interest to NRC. First, it is highly radiosensitive, especially in infancy and childhood. For some reason, girls are more sensitive than boys. Second, it is, as the doctors say, "avid" for iodine in all its forms. Thus releases of radioiodines after a major nuclear accident raise a danger that the

thyroids of exposed persons will soak up the radioiodine and later develop radiation-caused abnormalities. Fortunately, such abnormalities are comparatively rarely fatal.

The same avidity for iodine that puts thyroids at risk after a nuclear accident makes it possible to protect them effectively, if protective measures are taken in time. The thyroid has a limited capacity to hold iodine; once it is saturated, no more can be absorbed. Thus if there is a known risk of exposure to released radioiodine, it is a simple and inexpensive matter to administer iodine in a harmless form -- such as a pill of potassium iodide -- and thereby preclude subsequent uptake of harmful iodines. Laboratory workers using radioisotopes of iodine routinely take potassium iodide as a preventive measure. The NRC and FEMA recommend (in NUREG-0655/FEMA-REP-1) that licensees and State and local authorities keep stocks of potassium iodide on hand for use in the event of a nuclear accident -- but only for use by plant workers and institutionalized persons. With regard to the general public, the NRC's position is as indicated above.

The Kemeny Commission recommended in November 1979 that potassium iodide be stockpiled on a regional basis. As late as September 1980, in SECY-80-275A, the NRC staff itself was proposing that FEMA be asked to conduct "a study of the feasibility of establishing a single national stockpile and developing a distribution plan and system including estimates of times to transport and distribute the KI to the general public within various regions of the country." SECY-80-275A estimated the cost of purchasing stockpiles of potassium iodide at $.10 per person per year. (I have elsewhere seen even lower estimates.)

III. The Staff's Position Changes -- SECY-83-362

On August 30, 1983, in SECY-83-362 ("Emergency Planning - Predistribution/Stockpiling of Potassium Iodide for the General Public"), the Executive Director for Operations, Mr. Dircks, advised the Commission that "a cost/benefit uncertainty analysis performed by the staff conclusively shows that potassium iodide offers extremely small benefit in relation to its costs and is <u>not</u> cost effective as a preplanned emergency protective measure for the general public." The staff proposed that the NRC take this position in working with other federal agencies of the Federal Radiological Preparedness Coordinating Committee on the development of a coordinated federal policy statement on the stockpiling or predistribution of potassium iodide.

SECY-83-362 had several attachments. They included the following:

1) A report, "Radiation Protection: An Analysis of Thyroid Blocking," IAEA-CN-39/102, presented to an International Atomic Energy Agency conference in October 1980, by David C. Aldrich of Sandia National Laboratories and Roger M. Blond of the NRC staff. In the background section, that report explained:

> "The risk to the thyroid of exposed individuals posed by potential accidents is especially great for several reasons:
>
> -- Radioactive isotopes of iodine are produced in abundance by the fission process.
>
> -- Iodine and iodine compounds are normally quite volatile. Therefore, a sizeable fraction of core radioiodine inventories could be available for release to the atmosphere.
>
> -- Inhaled or ingested radioiodines are quickly absorbed into the bloodstream and concentrate preferentially in the thyroid.
>
> -- Iodines are eliminated from the thyroid with a relatively long biological half-life.
>
> As a result, the radiation dose to the thyroid is likely to far exceed the dose to the rest of the body, and thyroid damage is likely to affect more individuals than any other accident-induced health effect."

The report went on to discuss the pros and cons of using potassium iodide for thyroid blocking. It explained that radiation-caused thyroid nodules typically appear 10 to 40 years after exposure and may be benign or cancerous. It observed: "Most thyroid cancers are well differentiated, slow growing, and relatively amenable to therapy." The report noted that WASH-1400 (the 1975 Reactor Safety Study) assumed that 40% of accident-caused nodules would be cancerous, and that of these cancers, 10% would be fatal.

The report to the IAEA observed that in the event of an accident in the Core Melt Atmospheric category, "the thyroid dose levels of concern are likely to be exceeded at very large distances from the reactor (and correspondingly over very large areas if this type of accident were to occur." The report recognized that substantial uncertainties were involved in the underlying assumptions. Nevertheless based on the three factors it deemed relevant -- cost, degree of reduction of accident impacts by the use of potassium iodide, and accident probabilities -- it reached ti following conclusion:

> "To some extent, the large uncertainties in the above

assumptions hinder our ability to provide definitive guidance. Nevertheless, for the assumptions made, the calculated cost-benefit ratios are high; and even including uncertainties, KI appears only marginally cost-effective, at best."

2. "Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents," NUREG-CR-1433, prepared by Sandia Laboratories and, like the IAEA report, written by David C. Aldrich and Roger M. Blond of the NRC staff.

This report, longer and more detailed than the IAEA report, reached the same result. Its "Summary, Conclusions and Recommendations" section includes verbatim the paragraph just quoted from the IAEA report.

3. "ACRS Subcommittee Report on the Use of Potassium Iodide (KI) as a Thyroid Blocking Agent," May 17, 1983.

The ACRS subcommittee report made three comments on the NRC staff's proposed approach to the use of potassium iodide:

a. If the staff was correct in believing that the greatest risk of accident-caused fatalities came from whole body exposures rather than thyroid exposures, then the desirability of KI was questionable, and this issue should therefore be reevaluated.

b. Cost-benefit analyses to decide on the usefulness of potassium iodide "do not appear to be compatible with (or comparable to) approaches used in evaluating other aspects of nuclear emergency planning. For example, if the same evaluations were made, would there be justification for the conduct of emergency drills or the installation of warning sirens?"

c. The NRC should work with FEMA to develop guidance for state and local agencies on whether to use KI; should leave the decision to judgment of state and local authorities; and should not make stockpiling or predistribution of KI a licensing requirement.

The ACRS subcommittee report attached comments by Dr. Eugene L. Saenger of the University of Cincinnati Medical Center, writing on behalf of the National Council on Radiation Protection. He observed, among other things, that based on the information available to him, only 1.5 percent of the U.S. population lived within 10 miles of a nuclear reactor. Thus, he suggested, the NRC staff was overestimating the amount of potassium iodide that might need to be purchased, and this was incorrectly affecting the cost-benefit balance. He also commented: "In a period when

there are enormous investments in nuclear power plants many of which are not completed for various reasons and great concern by citizens concerning safety, it does not seem useful to engage in debates concerning the protection of the thyroid gland between agencies of the Government."

4. "Recommendations on the Use of Potassium Iodide as a Thyroid-Blocking Agent in Radiation Accidents: An FDA Update," by Dr. Bernard Schleien and four co-authors.

This report noted that in 1978, the Food and Drug Administration had issued a Federal Register notice stating "that potassium iodide is safe and effective for use as a thyroid-blocking agent in a radiation emergency in which radioiodines are accidently released into the environment." In this report, the authors reviewed the extensive debate on the subject, including the argument that there might be harmful side effects from using potassium iodide, and stated FDA's conclusion:

> "The paucity of human data relevant to the induction of radiation effects from iodine-131, particularly in children, has convinced the FDA that it is prudent to employ risk estimates from external irradiation studies in reaching the conclusions upon which its recommendations are based. From this evidence, the FDA concluded that the risks of radio-iodine induced thyroid nodules or cancer at a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released into the environment outweigh the risks from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency. The FDA recommends that potassium iodide in doses of 130 mg per day for adults and children 1 year and above, and 65 mg per day for children below 1 year of age, be considered in those persons likely to receive a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released to the environment."

The FDA noted that the American Thyroid Association had earlier commented, before certain animal studies were available, that at a threshold of 50 rads, potassium iodide should be given "to provide an added measure of protection for children and pregnant women." The FDA commented that "given that the most sensitive segments of the population should be protected the opinion of the American Thyroid Association and the conclusions of the FDA are not very far apart."

IV. The Staff Briefs the Commission on Potassium Iodide

On November 22, 1983, the Executive Director for Operations, accompanied by the co-author of NUREG-CR-1433

and another staff member, briefed the Commission on the document. Pertinent excerpts from the discussion appear in Appendix A to this memorandum. I hope I have done a fair job of representing the discussion, and capturing its flavor; I would have attached the entire transcript, but it is 82 pages long. I'll be glad to make you a copy if you would like it, however.

For simplicity's sake, let me try to summarize some of the major points of the staff's presentation (not necessarily in the same order as the staff) and offer my comments on each point. If the arguments you see made by the staff appear in places inconsistent with the IAEA report summarized earlier, I can only urge you to read the transcript and assure yourself that I am not mischaracterizing the discussion.

1. "The surviving question is not the question, and that's the piece that really should also be emphasized." Rather, the question is whether you "avert an illness."

Comment: The IAEA report and NUREG-CR-1433 itself assume, based on the Reactor Safety Study, that 40% of accident-caused nodules will be malignant, and that 10% of those malignancies will be fatal. Thus for 1 in 25 accident-caused nodules, survival *is* the issue.

2. If a person does develop a thyroid nodule as the result of an accident, $20,000 represents "the upper end of the scale" in terms of the cost of medical treatment and the loss of productivity: "There's a few days' loss from -- it's a relatively simple operation that's involved in removing the thyroid or removing the nodules --"

Comment: I once quoted that sentence to a doctor at NIH who is himself a thyroid cancer patient. He looked at me in incredulity and exclaimed, "They ought to have one!" In reality, radiation-caused thyroid abnormalities -- and recall that 40% of these nodules will be cancerous -- mean a lifetime of being followed up medically and of taking medication every day. In preparation for scanning, which may take place as often as every six months, the patient is taken off normal medication, so that the pituitary will produce thyroid stimulator hormone and any thyroid cells in the body will take up radioiodine when it is administered in a diagnostic dose. The withdrawal of the normal medication produces exhaustion, weakness, and extreme sensitivity to cold. It means going on sick leave. Radioiodine treatments for inpatients mean being placed in complete isolation for two to four days, with paper covering the floor to protect the hospital from the patient's radioactive footprints. Even at lower, outpatient doses, it means becoming a radioactive source and having to stay away from loved ones and even pets. (You may recall that when the First Lady

recently had a radioiodine treatment as an outpatient, she was told not to handle her dog's puppies for a few days.) For persons of childbearing years, it means, to be prudent, postponing conception for six months to two years. And though statistics on thyroid cancer are good, patients and their families are human and they worry.

From the economic standpoint, radiation-caused thyroid problems can quickly run up costs considerably above $20,000 in medical bills and time lost from work. From an environmental standpoint, diagnostic and therapeutic doses of radioiodine, eliminated through the kidneys, wind up in sewage systems. An NRC staff member who used to work for a state health department once told me that they always knew when someone was being treated locally for thyroid cancer because of the spike of radioactivity at the sewage treatment plant.

3. There are so few nodules likely to result from a nuclear accident that the actual cost of preventing a nodule is on the order of $10,000,000.

Comment: I am frankly not conversant with the latest estimates either on the source term or on accident probabilities, but if we assume $.10 per person per year cost for KI, you can protect the entire population of the United States for something like $25,000,000. For it to cost $10,000,000 to prevent a thyroid nodule must mean either extraordinarily low accident probabilities or extraordinarily minuscule releases if there is an accident. If that is the case, why -- as the ACRS asked in 1983 -- have emergency planning at all? I think that these statistics ought to be checked carefully by persons with expertise in this area.

4. Recommending in favor of potassium iodide stockpiling would mean "sponsoring an industry (the manufacture of potassium iodide) that may have a very low cost payoff in societal needs."

Comment: The NRC should make its decisions based on what the public health and safety requires, not on who will or will not make money as a result.

5. Potassium iodide may seem to be an inexpensive way to protect the public, but in reality it is like an inexpensive accident insurance policy for which, when you read the fine print, "there has to [be] a stampeding elephant that kills you."

Comment: The American Cancer Society estimates that there will be 11,300 new cases of thyroid cancer in 1989, and 1025 fatalities.

Toward the end of the briefing, Chairman Palladino alluded to the fact that the staff had earlier favored the use of potassium iodide. The Executive Director for Operations acknowledged that, commenting that in the rush to respond to the Three Mile Island accident, certain positions had been taken "quickly because it [the NRC] was under a good deal of pressure to move quickly." To go back and question those positions, he said, "takes a much more rational and sometimes courageous attitude."

The transcript shows Chairman Palladino expressing considerable reservations about the staff's cost-benefit analysis. At the direction of Chairman Palladino and the Commissioners, the staff agreed to prepare a letter to the Federal Emergency Management Agency that would "support the policy statement" on potassium iodide then being circulated in draft among the agencies of the interagency working group, while also offering the staff's view that use of the drug was not worthwhile.

V. Subsequent Developments

I will review subsequent developments only very summarily. At some point after the briefing, I had a discussion with one of the staff briefers in which he acknowledged, after checking, that the figure of $20,000 for costs associated with a thyroid nodule referred not to all nodules (including the 4% which will prove fatal), but only to those which will not prove fatal. Subsequently, arrangements were made -- I no longer remember by whom -- for me to meet with staff members involved with the potassium iodide issue, to address my questions. At that briefing, two more arguments against the use of potassium iodide were offered: that in the event of an accident, it would be necessary to follow exposed persons anyway [i.e., so there would be no cost savings to the Government in assuring that they were healthy rather than diseased], and that potassium iodide, while a good idea from a technical standpoint, might be used as an issue to hold up operating licenses. These views may well have reflected no more than the personal opinions of the individuals who offered them.

On January 20, 1984, the staff sent the Commission SECY-83-362A, "Use of Potassium Iodide for Thyroid Blocking." It included a draft letter to FEMA that urged that the interagency working group be "reconvened" to "develop a new policy statement" reflecting the staff's cost-benefit evaluation of potassium iodide. The Office of the General Counsel answered this on April 17, 1984 with a memorandum, written by me, which urged a more neutral approach, and which expressed "serious doubts about the validty of the staff's cost-benefit analysis," citing the staff's acknowledgment that the $20,000 figure represented the benefit associated with averting "only those nodules

which will not prove fatal." The Executive Director for Operations responded on April 30, 1984 with a memorandum, "Supplementary Information on Potassium Iodide for Thyroid Blocking," which took issue with the OGC paper. It asserted that fatal nodules had been "implicitly considered," and it said:

> "The analysis is sufficiently transparent that one could add explicit consideration of the latent cancer fatality component. For example, even taking the upper value of $1,000,000 per latent cancer fatality and a higher mortality rate of ten percent latent cancer fatalities per thyroid nodule would inject a cost component of $100,000 to the $20,000 used in the staff analysis, a five fold increase. This would still not change the staff conclusion that KI is not cost beneficial, since the lowest value at which KI use would be cost beneficial was determined in SECT-83-362 to be about $300,000 per thyroid nodule averted. In summary, the staff conclusion does not rest on whether $20,000 per thyroid nodule averted is an absolutely accurate value, but rather that it is significantly lower than the value at which use of KI does become cost beneficial."

In the end, resolution of the dispute between the staff and the Office of the General Counsel was deferred because of the imminence of a new draft of the policy statement.

On July 24, 1985, the Federal Government published its polciy statement on the use of potassium iodide. 50 Federal Register 30258. It provides:

> "While valid arguments may be made for the use of KI, the preponderance of information indicates that a nationwide requirement for the predistribution or stockpiling for use by the general public would not be worthwhile. This is based on the ability to evacuate the general population and the cost effectiveness of a nationwide program which has been analyzed by the NRC and DOE National Laboratories (NUREG/CR-1433). While the use of KI can clearly provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation problems indicates that the decision to use KI (and/or other protective actions) should be made by the states and, if appropriate, local authorities on a site specific basis."

In April 1986, the catastrophic accident at Chernobyl led to the first use of potassium iodide on a mass scale. According to one set of figures I have seen, 5,000,000 Russians and 6,000,000 Poles received potassium iodide. The NRC staff's report on the implications of Chernobyl,

NUREG-1241, reports that the Poles credit use of the drug with having "reduced the potential thyroid dose to children by factors of 6 to 10." The Soviets, according to the same report, said that at one relocation center, use of potassium iodide kept thyroid exposures within permissible limits for 97% of evacuees. The Soviets also reported "no serious adverse reactions from the use of KI," according to the staff.

The Chernobyl experience did not alter the [redacted] staff's view of the issue. It explained that, under the [redacted]05 federal policy statement, the effectiveness of [redacted]was acknowledged for emergency workers or institutionalized individuals, who may be exposed to the release for an extended period. For the general public, however, "these conditions generally are not applicable, because evacuation is generally feasible and, when carried out, is more effective in dose reduction than administration of KI, since it can reduce the dose for all body organs and not merely the thyroid gland." The staff report did not discuss the possible desirability of having the capacity, in the event of an accident, both to evacuate the affected public and to administer potassium iodide to evacuees.

The staff therefore concluded:

> "The apparently successful use of potassium iodide by the Soviets does not alter the validity of U.S. Government policy that predistributing or stockpiling potassium iodide for use by the general public should not be required. Rather, this decision should be made by individual States and by local authorities."

VI. Statement of Personal Interest

I feel that I ought to state, for the purpose of letting the reader know what biases I may bring to the issue, my own personal interest in it. In 1973, I had a partial thyroidectomy, for a malignancy resulting from x-ray treatment of enlarged tonsils and adenoids when I was two. In more recent years, I have had several radioiodine treatments at NIH, designed to ablate (burn out) any thyroid tissue in my neck. Since there is no way to know for sure whether such tissue is benign or not, the doctors proceed conservatively. In my case, statistics are very much on my side, and I have only to look around at the medical troubles that life has brought to some of my co-workers or their family members to realize how lightly, at least so far, I have gotten off.

But I'd be lying if I said that years of scans, treatments, periodic removal from medication with resulting exhaustion, or the accompanying anxieties, have been completely inconsequential in their effect on the quality of

life for my wife and me, at least from time to time. That certainly affects the intensity with which I feel that NUREG-CR-1433 is off base in recommending that society put its resources into treatment rather than prevention of thyroid abnormalities. I feel very strongly -- there is no point in pretending otherwise -- that if a dime's worth of medication sitting on the shelf of an evacuation center could someday prevent another family from having a similar experience, it would be a dime well spent.

I do not believe, however, that this strength of feeling on a personal level has interfered with my professional objectivity in evaluating the factual flaws in the staff's position. 1/ As noted above, the staff itself admitted in 1984 that the $20,000 cost-benefit figure for averting a thyroid nodule excluded those nodules which will prove fatal, and was thus inaccurate by a factor of five. That admission alone, in my view, is sufficient to warrant the withdrawal of NUREG-CR-1433. I might add that anyone who knows me or my work on behalf of this agency over the past 14+ years knows that I am not phobic either about nuclear power or radiation. 2/

VI. Conclusion.

Potassium iodide is not a panacea against radiation. It protects just a single gland -- albeit a highly radiosensitive gland. The NRC staff is correct in saying, in its discussion of the implications of Chernobyl, that evacuation is generally preferable to potassium iodide as a protective measure in a radiological emergency. <u>But there is no reason to have to choose between the two.</u> The real issue is whether in an emergency one wants to have the capability both to evacuate the public <u>and</u> administer potassium iodide to evacuees and others. If there are no stockpiles of potassium iodide in evacuation centers, emergency operations facilities, and the like, that option will not be available. As a society, we could have the potassium iodide option, and the additional protection it might afford, for a sum that is a drop in the bucket compared to the cost of other emergency preparedness measures we require. If an accident occurred today in Britain, a stockpile of thyroid-protecting drugs would be on hand, because Britain requires it. (The British use iodine in the iodate rather than the iodide form, but the principle is the same.) In this country, such drugs might well not be on hand, because the Federal Government, relying on the NRC's cost-benefit analysis, has been advising states and localities that to require the stockpiling of potassium iodide "would not be worthwhile."

There is not a person in the NRC who is not fully committed to seeing that our country never experiences another TMI or, what is worse, a Chernobyl. We all agree on

that; it is the goal toward which all of us are working. We all hope that the emergency requiring special protective measures never comes. But the premise from which we start is that a serious accident might happen, and that adequate protective measures have to be in place just in case. If there is ever such an accident in this country, no one should have grounds to say that the Russians and the Poles took better care of their children after Chernobyl than we took of ours, or that Americans failed to get adequate protection because the NRC had disseminated erroneous information. I believe that the NRC should promptly withdraw NUREG-CR-1433; advise states, localities, other federal agencies, and the public of the flaws and omissions in its analysis; and take affirmative steps to ensure that potassium iodide is stockpiled for possible emergencies.

cc: Chairman Zech
Commissioner Roberts
Commissioner Carr
Commissioner Rogers
Commissioner Curtiss
William C. Parler
Martin G. Malsch
The Director, NMSS

1/ For what it is worth, I did not become interested in the potassium iodide issue because I was a patient at NIH, but just the other way around. At the time I went to the November 1983 briefing, I believed my own thyroid problems to be far in the past. Because the statements I heard at the briefing seemed inconsistent with what I remembered from my own days as a thyroid patient, I called NIH seeking up-to-date information. The NIH doctors were most helpful in providing such information. They also told me, to my surprise, that my own medical history suggested that followup evaluation was appropriate. As a result, I became a patient there, and now know considerably more about the consequences of radiation-caused thyroid abnormalities than I did when I first wrote memos on the subject in 1984.

2/ It is perhaps ironic that in 1980 I was (I believe) alone in the General Counsel's office in asserting that irrational fear of radiation was not an environmental impact cognizable under the National Environmental Policy Act. (I believed then, as I believe now, that regulatory decisions affecting public health and safety should be made on the basis of sound technical information, honestly and professionally evaluated, without the intrusion of extraneous considerations.) As a result, when the Commission's 2-2 split on the issue had the effect of

excluding psychological impacts from the TMI restart proceeding, and the D.C. Circuit ruled against us in PANE v. NRC (a case I argued), I was made Acting General Counsel for a day to visit the Solicitor General and urge him to seek certiorari, along lines most favorable to the NRC. The Solicitor General took the case to the Supreme Court, where we won unanimously.

APPENDIX A

Excerpts from the NRC Staff Briefing to the Commission on NUREG-CR-1433

Mr. Blond (co-author of NUREG-CR-1433): At the bottom of this figure [a slide was on the screen] you see a dashed line at about the $20,000 figure, and that represents what we feel the cost-benefit breakpoint would be. If the cost of averting one nodule is on the order of $20,000, that's the cost that will be represented by the medical treatment and the loss of productivity of an individual if he had a thyroid nodule. And it's on the upper end of the values which we have seen. There's a few days' loss from -- it's a relatively simple operation that's involved in removing the thyroid or removing the nodules --

. . .

The whole point of the analysis focuses to this [$20,000] figure in some sense. When we look at this we feel we've done the analysis ... with a bias in favor of potassium iodide if anything. ... And our analysis still comes down and shows that ... this is not a viable measure to be taken, it is not something that we should consider in terms of our policy.

As far as we're concerned, the message couldn't be any clearer. Unfortunately, when we perform similar analyses or

I think when we've seen other analyses, we never get quite this clear a message that we're getting here, and that's the important point that from our perspective has to be driven home. We have taken every factor that we can think of into account; it's not just single arguments that we throw at each other; we have factored in all the uncertainties that we can think about, and this is where we come down to it, and the message is clear.

Chairman Palladino: But it sounds crass. It doesn't satisfy me as an individual.

Commissioner Asselstine: I must say I share that view.

Chairman Palladino: Something just does not sit with me right.

Mr. Blond: Let's move on to the next slide --

(Laughter.)

Mr. Dircks (Executive Director for Operations): Let me just add a point. This is not just a question of your mandating potassium iodide or outlining potassium iodide. I think the question is we have to go back to that policy

statement [interagency policy statement on potassium iodide, then being developed] -- and I guess you're coming to that point. Do you stand neutral and not bring these factors to the attention of the other federal agencies and to the state and local governments, or do you endorse it, or do you just stand aside and say it's not my business?

I think the fact is that because these other agencies do look to the Nuclear Regulatory Commission, we have data here that probably would be useful to factor into the decision, not only the federal agencies but the state and local agencies, the question is do we make this analysis available, do we make these conclusions available, or do we not.

Chairman Palladino: Yes. I'm not ready to even address that because I don't understand in the cost analysis -- for example, you say it costs -- what were your dollars? $10 million per nodule averted, and you said boy, that's pretty high. But then you tell me it's a low cost operation.

So now to me, for example, as an individual, what would it cost me for my pill? Twenty cents. So now, that sounds like a very low cost, and if I got the probability or possibility of averting a nodule -- . I don't understand my 20 cents versus $10 million.

Mr. Blond: You have to consider now what is the likelihood of your exceeding that 25 rem requirement that is the recommendation for you to take that pill.

. . .

Chairman Palladino: You're saying that there's [redacted] nodules you're going to get out of an accident --

. . .

Commissioner Bernthal: It's 20 cents per person to cover you, but so few nodules -- the probability of anybody getting a nodule is so small that it turns out to be $10 million.

Chairman Palladino: Yes, but that's from one perspective. As an individual I say boy, that's among the lowest-cost protection ...

Mr. Dircks: ... You may be sponsoring an industry [manufacturers of potassium iodide] that may have a very low cost payoff in societal needs. I mean, --

Mr. Blond: What we're indicating is from our perspective, the government should not sponsor that because we do not see the benefit in terms of its cost.

. . .

Chairman Palladino: I guess I was taking a more personal view of cost-benefit. 20 cents or some nominal amount of money every year or every five years to replace them seems like small change compared to the risk, from my perception.

Commissioner Bernthal. For the individual. But that's not the statistical argument; that's the sort of gut argument that an individual might make to himself.

Mr. Bernero (NRC staff): Mr. Chairman, there's a large industry in the United States selling cost-ineffective insurance policies to people but you will subscribe to a newspaper and you get $25,000 worth of accident insurance with enough clauses in it to certify that there has to [be] a stampeding elephant that kills you.

. . .

Chairman Palladino: ... [Y]ou said something that bothers me a little bit. You said that we were paying a low cost for something that wasn't worthwhile. You related it to a worthless insurance policy.

But as an individual, I may say the potential benefit is that I might survive a nuclear accident at that plant, which I live near.

Commissioner Asselstine: Or that you may not have to go through an operation --

Mr. Blond: Except that -- the surviving question is not the question, and that's the piece that really should also be emphasized.

Chairman Palladino: All right, survive in the terms of I avert --

Mr. Bernero: An illness. I will avert an illness which I might incur. But my father's argument in buying his insurance policies was the very same. He might leave my mother $10,000 from an accident insurance policy.

There was a residual chance that he would be killed by that stampeding elephant. It was not a well thought-out choice.

Chairman Palladino: Let's not carry analogies too far because then I start thinking of the analogy and don't think of the subject I'm supposed to be thinking about.

I agree, I'm paying low cost for averting a very improbable circumstance. I won't argue that. But it is a low cost.

Mr. Bernero: Yes.

Mr. Dircks: But that's again, an individual decision.

Chairman Palladino: I agree, and both sides of the picture must be examined because when you say they're high cost, I tend to think the risk of low cost -- and incidentally, I'm not pushing either side. I have intuitive feelings on this potential thing, but I'd like to understand your position.

[Later, the discussion turns to the question of what position the NRC should take in the interagency group developing a coordinated federal policy statement on the use of potassium iodide.]

Mr. Blond: What it really comes down to is the issue is, as Mr. Dircks indicated, from our perspective, we have two options. We can take a neutral position and indicate

that we, -- the state and locals should make their decision. Here is a body of information along with other bodies of information which might be taken into consideration. And from our point of view, that's a neutral position the Commission could take.

Or we could, if you so desire, take a stronger position and say from our perspective, we do not feel that federal or state or local governments should sponsor such programs, that it is not in the benefit of the public for the government establishments to sponsor such programs as potassium iodide.

On an individual basis [i.e., individuals purchasing their own potassium iodide over the counter for possible emergency use] that's another question, and I don't think we need take a position. If somebody wants to wear that amulet and have that available to them, that's their business, and that's where we'd stand on it.

Chairman Palladino: What does the staff recommend? I re-read the recommendation; I still would like to know what they recommend. I can read it. "Staff will proceed to recommend to the Federal Radiological Preparedness Coordinating Committee that federal policy in this area should be against requiring the planned stockpile or predistribution of KI [potassium iodide] for the general public."

Mr. Bernero: Or the staff offers the alternative, in the most recent memorandum, of taking a more neutral policy. Basically, the current draft policy statement is neutral itself, but that neutral policy statement would be accompanied by clear advice of the NRC providing its technical advice to competent local and state authorities that this material is not worthwhile for predistribution, general public use.

[Chairman Palladino tries several more times to get a clear picture of what the staff is asking the Commission to approve.]

* * *

Chairman Palladino: Bill [Dircks], could I ask you, suppose we went along with your proposal in your letter or the proposal in your report. How would we implement it; by writing a letter to --

Mr. Dircks: I think we would write a letter to FEMA outlining the basic conclusions reached in this analysis, transmitting the analysis along with it, and meeting with them to present this data.

Chairman Palladino: All right. I gather also that you would not interfere with the states going ahead and doing what they want.

Mr. Dircks: State and local, that's right.

Chairman Palladino: So you would support the policy statement but you would make available a statement that the protective measure is not cost-effective or not worthwhile.

Mr. Dircks: Yes.

. . .

Commissioner Asselstine: I have a question that I just thought of. Why did the other agencies [e.g. FDA] believe that it's a good idea to predistribute potassium iodide, and why did the state of Tennessee decide that they wanted to do that?

Chairman Palladino: Incidentally, we were among the other agencies that --

[Chairman Palladino is apparently referring to the fact that in 1980, after the Three Mile Island accident, the NRC

staff proposed that creation of a national stockpile of potassium iodide be studied. SECY-80-257A.]

Commissioner Asselstine: Originally that's right but I gather that view still prevails --

Mr. Bernero: I think you're touching on -- one of the great difficulties in a matter such as this, being on the side of potassium iodide is somewhat like being on the side of the angels.

(Laughter.)

The FDA has found it is not harmful for its potential benefit, and there is a large body of opinion, at least subconsciously, that we must recognize that coming out in favor of potassium iodide predistribution has the force of reminding people of nuclear reactor accidents and how dangerous nuclear reactors are, whereas coming out in favor of -- or rather against potassium iodide implies that the accident risks are low and you don't need such special precautions.

I think when you look at the thing, this colors people's decisions, that you don't want to get into that kind of argument. You just want to look at the thing and say is it worth doing, it it a worthwhile thing. And if you take the single element of a threat to an organ and you simplify the decision as much as possible, it appears to be, on a personal

basis, an excellent thing to do. An inexpensive tablet that -- like my father's insurance policy -- it's only a quarter a week, it's only 20 cents a tablet, and it's self-evidently good. It protects the thyroid under those circumstances. And I think approaching the decision from that point of view leads you to favor potassium iodide. It is quite inexpensive.

Mr. Dircks: But I think, going back to your other question about why the analysis that went into the -- say the rush of regulations after TMI in the emergency planning area, I think looking back on that experience, there wasn't that much analysis and weighing of alternatives and looking at options.

I think the agency moved quickly because it was under a good deal of pressure to move quickly, and there were very few people in the agency who were against going all out in the area of emergency planning. And I think we're seeing some of the effects of that rushed regulation right now, as we try to go back and question why we did certain things in that timeframe, and what should we be doing differently now. It takes a much more rational and sometimes courageous attitude to go back and question the network of emergency planning regulations, as well as some of the other regulations.