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CHAPTER 2

Insignificant and Invisible: The Human Toll of the Hanford Thyroid Disease Study

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THERE'S A JOB FOR YOU AT HANFORD

The Hanford nuclear site in the arid expanse of southeastern Washington State was home to the world's first full-scale plutonium production facility. The frigid waters of the mighty Columbia River and the isolation of this vast desert region drove Lt. Col. Franklin Matthias [1] to target the area as the future location of a secret atomic city—part of the Manhattan Project launched in 1942 to develop and build atomic bombs [2].

Hanford needed thousands of workers in order to succeed in this immense, top-secret effort. Government recruiters went across the country [3] offering high salaries, free transportation, and promotional stories of the "beauty" of the Hanford region, home to immense dust storms and desert extremes. Notices were posted in union halls and community centers across the country stating "There's a job for you at Hanford." Thousands of workers responded to the recruiting effort, including my father.

My dad was a highly patriotic U.S. Navy survivor of the attack on Pearl Harbor and graduate of UC Berkeley in mechanical engineering. He was drawn to Richland—the town nearest to the Hanford facility—eager to get in on the new science of the atom. In 1947 he moved his family into one of the Atomic Energy Commission's (AEC) alphabet-lettered homes, built to house engineers, physicists, chemists, and a smattering of pathologists who came to inhabit Richland and work at the Hanford nuclear site [4].

Richland

Richland was a peaceful town when the fierce desert sandstorms were at bay. As a child, I recall attending countless productions of *South Pacific* at the Richland community theater and coming away singing childlike renditions of "I'm gonna wash that man right outta my hair." My parents and many of our neighbors spent weekend evenings tuned in to Don Ho's *Hawaii Calls*, dreaming that they could recreate a little corner of Hawaii and the Pacific in the desert heat of southeastern Washington State. My favorite childhood haunt at the time was the Tahitian Room at the Uptown Mall, where tropical paradise came in the form of plastic palm trees and birds of paradise. The Uptown Mall, to this day, sports its original atomic symbol, rising proudly above store roofs. My City of the Atom expressed its pride through businesses such as "Atomic Bowling," "Atomic Foods," "Atomic Lawn Care," and a high school athletics team called the "Bombers," represented by an "R" outlined by a mushroom cloud. One writer noted that the people of Richland were "so proud of being citizens of America's 'atomic city' that when Richland finally became an independent municipality, the town fathers included a mock atomic explosion in the celebration" [5].

Hanford's gigantic nuclear reactors produced fissionable, man-made plutonium, a basic component of nuclear weapons. Hanford's location was far from other communities, so that, in case of reactor malfunction, any resulting accident would expose only a limited number of people to potentially massive radiation releases [6]. A declassified AEC memo referred to populations around nuclear weapons production sites like Hanford as ". . . low use segment[s] of the population" [7]. The towns of Richland, Kennewick, and Pasco, built to house project scientists, construction crews, and their families, would be the only nearby communities within the radiation contamination zone. Those of us who lived in this "sacrifice zone" would have had no chance of escape had one of the reactors malfunctioned. It is truly tortuous to understand now that the tranquil rows of government homes with their picket fences and well-manicured lawns of my hometown could have become killing grounds at any time, radiation-contaminated for decades to come.

Plutonium Production and Risk to Surrounding Communities

The first reactor, a huge graphite cylinder used in the production of plutonium, started up on September 27, 1944. Hanford's initial plutonium shipment left for Los Alamos by caravan on February 3, 1945 [8]. The first atomic bomb in the world was detonated at the Trinity Site in central New Mexico on July 16, 1945, relying on Hanford plutonium. Three weeks later, an almost identical plutonium bomb, called "Fat Man," was dropped on Nagasaki, also triggered by Hanford plutonium.

Back at the production site, Hanford secretly released hundreds of harmful radioactive substances into the environment through a chemical process used to

separate plutonium and uranium from fuel rods [9, 10]. Some of these releases were intentional and some accidental [11, 12]. In 1944, Hanford released its first several hundred curies of radioiodine-131 (I-131) [13]. I-131 is one of many short-lived radionuclides of iodine produced in large quantities during nuclear fission. I-131 very easily becomes airborne and can travel long distances [14]. People can be exposed to I-131 through inhalation and/or ingestion. In general, radioiodine is primarily uptaken by the thyroid gland and parathyroids at the base of the neck. If enough radioiodine reaches the thyroid, thyroid disease or thyroid cancer can result. If left untreated, hypothyroidism (underactive thyroid) can lead to loss of mental function and physical energy, and can even lead to coma and death. Hyperthyroidism (overactive thyroid) can cause a range of disabling conditions, including heart arrhythmias. Thyroid cancer, while often treatable, can kill; living with it can be a nightmare.

When the Hanford facility released radioiodine, it deposited in pastures downwind from the site where dairy cows and goats grazed. As a result, milk from the local dairies and backyard cows and goats contained radioiodine. This is of particular concern to children who often drink more milk than adults and are therefore at a greater risk of contracting thyroid diseases. Furthermore, compared with adults, children have smaller thyroid glands and receive a larger dose per unit of radioiodine ingested [15]. For example, a newborn's thyroid dose is about 16 times higher than an adult's dose, per ingested micro-curie of I-131 [16]. In addition to being exposed to I-131 through milk consumption, some members of communities surrounding the Hanford site were exposed by eating contaminated fruits and vegetables and breathing contaminated air.

Culture of Secrecy

During World War II, Hanford and the other Manhattan Project sites operated under a culture of secrecy. They adopted a security system known as "compartmentalization" where workers were told only what was necessary to perform their jobs [17, p. 3]. This compartmentalization continued after the end of World War II, as Hanford was transferred to civilian control.

The culture of secrecy was nearly a total preoccupation with Hanford workers and their families. The Federal Bureau of Investigation (FBI) maintained an ominous presence in the workplace and the neighborhoods of Hanford workers. One worker commented that, "We know there are a lot of FBI men working in the areas. There have been cases of men talking or telling their wives more than they should. We all know when a guy starts getting careless. And it isn't very long until he isn't around any more." To share concerns about Hanford's operations means dismissal and ostracism [17, p. 4].

My dad never talked about his work to anyone. In fact, before my mother passed away of aggressive cancer in 1999, she insisted to me that my dad's job at Hanford was merely to "produce power" through nuclear means. She reacted

in disbelief when I explained to her that the primary purpose of Hanford's reactors was production of plutonium, not power.

Worker and Community Concerns about Safety

Many scientists and Hanford officials claim that the large radiation releases from Hanford were allowed due to incomplete understanding among early Hanford scientists of the dangers from radiation. Yet, while Hanford officials' early knowledge of radiation harm may have been "incomplete," these same officials established guidelines early on for the amount of radiation they felt they could release into the environment without causing harm to workers or surrounding communities:

> Hanford officials knowingly exposed workers and the public to levels of radiation exposure which they considered dangerous. For example, for the atmospheric releases of radioactive iodine (I-131), the guidelines were routinely ignored from the beginning of plutonium separation in December 1944 into the early fifties [18, p. 3-4].

Furthermore, "reports declassified in 1986 show that health specialists at Hanford recognized the risks of releasing so much radiation and were aware that the emissions could endanger residents of the region" [19].

Once the first atomic bomb was dropped on Hiroshima and Hanford workers learned about the nature of their work, workers started to worry that building atomic bombs might not be safe. Two weeks after the bombings of Hiroshima and Nagasaki in August 1945, Herb Parker and another top health official, Dr. Simeon Cantril, wrote a memo to workers, responding to questions about Hanford's effect on surrounding communities. Parker and Cantril reassured workers that "the amounts [of radioactive iodine in Richland] are entirely innocuous" [20].

Public Suspicions Grow: Death Mile

Members of surrounding communities had reasons to be concerned. On a high plateau east of Hanford, outside of the small town of Mesa, there is a stretch of highway known as Glade Road. According to townspeople, of the 108 people who lived in 28 homes within a mile of the highway, 24 men, women, and children have become ill or died from cancer since the mid-1960s [21].

> Further east, in the cafes of Basin City, Eltopia, Connell, and Cunningham, men and women raise their chins to show visitors scars on their throats where surgeons removed diseased thyroids. In this region, the white slashes are called "downwinder scars." Mothers describe the horror of losing infants to unexplained illnesses. Husbands grow tearful remembering young wives who died from cancer, blood disorders, and other diseases [21].

As people began to talk about cancers and thyroid disease in their neighborhoods, near the Hanford plant, and as far away as Spokane and Walla Walla, Washington, public concern grew over the possibility that Hanford had secretly released radiation onto an unsuspecting population. It was known that disease sometimes takes decades to develop after exposure to environmental toxins such as radiation [22]. Could so much disease be the delayed effect of Hanford exposures?

Release of DOE Classified Information

The Hanford Education Action League (HEAL) [23] in Spokane made repeated Freedom of Information Act (FOIA) requests to get answers to these public concerns [24]. In February 1986, after mounting pressure, the Department of Energy (DOE) released the first 19,000 pages of previously classified Hanford historical documents. Journalist Karen Dorn Steele of the Spokesman Review in Spokane, Washington, educated the public about the contents of those documents. Her articles described Hanford's radiation releases and confirmed concerns among government officials, health officials, and the public living both near to and far from the Hanford facility about the extent of those releases. The public learned that between 1944 and 1972, Hanford released large quantities of radionuclides into the air [25]. The radionuclide released in the greatest amounts and the one for which the best documentation is available is I-131. Between 1944 and 1957, an estimated 750,000 [26] curies of I-131 were released into the atmosphere [27-29]. Furthermore, for the first 6 months of 1955, Hanford exceeded the permissible release amounts [17, 30]. In fact, the radioactive emissions from Hanford are the largest ever documented from an American nuclear plant [19].

According to Jerry Leitch, regional radiological representative for the U.S. Environmental Protection Agency in Seattle, off-site radiation exposures to releases from Hanford were "without precedent in terms of the number of people affected and the magnitude of the doses received" [31]. In addition to the magnitude of doses, the duration of exposure to radiation put people in the Hanford region at even greater risk. A DOE publication states that "the risks of adverse health effects are higher when exposure is spread over a long period than when the same dose is received at one time" [32]. Furthermore, health physicists have predicted that the kind of exposures that people potentially received from Hanford, such as beta-emitting I-131, would cause more serious long-term health effects than other exposures, such as gamma ray exposures [33, 34].

TWO STUDIES

The governors of Washington and Oregon made requests to study if and how these levels of radiation from the Hanford facility affected surrounding

communities. In March 1986, the CDC established an independent panel of scientists, the Hanford Health Effects Review Panel (HHERP), to evaluate the Hanford documents released by DOE. The panel recommended two studies:

- to estimate radiation doses received by area residents, the Hanford Environmental Dose Reconstruction Study (HEDR),
- to examine the feasibility of studying the potential health effects of iodine-131 among exposed populations. This led to the Hanford Thyroid Disease Study (HTDS) [35].

Hanford Environmental Dose-Reconstruction Study

The U.S. Department of Justice opposed a dose-reconstruction study as useless "public relations," but quickly changed its mind once the first suit for Hanford radiation damages was filed [36]. The DOE proposed that Batelle Pacific Northwest Laboratories, a long-term Hanford contractor, and Hanford Historical Documents Review Committee (HHDRC) conduct a joint dose-reconstruction study [37]. However, when the DOE refused to provide funding for the study, the effort was abandoned. This resulted in major public outcry. In response, the DOE insisted it would carry out its *own* dose-reconstruction study and formed the Technical Steering Panel (TSP) to direct Batelle in the HEDR study [38]. The aim of HEDR study was to estimate radiation doses from offsite releases during the 1940s, 1950s, and 1960s [39]. Preliminary results of the HEDR suggested that some infants and children were exposed to enough I-131 to destroy their thyroids [40].

Hanford Thyroid Disease Study

In September l988, President Reagan signed legislation authorizing the CDC to conduct a thyroid disease study to look at whether children exposed to Hanford's offsite I-131 releases were at increased risk of developing any of 12 categories of thyroid disease [41, 42]. The Fred Hutchinson Cancer Research Center (FHCRC) in Seattle was chosen to carry out the study, with the CDC to oversee and administer its work. The HTDS began in 1989 [43]. The study population was a sample of people born between 1940 and 1946 to mothers who lived in seven counties in eastern Washington State: Benton, Franklin, Adams, Walla Walla, Okanogan, Ferry, and Stevens [44]. Researchers identified birth certificates for 5,199 people born between 1940 and 1946, of which ninety-four percent was located. Of these, 4,350 were still living and 527 were deceased, for which 502 death certificates were obtained. A total of 3,400 people of the original 5,199 were willing and able to participate fully in the study [45].

Participants provided information, based upon their best recollection, about where they lived during 1944-1957 and the amounts of foods and milk they

consumed during that period [46]. Each participant had a complete diagnostic evaluation for thyroid disease in a medical clinic [47]. If the participant had a history of thyroid disease, medical records regarding that disease were sought. Each participant's radiation dose to the thyroid was then estimated using HEDR software [48].

HTDS FINAL REPORT AND COMMUNITY REACTION

> The US Centers for Disease Control and Prevention deserves an "F" for its presentation of the results of the Hanford thyroid study, a chorus of critics in the Northwest say [49].

This was the tone of much of the media coverage following the release of the HTDS draft final results on January 28, 1999. The HTDS draft Executive Summary claimed:

> [HTDS provides] rather strong evidence that exposure at these levels does not increase the risk of thyroid disease. These results should consequently provide a substantial degree of reassurance to the population exposed to Hanford radiation that the exposures are not likely to have affected their thyroid or parathyroid health [50, p. 18].

Just 3 years before this statement was released, I held my beloved father's hand as he lay dying from aggressive thyroid cancer. A tracheotomy tube protruded from a hole cut into his windpipe, allowing him to breathe, at least minimally, with an airway closed off by tumor growth. Tumors spread like wildfire to his lungs and brain. Just weeks after the FHCRC and the CDC declared that Hanford radiation exposures were not likely to affect thyroid health, I cradled my mother in my arms as she too died, having suffered from thyroid disease and hyperparathyroidism, wanting so much to live, but defeated by rapidly metastatic malignant melanoma.

It is very difficult to be *reassured*, as the HTDS summary suggested, when family members have died of thyroid cancer, and when one's whole family has developed thyroid disease, with no history of the disease anywhere in the extended family. To many of us who were children in the Hanford downwind region during I-131 releases, these "reassurances" were worthless, even insulting, to the memory of loved ones dead of thyroid cancer or suffering with thyroid and parathyroid disease. To place such a statement in public materials, knowing that many of those who were children in the Hanford region during I-131 releases were currently suffering from thyroid cancer, thyroid disease, or had lost family members to these diseases, was at best an exercise of very poor judgment and, at worst, just plain callous.

A *Seattle Times* article reported the following reactions to the HTDS results:

> We're 10 years older and $18 million poorer, but we still don't know whether Hanford downwinders were harmed by its radioactive emissions. We do know that 20 percent more of them are dead than expected. And we do know that eastern Washingtonians were found to have two to three times more thyroid disease than other populations generally.
>
> But those seemingly alarming findings may not mean a thing, according to researchers at the Centers for Disease Control in Atlanta and Seattle's Fred Hutchinson Cancer Research Center that studied downwinders.
>
> Then again, maybe the findings do mean something. No one, it seems, can say for certain.
>
> The Hanford downwinder thyroid disease study is one of the most maddening chapters in the annals of epidemiology [51].

An epidemiological study, by nature, is the study of populations. Populations, by definition, are composed of individuals, each with a very real-life experience. Suddenly, the HTDS and its results, released after months of hushed and restrictive secrecy, reflected not life as it was for those of us who grew up in the Hanford downwind area during release years, but as a funhouse mirror, distorting our lives, and denying our experience. I felt myself becoming deeply angered, yet I knew that angry outbursts would accomplish nothing with HTDS scientists. They needed to understand that too many of us—too many of the people I had grown up with—now had thyroid disease, and/or thyroid cancer. They needed to know that I, that *we,* were *not* reassured by the HTDS's purported "no harm" findings. It was up to us to let the world know that this epidemiologic study, for some reason, did not reflect our reality. This study had made us insignificant and invisible.

I had believed that the HTDS would finally show the world what had happened to all of us who lived in the shadow of Hanford. Yet, here we were, being fed a story of a reassuring, happy, healthy life next to a plutonium production facility, in spite of more than 750,000 curies of I-131 wafting through the air, landing on everything we touched or ate, and saturating my baby milk and ice cream. Those of us who had followed the progress of the HTDS and held out so much hope that it would reflect our reality concluded that something was amiss with either the data or the methodology on which HTDS was based [52]. We wanted to get to the bottom of this.

Fighting Back

And so the critiques began, by citizens and scientists alike. Articles and letters to the editor were appearing in regional papers from members of the American Nuclear Society and their allies, portraying these conclusions of the HTDS as final, irrefutable evidence that Hanford's I-131 had caused no harm to those exposed [53]. It was through the efforts of Dr. Owen Hoffman and his colleagues

at SENES Oak Ridge, Inc. Center for Risk Analysis that we were able to begin to understand what had gone wrong and how to discuss the scientific fallacies of this study publicly. Dr. Hoffman and his colleagues at SENES were able to translate complex statistical concepts into understandable terms, thus enabling us to raise these important issues with the HTDS researchers and the media.

Thus empowered, my colleague Tim Connor, an investigative journalist and Hanford activist, and I, armed with a letter of protest co-signed by more than 22 representatives of citizen groups from around the country, went to meet with Dr. Richard Jackson, then director of the National Center for Environmental Health at the CDC. This letter we hand-carried raised serious concerns with a number of scientific issues within the HTDS, and with the communication and interpretation of the findings of this study by FHCRC and CDC to the public, Congress, and the media. The concerns included:

- FHCRC scientists' presentation of this study as if it were conclusive proof of no thyroid or parathyroid harm from Hanford's I-131 releases,
- FHCRC's blatant exaggeration of the statistical power of the study, and
- the uncertainties in dose estimates and confounding Nevada Test Site atomic tests and global fallout I-131 dose were not specifically addressed for the HTDS cohort.

The letter went on to discuss significant problems created by the information blackout that kept even those citizens who had been following the study throughout its history from learning about the results of the preliminary draft of the study until we read about it in the *New York Times* on the morning of January 28, 1999.

Tim and I met with Dr. Jackson in a small conference room, down a long hallway, past empty cubicles and deserted copy machines in an underused area of the Humphrey Building of the Department of Health and Human Services Building in Washington, DC. We asked Dr. Jackson to support a precedent-setting extended review of the HTDS by the National Academy of Sciences (NAS), National Research Council (NRC) a review that would address both the scientific and communications aspects of HTDS. This would be far more extensive and public than the normal NAS review of CDC's studies [54]. Dr. Jackson, to his credit, listened to the anguish in our voices and quickly understood the importance of this review to those of us whose lives had been so impacted by Hanford [55].

EXPERT REVIEW

The Experts Look at What Went Wrong

The NRC Subcommittee concluded that while the study itself was well-designed, HTDS scientists reported the study's findings as more conclusive than

they really were purported to be [56]. "Shortcomings in the analytical and statistical methods used by the study's investigators overestimated the ability to detect radiation effects, which means the study results are less definitive than had been reported" [57, p. 1].

There were several important reasons why the HTDS was limited in its ability to detect radiation effects. The NRC Subcommittee saw the study's weakest link as the estimation of individual radiation doses from the 1940s and 1950s. The doses, which were being correlated to incidence of thyroid and parathyroid disease within the HTDS study group, were estimated based on assumptions about participants' milk consumption, their mother's milk consumption during periods when participants were breastfed, and the radioiodine levels of the milk and fresh food they consumed during the periods of greatest radioiodine releases from Hanford. These estimates depended on the accuracy of study participants' (or other informants') memories of the sources and quantity of milk intake decades in the past, as well as on estimates of how much radioiodine was released at specific times, where it was dispersed by wind and rain, how much was ingested or inhaled by dairy animals grazing on pasture or eating stored feed, and where the resulting milk (and other fresh food) was distributed [58]. Since records about these factors were not collected at the time downwinders were exposed, researchers used mathematical models, which have large uncertainties, to estimate HTDS participants' doses [59].

Computer-assisted telephone interviews (CATIs) were used within the HTDS to collect information about cohort members' early dietary habits, including times and durations of breastfeeding period, if any. Many of the HTDS cohort members reported being breastfed for part of their infancy. But, for some 1,212 participants in the HTDS, for whom there was no CATI data, a default diet of cows' milk was assigned. If any of these participants had actually consumed fresh sources of milk or breast milk, their doses could have been underestimated.

In addition, the technical review of the HTDS found evidence that the estimation of the amount of radioiodine that is passed into mothers' milk (the milk transfer coefficient) assumed in the HEDR was underestimated. This would also lead to an underestimate of true dose for cohort members who were breastfed as infants—particularly those born in 1945, during the highest I-131 releases from Hanford [59, p. 8]. If a subgroup of the HTDS cohort, such as this subgroup, received systematic overestimation or underestimation of dose, this would diminish the ability of the study to detect a relationship between radioiodine and thyroid disease, and lead to an overestimation of the study's ability to detect an effect.

Another possible explanation for uncertainty in dose estimates for HTDS cohort members is referred to as *inter-individual stochastic variability*. Some of the factors that may cause true dose to vary from the estimated dose include where the I-131 actually deposits, how much lands on vegetation, how much gets

into the food chain, how much people actually ingested or inhaled, individual variation in size of the thyroid mass, and uptake from blood to the thyroid gland. Individual variability in dose estimates may also be influenced by radiosensitivity differences or intake levels of iodized table salt (consumption of iodized table salt may reduce the levels of radioiodine taken up by the thyroid), as well as other individual factors. HTDS researchers only considered some of these factors, but they may help explain why, on a street in my town of Richland, it was possible for two families to live the same length of time during the same period and be exposed to the same I-131 releases, yet one family developed thyroid disease and the family next door had no thyroid health impact at all.

The technical review of the HTDS also found that certain factors in the study led to an underestimation of uncertainty of HTDS doses which would contribute to lowering the statistical power of the HTDS [59, p. 9]. Overall, the NRC Subcommittee found that the statistical power of the HTDS to detect an association between radioiodine and thyroid disease was not as high as claimed by the HTDS researchers due to inadequate allowance for imprecision in the dose estimates [60, 61].

Another source of uncertainty in the HTDS cohort dose estimation arises from the fact that, during the 1950s and early 1960s, two other environmental sources of I-131 contributed to the thyroid doses received around Hanford. The first of these was fallout from nuclear weapons tests detonated at the Nevada Test Site (NTS) during the 1950s. The second source was fallout from nuclear weapons tests ("global fallout") conducted by the United States and other countries outside of the U.S. mainland in the 1950s and 1960s, including Test Bravo in the Marshall Islands (1954), which deposited I-131 and other radionuclides within the Hanford downwind region. The issue raised by the NRC Subcommittee in its review of HTDS was that, if NTS or global fallout could have resulted in significant I-131 exposures in the HTDS study area, and if the variation within the area was large, then it was very important to take both global and NTS fallout into account in the HTDS [60, p. 8]. Rather, the HTDS analysis of NTS I-131 doses was based upon a median dose for all subjects, causing them to be essentially disregarded [62]. The expert review concluded that HTDS could not rule out the possibility that dose-response relationships were actually present, but not able to be seen due to the fact that these confounding exposures from global and NTS fallout were not explored thoroughly [62, p. 11]. The uncertainty in dose due to the fact that doses were, of necessity, modeled and possibly confounded by global and NTS fallout, should have been communicated at the HTDS public briefing on January 28, 1999.

In a letter transmitted to the CDC just 10 days before HTDS results were made public, the NRC Committee on the Assessment of CDC's Radiation studies raised and emphasized problems with the uncertainties of individual doses calculated with the HEDR methods used in conjunction with the HTDS:

> It should be noted that the inherent uncertainty associated with the individual doses will decrease the likelihood of determining a meaningful risk coefficient for the effects of radioiodine on the target population [63].

Scott Davis, the principal HTDS investigator, is reported to have said that "he couldn't agree more" that there should have been a more thorough scientific review of the study before it was released [64]. A citizens' letter to the director of the NCEH stated, "It is appalling that CDC would go forward with the release of the HTDS under such circumstances, and so quickly after its NRC review committee had identified such major problems" [65].

Loss of High Percentage of the HTDS Study Group

Of particular concern to experts and public alike was the failure of HTDS scientists to account for uncertainty due to deaths and nonparticipation. An original 5,199 people were identified as possible HTDS participants based on time and location of birth. Of these, approximately two-thirds (3,447) completed the HTDS clinical exam and some withdrew after the exam. The other one-third of the originally identified potential subject group had either died before the study began or didn't wish to participate. This is considered a rather high rate of cohort loss [59, p. 17], and this level of cohort loss can seriously bias study results, even if the losses were of equal proportions with regard to exposure or disease categories [66].

Experts reviewing the HTDS felt that the loss of one-third of the cohort was probably not random in ways that were relevant to the study [59, p. 17]. Those who knew or suspected that they had been exposed to Hanford radiation or who had thyroid disease may have been more likely to participate in the HTDS. Deaths may have been exposure related. (Sometimes this is called *selective survival*.) The review concluded "that this uncertainty was not addressed analytically is another reason why the HTDS report overstates the strength of conclusions with regard to the size of effect that may be present in light of the data" [59].

An Important Finding Overlooked

> The [study] population also had a surprising amount of thyroid disease although its prevalence was not dose related. The overall incidence of almost 19 percent autoimmune thyroiditis with this number reaching 24 percent for women in the study is more than might be expected from results of normal population studies. The numbers for hypothyroidism (19% of the total population, 27.5 percent of the women) is also higher than one might expect from other epidemiological studies of presumably normal populations [67, p. 6].

HTDS conclusions were focused entirely upon the lack of any correlation between estimates of the participants' thyroid doses and the subsequent occurrence of thyroid illness. There was no recognition of the excess rates of thyroid disease found within the study group as compared with what would be expected from an unexposed group. Although the comparison of thyroid disease rates of HTDS participants to rates in other populations is made difficult due to the study's protocol for thyroid screening, something that does not occur in other populations, the observation of excess occurrence of thyroid disease in the HTDS was not seriously considered when study conclusions were drawn.

The importance of attending to diverse and conflicting findings in epidemiological studies was emphasized by Alice Stewart, the epidemiologist who discovered the link between obstetric x-rays and childhood cancer:

> The epidemiologist is like a conductor—you must hear every note, you must be able to detect a false note anywhere. If you hear a false note, you don't send the violins away: you try to work with them. You must include all types of seemingly extraneous data in the collection process, it might be the key to unraveling a mystery. Handling the noise is the greatest thing in epidemiology [68, p. 216].

Had this been a thyroid disease prevalence study rather than a dose/incidence comparison, high prevalence of thyroid disease would have been found. As Stewart said, "The best way not to find something is not to look for it" [68, p. 193].

While looking at estimated dose and levels of thyroid disease among the study group, the HTDS found 20 thyroid cancers out of a participating study group of 3,441 (.58 percent). Based upon the amounts of I-131 released from Hanford, the Agency for Toxic Substances and Disease Registry had predicted that its medical monitoring program would find 90 thyroid cancers out of a study group of 14,000 (.64 percent) [69].

The Connecticut Tumor Registry (CTR) is the oldest population-based tumor registry in the country and is similar to the HTDS in that both require histological confirmation of thyroid cancer diagnosis. There would be 5.3 cancers projected by the CTR for a group of 3,441 (probability of thyroid cancer, $0.00153983 \times 3441 = 5.3$). The ratio of observed cancer *found* by the HTDS is nearly four times the rate of residents in Connecticut.

Hypothyroidism occurs in approximately 2 percent of the population [70]. The HTDS found 7.8 percent confirmed hypothyroid prevalence. Benign thyroid nodules occur in 2-4 percent of the general population. Over 7 percent prevalence was found in the HTDS. In the final HTDS report, under the "second alternative" of diagnosis, there were 297 cases of nodules (8.6 percent). Goiter and other disorders of the thyroid are reported to occur in 2.6 percent of the

population, according to the National Health Interview Statistics data. The HTDS found autoimmune thyroiditis, alone, was 18.9 percent. Eight hundred and six (23.4 percent) were found to be antibody positive, although this was not discussed in the summary report.

Strength of the HTDS Findings Overstated

> The subcommittee is concerned that the results of the study were reported—and interpreted—in black and white terms of whether a statistical test was passed or failed. It recommends that confidence limits be provided throughout the report to allow the readers to judge how large a radiation effect might be consistent with the data. It feels that the HTDS investigators probably overstated the strength of their finding that there was no radiation effect [60, p. 81].

The expert technical review of the HTDS commended HTDS authors for responding to the NRC Subcommittee's recommendation to include confidence intervals [59]. Yet, the final report failed to make full use of the confidence intervals in interpreting study results. Had confidence intervals been used as counterpoint to HTDS authors' reliance on statistical significance in drawing conclusions, HTDS authors' results would have demonstrated inconclusiveness [59, p. 18].

Correct interpretation of lack of significance in the HTDS report

> . . . is simply that, when examined using the models and methods of the authors, the data do not overwhelmingly favor any alternative over the null. This correct interpretation leaves open the possibility that the evidence favors the alternative (that there is an effect) albeit not very strongly when using the authors' approach [59, p. 18].

HTDS researchers' statements such as "the results of the HTDS provide no evidence of a statistically significant association" conflate absence of statistical significance with absence of evidence [59, p. 18; 72]. The two concepts must be separated, at which point, it can be seen that there is a lack of significance, but that some of the evidence provides weak support for the possibility of small effects [59, p. 18].

The problems that have been discussed regarding power and dosimetry uncertainty in HTDS require more thorough analysis, which would have had a "serious impact on the interpretation of the study, leading to even more ambiguous results, which in turn should lead to even more cautious and limited interpretation" [59, p. 19].

HTDS: Consistent With Other I-131 Studies Showing Risk

The HTDS final report stated, "There is little evidence in the literature to suggest that people exposed to I-131 at the levels found in this study over a period of months or years would experience higher rates of thyroid or parathyroid disease as a result of their exposure" [59, p. 19; 71, p. 543].

Technical reviewers challenged this statement and found no studies published in the scientific literature that study protracted exposures at the levels found within the HTDS. The reviewers concluded that "The reason that there is little evidence is due to the absence of evidence, not to the existence of studies that actually show no risks from protracted exposures" [59, p. 20]. Furthermore, the technical reviewers concluded that

> The results and conclusions of the Final Report of the Hanford Thyroid Disease Study (HTDS) . . . cannot be used to rule out important risks for thyroid cancer, neoplasms, or hypothyroidism from exposures to iodine-131 (I-131) from the Hanford nuclear facility [73].

Considering the HTDS limitations in measurement and resulting uncertainties, expert review of the study found that even though HTDS findings did not show statistically significant elevations in risk, HTDS results are not inconsistent with other published studies supporting risks for certain thyroid diseases from I-131 exposures, if the upper bounds of the reported confidence intervals are considered [74].

HTDS authors used three different approaches to analyze whether their results were inconclusive because of dose uncertainties in the primary analyses [71, p. 603]. They found similar results in each of their analyses, which the technical review found to be consistent with low statistical power in each of the three approaches, rather than consistent with a hypothesis that there is no relation between exposure and disease [59, p. 20].

The final sentences of the HTDS report state:

> These findings do not definitively rule out the possibility that Hanford radiation exposures are associated with an increase in one or more of the outcomes under investigation. However, it does mean that if such associations exist, they were likely too small to detect using the best epidemiologic methods available [72, p. 21].

HTDS findings do not rule out the possibility that Hanford I-131 exposures are associated with an increase in thyroid health outcomes [75]. HTDS findings are compatible with significant increase in health risk from these exposures as well as with no increase. "Even the best epidemiologic methods are not enough to compensate for a study population that is too small and measurements too uncertain to detect even large risks" [59, p. 21].

HTDS ETHICAL ISSUES

Poor Communication of Results

The NRC Subcommittee found that in media and public briefings on HTDS, the investigators failed to pay sufficient attention to the health concerns of the public, and that HTDS investigators and CDC officials should have offered more balanced, and possibly alternative, interpretations of the findings and discussed their implications for individuals [60, p. 13]. The public's disapproval of the researchers' conclusions and interpretations was reflected at the public briefing in Hanford on January 28, 1999, when, throughout the entire several-hour briefing, an exposed Hanford resident held up a hand-painted sign, reading "I DON'T BELIEVE YOU."

NRC Subcommittee members identified significant risk communication problems with the release of the report [76], including the way HTDS investigators overstated the certainty of their results in the media by claiming that the study findings were "clear and unequivocal" [77] and that the HTDS was "a very powerful study" [78] with "sufficient statistical power" [79] and "a very high probability of detecting relationships between Hanford radiation dose and diseases under study if such relationships exist" [80].

The HTDS Sounds the Death Knell for Hanford Public Health Programs

In addition to disappointment and confusion, the inappropriate communication with the public concerning the HTDS draft results harmed people exposed to Hanford's I-131 emissions in other ways. Prior to the release of the HTDS draft final report, the federal Agency for Toxic Substances and Disease Registry (ATSDR) determined that a medical monitoring program was merited for people exposed as children to I-131 released from Hanford between 1945 and 1951:

> ATSDR has determined that about 14,000 children who lived in areas downwind of Hanford from 1945 to 1951 received high exposure to I-131 through drinking contaminated milk, and are at risk of having thyroid and parathyroid abnormalities, including thyroid cancer and hypothyroidism, as a result [81].

The proposed medical monitoring program would have been the first concrete assistance offered to downwinders after years of scientific studies and legal battles [82].

The ATSDR also proposed an I-131 subregistry for Hanford to include people exposed as children during the years of highest releases of I-131 from Hanford. Specifically, the subregistry was to include people born in Adams, Benton, or Franklin counties between 1940 and 1951, and people who lived in these counties

who were 5 years of age or younger and lived there more than 30 days during 1945-51. I was very relieved that, finally, there would be data collected on people like me, who were too young to be included within the HTDS cohort, but who had developed thyroid disease or thyroid cancers and had lived within the Hanford downwind area during childhood. The subregistry would track the health of approximately 17,000 people to take a look at illnesses they may have developed. Finally, the world would begin to get a better picture of what had happened to those of us exposed as children to Hanford's radiation releases.

However, the FHCRC's claim that the HTDS was evidence of "no harm" from Hanford sounded the death knell for both of these programs [83]. At the public meeting on HTDS on January 28, 1999, the CDC announced that they would recommend a change in plans for medical monitoring [84]. We were to receive no help in the form of medical monitoring and there would be no gathering of information on our current health. This was not the fault of the ATSDR, whose officials had tried valiantly to secure funding for these programs after a multitude of planning meetings with significant expert advice and public involvement. This was a case of the proverbial fox guarding the henhouse. The DOE, the source of our involuntary exposures, refused to fund these programs to finally help us in spite of the recommendation to do so by the ATSDR. Hanford downwinders' attempts to appeal to the legal system was spectacularly unsuccessful in resolving the DOE's refusal to fund these needed programs for the very people it exposed [85]. Based on the draft results of the HTDS and a report from the Institute of Medicine questioning the value of medical monitoring [86], the CDC denied Hanford's downwinders the only concrete help they had ever been offered.

There is something both intrinsically wrong and ethically abhorrent in a system that allows the wrongdoer, in this case, DOE, successor to the Atomic Energy Commission—the power to decide whether public health programs recommended by the ATSDR for populations that the DOE itself exposed and injured, should be funded. The experience at Hanford illustrates that this structure, with the ATSDR dependent upon the DOE's whims and politics for its funding of public health programs for exposed populations injured by DOE activities at federal facilities such as Hanford, serves only the interest of the DOE, inflicting yet more harm on already hurting populations. The ATSDR must have adequate funding to do its work, independent of any control or influence by DOE.

Environmental Epidemiology

The very nature of the HTDS as environmental epidemiology provides another reason for the inappropriateness of the conclusions that the HTDS investigators made. Environmental epidemiology is an observational study of the effect on human health of physical, biological, and chemical factors in the external environment [87]. The aim of the HTDS was to study the effect of I-131 on thyroid disease. The HTDS can be further characterized as "risk-factor epidemiology"

[88-90] because it focuses on factors associated with excess disease in groups, such as thyroid disease, but lacks the direct evidence to "specify the cause of any particular case of disease" [91]. Risk-factor epidemiology has the capacity to produce a generalized statement about the probability or risk that members of a population have developed or will develop a given disease due to this exposure, but it is not able to deliver a definitive answer for people like my family and our former Richland neighbors who now suffer with thyroid cancer and thyroid disease. For this reason, the HTDS should never have been portrayed as a source of "reassurance" to us that our health has not been harmed by radiation emissions from Hanford.

The Hanford Health Information Network published an article that expounds on this point:

> Regrettably, given the way in which the draft results of the study were communicated, the HTDS actually inflicted a good deal of harm on those whom the study was intended to serve.
>
> The cause of this harm is not the fact that the HTDS investigators found no link between Hanford radiation and thyroid disease. The fact is, it is rare for individual epidemiologic studies to provide strong evidence for connections between low-dose exposures and diseases like cancer. More often than not, the results are inconclusive.
>
> The problem with the January 1999 release of the HTDS is that the draft results of the study were presented as if they were conclusive. The message from the researchers was that if you are among those who suspected (or believed) that Hanford emissions are responsible for an increase in thyroid disease among downwinders, you should be "reassured" that there is no such connection.
>
> Such statements by scientists are practically unheard of in connection with environmental epidemiologic studies. The simple reason for this is that scientists understand that the results of any such study (whether it finds a link, or doesn't) have to be viewed as a piece in a larger puzzle. This is because environmental epidemiology is not laboratory science where researchers conduct carefully controlled experiments that can be repeated by other scientists. It is an observational science, where a given hypothesis must be tested via repeated observations and evaluated within the context of animal studies, cellular and molecular research, etc.
>
> In the case of the HTDS, there is considerable evidence from previous studies that exposure to radioactive iodine does cause increases in thyroid diseases. Why the HTDS team would offer "reassurance" in light of this other evidence is puzzling. The mildest criticism one can offer is that their statements do not reflect the circumspection and caution that is the hallmark of the science [92, p. 5].

THE PERSONAL IMPACT OF THYROID DISEASE

It is important while discussing the vastness of a "truth" attempted through environmental epidemiology to take a moment to see through the statistics and

power calculations to the impact of disease on the individual. Thyroid disease may seem like a minor inconvenience to those who have not experienced this disease firsthand.

As a child, I hadn't yet passed through the "latency" period before exposure-caused disease manifested itself. My family and neighbors in Richland remember me as a healthy child. It wasn't until my teens that I began to experience the first uncomfortable symptoms of the failure of my thyroid.

My childhood was a happy one, playing in picket-fenced yards in back of our two story "F" house or in the front yard of our neighbor's "B." We boated on the Columbia River, played on its windswept islands, and made mud pies in the wet sands of the riverbanks. It wasn't until almost four decades later that we would learn that the milk we drank from the local dairy was laced with radio-iodine, and that the muddy sands were infused with cobalt-60 released from the reactors into the Columbia. After my anger and shock at the fact that I had been involuntarily exposed to stuff that was very bad for children, and that there was nothing I could do about it, I, like many of my neighbors and friends from those days in Richland, trusted that the HTDS would finally answer our questions about why we had developed thyroid disease and thyroid cancer, diseases previously unknown within our families.

Thyroid disease is a mean disease. If you haven't been unlucky enough to experience thyroid disorder, it isn't a mere inconvenience. Many of us who developed thyroid disease after our time within Hanford's downwind region suffered for years with unexplained symptoms that we experienced as extreme, disabling discomfort. These symptoms included migraines, intense pressure in the head, dizziness, gastrointestinal problems, extreme fatigue, and severe muscle contractions, all without a correct diagnosis. In my own case, since there was no thyroid disease in my family, medical personnel were not looking in that direction. From testing, they knew it wasn't diabetes, and it didn't appear to be leukemia. These problems would worsen and remain mysterious for decades. And with its disabling effects came decreased hours on the job due to chronic fatigue, days of disabling pain, life's goals lost, not knowing the cause. So many of the women who grew up with me experienced miscarriage or infertility, some of the greatest losses a woman may experience. My father's death of thyroid cancer was one of extreme pain; his esophagus and trachea quickly closed off by the wildfire spread of tumorous growths that metastasized from his thyroid. Tracheotomy tube protruding from his neck, his airway suctioned every hour, he died a death of irony and of extreme pain. Irony because he believed in the safety of Hanford operations and the reassurances of his bosses, the Hanford site contractor at the time, General Electric. Even when it was finally revealed in 1986 that Hanford had covertly released an estimated 750,000 curies of I-131 in addition to other biologically harmful radioactive substances off-site, my father still clung to his trust that Hanford's contractors and the AEC had been upfront in their operations of the Hanford facility. Only when he

was diagnosed with rapidly metastatic thyroid cancer did he begin to understand that it was too late.

The HTDS was the study that was intended to bring some closure, some answers to those of us who now deal with the debilitating health impacts of thyroid disease. My mother, who suffered from hyperparathyroidism and thyroid disease, had hoped that such answers would come from the HTDS. She died of a very aggressive form of malignant melanoma just after the January 28, 1999 public pronouncements of the Fred Hutchinson/CDC researchers that we should be reassured that our health had not been harmed from Hanford's releases.

For those of us who suffer now with thyroid disease, thyroid cancer, or who have lost those who are very important to our lives to thyroid or other cancers, the HTDS gives a very unclear picture of what really happened at Hanford. Perhaps all we can ask is public acknowledgment that HTDS is not consistent with the results of other studies on I-131 exposed populations, in which increased incidence of thyroid disease and thyroid cancer was found, and that the HTDS is inconclusive at best. A health survey conducted by the Northwest Radiation Health Alliance (NWRHA), an alliance of Hanford downwinders, physicians, scientists, and social activists, found an excess of illness, including thyroid disease and cancer, among Hanford exposed participants [93]. The R-11 Health Study, a study of the rate of prevalence of radiogenic illnesses in selected populations in the Hanford downwind areas, found that there was considerably more goiter (hyperthyroidism) and other diseases of the thyroid reported than in national survey data [94]. The burden should be upon those who *released* radioactive iodine onto our communities to show that our thyroid disease was *not* caused by their releases, not upon those of us with thyroid disease or who have lost family members to the cruelty of thyroid cancer to prove that our disease was more likely than not caused by our involuntary exposures. We already carry the burden of a lifetime of suffering.

This is not true closure for those of us dealing with the debilitating effects of thyroid disease or with loss of family members who we really need to be here, but it at least does not carry the distorted and insulting message that no harm came from Hanford's radioactive contamination of the air we breathed and the milk we drank day after day after day. If more than 750,000 curies of I-131 released onto the playgrounds and entered into the milk of babies does not cause harm, then why is the U.S. government currently distributing potassium iodide tablets to protect its citizens against terrorists using dirty bombs possibly containing radioiodine? If so much I-131 in my baby milk, air, and water didn't cause me harm, then it's time for the DOE, the successor agency to the Atomic Energy Commission which put me in harm's way, to bear the burden of showing where this debilitating disease, prevalent in so many of my neighbors from 1940s and 1950s in the Tri-Cities, *did* come from. Until that time, the HTDS is just an epidemiologic attempt to answer the question, inconclusive at best.

APPENDIX:
Letter of 18 February 1999 to Dr. Richard Jackson, director, NCEH Signed by over 22 representatives of the Native American and Downwinder groups

The introductory portion of the letter to Dr. Jackson appears below:

February 18, 1999

Dear Dr. Jackson,

We are writing to express our profound dismay and objections to the manner and process by which the results of the Hanford Thyroid Disease Study were released last month. The way in which the report was realized showed a contemptible lack of sensitivity to the individuals whose personal well-being and family and community health have been, and continue to be, jeopardized by past exposures to Hanford radiation. Moreover, it is already clear that the substantive basis for the report's conclusions is dubious; that uncertainties about the accuracy of the doses assigned to study subjects should have [been] reconciled before such definitive conclusions were offered to the Congress, the press, and the public at large.

We would like to emphasize at the outset that we are not objecting to the news, per se, that an epidemiologic investigation could detect no correlation between exposures and health outcomes. Obviously, such findings are going to occur, more often than not, as scientists test environmental epidemiologic hypotheses with limited observational tools. That's not the issue here.

Our grievance with the Hanford Thyroid Disease Study is that the conclusiveness of the study's findings is not yet warranted by the quality of the science. Officials and scientists at the Centers for Disease Control and Prevention had advance knowledge of these shortcomings and limitations. It is inexplicable that they failed to publicly disclose them. Furthermore, it is inexcusable that they did not seek to explain how the conclusions drawn in the draft report are, at best, premature.

NOTES

1. Lt. Col. Matthias had been sent from the East Coast by Gen Leslie Groves, who took command of the US secret atomic weapons project in September of 1942. D'Antonio, M. 1993. *Atomic harvest: Hanford and the lethal toll of America's nuclear arsenal*. New York: Crown.
2. The Manhattan Project took its name from the fact that the first headquarters of the Corps of Engineers district in charge of bomb work was located in Manhattan. The Manhattan Project encompassed research and scientific projects in 37 facilities

throughout the U.S. and Canada, but the key to the project was the creation of three "top secret" atomic cities, Los Alamos (Site Y), the Clinton Engineer Works (later called Oak Ridge) (Site X), and Hanford (Site W). Sanger, S. L. 1995. *Working on the bomb: An oral history of WWII Hanford*. Portland, OR: Portland State University.

3. Except to the Pacific Northwest, New Mexico, and Tennessee.
4. There were 22 house plans available, mostly entitled with letters of the alphabet, in the later 1940s and 1950s. Many of these houses still stand in Richland, with minor modifications made by owners. See http://hanford.houses.tripod.com/
5. D'Antonio, M. 1993. *Atomic harvest: Hanford and the lethal toll of America's nuclear arsenal*. New York: Crown.
6. Groves, L. R. 1962, 1983. *Now it can be told: The story of the Manhattan Project.* New York: Da Capo.
7. Gallagher, C. 1993. *American ground zero: The secret nuclear war*, xxiii and 109ff. Cambridge, MA: MIT Press.
8. Sanger, S. L. 1995. *Working on the bomb: An oral history of WWII Hanford.* Portland, OR: Portland State University.
9. Chemical separation involves dissolving spent fuel rods and then isolating and concentrating the plutonium, uranium, and other radionuclides they contain.
10. When irradiated fuel rods from production reactors were immersed in an acid solution to dissolve the metal cladding, radiation was released into the atmosphere.
11. Aside from "normal" operations, Hanford conducted at least three experiments that released large amounts of radioiodine. The "Green Run" occurred December 2-3, 1949, releasing 7,800 curies of I-131.
12. Thomas, J. 1990. Hanford Education Action League. The human toll. *Perspective* (3):6.
13. A curie is the amount of a radioactive species which produces 37 billion radioactive decays per second.
14. It would eventually be revealed that Hanford's I-131 exposed large areas of eastern Washington State, Idaho, western Montana, northeastern Oregon, and traveled into parts of western Canada.
15. D'Antonio, M. 1993. *Atomic harvest: Hanford and the lethal toll of America's nuclear arsenal*. New York: Crown.
16. A micro-curie is one millionth of one curie. A curie is the amount of a radioactive species which produces 37 billion radioactive decays per second.
17. Thomas, J. 1992. Hanford Education Action League. Atomic deception: Oh, what a tangled web! *Perspective* (10-11):3.
18. Thomas, J. 1990. Hanford Education Action League. The human toll. *Perspective* (3):3-4.
19. Schneider, K. 1988. Seeking victims of radiation near weapon plant. *New York Times,* October 17.
20. Cantril, S. T., and Parker, H. M. 1945. Status of health protection at Hanford Engineer Works. HW-7-2136. (RL: HEW, August 24, 1945), p. 1. See also: *Diary of Colonel Franklin T. Matthias*. 24 August 1945, p. 104.
21. Leon and Juanita Andrewjeski, who lived on one of the farms closest to the Hanford reservation in Ringold had also kept track of the cancer and heart ailments in the area after Leon was first diagnosed with heart disease. By 1985, Juanita's map indicated

35 heart attacks among people of relatively young age—in their fifties—and 32 cases of cancer. D'Antonio, M. 1993. *Atomic harvest: Hanford and the lethal toll of America's nuclear arsenal*. New York: Crown.

22. See http://nuclearhistory.tripod.com/radiation.html
23. HEAL was formed in 1984 to raise questions about the past and present safety of Hanford.
24. The Freedom of Information Act established a procedure for citizens to receive government documents, but it also allowed agencies to hold documents deemed sensitive to national security. See 5 USC. § 552, As Amended By Public Law No. 104-231, 110 Stat. 3048.
25. Hanford Health Information Network. September 1996. A listing of radionuclides released from Hanford.
26. This estimate is associated with appreciable uncertainty because it depends on the use of mathematical models to substitute for direct measurements.
27. Heeb, C. M., Gydesen, S. P., Simpson, J. C., and Bates, D. J. 1966. Reconstruction of radionuclide releases from the Hanford Site, 1944-72. *Health Physics Journal* 71:545-555.
28. Napier, B. A. 2002. A re-evaluation of the I-131 atmospheric releases from the Hanford site. *Health Physics Journal* 83:204-226.
29. When the Three Mile Island reactor accident in Pennsylvania in 1979 released between 15 and 24 curies of I-131, people were evacuated and milk was impounded near the plant.
30. The average for the first half of 1955 was 5.1 curies per day, HW-55569 RD, p. 6.
31. Steele, K. D. 1987. Downwinders. *Spokesman Review* 2 Dec:A10.
32. Office of Environmental Management. January 1995. Closing the circle on the splitting of the atom. Washington, DC: USDOE.
33. Manning, M. 1995. Atomic vets battle time. *Bulletin of Atomic Scientists* 51:54-60.
34. Nussbaum, R. H., and Kohnlein, W. 1995. Health consequences of exposures to ionizing radiation from external and internal sources: Challenges to radiation protection standards and biomedical research. *Medicine and Global Survival* 2(4):195-213.
35. CDC established a second independent panel, the Hanford Historical Documents Review Committee (HHDRC), to continue analysis of DOE documents. See http://www.cdc.gov/nceh/radiation/hanford/htdsweb/guide/timeline.htm
36. Steele, K. D. 2005. Radiation study set up as defense records show. *Spokesman Review* 23 February.
37. This dose reconstruction study was to be conducted in a joint effort with the HHDRC.
38. The DOE completely de-funded the HHDRC by early 1988.
39. The Native American Working Group coordinated Hanford-related tribal research and recommended research activities to the TSP. Batelle altered its conflict of interest policies in 1992 to prohibit HEDR staff from also working for legal defense in the Hanford litigation, yet Batelle's chief records manager continued for work for both the study and for the government's defense litigation team in the Hanford litigation. These clear conflicts of interest raise major concerns over the independence, credibility, and integrity of HEDR. If HEDR source code or radiation estimates were inaccurate, this could greatly impact the outcome of the Hanford Thyroid

Disease Study, since it was the HEDR data used in the study to explore the link between Hanford's I-131 releases and thyroid disease in 3,440 study participants, exposed as children within the Hanford downwind region. Some of the Batelle staff in Richland who worked on HEDR also worked for the Justice Department and for Kirkland and Ellis, the Chicago law firm hired to defend Hanford contractors against radiation injury claims.

40. "Initial Hanford Radiation Dose Estimates," Technical Steering Panel, Hanford Environmental Dose Reconstruction Project, 1990.
41. Hanford Thyroid Disease Study. 1999. *Summary final report of the Hanford Thyroid Disease Study*, Seattle, WA: Fred Hutchinson Cancer Research Center. p. 56.
42. Public Law 100-607, directing CDC to conduct a study of thyroid morbidity among persons who lived near the Hanford Nuclear Site between 1944 and 1957.
43. The study used computer software developed under the HEDR project to estimate the radiation doses to the thyroid that HTDS participants received as children while living within the HEDR area, limited to the 246 by 306 mile area around the Hanford facility.
44. HTDS studied those exposed as children because exposure to radioactive iodine would most likely have affected children, who are more sensitive to the harmful effects of radiation than are adults.
45. There was an element of HTDS that looked at the feasibility of a similar design for the nine Native American tribes exposed to Hanford's I-131 releases. It was determined that a study with the same design as HTDS would not be capable of detecting radiation effects that existed. See transcript of Hanford Health Effects Subcommittee Meeting, 26-29 February 1999.
46. When possible, the participant's mother or another close family member was asked about dietary habits for the participant.
47. The evaluation included: residential and dietary history, past medical or occupational radiation exposures, and any history of thyroid disease, thyroid ultrasound evaluation, blood sample to test for thyroid function, the presence of antibody markers for autoimmune thyroiditis, and physical exam of the thyroid. Serum calcium levels were taken to check for hyperparathyroidism. See *A Guide to the Hanford Thyroid Disease Study Final Report.* CDC/FHCRC. 21 June 2002.
48. HTDS was conducted first as a pilot study, to test the feasibility of the methods proposed, and then as a full scale epidemiologic study. The full study fieldwork was completed in 1997.
49. Steele, K. D. 1999. Fallout from thyroid study: Critics fault CDC for early release of Hanford results, unreviewed research. *Spokesman Review.* 14 February.
50. Davis, S., and Kopecky, K. 1998. Executive summary. *HTDS draft final report*, 18. Seattle, WA: Fred Hutchinson Cancer Research Center.
51. Torvik, S. 1999. Study further muddies Hanford waters. *Seattle Times.* 28 February 1999.
52. Over much of the course of HTDS, I served as a long-term member of the Hanford Health Effects Subcommittee (HHES), a citizens' advisory committee to the Agency for Toxic Substances and Disease Registry and CDC, which had been following the development of HTDS. I had had great faith in science to reflect reality, and that the downwinders like me would hear the story of our lives and our damaged health confirmed within the results of HTDS.

53. Cary, A. 1999. Thyroid study to continue. *TriCity Herald.* 29 January 1999. See also: Hanford downwinders up against study results. *TriCity Herald.* 29 October 2004. http://www.hanfordnews.com
54. The NRC is the principal operating arm of the NAS (chartered in 1963) and the National Academy of Engineering. Its work is funded by the CDC. It is a private nonprofit organization that provides advice on science and technology under a congressional charter. As part of the extended NRC Subcommittee review of the HTDS draft report, the CDC included both communications questions and scientific questions within the charge to the NAS committee. The three communications questions asked were:
    1. Was the material accurate and appropriate in providing guidance to the public in understanding the study's findings?
    2. If these messages needed to be amended, how should the revised messages best be communicated to the public?
    3. How can the CDC improve the public communication process in the release of future study reports?
55. This is one of the first such extended reviews to be carried out by NAS, requested by people affected by Hanford's I-131 releases, reviewing not just the scientific components and qualities of a study typically involved in such a review, but concentrating as well upon the way the study's preliminary findings were communicated to the public, Congress, and the media.
56. The National Academy of Science's National Research Council (NRC) Subcommittee of the Board on Radiation Effects Research released the results of its extended review of the draft final HTDS report on 12 December 1999 in a public meeting in Spokane, Washington
57. NAS review report. 14 December 1999, p. 1.
58. The milk pathway is one of the primary means by which radioiodine is ingested, and is a particular concern with infants and children. The radioiodine deposits on pasture grass, the cows or goats eat the contaminated grass, and then the radioiodine is ingested by humans as the milk is consumed. A child's thyroid uptakes far more radioiodine than an adult's thyroid. This is because children often consume a greater quantity of milk than adults, because their thyroids are smaller and more vulnerable than those of adults, and because of a faster metabolism than that of adults.
59. See Ruttenber, A. J., et al. 30 March 2004. *A technical review of the final report of the Hanford Thyroid Disease Study.* p. 3, citing Hoffman 1991, Hoffman et al., 1993, Hoffman et al., 1996, Hoffman 1999. Prepared as an expert report for the Hanford litigation, to respond to suggestions and recommendations of the NRC Subcommittee's 2002 Hanford Thyroid Disease Study Draft Final Report. See also Hoffman, F. O., Ruttenber, A. J., Apostoaei, A. L., Carroll, R. J., and Greenland, S. 2007. The Hanford Thyroid Disease Study: An alternative view of the findings. *Health Physics Journal* 92(2):99-111.

    a. HTDS results do not show statistically significant elevations in risk but are not inconsistent with other published studies *supporting* risks for certain thyroid diseases from I-131 exposures, if the upper bounds of the calculated confidence intervals are considered (as pointed out for the situation of thyroid cancer and I-131 exposure from NTS fallout by the NRC). [emphasis added]

b. Applying a strict interpretation of the lack of statistical significance found in the results of HTDS, we find that the results of HTDS are consistent with the finding of thyroid risk in some but not all studies of I-131 exposures, but not consistent with those studies which show elevated thyroid risk, or;

c. If the results are subjected to strict interpretation based upon statistical significance, then HTDS is not inconsistent with other studies which show that chronic exposure to I-131 is not associated with thyroid disease.

60. NAS-BRER. 2000. Review of the Hanford Thyroid Disease Study draft final report. Washington, DC: National Academy Press, p. 7.
61. Ruttenber, A. J., et al. 30 March 2004. *A technical review of the final report of the Hanford Thyroid Disease Study.* p. 3 See also Hoffman, F. O., Ruttenber, A. J., Apostoaei, A. L., Carroll, R. J., and Greenland, S. Feb. 2007. The Hanford Thyroid Disease Study: An alternative view of the findings. *Health Physics Journal* 92(2): 99-111.
62. Instead, only NTS fallout was taken into account within HTDS. Doses were divided into two parts based on the median dose for all subjects (5.3 mGy) and then put through simple analysis as a confounder or effect modifier in dose-response models. These simple analyses caused HTDS authors to conclude that NTS fallout doses were not confounders or effect modifiers in any model, and so could be disregarded. The expert panel found that, for people who consumed fresh milk, the cut-off dose utilized for NTS fallout I-131 exposures within HTDS appeared to be very low and relevant only to people who did not consume fresh milk. Use of the National Cancer Institute's online I-131 NTS fallout dose calculator http://ntsi131.nci.nih.gov/ shows, for counties included in HTDS, that typical NTS doses from drinking fresh milk are much higher than 5.3 mGy. For those individuals who had not consumed any milk at all, other milk consumption scenarios reveal NTS I-131 doses which were substantially higher than the 5.3 mGy assigned within HTDS. 1,616 of the HTDS participants were assigned NTS I-131 doses of less than 5.3 mGy by HTDS researchers. Because only 8 percent of HTDS participants reported no consumption of raw or processed milk products, it was not reasonable that 1,616 participants would have NTS doses less than 5.3 mGy. "Therefore, it appears that the NTS doses calculated for members of the HTDS cohort have been underestimated." Ruttenber, A. J., et al. 30 March 2004. *A technical review of the final report of the Hanford Thyroid Disease Study*, p. 9.
63. See Commission on Life Sciences. 1998. Letter report-review of analysis plan for the Hanford Thyroid Disease Study (HTDS). National Academies of Science.
64. Fallout from thyroid study: Critics fault CDC for early, unreviewed results. *Spokesman Review*, 19 February 1999.
65. Letter of 18 February 1999 to Dr. Dick Jackson, then Director of NCEH, re: problems with HTDS, signed by more than 22 citizen groups.
66. Greenland, S. 1977. Response and follow-up bias in cohort studies. *American Journal of Epidemiology* 106(3):184-187.
67. Fred Hutchinson Cancer Research Center/CDC. 1998. Preliminary technical review of the Hanford Thyroid Disease Study draft final report, p. 6.
68. Greene, G. 1999. *The woman who knew too much: Alice Stewart and the secrets of radiation.* Ann Arbor, MI: University of Michigan Press, p. 216.

69. The incidence of thyroid cancer found within HTDS was very close to that which was predicted by the medical monitoring program plan. See Spengler, R. F. July 1997. Hanford medical monitoring program: Background consideration document and ATSDR decision. US DHHS, ATSDR.
70. HTDS Newsletter, February 1997.
71. Davis, S., Kopecky, K. J, and Hamilton, T. E. 1999. Hanford Thyroid Disease Study final report, p. 326, 370.
72. Davis, S., and Kopecky, K. 1998. HTDS final report, summary and conclusions, p. 5
73. Ruttenber, A. J., et al. 30 March 2004. *A technical review of the final report of the Hanford Thyroid Disease Study.* This technical report was written in support of Hanford plaintiffs in litigation. The report as such is not independent, but it has no relationship to the authors of HTDS nor CDC.
74. This was the most supportable interpretation, particularly because of the HTDS overestimates of statistical power and the incomplete characterization of the effects of dose uncertainty.
75. Considerably more goiter and other thyroid disease was reported in the R-11 Hanford Survey than in national survey data. See Report of R-11 survey results. 14 November 1995. JSI Center for Environmental Health Studies. See also Grossman, C. M., Morton, W. E., and Nussbaum, R. H. 1997. Malignancies among Hanford downwinders. Presented at the Health of the Hanford Site Conference, 3 December 1997.
76. Friedman, S. M. 2001. Risk communication, the Hanford Thyroid Disease Study and draft reports. 12 *Risk: Health, Safety & Environment.* 91(Spring):91-103. The initial seven members of the HTDS Advisory Committee were appointed in early 1991. The committee was disbanded 6 months before the release of the draft final HTDS, without communicating with committee members. CDC then did not renew the committee's charter, also without explanation to the Advisory Committee.
77. See David, S., Kopecky, K., and Hamilton, T. 1999. Letter to the Editor. Findings of study "clear and unequivocal." *Seattle Post-Intelligencer,* 14 March 1999.
78. See Centers for Disease Control and Prevention. 1999. Press release. Draft report: Results of the Hanford Thyroid Disease Study 28 January 1999. Quoting Scott Davis.
79. See Congressional Briefing. 27 January 1999. Document on Hanford Thyroid Disease Study. Centers for Disease Control and Prevention, Summary of the Study and the Primary Findings.
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81. *Hanford Medical Monitoring Program.* January 1998. A publication of the Agency for Toxic Substances and Disease Registry.
82. Downwinders program gets 5 million from DOE. *TriCity Herald.* 23 January 1998. http://www.hanfordnews.com
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85. See *Trisha T. Pritikin v. United States Department of Energy et al.,* 47 F. Supp. 2d 1225 (E.D. Wash. 1999), affirmed at 254 F.3d 791 (9th Cir. 2001), cert. denied 19 February 2002 at 534 US 1133; 122 S.Ct. 1076; 151 L.Ed.2d 977.
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87. National Research Council's Committee on Environmental Epidemiology's definition. See Connor, T. 1997. *Burdens of proof.* Energy Research Foundation, p. 11.
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92. Hanford Health Information Network. March 2000. Perspectives on the Hanford Thyroid Disease Study: The HTDS has done more harm than good for Hanford downwinders, p. 5.
93. See Nussbaum, R. H., Hoover, P. P., Grossman, C. M., and Nussbaum, F. D. 2004. Community-based participatory health survey of Hanford, WA, downwinders: A model for citizen empowerment. *Society and Natural Resources* 17:547-559.
94. R-11 study respondents reported goiter and other thyroid diseases approximately 6-10 times as frequently as respondents in the latest National Health Interview Survey. See Report of R-11 survey results. 14 November 1995. JSI Center for Environmental Health Studies.