

**DECISION-MAKING AND RADIOLOGICAL PROTECTION AT THREE MILE ISLAND:  
RESPONSE OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE<sup>1,2</sup>**

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**INTRODUCTION**

Decision-making by decision-makers during the nuclear accident at Three Mile Island all had to do in some way, and impacted on the public health and safety, the health and safety of the workers, and emergency preparedness and health care. This paper reviews the activities of only one federal agency during the accident, the Department of Health, Education, and Welfare (HEW), and its effectiveness in its role as the leading institution responsible for protecting the public health during the first accident in a nuclear power plant designed for the commercial generation of electricity in the United States. My comments are limited to only three acts dealing with radiological health and protection: the struggle for power and assertion of leadership in response to possible health consequences of the accident; the decisions to evacuate the area during the radiological emergency; and the use of potassium iodide as a means of protecting the public and the workers from the hazards of exposure to radioactive iodine released to the environment. I have chosen a narrative form and have drawn freely from our Report of the President's Commission on the Accident at Three Mile Island, derived mainly from the labors of the health scientists of our task force on public health and epidemiology, and particularly my very able health policy assistant on the commission, Ms Maura Bluestone (1).

**RESPONSE OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE (HEW)**

The HEW response involved two different areas of activity: (1) the deliberations and recommendations of senior officials in Washington, DC; and (2) the direct provision of support services and assistance in Pennsylvania. These activities were based on legal authorities, but were implemented in an ad hoc manner rather than in accordance with any established plans.

**Notification.** HEW Secretary Joseph Califano was notified of the accident by General Counsel Peter Libassi, midafternoon on Wednesday, March 28th. Libassi had been called by the Nuclear

Regulatory Commission (NRC) staff who had served on the Inter-agency Task Force on the Health Effects of Ionizing Radiation which Libassi had chaired. Califano's immediate reaction was to call Dr. William Foege, director of the Center for Disease Control (CDC) with instructions to contact Pennsylvania state health authorities and offer assistance. Califano did not turn to CDC because of any particular radiation health capability or defined responsibility in that agency. Rather, CDC, with its national network of Public Health Service (PHS) Epidemiologic Investigation Service (EIS) officers available to assist in disease surveillance and control, was recognized as the primary agency within HEW which had a working relationship with the Pennsylvania Health Department and through which assistance could be offered. Foege's staff promptly contacted Dr. Beauford Washington, deputy secretary of health in Pennsylvania, and was informed that the state Bureau of Radiation Protection (BRP) in the Department of Environmental Resources (DER), rather than the Health Department (DOH), was handling the situation of the accident. ¶For the first two days of the accident, the only information available to the HEW secretary's office in Washington, DC, came from CDC and the news media. No official communications channel had been established with the NRC or any other federal or state agency or office. Some activity had begun with HEW, but not in response to directive or request from Califano. For example, on Thursday morning, March 29th, Dr. Anthony Robbins, director of NIOSH, had spoken to Mr. Richard Cotton, executive secretary to HEW, expressing concern about the uncertainty of the situation, and the locus of public health response. On Thursday, Robbins also placed a personal call to Dr. Gordon MacLeod, Pennsylvania secretary of health, to inquire about the situation and offer help. MacLeod informed Robbins that the DER, not his DOH, had responsibility in radiological matters such as the TMI nuclear reactor accident. The Bureau of Radiological Health (BRH) in the FDA, which is part of HEW, had also begun by Thursday to sample food and water in the TMI area for radioactive contamination without having informed Califano's office.

Initial Meetings. ¶HEW, through Califano's office, finally became officially involved on Friday, March 30th, following a call to him from an unidentified Washington Senator inquiring how HEW was responding to the TMI nuclear accident situation. Two major meetings were held late that day to make assignments to senior HEW health officials for agency response. ¶The first meeting involved HEW Secretary Califano, EPA Administrator Douglas Costle, NRC Commissioners Victor Gilinsky and Peter Bradford, and Ms. Jessica Mathews of the National Security Council. Review of the information concerning the situation at the TMI site at that time led to the conclusion that circumstances

were possibly much worse than originally understood. HEW and EPA arranged to place representatives in the NRC Incident Response Center in Bethesda, Maryland in order to share data and information. Califano and Costle expressed concern about minimizing radiation releases of any type from the reactor, following on the events of the previous night, when TMI had discharged nonradioactive liquid industrial wastes into the Susquehanna River. They also expressed concern for the need to evaluate the evacuation implications of various potential developments in the reactor systems. Califano also expressed concern for the adequacy of data which would be available for use in possible long-term follow-up studies, particularly in the aftermath of Congressional hearings begun on the "Smoky" veterans at the Nevada Test Sites in the 1950s. ¶The second meeting was the first in a series of meetings held by Califano with senior PHS health officials who were to advise him throughout the duration of the accident. Over the course of the weekend, this group included Dr. Julius Richmond, Surgeon General and assistant secretary for health, HEW; Dr. Donald Frederickson, director of the National Institutes of Health; Dr. Donald Kennedy, FDA administrator; Dr. William Foege, CDC director; Dr. Arthur Upton, director of the National Cancer Institute; Dr. Anthony Robbins, NIOSH director; and various assistants and additional chiefs and experts from those agencies. ¶Two major items were covered at the initial Friday, March 30th meeting. First, there was considerable discussion whether evacuation of the area surrounding Three Mile Island should be recommended. The group felt unable to make a definite recommendation on evacuation, however, because of the paucity of information available from NRC. The PHS officials felt that they did not have a full understanding or indeed almost any understanding of what the situation was with respect to the reactor. There was consensus, however, that the population should be notified of the nature of the problem and the possible need to evacuate, especially if NRC could not give assurances either that no further significant radiation releases would occur or warning could be given at least 6 hours prior to such a release. ¶Second, assignments were made for departmental activities. Mr. Cotton was named overall coordinator; Mr. John Villforth, director of the BRH, was named operational coordinator; and Mr. Charles Cox, Villforth's assistant, was sent to Harrisburg, Pennsylvania to act as the HEW on-the-scene coordinator. Specific assignments, summarized in a March 31st memorandum from Califano to his agency heads, outlined the direct assistance level of HEW response: (1) BRH/FDA sampling of food and water, and communication of that monitoring data to the NRC command center and Califano; (2) placement of FDA staff on a 24-hour basis in the NRC command center in Harrisburg to gather monitoring and

reactor status information for communication to PHS health and medical officials and scientists who were analyzing public health implications and protective actions to be recommended; (3) procurement by FDA of adequate supplies of potassium iodide for emergency use by persons living within a 10-mile radius of TMI; (4) collaboration of FDA with White House and Pennsylvania state authorities in making arrangements for distribution of potassium iodide; (5) review of the PHS readiness to provide the emergency assistance authorized in the PHS Act; (6) arrangements to train PHS hospital personnel in the treatment of radiation injuries in case such assistance is requested by the state; and (7) assessment of the adequacy of data collection efforts by all federal agencies in anticipation of information needs of future epidemiological studies.

Evacuation Considerations. ¶ Meetings of the PHS officials with Califano continued through the weekend. On Saturday, March 31st, the group discussed further not just the possibility of evacuation, but the appropriate geographic area to be evacuated. A 5-mile radius was considered too small; there was debate over the adequacy of 10 miles versus 20 miles. NCI Director Upton was recommending a 20-mile radius based on his recollection of evacuation speed and radiation casualties analyzed in the WASH-1400 Report. The group accepted Upton's advice. Consideration was also given to precautionary evacuation of special populations such as hospital and nursing-home patients, and prison inmates. All of these discussions, however, led only to recommendations to consider evacuation, not to recommend evacuation; no actual evacuation recommendation was made. The deliberations of the group were summarized in a noon, March 31st memorandum from HEW Secretary Califano to Watson of the White House staff.

HEW ACTIVITIES IN PENNSYLVANIA

While the HEW officials in Washington, DC were discussing evacuation considerations and seeking to obtain information in Washington on Saturday and Sunday, March 30th and 31st, other PHS personnel were busy carrying out the operational assignments made at the Friday evening meeting in Califano's office. FDA was involved in two types of environmental monitoring activity in the TMI area. The first was the continuous sampling of food, water and milk; the second was placement of approximately 250 thermoluminescent dosimeters (TLDs) for environmental monitoring of the radioactivity released. The former activity was based on established authority to monitor for contamination of foods and food products which might be subject to interstate commerce. Such monitoring was also consistent with the HEW protective action guidance on contamination of food and animal feeds resulting from a radiation emergency. ¶ The latter TLD environmental monitoring activity, however, was not an official responsibility of HEW. By coincidence, the supply of TLDs was

available from the FDA/BRH x-ray mammography monitoring program. Knowing of the limited monitoring capacity of the Pennsylvania BRP, the FDA/BRH offered to place the x-ray mammography program TLDs for collection of additional environmental data. CDC sent two EIS officers, neither of whom was experienced in any aspect of radiological protection or radiation health, to the scene in Harrisburg to assist in developing the protocol for TLD placement and in identifying data which might be needed for later epidemiological studies. HEW personnel in the area also began attending a series of Department of Energy (DOE) briefings at their command center (Trailer City) in the Harrisburg Capital City Airport near TMI to share accident information, particularly environmental monitoring, being collected by the various agencies involved in monitoring procedures, including DOE, EPA, HEW, and NRC.

#### THE POTASSIUM IODIDE STORY

Full-scale efforts to obtain supersaturated potassium iodide supplies also began in the early hours of Saturday, March 31, 3 days after the accident began. Over 15 years ago, potassium iodide had been considered an effective pharmacologic agent for blocking absorption of radioactive iodine by the thyroid gland. Although approved and available as a prescription drug for treatment of several medical conditions, use of potassium iodide as a protective measure for large populations in the event of a radiological emergency was not considered in the United States until mid-1977 with release of a report by the National Council on Radiation Protection and Measurements (2). Furthermore, the drug was not officially approved for such use by the FDA until publication of a New Drug Application notice in the Federal Register in December 1978. At the time of the accident at TMI, no pharmaceutical or chemical company had responded to that notice, presumably because there was no perceived market for the drug, since no nuclear accidents had occurred, and since no nuclear accidents were anticipated. As a result, it was apparent on Friday, March 30th, when the decision was made to obtain potassium iodide for possible use in Pennsylvania, that the large quantity of potassium iodide needed, over 250,000 doses, even considering that used in other clinical situations, was not available. ¶ Mr. Jerome Halperin, the Deputy Director at the FDA Bureau of Drugs, immediately began seeking a possible manufacturer of the drug. FDA reached agreement with the president of the Mallinckrodt Chemical Company in St. Louis, Mo. at approximately 3:00 AM on Saturday morning, March 31st. An around-the-clock effort ensued involving the Mallinckrodt Company in St. Louis, the Parke-Davis Company in Detroit, and a dropper manufacturer in New Jersey to produce approximately 250,000 one-ounce bottles of supersaturated potassium iodide solution with accompanying medicinal droppers. The FDA in Rock-

ville, Md., began to print patient information leaflets and wrote labeling instructions to be placed on the bottles. This was done throughout Saturday and into the night. The first shipment of bottled potassium iodide solution sent by U.S. Air Force C57 cargo plane arrived in Harrisburg, PA about 1:30 AM Sunday; by Wednesday, April 4th, the full supply of 237,013 bottles together with droppers had been delivered to Pennsylvania. ¶ Now, according to the Federal Preparedness Agency's Federal Register Notices assigning radiation emergency responsibilities to various federal agencies, the official HEW responsibility regarding potassium iodide is to assist state authorities in developing plans for the prevention of adverse health effects of radiation exposure, including the use of prophylactic or protective drugs. The actual procurement of the drug by FDA for use in Pennsylvania following the accident was an ad hoc decision by HEW in Washington in response to the realization that none was available on the open market for direct purchase by the state. ¶ On Monday, April 2nd, the potassium iodide story developed further with the involvement of Washington-based health officials. When the FDA first became involved in this issue, there was an understanding that the federal agency would only be involved in arranging for production and transport of the drug to Pennsylvania. It would not give directions on its distribution or use; the distribution would be determined at the state and local levels; this position reflected that discussed in NCRP Report No. 55 on potassium iodide (2) and summarized by the FDA in its New Drug Application Notice. ¶ On Monday, April 2nd, however, Secretary Califano's office at HEW received from Watson in the White House, a request for HEW recommendations on the distribution and use of the potassium iodide supplies in Pennsylvania. It was implied that the request was initiated by Pennsylvania Governor Richard Thornburgh. The request was forwarded to Dr. Julius Richmond for PHS response. Dr. Frederickson, Director of the National Institutes of Health, had begun collecting information on the use of potassium iodide as a thyroid-blocking agent following the Friday evening meeting at which the decision was made to secure supplies for Pennsylvania. On Monday, he gathered a number of NIH medical scientists together to discuss possible administration of the drug. Several recommendations emerged from this meeting and were incorporated in a memo from US Surgeon General Richmond to HEW Secretary Califano on April 2nd. The significant recommendations were to: (1) administer potassium iodide immediately to workers on Three Mile Island; (2) have potassium iodide available to all people who would have less than 30 minutes warning of a radioactive iodine release (perhaps within a 10-mile distance from TMI); and (3) have local authorities in Pennsylvania assess the recommendations in light of their first-hand

knowledge of the situation. HEW spokesman insist that this last recommendation was genuinely intended to leave acceptance or rejection of each recommendation to the discretion of state authorities. ¶ Pennsylvania Health Secretary MacLeod, however, interpreted the White House letter containing recommendations from Secretary Califano of HEW to Govern. Thornburgh to be a set of directives to the Pennsylvania state health officials to carry out specific recommendations. MacLeod and his advisors did not agree with these as recommendations, and chose not to accept them. In so doing, the provoked a difficult confrontation with HEW officials in Washington, DC. ¶ The first few days of the week of April 2nd were marked by a number of clashes and confusion over these health-related decisions, that such as the confrontation that developed between MacLeod and PHS officials over distribution and use of the potassium iodide provided by the FDA. MacLeod had assumed responsibility for the supply of drugs on Saturday morning. He then called the FDA Bureau of Drugs to consult with an endocrinologist there about the process by which the drug had been manufactured, and possible adverse side effects from its administration. MacLeod also placed a call to HEW Secretary Califano, his "counterpart at DHEW," in search of advice on medical aspects of radiation exposure. Although Califano could not be reached, NCI Director Upton did return the call later with several suggestions of physicians knowledgeable in the field of radiation health to whom MacLeod could turn for advice. There was no immediately identifiable unit within HEW to which the state health officer could turn for such assistance, and that, once contact was made, the advice given was to consult several physicians and scientists in academic or other institutions across the country rather than within HEW or PHS MacLeod appointed Dr. Neil Wald from the University of Pittsburgh to advise him on radiation-related health matters, including the use of potassium iodide. ¶ As the potassium iodide arrived in Harriburg, it was stored under armed guard in a central warehouse. No plans had been made for distribution of the drug on Saturday because none had yet arrived. Local deployment sites were identified on Sunday. On Monday, April 2nd, following discussion with outside consultants, MacLeod decided to stock and guard the potassium iodide at the central warehouse because he was told that several civil defense people had fled the area, thus hampering security coverage if the drug were stored at the local distribution points. ¶ On that same day, Monday, April 2nd, MacLeod heard that a memorandum was being prepared by HEW advising distribution and use of potassium iodide to the workers and high-risk individuals in the general population. Dr. MacLeod, Dr. Neil Wald, Mr. Harold Denton of the NRC, and the governor's office had already agreed to withhold distribution and use, and communicated their



thinking on the matter in a telephone conversation with the White House. Nevertheless, the White House letter containing HEW recommendations to administer potassium iodide immediately to all workers at TMI and distribute the drug to all persons within a 10-mile radius was sent to Governor Thornburgh on Tuesday. Denton had already rejected the idea of administering it to the workers since there had been no radioactive exposures to indicate such use. MacLeod rejected the second recommendation on the basis of prior considerations. (1) Radioiodine levels were far below that for which such protective action was indicated; (2) public anxiety would increase and people might administer the drug without being so advised; (3) by Monday, the likelihood of a high-level release from the damaged reactor was diminishing rapidly; (4) the possibility of adverse side effects presented a potential public health problem; and (5) inappropriate dropper sizes, questionable quality of the drug supplies, and conflicting recommendations over the length of administration could lead to inappropriate or harmful use of the drug.

The potassium iodide supplies remained in the central warehouse. By midsummer, the FDA had relocated the drugs to a repository in Little Rock, Arkansas to be maintained as a national stockpile.

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**REFERENCES** (1) Report of The President's Commission on the Accident at Three Mile Island. The Need for Change: The Legacy of TMI, Washington DC, 1979. (2) Protection of the Thyroid Gland in the Event of Releases of Radioiodine. NCRP, Washington DC, 1977.