The Commonwealth of Massachusetts
Executive Office of Health & Human Services
Department of Mental Retardation
160 North Washington Street
Boston, MA 02114

Philip Campbell
Commissioner

Area Code (617)
727-5608
TDD Line,
727-9866

Dear , :

Enclosed you will find the complete set of records we have in our file for [NAME] including a xerox of a photograph that was taken of them as a resident; any immunization, medical, and dental records; and, any birth, confirmation or baptismal records we could locate.

Before you read the records, I wanted to personally apologize for the archaic, and frankly, insulting language of that era that you may find in this old records. The use of the terms such as "moron", "imbecile" or "idiot" were actually the standard medical terminology of the day. However, the use of such terms is appalling to those of us who serve citizens who are retarded today.

Also, it is important to note that not all residents of Fernald were admitted due to mental retardation. Society allowed many persons to be admitted to Fernald School for a multitude of reasons aside from mental retardation and no one should assume that they are mentally retarded just by virtue of their having been a student here.

There is also a possibility you will see similarly disparaging language or reporting on the parents of our former residents/students. Please understand that it was the type of judgement and categorization allowed at that time. However, it can be very upsetting to read today by our former residents, their spouses, children, or significant others.

Again, please accept my sincere apologies for any disturbing language you find and know that we are working diligently today to assure the dignity of all of our citizens, residents and consumers served by the Department of Mental Retardation do not face such derogatory language or treatment again.

Very truly yours,

Philip Campbell
Commissioner

WHAT HAPPENED?

Of significant note is that no research was identified by the Task Force that involved testing the effect of radiation on human beings by introducing radioactive materials purposefully into their bodies to measure or monitor such effects. The nutritional research studies used small amounts of radioactive material as tracer elements to understand how the body functioned or obtained elements from the diet; the Thyroid studies used small to large amounts of tracer materials, also to learn about body functions; and, the so-called Cold War study at Wrentham differed in that the tracer materials were used to find the point at which administration of iodine blocked the uptake of radioactive materials that would be found in nuclear fallout.

Nutritional Research Studies

1946 — **Iron Study**
17 subjects: all identified

1950-53 — **Calcium Studies**
17 separate experiments done over three years
57 subjects total: all identified

1955 — **Radioactive Calcium Study**
Proposed but no confirming records found
33 potential subjects: all identified

Thyroid Studies

1952 — **Thyroid Function in Myotonia Dystrophica**
6 subjects: identities still undetermined

1957 — **Thyroid Function in Down Syndrome: Fernald**
28 subjects: identities still undetermined

1961 — **Nuclear Fallout Study: Wrentham**
70 subjects: identifies still undetermined

1961 — **Thyroid Function in Down Syndrome: Wrentham**
104-167 subjects: 12 identified to date

Therapeutic/Diagnostic Use of Radioactive Isotopes

1962-73 — Five archival records were found documenting tracer studies or the therapeutic use of radioactive materials involving residents with specific metabolic disorders

To address the issue of the potential risk incurred by these dosage levels, five opinions by experts within the fields of radiation and epidemiology have been included to outline an assessment of that risk factor. The full text of these opinions can be found in Appendix G. Also, a brief summary of the nature of ionizing radiation and what is meant by the effective whole body dose equivalents is included in Appendix F.

■ Research Studies Identified by the Task Force

This section contains all of the facts that the Task Force has been able to identify, as of this time, concerning the research studies that involved residents at two Massachusetts state schools: Fernald and Wrentham. Many of the findings and discussions in other sections of the report are based on the material presented in this and the next section, "Archival Record Chronology." The information is presented objectively, including only those notes necessary to assist the reader by clarifying or expanding the information being presented. The chart on the previous page summarizes all of the studies found. A study-by-study outline follows.

The research studies are grouped into the following three categories:

■ Nutritional Research Studies

Two nutritional research studies were done that used radioactive iron (1946) and radioactive calcium (1950-53) as metabolic tracers. Both research studies were carried out using Fernald residents as subjects. These are the two studies that archival records have allowed this report to present in great detail. The Task Force can positively identify all of the subjects from these studies and have found the six journal articles that arose from them.

■ Thyroid Studies

Throughout the 1950s and 1960s there were three identified research studies in which radioactive iodine was used as a tracer to understand the function of the thyroid gland. These appear to have involved residents of Fernald, family members of Fernald residents, and residents of Wrentham. However, the amount and type of tracer materials used went beyond the minimal tracer levels of the nutritional research studies and into levels that create concern for the need of follow-up medical and epidemiological study. The Task Force will allow the follow-up working group to conduct that next level of research and analysis for reporting at a later date and so will not focus on these studies in this report.

One Thyroid study in 1961 stood out from the others. This was a study, using children who were residents of Wrentham, to determine how much normal iodine was needed to be added to the diet of children to block the uptake of radioactive iodine from fallout following a nuclear attack or accident. This study can be called a Cold War experiment and stands alone in fitting that categorization. The Task Force learned that the results of this study were actually referenced at a 1989 European conference after the nuclear accident at Chernobyl.

■ Therapeutic/Diagnostic Use of Radioactive Isotopes

Archival records were found that dealt with the use of radioactive isotopes for therapeutic or diagnostic testing on a select number of residents who had specific medical conditions.

Nutritional Research Studies

During the time period leading up to and surrounding these studies, the focus of experimentation nationally had shifted in part to nutritional and digestive issues relating to malnutrition and feeding of large populations: "The study of human digestion was a major focus of American medical research [and] metabolic studies of both normal and sick children were also reported...As early as the 1870s, physicians used dyes and other chemicals for gastrointestinal studies in adults. Beginning about 1909 pediatricians conducted similar studies in infants and children."[1]

The purpose of the research involving the residents at Fernald was to understand how the body obtained the minerals iron and calcium from dietary sources and to find out whether compounds in cereals affected their absorption. It had been known from nutritional studies of bread in the late 1930s that a class of chemical compounds, inositol hexaphosphates (commonly called phytates), could form insoluble compounds with iron to prevent its absorption from food. Phytates are commonly located in the outer covering (integument) of grain and were present in poorly milled white flour. Some cereals (e.g., rolled oats) contained phytates; others (e.g., farina, commonly known as Cream of Wheat) did not. The immediate goal of the research was to understand if either of these cereals was preferable from a nutritional point of view.

☐ Iron Study: 1946

This study involved 17 subjects who received seven breakfasts, each with a minute amount of radioactive iron as a tracer mixed into the milk that was served over the cereal. The subjects received the first five breakfasts over a period of about 12 weeks. After a wait of 25 weeks, they received two more breakfasts: the sixth at week number 37 and the seventh at week number 40.

Calculating the dose was complicated, because different amounts of iron were absorbed from each breakfast, and two different kinds of radioactive iron were used (^{55}Fe and ^{59}Fe). However, there was sufficient information available in the single published article[2] as well as in the doctoral thesis of Dr. Leonard M. Sharpe, submitted to the Task Force by the Massachusetts Institute of Technology (MIT), to permit this calculation.

The chart (see Figure 1) shows the amount of radiation each subject received from participation in the Iron study, along with the 300 millirem annual effective whole body dose equivalent of radiation from natural background sources in the Boston area. For comparison, the higher 400 millirem natural background dose received by a resident of Denver is also shown.

The researchers were from MIT and Fernald. The research was supported by the Quaker Oats Company.

☐ Calcium Studies: 1950-53

The same motivation for understanding the role and impact of phytates was the foundation for this study, but the researchers now used a minute amount of radioactive calcium tracer. This study involved 15 subexperiments conducted over a three-year time frame and served as the basis for five published articles.

The best knowledge of this research comes from Dr. Felix Bronner's doctoral thesis. A series of progress notes that had been sent to Dr. Clemens E. Benda, Medical Director at Fernald at that time, were secured from the

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[1] M.A. Grodin and L.E. Glantz, *Children as Research Subjects: Science, Ethics & Law* (New York City: Oxford University Press), 1993, p.9.

[2] L.M. Sharpe, W.C. Peacock, R.Cooke, and R.S. Harris, "The Effect of Phytate and Other Food Factors on Iron Absorption," *J Nutrition* 41, 433-446 (1950)

papers donated by his estate to Harvard University. Three of the published articles[3,4,5] also contained substantial information that allowed these calculations.

In the main set of experiments, there was a total of 54 subjects, who were listed only by weight and age in the appendix of Bronner's thesis. There were 8 subjects who were not mentioned in the published articles but were noted in the progress report as having served as controls. The next 36 subjects received two breakfasts with 0.85 microcuries of ^{45}CA in each. Another 9 subjects each received a single injection of 0.75 microcuries of ^{45}CA, as well as a single breakfast containing an additional 0.85 microcuries of ^{45}CA. These subjects each weighed between 63 and 92 pounds and received 1.0 microcuries of ^{45}CA orally. The effective whole body dose equivalents they received ranged from 6.4 to 4.4 millirems. There was 1 unidentified adult who also received an injection containing 2.02 microcuries of ^{45}CA. The final 3 subjects (for the final total of 57 subjects overall) were not involved in the main set of experiments but received a single injection each for a "long-term follow-up study."

The largest effective whole body dose equivalent received by any of the subjects was 15 millirems, and the smallest was 4 millirems. Figure 1 illustrates the amount of radiation each subject received from participation in the Calcium studies, along with the dose equivalent of radiation from natural background sources in the Boston and Denver areas as previously discussed. For comparison, the doses persons receive today in common medical diagnostic procedures, ranging from a chest X-ray to a brain scan, are also given in a third chart.

One of the subexperiments within the calcium metabolism study involved a 10-year-old patient who was terminally ill with Hurler-Hunter syndrome (which in that time period was also referred to by the archaic and unacceptable term "gargoylism"), a degenerative disease of the nervous system associated with defective mucopolysaccharide metabolism. The patient was given 80 microcuries of ^{45}CA and was found to have abnormal calcium metabolism, but he died before the study could be completed.

The researchers were from MIT, the Harvard Medical School, and Fernald. The research was supported by the Quaker Oats Company and the Atomic Energy Commission.

The risk assessment done by Dr. Joseph L. Lyon, an outside epidemiologist with a specialty in radiation medicine (see full text in Appendix G), was very reassuring to the Task Force on these nutritional research studies. Dr. Lyon not only concurred with the dosimetry done by Dr. Litster (also in Appendix G), and supported the findings of the other three expert opinions received, but he was also able, as an epidemiologist, to state that "children exposed to ionizing radiation generally manifest the excess risk of leukemia in the first 15 years after the exposure." Between 40 to 50 years have now passed since these research studies were done, allowing Dr. Lyon to speculate that if the subjects did not exhibit a leukemia between 1961-1970, then it is unlikely that they would suffer this most severe of potential medical risks from either the Calcium or Iron tracer studies.

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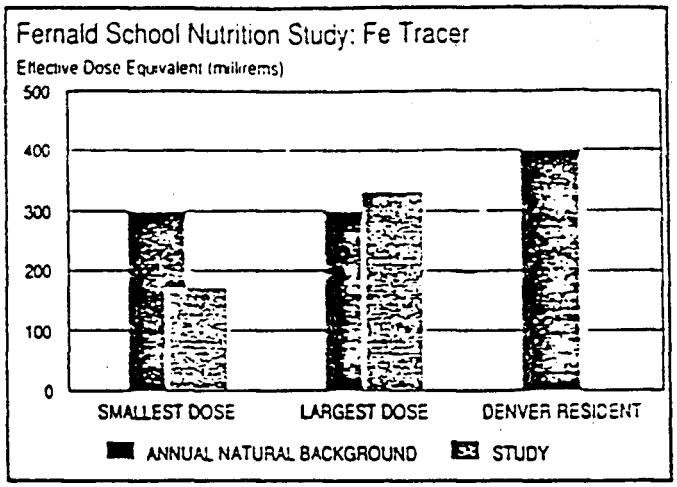
[3] F. Bronner, R.S. Harris, C.J. Maletskos, and C.E. Benda, "Studies in Calcium Metabolism. Effect of Food Phytates on CA^{45} Uptake in Children on Low-Calcium Breakfasts," *J Nutrition* 54, 523-542 (1954).

[4] F. Bronner, R.S. Harris, C.J. Maletskos, and C.E. Benda, "Studies in Calcium Metabolism. Effect of Food Phytates on ^{45}CA Uptake in Boys on a Moderate Calcium Breakfast," *J.Nutrition* 59, 393-406 (1956).

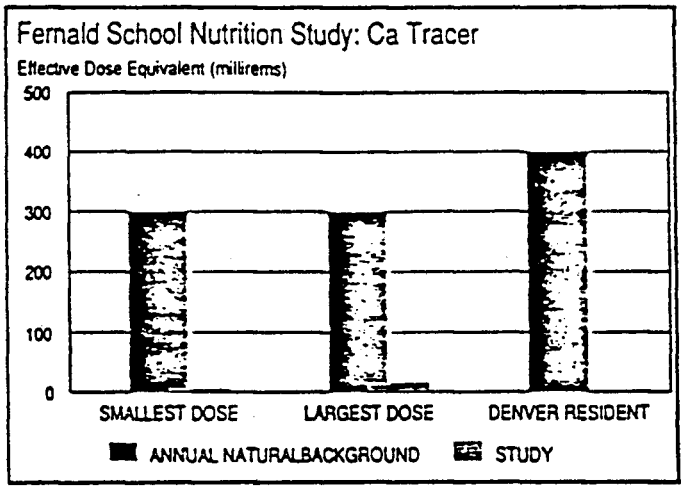
[5] F. Bronner, R.S. Harris, C.J. Maletskos, and C.E. Benda, "Studies in Calcium Metabolism. The Fate of Intravenously Injected Radiocalcium in Human Beings," *J Clin Invest* 35, 78-88 (1956).

Figure 1: Calcium & Iron Studies Compared with Annual Background Exposure to Radiation in Boston, in Denver, and in Common Medical Procedures

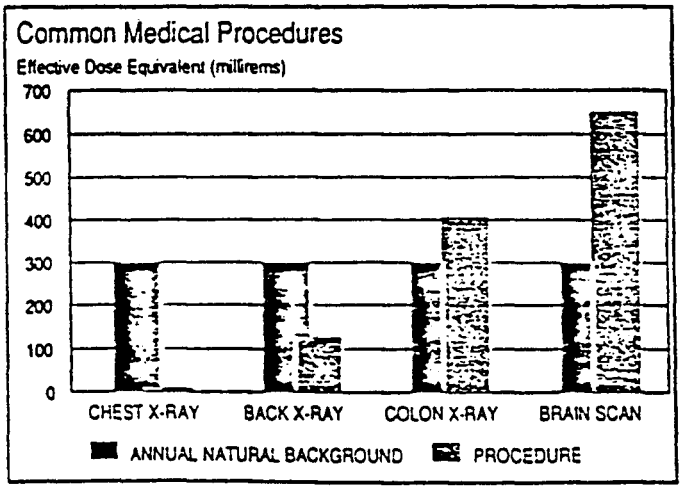
1946
IRON STUDY



1950-53
CALCIUM
STUDY



COMMON
MEDICAL
PROCEDURES



SPECIAL NOTE: During the archival review, the Task Force compiled a comprehensive set of records that address key areas of concern. These include an outline of the understanding of tracer studies in the 1940s; the rationale for the nutritional research studies; reasons the studies were done at Fernald; the existing policies and guidelines for conducting research on human subjects in that era, including steps taken by the researchers to gain permission from the state and federal authorities to conduct the research; and the methods used to obtain consent from parents/guardians. Permission for wards of the state to participate was given by the superintendent of the institution. An outline of the contents of these records is in the following section, "Archival Record Chronology," and copies of the original archival records can be found in Appendix B.

■ Thyroid Studies

Unlike the nutritional research studies, this report will not contain dose interpretation or risk assessment for the Thyroid studies. This will be conducted by the follow-up working group.

☐ Nuclear Fallout Study: Wrentham

This study was singled out for special and immediate treatment due to the nature of the study. A press release was issued by the Task Force on February 8, 1994, alerting the public to its discovery. Studies of this nature fall under what society has come to call "Cold War experiments," focusing on the medical effects a civilian population will suffer from fallout following a nuclear attack or accident.

The body requires iodine as a nutrient, and uptake of the small amounts normally present in the diet is high. The purpose of this study was to determine how much normal iodine was needed to be added to the diet of children to block the uptake of radioactive iodine they might be exposed to from nuclear fallout.

The study[6] involved 70 subjects, who ranging in age from 1 to 11 who were residents of the Wrentham School. The 63 primary subjects were given daily dietary supplements of stable (nonradioactive) sodium iodide, ranging from 100 micrograms to 1,000 micrograms, for a period of 12 weeks. An additional 7 subjects were given a single dose of 1,500 micrograms per square meter of body surface of stable iodide.

Radioactive iodine, ^{131}I, was given as a tracer to measure the rate of uptake of stable dietary iodine. One of the researchers has since died and the other two were unable to provide any significant additional details, but it appears from Figure 1 of the article[7] that 1 microcurie of ^{131}I was given to 5 2-year-old subjects every 2 weeks for 14 weeks. Thus, each subject received a total of 8 microcuries of ^{131}I. Similar doses were probably given to the other subjects in the study.

The researchers were from the Harvard Medical School, Massachusetts General Hospital, and the Boston University School of Medicine. The research was supported by the Division of Radiological Health, Research Branch, of the U.S. Public Health Service.

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[6] K.M. Saxena, E.M. Chapman, and C.V. Pryles, "Minimal Dosage of Iodide Required to Suppress Uptake of Iodine-131 by Normal Thyroid," *Science* 138, 430-31 (1962).

[7] Ibid

The Task Force has been informed by the outside experts that the stable iodine should have posed no risk in and of itself as it is a normal dietary requirement. Literature cited in the journal article arising from this study stated that even unusually high levels of ordinary iodine would only pose problems if administered for several years. With enriched flour and other foods, the modern diet can easily include about 1,000 micrograms per day of iodide.

Of concern, however, is the dose of the radioactive iodine to the thyroid gland and the potential for the subjects to have developed thyroid nodules and cancers. Previous studies, completely unrelated to residents of these state-operated facilities, had shown that some children treated with large doses of X-rays to the head and neck developed both. Yet, in other nationally published studies, injection of ^{131}I has appeared to be about three times less likely than an equivalent external dose of X-rays to produce disease, probably because the dose is spread out in time and is less uniformly distributed in the thyroid.

Further investigation revealed a large epidemiological study of 35,074 patients in Sweden[8] who were given ^{131}I for diagnostic purposes. The patients did not show an increase from the normal risk of cancer found nationally after periods of 10 to 20 years. The average dose to the thyroid gland in the Swedish studies was 50 rads, about the same as the maximum dose to any subject in the Wrentham study. Yet, again, opposing statistics were found in a second large epidemiological study[9] of persons living in the United States who were followed for evidence of thyroid disease as a result of exposure to radioactive fallout from weapons testing. These subjects did show an increase in the percentage of thyroid disease above the expected range.

Clearly, there is no definitive theory as to the absolute long-term risk in the area of ^{131}I exposure. Wanting to err on the side of not ignoring any potential for risk, one of the authors of this latter study, Dr. Lyon, was one of the experts called upon for an opinion of risk assessment on the nutritional research studies for this report.

☐ **Thyroid Function in Down Syndrome: Wrentham**

There was a second study published in 1965[10] by two of the three authors of the Wrentham nuclear fallout study noted above. From conversations the Project Coordinator had with Dr. Saxena, this second study was created with some degree of overlap in subject data. The purpose was to test the thyroid function in children with Down syndrome and to compare it with children whose thyroid function was normal.

The study involved 53 children with Down syndrome, along with 51 other children with mental retardation of other etiology from Wrentham: ages ranged from 1 through 15. The published article does not give information on the dose of radioisotopes the subjects may have received. Neither Dr. Saxena nor Dr. Pryles have any records from that study still in their possession.

The conclusion from the research was that iodine uptake and plasma levels of thyroid hormones were within the normal range for these subjects. The researchers also concluded that red blood cell uptake of the thyroid hormone triiodothyronine labeled with ^{131}I could be used as a test of thyroid function. This was an in vitro test and did not require giving radioactive iodine to the children.

The researchers were from the Harvard Medical School, Massachusetts General Hospital, and the Boston University School of Medicine. The research was supported by the Division of Radiological Health, Research Branch, of the U.S. Public Health Service.

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[8] L.E. Horn, K.E. Wiklund, G.E. Lundel, N.A. Bergman, G. Bjelkengren, U.C. Ericsson, E.S. Cederquist, M.E. Lidberg, H.V. Wicklund, and J.D. Boice, Jr., "Cancer Risk in Population Examined with Doses of I-131," *J. Nat.Cancer Inst.* 81, 302-306 (1989).

[9] - "A Cohort Study of Thyroid Disease in Relation to Fallout from Nuclear Weapons Testing," *JAMA* 270, 2076-2082 (1993).

[10] K.M. Saxena and C.V. Pryles, "Thyroid Function in Mongolism," *J.Pediatrics* 67, 363-370 (1965).

☐ **Thyroid Function in Myotonia Dystrophica**

This research involved a study at Beth Israel Hospital of thyroid function in 6 patients with myotonia dystrophica,[11] a severe chronic neurological disorder. Thyroid pathology had been observed to accompany this disease, but the relation between myotonia dystrophica and thyroid problems was unknown. The goal of this study was to clarify the situation.

The 6 patients were all male and are identified by their initials in the published article but their ages are not given. The only indication they might be connected with Fernald is that Dr. Benda, the Medical Director for Fernald at that time, was the first author of the published article. Just as this report was going to press, the Task Force had received additional papers directly from the Benda estate, and there appears to be more definitive and identifying information available to the follow-up working group.

The conclusion was that thyroid function in these subjects, as measured by uptake of the radioactive tracer, was within the normal range. As pathology reports indicated that the thyroid gland was found to be larger than normal in most patients with myotonia dystrophica, the authors concluded that in patients with this disease the thyroid gland operates at a lower than normal capacity, but the capacity is sufficient to maintain an output that is clinically, biophysically, and biochemically within normal range.

The researchers were from MIT, the Harvard Medical School, and Fernald. The research was supported by the Atomic Energy Commission and other unidentified sponsors.

☐ **Thyroid Function in Down Syndrome: Fernald**

At the time of this study, the origin of Down syndrome (mongolism was the archaic and unacceptable term used for this syndrome at that time) was unknown, but children with this condition were reported to have abnormal thyroid glands, as were their mothers. The purpose of this research[12] was to examine thyroid function in 21 residents at Fernald as well as in 7 parents. The parents who were used as subjects in this study did not necessarily their own children participating in this study but had been recruited by Dr. Benda who knew them as parents from Fernald.

The level of radioactive iodine tracer ^{131}I used in the study, again, caused the Task Force serious concern and will be a key study in the follow-up analysis being done by the working group.

The conclusion was that thyroid function in both the subjects with Down syndrome and the parents was normal. Those with Down syndrome demonstrated higher turnover rates of iodine, which suggested that a smaller effective portion of the thyroid gland was working at an intense rate in order to maintain normal levels of thyroid hormones.

The researchers were from Harvard Medical School and the Beth Israel Hospital. The research was supported by the National Institute of Arthritis and Metabolic Diseases and the Atomic Energy Commission.

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[11] C.E. Benda, C.J. Maletskos, J.C. Hutchinson, and E.B. Thomas, "Studies of Thyroid Function in Myotonia Dystrophica," *Am.J.of Medical Sciences* 228, 668-672 (1954).

[12] G.S. Kurland, J Fishman, M.W. Hamolsky, and A.S. Freedberg, "Radioisotope Study of Thyroid Function in 21 Mongoloid Subjects, including Observations in 7 Parents," *J Clin Endoc and Metab* 17, 552-560 (1957).